

Population: ITT.
 Endpoint: Descriptive statistics of centers, countries and geographical regions.
 Model: --.
 Study: BP39055 SUNFISH - Part 2.

Category	Center				Country				Geographical region (2)			
	N (3)	% (3)	N of patients randomized (4)	% randomized patients (5)	N (3)	% (3)	N of patients randomized (4)	% randomized patients (5)	N (3)	% (3)	N of patients randomized (4)	% randomized patients (5)
Overall	42	100	180	100	14	100	180	100	2	100	180	100
with <10 patients per arm (1)	42	100	180	100	14	100	180	100	0	0	0	0
with >=10 patients per arm (1)	0	0	0	0	0	0	0	0	2	100	180	100

(1) <10 patients category if at least one treatment arm has <10 patients. >=10 patients category if both treatment arms have >=10 patients.
 (2) Geographical region: Europe, Rest of the world.
 (3) N = number of centers / countries / regions. % compared to overall number.
 (4) Number of patients randomized in the corresponding category (e.g. number of patients randomized in centers with <10 pts per arm).
 (5) % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
 Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_center.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_center_IT.xls
 12JUN2020 10:35

POPULATION: Safety-Evaluable Population
ENDPOINT: --
MODEL: descriptive
STUDY: BP39055 SUNFISH - Part 1
Number of Patients who Died including Primary Reason

Null Report: No observations met the reporting criteria for inclusion in this output.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_dd.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_dd_SE_P1.xls
11MAR2021 20:42

Population: ITT.

Endpoint: Number of Patients by Country and Study Site.

Model: --.

Study: BP39055 SUNFISH - Part 2.

	Risdiplam (N=120)	Placebo (N=60)	Total (N=180)
Country			
n	120	60	180
Belgium	11 (9.2%)	5 (8.3%)	16 (8.9%)
Brazil	1 (0.8%)	1 (1.7%)	2 (1.1%)
Canada	13 (10.8%)	5 (8.3%)	18 (10.0%)
China	11 (9.2%)	5 (8.3%)	16 (8.9%)
Spain	12 (10.0%)	9 (15.0%)	21 (11.7%)
France	14 (11.7%)	7 (11.7%)	21 (11.7%)
Croatia	10 (8.3%)	1 (1.7%)	11 (6.1%)
Italy	5 (4.2%)	6 (10.0%)	11 (6.1%)
Japan	10 (8.3%)	5 (8.3%)	15 (8.3%)
Poland	24 (20.0%)	8 (13.3%)	32 (17.8%)
Russian Federation	1 (0.8%)	3 (5.0%)	4 (2.2%)
Serbia	4 (3.3%)	4 (6.7%)	8 (4.4%)
Turkey	1 (0.8%)	0	1 (0.6%)
United States	3 (2.5%)	1 (1.7%)	4 (2.2%)
Study Site by country			
Belgium			
n	11	5	16
21818	7 (63.6%)	1 (20.0%)	8 (50.0%)
41339	2 (18.2%)	3 (60.0%)	5 (31.3%)
96838	2 (18.2%)	1 (20.0%)	3 (18.8%)
Brazil			
n	1	1	2

45324	1 (100%)	1 (100%)	2 (100%)
Canada			
n	13	5	18
109916	5 (38.5%)	2 (40.0%)	7 (38.9%)
111756	4 (30.8%)	1 (20.0%)	5 (27.8%)
113204	4 (30.8%)	2 (40.0%)	6 (33.3%)
China			
n	11	5	16
119348	6 (54.5%)	2 (40.0%)	8 (50.0%)
94105	5 (45.5%)	3 (60.0%)	8 (50.0%)
Spain			
n	12	9	21
119497	3 (25.0%)	2 (22.2%)	5 (23.8%)
34744	1 (8.3%)	1 (11.1%)	2 (9.5%)
43830	6 (50.0%)	4 (44.4%)	10 (47.6%)
91658	2 (16.7%)	2 (22.2%)	4 (19.0%)
France			
n	14	7	21
102419	1 (7.1%)	0	1 (4.8%)
109229	3 (21.4%)	2 (28.6%)	5 (23.8%)
119482	2 (14.3%)	1 (14.3%)	3 (14.3%)
54061	7 (50.0%)	4 (57.1%)	11 (52.4%)
65435	1 (7.1%)	0	1 (4.8%)
Croatia			
n	10	1	11
119476	10 (100%)	1 (100%)	11 (100%)
Italy			
n	5	6	11
105090	0	1 (16.7%)	1 (9.1%)
107431	0	1 (16.7%)	1 (9.1%)
111203	0	2 (33.3%)	2 (18.2%)
113484	3 (60.0%)	1 (16.7%)	4 (36.4%)
113485	2 (40.0%)	1 (16.7%)	3 (27.3%)
Japan			
n	10	5	15
112922	1 (10.0%)	0	1 (6.7%)
116969	0	1 (20.0%)	1 (6.7%)

116970	1 (10.0%)	0	1 (6.7%)
116971	1 (10.0%)	0	1 (6.7%)
116974	2 (20.0%)	0	2 (13.3%)
117424	1 (10.0%)	0	1 (6.7%)
55965	3 (30.0%)	0	3 (20.0%)
94326	1 (10.0%)	2 (40.0%)	3 (20.0%)
94348	0	1 (20.0%)	1 (6.7%)
96007	0	1 (20.0%)	1 (6.7%)
Poland			
n	24	8	32
113502	10 (41.7%)	3 (37.5%)	13 (40.6%)
118492	10 (41.7%)	1 (12.5%)	11 (34.4%)
118493	4 (16.7%)	4 (50.0%)	8 (25.0%)
Russian Federation			
n	1	3	4
119495	1 (100%)	3 (100%)	4 (100%)
Serbia			
n	4	4	8
119862	4 (100%)	4 (100%)	8 (100%)
Turkey			
n	1	0	1
107710	1 (100%)	0	1 (100%)
United States			
n	3	1	4
47566	2 (66.7%)	1 (100%)	3 (75.0%)
48342	1 (33.3%)	0	1 (25.0%)

Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm2.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm2_IT.xls
10MAR2021 12:32

Population: ITT.

Endpoint: Number of Patients by Country and Study Site.

Model: --.

Study: BP39055 SUNFISH - Part 1.

	Risdiplam (N=35)	Placebo (N=16)	Total (N=51)
Country			
n	35	16	51
Belgium	3 (8.6%)	0	3 (5.9%)
Germany	4 (11.4%)	0	4 (7.8%)
France	2 (5.7%)	2 (12.5%)	4 (7.8%)
Italy	26 (74.3%)	14 (87.5%)	40 (78.4%)
Study Site by country			
Belgium			
n	3	0	3
96838	3 (100%)	0	3 (100%)
Germany			
n	4	0	4
114822	4 (100%)	0	4 (100%)
France			
n	2	2	4
54061	2 (100%)	2 (100%)	4 (100%)
Italy			
n	26	14	40
105090	15 (57.7%)	7 (50.0%)	22 (55.0%)
107431	11 (42.3%)	7 (50.0%)	18 (45.0%)

Clinical Cutoff Date: 09JAN2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part1/prod/program/t_dm2.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part1/prod/output/t_dm2_IT_P1.xls
12MAR2021 12:02

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39055 SUNFISH - Part 1

Patients who Discontinued Study including Reason

	Risdiplam (N=35)	Placebo (N=16)
Discontinued study		
n	1 (2.9%)	0
Withdrawal by subject	1 (2.9%)	0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_dsstu.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_dsstu_IT_P1.xls

11MAR2021 20:42

Population: ITT.
Endpoint: Patient disposition.
Model: --.
Study: BP39055 SUNFISH - Part 2.

		Risdiplam (N=120)		Placebo (N=60)		Total (N=180)	
Type	Reason	N	%	N	%	N	%
Discontinued Study		3	2.5	1	1.7	4	2.2
	OTHER	3	2.5	1	1.7	4	2.2

211 patients were screened with 31 screening failures. These are listed on pp. 7304-7305 of the Clinical Study Report (report no. 1099250 dated 27FEB2020).

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_ds.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_ds_IT.xls
12JUN2020 10:38

Population: ITT.

Endpoint: Duration of Follow-up.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo	Total
Follow-up Duration (days)	n	120	60	180
	Mean (SD)	436.82 (73.06)	443.18 (72.12)	438.94 (72.61)
	Median	422.50	422.50	422.50
	Min - Max	100.0 - 673.0	182.0 - 696.0	100.0 - 696.0
MFM Follow-up Duration (days)	n	120	60	180
	Mean (SD)	400.94 (54.21)	404.33 (51.39)	402.07 (53.17)
	Median	393.00	391.00	392.00
	Min - Max	155.0 - 575.0	312.0 - 582.0	155.0 - 582.0

Follow-up duration is the date of the last visit minus the date of the first visit plus one day.

Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_fu.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_fu_IT.xls
12JUN2020 10:39

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39055 SUNFISH - Part 2

Follow-up by Endpoint

		Risdiplam (N=120)	Placebo (N=60)	All (N=180)
Follow-up Duration (days)	n	120	60	180
	Mean (SD)	794.74 (118.87)	811.95 (114.43)	800.48 (117.37)
	Median	810	812.5	811
	Min - Max	100.0 - 1066.0	182.0 - 1086.0	100.0 - 1086.0
MFM Follow-up Duration (days)	n	120	60	180
	Mean (SD)	757.73 (110.69)	746.85 (97.37)	754.11 (106.29)
	Median	758	756.5	757
	Min - Max	155.0 - 961.0	312.0 - 937.0	155.0 - 961.0

MFM Follow-up Duration is the date of the last visit minus the date of the first visit plus one day.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_fu.sas

Output: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_fu_IT_P2.xls

25FEB2021 10:46

Population: Type III SMA.

Endpoint: Demographics and baseline characteristics.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo	Total
N		36	16	52
Age [years] at screening	n	36	16	52
	Mean (SD)	12.6 (5.6)	12.2 (6.8)	12.5 (5.9)
	Median	13.5	12.0	13.5
	IQR	9 - 17	6 - 18	8 - 17
	Min - Max	2 - 25	3 - 24	2 - 25
Age group [years]	n	36	16	52
	2 - <6	4 (11.1%)	4 (25.0%)	8 (15.4%)
	6 - 11	11 (30.6%)	4 (25.0%)	15 (28.8%)
	12 - 17	15 (41.7%)	4 (25.0%)	19 (36.5%)
	18 - 25	6 (16.7%)	4 (25.0%)	10 (19.2%)
Sex	n	36	16	52
	Male	19 (52.8%)	8 (50.0%)	27 (51.9%)
	Female	17 (47.2%)	8 (50.0%)	25 (48.1%)
Race	n	36	16	52
	Asian	5 (13.9%)	1 (6.3%)	6 (11.5%)
	Black or African American	2 (5.6%)	0	2 (3.8%)
	White	25 (69.4%)	13 (81.3%)	38 (73.1%)
	Unknown	4 (11.1%)	2 (12.5%)	6 (11.5%)
Ethnicity	n	36	16	52

	Not Hispanic or Latino	36 (100%)	16 (100%)	52 (100%)

Patients are grouped by initial treatment received.

Clinical Cutoff Date: 06SEP2019.

Subgroup categories with 0 patients not reported.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_IT_T3.xls

12JUN2020 10:37

Population: Type III SMA.

Endpoint: Motor Function Scale Scores by Treatment Arm Group at Baseline.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo
N		36	16
MFM32 total score	n	35	15
	Median (min-max)	55.21 (29.2-71.9)	58.33 (35.4-71.9)
	Mean (SD)	54.35 (9.62)	55.14 (9.63)
RULM total score	n	36	16
	Median (min-max)	27.00 (13.0-36.0)	25.50 (15.0-38.0)
	Mean (SD)	25.56 (6.58)	25.31 (7.14)
HFMSE total score	n	36	16
	Median (min-max)	25.50 (2.0-48.0)	29.00 (4.0-43.0)
	Mean (SD)	25.50 (12.81)	24.81 (13.53)

Patients are grouped by initial treatment. HFMSE=Hammersmith Functional Motor Scale Expanded; MFM32=Motor Function Measure 32; RULM=Revised Upper Limb Module.
Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm_mfss.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_mfss_IT_P2_T3.xls

26OCT2020 9:07

Population: Type III SMA.

Endpoint: SMA Baseline Disease Characteristics.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo	Total
N		36	16	52
SMN2 copy number	2	2 (5.6%)	0	2 (3.8%)
	3	24 (66.7%)	10 (62.5%)	34 (65.4%)
	4	10 (27.8%)	6 (37.5%)	16 (30.8%)
SMA type	TYPE III	36 (100%)	16 (100%)	52 (100%)
Age of onset of initial symptoms (in Months)	n	36	16	52
	Mean (SD)	19.8 (10.9)	33.3 (36.8)	24.0 (22.8)
	Median	17.3	18.4	17.8
	Min - Max	0 - 57	8 - 135	0 - 135
Time between onset of initial SMA symptoms to first treatment (in Months)	n	36	16	52
	Mean (SD)	138.4 (65.7)	118.8 (82.1)	132.4 (70.9)
	Median	144.6	110.3	143.0
	Min - Max	19 - 275	1 - 243	1 - 275
Number and percentage of patients that could or could not stand	Standing	11 (30.6%)	4 (25.0%)	15 (28.8%)
	Could not stand	25 (69.4%)	12 (75.0%)	37 (71.2%)
Number and percentage of patients that could or could not walk (walkers and non-walkers)	Walking	3 (8.3%)	1 (6.3%)	4 (7.7%)
	Could not walk	33 (91.7%)	15 (93.8%)	48 (92.3%)
Number of fractures (None, 1-2, 3-5 or >= 6)	NONE	27 (75.0%)	14 (87.5%)	41 (78.8%)
	1-2	9 (25.0%)	2 (12.5%)	11 (21.2%)
Scoliosis (yes/no)	Yes	24 (66.7%)	11 (68.8%)	35 (67.3%)
	No	12 (33.3%)	5 (31.3%)	17 (32.7%)
Degree of curvature due to scoliosis (<10, 10-40, >40)	0-10	8 (22.2%)	3 (18.8%)	11 (21.2%)
	10-40	7 (19.4%)	4 (25.0%)	11 (21.2%)
	>40	9 (25.0%)	4 (25.0%)	13 (25.0%)
Surgery for scoliosis before screening (yes/no)	Yes	5 (13.9%)	4 (25.0%)	9 (17.3%)
	No	23 (63.9%)	10 (62.5%)	33 (63.5%)
Hip subluxation or dislocation (yes/no)	Yes	6 (16.7%)	4 (25.0%)	10 (19.2%)
	No	30 (83.3%)	12 (75.0%)	42 (80.8%)
Hip surgery (yes/no)	Yes	2 (5.6%)	2 (12.5%)	4 (7.7%)
	No	34 (94.4%)	14 (87.5%)	48 (92.3%)

Patients are grouped by initial treatment received. Standing is defined as with MFM item 25 score ≥ 1 at baseline. Walking is defined as with HFMSE item 20 score ≥ 2 at baseline. Ambulatory is defined as having the ability to walk unassisted for 10 metres or more.
Clinical Cutoff Date: 06SEP2019.
Subgroup categories with 0 patients not reported.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm_sma.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_sma_IT_P2_T3.xls
30JUL2020 15:17

Population: ITT, Type III SMA.

Endpoint: Change from Baseline in Total score of the RULM (Analysis of MMRM) (Placebo Controlled Period).

Model: Stratified analysis.

Study: BP39055 SUNFISH - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics		Placebo Statistics		Difference between treatments (Risdiplam - Placebo)							Population/Method (4)		
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (LL)	95% CI Hedges g (UL)			
All	n/a	Baseline	36	36	0	16	16	0													ITT	Adjusted
		Week 17	36	36	36	16	16	16	0.86	0.35	-0.11	0.48	0.74	0.60	-0.46	1.95	0.37	-0.22	0.95		ITT	Adjusted
		Week 35	35	35	35	16	16	16	1.03	0.44	-0.76	0.62	1.79	0.76	0.26	3.31	0.70	0.10	1.30		ITT	Adjusted
		Week 52	34	34	34	15	15	15	1.74	0.42	-0.45	0.60	2.19	0.74	0.71	3.67	0.91	0.28	1.53		ITT	Adjusted

1) Patients with a value at baseline and a post-baseline value at the respective visit.

2) LSMeans of change from baseline from MMRM.

3) Contrasts from MMRM.

4) Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction. Adjusted for randomization stratification factors.

Data as observed (no imputation of missing values).

Covariance matrix: unstructured. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mmrn_IT_T3_DB_RULM.xls

04MAR2021 13:59

Population: Type III SMA.

Endpoint: Summary of RULM Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=36)						Placebo (N=16)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All	Baseline	36	100	36	100	25.56	6.58	16	100	16	100	25.31	7.14
		Week 17	36	100	36	100	26.19	6.60	16	100	16	100	25.44	7.06
		Week 35	36	100	35	97.2	26.40	7.37	16	100	16	100	24.56	6.09
		Week 52	36	100	34	94.4	27.09	7.00	15	100	15	100	24.73	6.73

1) In study: number of patients in study at the respective visit.

2) % based on the number of patients with observations at respective visit.

3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.

4) % based on patients in study at the respective visit.

5) Mean: descriptive statistics - absolute values.

Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_DB_RULM.xls

14DEC2020 17:38

Population: Type III SMA.
 Endpoint: Change from Baseline Response >= 2 in Total score of the RULM.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risediplam				Placebo				Risediplam vs. Placebo										Placebo vs. Risediplam						
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)			Absolute Risk Difference (2)			Relative Risk (2)				Relative Risk (2)						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	--	36	100	16	44.4	16	100	3	18.8	4.47	Algorithm converged.	0.96	20.81	0.293	Algorithm converged.	-0.011	0.597	2.44	Algorithm converged.	0.81	7.33	0.1104	0.41	Algorithm converged.	0.14	1.23

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qe/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qe/output/t_eff_gresp_IT_T3_DB_RULM_GE2.xls
 15SEP2020 14:15

Population: Type III SMA.
 Endpoint: Change from Baseline Response \geq 0 in Total score of the RULM.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risdiplam				Placebo				Risdiplam vs. Placebo										Placebo vs. Risdiplam						
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)			Absolute Risk Difference (2)			Relative Risk (2)				Relative Risk (2)						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	--	36	100	26	72.2	16	100	7	43.8	3.39	Algorithm converged.	0.92	12.43	0.266	Algorithm converged.	-0.029	0.562	1.54	Algorithm converged.	0.83	2.84	0.1643	0.65	Algorithm converged.	0.35	1.20

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qe/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qe/output/t_eff_gresp_IT_T3_DB_RULM_GEO.xls
 15SEP2020 14:01

Population: ITT, Type III SMA.

Endpoint: Change from Baseline in Total score of the MFM-32 (Analysis of MMRM) (Placebo Controlled Period) - Treatment policy strategy estimand*.

Model: Stratified analysis.

Study: BP39055 SUNFISH - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics		Placebo Statistics		Difference between treatments (Risdiplam - Placebo)							Population/Method (4)		
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (LL)	95% CI Hedges g (UL)			
All	n/a	Baseline	36	35	0	16	15	0													ITT	Adjusted
		Week 17	35	35	35	15	15	15	0.72	0.40	0.36	0.54	0.36	0.66	-0.98	1.70	0.16	-0.43	0.76		ITT	Adjusted
		Week 35	35	35	35	15	15	15	0.65	0.56	-0.45	0.81	1.10	0.98	-0.88	3.08	0.34	-0.26	0.94		ITT	Adjusted
		Week 52	35	35	35	14	14	14	0.89	0.50	-0.58	0.73	1.48	0.88	-0.29	3.24	0.52	-0.09	1.14		ITT	Adjusted

1) Patients with a value at baseline and a post-baseline value at the respective visit.

2) LSMeans of change from baseline from MMRM.

3) Contrasts from MMRM.

4) Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction. Adjusted for randomization stratification factors.

* Data after use of prohibited medication is included. Data as observed (no imputation of missing values).

Covariance matrix: unstructured. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mmrn_IT_T3_DB_MFM.xls

04MAR2021 13:58

Population: Type III SMA and Hypothetical strategy estimand: data after use of prohibited medication not included.

Endpoint: Summary of MFM-32 Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=36)						Placebo (N=16)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All		0		0	NE	NE	NE	0		0	NE	NE	NE
		Baseline	36	100	35	97.2	54.35	9.62	16	100	15	93.8	55.14	9.63
		Week 17	36	100	35	97.2	54.76	9.81	16	100	15	93.8	55.42	10.30
		Week 35	36	100	35	97.2	54.70	10.13	16	100	15	93.8	54.58	9.00
		Week 52	36	100	35	97.2	54.94	9.86	15	100	14	93.3	54.17	9.92

1) In study: number of patients in study at the respective visit.

2) % based on the number of patients with observations at respective visit.

3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.

4) % based on patients in study at the respective visit.

5) Mean: descriptive statistics - absolute values.

Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_HYP_DB_MFM.xls

14DEC2020 17:49

Population: Type III SMA.

Endpoint: Summary of MFM-32 Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=36)						Placebo (N=16)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All	Baseline	36	100	35	97.2	54.35	9.62	16	100	15	93.8	55.14	9.63
		Week 17	36	100	35	97.2	54.76	9.81	16	100	15	93.8	55.42	10.30
		Week 35	36	100	35	97.2	54.70	10.13	16	100	15	93.8	54.58	9.00
		Week 52	36	100	35	97.2	54.94	9.86	15	100	14	93.3	54.17	9.92

1) In study: number of patients in study at the respective visit.

2) % based on the number of patients with observations at respective visit.

3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.

4) % based on patients in study at the respective visit.

5) Mean: descriptive statistics - absolute values.

Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_DB_MFM.xls

14DEC2020 17:37

Population: Type III SMA.
 Endpoint: Change from Baseline Response >= 3 in Total score of the MFM-32.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risediplam				Placebo						Risediplam vs. Placebo								Placebo vs. Risediplam										
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)		Absolute Risk Difference (2)				Relative Risk (2)				Relative Risk (2)										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL				
All	--	35	100	8	22.9	15	100	0	0.0	Infinity	*		0.00	Infinity	0.349		Algorithm converged.	-0.649	1.346	Infinity		Algorithm converged.	0.11	Infinity	0.3079	0.00		Algorithm converged.	0.00	9.17

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_gresp_IT_T3_DB_MFM_GB3.xls
 15SEP2020 14:25

Population: Type III SMA.
 Endpoint: Change from Baseline Response \geq 0 in Total score of the MPM-32.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risediplam				Placebo				Risediplam vs. Placebo										Placebo vs. Risediplam						
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)			Absolute Risk Difference (2)			Relative Risk (2)				Relative Risk (2)						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	--	35	100	25	71.4	15	100	8	53.3	2.93	Algorithm converged.	0.73	11.85	0.241	Algorithm converged.	-0.075	0.557	1.45	Algorithm converged.	0.78	2.69	0.2343	0.69	Algorithm converged.	0.37	1.28

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_gresp_IT_T3_DB_MPM_GRD.xls
 15SEP2020 13:59

Population: ITT, Type III SMA.

Endpoint: Change from Baseline in Total score of the MFM-32 (Analysis of MMRM) (Placebo Controlled Period) - Hypothetical strategy estimand*.

Model: Stratified analysis.

Study: BP39055 SUNFISH - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics		Placebo Statistics		Difference between treatments (Risdiplam - Placebo)							Population/Method (4)		
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (LL)	95% CI Hedges g (UL)			
All	n/a	Baseline	36	35	0	16	15	0													ITT	Adjusted
		Week 17	35	35	35	15	15	15	0.72	0.40	0.36	0.54	0.36	0.66	-0.98	1.70	0.16	-0.43	0.76		ITT	Adjusted
		Week 35	35	35	35	15	15	15	0.65	0.56	-0.45	0.81	1.10	0.98	-0.88	3.08	0.34	-0.26	0.94		ITT	Adjusted
		Week 52	35	35	35	14	14	14	0.89	0.50	-0.58	0.73	1.48	0.88	-0.29	3.24	0.52	-0.09	1.14		ITT	Adjusted

1) Patients with a value at baseline and a post-baseline value at the respective visit.

2) LSMeans of change from baseline from MMRM.

3) Contrasts from MMRM.

4) Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction. Adjusted for randomization stratification factors.

* Data after use of prohibited medication not included. Data as observed (no imputation of missing values).

Covariance matrix: unstructured. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mmrn_IT_T3_HYP_DB_MFM.xls

04MAR2021 14:08

Population: Type III SMA and Hypothetical strategy estimand: data after use of prohibited medication not included.
 Endpoint: Change from Baseline Response \geq 3 in Total score of the MPM-32.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Risdiplam				Placebo				Odds Ratio (2)				Risdiplam vs. Placebo				Relative Risk (2)				Placebo vs. Risdiplam				
		Patients		Responders (1)		Patients		Responders (1)		Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
		n	%	n	%	n	%	n	%																	
All	--	35	100	8	22.9	15	100	0	0.0	Infinity	*	0.00	Infinity	0.349	Algorithm converged.	-0.649	1.346	Infinity	Algorithm converged.	0.11	Infinity	0.3079	0.00	Algorithm converged.	0.00	9.17

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_gresp_IT_T3_HYP_DB_MPM_GE3.xls
 15SEP2020 14:26

Population: Type III SMA and Hypothetical strategy estimand: data after use of prohibited medication not included.
 Endpoint: Change from Baseline Response \geq 0 in Total score of the MPM-32.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risediplam				Placebo				Risediplam vs. Placebo										Placebo vs. Risediplam						
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)			Absolute Risk Difference (2)			Relative Risk (2)				Relative Risk (2)						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	--	35	100	25	71.4	15	100	8	53.3	2.93	Algorithm converged.	0.73	11.85	0.241	Algorithm converged.	-0.075	0.557	1.45	Algorithm converged.	0.78	2.69	0.2343	0.69	Algorithm converged.	0.37	1.28

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_gresp_IT_T3_HYP_DB_MPM_GEO.xls
 15SEP2020 13:59

Population: Type III SMA.
 Endpoint: Change from Baseline Response >= 2 in Total score of the HFMSF.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Risediplam				Placebo				Risediplam vs. Placebo					Placebo vs. Risediplam															
		Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)		Absolute Risk Difference (2)			Relative Risk (2)		Relative Risk (2)													
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL				
All	--	36	100	11	30.6	16	100	4	25.0	1.65	*		0.36	7.63	0.073		Algorithm converged.	-0.286	0.432	1.38		Algorithm converged.	0.54	3.51	0.4977	0.73		Algorithm converged.	0.28	1.86

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_gresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_gresp_IT_T3_DB_HFMSF_GE2.xls
 15SEP2020 14:14

Population: Type III SMA.

Endpoint: Summary of HFMSE Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=36)						Placebo (N=16)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All	Baseline	36	100	36	100	25.50	12.81	16	100	16	100	24.81	13.53
		Week 17	36	100	36	100	26.25	13.07	16	100	16	100	24.50	12.89
		Week 35	36	100	36	100	25.92	12.82	16	100	16	100	23.38	12.91
		Week 52	36	100	34	94.4	25.00	12.88	15	100	15	100	23.07	12.59

- 1) In study: number of patients in study at the respective visit.
 - 2) % based on the number of patients with observations at respective visit.
 - 3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.
 - 4) % based on patients in study at the respective visit.
 - 5) Mean: descriptive statistics - absolute values.
- Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_DB_HFMSE.xls

14DEC2020 17:37

Population: Type III SMA.
 Endpoint: Change from Baseline Response >= 0 in Total score of the HPMSE.
 Model: Stratified analysis.
 Study: BP39055 SONFISH - Part 2.

		Risediplam				Placebo				Risediplam vs. Placebo										Placebo vs. Risediplam						
Subgroup	Level	Patients		Responders (1)		Patients		Responders (1)		Odds Ratio (2)			Absolute Risk Difference (2)			Relative Risk (2)				Relative Risk (2)						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	--	36	100	23	63.9	16	100	8	50.0	1.80	Algorithm converged.	0.51	6.39	0.128	Algorithm converged.	-0.185	0.441	1.21	Algorithm converged.	0.68	2.13	0.5121	0.83	Algorithm converged.	0.47	1.47

1) Patients with response at week 52. Patients with no response information at week 52 are counted as nonresponders.
 2) Factors/Covariates: treatment, baseline value. Adjusted for randomization stratification factors.
 When there are no patients with/ without response in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no patients with/ without response in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 Clinical Cutoff Date: 06SEP2019.
 NE when shown, means Not Estimable. * when shown, indicates convergence problem: result is uninterpretable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/program/t_eff_qresp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qs/output/t_eff_qresp IT T3 DB HPMSE GE0.xls
 15SEP2020 14:00

Population: ITT, Type III SMA.

Endpoint: Change from Baseline in Total score of the HFMSSE (Analysis of MMRM) (Placebo Controlled Period).

Model: Stratified analysis.

Study: BP39055 SUNFISH - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics		Placebo Statistics		Difference between treatments (Risdiplam - Placebo)							Population/Method (4)		
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (LL)	95% CI Hedges g (UL)			
All	n/a	Baseline	36	36	0	16	16	0													ITT	Adjusted
		Week 17	36	36	36	16	16	16	0.79	0.43	-0.32	0.59	1.11	0.73	-0.37	2.58	0.45	-0.14	1.03		ITT	Adjusted
		Week 35	36	36	36	16	16	16	0.47	0.64	-1.45	0.92	1.92	1.12	-0.32	4.17	0.51	-0.08	1.10		ITT	Adjusted
		Week 52	34	34	34	15	15	15	0.21	0.62	-0.68	0.89	0.89	1.09	-1.30	3.07	0.25	-0.35	0.85		ITT	Adjusted

1) Patients with a value at baseline and a post-baseline value at the respective visit.

2) LSMeans of change from baseline from MMRM.

3) Contrasts from MMRM.

4) Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction. Adjusted for randomization stratification factors.

Data as observed (no imputation of missing values).

Covariance matrix: unstructured. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mmrn_IT_T3_DB_HFMSSE.xls

04MAR2021 13:58

INFORMATION FOR THE U.S. HOUSE OF REPRESENTATIVES
 REPORT NO. 100-1000
 HOUSE OF REPRESENTATIVES
 COMMITTEE ON THE BUDGET
 FISCAL YEAR 1991
 ESTIMATED REVENUE BY CATEGORY (BILLIONS)

Category	1989										1990										1991									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Individual Income Tax	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Corporate Income Tax	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Excise Tax	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
State and Local Tax	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Other	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Total	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500

Note: The information reported on this table is preliminary and subject to change.

Source: U.S. Department of the Treasury, Office of Management and Enterprise Budgeting.

Prepared by the Congressional Budget Office.

Date: 10/1/90

Population: ITT, Type III SMA, Patients aged >= 12 years at Baseline.
 Endpoint: Change from Baseline in EQ5D5L Y (Analysis of MMRM) (Placebo Controlled Period).
 Model: Stratified analysis.
 Study: BP39055 SUNFISH - Part 2.

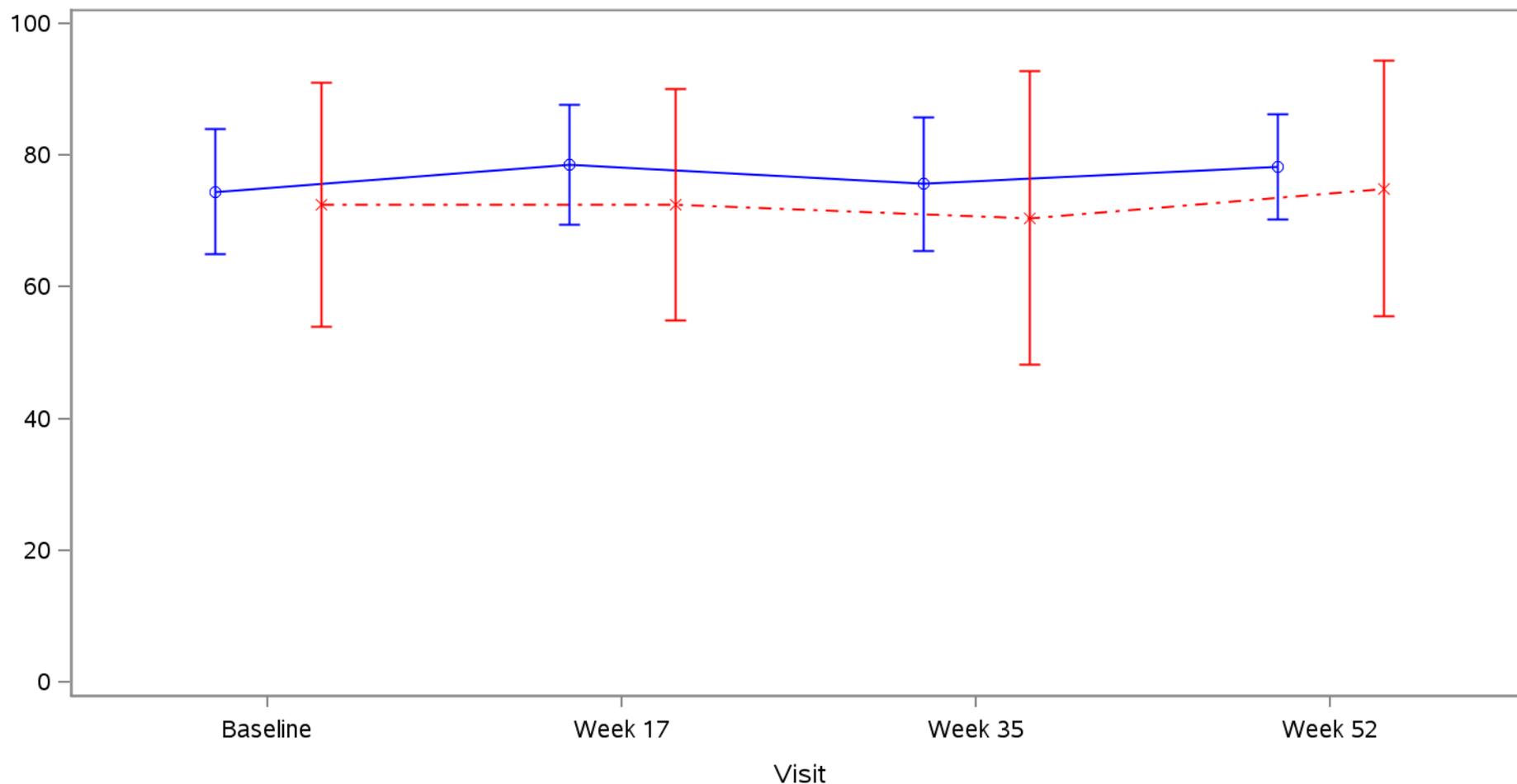
Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics		Placebo Statistics		Difference between treatments (Risdiplam - Placebo)							Population/Method (4)		
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (LL)	95% CI Hedges g (UL)			
All	n/a	Baseline	21	21	0	8	8	0													ITT	Adjusted
		Week 17	20	20	20	8	8	8	4.43	2.78	-0.35	4.16	4.78	5.00	-5.51	15.07	0.39	-0.41	1.19		ITT	Adjusted
		Week 35	21	21	21	8	8	8	1.57	3.49	-2.20	5.42	3.77	6.44	-9.47	17.01	0.24	-0.56	1.03		ITT	Adjusted
		Week 52	21	21	21	8	8	8	4.26	2.81	2.09	4.26	2.17	5.10	-8.33	12.66	0.17	-0.62	0.96		ITT	Adjusted

1) Patients with a value at baseline and a post-baseline value at the respective visit.
 2) LSMeans of change from baseline from MMRM.
 3) Contrasts from MMRM.
 4) Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction. Adjusted for randomization stratification factors.
 Data as observed (no imputation of missing values).
 Covariance matrix: unstructured. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mmrn_IT_T3_DB_BAGE12_EQY.xls
 04MAR2021 14:17

Mean and 95% CI Plot of EQ5D5L Y at Each Time Point, Intent-to-Treat Patients, SMA Type III

Protocol: BP39055 SUNFISH - Part 2



Treatment Group — Risdiplam - - - Placebo

	Baseline	Week 17	Week 35	Week 52
Risdiplam	21 (74.48)	20 (78.55)	21 (75.67)	21 (78.29)
Placebo	8 (72.50)	8 (72.50)	8 (70.50)	8 (75.00)

Baseline is last measurement prior to patients' first dose of risdiplam or placebo.
 patients are grouped by initial treatment received.
 Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/g_mean_plot.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/g_mean_plot_IT_T3_DB_EQY.pdf

Population: Type III SMA, Patients aged >= 12 years at any study visit.

Endpoint: Summary of EQ5D5L Y Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=22)						Placebo (N=8)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All	Baseline	21	100	21	100	74.48	20.89	8	100	8	100	72.50	22.20
		Week 17	22	100	20	90.9	78.55	19.48	8	100	8	100	72.50	21.04
		Week 35	22	100	21	95.5	75.67	22.37	8	100	8	100	70.50	26.63
		Week 52	22	100	21	95.5	78.29	17.60	8	100	8	100	75.00	23.15

1) In study: number of patients in study at the respective visit.

2) % based on the number of patients with observations at respective visit.

3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.

4) % based on patients in study at the respective visit.

5) Mean: descriptive statistics - absolute values.

Only patients aged >= 12 years at the respective visit are included. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_DB_AGE12_EQY.xls

10FEB2021 13:56

Population: Type III SMA, Patients aged >= 12 years at any study visit.

Endpoint: Summary of patient reported SMAIS Total Score at each timepoint up to month 12 (Placebo Controlled Period).

Model: --

Study: BP39055 SUNFISH - Part 2.

			Risdiplam (N=22)						Placebo (N=8)					
			Patients			Statistics			Patients				Statistics	
Name	Level	Visit	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD	in study (1)	% (2)	with value (3)	% (4)	mean (5)	SD
All	All	Baseline	21	100	21	100	35.86	7.42	8	100	8	100	34.13	10.20
		Week 17	22	100	20	90.9	36.40	7.49	8	100	8	100	36.00	7.52
		Week 35	22	100	20	90.9	36.85	7.90	8	100	8	100	35.25	6.76
		Week 52	22	100	20	90.9	37.10	7.40	8	100	8	100	35.50	6.46

1) In study: number of patients in study at the respective visit.

2) % based on the number of patients with observations at respective visit.

3) With value: number of patients in study and with values at the respective visit - used for the calculation of the mean and SD.

4) % based on patients in study at the respective visit.

5) Mean: descriptive statistics - absolute values.

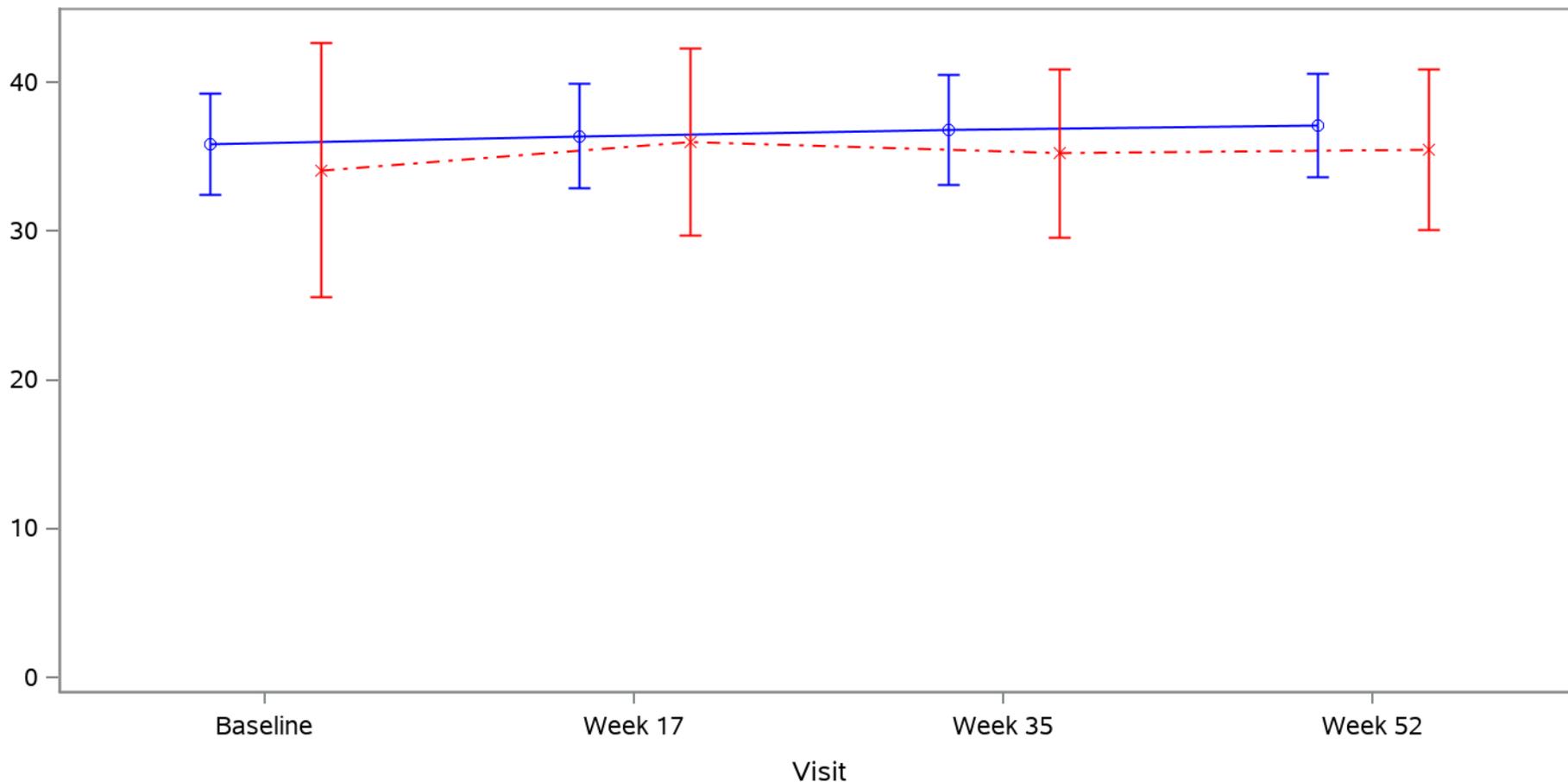
Only patients aged >= 12 years at the respective visit are included. Clinical Cutoff Date: 06SEP2019. NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_eff_mean_IT_T3_DB_AGE12_SMAIS.xls

10FEB2021 14:00

Mean and 95% CI Plot of Patient Reported SMAIS at Each Time Point, Intent-to-Treat Patients, Patients aged >= 12 years at any study visit, SMA Type III
Protocol: BP39055 SUNFISH - Part 2



Treatment Group — Risdiplam - - - Placebo

	Baseline	Week 17	Week 35	Week 52
n (mean)				
Risdiplam	21 (35.86)	20 (36.40)	20 (36.85)	20 (37.10)
Placebo	8 (34.13)	8 (36.00)	8 (35.25)	8 (35.50)

Baseline is last measurement prior to patients' first dose of risdiplam or placebo.
 patients are grouped by planned initial treatment.
 Clinical Cutoff Date: 06SEP2019.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/g_mean_plot.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/g_mean_plot_IT_T3_DB_AGE12_SMAIS.pdf

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk				Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	--	36	100	33	91.7	16	100	15	93.8	0.73				-0.021				0.98				0.7847	1.02			0.87	1.21

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DR.xls
 09JUN2020 12:29

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 1 Including Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam								
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk				Relative Risk				Relative Risk				
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	--	36	100	11	30.6	16	100	4	25.0	1.32	Algorithm converged.	0.34	5.19	0.056	Algorithm converged.	-0.211	0.322	1.22	Algorithm converged.	0.45	3.34	0.6902	0.82	Algorithm converged.	0.30	2.24

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable.

Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GRI.xls

09JUN2020 14:43

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 1 or 2 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk				Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	--	36	100	30	83.3	16	100	10	62.5	3.00				0.208				1.33				0.1718	0.75			0.49	1.14

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GRI2.xls
 09JUN2020 14:43

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 3 Including Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo					Placebo vs. Ridiplam													
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk		Relative Risk			Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
All	--	36	100	3	8.3	16	100	4	25.0	0.27				-0.167				0.33				0.1240	3.00				0.73	12.29

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable.

Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GR3.xls

09JUN2020 14:44

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 3 Excluding Narrow Basket Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Risdiplam				Placebo				Risdiplam vs. Placebo							Placebo vs. Risdiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	--	36	100	2	5.6	16	100	3	18.8	0.25	Algorithm converged.	0.04	1.79	-0.132	Algorithm converged.	-0.342	0.079	0.30	Algorithm converged.	0.05	1.67	0.1644	3.37	Algorithm converged.	0.60	19.06

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable. Disease related events are defined as those under the narrow prospective-LIT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_oe_raw.sas

Output: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_oe_raw_SE_T3_DB_GR3_EXCLM.xls

15OCT2020 10:47

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 3 Excluding Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Risdiplam				Placebo				Risdiplam vs. Placebo					Placebo vs. Risdiplam													
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk		Relative Risk			Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI		
All	--	36	100	2	5.6	16	100	2	12.5	0.41				-0.069				0.44				0.3993	2.25				0.33	15.28

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable.

Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GR3_EXCL.xls

09JUN2020 14:43

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 4 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Riadiplam				Placebo				Riadiplam vs. Placebo				Relative Risk				Placebo vs. Riadiplam								
		Patients	Patients with Event	Patients	Patients with Event	Odds Ratio	Absolute Risk Difference			Relative Risk				Relative Risk												
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
all	--	36	100	0	0	16	100	0	0	NR	Algorithm converged.	NR	NR	0	Algorithm converged.	NR	NR	NR	Algorithm converged.	NR	NR	NR	NR	Algorithm converged.	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_se_raw_SE_T3_DB_G84.xls
 23APR2020 16:54

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 4 Excluding Narrow Basket Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPWR38 - Part 2.

		Rindiplam				Placebo				Rindiplam vs. Placebo										Placebo vs. Rindiplam							
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Subgroup	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	--	16	100	0	0.0	16	100	0	0.0	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NR when shown, means Not Estimable. Disease related events are defined as those under the narrow prospective-LIT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_oe_raw.sas

Output: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_oe_raw_SE_T3_DB_GR4_EXCLM.xls

15OCT2020 10:48

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 4 Excluding Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Risdiplam				Placebo				Risdiplam vs. Placebo				Relative Risk				Relative Risk								
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
all	--	36	100	0	0	16	100	0	0	NR	Algorithm converged.	NR	NR	0	Algorithm converged.	NR	NR	NR	Algorithm converged.	NR	NR	NR	NR	Algorithm converged.	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_se_raw_SE_T3_DB_EXCL.xls
 23APR2020 16:57

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 5 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Riadiplam				Placebo				Riadiplam vs. Placebo				Relative Risk				Placebo vs. Riadiplam								
		Patients	Patients with Event	Patients	Patients with Event	Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
all	--	36	100	0	0	16	100	0	0	NR	Algorithm converged.	NR	NR	0	Algorithm converged.	NR	NR	NR	Algorithm converged.	NR	NR	NR	NR	Algorithm converged.	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_se_raw_SE_T3_DB_G85.xls
 23APR2020 17:00

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade 5 Excluding Narrow Basket Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPWR3H - Part 2.

		Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Subgroup	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	--	36	100	0	0.0	16	100	0	0.0	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable. Disease related events are defined as those under the narrow prospective-LIT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_oe_raw.sas

Output: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_oe_raw_SE_T3_DB_GR5_EXCLM.xls

15OCT2020 10:49

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 5 Excluding Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	Level	Risdiplam				Placebo				Risdiplam vs. Placebo				Relative Risk				Relative Risk								
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
all	--	36	100	0	0	16	100	0	0	NR	Algorithm converged.	NR	NR	0	Algorithm converged.	NR	NR	NR	Algorithm converged.	NR	NR	NR	NR	Algorithm converged.	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_se_raw_SE_T3_DB_GR5_EXCL.xls
 23APR2020 17:04

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade Greater than or Equal to 3 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo					Placebo vs. Ridiplam											
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk		Relative Risk			Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	--	36	100	3	8.3	16	100	4	25.0	0.27	Algorithm converged.	0.05	1.46	-0.167	Algorithm converged.	-0.403	0.070	0.33	Algorithm converged.	0.08	1.37	0.1240	3.00	Algorithm converged.	0.73	12.29

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GRGE3.xls
 09JUN2020 16:20

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Grade Greater than or Equal to 3 Excluding Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo					Placebo vs. Ridiplam											
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk		Relative Risk			Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	--	36	100	2	5.6	16	100	2	12.5	0.41				-0.069				0.44				0.3993	2.25			

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable.

Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_ae_raw_T3_DB_GRGE3_EXCL.xls

09JUN2020 16:23

Population: SAFETY, Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event Leading to Treatment Discontinuation Including Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPWRISM - Part 2.

		Rindiplam				Placebo				Rindiplam vs. Placebo								Placebo vs. Rindiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Subgroup	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	--	16	100	0	0.0	16	100	0	0.0	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable.

Program: root/clinical_studies/RO7034047/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_oe_raw.sas

Output: root/clinical_studies/RO7034047/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_oe_raw_SE_T3_AELDIS_DB.xls

12APR2021 19:09

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Serious Adverse Event Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk				Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	--	36	100	1	2.8	16	100	5	31.3	0.06				-0.285				0.09				0.0258	11.25			1.36	93.34

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_se_raw_T3_SAB_DB.xls
 09JUN2020 18:47

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Serious Adverse Event Excluding Narrow Basket Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Risdiplam				Placebo				Risdiplam vs. Placebo										Placebo vs. Risdiplam						
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	--	36	100	0	0.0	16	100	4	25.0	0.00	Algorithm converged.	0.00	NE	-0.250	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	38E288	0.9676	Infinity	Algorithm converged.	0.00	Infinity

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable. Disease related events are defined as those under the narrow prospective-LIT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_se_raw.sas
 Output: root/clinical_studies/SO7034067/CDP7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_se_raw_SE_T3_SAE_DB_EXCLM.xls
 15OCT2020 11:03

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Serious Adverse Event Excluding Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SPVRISM - Part 2.

Subgroup	Level	Ridiplam				Placebo				Ridiplam vs. Placebo										Placebo vs. Ridiplam							
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	--	36	100	0	0.0	16	100	3	18.8	0.00				-0.188				0.00				0.9682	Infinity				

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_saf_se_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_saf_se_raw_T3_SAB_DB_EXCL.xls
 09JUN2020 18:49

Population: Type III SMA.

Endpoint: Patients who Experienced at least One Adverse Event of Special Interest Including Disease Related Adverse Events.

Model: Unstratified analysis.

Study: BP39055 SPWR3H - Part 2.

		Ridiplam				Placebo				Ridiplam vs. Placebo								Placebo vs. Ridiplam									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Subgroup	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	--	36	100	0	0.0	16	100	0	0.0	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.

Clinical Cutoff Date: 06SEP2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).

NE when shown, means Not Estimable. Disease related events are defined as those under the broad perspective-PT basket.

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/output/t_saf_ae_raw_SE_T3_SFI_DB.xls

25SEP2020 13:29

Population: Type 111 500.
 Reported: Patients who Experienced at Least One Adverse Event Including Disease Related Adverse Events.
 Model: Outpatient analysis.
 Study: R03905 SURFEM - Part 2.

Adverse Event	ICD	ICD Description	Level	Fluoxetine				Fluoxetine vs. Fluoxetine				Fluoxetine vs. Fluoxetine				Fluoxetine vs. Fluoxetine												
				Patients		Patients with Event		Odds Ratio		Odds Ratio		Relative Risk		Relative Risk		Relative Risk		Relative Risk										
				n	%	n	%	95% Lower CI	95% Upper CI	95% Lower CI	95% Upper CI	95% Lower CI	95% Upper CI	95% Lower CI	95% Upper CI	95% Lower CI	95% Upper CI	95% Lower CI	95% Upper CI									
All		Infections and infestations	--	34	100	28	77.8	16	100	13	81.3	0.81	Algorithm covered	0.18	3.48	-0.335	Algorithm covered	-0.275	0.206	0.46	Algorithm covered	0.71	1.29	0.774	1.04	Algorithm covered	0.77	1.43
		Upper respiratory tract infection	--	34	100	12	33.3	16	100	5	31.3	1.10	Algorithm covered	0.30	4.02	0.021	Algorithm covered	-0.260	0.302	1.07	Algorithm covered	0.44	2.58	0.898	0.94	Algorithm covered	0.39	2.27
		Herpeszoster	--	34	100	4	14.7	16	100	2	12.5	1.40	Algorithm covered	0.24	8.17	0.047	Algorithm covered	-0.164	0.249	1.33	Algorithm covered	0.23	6.11	0.765	0.75	Algorithm covered	0.14	3.42
		Respiratory tract infection	--	34	100	3	8.8	16	100	2	12.5	0.64	Algorithm covered	0.09	4.44	-0.842	Algorithm covered	-0.232	0.148	0.40	Algorithm covered	0.12	3.77	0.640	1.50	Algorithm covered	0.27	8.47
		Gastroenteritis	--	34	100	2	5.6	16	100	2	12.5	0.41	Algorithm covered	0.05	3.39	-0.749	Algorithm covered	-0.252	0.111	0.44	Algorithm covered	0.12	3.01	0.393	2.25	Algorithm covered	0.33	15.29
		Pharyngitis	--	34	100	3	8.8	16	100	1	6.3	1.36	Algorithm covered	0.12	15.06	0.021	Algorithm covered	-0.132	0.474	1.33	Algorithm covered	0.14	10.32	0.374	0.75	Algorithm covered	0.09	7.04
		Bronchitis	--	34	100	1	2.8	16	100	2	12.5	0.20	Algorithm covered	0.02	2.54	-0.997	Algorithm covered	-0.273	0.078	0.22	Algorithm covered	0.02	2.41	0.211	4.50	Algorithm covered	0.41	49.86
		Gastroenteric viral	--	34	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.054	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.907	0.00	Algorithm covered	0.00	NE
		Hand-foot-and-mouth disease	--	34	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.054	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.907	0.00	Algorithm covered	0.00	NE
		Scarlet fever	--	34	100	1	2.8	16	100	1	6.3	0.43	Algorithm covered	0.02	7.85	-0.335	Algorithm covered	-0.168	0.099	0.44	Algorithm covered	0.03	7.13	0.560	2.25	Algorithm covered	0.14	34.11
		Stomatitis	--	34	100	0	0.0	16	100	1	6.3	0.07	Algorithm covered	0.00	NE	-0.643	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Appendicitis	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.643	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Poliomyelitis	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Fungal skin infection	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Furunculosis	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Gastrointestinal viral infection	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Oral infection fungal	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Stomatitis	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.00	NE
		Herpes	--	34	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered	0.00	NE	-0.543	Algorithm covered	NE	NE	0.00	Algorithm covered	0.00	19229	0.778	Infinity	Algorithm covered	0.00	Infinity
		Herpes	--	34	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.029	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.918	0.00	Algorithm covered	0.	

Adverse Event	SOC	SPL	Placebo			Placebo			Placebo			Placebo			Placebo			Placebo			Placebo											
			Patients	%	95% CI	Patients	%	95% CI	Patients	%	95% CI	Patients	%	95% CI	Patients	%	95% CI	Patients	%	95% CI	Patients	%	95% CI									
All	Infections and infestations	--	16	100	14	38.9	16	100	5	31.3	1.40	Algorithm covered	0.39	5.05	-0.076	Algorithm covered	-0.208	0.361	1.24	Algorithm covered	0.53	2.93	0.406	0.80	Algorithm covered	0.34	1.83					
			Upper respiratory tract infection	16	100	6	16.7	16	100	2	12.5	1.40	Algorithm covered	0.24	8.17	-0.042	Algorithm covered	-0.164	0.249	1.33	Algorithm covered	0.29	6.13	0.763	0.75	Algorithm covered	0.14	3.43				
			Herpes zoster	16	100	5	13.9	16	100	2	12.5	1.33	Algorithm covered	0.19	6.49	-0.014	Algorithm covered	-0.189	0.216	1.21	Algorithm covered	0.23	5.31	0.832	0.80	Algorithm covered	0.19	4.32				
			Shingles	16	100	2	5.6	16	100	1	6.3	0.88	Algorithm covered	0.07	11.16	-0.007	Algorithm covered	-0.151	0.69	0.89	Algorithm covered	0.08	6.65	0.014	1.12	Algorithm covered	0.10	19.21				
			Bronchitis	16	100	1	2.8	16	100	1	6.3	0.43	Algorithm covered	0.02	7.85	-0.031	Algorithm covered	-0.188	0.099	0.44	Algorithm covered	0.03	7.13	0.600	2.25	Algorithm covered	0.14	16.11				
			Gastroenteritis	16	100	1	2.8	16	100	1	6.3	0.43	Algorithm covered	0.02	7.85	-0.031	Algorithm covered	-0.168	0.099	0.44	Algorithm covered	0.03	7.13	0.600	2.25	Algorithm covered	0.14	16.11				
			Parvovirus	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Gastrointestinal viral infection	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Gastrointestinal fungal infection	16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity			
			Genital infection fungal	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Candidiasis	16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity			
			Histoplasmosis	16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity			
			Coccidioidomycosis	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Ornithosis	16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity			
			Chlamydia	16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity			
Gastrointestinal disorders	--	16	100	11	39.4	16	100	4	25.0	1.32	Algorithm covered	0.34	5.19	0.054	Algorithm covered	-0.211	0.322	1.22	Algorithm covered	0.43	3.34	0.602	0.82	Algorithm covered	0.30	2.24						
			Diarrhea	16	100	7	19.4	16	100	1	6.3	3.62	Algorithm covered	0.39	18.49	0.130	Algorithm covered	-0.048	0.312	3.11	Algorithm covered	0.40	24.43	0.739	0.32	Algorithm covered	0.04	2.52				
			Nausea	16	100	4	11.1	16	100	4	25.0	0.38	Algorithm covered	0.08	1.81	-0.113	Algorithm covered	-0.380	0.103	0.44	Algorithm covered	0.12	1.61	0.111	2.25	Algorithm covered	0.02	8.10				
			Abdominal pain	16	100	5	8.3	16	100	1	6.3	1.36	Algorithm covered	0.12	15.04	-0.021	Algorithm covered	-0.132	0.274	1.33	Algorithm covered	0.14	12.52	0.794	0.75	Algorithm covered	0.08	7.04				
			Abdominal pain upper	16	100	3	8.3	16	100	1	6.3	1.36	Algorithm covered	0.12	15.06	-0.021	Algorithm covered	-0.132	0.274	1.33	Algorithm covered	0.14	12.52	0.794	0.75	Algorithm covered	0.08	7.04				
			Constipation	16	100	3	8.3	16	100	1	6.3	1.36	Algorithm covered	0.12	15.04	-0.021	Algorithm covered	-0.132	0.274	1.33	Algorithm covered	0.14	12.52	0.794	0.75	Algorithm covered	0.08	7.04				
			Flatulence	16	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.056	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.987	0.00	Algorithm covered	0.00	NE				
			Stomach pain	16	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.056	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.987	0.00	Algorithm covered	0.00	NE				
			Abdominal distention	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Feces soft	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Flatulence	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Stool incontinence	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Tongue pain	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE				
			Respiratory, thoracic and mediastinal disorders	--	16	100	6	16.7	16	100	4	25.0	0.40	Algorithm covered	0.14	2.40	-0.043	Algorithm covered	-0.334	0.167	0.47	Algorithm covered	0.21	2.10	0.812	1.50	Algorithm covered	0.48	4.73			
			Cough			16	100	4	11.1	16	100	1	10.5	0.88	Algorithm covered	0.14	5.30	-0.044	Algorithm covered	-0.210	0.283	0.89	Algorithm covered	0.17	4.54	0.853	1.11	Algorithm covered	0.20	5.70		
Intertrigo	16	100	2			5.6	16	100	4	25.0	0.80	Algorithm covered	0.00	NE	-0.250	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.876	Infinity	Algorithm covered	0.00	Infinity				
Rhinitis	16	100	1			2.8	16	100	1	6.3	0.43	Algorithm covered	0.02	7.85	-0.031	Algorithm covered	-0.168	0.099	0.44	Algorithm covered	0.03	7.13	0.600	2.25	Algorithm covered	0.14	16.11					
Respiratory hypersensitivity	16	100	1			2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE					
General disorders and administration site conditions	--	16	100			4	16.7	16	100	2	12.5	1.40	Algorithm covered	0.24	8.17	-0.042	Algorithm covered	-0.164	0.249	1.33	Algorithm covered	0.29	6.13	0.763	0.75	Algorithm covered	0.14	3.43				
Pruritus			16			100	3	8.3	16	100	2	12.5	0.64	Algorithm covered	0.09	4.44	-0.042	Algorithm covered	-0.232	0.148	0.47	Algorithm covered	0.12	3.77	0.401	1.50	Algorithm covered	0.27	8.47			
Swelling abnormal			16			100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Exosmosis			16			100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Physical deconditioning			16			100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual cycle disorders			--			16	100	7	19.4	16	100	1	6.3	3.62	Algorithm covered	0.39	18.49	0.130	Algorithm covered	-0.048	0.312	3.11	Algorithm covered	0.40	24.43	0.739	0.32	Algorithm covered	0.04	2.52		
Headache							16	100	7	19.4	16	100	1	6.3	3.62	Algorithm covered	0.39	18.49	0.130	Algorithm covered	-0.048	0.312	3.11	Algorithm covered	0.40	24.43	0.739	0.32	Algorithm covered	0.04	2.52	
Menstrual pain							16	100	0	0.0	16	100	1	6.3	0.40	Algorithm covered	0.00	NE	-0.043	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	158289	0.708	Infinity	Algorithm covered	0.00	Infinity
Menstrual pain							16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE	
Menstrual pain							16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE	
Menstrual pain				16	100		1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual pain				16	100		1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual pain				16	100		1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual pain				16	100		1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual pain				16	100		1	2.8	16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE			
Menstrual pain	16	100		1	2.8		16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE					
Menstrual pain	16	100		1	2.8		16	100	0	0.0	Infinity	Algorithm covered	0.00	Infinity	0.028	Algorithm covered	NE	NE	Infinity	Algorithm covered	0.00	Infinity	0.981	0.00	Algorithm covered	0.00	NE					
Menstr																																

Population: Type 1II SMO.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 2 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SURFEM - Part 2.

Adverse Event	ICD	SPL	Placebo		Flamox		Odds Ratio	Placebo vs. Flamox				Relative Risk															
			n	%	n	%		Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI									
All	Infections and infestations	--	16	100	14	38.9	16	100	3	43.8	0.89	Algorithm converged.	0.24	2.78	<0.001	Algorithm converged.	-0.346	0.249	0.89	Algorithm converged.	0.44	1.85	0.794	1.13	Algorithm converged.	0.35	2.28
	Upper respiratory tract infection	--	16	100	6	16.7	16	100	3	18.8	0.87	Algorithm converged.	0.18	4.16	<0.001	Algorithm converged.	-0.251	0.211	0.89	Algorithm converged.	0.25	3.22	0.848	1.13	Algorithm converged.	0.31	4.07
	Respiratory tract infection	--	16	100	3	8.3	16	100	2	12.5	0.64	Algorithm converged.	0.09	4.44	<0.001	Algorithm converged.	-0.232	0.148	0.67	Algorithm converged.	0.12	3.77	0.640	1.00	Algorithm converged.	0.27	8.47
	Gastroenteritis	--	16	100	1	2.8	16	100	1	6.3	0.63	Algorithm converged.	0.02	3.85	<0.001	Algorithm converged.	-0.168	0.099	0.64	Algorithm converged.	0.01	7.13	0.640	2.25	Algorithm converged.	0.14	16.11
	Head/face-and-mouth disease	--	16	100	2	5.4	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.04	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.887	0.00	Algorithm converged.	0.00	NE
	Almondria	--	16	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	<0.001	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	15289	0.708	Infinity	Algorithm converged.	0.00	Infinity
	Mononitria	--	16	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	<0.001	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	15289	0.708	Infinity	Algorithm converged.	0.00	Infinity
	Cellulitria	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Fungal skin infection	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Gastroenteritria viral	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Influenza	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Salmonella infection	--	16	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	<0.001	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	15289	0.708	Infinity	Algorithm converged.	0.00	Infinity
	Resonborrhagia	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Pharyngitria	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Pharyngitria bacterial	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Dysmenria	--	16	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	<0.001	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	15289	0.708	Infinity	Algorithm converged.	0.00	Infinity
	Cellulitria	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Upper respiratory tract infection bacterial	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Herpetic	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Viral upper respiratory tract infection	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Gastrointestinal disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Diarrhea	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Abdominal discomfort	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Abdominal pain	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Constipation	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Overdose	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Fluorence	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Tooth formation	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Vertigo	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Nervous system disorders	--	16	100	4	11.1	16	100	1	6.3	1.87	Algorithm converged.	0.18	19.31	0.049	Algorithm converged.	-0.112	0.209	1.78	Algorithm converged.	0.20	15.46	0.955	0.56	Algorithm converged.	0.04	4.89
	Headache	--	16	100	4	11.1	16	100	1	6.3	1.87	Algorithm converged.	0.18	19.31	0.049	Algorithm converged.	-0.112	0.209	1.78	Algorithm converged.	0.20	15.46	0.955	0.56	Algorithm converged.	0.04	4.89
	General disorders and administration site conditions	--	16	100	4	11.1	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.111	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9796	0.00	Algorithm converged.	0.00	NE
	Dyscresia	--	16	100	4	11.1	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.111	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9796	0.00	Algorithm converged.	0.00	NE
	Medical device pain	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Musculoskeletal and connective tissue disorders	--	16	100	3	8.3	16	100	1	6.3	1.36	Algorithm converged.	0.12	15.06	0.021	Algorithm converged.	-0.132	0.174	1.53	Algorithm converged.	0.14	12.59	0.794	0.75	Algorithm converged.	0.08	7.04
	Arthralgia	--	16	100	2	5.4	16	100	1	6.3	0.88	Algorithm converged.	0.07	11.16	<0.001	Algorithm converged.	-0.151	0.137	0.89	Algorithm converged.	0.08	8.65	0.924	1.12	Algorithm converged.	0.10	12.21
	Blood and lymphatic system disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Iron deficiency anemia	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Endocrine disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Hypocalcaemia	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Immune system disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Seasonal allergy	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Injury, poisoning and procedural complications	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Joint dislocation	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Metabolic and nutrition disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Hypernatremia	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Skin and subcutaneous tissue disorders	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE
	Stomatitria cancer	--	16	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	Algorithm converged.	0.00	NE

* When shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 16SEP2015.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NE" (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective=PT basket. Only AEs of highest severity are counted.
 Program: /root/clinical_studies/07034067/CDPT916/BP39055/data_analysis/ACE_CSP_part2/prod/program/t_naf_wa_raw_001.sas
 Output: /root/clinical_studies/07034067/CDPT916/BP39055/data_analysis/ACE_CSP_part2/prod/outputs/t_naf_wa_raw_001_002.xls
 19/09/2015 15:14

Population: Type III RMA.
 Endpoint: Patients who Experienced at Least One Adverse Event of Grade 3 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055_S0M12H - Part 2.

Subgroup	SOC	PT	Placebo				Placebo				Radiolium vs. Placebo												Placebo vs. Radiolium				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	95% Lower CI	95% Upper CI				
All	Gastrointestinal disorders	--	36	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.056	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9807	0.00	Algorithm covered.	0.00	NE
	Constipation	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Dental necrosis	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Injury, poisoning and procedural complications	--	36	100	0	0.0	16	100	2	12.5	0.00	Algorithm covered.	0.00	NE	+0.125	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	75228	0.9692	Infinity	Algorithm covered.	0.00	Infinity
	Open fracture	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Procedural pain	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Blood and lymphatic system disorders	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Leukopenia	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Neutropenia	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Infections and infestations	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Appendicitis	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Investigations	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Oxygen saturation decreased	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Nervous system disorders	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Respiratory, thoracic and mediastinal disorders	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Sleep apnoea syndrome	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity

* When shown, indicates convergence problem. Result is uninterpretable.

Clinical cutoff dates: 06/29/2019.

When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.

When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).

NE when shown, means Not Estimable.

Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/program/t_saf_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/output/t_saf_raw_soc_NE_T3_Q3.xls
 09/20/2019 12:33

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 4 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SUNFISH - Part 2.

Subgroup	SOC	PT	Level	Risdiplam				Placebo				Risdiplam vs. Placebo								Placebo vs. Risdiplam							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL
All	--	--	--	0	0	0	0	0	0	0	0	0	0	NR	*	NR	NR	NR	*	NR	NR	NR	NR	NR	*	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPF7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPF7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_ae_raw_soc_SE_T3_DB_GR4.xls
 30APR2020 13:23

Population: Type III SMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade 5 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SUNFISH - Part 2.

Subgroup	SOC	PT	Level	Risdiplam				Placebo				Risdiplam vs. Placebo					Placebo vs. Risdiplam										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL
All	--	--	--	0	0	0	0	0	0	0	0	0	NR	*	NR	NR	NR	NR	*	NR	NR	NR	NR	*	NR	NR	NR

* when shown, indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 06SEP2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to 'NR' (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket.

Program: root/clinical_studies/RO7034067/CDPF7916/BP39055/data_analysis/ACE_Base/work/work_all/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPF7916/BP39055/data_analysis/ACE_Base/work/work_all/output/t_saf_ae_raw_soc_SE_T3_DB_GRS.xls
 29APR2020 14:53

Population: Type III RMA.
 Endpoint: Patients who Experienced at least One Adverse Event of Grade Greater than or Equal to 3 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055_S0M12H - Part 2.

Subgroup	SOC	PT	Placebo				Placebo				Radiolium vs. Placebo												Placebo vs. Radiolium				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk	95% Lower CI	95% Upper CI				
All	Gastrointestinal disorders	--	36	100	2	5.6	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.056	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9807	0.00	Algorithm covered.	0.00	NE
	Constipation	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Dental necrosis	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Injury, poisoning and procedural complications	--	36	100	0	0.0	16	100	2	12.5	0.00	Algorithm covered.	0.00	NE	+0.125	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	75228	0.6692	Infinity	Algorithm covered.	0.00	Infinity
	Open fracture	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Procedural pain	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Blood and lymphatic system disorders	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Leukopenia	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Neutropenia	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Infections and infestations	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Appendicitis	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Investigations	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Oxygen saturation decreased	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity
	Nervous system disorders	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Respiratory, thoracic and mediastinal disorders	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm covered.	0.00	Infinity	0.028	Algorithm covered.	NE	NE	Infinity	Algorithm covered.	0.00	Infinity	0.9818	0.00	Algorithm covered.	0.00	NE
	Sleep apnoea syndrome	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm covered.	0.00	NE	+0.063	Algorithm covered.	NE	NE	0.00	Algorithm covered.	0.00	15228	0.9708	Infinity	Algorithm covered.	0.00	Infinity

* When shown, indicates convergence problem. Result is uninterpretable.
 Clinical cutoff date: 06/29/2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/program/t_saf_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/output/t_saf_raw_soc_R3_DB_GM33.v1x
 09/20/2020 16:34

Population: Type III OMA.
 Endpoint: Patients who Experienced at Least One Serious Adverse Event Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SONFISH - Part 2.

Subgroup	SOC	PT	Placebo				Placebo				Placebo vs. Placebo										Placebo vs. Placebo								
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk						
			n	%	n	%	n	%	n	%	OR	95% Lower CI	95% Upper CI	AR	95% Lower CI	95% Upper CI	RR	95% Lower CI	95% Upper CI	OR	95% Lower CI	95% Upper CI	OR	95% Lower CI	95% Upper CI				
All	Infections and infestations	--	36	100	0	0.0	16	100	3	18.8	0.00	Algorithm converged.	0.00	NE	+0.188	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	58289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Appendicitis	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Gastroenteritis	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Lymph gland infection	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Gastrointestinal disorders	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	0.00	Algorithm converged.	0.00	NE	
	Injury, poisoning and procedural complications	Constipation	--	36	100	1	2.8	16	100	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.028	Algorithm converged.	NE	NE	Infinity	Algorithm converged.	0.00	Infinity	0.9818	0.00	0.00	Algorithm converged.	0.00	NE
	Fracture, pathological and traumatic	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Fracture, non-traumatic and non-pathological	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Investigations	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity		
	Respiratory, thoracic and mediastinal disorders	Oxygen saturation decreased	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity	
	Sleep disorders	Sleep apnoea syndrome	--	36	100	0	0.0	16	100	1	6.3	0.00	Algorithm converged.	0.00	NE	+0.063	Algorithm converged.	NE	NE	0.00	Algorithm converged.	0.00	152289	0.9708	Infinity	Algorithm converged.	0.00	Infinity	

* When shown, indicates convergence problem. Result is uninterpretable.
 Clinical cutoff dates: 06/09/2019.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NE when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/program/t_saf_se_raw_soc.asx
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACR_CSR_part2/prod/output/t_saf_se_raw_soc_SE_T3_SAE_CR.xls
 09/20/2019 19:03

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	9	60.0

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AAE_SE_P2_OLE_SW_T3_EXCL.xls

08MAR2021 12:57

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	10	66.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AAE_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 11:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any AEs excluding Broad Basket Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	36	100.0	16	100.0	15	93.8

Only AEs of highest severity are counted.
 Disease related events are defined as those under the broad prospective-PT basket.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AAE_SE_P2_T3_EXCL.xls
 18DEC2020 9:15

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: Any AEs excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	36	100.0	16	100.0	15	93.8

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AAE_SE_P2_T3_EXCLN.xls

18DEC2020 9:16

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade ≥ 3 excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG345_SE_P2_OLE_SW_T3_EXCL.xls
08MAR2021 13:08

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade ≥ 3 excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG345_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 13:08

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 excluding Broad Basket Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	4	11.1	16	100.0	3	18.8

Only AEs of highest severity are counted.
 Disease related events are defined as those under the broad prospective-PT basket.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG345_SE_P2_T3_EXCL.xls
 18DEC2020 9:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 excluding Narrow Basket Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	4	11.1	16	100.0	4	25.0

Only AEs of highest severity are counted.
 Disease related events are defined as those under the narrow prospective-LLT basket.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG345_SE_P2_T3_EXCLN.xls
 18DEC2020 9:35

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG3_SE_P2_OLE_SW_T3_EXCL.xls

08MAR2021 13:03

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG3_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 13:03

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 3 excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	4	11.1	16	100.0	3	18.8

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG3_SE_P2_T3_EXCL.xls

18DEC2020 9:25

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 3 excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	4	11.1	16	100.0	4	25.0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG3_SE_P2_T3_EXCLN.xls

18DEC2020 9:26

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 4 excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG4_SE_P2_OLE_SW_T3_EXCL.xls

08MAR2021 13:05

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 4 excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG4_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 13:05

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 4 excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG4_SE_P2_T3_EXCL.xls

18DEC2020 9:28

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 4 excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG4_SE_P2_T3_EXCLN.xls

18DEC2020 9:29

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 5 (AEs leading to death) excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG5_SE_P2_OLE_SW_T3_EXCL.xls

08MAR2021 13:06

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 5 (AEs leading to death) excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG5_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 13:06

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG5_SE_P2_T3_EXCL.xls

18DEC2020 9:30

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_AEG5_SE_P2_T3_EXCLN.xls

18DEC2020 9:33

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_ASAE_SE_P2_OLE_SW_T3_EXCL.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_ASAE_SE_P2_OLE_SW_T3_EXCLN.xls

08MAR2021 13:09

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: Any SAEs excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	1	2.8	16	100.0	3	18.8

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_ASAE_SE_P2_T3_EXCL.xls

18DEC2020 9:36

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: Any SAEs excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	2	5.6	16	100.0	5	31.3

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_ASAE_SE_P2_T3_EXCLN.xls

18DEC2020 9:38

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	11	73.3
Sex	Male	8	53.3	6	75.0
	Female	7	46.7	5	71.4
Age (at randomization)	2 to 5 years	3	20.0	3	100.0
	6 to 11 years	4	26.7	2	50.0
	12 to 17 years	4	26.7	2	50.0
	18 to 25 years	4	26.7	4	100.0
SMA Type	Type III	15	100.0	11	73.3
Geographic region	Europe	14	93.3	10	71.4
	Rest of the World	1	6.7	1	100.0
Race/ethnicity	White	12	80.0	8	66.7
	Asian/Black or African American/Multiple	1	6.7	1	100.0
	Unknown	2	13.3	2	100.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	2	50.0
	No	11	73.3	9	81.8
Disease Severity	<=Q1	1	6.7	1	100.0
	>Q1 to <=Q3	4	26.7	2	50.0
	>Q3	9	60.0	7	77.8
	Missing	1	6.7	1	100.0
SMN2 Copy Number	3	10	66.7	7	70.0
	4	5	33.3	4	80.0

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Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AAE_SE_P2_OLE_SW_T3.xls

08MAR2021 12:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	36	100.0	16	100.0	16	100.0
Sex	Male	19	52.8	19	100.0	8	50.0	8	100.0
	Female	17	47.2	17	100.0	8	50.0	8	100.0
Age (at randomization)	2 to 5 years	4	11.1	4	100.0	4	25.0	4	100.0
	6 to 11 years	11	30.6	11	100.0	4	25.0	4	100.0
	12 to 17 years	15	41.7	15	100.0	4	25.0	4	100.0
	18 to 25 years	6	16.7	6	100.0	4	25.0	4	100.0
SMA Type	Type III	36	100.0	36	100.0	16	100.0	16	100.0
Geographic region	Europe	28	77.8	28	100.0	14	87.5	14	100.0
	Rest of the World	8	22.2	8	100.0	2	12.5	2	100.0
Race/ethnicity	White	25	69.4	25	100.0	13	81.3	13	100.0
	Asian/Black or African American/Multiple	7	19.4	7	100.0	1	6.3	1	100.0
	Unknown	4	11.1	4	100.0	2	12.5	2	100.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	7	100.0	4	25.0	4	100.0
	No	29	80.6	29	100.0	12	75.0	12	100.0
Disease Severity	<=Q1	3	8.3	3	100.0	1	6.3	1	100.0
	>Q1 to <=Q3	12	33.3	12	100.0	4	25.0	4	100.0
	>Q3	20	55.6	20	100.0	10	62.5	10	100.0
	Missing	1	2.8	1	100.0	1	6.3	1	100.0
SMN2 Copy Number	2	2	5.6	2	100.0	0	0.0	0	0.0
	3	24	66.7	24	100.0	10	62.5	10	100.0
	4	10	27.8	10	100.0	6	37.5	6	100.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AAE_SE_P2_T3.xls
 18DEC2020 9:15

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	10	66.7
Sex	Male	8	53.3	6	75.0
	Female	7	46.7	4	57.1
Age (at randomization)	2 to 5 years	3	20.0	2	66.7
	6 to 11 years	4	26.7	2	50.0
	12 to 17 years	4	26.7	2	50.0
	18 to 25 years	4	26.7	4	100.0
SMA Type	Type III	15	100.0	10	66.7
Geographic region	Europe	14	93.3	9	64.3
	Rest of the World	1	6.7	1	100.0
Race/ethnicity	White	12	80.0	7	58.3
	Asian/Black or African American/Multiple	1	6.7	1	100.0
	Unknown	2	13.3	2	100.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	2	50.0
	No	11	73.3	8	72.7
Disease Severity	<=Q1	1	6.7	1	100.0
	>Q1 to <=Q3	4	26.7	2	50.0
	>Q3	9	60.0	7	77.8
	Missing	1	6.7	0	0.0
SMN2 Copy Number	3	10	66.7	6	60.0
	4	5	33.3	4	80.0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG12_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	30	83.3	16	100.0	11	68.8
Sex	Male	19	52.8	16	84.2	8	50.0	4	50.0
	Female	17	47.2	14	82.4	8	50.0	7	87.5
Age (at randomization)	2 to 5 years	4	11.1	3	75.0	4	25.0	2	50.0
	6 to 11 years	11	30.6	9	81.8	4	25.0	1	25.0
	12 to 17 years	15	41.7	12	80.0	4	25.0	4	100.0
	18 to 25 years	6	16.7	6	100.0	4	25.0	4	100.0
SMA Type	Type III	36	100.0	30	83.3	16	100.0	11	68.8
Geographic region	Europe	28	77.8	22	78.6	14	87.5	10	71.4
	Rest of the World	8	22.2	8	100.0	2	12.5	1	50.0
Race/ethnicity	White	25	69.4	20	80.0	13	81.3	10	76.9
	Asian/Black or African American/Multiple	7	19.4	7	100.0	1	6.3	0	0.0
	Unknown	4	11.1	3	75.0	2	12.5	1	50.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	6	85.7	4	25.0	4	100.0
	No	29	80.6	24	82.8	12	75.0	7	58.3
Disease Severity	<=Q1	3	8.3	2	66.7	1	6.3	1	100.0
	>Q1 to <=Q3	12	33.3	11	91.7	4	25.0	4	100.0
	>Q3	20	55.6	16	80.0	10	62.5	6	60.0
	Missing	1	2.8	1	100.0	1	6.3	0	0.0
SMN2 Copy Number	2	2	5.6	1	50.0	0	0.0	0	0.0
	3	24	66.7	22	91.7	10	62.5	7	70.0
	4	10	27.8	7	70.0	6	37.5	4	66.7

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG12_SE_P2_T3.xls
 18DEC2020 9:24

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	5	33.3
Sex	Male	8	53.3	2	25.0
	Female	7	46.7	3	42.9
Age (at randomization)	2 to 5 years	3	20.0	1	33.3
	6 to 11 years	4	26.7	2	50.0
	12 to 17 years	4	26.7	1	25.0
	18 to 25 years	4	26.7	1	25.0
SMA Type	Type III	15	100.0	5	33.3
Geographic region	Europe	14	93.3	5	35.7
	Rest of the World	1	6.7	0	0.0
Race/ethnicity	White	12	80.0	3	25.0
	Asian/Black or African American/Multiple	1	6.7	0	0.0
	Unknown	2	13.3	2	100.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	1	25.0
	No	11	73.3	4	36.4
Disease Severity	<=Q1	1	6.7	1	100.0
	>Q1 to <=Q3	4	26.7	0	0.0
	>Q3	9	60.0	4	44.4
	Missing	1	6.7	0	0.0
SMN2 Copy Number	3	10	66.7	5	50.0
	4	5	33.3	0	0.0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 12:58

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
Name	Level	Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	7	19.4	16	100.0	4	25.0
Sex	Male	19	52.8	4	21.1	8	50.0	0	0.0
	Female	17	47.2	3	17.6	8	50.0	4	50.0
Age (at randomization)	2 to 5 years	4	11.1	3	75.0	4	25.0	1	25.0
	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
	12 to 17 years	15	41.7	1	6.7	4	25.0	2	50.0
	18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
SMA Type	Type III	36	100.0	7	19.4	16	100.0	4	25.0
Geographic region	Europe	28	77.8	4	14.3	14	87.5	3	21.4
	Rest of the World	8	22.2	3	37.5	2	12.5	1	50.0
Race/ethnicity	White	25	69.4	4	16.0	13	81.3	3	23.1
	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	2	28.6	4	25.0	2	50.0
	No	29	80.6	5	17.2	12	75.0	2	16.7
Disease Severity	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	2	50.0
	>Q3	20	55.6	2	10.0	10	62.5	2	20.0
	Missing	1	2.8	1	100.0	1	6.3	0	0.0
SMN2 Copy Number	2	2	5.6	1	50.0	0	0.0	0	0.0
	3	24	66.7	5	20.8	10	62.5	3	30.0
	4	10	27.8	1	10.0	6	37.5	1	16.7

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG1_SE_P2_T3.xls

18DEC2020 9:18

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	5	33.3
Sex	Male	8	53.3	4	50.0
	Female	7	46.7	1	14.3
Age (at randomization)	2 to 5 years	3	20.0	1	33.3
	6 to 11 years	4	26.7	0	0.0
	12 to 17 years	4	26.7	1	25.0
	18 to 25 years	4	26.7	3	75.0
SMA Type	Type III	15	100.0	5	33.3
Geographic region	Europe	14	93.3	4	28.6
	Rest of the World	1	6.7	1	100.0
Race/ethnicity	White	12	80.0	4	33.3
	Asian/Black or African American/Multiple	1	6.7	1	100.0
	Unknown	2	13.3	0	0.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	1	25.0
	No	11	73.3	4	36.4
Disease Severity	<=Q1	1	6.7	0	0.0
	>Q1 to <=Q3	4	26.7	2	50.0
	>Q3	9	60.0	3	33.3
	Missing	1	6.7	0	0.0
SMN2 Copy Number	3	10	66.7	1	10.0
	4	5	33.3	4	80.0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG2_SE_P2_OLE_SW_T3.xls

08MAR2021 13:00

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
Name	Level	Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	23	63.9	16	100.0	7	43.8
Sex	Male	19	52.8	12	63.2	8	50.0	4	50.0
	Female	17	47.2	11	64.7	8	50.0	3	37.5
Age (at randomization)	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
	6 to 11 years	11	30.6	8	72.7	4	25.0	1	25.0
	12 to 17 years	15	41.7	11	73.3	4	25.0	2	50.0
	18 to 25 years	6	16.7	4	66.7	4	25.0	3	75.0
SMA Type	Type III	36	100.0	23	63.9	16	100.0	7	43.8
Geographic region	Europe	28	77.8	18	64.3	14	87.5	7	50.0
	Rest of the World	8	22.2	5	62.5	2	12.5	0	0.0
Race/ethnicity	White	25	69.4	16	64.0	13	81.3	7	53.8
	Asian/Black or African American/Multiple	7	19.4	5	71.4	1	6.3	0	0.0
	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	4	57.1	4	25.0	2	50.0
	No	29	80.6	19	65.5	12	75.0	5	41.7
Disease Severity	<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
	>Q1 to <=Q3	12	33.3	8	66.7	4	25.0	2	50.0
	>Q3	20	55.6	14	70.0	10	62.5	4	40.0
	Missing	1	2.8	0	0.0	1	6.3	0	0.0
SMN2 Copy Number	2	2	5.6	0	0.0	0	0.0	0	0.0
	3	24	66.7	17	70.8	10	62.5	4	40.0
	4	10	27.8	6	60.0	6	37.5	3	50.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG2_SE_P2_T3.xls

18DEC2020 9:21

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7
Sex	Male	8	53.3	0	0.0
	Female	7	46.7	1	14.3
Age (at randomization)	2 to 5 years	3	20.0	1	33.3
	6 to 11 years	4	26.7	0	0.0
	12 to 17 years	4	26.7	0	0.0
	18 to 25 years	4	26.7	0	0.0
SMA Type	Type III	15	100.0	1	6.7
Geographic region	Europe	14	93.3	1	7.1
	Rest of the World	1	6.7	0	0.0
Race/ethnicity	White	12	80.0	1	8.3
	Asian/Black or African American/Multiple	1	6.7	0	0.0
	Unknown	2	13.3	0	0.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0.0
	No	11	73.3	1	9.1
Disease Severity	\leq Q1	1	6.7	0	0.0
	>Q1 to \leq Q3	4	26.7	0	0.0
	>Q3	9	60.0	0	0.0
	Missing	1	6.7	1	100.0
SMN2 Copy Number	3	10	66.7	1	10.0
	4	5	33.3	0	0.0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:08

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
Name	Level	Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	6	16.7	16	100.0	5	31.3
Sex	Male	19	52.8	3	15.8	8	50.0	4	50.0
	Female	17	47.2	3	17.6	8	50.0	1	12.5
Age (at randomization)	2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
	6 to 11 years	11	30.6	2	18.2	4	25.0	3	75.0
	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
SMA Type	Type III	36	100.0	6	16.7	16	100.0	5	31.3
Geographic region	Europe	28	77.8	6	21.4	14	87.5	4	28.6
	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Race/ethnicity	White	25	69.4	5	20.0	13	81.3	3	23.1
	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	1	14.3	4	25.0	0	0.0
	No	29	80.6	5	17.2	12	75.0	5	41.7
Disease Severity	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
	>Q3	20	55.6	4	20.0	10	62.5	4	40.0
	Missing	1	2.8	0	0.0	1	6.3	1	100.0
SMN2 Copy Number	2	2	5.6	1	50.0	0	0.0	0	0.0
	3	24	66.7	2	8.3	10	62.5	3	30.0
	4	10	27.8	3	30.0	6	37.5	2	33.3

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG345_SE_P2_T3.xls

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7
Sex	Male	8	53.3	0	0.0
	Female	7	46.7	1	14.3
Age (at randomization)	2 to 5 years	3	20.0	1	33.3
	6 to 11 years	4	26.7	0	0.0
	12 to 17 years	4	26.7	0	0.0
	18 to 25 years	4	26.7	0	0.0
SMA Type	Type III	15	100.0	1	6.7
Geographic region	Europe	14	93.3	1	7.1
	Rest of the World	1	6.7	0	0.0
Race/ethnicity	White	12	80.0	1	8.3
	Asian/Black or African American/Multiple	1	6.7	0	0.0
	Unknown	2	13.3	0	0.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0.0
	No	11	73.3	1	9.1
Disease Severity	<=Q1	1	6.7	0	0.0
	>Q1 to <=Q3	4	26.7	0	0.0
	>Q3	9	60.0	0	0.0
	Missing	1	6.7	1	100.0
SMN2 Copy Number	3	10	66.7	1	10.0
	4	5	33.3	0	0.0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:03

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
Name	Level	Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	6	16.7	16	100.0	5	31.3
Sex	Male	19	52.8	3	15.8	8	50.0	4	50.0
	Female	17	47.2	3	17.6	8	50.0	1	12.5
Age (at randomization)	2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
	6 to 11 years	11	30.6	2	18.2	4	25.0	3	75.0
	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
SMA Type	Type III	36	100.0	6	16.7	16	100.0	5	31.3
Geographic region	Europe	28	77.8	6	21.4	14	87.5	4	28.6
	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Race/ethnicity	White	25	69.4	5	20.0	13	81.3	3	23.1
	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	1	14.3	4	25.0	0	0.0
	No	29	80.6	5	17.2	12	75.0	5	41.7
Disease Severity	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
	>Q3	20	55.6	4	20.0	10	62.5	4	40.0
	Missing	1	2.8	0	0.0	1	6.3	1	100.0
SMN2 Copy Number	2	2	5.6	1	50.0	0	0.0	0	0.0
	3	24	66.7	2	8.3	10	62.5	3	30.0
	4	10	27.8	3	30.0	6	37.5	2	33.3

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG3_SE_P2_T3.xls

18DEC2020 9:27

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 4 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0
Sex	Male	8	53.3	0	0
	Female	7	46.7	0	0
Age (at randomization)	2 to 5 years	3	20.0	0	0
	6 to 11 years	4	26.7	0	0
	12 to 17 years	4	26.7	0	0
	18 to 25 years	4	26.7	0	0
SMA Type	Type III	15	100.0	0	0
Geographic region	Europe	14	93.3	0	0
	Rest of the World	1	6.7	0	0
Race/ethnicity	White	12	80.0	0	0
	Asian/Black or African American/Multiple	1	6.7	0	0
	Unknown	2	13.3	0	0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0
	No	11	73.3	0	0
Disease Severity	<=Q1	1	6.7	0	0
	>Q1 to <=Q3	4	26.7	0	0
	>Q3	9	60.0	0	0
	Missing	1	6.7	0	0
SMN2 Copy Number	3	10	66.7	0	0
	4	5	33.3	0	0

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Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG4_SE_P2_OLE_SW_T3.xls

08MAR2021 13:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 4 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0
Sex	Male	19	52.8	0	0	8	50.0	0	0
	Female	17	47.2	0	0	8	50.0	0	0
Age (at randomization)	2 to 5 years	4	11.1	0	0	4	25.0	0	0
	6 to 11 years	11	30.6	0	0	4	25.0	0	0
	12 to 17 years	15	41.7	0	0	4	25.0	0	0
	18 to 25 years	6	16.7	0	0	4	25.0	0	0
SMA Type	Type III	36	100.0	0	0	16	100.0	0	0
Geographic region	Europe	28	77.8	0	0	14	87.5	0	0
	Rest of the World	8	22.2	0	0	2	12.5	0	0
Race/ethnicity	White	25	69.4	0	0	13	81.3	0	0
	Asian/Black or African American/Multiple	7	19.4	0	0	1	6.3	0	0
	Unknown	4	11.1	0	0	2	12.5	0	0
History of scoliosis surgery or hip surgery	Yes	7	19.4	0	0	4	25.0	0	0
	No	29	80.6	0	0	12	75.0	0	0
Disease Severity	<=Q1	3	8.3	0	0	1	6.3	0	0
	>Q1 to <=Q3	12	33.3	0	0	4	25.0	0	0
	>Q3	20	55.6	0	0	10	62.5	0	0
	Missing	1	2.8	0	0	1	6.3	0	0
SMN2 Copy Number	2	2	5.6	0	0	0	0.0	0	0
	3	24	66.7	0	0	10	62.5	0	0
	4	10	27.8	0	0	6	37.5	0	0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG4_SE_P2_T3.xls
 18DEC2020 9:30

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 5 (AEs leading to death) including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0
Sex	Male	8	53.3	0	0
	Female	7	46.7	0	0
Age (at randomization)	2 to 5 years	3	20.0	0	0
	6 to 11 years	4	26.7	0	0
	12 to 17 years	4	26.7	0	0
	18 to 25 years	4	26.7	0	0
SMA Type	Type III	15	100.0	0	0
Geographic region	Europe	14	93.3	0	0
	Rest of the World	1	6.7	0	0
Race/ethnicity	White	12	80.0	0	0
	Asian/Black or African American/Multiple	1	6.7	0	0
	Unknown	2	13.3	0	0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0
	No	11	73.3	0	0
Disease Severity	<=Q1	1	6.7	0	0
	>Q1 to <=Q3	4	26.7	0	0
	>Q3	9	60.0	0	0
	Missing	1	6.7	0	0
SMN2 Copy Number	3	10	66.7	0	0
	4	5	33.3	0	0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG5_SE_P2_OLE_SW_T3.xls

08MAR2021 13:07

POPULATION: SMA Type III, Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Name	Level	Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0
Sex	Male	19	52.8	0	0	8	50.0	0	0
	Female	17	47.2	0	0	8	50.0	0	0
Age (at randomization)	2 to 5 years	4	11.1	0	0	4	25.0	0	0
	6 to 11 years	11	30.6	0	0	4	25.0	0	0
	12 to 17 years	15	41.7	0	0	4	25.0	0	0
	18 to 25 years	6	16.7	0	0	4	25.0	0	0
SMA Type	Type III	36	100.0	0	0	16	100.0	0	0
Geographic region	Europe	28	77.8	0	0	14	87.5	0	0
	Rest of the World	8	22.2	0	0	2	12.5	0	0
Race/ethnicity	White	25	69.4	0	0	13	81.3	0	0
	Asian/Black or African American/Multiple	7	19.4	0	0	1	6.3	0	0
	Unknown	4	11.1	0	0	2	12.5	0	0
History of scoliosis surgery or hip surgery	Yes	7	19.4	0	0	4	25.0	0	0
	No	29	80.6	0	0	12	75.0	0	0
Disease Severity	<=Q1	3	8.3	0	0	1	6.3	0	0
	>Q1 to <=Q3	12	33.3	0	0	4	25.0	0	0
	>Q3	20	55.6	0	0	10	62.5	0	0
	Missing	1	2.8	0	0	1	6.3	0	0
SMN2 Copy Number	2	2	5.6	0	0	0	0.0	0	0
	3	24	66.7	0	0	10	62.5	0	0
	4	10	27.8	0	0	6	37.5	0	0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AEG5_SE_P2_T3.xls

18DEC2020 9:34

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs leading to treatment discontinuation including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	0	0
Sex	Male	8	53.3	0	0
	Female	7	46.7	0	0
Age (at randomization)	2 to 5 years	3	20.0	0	0
	6 to 11 years	4	26.7	0	0
	12 to 17 years	4	26.7	0	0
	18 to 25 years	4	26.7	0	0
SMA Type	Type III	15	100.0	0	0
Geographic region	Europe	14	93.3	0	0
	Rest of the World	1	6.7	0	0
Race/ethnicity	White	12	80.0	0	0
	Asian/Black or African American/Multiple	1	6.7	0	0
	Unknown	2	13.3	0	0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0
	No	11	73.3	0	0
Disease Severity	<=Q1	1	6.7	0	0
	>Q1 to <=Q3	4	26.7	0	0
	>Q3	9	60.0	0	0
	Missing	1	6.7	0	0
SMN2 Copy Number	3	10	66.7	0	0
	4	5	33.3	0	0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AELDIS_SE_P2_OLE_SW_T3.xls

08MAR2021 13:12

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs leading to treatment discontinuation including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0
Sex	Male	19	52.8	0	0	8	50.0	0	0
	Female	17	47.2	0	0	8	50.0	0	0
Age (at randomization)	2 to 5 years	4	11.1	0	0	4	25.0	0	0
	6 to 11 years	11	30.6	0	0	4	25.0	0	0
	12 to 17 years	15	41.7	0	0	4	25.0	0	0
	18 to 25 years	6	16.7	0	0	4	25.0	0	0
SMA Type	Type III	36	100.0	0	0	16	100.0	0	0
Geographic region	Europe	28	77.8	0	0	14	87.5	0	0
	Rest of the World	8	22.2	0	0	2	12.5	0	0
Race/ethnicity	White	25	69.4	0	0	13	81.3	0	0
	Asian/Black or African American/Multiple	7	19.4	0	0	1	6.3	0	0
	Unknown	4	11.1	0	0	2	12.5	0	0
History of scoliosis surgery or hip surgery	Yes	7	19.4	0	0	4	25.0	0	0
	No	29	80.6	0	0	12	75.0	0	0
Disease Severity	<=Q1	3	8.3	0	0	1	6.3	0	0
	>Q1 to <=Q3	12	33.3	0	0	4	25.0	0	0
	>Q3	20	55.6	0	0	10	62.5	0	0
	Missing	1	2.8	0	0	1	6.3	0	0
SMN2 Copy Number	2	2	5.6	0	0	0	0.0	0	0
	3	24	66.7	0	0	10	62.5	0	0
	4	10	27.8	0	0	6	37.5	0	0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AELDIS_SE_P2_T3.xls
 18DEC2020 9:42

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AESI including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
		n	%	n	%
All	n/a	15	100.0	0	0
Sex	Male	8	53.3	0	0
	Female	7	46.7	0	0
Age (at randomization)	2 to 5 years	3	20.0	0	0
	6 to 11 years	4	26.7	0	0
	12 to 17 years	4	26.7	0	0
	18 to 25 years	4	26.7	0	0
SMA Type	Type III	15	100.0	0	0
Geographic region	Europe	14	93.3	0	0
	Rest of the World	1	6.7	0	0
Race/ethnicity	White	12	80.0	0	0
	Asian/Black or African American/Multiple	1	6.7	0	0
	Unknown	2	13.3	0	0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0
	No	11	73.3	0	0
Disease Severity	<=Q1	1	6.7	0	0
	>Q1 to <=Q3	4	26.7	0	0
	>Q3	9	60.0	0	0
	Missing	1	6.7	0	0
SMN2 Copy Number	3	10	66.7	0	0
	4	5	33.3	0	0

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AESI_SE_P2_OLE_SW_T3.xls
 08MAR2021 13:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AESI including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Risdiplam (N=36)				Placebo (N=16)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	0	0	16	100.0	0	0
Sex	Male	19	52.8	0	0	8	50.0	0	0
	Female	17	47.2	0	0	8	50.0	0	0
Age (at randomization)	2 to 5 years	4	11.1	0	0	4	25.0	0	0
	6 to 11 years	11	30.6	0	0	4	25.0	0	0
	12 to 17 years	15	41.7	0	0	4	25.0	0	0
	18 to 25 years	6	16.7	0	0	4	25.0	0	0
SMA Type	Type III	36	100.0	0	0	16	100.0	0	0
Geographic region	Europe	28	77.8	0	0	14	87.5	0	0
	Rest of the World	8	22.2	0	0	2	12.5	0	0
Race/ethnicity	White	25	69.4	0	0	13	81.3	0	0
	Asian/Black or African American/Multiple	7	19.4	0	0	1	6.3	0	0
	Unknown	4	11.1	0	0	2	12.5	0	0
History of scoliosis surgery or hip surgery	Yes	7	19.4	0	0	4	25.0	0	0
	No	29	80.6	0	0	12	75.0	0	0
Disease Severity	<=Q1	3	8.3	0	0	1	6.3	0	0
	>Q1 to <=Q3	12	33.3	0	0	4	25.0	0	0
	>Q3	20	55.6	0	0	10	62.5	0	0
	Missing	1	2.8	0	0	1	6.3	0	0
SMN2 Copy Number	2	2	5.6	0	0	0	0.0	0	0
	3	24	66.7	0	0	10	62.5	0	0
	4	10	27.8	0	0	6	37.5	0	0

Only AEs of highest severity are counted.

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_AESI_SE_P2_T3.xls
 18DEC2020 9:45

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

		Placebo/Risdiplam (N=15)			
		Patients		Patients with Event	
Name	Level	n	%	n	%
All	n/a	15	100.0	1	6.7
Sex	Male	8	53.3	1	12.5
	Female	7	46.7	0	0.0
Age (at randomization)	2 to 5 years	3	20.0	0	0.0
	6 to 11 years	4	26.7	0	0.0
	12 to 17 years	4	26.7	0	0.0
	18 to 25 years	4	26.7	1	25.0
SMA Type	Type III	15	100.0	1	6.7
Geographic region	Europe	14	93.3	1	7.1
	Rest of the World	1	6.7	0	0.0
Race/ethnicity	White	12	80.0	1	8.3
	Asian/Black or African American/Multiple	1	6.7	0	0.0
	Unknown	2	13.3	0	0.0
History of scoliosis surgery or hip surgery	Yes	4	26.7	0	0.0
	No	11	73.3	1	9.1
Disease Severity	<=Q1	1	6.7	0	0.0
	>Q1 to <=Q3	4	26.7	0	0.0
	>Q3	9	60.0	1	11.1
	Missing	1	6.7	0	0.0
SMN2 Copy Number	3	10	66.7	0	0.0
	4	5	33.3	1	20.0

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Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

		Risdiplam (N=36)				Placebo (N=16)			
Name	Level	Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	36	100.0	4	11.1	16	100.0	6	37.5
Sex	Male	19	52.8	2	10.5	8	50.0	6	75.0
	Female	17	47.2	2	11.8	8	50.0	0	0.0
Age (at randomization)	2 to 5 years	4	11.1	0	0.0	4	25.0	2	50.0
	6 to 11 years	11	30.6	2	18.2	4	25.0	3	75.0
	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
SMA Type	Type III	36	100.0	4	11.1	16	100.0	6	37.5
Geographic region	Europe	28	77.8	4	14.3	14	87.5	5	35.7
	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Race/ethnicity	White	25	69.4	3	12.0	13	81.3	4	30.8
	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
History of scoliosis surgery or hip surgery	Yes	7	19.4	1	14.3	4	25.0	0	0.0
	No	29	80.6	3	10.3	12	75.0	6	50.0
Disease Severity	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
	>Q3	20	55.6	2	10.0	10	62.5	6	60.0
	Missing	1	2.8	0	0.0	1	6.3	0	0.0
SMN2 Copy Number	2	2	5.6	1	50.0	0	0.0	0	0.0
	3	24	66.7	1	4.2	10	62.5	3	30.0
	4	10	27.8	2	20.0	6	37.5	3	50.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_sg_ASAE_SE_P2_T3.xls

18DEC2020 9:39

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders		6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders		12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders		18 to 25 years	4	26.7	2	50.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Vomiting	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Vomiting	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions		2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions		6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions		12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions		18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions	Malaise	2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	4	26.7	1	25.0
Immune system disorders		2 to 5 years	3	20.0	0	0.0
Immune system disorders		6 to 11 years	4	26.7	0	0.0
Immune system disorders		12 to 17 years	4	26.7	1	25.0
Immune system disorders		18 to 25 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	3	20.0	0	0.0
Immune system disorders	Hypersensitivity	6 to 11 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	4	26.7	0	0.0

Infections and infestations		2 to 5 years	3	20.0	2	66.7
Infections and infestations		6 to 11 years	4	26.7	1	25.0
Infections and infestations		12 to 17 years	4	26.7	1	25.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Bronchitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	12 to 17 years	4	26.7	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Enterovirus infection	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Nasopharyngitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Subcutaneous abscess	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Subcutaneous abscess	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	18 to 25 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications		6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications		18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Contusion	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Contusion	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	12 to 17 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	18 to 25 years	4	26.7	0	0.0
Investigations		2 to 5 years	3	20.0	1	33.3
Investigations		6 to 11 years	4	26.7	0	0.0
Investigations		12 to 17 years	4	26.7	0	0.0
Investigations		18 to 25 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	2 to 5 years	3	20.0	1	33.3
Investigations	C-reactive protein increased	6 to 11 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	12 to 17 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	3	20.0	2	66.7
Musculoskeletal and connective tissue disorders		6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	4	26.7	2	50.0

Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	4	26.7	0	0.0
Nervous system disorders		2 to 5 years	3	20.0	0	0.0
Nervous system disorders		6 to 11 years	4	26.7	1	25.0
Nervous system disorders		12 to 17 years	4	26.7	0	0.0
Nervous system disorders		18 to 25 years	4	26.7	1	25.0
Nervous system disorders	Headache	2 to 5 years	3	20.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	4	26.7	1	25.0
Nervous system disorders	Headache	12 to 17 years	4	26.7	0	0.0
Nervous system disorders	Headache	18 to 25 years	4	26.7	1	25.0
Psychiatric disorders		2 to 5 years	3	20.0	0	0.0
Psychiatric disorders		6 to 11 years	4	26.7	0	0.0
Psychiatric disorders		12 to 17 years	4	26.7	0	0.0
Psychiatric disorders		18 to 25 years	4	26.7	1	25.0
Psychiatric disorders	Anxiety	2 to 5 years	3	20.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	12 to 17 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18 to 25 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders		6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	4	26.7	0	0.0

Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	4	26.7	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_OLE_SW_T3.xls

08MAR2021 12:57

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		n/a	15	100.0	3	20.0
Gastrointestinal disorders	Abdominal pain	n/a	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	n/a	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	n/a	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	n/a	15	100.0	1	6.7
General disorders and administration site conditions		n/a	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	n/a	15	100.0	1	6.7
Immune system disorders		n/a	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	n/a	15	100.0	1	6.7
Infections and infestations		n/a	15	100.0	4	26.7
Infections and infestations	Bronchitis	n/a	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	n/a	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	n/a	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	n/a	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications		n/a	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	n/a	15	100.0	1	6.7
Investigations		n/a	15	100.0	1	6.7
Investigations	C-reactive protein increased	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		n/a	15	100.0	4	26.7
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	15	100.0	1	6.7
Nervous system disorders		n/a	15	100.0	2	13.3
Nervous system disorders	Headache	n/a	15	100.0	2	13.3
Psychiatric disorders		n/a	15	100.0	1	6.7
Psychiatric disorders	Anxiety	n/a	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		n/a	15	100.0	1	6.7

Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	15	100.0	1	6.7
Skin and subcutaneous tissue disorders		n/a	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	n/a	15	100.0	1	6.7

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_OLE_SW_T3.xls

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POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		White	12	80.0	1	8.3
Gastrointestinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders		Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Abdominal pain	White	12	80.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Diarrhoea	White	12	80.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	2	13.3	1	50.0
Gastrointestinal disorders	Toothache	White	12	80.0	1	8.3
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Unknown	2	13.3	0	0.0
Gastrointestinal disorders	Vomiting	White	12	80.0	0	0.0
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	2	13.3	1	50.0
General disorders and administration site conditions		White	12	80.0	1	8.3
General disorders and administration site conditions		Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions		Unknown	2	13.3	0	0.0
General disorders and administration site conditions	Malaise	White	12	80.0	1	8.3
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Unknown	2	13.3	0	0.0
Immune system disorders		White	12	80.0	1	8.3
Immune system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders		Unknown	2	13.3	0	0.0
Immune system disorders	Hypersensitivity	White	12	80.0	1	8.3
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Unknown	2	13.3	0	0.0
Infections and infestations		White	12	80.0	2	16.7
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations		Unknown	2	13.3	1	50.0
Infections and infestations	Bronchitis	White	12	80.0	1	8.3
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Bronchitis	Unknown	2	13.3	0	0.0
Infections and infestations	Enterovirus infection	White	12	80.0	1	8.3
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Unknown	2	13.3	0	0.0

Infections and infestations	Gastroenteritis	White	12	80.0	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Unknown	2	13.3	1	50.0
Infections and infestations	Nasopharyngitis	White	12	80.0	0	0.0
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	2	13.3	0	0.0
Infections and infestations	Subcutaneous abscess	White	12	80.0	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	2	13.3	1	50.0
Injury, poisoning and procedural complications		White	12	80.0	2	16.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications		Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Contusion	White	12	80.0	1	8.3
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	12	80.0	1	8.3
Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	2	13.3	0	0.0
Investigations		White	12	80.0	0	0.0
Investigations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations		Unknown	2	13.3	0	0.0
Investigations	C-reactive protein increased	White	12	80.0	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations	C-reactive protein increased	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders		White	12	80.0	2	16.7
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	2	13.3	0	0.0
Nervous system disorders		White	12	80.0	1	8.3
Nervous system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders		Unknown	2	13.3	1	50.0
Nervous system disorders	Headache	White	12	80.0	1	8.3
Nervous system disorders	Headache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders	Headache	Unknown	2	13.3	1	50.0
Psychiatric disorders		White	12	80.0	0	0.0

Psychiatric disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders		Unknown	2	13.3	1	50.0
Psychiatric disorders	Anxiety	White	12	80.0	0	0.0
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Unknown	2	13.3	1	50.0
Respiratory, thoracic and mediastinal disorders		White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Unknown	2	13.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders		White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	2	13.3	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

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08MAR2021 12:57

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Europe	14	93.3	3	21.4
Gastrointestinal disorders		Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	14	93.3	2	14.3
Gastrointestinal disorders	Abdominal pain	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Diarrhoea	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Vomiting	Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions		Europe	14	93.3	1	7.1
General disorders and administration site conditions		Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Europe	14	93.3	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	1	6.7	0	0.0
Immune system disorders		Europe	14	93.3	1	7.1
Immune system disorders		Rest of the World	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Europe	14	93.3	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	1	6.7	0	0.0
Infections and infestations		Europe	14	93.3	3	21.4
Infections and infestations		Rest of the World	1	6.7	1	100.0
Infections and infestations	Bronchitis	Europe	14	93.3	1	7.1
Infections and infestations	Bronchitis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Europe	14	93.3	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Europe	14	93.3	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	Europe	14	93.3	0	0.0
Infections and infestations	Nasopharyngitis	Rest of the World	1	6.7	1	100.0
Infections and infestations	Subcutaneous abscess	Europe	14	93.3	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications		Europe	14	93.3	2	14.3
Injury, poisoning and procedural complications		Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	14	93.3	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	14	93.3	1	7.1

Injury, poisoning and procedural complications	Muscle strain	Rest of the World	1	6.7	0	0.0
Investigations		Europe	14	93.3	0	0.0
Investigations		Rest of the World	1	6.7	1	100.0
Investigations	C-reactive protein increased	Europe	14	93.3	0	0.0
Investigations	C-reactive protein increased	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Europe	14	93.3	3	21.4
Musculoskeletal and connective tissue disorders		Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	14	93.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	1	6.7	0	0.0
Nervous system disorders		Europe	14	93.3	2	14.3
Nervous system disorders		Rest of the World	1	6.7	0	0.0
Nervous system disorders	Headache	Europe	14	93.3	2	14.3
Nervous system disorders	Headache	Rest of the World	1	6.7	0	0.0
Psychiatric disorders		Europe	14	93.3	1	7.1
Psychiatric disorders		Rest of the World	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Europe	14	93.3	1	7.1
Psychiatric disorders	Anxiety	Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders		Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	1	6.7	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

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POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		<=Q1	1	6.7	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders		>Q3	9	60.0	2	22.2
Gastrointestinal disorders		Missing	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	9	60.0	2	22.2
Gastrointestinal disorders	Abdominal pain	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Diarrhoea	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders	Toothache	>Q3	9	60.0	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Vomiting	Missing	1	6.7	0	0.0
General disorders and administration site conditions		<=Q1	1	6.7	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions		>Q3	9	60.0	1	11.1
General disorders and administration site conditions		Missing	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	>Q3	9	60.0	1	11.1
General disorders and administration site conditions	Malaise	Missing	1	6.7	0	0.0
Immune system disorders		<=Q1	1	6.7	0	0.0
Immune system disorders		>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders		>Q3	9	60.0	0	0.0
Immune system disorders		Missing	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	>Q3	9	60.0	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	6.7	0	0.0

Infections and infestations		<=Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations		>Q3	9	60.0	2	22.2
Infections and infestations		Missing	1	6.7	1	100.0
Infections and infestations	Bronchitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations	Bronchitis	>Q3	9	60.0	0	0.0
Infections and infestations	Bronchitis	Missing	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	<=Q1	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	>Q3	9	60.0	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	6.7	1	100.0
Infections and infestations	Gastroenteritis	<=Q1	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	>Q3	9	60.0	1	11.1
Infections and infestations	Gastroenteritis	Missing	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	9	60.0	1	11.1
Infections and infestations	Nasopharyngitis	Missing	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	9	60.0	1	11.1
Infections and infestations	Subcutaneous abscess	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications		<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications		>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications		Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications	Contusion	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	9	60.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	6.7	0	0.0
Investigations		<=Q1	1	6.7	0	0.0
Investigations		>Q1 to <=Q3	4	26.7	0	0.0
Investigations		>Q3	9	60.0	1	11.1
Investigations		Missing	1	6.7	0	0.0
Investigations	C-reactive protein increased	<=Q1	1	6.7	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	4	26.7	0	0.0
Investigations	C-reactive protein increased	>Q3	9	60.0	1	11.1
Investigations	C-reactive protein increased	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	9	60.0	4	44.4
Musculoskeletal and connective tissue disorders		Missing	1	6.7	0	0.0

Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	6.7	0	0.0
Nervous system disorders		<=Q1	1	6.7	0	0.0
Nervous system disorders		>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders		>Q3	9	60.0	2	22.2
Nervous system disorders		Missing	1	6.7	0	0.0
Nervous system disorders	Headache	<=Q1	1	6.7	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders	Headache	>Q3	9	60.0	2	22.2
Nervous system disorders	Headache	Missing	1	6.7	0	0.0
Psychiatric disorders		<=Q1	1	6.7	0	0.0
Psychiatric disorders		>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders		>Q3	9	60.0	1	11.1
Psychiatric disorders		Missing	1	6.7	0	0.0
Psychiatric disorders	Anxiety	<=Q1	1	6.7	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders	Anxiety	>Q3	9	60.0	1	11.1
Psychiatric disorders	Anxiety	Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		>Q3	9	60.0	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	6.7	1	100.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	9	60.0	0	0.0

Skin and subcutaneous tissue disorders	Urticaria	Missing	1	6.7	1	100.0

Clinical cut-off: 30SEP2020

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Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_OLE_SW_T3.xls

08MAR2021 12:57

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Male	8	53.3	2	25.0
Gastrointestinal disorders		Female	7	46.7	1	14.3
Gastrointestinal disorders	Abdominal pain	Male	8	53.3	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	7	46.7	1	14.3
Gastrointestinal disorders	Diarrhoea	Male	8	53.3	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	7	46.7	0	0.0
Gastrointestinal disorders	Toothache	Male	8	53.3	1	12.5
Gastrointestinal disorders	Toothache	Female	7	46.7	0	0.0
Gastrointestinal disorders	Vomiting	Male	8	53.3	0	0.0
Gastrointestinal disorders	Vomiting	Female	7	46.7	1	14.3
General disorders and administration site conditions		Male	8	53.3	1	12.5
General disorders and administration site conditions		Female	7	46.7	0	0.0
General disorders and administration site conditions	Malaise	Male	8	53.3	1	12.5
General disorders and administration site conditions	Malaise	Female	7	46.7	0	0.0
Immune system disorders		Male	8	53.3	0	0.0
Immune system disorders		Female	7	46.7	1	14.3
Immune system disorders	Hypersensitivity	Male	8	53.3	0	0.0
Immune system disorders	Hypersensitivity	Female	7	46.7	1	14.3
Infections and infestations		Male	8	53.3	2	25.0
Infections and infestations		Female	7	46.7	2	28.6
Infections and infestations	Bronchitis	Male	8	53.3	0	0.0
Infections and infestations	Bronchitis	Female	7	46.7	1	14.3
Infections and infestations	Enterovirus infection	Male	8	53.3	0	0.0
Infections and infestations	Enterovirus infection	Female	7	46.7	1	14.3
Infections and infestations	Gastroenteritis	Male	8	53.3	1	12.5
Infections and infestations	Gastroenteritis	Female	7	46.7	0	0.0
Infections and infestations	Nasopharyngitis	Male	8	53.3	1	12.5
Infections and infestations	Nasopharyngitis	Female	7	46.7	0	0.0
Infections and infestations	Subcutaneous abscess	Male	8	53.3	1	12.5
Infections and infestations	Subcutaneous abscess	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications		Male	8	53.3	1	12.5
Injury, poisoning and procedural complications		Female	7	46.7	1	14.3
Injury, poisoning and procedural complications	Contusion	Male	8	53.3	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	8	53.3	0	0.0

Injury, poisoning and procedural complications	Muscle strain	Female	7	46.7	1	14.3
Investigations		Male	8	53.3	1	12.5
Investigations		Female	7	46.7	0	0.0
Investigations	C-reactive protein increased	Male	8	53.3	1	12.5
Investigations	C-reactive protein increased	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders		Male	8	53.3	3	37.5
Musculoskeletal and connective tissue disorders		Female	7	46.7	1	14.3
Musculoskeletal and connective tissue disorders	Arthralgia	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	8	53.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	7	46.7	1	14.3
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	7	46.7	0	0.0
Nervous system disorders		Male	8	53.3	0	0.0
Nervous system disorders		Female	7	46.7	2	28.6
Nervous system disorders	Headache	Male	8	53.3	0	0.0
Nervous system disorders	Headache	Female	7	46.7	2	28.6
Psychiatric disorders		Male	8	53.3	0	0.0
Psychiatric disorders		Female	7	46.7	1	14.3
Psychiatric disorders	Anxiety	Male	8	53.3	0	0.0
Psychiatric disorders	Anxiety	Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders		Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	7	46.7	1	14.3
Skin and subcutaneous tissue disorders		Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders		Female	7	46.7	1	14.3
Skin and subcutaneous tissue disorders	Urticaria	Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	7	46.7	1	14.3

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_OLE_SW_T3.xls

08MAR2021 12:57

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Type III	15	100.0	3	20.0
Gastrointestinal disorders	Abdominal pain	Type III	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	Type III	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	Type III	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	Type III	15	100.0	1	6.7
General disorders and administration site conditions		Type III	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	Type III	15	100.0	1	6.7
Immune system disorders		Type III	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	Type III	15	100.0	1	6.7
Infections and infestations		Type III	15	100.0	4	26.7
Infections and infestations	Bronchitis	Type III	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	Type III	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	Type III	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	Type III	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications		Type III	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	Type III	15	100.0	1	6.7
Investigations		Type III	15	100.0	1	6.7
Investigations	C-reactive protein increased	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		Type III	15	100.0	4	26.7
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	15	100.0	1	6.7
Nervous system disorders		Type III	15	100.0	2	13.3
Nervous system disorders	Headache	Type III	15	100.0	2	13.3
Psychiatric disorders		Type III	15	100.0	1	6.7
Psychiatric disorders	Anxiety	Type III	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		Type III	15	100.0	1	6.7

Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	15	100.0	1	6.7
Skin and subcutaneous tissue disorders		Type III	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	Type III	15	100.0	1	6.7

Clinical cut-off: 30SEP2020

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POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		3	10	66.7	2	20.0
Gastrointestinal disorders		4	5	33.3	1	20.0
Gastrointestinal disorders	Abdominal pain	3	10	66.7	2	20.0
Gastrointestinal disorders	Abdominal pain	4	5	33.3	0	0.0
Gastrointestinal disorders	Diarrhoea	3	10	66.7	1	10.0
Gastrointestinal disorders	Diarrhoea	4	5	33.3	0	0.0
Gastrointestinal disorders	Toothache	3	10	66.7	0	0.0
Gastrointestinal disorders	Toothache	4	5	33.3	1	20.0
Gastrointestinal disorders	Vomiting	3	10	66.7	1	10.0
Gastrointestinal disorders	Vomiting	4	5	33.3	0	0.0
General disorders and administration site conditions		3	10	66.7	0	0.0
General disorders and administration site conditions		4	5	33.3	1	20.0
General disorders and administration site conditions	Malaise	3	10	66.7	0	0.0
General disorders and administration site conditions	Malaise	4	5	33.3	1	20.0
Immune system disorders		3	10	66.7	1	10.0
Immune system disorders		4	5	33.3	0	0.0
Immune system disorders	Hypersensitivity	3	10	66.7	1	10.0
Immune system disorders	Hypersensitivity	4	5	33.3	0	0.0
Infections and infestations		3	10	66.7	3	30.0
Infections and infestations		4	5	33.3	1	20.0
Infections and infestations	Bronchitis	3	10	66.7	1	10.0
Infections and infestations	Bronchitis	4	5	33.3	0	0.0
Infections and infestations	Enterovirus infection	3	10	66.7	1	10.0
Infections and infestations	Enterovirus infection	4	5	33.3	0	0.0
Infections and infestations	Gastroenteritis	3	10	66.7	1	10.0
Infections and infestations	Gastroenteritis	4	5	33.3	0	0.0
Infections and infestations	Nasopharyngitis	3	10	66.7	0	0.0
Infections and infestations	Nasopharyngitis	4	5	33.3	1	20.0
Infections and infestations	Subcutaneous abscess	3	10	66.7	1	10.0
Infections and infestations	Subcutaneous abscess	4	5	33.3	0	0.0
Injury, poisoning and procedural complications		3	10	66.7	1	10.0
Injury, poisoning and procedural complications		4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Contusion	3	10	66.7	0	0.0
Injury, poisoning and procedural complications	Contusion	4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Muscle strain	3	10	66.7	1	10.0

Injury, poisoning and procedural complications	Muscle strain	4	5	33.3	0	0.0
Investigations		3	10	66.7	0	0.0
Investigations		4	5	33.3	1	20.0
Investigations	C-reactive protein increased	3	10	66.7	0	0.0
Investigations	C-reactive protein increased	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders		3	10	66.7	2	20.0
Musculoskeletal and connective tissue disorders		4	5	33.3	2	40.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Back pain	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	5	33.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4	5	33.3	0	0.0
Nervous system disorders		3	10	66.7	2	20.0
Nervous system disorders		4	5	33.3	0	0.0
Nervous system disorders	Headache	3	10	66.7	2	20.0
Nervous system disorders	Headache	4	5	33.3	0	0.0
Psychiatric disorders		3	10	66.7	1	10.0
Psychiatric disorders		4	5	33.3	0	0.0
Psychiatric disorders	Anxiety	3	10	66.7	1	10.0
Psychiatric disorders	Anxiety	4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders		3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders		4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	5	33.3	0	0.0
Skin and subcutaneous tissue disorders		3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders		4	5	33.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	5	33.3	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

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POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any AEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Yes	4	26.7	0	0.0
Gastrointestinal disorders		No	11	73.3	3	27.3
Gastrointestinal disorders	Abdominal pain	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	No	11	73.3	2	18.2
Gastrointestinal disorders	Diarrhoea	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	No	11	73.3	1	9.1
Gastrointestinal disorders	Toothache	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	No	11	73.3	1	9.1
Gastrointestinal disorders	Vomiting	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	No	11	73.3	1	9.1
General disorders and administration site conditions		Yes	4	26.7	0	0.0
General disorders and administration site conditions		No	11	73.3	1	9.1
General disorders and administration site conditions	Malaise	Yes	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	No	11	73.3	1	9.1
Immune system disorders		Yes	4	26.7	1	25.0
Immune system disorders		No	11	73.3	0	0.0
Immune system disorders	Hypersensitivity	Yes	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	No	11	73.3	0	0.0
Infections and infestations		Yes	4	26.7	1	25.0
Infections and infestations		No	11	73.3	3	27.3
Infections and infestations	Bronchitis	Yes	4	26.7	1	25.0
Infections and infestations	Bronchitis	No	11	73.3	0	0.0
Infections and infestations	Enterovirus infection	Yes	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	No	11	73.3	1	9.1
Infections and infestations	Gastroenteritis	Yes	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	No	11	73.3	1	9.1
Infections and infestations	Nasopharyngitis	Yes	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	No	11	73.3	1	9.1
Infections and infestations	Subcutaneous abscess	Yes	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	No	11	73.3	1	9.1
Injury, poisoning and procedural complications		Yes	4	26.7	1	25.0
Injury, poisoning and procedural complications		No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Contusion	Yes	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Muscle strain	Yes	4	26.7	1	25.0

Injury, poisoning and procedural complications	Muscle strain	No	11	73.3	0	0.0
Investigations		Yes	4	26.7	0	0.0
Investigations		No	11	73.3	1	9.1
Investigations	C-reactive protein increased	Yes	4	26.7	0	0.0
Investigations	C-reactive protein increased	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders		Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		No	11	73.3	4	36.4
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Back pain	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	11	73.3	1	9.1
Nervous system disorders		Yes	4	26.7	0	0.0
Nervous system disorders		No	11	73.3	2	18.2
Nervous system disorders	Headache	Yes	4	26.7	0	0.0
Nervous system disorders	Headache	No	11	73.3	2	18.2
Psychiatric disorders		Yes	4	26.7	0	0.0
Psychiatric disorders		No	11	73.3	1	9.1
Psychiatric disorders	Anxiety	Yes	4	26.7	0	0.0
Psychiatric disorders	Anxiety	No	11	73.3	1	9.1
Respiratory, thoracic and mediastinal disorders		Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		No	11	73.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	11	73.3	0	0.0
Skin and subcutaneous tissue disorders		Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		No	11	73.3	1	9.1
Skin and subcutaneous tissue disorders	Urticaria	Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	11	73.3	1	9.1

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_OLE_SW_T3.xls

08MAR2021 12:57

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Leukopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Neutropenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Thrombocytopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Ear and labyrinth disorders	Deafness neurosensory	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Ear and labyrinth disorders	Hypoacusis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Endocrine disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Eye disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	2	50.0
Eye disorders	Conjunctival haemorrhage	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Eye disorders	Conjunctivitis allergic	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders	Dry eye	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders	Eye pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Eye disorders	Ocular hyperaemia	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders		6 to 11 years	11	30.6	8	72.7	4	25.0	1	25.0
Gastrointestinal disorders		12 to 17 years	15	41.7	9	60.0	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	4	66.7	4	25.0	2	50.0
Gastrointestinal disorders	Abdominal discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Dental necrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	11	30.6	5	45.5	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0

Gastrointestinal disorders	Faeces soft	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders	Vomiting	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions		6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0
General disorders and administration site conditions		12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
General disorders and administration site conditions		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
General disorders and administration site conditions	Feeling abnormal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Medical device pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Immune system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0

Immune system disorders	Hypersensitivity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Immune system disorders	Seasonal allergy	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	4	100.0	4	25.0	4	100.0
Infections and infestations		6 to 11 years	11	30.6	11	100.0	4	25.0	2	50.0
Infections and infestations		12 to 17 years	15	41.7	15	100.0	4	25.0	4	100.0
Infections and infestations		18 to 25 years	6	16.7	6	100.0	4	25.0	3	75.0
Infections and infestations	Adenoiditis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Adenoiditis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Appendicitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Infections and infestations	Bronchitis	12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Device related infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Enterovirus infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Folliculitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Furuncle	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	2	18.2	4	25.0	2	50.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastrointestinal viral infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Gingivitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Gingivitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Infections and infestations	Hordeolum	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Hordeolum	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Infective thrombosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Influenza	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Influenza	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Lymph gland infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	4	11.1	2	50.0	4	25.0	3	75.0
Infections and infestations	Nasopharyngitis	6 to 11 years	11	30.6	4	36.4	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Otitis media acute	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Pharyngitis	12 to 17 years	15	41.7	2	13.3	4	25.0	1	25.0
Infections and infestations	Pharyngitis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Pneumonia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Respiratory tract infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Respiratory tract infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Respiratory tract infection	12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Infections and infestations	Rhinitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Rhinitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Rhinitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Rhinitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Subcutaneous abscess	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Tracheitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Injury, poisoning and procedural complications	Ligament sprain	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Muscle strain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Procedural pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Investigations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Activated partial thromboplastin time shortened	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Blood bicarbonate decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	C-reactive protein increased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Oxygen saturation decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Metabolism and nutrition disorders	Obesity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Exostosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Musculoskeletal and connective tissue disorders	Haemarthrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Scoliosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0
Nervous system disorders		12 to 17 years	15	41.7	7	46.7	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	5	83.3	4	25.0	3	75.0
Nervous system disorders	Amnesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Nervous system disorders	Dizziness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Headache	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0
Nervous system disorders	Headache	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Nervous system disorders	Headache	18 to 25 years	6	16.7	5	83.3	4	25.0	3	75.0
Nervous system disorders	Migraine	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Migraine	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0

Nervous system disorders	Partial seizures	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Presyncope	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Psychiatric disorders	Anxiety	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders	Anxiety	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Renal and urinary disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders		12 to 17 years	15	41.7	3	20.0	4	25.0	1	25.0
Reproductive system and breast disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	4	36.4	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	3	50.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Cough	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Papule	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Surgical and medical procedures	Dental implantation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Vascular disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders	Varicose vein	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Thrombocytopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Ear and labyrinth disorders	Deafness neurosensory	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Ear pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypoacusis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		n/a	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		n/a	36	100.0	23	63.9	16	100.0	5	31.3
Gastrointestinal disorders	Abdominal discomfort	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal distension	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	n/a	36	100.0	6	16.7	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	n/a	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Dental necrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Diarrhoea	n/a	36	100.0	12	33.3	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	n/a	36	100.0	5	13.9	16	100.0	4	25.0
General disorders and administration site conditions		n/a	36	100.0	10	27.8	16	100.0	3	18.8
General disorders and administration site conditions	Feeling abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Malaise	n/a	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	n/a	36	100.0	7	19.4	16	100.0	2	12.5
Immune system disorders		n/a	36	100.0	1	2.8	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations		n/a	36	100.0	36	100.0	16	100.0	13	81.3

Infections and infestations	Adenoiditis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Appendicitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	n/a	36	100.0	2	5.6	16	100.0	3	18.8
Infections and infestations	Device related infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Folliculitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Fungal skin infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Furuncle	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	n/a	36	100.0	7	19.4	16	100.0	2	12.5
Infections and infestations	Gastroenteritis viral	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hand-foot-and-mouth disease	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Influenza	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	n/a	36	100.0	11	30.6	16	100.0	3	18.8
Infections and infestations	Otitis externa	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Otitis media	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	n/a	36	100.0	4	11.1	16	100.0	1	6.3
Infections and infestations	Pharyngitis bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	n/a	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Sinusitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tonsillitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tracheitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	n/a	36	100.0	14	38.9	16	100.0	5	31.3
Infections and infestations	Upper respiratory tract infection bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Variocella	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Viral pharyngitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	10	27.8	16	100.0	5	31.3
Injury, poisoning and procedural complications	Anaemia postoperative	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Contusion	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Hand fracture	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Tooth fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		n/a	36	100.0	2	5.6	16	100.0	1	6.3
Metabolism and nutrition disorders	Dehydration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Obesity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		n/a	36	100.0	9	25.0	16	100.0	5	31.3
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Exostosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Musculoskeletal and connective tissue disorders	Haemarthrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		n/a	36	100.0	18	50.0	16	100.0	4	25.0
Nervous system disorders	Amnesia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	n/a	36	100.0	12	33.3	16	100.0	4	25.0
Nervous system disorders	Migraine	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Nervous system disorders	Partial seizures	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Psychiatric disorders		n/a	36	100.0	0	0.0	16	100.0	2	12.5
Psychiatric disorders	Anxiety	n/a	36	100.0	0	0.0	16	100.0	2	12.5
Renal and urinary disorders		n/a	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	9	25.0	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	n/a	36	100.0	5	13.9	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		n/a	36	100.0	15	41.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	n/a	36	100.0	0	0.0	16	100.0	1	6.3

Vascular disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_T3.xls
18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Anaemia	White	25	69.4	2	8.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	White	25	69.4	1	4.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Leukopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Neutropenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Thrombocytopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders		Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Ear and labyrinth disorders	Deafness neurosensory	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Ear pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders	Ear pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Ear and labyrinth disorders	Hypoacusis	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Endocrine disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Endocrine disorders	Hypopituitarism	White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders	Hypopituitarism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders		White	25	69.4	2	8.0	13	81.3	1	7.7
Eye disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Eye disorders	Conjunctival haemorrhage	White	25	69.4	0	0.0	13	81.3	1	7.7
Eye disorders	Conjunctival haemorrhage	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Conjunctivitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Conjunctivitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Dry eye	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Dry eye	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Eye pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Eye pain	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0

Eye disorders	Eye pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Eye disorders	Ocular hyperaemia	White	25	69.4	0	0.0	13	81.3	0	0.0
Eye disorders	Ocular hyperaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	13	52.0	13	81.3	3	23.1
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	6	85.7	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	4	100.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal distension	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	White	25	69.4	5	20.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	4	11.1	1	25.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal pain upper	White	25	69.4	3	12.0	13	81.3	1	7.7
Gastrointestinal disorders	Abdominal pain upper	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	3	12.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Dental necrosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Diarrhoea	White	25	69.4	8	32.0	13	81.3	1	7.7
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Dyspepsia	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faecaloma	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Faecaloma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Faeces soft	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Flatulence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Nausea	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Nausea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	White	25	69.4	1	4.0	13	81.3	1	7.7
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	White	25	69.4	2	8.0	13	81.3	2	15.4
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	4	11.1	1	25.0	2	12.5	2	100.0
General disorders and administration site conditions		White	25	69.4	7	28.0	13	81.3	1	7.7
General disorders and administration site conditions		Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	1	100.0
General disorders and administration site conditions		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

General disorders and administration site conditions	Hyperpyrexia	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	White	25	69.4	0	0.0	13	81.3	1	7.7
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Medical device pain	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Medical device pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	White	25	69.4	5	20.0	13	81.3	0	0.0
General disorders and administration site conditions	Pyrexia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
General disorders and administration site conditions	Pyrexia	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Immune system disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Immune system disorders	Hypersensitivity	White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	White	25	69.4	0	0.0	13	81.3	0	0.0
Immune system disorders	Seasonal allergy	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations		White	25	69.4	25	100.0	13	81.3	10	76.9
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	7	100.0	1	6.3	1	100.0
Infections and infestations		Unknown	4	11.1	4	100.0	2	12.5	2	100.0
Infections and infestations	Adenoiditis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Adenoiditis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Appendicitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Appendicitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Bronchitis	White	25	69.4	2	8.0	13	81.3	2	15.4
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Device related infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Device related infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Folliculitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Folliculitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Folliculitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Fungal skin infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Furuncle	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Furuncle	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Furuncle	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	4	16.0	13	81.3	1	7.7
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Infections and infestations	Gastroenteritis viral	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis viral	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Genital infection fungal	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Genital infection fungal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	White	25	69.4	0	0.0	13	81.3	0	0.0

Infections and infestations	Gingivitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Infections and infestations	Gingivitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Hordeolum	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Hordeolum	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Infective thrombosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Infective thrombosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Influenza	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Influenza	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Lymph gland infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	White	25	69.4	6	24.0	13	81.3	2	15.4
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Infections and infestations	Otitis externa	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Otitis externa	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Otitis media	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Otitis media acute	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	White	25	69.4	3	12.0	13	81.3	1	7.7
Infections and infestations	Pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Pneumonia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	White	25	69.4	3	12.0	13	81.3	2	15.4
Infections and infestations	Respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Sinusitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Soft tissue infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Tonsillitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Tonsillitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Tracheitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Tracheitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	White	25	69.4	9	36.0	13	81.3	5	38.5
Infections and infestations	Upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	5	71.4	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Urinary tract infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Varicella	White	25	69.4	1	4.0	13	81.3	1	7.7
Infections and infestations	Varicella	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	White	25	69.4	1	4.0	13	81.3	0	0.0

Infections and infestations	Viral pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Viral rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	6	24.0	13	81.3	3	23.1
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Injury, poisoning and procedural complications		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Anaemia postoperative	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Contusion	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Fall	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Fall	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Femur fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Procedural pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Activated partial thromboplastin time shortened	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Blood bicarbonate decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Blood bicarbonate decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Blood bicarbonate decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	C-reactive protein increased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	C-reactive protein increased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Oxygen saturation decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Oxygen saturation decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Oxygen saturation decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	2	8.0	13	81.3	0	0.0

Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Dehydration	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Obesity	White	25	69.4	0	0.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Obesity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders	Obesity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	5	20.0	13	81.3	3	23.1
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	25	69.4	2	8.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	White	25	69.4	2	8.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Scoliosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	13	52.0	13	81.3	3	23.1
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Nervous system disorders	Amnesia	White	25	69.4	0	0.0	13	81.3	1	7.7
Nervous system disorders	Amnesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness postural	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness postural	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Headache	White	25	69.4	9	36.0	13	81.3	3	23.1
Nervous system disorders	Headache	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Headache	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Nervous system disorders	Migraine	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Migraine	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	White	25	69.4	1	4.0	13	81.3	0	0.0

Nervous system disorders	Occipital neuralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	White	25	69.4	3	12.0	13	81.3	0	0.0
Nervous system disorders	Paraesthesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Partial seizures	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Presyncope	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Psychiatric disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Psychiatric disorders	Anxiety	White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Renal and urinary disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Renal and urinary disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Haematuria	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Haematuria	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Renal cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Reproductive system and breast disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Reproductive system and breast disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	White	25	69.4	0	0.0	13	81.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	White	25	69.4	0	0.0	13	81.3	1	7.7
Reproductive system and breast disorders	Polycystic ovaries	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	5	20.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	White	25	69.4	2	8.0	13	81.3	1	7.7
Respiratory, thoracic and mediastinal disorders	Cough	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Cough	Unknown	4	11.1	3	75.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	White	25	69.4	1	4.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	25	69.4	2	8.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Unknown	4	11.1	1	25.0	2	12.5	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	9	36.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	4	57.1	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	25	69.4	0	0.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		White	25	69.4	0	0.0	13	81.3	0	0.0

Surgical and medical procedures		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Surgical and medical procedures	Dental implantation	White	25	69.4	0	0.0	13	81.3	0	0.0
Surgical and medical procedures	Dental implantation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Vascular disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders	Varicose vein	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Blood and lymphatic system disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Leukopenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Neutropenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Thrombocytopenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Cardiac disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Ear and labyrinth disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders	Ear pain	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Ear and labyrinth disorders	Ear pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Endocrine disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Endocrine disorders	Hypopituitarism	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders	Hypopituitarism	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders		Europe	28	77.8	2	7.1	14	87.5	2	14.3
Eye disorders		Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders	Conjunctival haemorrhage	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders	Conjunctival haemorrhage	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders	Conjunctivitis allergic	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Eye disorders	Conjunctivitis allergic	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Eye disorders	Dry eye	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders	Dry eye	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders	Eye pain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders	Eye pain	Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders	Ocular hyperaemia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders	Ocular hyperaemia	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders		Europe	28	77.8	16	57.1	14	87.5	4	28.6
Gastrointestinal disorders		Rest of the World	8	22.2	7	87.5	2	12.5	1	50.0
Gastrointestinal disorders	Abdominal discomfort	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	28	77.8	6	21.4	14	87.5	2	14.3
Gastrointestinal disorders	Abdominal pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
Gastrointestinal disorders	Aphthous ulcer	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	4	14.3	14	87.5	1	7.1
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0

Gastrointestinal disorders	Dental necrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	28	77.8	9	32.1	14	87.5	2	14.3
Gastrointestinal disorders	Diarrhoea	Rest of the World	8	22.2	3	37.5	2	12.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faecaloma	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Faecaloma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Faeces soft	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Flatulence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Nausea	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Nausea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Gastrointestinal disorders	Vomiting	Rest of the World	8	22.2	3	37.5	2	12.5	1	50.0
General disorders and administration site conditions		Europe	28	77.8	8	28.6	14	87.5	2	14.3
General disorders and administration site conditions		Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	Europe	28	77.8	0	0.0	14	87.5	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Medical device pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Medical device pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Europe	28	77.8	0	0.0	14	87.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	Europe	28	77.8	6	21.4	14	87.5	1	7.1
General disorders and administration site conditions	Pyrexia	Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Immune system disorders		Europe	28	77.8	0	0.0	14	87.5	2	14.3
Immune system disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Immune system disorders	Hypersensitivity	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Seasonal allergy	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	28	100.0	14	87.5	11	78.6
Infections and infestations		Rest of the World	8	22.2	8	100.0	2	12.5	2	100.0
Infections and infestations	Adenoiditis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Adenoiditis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Appendicitis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Appendicitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Bronchitis	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Infections and infestations	Bronchitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Device related infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Device related infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Folliculitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Folliculitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Fungal skin infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Furuncle	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Furuncle	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	7	25.0	14	87.5	2	14.3
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis viral	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Gastroenteritis viral	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Infections and infestations	Gastrointestinal infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastrointestinal infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastrointestinal viral infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Genital infection fungal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Genital infection fungal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Gingivitis	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Infections and infestations	Hand-foot-and-mouth disease	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Hordeolum	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Infective thrombosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Influenza	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Infections and infestations	Influenza	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Lymph gland infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	Europe	28	77.8	7	25.0	14	87.5	1	7.1
Infections and infestations	Nasopharyngitis	Rest of the World	8	22.2	4	50.0	2	12.5	2	100.0
Infections and infestations	Otitis externa	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Otitis externa	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Otitis media	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Otitis media acute	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	Europe	28	77.8	4	14.3	14	87.5	1	7.1
Infections and infestations	Pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Pneumonia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	Europe	28	77.8	3	10.7	14	87.5	2	14.3
Infections and infestations	Respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Sinusitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Soft tissue infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tonsillitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tonsillitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tracheitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tracheitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	Europe	28	77.8	9	32.1	14	87.5	5	35.7
Infections and infestations	Upper respiratory tract infection	Rest of the World	8	22.2	5	62.5	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Urinary tract infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Varicella	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Infections and infestations	Varicella	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Europe	28	77.8	4	14.3	14	87.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	8	28.6	14	87.5	4	28.6
Injury, poisoning and procedural complications		Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Anaemia postoperative	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Fall	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Fall	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1

Injury, poisoning and procedural complications	Femur fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Muscle strain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Injury, poisoning and procedural complications	Tooth fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Tooth fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Activated partial thromboplastin time shortened	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Blood bicarbonate decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Blood bicarbonate decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	C-reactive protein increased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	C-reactive protein increased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Oxygen saturation decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Oxygen saturation decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Metabolism and nutrition disorders	Dehydration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Obesity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Obesity	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	8	28.6	14	87.5	4	28.6
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Scoliosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders		Europe	28	77.8	14	50.0	14	87.5	4	28.6
Nervous system disorders		Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0
Nervous system disorders	Amnesia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Nervous system disorders	Amnesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Nervous system disorders	Dizziness	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Dizziness postural	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness postural	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Headache	Europe	28	77.8	11	39.3	14	87.5	4	28.6
Nervous system disorders	Headache	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Migraine	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Migraine	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Occipital neuralgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Nervous system disorders	Paraesthesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Partial seizures	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Presyncope	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders		Europe	28	77.8	0	0.0	14	87.5	2	14.3
Psychiatric disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders	Anxiety	Europe	28	77.8	0	0.0	14	87.5	2	14.3
Psychiatric disorders	Anxiety	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Renal and urinary disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Renal and urinary disorders	Haematuria	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Haematuria	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Renal cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Reproductive system and breast disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Reproductive system and breast disorders	Polycystic ovaries	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	7	25.0	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	2	25.0	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Europe	28	77.8	4	14.3	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Rest of the World	8	22.2	1	12.5	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Respiratory, thoracic and mediastinal disorders	Epistaxis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	11	39.3	14	87.5	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Europe	28	77.8	1	3.6	14	87.5	0	0.0

Skin and subcutaneous tissue disorders	Dermatitis contact	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures	Dental implantation	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures	Dental implantation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders	Varicose vein	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Neutropenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Thrombocytopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Cardiac disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Ear and labyrinth disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders	Hypopituitarism	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Eye disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders		>Q3	20	55.6	3	15.0	10	62.5	2	20.0
Eye disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Eye disorders	Conjunctival haemorrhage	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Dry eye	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Eye disorders	Dry eye	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Eye disorders	Eye pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	8	66.7	4	25.0	1	25.0
Gastrointestinal disorders		>Q3	20	55.6	14	70.0	10	62.5	3	30.0
Gastrointestinal disorders		Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Abdominal discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	20	55.6	2	10.0	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Gastrointestinal disorders	Abdominal pain upper	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	20	55.6	8	40.0	10	62.5	1	10.0
Gastrointestinal disorders	Diarrhoea	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Dyspepsia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faecaloma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	>Q3	20	55.6	1	5.0	10	62.5	0	0.0

Gastrointestinal disorders	Faeces soft	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	1	25.0
Gastrointestinal disorders	Toothache	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	20	55.6	2	10.0	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	Missing	1	2.8	1	100.0	1	6.3	1	100.0
General disorders and administration site conditions		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
General disorders and administration site conditions		>Q3	20	55.6	5	25.0	10	62.5	3	30.0
General disorders and administration site conditions		Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
General disorders and administration site conditions	Malaise	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
General disorders and administration site conditions	Pyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Immune system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Immune system disorders	Hypersensitivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	3	100.0	1	6.3	1	100.0
Infections and infestations		>Q1 to <=Q3	12	33.3	12	100.0	4	25.0	4	100.0
Infections and infestations		>Q3	20	55.6	20	100.0	10	62.5	7	70.0
Infections and infestations		Missing	1	2.8	1	100.0	1	6.3	1	100.0
Infections and infestations	Adenoiditis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Adenoiditis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Appendicitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Appendicitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Infections and infestations	Bronchitis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Device related infection	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Device related infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Device related infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Folliculitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Folliculitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Folliculitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Furuncle	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Furuncle	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Genital infection fungal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gingivitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Infections and infestations	Hordeolum	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Hordeolum	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Infective thrombosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Influenza	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Influenza	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	20	55.6	7	35.0	10	62.5	2	20.0
Infections and infestations	Nasopharyngitis	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Infections and infestations	Otitis externa	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Otitis externa	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media acute	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pneumonia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Sinusitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Sinusitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tracheitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Infections and infestations	Upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	>Q1 to <=Q3	12	33.3	6	50.0	4	25.0	3	75.0
Infections and infestations	Upper respiratory tract infection	>Q3	20	55.6	8	40.0	10	62.5	2	20.0
Infections and infestations	Upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Infections and infestations	Varicella	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	6	30.0	10	62.5	4	40.0
Injury, poisoning and procedural complications		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Contusion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Femur fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0

Injury, poisoning and procedural complications	Ligament sprain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Procedural pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Activated partial thromboplastin time shortened	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Blood bicarbonate decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	C-reactive protein increased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Oxygen saturation decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Metabolism and nutrition disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Metabolism and nutrition disorders	Obesity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	7	35.0	10	62.5	5	50.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Musculoskeletal and connective tissue disorders	Haemarthrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	20	55.6	3	15.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Scoliosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	2	66.7	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	7	58.3	4	25.0	1	25.0
Nervous system disorders		>Q3	20	55.6	8	40.0	10	62.5	3	30.0
Nervous system disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Nervous system disorders	Amnesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Dizziness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	12	33.3	5	41.7	4	25.0	1	25.0
Nervous system disorders	Headache	>Q3	20	55.6	6	30.0	10	62.5	3	30.0
Nervous system disorders	Headache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0

Nervous system disorders	Partial seizures	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Partial seizures	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Psychiatric disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Psychiatric disorders	Anxiety	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders		<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Reproductive system and breast disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders	Polycystic ovaries	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	5	25.0	10	62.5	3	30.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0

Respiratory, thoracic and mediastinal disorders	Cough	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Cough	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	2	66.7	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	9	45.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Skin and subcutaneous tissue disorders	Alopecia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Skin and subcutaneous tissue disorders	Papule	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Surgical and medical procedures		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Vascular disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_T3.xls
18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	2	11.8	8	50.0	1	12.5
Blood and lymphatic system disorders	Anaemia	Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders	Anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Neutropenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Thrombocytopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Cardiac disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Female	17	47.2	1	5.9	8	50.0	0	0.0
Ear and labyrinth disorders		Male	19	52.8	3	15.8	8	50.0	0	0.0
Ear and labyrinth disorders		Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Deafness neurosensory	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Female	17	47.2	0	0.0	8	50.0	0	0.0
Ear and labyrinth disorders	Ear pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Ear pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Hypoacusis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Endocrine disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Eye disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Eye disorders		Female	17	47.2	3	17.6	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Male	19	52.8	0	0.0	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Female	17	47.2	1	5.9	8	50.0	0	0.0
Eye disorders	Eye pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Eye pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Eye disorders	Ocular hyperaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Ocular hyperaemia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders		Male	19	52.8	13	68.4	8	50.0	2	25.0
Gastrointestinal disorders		Female	17	47.2	10	58.8	8	50.0	3	37.5
Gastrointestinal disorders	Abdominal discomfort	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	17	47.2	5	29.4	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain upper	Male	19	52.8	4	21.1	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Female	17	47.2	1	5.9	8	50.0	1	12.5
Gastrointestinal disorders	Aphthous ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	4	21.1	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	1	5.9	8	50.0	1	12.5
Gastrointestinal disorders	Dental necrosis	Male	19	52.8	0	0.0	8	50.0	0	0.0

Gastrointestinal disorders	Dental necrosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Male	19	52.8	8	42.1	8	50.0	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	17	47.2	4	23.5	8	50.0	1	12.5
Gastrointestinal disorders	Dyspepsia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dyspepsia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Faecaloma	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Faecaloma	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Nausea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Nausea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Toothache	Male	19	52.8	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders	Toothache	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Vomiting	Male	19	52.8	3	15.8	8	50.0	1	12.5
Gastrointestinal disorders	Vomiting	Female	17	47.2	2	11.8	8	50.0	3	37.5
General disorders and administration site conditions		Male	19	52.8	6	31.6	8	50.0	3	37.5
General disorders and administration site conditions		Female	17	47.2	4	23.5	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Malaise	Male	19	52.8	0	0.0	8	50.0	1	12.5
General disorders and administration site conditions	Malaise	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Pyrexia	Male	19	52.8	4	21.1	8	50.0	2	25.0
General disorders and administration site conditions	Pyrexia	Female	17	47.2	3	17.6	8	50.0	0	0.0
Immune system disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Immune system disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Hypersensitivity	Male	19	52.8	0	0.0	8	50.0	0	0.0
Immune system disorders	Hypersensitivity	Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Male	19	52.8	1	5.3	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	19	100.0	8	50.0	6	75.0
Infections and infestations		Female	17	47.2	17	100.0	8	50.0	7	87.5
Infections and infestations	Adenoiditis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Adenoiditis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Bronchitis	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Bronchitis	Female	17	47.2	1	5.9	8	50.0	2	25.0
Infections and infestations	Device related infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Device related infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Folliculitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Folliculitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Fungal skin infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Fungal skin infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Furuncle	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Furuncle	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Male	19	52.8	3	15.8	8	50.0	2	25.0
Infections and infestations	Gastroenteritis	Female	17	47.2	4	23.5	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Female	17	47.2	2	11.8	8	50.0	0	0.0

Infections and infestations	Gastrointestinal infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastrointestinal infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastrointestinal viral infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gingivitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gingivitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Hordeolum	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Hordeolum	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Infective thrombosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Influenza	Male	19	52.8	3	15.8	8	50.0	0	0.0
Infections and infestations	Influenza	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Lymph gland infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Lymph gland infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Nasopharyngitis	Male	19	52.8	5	26.3	8	50.0	1	12.5
Infections and infestations	Nasopharyngitis	Female	17	47.2	6	35.3	8	50.0	2	25.0
Infections and infestations	Otitis externa	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis externa	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Otitis media	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Otitis media acute	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media acute	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Male	19	52.8	3	15.8	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Pharyngitis bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pneumonia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pneumonia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Male	19	52.8	2	10.5	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Rhinitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Rhinitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Sinusitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Sinusitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Subcutaneous abscess	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Subcutaneous abscess	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tracheitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tracheitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Male	19	52.8	5	26.3	8	50.0	3	37.5
Infections and infestations	Upper respiratory tract infection	Female	17	47.2	9	52.9	8	50.0	2	25.0
Infections and infestations	Upper respiratory tract infection bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Varicella	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Varicella	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Male	19	52.8	2	10.5	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Female	17	47.2	2	11.8	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	8	42.1	8	50.0	3	37.5
Injury, poisoning and procedural complications		Female	17	47.2	2	11.8	8	50.0	2	25.0
Injury, poisoning and procedural complications	Anaemia postoperative	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Male	19	52.8	0	0.0	8	50.0	1	12.5

Injury, poisoning and procedural complications	Femur fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Male	19	52.8	2	10.5	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Female	17	47.2	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Female	17	47.2	0	0.0	8	50.0	1	12.5
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Activated partial thromboplastin time shortened	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Blood bicarbonate decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Blood bicarbonate decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	C-reactive protein increased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	C-reactive protein increased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Oxygen saturation decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Oxygen saturation decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Metabolism and nutrition disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Male	19	52.8	1	5.3	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Metabolism and nutrition disorders	Obesity	Male	19	52.8	0	0.0	8	50.0	1	12.5
Metabolism and nutrition disorders	Obesity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	3	15.8	8	50.0	4	50.0
Musculoskeletal and connective tissue disorders		Female	17	47.2	6	35.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	17	47.2	3	17.6	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	17	47.2	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	19	52.8	1	5.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	17	47.2	2	11.8	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Scoliosis	Female	17	47.2	2	11.8	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	17	47.2	0	0.0	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders		Male	19	52.8	10	52.6	8	50.0	2	25.0
Nervous system disorders		Female	17	47.2	8	47.1	8	50.0	2	25.0
Nervous system disorders	Amnesia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Nervous system disorders	Amnesia	Female	17	47.2	0	0.0	8	50.0	0	0.0

Nervous system disorders	Dizziness	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Dizziness	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Dizziness postural	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Dizziness postural	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Headache	Male	19	52.8	6	31.6	8	50.0	2	25.0
Nervous system disorders	Headache	Female	17	47.2	6	35.3	8	50.0	2	25.0
Nervous system disorders	Migraine	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Migraine	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Presyncope	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Presyncope	Female	17	47.2	1	5.9	8	50.0	0	0.0
Psychiatric disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders		Female	17	47.2	0	0.0	8	50.0	2	25.0
Psychiatric disorders	Anxiety	Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders	Anxiety	Female	17	47.2	0	0.0	8	50.0	2	25.0
Renal and urinary disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders		Female	17	47.2	2	11.8	8	50.0	0	0.0
Renal and urinary disorders	Haematuria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Haematuria	Female	17	47.2	2	11.8	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Female	17	47.2	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Female	17	47.2	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Female	17	47.2	4	23.5	8	50.0	1	12.5
Reproductive system and breast disorders	Amenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	7	36.8	8	50.0	2	25.0
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	2	11.8	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Male	19	52.8	4	21.1	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Cough	Female	17	47.2	1	5.9	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	17	47.2	1	5.9	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	8	42.1	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	7	41.2	8	50.0	1	12.5
Skin and subcutaneous tissue disorders	Alopecia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Male	19	52.8	1	5.3	8	50.0	0	0.0

Skin and subcutaneous tissue disorders	Dermatitis contact	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Female	17	47.2	2	11.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Female	17	47.2	2	11.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	17	47.2	0	0.0	8	50.0	1	12.5
Surgical and medical procedures		Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures		Female	17	47.2	0	0.0	8	50.0	1	12.5
Surgical and medical procedures	Dental implantation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures	Dental implantation	Female	17	47.2	0	0.0	8	50.0	1	12.5
Vascular disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Vascular disorders	Varicose vein	Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders	Varicose vein	Female	17	47.2	1	5.9	8	50.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Thrombocytopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Ear and labyrinth disorders	Deafness neurosensory	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Ear pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypoacusis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		Type III	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		Type III	36	100.0	23	63.9	16	100.0	5	31.3
Gastrointestinal disorders	Abdominal discomfort	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Type III	36	100.0	6	16.7	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	Type III	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Dental necrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Type III	36	100.0	12	33.3	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	Type III	36	100.0	5	13.9	16	100.0	4	25.0
General disorders and administration site conditions		Type III	36	100.0	10	27.8	16	100.0	3	18.8
General disorders and administration site conditions	Feeling abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Malaise	Type III	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	Type III	36	100.0	7	19.4	16	100.0	2	12.5
Immune system disorders		Type III	36	100.0	1	2.8	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations		Type III	36	100.0	36	100.0	16	100.0	13	81.3

Infections and infestations	Adenoiditis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Appendicitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	Type III	36	100.0	2	5.6	16	100.0	3	18.8
Infections and infestations	Device related infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Folliculitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Fungal skin infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Furuncle	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	Type III	36	100.0	7	19.4	16	100.0	2	12.5
Infections and infestations	Gastroenteritis viral	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hand-foot-and-mouth disease	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Influenza	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	Type III	36	100.0	11	30.6	16	100.0	3	18.8
Infections and infestations	Otitis externa	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Otitis media	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	Type III	36	100.0	4	11.1	16	100.0	1	6.3
Infections and infestations	Pharyngitis bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	Type III	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Sinusitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tonsillitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tracheitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Type III	36	100.0	14	38.9	16	100.0	5	31.3
Infections and infestations	Upper respiratory tract infection bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Variocella	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Viral pharyngitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	10	27.8	16	100.0	5	31.3
Injury, poisoning and procedural complications	Anaemia postoperative	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Hand fracture	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Tooth fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		Type III	36	100.0	2	5.6	16	100.0	1	6.3
Metabolism and nutrition disorders	Dehydration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Obesity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		Type III	36	100.0	9	25.0	16	100.0	5	31.3
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Exostosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Musculoskeletal and connective tissue disorders	Haemarthrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		Type III	36	100.0	18	50.0	16	100.0	4	25.0
Nervous system disorders	Amnesia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	Type III	36	100.0	12	33.3	16	100.0	4	25.0
Nervous system disorders	Migraine	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Nervous system disorders	Partial seizures	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Psychiatric disorders		Type III	36	100.0	0	0.0	16	100.0	2	12.5
Psychiatric disorders	Anxiety	Type III	36	100.0	0	0.0	16	100.0	2	12.5
Renal and urinary disorders		Type III	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	9	25.0	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Type III	36	100.0	5	13.9	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		Type III	36	100.0	15	41.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	Type III	36	100.0	0	0.0	16	100.0	1	6.3

Vascular disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_T3.xls
18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders		3	24	66.7	4	16.7	10	62.5	1	10.0
Blood and lymphatic system disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Anaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Anaemia	3	24	66.7	3	12.5	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	3	24	66.7	1	4.2	10	62.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	3	24	66.7	0	0.0	10	62.5	1	10.0
Blood and lymphatic system disorders	Leukopenia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	3	24	66.7	0	0.0	10	62.5	1	10.0
Blood and lymphatic system disorders	Neutropenia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	3	24	66.7	0	0.0	10	62.5	1	10.0
Blood and lymphatic system disorders	Thrombocytopenia	4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	4	10	27.8	0	0.0	6	37.5	0	0.0
Ear and labyrinth disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders		3	24	66.7	2	8.3	10	62.5	1	10.0
Ear and labyrinth disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	3	24	66.7	1	4.2	10	62.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	4	10	27.8	0	0.0	6	37.5	0	0.0
Ear and labyrinth disorders	Ear pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Ear pain	3	24	66.7	0	0.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	3	24	66.7	1	4.2	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	4	10	27.8	0	0.0	6	37.5	0	0.0
Endocrine disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Endocrine disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Endocrine disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Endocrine disorders	Hypopituitarism	2	2	5.6	0	0.0	0	0.0	0	0.0
Endocrine disorders	Hypopituitarism	3	24	66.7	1	4.2	10	62.5	0	0.0
Endocrine disorders	Hypopituitarism	4	10	27.8	0	0.0	6	37.5	0	0.0
Eye disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders		3	24	66.7	1	4.2	10	62.5	1	10.0
Eye disorders		4	10	27.8	3	30.0	6	37.5	1	16.7
Eye disorders	Conjunctival haemorrhage	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctival haemorrhage	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctival haemorrhage	4	10	27.8	0	0.0	6	37.5	1	16.7
Eye disorders	Conjunctivitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctivitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Dry eye	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Dry eye	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Dry eye	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Eye pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Eye pain	3	24	66.7	1	4.2	10	62.5	1	10.0

Eye disorders	Eye pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Ocular hyperaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Ocular hyperaemia	3	24	66.7	1	4.2	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders		3	24	66.7	15	62.5	10	62.5	3	30.0
Gastrointestinal disorders		4	10	27.8	7	70.0	6	37.5	2	33.3
Gastrointestinal disorders	Abdominal discomfort	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal distension	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal distension	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal pain	3	24	66.7	3	12.5	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	3	24	66.7	2	8.3	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	4	10	27.8	3	30.0	6	37.5	1	16.7
Gastrointestinal disorders	Aphthous ulcer	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Constipation	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Constipation	3	24	66.7	2	8.3	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	4	10	27.8	3	30.0	6	37.5	0	0.0
Gastrointestinal disorders	Dental necrosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Dental necrosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Dental necrosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Diarrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Diarrhoea	3	24	66.7	7	29.2	10	62.5	2	20.0
Gastrointestinal disorders	Diarrhoea	4	10	27.8	5	50.0	6	37.5	0	0.0
Gastrointestinal disorders	Dyspepsia	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Dyspepsia	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Faecaloma	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Faecaloma	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faecaloma	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Faeces soft	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Faeces soft	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faeces soft	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Flatulence	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Flatulence	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Nausea	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Nausea	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Tooth malformation	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Tooth malformation	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Tooth malformation	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Toothache	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Toothache	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	4	10	27.8	1	10.0	6	37.5	1	16.7
Gastrointestinal disorders	Vomiting	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Vomiting	3	24	66.7	2	8.3	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	4	10	27.8	2	20.0	6	37.5	1	16.7
General disorders and administration site conditions		2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions		3	24	66.7	5	20.8	10	62.5	1	10.0
General disorders and administration site conditions		4	10	27.8	5	50.0	6	37.5	2	33.3
General disorders and administration site conditions	Feeling abnormal	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	3	24	66.7	1	4.2	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	4	10	27.8	0	0.0	6	37.5	0	0.0

General disorders and administration site conditions	Hyperpyrexia	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Influenza like illness	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Influenza like illness	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Malaise	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Malaise	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Malaise	4	10	27.8	0	0.0	6	37.5	1	16.7
General disorders and administration site conditions	Medical device pain	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Medical device pain	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Pyrexia	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Pyrexia	3	24	66.7	4	16.7	10	62.5	1	10.0
General disorders and administration site conditions	Pyrexia	4	10	27.8	3	30.0	6	37.5	1	16.7
Immune system disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders		3	24	66.7	0	0.0	10	62.5	2	20.0
Immune system disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Immune system disorders	Hypersensitivity	2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Hypersensitivity	3	24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Hypersensitivity	4	10	27.8	0	0.0	6	37.5	0	0.0
Immune system disorders	Seasonal allergy	2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Seasonal allergy	3	24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations		2	2	5.6	2	100.0	0	0.0	0	0.0
Infections and infestations		3	24	66.7	24	100.0	10	62.5	8	80.0
Infections and infestations		4	10	27.8	10	100.0	6	37.5	5	83.3
Infections and infestations	Adenoiditis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Adenoiditis	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Adenoiditis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Appendicitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Appendicitis	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Appendicitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Bronchitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Bronchitis	3	24	66.7	1	4.2	10	62.5	3	30.0
Infections and infestations	Bronchitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Device related infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Device related infection	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Device related infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Enterovirus infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Enterovirus infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Enterovirus infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Folliculitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Folliculitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Folliculitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Fungal skin infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Fungal skin infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Furuncle	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Furuncle	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Furuncle	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis	3	24	66.7	4	16.7	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	4	10	27.8	3	30.0	6	37.5	1	16.7
Infections and infestations	Gastroenteritis viral	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis viral	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal infection	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Genital infection fungal	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Genital infection fungal	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Genital infection fungal	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gingivitis	2	2	5.6	0	0.0	0	0.0	0	0.0

Infections and infestations	Gingivitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gingivitis	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Hand-foot-and-mouth disease	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Hordeolum	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hordeolum	3	24	66.7	1	4.2	10	62.5	1	10.0
Infections and infestations	Hordeolum	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Infective thrombosis	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Infective thrombosis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Infective thrombosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Influenza	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Influenza	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Influenza	4	10	27.8	3	30.0	6	37.5	0	0.0
Infections and infestations	Lymph gland infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Lymph gland infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Nasopharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Nasopharyngitis	3	24	66.7	6	25.0	10	62.5	1	10.0
Infections and infestations	Nasopharyngitis	4	10	27.8	5	50.0	6	37.5	2	33.3
Infections and infestations	Otitis externa	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis externa	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis externa	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Otitis media	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Otitis media	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Otitis media acute	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media acute	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis media acute	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis	3	24	66.7	3	12.5	10	62.5	1	10.0
Infections and infestations	Pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis bacterial	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pneumonia	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pneumonia	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Pneumonia	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Respiratory tract infection	3	24	66.7	3	12.5	10	62.5	1	10.0
Infections and infestations	Respiratory tract infection	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Rhinitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Sinusitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Sinusitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Sinusitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Soft tissue infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Soft tissue infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Subcutaneous abscess	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Subcutaneous abscess	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Tonsillitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Tonsillitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Tracheitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Tracheitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Tracheitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Upper respiratory tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection	3	24	66.7	12	50.0	10	62.5	2	20.0
Infections and infestations	Upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	3	50.0
Infections and infestations	Upper respiratory tract infection bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Urinary tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Urinary tract infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Varicella	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Varicella	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Varicella	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0

Infections and infestations	Viral pharyngitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral rhinitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	3	24	66.7	3	12.5	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications		2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications		3	24	66.7	4	16.7	10	62.5	3	30.0
Injury, poisoning and procedural complications		4	10	27.8	5	50.0	6	37.5	2	33.3
Injury, poisoning and procedural complications	Anaemia postoperative	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Concussion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Concussion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Contusion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Contusion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Contusion	4	10	27.8	1	10.0	6	37.5	1	16.7
Injury, poisoning and procedural complications	Fall	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Fall	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Femur fracture	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Muscle strain	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	4	10	27.8	1	10.0	6	37.5	1	16.7
Injury, poisoning and procedural complications	Tooth fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	4	10	27.8	0	0.0	6	37.5	0	0.0
Investigations		2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations		3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations		4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Activated partial thromboplastin time shortened	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Blood bicarbonate decreased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Blood bicarbonate decreased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Blood bicarbonate decreased	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	C-reactive protein increased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	C-reactive protein increased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	C-reactive protein increased	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Oxygen saturation decreased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Oxygen saturation decreased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Oxygen saturation decreased	4	10	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders		2	2	5.6	0	0.0	0	0.0	0	0.0

Metabolism and nutrition disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders		4	10	27.8	1	10.0	6	37.5	1	16.7
Metabolism and nutrition disorders	Dehydration	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Dehydration	3	24	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	4	10	27.8	1	10.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	4	10	27.8	0	0.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Obesity	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Obesity	3	24	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Obesity	4	10	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	24	66.7	7	29.2	10	62.5	2	20.0
Musculoskeletal and connective tissue disorders		4	10	27.8	2	20.0	6	37.5	3	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	24	66.7	2	8.3	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	10	27.8	1	10.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Back pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	10	27.8	1	10.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Exostosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3	24	66.7	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	3	24	66.7	2	8.3	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	3	24	66.7	2	8.3	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	4	10	27.8	0	0.0	6	37.5	1	16.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		4	10	27.8	1	10.0	6	37.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders		3	24	66.7	10	41.7	10	62.5	2	20.0
Nervous system disorders		4	10	27.8	7	70.0	6	37.5	2	33.3
Nervous system disorders	Amnesia	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Amnesia	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Amnesia	4	10	27.8	0	0.0	6	37.5	1	16.7
Nervous system disorders	Dizziness	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness	4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Dizziness postural	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness postural	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Headache	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Headache	3	24	66.7	8	33.3	10	62.5	2	20.0
Nervous system disorders	Headache	4	10	27.8	4	40.0	6	37.5	2	33.3
Nervous system disorders	Migraine	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Migraine	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Occipital neuralgia	2	2	5.6	0	0.0	0	0.0	0	0.0

Nervous system disorders	Occipital neuralgia	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Paraesthesia	2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders	Paraesthesia	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Partial seizures	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Partial seizures	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Partial seizures	4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Presyncope	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Presyncope	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	4	10	27.8	1	10.0	6	37.5	0	0.0
Psychiatric disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders		3	24	66.7	0	0.0	10	62.5	2	20.0
Psychiatric disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Psychiatric disorders	Anxiety	2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders	Anxiety	3	24	66.7	0	0.0	10	62.5	2	20.0
Psychiatric disorders	Anxiety	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders		3	24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Haematuria	2	2	5.6	0	0.0	0	0.0	0	0.0
Renal and urinary disorders	Haematuria	3	24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Renal cyst	2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Renal cyst	3	24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Urinary incontinence	2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Urinary incontinence	3	24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders		3	24	66.7	3	12.5	10	62.5	1	10.0
Reproductive system and breast disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	3	24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	3	24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	3	24	66.7	0	0.0	10	62.5	1	10.0
Reproductive system and breast disorders	Polycystic ovaries	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	24	66.7	5	20.8	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders		4	10	27.8	3	30.0	6	37.5	3	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	3	24	66.7	1	4.2	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	3	24	66.7	3	12.5	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	4	10	27.8	2	20.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	3	24	66.7	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	24	66.7	1	4.2	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	10	27.8	1	10.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	4	10	27.8	0	0.0	6	37.5	1	16.7
Skin and subcutaneous tissue disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	24	66.7	12	50.0	10	62.5	1	10.0
Skin and subcutaneous tissue disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	24	66.7	0	0.0	10	62.5	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures		2	2	5.6	0	0.0	0	0.0	0	0.0

Surgical and medical procedures		3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures	Dental implantation	2	2	5.6	0	0.0	0	0.0	0	0.0
Surgical and medical procedures	Dental implantation	3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	4	10	27.8	0	0.0	6	37.5	0	0.0
Vascular disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Vascular disorders	Varicose vein	2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders	Varicose vein	3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	4	10	27.8	1	10.0	6	37.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:39

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: Any AEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Blood and lymphatic system disorders	Anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	No	29	80.6	0	0.0	12	75.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Neutropenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Thrombocytopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Cardiac disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	No	29	80.6	1	3.4	12	75.0	0	0.0
Ear and labyrinth disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Ear and labyrinth disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Deafness neurosensory	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	No	29	80.6	0	0.0	12	75.0	0	0.0
Ear and labyrinth disorders	Ear pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Hypoacusis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	No	29	80.6	0	0.0	12	75.0	0	0.0
Endocrine disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Endocrine disorders	Hypopituitarism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders		No	29	80.6	4	13.8	12	75.0	2	16.7
Eye disorders	Conjunctival haemorrhage	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	No	29	80.6	0	0.0	12	75.0	1	8.3
Eye disorders	Conjunctivitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Dry eye	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Eye pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Eye disorders	Ocular hyperaemia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders		Yes	7	19.4	3	42.9	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	20	69.0	12	75.0	5	41.7
Gastrointestinal disorders	Abdominal discomfort	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	No	29	80.6	5	17.2	12	75.0	2	16.7
Gastrointestinal disorders	Abdominal pain upper	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	No	29	80.6	4	13.8	12	75.0	1	8.3
Gastrointestinal disorders	Aphthous ulcer	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	4	13.8	12	75.0	1	8.3
Gastrointestinal disorders	Dental necrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Gastrointestinal disorders	Dental necrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	No	29	80.6	11	37.9	12	75.0	2	16.7
Gastrointestinal disorders	Dyspepsia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Faecaloma	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Faeces soft	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Flatulence	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Nausea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Toothache	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	No	29	80.6	1	3.4	12	75.0	1	8.3
Gastrointestinal disorders	Vomiting	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	No	29	80.6	4	13.8	12	75.0	4	33.3
General disorders and administration site conditions		Yes	7	19.4	2	28.6	4	25.0	0	0.0
General disorders and administration site conditions		No	29	80.6	8	27.6	12	75.0	3	25.0
General disorders and administration site conditions	Feeling abnormal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	No	29	80.6	0	0.0	12	75.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Malaise	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	No	29	80.6	0	0.0	12	75.0	1	8.3
General disorders and administration site conditions	Medical device pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Pyrexia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	No	29	80.6	6	20.7	12	75.0	2	16.7
Immune system disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders		No	29	80.6	1	3.4	12	75.0	1	8.3
Immune system disorders	Hypersensitivity	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	No	29	80.6	0	0.0	12	75.0	0	0.0
Immune system disorders	Seasonal allergy	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations		Yes	7	19.4	7	100.0	4	25.0	4	100.0
Infections and infestations		No	29	80.6	29	100.0	12	75.0	9	75.0
Infections and infestations	Adenoiditis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Appendicitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Bronchitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	No	29	80.6	2	6.9	12	75.0	2	16.7
Infections and infestations	Device related infection	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Device related infection	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Enterovirus infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Folliculitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Fungal skin infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Furuncle	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Furuncle	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gastroenteritis	Yes	7	19.4	2	28.6	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	5	17.2	12	75.0	2	16.7
Infections and infestations	Gastroenteritis viral	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	No	29	80.6	2	6.9	12	75.0	0	0.0

Infections and infestations	Gastrointestinal infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Genital infection fungal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gingivitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Hand-foot-and-mouth disease	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Hordeolum	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Infective thrombosis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Influenza	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Influenza	No	29	80.6	3	10.3	12	75.0	0	0.0
Infections and infestations	Lymph gland infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Nasopharyngitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	No	29	80.6	10	34.5	12	75.0	3	25.0
Infections and infestations	Otitis externa	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Otitis media	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Otitis media acute	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Pharyngitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	No	29	80.6	4	13.8	12	75.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Pneumonia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	No	29	80.6	3	10.3	12	75.0	1	8.3
Infections and infestations	Rhinitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Rhinitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Sinusitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Soft tissue infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Subcutaneous abscess	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Tonsillitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Tracheitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Yes	7	19.4	4	57.1	4	25.0	2	50.0
Infections and infestations	Upper respiratory tract infection	No	29	80.6	10	34.5	12	75.0	3	25.0
Infections and infestations	Upper respiratory tract infection bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Urinary tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Varicella	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations	Viral pharyngitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Viral rhinitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	No	29	80.6	4	13.8	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	2	28.6	4	25.0	1	25.0
Injury, poisoning and procedural complications		No	29	80.6	8	27.6	12	75.0	4	33.3
Injury, poisoning and procedural complications	Anaemia postoperative	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	No	29	80.6	1	3.4	12	75.0	1	8.3
Injury, poisoning and procedural complications	Fall	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Injury, poisoning and procedural complications	Femur fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Injury, poisoning and procedural complications	Hand fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	No	29	80.6	2	6.9	12	75.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Muscle strain	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	No	29	80.6	1	3.4	12	75.0	1	8.3
Injury, poisoning and procedural complications	Tooth fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Activated partial thromboplastin time shortened	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Blood bicarbonate decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	C-reactive protein increased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Oxygen saturation decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Metabolism and nutrition disorders	Dehydration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders	Obesity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	7	24.1	12	75.0	5	41.7
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	7	19.4	2	28.6	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	29	80.6	1	3.4	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Exostosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	29	80.6	3	10.3	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Scoliosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	No	29	80.6	2	6.9	12	75.0	1	8.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		No	29	80.6	1	3.4	12	75.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders		Yes	7	19.4	5	71.4	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	13	44.8	12	75.0	4	33.3
Nervous system disorders	Amnesia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	No	29	80.6	0	0.0	12	75.0	1	8.3

Nervous system disorders	Dizziness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Dizziness postural	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	No	29	80.6	0	0.0	12	75.0	0	0.0
Nervous system disorders	Headache	Yes	7	19.4	3	42.9	4	25.0	0	0.0
Nervous system disorders	Headache	No	29	80.6	9	31.0	12	75.0	4	33.3
Nervous system disorders	Migraine	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Occipital neuralgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Paraesthesia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	No	29	80.6	2	6.9	12	75.0	0	0.0
Nervous system disorders	Partial seizures	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Presyncope	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	No	29	80.6	1	3.4	12	75.0	0	0.0
Psychiatric disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders		No	29	80.6	0	0.0	12	75.0	2	16.7
Psychiatric disorders	Anxiety	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	No	29	80.6	0	0.0	12	75.0	2	16.7
Renal and urinary disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Renal and urinary disorders	Haematuria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	No	29	80.6	2	6.9	12	75.0	0	0.0
Renal and urinary disorders	Renal cyst	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	No	29	80.6	0	0.0	12	75.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders		Yes	7	19.4	1	14.3	4	25.0	1	25.0
Reproductive system and breast disorders		No	29	80.6	3	10.3	12	75.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	No	29	80.6	0	0.0	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	9	31.0	12	75.0	4	33.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	No	29	80.6	5	17.2	12	75.0	2	16.7
Respiratory, thoracic and mediastinal disorders	Epistaxis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	No	29	80.6	1	3.4	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	29	80.6	2	6.9	12	75.0	3	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	No	29	80.6	0	0.0	12	75.0	1	8.3
Skin and subcutaneous tissue disorders		Yes	7	19.4	4	57.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	11	37.9	12	75.0	1	8.3
Skin and subcutaneous tissue disorders	Alopecia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Dermatitis contact	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	No	29	80.6	2	6.9	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	No	29	80.6	2	6.9	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhea	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	29	80.6	0	0.0	12	75.0	1	8.3
Surgical and medical procedures		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		No	29	80.6	0	0.0	12	75.0	1	8.3
Surgical and medical procedures	Dental implantation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	No	29	80.6	0	0.0	12	75.0	1	8.3
Vascular disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Vascular disorders	Varicose vein	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	No	29	80.6	1	3.4	12	75.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AAE_SE_P2_T3.xls
18DEC2020 9:39

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders		6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders		12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders		18 to 25 years	4	26.7	2	50.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Vomiting	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Vomiting	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions		2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions		6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions		12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions		18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions	Malaise	2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	4	26.7	1	25.0
Immune system disorders		2 to 5 years	3	20.0	0	0.0
Immune system disorders		6 to 11 years	4	26.7	0	0.0
Immune system disorders		12 to 17 years	4	26.7	1	25.0
Immune system disorders		18 to 25 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	3	20.0	0	0.0
Immune system disorders	Hypersensitivity	6 to 11 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	4	26.7	0	0.0

Infections and infestations		2 to 5 years	3	20.0	1	33.3
Infections and infestations		6 to 11 years	4	26.7	1	25.0
Infections and infestations		12 to 17 years	4	26.7	1	25.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Bronchitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	12 to 17 years	4	26.7	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Nasopharyngitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Subcutaneous abscess	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Subcutaneous abscess	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	18 to 25 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications		6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications		18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Contusion	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Contusion	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	12 to 17 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	18 to 25 years	4	26.7	0	0.0
Investigations		2 to 5 years	3	20.0	1	33.3
Investigations		6 to 11 years	4	26.7	0	0.0
Investigations		12 to 17 years	4	26.7	0	0.0
Investigations		18 to 25 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	2 to 5 years	3	20.0	1	33.3
Investigations	C-reactive protein increased	6 to 11 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	12 to 17 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	3	20.0	2	66.7
Musculoskeletal and connective tissue disorders		6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	4	26.7	2	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	4	26.7	0	0.0

Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	4	26.7	0	0.0
Nervous system disorders		2 to 5 years	3	20.0	0	0.0
Nervous system disorders		6 to 11 years	4	26.7	1	25.0
Nervous system disorders		12 to 17 years	4	26.7	0	0.0
Nervous system disorders		18 to 25 years	4	26.7	1	25.0
Nervous system disorders	Headache	2 to 5 years	3	20.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	4	26.7	1	25.0
Nervous system disorders	Headache	12 to 17 years	4	26.7	0	0.0
Nervous system disorders	Headache	18 to 25 years	4	26.7	1	25.0
Psychiatric disorders		2 to 5 years	3	20.0	0	0.0
Psychiatric disorders		6 to 11 years	4	26.7	0	0.0
Psychiatric disorders		12 to 17 years	4	26.7	0	0.0
Psychiatric disorders		18 to 25 years	4	26.7	1	25.0
Psychiatric disorders	Anxiety	2 to 5 years	3	20.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	12 to 17 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18 to 25 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders		6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	4	26.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls
08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		n/a	15	100.0	3	20.0
Gastrointestinal disorders	Abdominal pain	n/a	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	n/a	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	n/a	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	n/a	15	100.0	1	6.7
General disorders and administration site conditions		n/a	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	n/a	15	100.0	1	6.7
Immune system disorders		n/a	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	n/a	15	100.0	1	6.7
Infections and infestations		n/a	15	100.0	3	20.0
Infections and infestations	Bronchitis	n/a	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	n/a	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	n/a	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications		n/a	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	n/a	15	100.0	1	6.7
Investigations		n/a	15	100.0	1	6.7
Investigations	C-reactive protein increased	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		n/a	15	100.0	4	26.7
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	15	100.0	1	6.7
Nervous system disorders		n/a	15	100.0	2	13.3
Nervous system disorders	Headache	n/a	15	100.0	2	13.3
Psychiatric disorders		n/a	15	100.0	1	6.7
Psychiatric disorders	Anxiety	n/a	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		n/a	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	15	100.0	1	6.7

Skin and subcutaneous tissue disorders		n/a	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		White	12	80.0	1	8.3
Gastrointestinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders		Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Abdominal pain	White	12	80.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Diarrhoea	White	12	80.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	2	13.3	1	50.0
Gastrointestinal disorders	Toothache	White	12	80.0	1	8.3
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Unknown	2	13.3	0	0.0
Gastrointestinal disorders	Vomiting	White	12	80.0	0	0.0
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	2	13.3	1	50.0
General disorders and administration site conditions		White	12	80.0	1	8.3
General disorders and administration site conditions		Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions		Unknown	2	13.3	0	0.0
General disorders and administration site conditions	Malaise	White	12	80.0	1	8.3
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Unknown	2	13.3	0	0.0
Immune system disorders		White	12	80.0	1	8.3
Immune system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders		Unknown	2	13.3	0	0.0
Immune system disorders	Hypersensitivity	White	12	80.0	1	8.3
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Unknown	2	13.3	0	0.0
Infections and infestations		White	12	80.0	1	8.3
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations		Unknown	2	13.3	1	50.0
Infections and infestations	Bronchitis	White	12	80.0	1	8.3
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Bronchitis	Unknown	2	13.3	0	0.0
Infections and infestations	Gastroenteritis	White	12	80.0	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Unknown	2	13.3	1	50.0

Infections and infestations	Nasopharyngitis	White	12	80.0	0	0.0
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	2	13.3	0	0.0
Infections and infestations	Subcutaneous abscess	White	12	80.0	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	2	13.3	1	50.0
Injury, poisoning and procedural complications		White	12	80.0	2	16.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications		Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Contusion	White	12	80.0	1	8.3
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	12	80.0	1	8.3
Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	2	13.3	0	0.0
Investigations		White	12	80.0	0	0.0
Investigations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations		Unknown	2	13.3	0	0.0
Investigations	C-reactive protein increased	White	12	80.0	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations	C-reactive protein increased	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders		White	12	80.0	2	16.7
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	2	13.3	0	0.0
Nervous system disorders		White	12	80.0	1	8.3
Nervous system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders		Unknown	2	13.3	1	50.0
Nervous system disorders	Headache	White	12	80.0	1	8.3
Nervous system disorders	Headache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders	Headache	Unknown	2	13.3	1	50.0
Psychiatric disorders		White	12	80.0	0	0.0
Psychiatric disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders		Unknown	2	13.3	1	50.0
Psychiatric disorders	Anxiety	White	12	80.0	0	0.0

Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Unknown	2	13.3	1	50.0
Respiratory, thoracic and mediastinal disorders		White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Unknown	2	13.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders		White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	2	13.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

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08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Europe	14	93.3	3	21.4
Gastrointestinal disorders		Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	14	93.3	2	14.3
Gastrointestinal disorders	Abdominal pain	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Diarrhoea	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Vomiting	Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions		Europe	14	93.3	1	7.1
General disorders and administration site conditions		Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Europe	14	93.3	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	1	6.7	0	0.0
Immune system disorders		Europe	14	93.3	1	7.1
Immune system disorders		Rest of the World	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Europe	14	93.3	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	1	6.7	0	0.0
Infections and infestations		Europe	14	93.3	2	14.3
Infections and infestations		Rest of the World	1	6.7	1	100.0
Infections and infestations	Bronchitis	Europe	14	93.3	1	7.1
Infections and infestations	Bronchitis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Europe	14	93.3	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	Europe	14	93.3	0	0.0
Infections and infestations	Nasopharyngitis	Rest of the World	1	6.7	1	100.0
Infections and infestations	Subcutaneous abscess	Europe	14	93.3	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications		Europe	14	93.3	2	14.3
Injury, poisoning and procedural complications		Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	14	93.3	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	14	93.3	1	7.1
Injury, poisoning and procedural complications	Muscle strain	Rest of the World	1	6.7	0	0.0

Investigations		Europe	14	93.3	0	0.0
Investigations		Rest of the World	1	6.7	1	100.0
Investigations	C-reactive protein increased	Europe	14	93.3	0	0.0
Investigations	C-reactive protein increased	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Europe	14	93.3	3	21.4
Musculoskeletal and connective tissue disorders		Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	14	93.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	1	6.7	0	0.0
Nervous system disorders		Europe	14	93.3	2	14.3
Nervous system disorders		Rest of the World	1	6.7	0	0.0
Nervous system disorders	Headache	Europe	14	93.3	2	14.3
Nervous system disorders	Headache	Rest of the World	1	6.7	0	0.0
Psychiatric disorders		Europe	14	93.3	1	7.1
Psychiatric disorders		Rest of the World	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Europe	14	93.3	1	7.1
Psychiatric disorders	Anxiety	Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders		Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	1	6.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls

08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		<=Q1	1	6.7	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders		>Q3	9	60.0	2	22.2
Gastrointestinal disorders		Missing	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	9	60.0	2	22.2
Gastrointestinal disorders	Abdominal pain	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Diarrhoea	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders	Toothache	>Q3	9	60.0	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Vomiting	Missing	1	6.7	0	0.0
General disorders and administration site conditions		<=Q1	1	6.7	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions		>Q3	9	60.0	1	11.1
General disorders and administration site conditions		Missing	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	>Q3	9	60.0	1	11.1
General disorders and administration site conditions	Malaise	Missing	1	6.7	0	0.0
Immune system disorders		<=Q1	1	6.7	0	0.0
Immune system disorders		>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders		>Q3	9	60.0	0	0.0
Immune system disorders		Missing	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	>Q3	9	60.0	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	6.7	0	0.0

Infections and infestations		<=Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations		>Q3	9	60.0	2	22.2
Infections and infestations		Missing	1	6.7	0	0.0
Infections and infestations	Bronchitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations	Bronchitis	>Q3	9	60.0	0	0.0
Infections and infestations	Bronchitis	Missing	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	>Q3	9	60.0	1	11.1
Infections and infestations	Gastroenteritis	Missing	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	9	60.0	1	11.1
Infections and infestations	Nasopharyngitis	Missing	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	9	60.0	1	11.1
Infections and infestations	Subcutaneous abscess	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications		<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications		>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications		Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications	Contusion	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	9	60.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	6.7	0	0.0
Investigations		<=Q1	1	6.7	0	0.0
Investigations		>Q1 to <=Q3	4	26.7	0	0.0
Investigations		>Q3	9	60.0	1	11.1
Investigations		Missing	1	6.7	0	0.0
Investigations	C-reactive protein increased	<=Q1	1	6.7	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	4	26.7	0	0.0
Investigations	C-reactive protein increased	>Q3	9	60.0	1	11.1
Investigations	C-reactive protein increased	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	9	60.0	4	44.4
Musculoskeletal and connective tissue disorders		Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	6.7	0	0.0

Musculoskeletal and connective tissue disorders	Back pain	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	6.7	0	0.0
Nervous system disorders		<=Q1	1	6.7	0	0.0
Nervous system disorders		>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders		>Q3	9	60.0	2	22.2
Nervous system disorders		Missing	1	6.7	0	0.0
Nervous system disorders	Headache	<=Q1	1	6.7	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders	Headache	>Q3	9	60.0	2	22.2
Nervous system disorders	Headache	Missing	1	6.7	0	0.0
Psychiatric disorders		<=Q1	1	6.7	0	0.0
Psychiatric disorders		>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders		>Q3	9	60.0	1	11.1
Psychiatric disorders		Missing	1	6.7	0	0.0
Psychiatric disorders	Anxiety	<=Q1	1	6.7	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders	Anxiety	>Q3	9	60.0	1	11.1
Psychiatric disorders	Anxiety	Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		>Q3	9	60.0	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	6.7	1	100.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	9	60.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Missing	1	6.7	1	100.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls
08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Male	8	53.3	2	25.0
Gastrointestinal disorders		Female	7	46.7	1	14.3
Gastrointestinal disorders	Abdominal pain	Male	8	53.3	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	7	46.7	1	14.3
Gastrointestinal disorders	Diarrhoea	Male	8	53.3	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	7	46.7	0	0.0
Gastrointestinal disorders	Toothache	Male	8	53.3	1	12.5
Gastrointestinal disorders	Toothache	Female	7	46.7	0	0.0
Gastrointestinal disorders	Vomiting	Male	8	53.3	0	0.0
Gastrointestinal disorders	Vomiting	Female	7	46.7	1	14.3
General disorders and administration site conditions		Male	8	53.3	1	12.5
General disorders and administration site conditions		Female	7	46.7	0	0.0
General disorders and administration site conditions	Malaise	Male	8	53.3	1	12.5
General disorders and administration site conditions	Malaise	Female	7	46.7	0	0.0
Immune system disorders		Male	8	53.3	0	0.0
Immune system disorders		Female	7	46.7	1	14.3
Immune system disorders	Hypersensitivity	Male	8	53.3	0	0.0
Immune system disorders	Hypersensitivity	Female	7	46.7	1	14.3
Infections and infestations		Male	8	53.3	2	25.0
Infections and infestations		Female	7	46.7	1	14.3
Infections and infestations	Bronchitis	Male	8	53.3	0	0.0
Infections and infestations	Bronchitis	Female	7	46.7	1	14.3
Infections and infestations	Gastroenteritis	Male	8	53.3	1	12.5
Infections and infestations	Gastroenteritis	Female	7	46.7	0	0.0
Infections and infestations	Nasopharyngitis	Male	8	53.3	1	12.5
Infections and infestations	Nasopharyngitis	Female	7	46.7	0	0.0
Infections and infestations	Subcutaneous abscess	Male	8	53.3	1	12.5
Infections and infestations	Subcutaneous abscess	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications		Male	8	53.3	1	12.5
Injury, poisoning and procedural complications		Female	7	46.7	1	14.3
Injury, poisoning and procedural complications	Contusion	Male	8	53.3	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	8	53.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Female	7	46.7	1	14.3

Investigations		Male	8	53.3	1	12.5
Investigations		Female	7	46.7	0	0.0
Investigations	C-reactive protein increased	Male	8	53.3	1	12.5
Investigations	C-reactive protein increased	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders		Male	8	53.3	3	37.5
Musculoskeletal and connective tissue disorders		Female	7	46.7	1	14.3
Musculoskeletal and connective tissue disorders	Arthralgia	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	8	53.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	7	46.7	1	14.3
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	7	46.7	0	0.0
Nervous system disorders		Male	8	53.3	0	0.0
Nervous system disorders		Female	7	46.7	2	28.6
Nervous system disorders	Headache	Male	8	53.3	0	0.0
Nervous system disorders	Headache	Female	7	46.7	2	28.6
Psychiatric disorders		Male	8	53.3	0	0.0
Psychiatric disorders		Female	7	46.7	1	14.3
Psychiatric disorders	Anxiety	Male	8	53.3	0	0.0
Psychiatric disorders	Anxiety	Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders		Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	7	46.7	1	14.3
Skin and subcutaneous tissue disorders		Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders		Female	7	46.7	1	14.3
Skin and subcutaneous tissue disorders	Urticaria	Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	7	46.7	1	14.3

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls

08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Type III	15	100.0	3	20.0
Gastrointestinal disorders	Abdominal pain	Type III	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	Type III	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	Type III	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	Type III	15	100.0	1	6.7
General disorders and administration site conditions		Type III	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	Type III	15	100.0	1	6.7
Immune system disorders		Type III	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	Type III	15	100.0	1	6.7
Infections and infestations		Type III	15	100.0	3	20.0
Infections and infestations	Bronchitis	Type III	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	Type III	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	Type III	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications		Type III	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	Type III	15	100.0	1	6.7
Investigations		Type III	15	100.0	1	6.7
Investigations	C-reactive protein increased	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		Type III	15	100.0	4	26.7
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	15	100.0	1	6.7
Nervous system disorders		Type III	15	100.0	2	13.3
Nervous system disorders	Headache	Type III	15	100.0	2	13.3
Psychiatric disorders		Type III	15	100.0	1	6.7
Psychiatric disorders	Anxiety	Type III	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		Type III	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	15	100.0	1	6.7

Skin and subcutaneous tissue disorders		Type III	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	Type III	15	100.0	1	6.7

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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08MAR2021 13:07

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		3	10	66.7	2	20.0
Gastrointestinal disorders		4	5	33.3	1	20.0
Gastrointestinal disorders	Abdominal pain	3	10	66.7	2	20.0
Gastrointestinal disorders	Abdominal pain	4	5	33.3	0	0.0
Gastrointestinal disorders	Diarrhoea	3	10	66.7	1	10.0
Gastrointestinal disorders	Diarrhoea	4	5	33.3	0	0.0
Gastrointestinal disorders	Toothache	3	10	66.7	0	0.0
Gastrointestinal disorders	Toothache	4	5	33.3	1	20.0
Gastrointestinal disorders	Vomiting	3	10	66.7	1	10.0
Gastrointestinal disorders	Vomiting	4	5	33.3	0	0.0
General disorders and administration site conditions		3	10	66.7	0	0.0
General disorders and administration site conditions		4	5	33.3	1	20.0
General disorders and administration site conditions	Malaise	3	10	66.7	0	0.0
General disorders and administration site conditions	Malaise	4	5	33.3	1	20.0
Immune system disorders		3	10	66.7	1	10.0
Immune system disorders		4	5	33.3	0	0.0
Immune system disorders	Hypersensitivity	3	10	66.7	1	10.0
Immune system disorders	Hypersensitivity	4	5	33.3	0	0.0
Infections and infestations		3	10	66.7	2	20.0
Infections and infestations		4	5	33.3	1	20.0
Infections and infestations	Bronchitis	3	10	66.7	1	10.0
Infections and infestations	Bronchitis	4	5	33.3	0	0.0
Infections and infestations	Gastroenteritis	3	10	66.7	1	10.0
Infections and infestations	Gastroenteritis	4	5	33.3	0	0.0
Infections and infestations	Nasopharyngitis	3	10	66.7	0	0.0
Infections and infestations	Nasopharyngitis	4	5	33.3	1	20.0
Infections and infestations	Subcutaneous abscess	3	10	66.7	1	10.0
Infections and infestations	Subcutaneous abscess	4	5	33.3	0	0.0
Injury, poisoning and procedural complications		3	10	66.7	1	10.0
Injury, poisoning and procedural complications		4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Contusion	3	10	66.7	0	0.0
Injury, poisoning and procedural complications	Contusion	4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Muscle strain	3	10	66.7	1	10.0
Injury, poisoning and procedural complications	Muscle strain	4	5	33.3	0	0.0

Investigations		3	10	66.7	0	0.0
Investigations		4	5	33.3	1	20.0
Investigations	C-reactive protein increased	3	10	66.7	0	0.0
Investigations	C-reactive protein increased	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders		3	10	66.7	2	20.0
Musculoskeletal and connective tissue disorders		4	5	33.3	2	40.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Back pain	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	5	33.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4	5	33.3	0	0.0
Nervous system disorders		3	10	66.7	2	20.0
Nervous system disorders		4	5	33.3	0	0.0
Nervous system disorders	Headache	3	10	66.7	2	20.0
Nervous system disorders	Headache	4	5	33.3	0	0.0
Psychiatric disorders		3	10	66.7	1	10.0
Psychiatric disorders		4	5	33.3	0	0.0
Psychiatric disorders	Anxiety	3	10	66.7	1	10.0
Psychiatric disorders	Anxiety	4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders		3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders		4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	5	33.3	0	0.0
Skin and subcutaneous tissue disorders		3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders		4	5	33.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	5	33.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls

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POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1-2 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Yes	4	26.7	0	0.0
Gastrointestinal disorders		No	11	73.3	3	27.3
Gastrointestinal disorders	Abdominal pain	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	No	11	73.3	2	18.2
Gastrointestinal disorders	Diarrhoea	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	No	11	73.3	1	9.1
Gastrointestinal disorders	Toothache	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	No	11	73.3	1	9.1
Gastrointestinal disorders	Vomiting	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	No	11	73.3	1	9.1
General disorders and administration site conditions		Yes	4	26.7	0	0.0
General disorders and administration site conditions		No	11	73.3	1	9.1
General disorders and administration site conditions	Malaise	Yes	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	No	11	73.3	1	9.1
Immune system disorders		Yes	4	26.7	1	25.0
Immune system disorders		No	11	73.3	0	0.0
Immune system disorders	Hypersensitivity	Yes	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	No	11	73.3	0	0.0
Infections and infestations		Yes	4	26.7	1	25.0
Infections and infestations		No	11	73.3	2	18.2
Infections and infestations	Bronchitis	Yes	4	26.7	1	25.0
Infections and infestations	Bronchitis	No	11	73.3	0	0.0
Infections and infestations	Gastroenteritis	Yes	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	No	11	73.3	1	9.1
Infections and infestations	Nasopharyngitis	Yes	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	No	11	73.3	1	9.1
Infections and infestations	Subcutaneous abscess	Yes	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	No	11	73.3	1	9.1
Injury, poisoning and procedural complications		Yes	4	26.7	1	25.0
Injury, poisoning and procedural complications		No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Contusion	Yes	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Muscle strain	Yes	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	No	11	73.3	0	0.0

Investigations		Yes	4	26.7	0	0.0
Investigations		No	11	73.3	1	9.1
Investigations	C-reactive protein increased	Yes	4	26.7	0	0.0
Investigations	C-reactive protein increased	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders		Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		No	11	73.3	4	36.4
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Back pain	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	11	73.3	1	9.1
Nervous system disorders		Yes	4	26.7	0	0.0
Nervous system disorders		No	11	73.3	2	18.2
Nervous system disorders	Headache	Yes	4	26.7	0	0.0
Nervous system disorders	Headache	No	11	73.3	2	18.2
Psychiatric disorders		Yes	4	26.7	0	0.0
Psychiatric disorders		No	11	73.3	1	9.1
Psychiatric disorders	Anxiety	Yes	4	26.7	0	0.0
Psychiatric disorders	Anxiety	No	11	73.3	1	9.1
Respiratory, thoracic and mediastinal disorders		Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		No	11	73.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	11	73.3	0	0.0
Skin and subcutaneous tissue disorders		Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		No	11	73.3	1	9.1
Skin and subcutaneous tissue disorders	Urticaria	Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	11	73.3	1	9.1

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_OLE_SW_T3.xls

08MAR2021 13:07

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Thrombocytopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Ear and labyrinth disorders	Deafness neurosensory	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Ear and labyrinth disorders	Hypoacusis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Endocrine disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	2	50.0
Eye disorders	Conjunctival haemorrhage	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0

Eye disorders	Conjunctivitis allergic	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders	Dry eye	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders	Eye pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Eye disorders	Ocular hyperaemia	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders		6 to 11 years	11	30.6	8	72.7	4	25.0	1	25.0
Gastrointestinal disorders		12 to 17 years	15	41.7	8	53.3	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	4	66.7	4	25.0	2	50.0
Gastrointestinal disorders	Abdominal discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	11	30.6	5	45.5	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0

Gastrointestinal disorders	Mouth ulceration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders	Vomiting	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions		6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0
General disorders and administration site conditions		12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
General disorders and administration site conditions		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
General disorders and administration site conditions	Feeling abnormal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Medical device pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Immune system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Immune system disorders	Seasonal allergy	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	4	100.0	4	25.0	4	100.0
Infections and infestations		6 to 11 years	11	30.6	11	100.0	4	25.0	2	50.0
Infections and infestations		12 to 17 years	15	41.7	14	93.3	4	25.0	4	100.0
Infections and infestations		18 to 25 years	6	16.7	6	100.0	4	25.0	3	75.0

Infections and infestations	Adenoiditis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Adenoiditis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Infections and infestations	Bronchitis	12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Folliculitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Furuncle	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastrointestinal viral infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Gingivitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Gingivitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Hordeolum	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Influenza	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Influenza	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Influenza	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Lymph gland infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	4	11.1	2	50.0	4	25.0	3	75.0
Infections and infestations	Nasopharyngitis	6 to 11 years	11	30.6	4	36.4	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Investigations	C-reactive protein increased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Exostosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Scoliosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0

Nervous system disorders		12 to 17 years	15	41.7	7	46.7	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	5	83.3	4	25.0	3	75.0
Nervous system disorders	Amnesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Nervous system disorders	Dizziness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Headache	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	11	30.6	4	36.4	4	25.0	1	25.0
Nervous system disorders	Headache	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Nervous system disorders	Headache	18 to 25 years	6	16.7	5	83.3	4	25.0	3	75.0
Nervous system disorders	Migraine	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Migraine	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Psychiatric disorders	Anxiety	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders	Anxiety	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Renal and urinary disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders		12 to 17 years	15	41.7	3	20.0	4	25.0	1	25.0
Reproductive system and breast disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0

Reproductive system and breast disorders	Menstrual disorder	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	4	36.4	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	3	50.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Cough	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	1	25.0
Skin and subcutaneous tissue disorders		6 to 11 years	11	30.6	5	45.5	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	15	41.7	6	40.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Eczema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Surgical and medical procedures	Dental implantation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Vascular disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders	Varicose vein	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_T3.xls
18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Ear and labyrinth disorders	Deafness neurosensory	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Ear pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypacusis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		n/a	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		n/a	36	100.0	22	61.1	16	100.0	5	31.3
Gastrointestinal disorders	Abdominal discomfort	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal distension	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	n/a	36	100.0	6	16.7	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	n/a	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	4	11.1	16	100.0	1	6.3
Gastrointestinal disorders	Diarrhoea	n/a	36	100.0	12	33.3	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	n/a	36	100.0	5	13.9	16	100.0	4	25.0
General disorders and administration site conditions		n/a	36	100.0	10	27.8	16	100.0	3	18.8
General disorders and administration site conditions	Feeling abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Malaise	n/a	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	n/a	36	100.0	7	19.4	16	100.0	2	12.5
Immune system disorders		n/a	36	100.0	1	2.8	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations		n/a	36	100.0	35	97.2	16	100.0	13	81.3
Infections and infestations	Adenoiditis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	n/a	36	100.0	2	5.6	16	100.0	3	18.8
Infections and infestations	Folliculitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Infections and infestations	Fungal skin infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Furuncle	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	n/a	36	100.0	7	19.4	16	100.0	1	6.3
Infections and infestations	Gastroenteritis viral	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hand-foot-and-mouth disease	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Influenza	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	n/a	36	100.0	11	30.6	16	100.0	3	18.8
Infections and infestations	Otitis externa	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Otitis media	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	n/a	36	100.0	4	11.1	16	100.0	1	6.3
Infections and infestations	Pharyngitis bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	n/a	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Sinusitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tonsillitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tracheitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	n/a	36	100.0	14	38.9	16	100.0	5	31.3
Infections and infestations	Upper respiratory tract infection bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Varicella	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Viral pharyngitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	10	27.8	16	100.0	3	18.8
Injury, poisoning and procedural complications	Anaemia postoperative	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Contusion	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		n/a	36	100.0	2	5.6	16	100.0	0	0.0
Metabolism and nutrition disorders	Dehydration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		n/a	36	100.0	9	25.0	16	100.0	5	31.3
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Exostosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Nervous system disorders		n/a	36	100.0	18	50.0	16	100.0	4	25.0
Nervous system disorders	Amnesia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	n/a	36	100.0	12	33.3	16	100.0	4	25.0
Nervous system disorders	Migraine	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Psychiatric disorders		n/a	36	100.0	0	0.0	16	100.0	2	12.5
Psychiatric disorders	Anxiety	n/a	36	100.0	0	0.0	16	100.0	2	12.5
Renal and urinary disorders		n/a	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	9	25.0	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	n/a	36	100.0	5	13.9	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		n/a	36	100.0	15	41.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Vascular disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Anaemia	White	25	69.4	2	8.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	White	25	69.4	1	4.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Thrombocytopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders		Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Ear and labyrinth disorders	Deafness neurosensory	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Ear pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders	Ear pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Ear and labyrinth disorders	Hypoacusis	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Endocrine disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Endocrine disorders	Hypopituitarism	White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders	Hypopituitarism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders		White	25	69.4	2	8.0	13	81.3	1	7.7
Eye disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Eye disorders	Conjunctival haemorrhage	White	25	69.4	0	0.0	13	81.3	1	7.7
Eye disorders	Conjunctival haemorrhage	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Conjunctivitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Conjunctivitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Dry eye	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Dry eye	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Eye pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Eye pain	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders	Eye pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Eye disorders	Ocular hyperaemia	White	25	69.4	0	0.0	13	81.3	0	0.0
Eye disorders	Ocular hyperaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	12	48.0	13	81.3	3	23.1

Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	6	85.7	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	4	100.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal distension	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	White	25	69.4	5	20.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	4	11.1	1	25.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal pain upper	White	25	69.4	3	12.0	13	81.3	1	7.7
Gastrointestinal disorders	Abdominal pain upper	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Diarrhoea	White	25	69.4	8	32.0	13	81.3	1	7.7
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Dyspepsia	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faecaloma	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Faecaloma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Faeces soft	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Flatulence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Nausea	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Nausea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	White	25	69.4	1	4.0	13	81.3	1	7.7
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	White	25	69.4	2	8.0	13	81.3	2	15.4
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	4	11.1	1	25.0	2	12.5	2	100.0
General disorders and administration site conditions		White	25	69.4	7	28.0	13	81.3	1	7.7
General disorders and administration site conditions		Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	1	100.0
General disorders and administration site conditions		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	White	25	69.4	0	0.0	13	81.3	1	7.7
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

General disorders and administration site conditions	Medical device pain	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Medical device pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	White	25	69.4	5	20.0	13	81.3	0	0.0
General disorders and administration site conditions	Pyrexia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
General disorders and administration site conditions	Pyrexia	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Immune system disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Immune system disorders	Hypersensitivity	White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	White	25	69.4	0	0.0	13	81.3	0	0.0
Immune system disorders	Seasonal allergy	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations		White	25	69.4	24	96.0	13	81.3	10	76.9
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	7	100.0	1	6.3	1	100.0
Infections and infestations		Unknown	4	11.1	4	100.0	2	12.5	2	100.0
Infections and infestations	Adenoiditis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Adenoiditis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Bronchitis	White	25	69.4	2	8.0	13	81.3	2	15.4
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Folliculitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Folliculitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Folliculitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Fungal skin infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Furuncle	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Furuncle	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Furuncle	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	4	16.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Infections and infestations	Gastroenteritis viral	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis viral	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Genital infection fungal	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Genital infection fungal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gingivitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Infections and infestations	Gingivitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Hordeolum	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Hordeolum	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Influenza	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Influenza	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Lymph gland infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	White	25	69.4	6	24.0	13	81.3	2	15.4
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Infections and infestations	Otitis externa	White	25	69.4	2	8.0	13	81.3	0	0.0

Infections and infestations	Otitis externa	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Otitis media	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Otitis media acute	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	White	25	69.4	3	12.0	13	81.3	1	7.7
Infections and infestations	Pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Pneumonia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	White	25	69.4	3	12.0	13	81.3	2	15.4
Infections and infestations	Respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Sinusitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Soft tissue infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Tonsillitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Tonsillitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Tracheitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Tracheitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	White	25	69.4	9	36.0	13	81.3	5	38.5
Infections and infestations	Upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	5	71.4	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Urinary tract infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Varicella	White	25	69.4	1	4.0	13	81.3	1	7.7
Infections and infestations	Varicella	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Viral pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Viral rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	6	24.0	13	81.3	2	15.4
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Injury, poisoning and procedural complications		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Anaemia postoperative	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Contusion	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	4	11.1	1	25.0	2	12.5	0	0.0

Injury, poisoning and procedural complications	Fall	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Fall	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Activated partial thromboplastin time shortened	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Blood bicarbonate decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Blood bicarbonate decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Blood bicarbonate decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	C-reactive protein increased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	C-reactive protein increased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Dehydration	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	5	20.0	13	81.3	3	23.1
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	25	69.4	2	8.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Musculoskeletal and connective tissue disorders	Limb discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	White	25	69.4	2	8.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Scoliosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	13	52.0	13	81.3	3	23.1
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Nervous system disorders	Amnesia	White	25	69.4	0	0.0	13	81.3	1	7.7
Nervous system disorders	Amnesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness postural	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness postural	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Headache	White	25	69.4	9	36.0	13	81.3	3	23.1
Nervous system disorders	Headache	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Headache	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Nervous system disorders	Migraine	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Migraine	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Occipital neuralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	White	25	69.4	3	12.0	13	81.3	0	0.0
Nervous system disorders	Paraesthesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Psychiatric disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Psychiatric disorders	Anxiety	White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Renal and urinary disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Renal and urinary disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Haematuria	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Haematuria	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Renal cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Reproductive system and breast disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Reproductive system and breast disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0

Reproductive system and breast disorders	Amenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	White	25	69.4	0	0.0	13	81.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	White	25	69.4	0	0.0	13	81.3	1	7.7
Reproductive system and breast disorders	Polycystic ovaries	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	5	20.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	White	25	69.4	2	8.0	13	81.3	1	7.7
Respiratory, thoracic and mediastinal disorders	Cough	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Cough	Unknown	4	11.1	3	75.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	White	25	69.4	1	4.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	25	69.4	2	8.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	9	36.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	4	57.1	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0

Skin and subcutaneous tissue disorders	Hair texture abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	25	69.4	0	0.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		White	25	69.4	0	0.0	13	81.3	0	0.0
Surgical and medical procedures		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Surgical and medical procedures	Dental implantation	White	25	69.4	0	0.0	13	81.3	0	0.0
Surgical and medical procedures	Dental implantation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Vascular disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders	Varicose vein	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

MedDRA System Organ Class			MedDRA Preferred Term			Level			Risdiplam (N=36)				Placebo (N=16)			
									Patients		Patients with Event		Patients		Patients with Event	
									n	%	n	%	n	%	n	%
Blood and lymphatic system disorders			Europe						28	77.8	3	10.7	14	87.5	1	7.1
Blood and lymphatic system disorders			Rest of the World						8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders			Anaemia			Europe			28	77.8	2	7.1	14	87.5	0	0.0
Blood and lymphatic system disorders			Anaemia			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders			Iron deficiency anaemia			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Blood and lymphatic system disorders			Iron deficiency anaemia			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders			Thrombocytopenia			Europe			28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders			Thrombocytopenia			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Cardiac disorders			Europe						28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders			Rest of the World						8	22.2	1	12.5	2	12.5	0	0.0
Cardiac disorders			Atrioventricular block first degree			Europe			28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders			Atrioventricular block first degree			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders			Europe						28	77.8	3	10.7	14	87.5	1	7.1
Ear and labyrinth disorders			Rest of the World						8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders			Deafness neurosensory			Europe			28	77.8	0	0.0	14	87.5	0	0.0
Ear and labyrinth disorders			Deafness neurosensory			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders			Ear pain			Europe			28	77.8	2	7.1	14	87.5	1	7.1
Ear and labyrinth disorders			Ear pain			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders			Hypoacusis			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Ear and labyrinth disorders			Hypoacusis			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Endocrine disorders			Europe						28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders			Rest of the World						8	22.2	0	0.0	2	12.5	0	0.0
Endocrine disorders			Hypopituitarism			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders			Hypopituitarism			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders			Europe						28	77.8	2	7.1	14	87.5	2	14.3
Eye disorders			Rest of the World						8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders			Conjunctival haemorrhage			Europe			28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders			Conjunctival haemorrhage			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders			Conjunctivitis allergic			Europe			28	77.8	0	0.0	14	87.5	0	0.0
Eye disorders			Conjunctivitis allergic			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Eye disorders			Dry eye			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders			Dry eye			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders			Eye pain			Europe			28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders			Eye pain			Rest of the World			8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders			Ocular hyperaemia			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders			Ocular hyperaemia			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders			Europe						28	77.8	15	53.6	14	87.5	4	28.6
Gastrointestinal disorders			Rest of the World						8	22.2	7	87.5	2	12.5	1	50.0
Gastrointestinal disorders			Abdominal discomfort			Europe			28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders			Abdominal discomfort			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders			Abdominal distension			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders			Abdominal distension			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders			Abdominal pain			Europe			28	77.8	6	21.4	14	87.5	2	14.3
Gastrointestinal disorders			Abdominal pain			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders			Abdominal pain upper			Europe			28	77.8	3	10.7	14	87.5	0	0.0
Gastrointestinal disorders			Abdominal pain upper			Rest of the World			8	22.2	2	25.0	2	12.5	1	50.0
Gastrointestinal disorders			Aphthous ulcer			Europe			28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders			Aphthous ulcer			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders			Constipation			Europe			28	77.8	3	10.7	14	87.5	1	7.1
Gastrointestinal disorders			Constipation			Rest of the World			8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders			Diarrhoea			Europe			28	77.8	9	32.1	14	87.5	2	14.3
Gastrointestinal disorders			Diarrhoea			Rest of the World			8	22.2	3	37.5	2	12.5	0	0.0
Gastrointestinal disorders			Dyspepsia			Europe			28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders			Dyspepsia			Rest of the World			8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders			Faecaloma			Europe			28	77.8	1	3.6	14	87.5	0	0.0

Gastrointestinal disorders	Faecaloma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Faeces soft	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Flatulence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Nausea	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Nausea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Gastrointestinal disorders	Vomiting	Rest of the World	8	22.2	3	37.5	2	12.5	1	50.0
General disorders and administration site conditions		Europe	28	77.8	8	28.6	14	87.5	2	14.3
General disorders and administration site conditions		Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	Europe	28	77.8	0	0.0	14	87.5	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Medical device pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Medical device pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Europe	28	77.8	0	0.0	14	87.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	Europe	28	77.8	6	21.4	14	87.5	1	7.1
General disorders and administration site conditions	Pyrexia	Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Immune system disorders		Europe	28	77.8	0	0.0	14	87.5	2	14.3
Immune system disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Immune system disorders	Hypersensitivity	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Seasonal allergy	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	27	96.4	14	87.5	11	78.6
Infections and infestations		Rest of the World	8	22.2	8	100.0	2	12.5	2	100.0
Infections and infestations	Adenoiditis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Adenoiditis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Bronchitis	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Infections and infestations	Bronchitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Folliculitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Folliculitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Fungal skin infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Furuncle	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Furuncle	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	7	25.0	14	87.5	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis viral	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Gastroenteritis viral	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastrointestinal infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastrointestinal viral infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Genital infection fungal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Genital infection fungal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Gingivitis	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Infections and infestations	Hand-foot-and-mouth disease	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Hordeolum	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0

Infections and infestations	Influenza	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Infections and infestations	Influenza	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Lymph gland infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	Europe	28	77.8	7	25.0	14	87.5	1	7.1
Infections and infestations	Nasopharyngitis	Rest of the World	8	22.2	4	50.0	2	12.5	2	100.0
Infections and infestations	Otitis externa	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Otitis externa	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Otitis media	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Otitis media acute	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	Europe	28	77.8	4	14.3	14	87.5	1	7.1
Infections and infestations	Pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Pneumonia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	Europe	28	77.8	3	10.7	14	87.5	2	14.3
Infections and infestations	Respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Sinusitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Soft tissue infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tonsillitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tonsillitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tracheitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tracheitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	Europe	28	77.8	9	32.1	14	87.5	5	35.7
Infections and infestations	Upper respiratory tract infection	Rest of the World	8	22.2	5	62.5	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Urinary tract infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Varicella	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Infections and infestations	Varicella	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Europe	28	77.8	4	14.3	14	87.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	8	28.6	14	87.5	3	21.4
Injury, poisoning and procedural complications		Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Fall	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Fall	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Muscle strain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Europe	28	77.8	0	0.0	14	87.5	0	0.0

Injury, poisoning and procedural complications	Procedural pain	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Tooth fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Activated partial thromboplastin time shortened	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Blood bicarbonate decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Blood bicarbonate decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	C-reactive protein increased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	C-reactive protein increased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	8	28.6	14	87.5	4	28.6
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Scoliosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders		Europe	28	77.8	14	50.0	14	87.5	4	28.6
Nervous system disorders		Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0
Nervous system disorders	Amnesia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Nervous system disorders	Amnesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Dizziness postural	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness postural	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Headache	Europe	28	77.8	11	39.3	14	87.5	4	28.6
Nervous system disorders	Headache	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Migraine	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Migraine	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Occipital neuralgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Nervous system disorders	Paraesthesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders		Europe	28	77.8	0	0.0	14	87.5	2	14.3
Psychiatric disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders	Anxiety	Europe	28	77.8	0	0.0	14	87.5	2	14.3
Psychiatric disorders	Anxiety	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Renal and urinary disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0

Renal and urinary disorders	Haematuria	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Haematuria	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Renal cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Reproductive system and breast disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Reproductive system and breast disorders	Polycystic ovaries	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	7	25.0	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	2	25.0	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Europe	28	77.8	4	14.3	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Rest of the World	8	22.2	1	12.5	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Respiratory, thoracic and mediastinal disorders	Epistaxis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	11	39.3	14	87.5	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0

Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures	Dental implantation	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures	Dental implantation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders	Varicose vein	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_T3.xls
18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Cardiac disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Ear and labyrinth disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders	Hypopituitarism	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders		>Q3	20	55.6	3	15.0	10	62.5	2	20.0
Eye disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Eye disorders	Conjunctival haemorrhage	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Eye disorders	Conjunctivitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Dry eye	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Eye disorders	Dry eye	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Eye disorders	Eye pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	8	66.7	4	25.0	1	25.0
Gastrointestinal disorders		>Q3	20	55.6	13	65.0	10	62.5	3	30.0
Gastrointestinal disorders		Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Abdominal discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	20	55.6	2	10.0	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Gastrointestinal disorders	Abdominal pain upper	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	20	55.6	8	40.0	10	62.5	1	10.0
Gastrointestinal disorders	Diarrhoea	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Dyspepsia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faecaloma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Faeces soft	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q3	20	55.6	1	5.0	10	62.5	0	0.0

Gastrointestinal disorders	Mouth ulceration	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	1	25.0
Gastrointestinal disorders	Toothache	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	20	55.6	2	10.0	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	Missing	1	2.8	1	100.0	1	6.3	1	100.0
General disorders and administration site conditions		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
General disorders and administration site conditions		>Q3	20	55.6	5	25.0	10	62.5	3	30.0
General disorders and administration site conditions		Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
General disorders and administration site conditions	Malaise	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
General disorders and administration site conditions	Pyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Immune system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	2	66.7	1	6.3	1	100.0
Infections and infestations		>Q1 to <=Q3	12	33.3	12	100.0	4	25.0	4	100.0
Infections and infestations		>Q3	20	55.6	20	100.0	10	62.5	7	70.0
Infections and infestations		Missing	1	2.8	1	100.0	1	6.3	1	100.0

Infections and infestations	Adenoiditis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Adenoiditis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Bronchitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Infections and infestations	Bronchitis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Folliculitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Folliculitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Folliculitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Furuncle	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Furuncle	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	4	20.0	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Genital infection fungal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gingivitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Hordeolum	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Influenza	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Influenza	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	20	55.6	7	35.0	10	62.5	2	20.0
Infections and infestations	Nasopharyngitis	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Infections and infestations	Otitis externa	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Otitis externa	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Infections and infestations	Otitis media acute	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media acute	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pneumonia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Sinusitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Sinusitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tracheitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	>Q1 to <=Q3	12	33.3	6	50.0	4	25.0	3	75.0
Infections and infestations	Upper respiratory tract infection	>Q3	20	55.6	8	40.0	10	62.5	2	20.0
Infections and infestations	Upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Infections and infestations	Varicella	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Injury, poisoning and procedural complications		<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	6	30.0	10	62.5	2	20.0
Injury, poisoning and procedural complications		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Contusion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Activated partial thromboplastin time shortened	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Blood bicarbonate decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0

Investigations	C-reactive protein increased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	C-reactive protein increased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Metabolism and nutrition disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	7	35.0	10	62.5	5	50.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	20	55.6	3	15.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Scoliosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	2	66.7	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	7	58.3	4	25.0	1	25.0

Nervous system disorders		>Q3	20	55.6	8	40.0	10	62.5	3	30.0
Nervous system disorders		Missing	1	2.8	0	100.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Nervous system disorders	Amnesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Dizziness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	12	33.3	5	41.7	4	25.0	1	25.0
Nervous system disorders	Headache	>Q3	20	55.6	6	30.0	10	62.5	3	30.0
Nervous system disorders	Headache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Psychiatric disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Psychiatric disorders	Anxiety	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders		<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Reproductive system and breast disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q3	20	55.6	0	0.0	10	62.5	0	0.0

Reproductive system and breast disorders	Menstrual disorder	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders	Polycystic ovaries	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	5	25.0	10	62.5	3	30.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Cough	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	2	66.7	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	9	45.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Skin and subcutaneous tissue disorders	Alopecia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Skin and subcutaneous tissue disorders	Eczema	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Surgical and medical procedures		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Vascular disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_T3.xls
18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex			Risperidone (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	2	11.8	8	50.0	1	12.5
Blood and lymphatic system disorders	Anaemia	Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders	Anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Cardiac disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Female	17	47.2	1	5.9	8	50.0	0	0.0
Ear and labyrinth disorders		Male	19	52.8	3	15.8	8	50.0	0	0.0
Ear and labyrinth disorders		Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Deafness neurosensory	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Female	17	47.2	0	0.0	8	50.0	0	0.0
Ear and labyrinth disorders	Ear pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Ear pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Hypoacusis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Endocrine disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Eye disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Eye disorders		Female	17	47.2	3	17.6	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Male	19	52.8	0	0.0	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Female	17	47.2	1	5.9	8	50.0	0	0.0
Eye disorders	Eye pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Eye pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Eye disorders	Ocular hyperaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Ocular hyperaemia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders		Male	19	52.8	13	68.4	8	50.0	2	25.0
Gastrointestinal disorders		Female	17	47.2	9	52.9	8	50.0	3	37.5
Gastrointestinal disorders	Abdominal discomfort	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	17	47.2	5	29.4	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain upper	Male	19	52.8	4	21.1	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Female	17	47.2	1	5.9	8	50.0	1	12.5
Gastrointestinal disorders	Aphthous ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	3	15.8	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	1	5.9	8	50.0	1	12.5
Gastrointestinal disorders	Diarrhoea	Male	19	52.8	8	42.1	8	50.0	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	17	47.2	4	23.5	8	50.0	1	12.5
Gastrointestinal disorders	Dyspepsia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dyspepsia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Faecaloma	Male	19	52.8	0	0.0	8	50.0	0	0.0

Gastrointestinal disorders	Faecaloma	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Nausea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Nausea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Toothache	Male	19	52.8	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders	Toothache	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Vomiting	Male	19	52.8	3	15.8	8	50.0	1	12.5
Gastrointestinal disorders	Vomiting	Female	17	47.2	2	11.8	8	50.0	3	37.5
General disorders and administration site conditions		Male	19	52.8	6	31.6	8	50.0	3	37.5
General disorders and administration site conditions		Female	17	47.2	4	23.5	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Malaise	Male	19	52.8	0	0.0	8	50.0	1	12.5
General disorders and administration site conditions	Malaise	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Pyrexia	Male	19	52.8	4	21.1	8	50.0	2	25.0
General disorders and administration site conditions	Pyrexia	Female	17	47.2	3	17.6	8	50.0	0	0.0
Immune system disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Immune system disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Hypersensitivity	Male	19	52.8	0	0.0	8	50.0	0	0.0
Immune system disorders	Hypersensitivity	Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Male	19	52.8	1	5.3	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	18	94.7	8	50.0	6	75.0
Infections and infestations		Female	17	47.2	17	100.0	8	50.0	7	87.5
Infections and infestations	Adenoiditis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Adenoiditis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Bronchitis	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Bronchitis	Female	17	47.2	1	5.9	8	50.0	2	25.0
Infections and infestations	Folliculitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Folliculitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Fungal skin infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Fungal skin infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Furuncle	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Furuncle	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Male	19	52.8	3	15.8	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Female	17	47.2	4	23.5	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Gastrointestinal infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastrointestinal infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastrointestinal viral infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gingivitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gingivitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Hordeolum	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Hordeolum	Female	17	47.2	0	0.0	8	50.0	1	12.5

Infections and infestations	Influenza	Male	19	52.8	3	15.8	8	50.0	0	0.0
Infections and infestations	Influenza	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Lymph gland infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Lymph gland infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Nasopharyngitis	Male	19	52.8	5	26.3	8	50.0	1	12.5
Infections and infestations	Nasopharyngitis	Female	17	47.2	6	35.3	8	50.0	2	25.0
Infections and infestations	Otitis externa	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis externa	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Otitis media	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Otitis media acute	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media acute	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Male	19	52.8	3	15.8	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Pharyngitis bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pneumonia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pneumonia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Male	19	52.8	2	10.5	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Rhinitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Rhinitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Sinusitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Sinusitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Subcutaneous abscess	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Subcutaneous abscess	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tracheitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tracheitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Male	19	52.8	5	26.3	8	50.0	3	37.5
Infections and infestations	Upper respiratory tract infection	Female	17	47.2	9	52.9	8	50.0	2	25.0
Infections and infestations	Upper respiratory tract infection bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Varicella	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Varicella	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Male	19	52.8	2	10.5	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Female	17	47.2	2	11.8	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	8	42.1	8	50.0	1	12.5
Injury, poisoning and procedural complications		Female	17	47.2	2	11.8	8	50.0	2	25.0
Injury, poisoning and procedural complications	Anaemia postoperative	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Male	19	52.8	2	10.5	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Female	17	47.2	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Male	19	52.8	1	5.3	8	50.0	0	0.0

Injury, poisoning and procedural complications	Procedural pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Female	17	47.2	0	0.0	8	50.0	1	12.5
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Activated partial thromboplastin time shortened	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Blood bicarbonate decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Blood bicarbonate decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	C-reactive protein increased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	C-reactive protein increased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Metabolism and nutrition disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Male	19	52.8	1	5.3	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	3	15.8	8	50.0	4	50.0
Musculoskeletal and connective tissue disorders		Female	17	47.2	6	35.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	17	47.2	3	17.6	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	17	47.2	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	19	52.8	1	5.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	17	47.2	2	11.8	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Scoliosis	Female	17	47.2	2	11.8	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	17	47.2	0	0.0	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders		Male	19	52.8	10	52.6	8	50.0	2	25.0
Nervous system disorders		Female	17	47.2	8	47.1	8	50.0	2	25.0
Nervous system disorders	Amnesia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Nervous system disorders	Amnesia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Dizziness	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Dizziness	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Dizziness postural	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Dizziness postural	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Headache	Male	19	52.8	6	31.6	8	50.0	2	25.0
Nervous system disorders	Headache	Female	17	47.2	6	35.3	8	50.0	2	25.0
Nervous system disorders	Migraine	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Migraine	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Psychiatric disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders		Female	17	47.2	0	0.0	8	50.0	2	25.0
Psychiatric disorders	Anxiety	Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders	Anxiety	Female	17	47.2	0	0.0	8	50.0	2	25.0
Renal and urinary disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders		Female	17	47.2	2	11.8	8	50.0	0	0.0

Renal and urinary disorders	Haematuria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Haematuria	Female	17	47.2	2	11.8	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Female	17	47.2	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Female	17	47.2	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Female	17	47.2	4	23.5	8	50.0	1	12.5
Reproductive system and breast disorders	Amenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	7	36.8	8	50.0	2	25.0
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	2	11.8	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Male	19	52.8	4	21.1	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Cough	Female	17	47.2	1	5.9	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	17	47.2	1	5.9	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	8	42.1	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	7	41.2	8	50.0	1	12.5
Skin and subcutaneous tissue disorders	Alopecia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Female	17	47.2	2	11.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Female	17	47.2	2	11.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Male	19	52.8	0	0.0	8	50.0	0	0.0

Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	17	47.2	0	0.0	8	50.0	1	12.5
Surgical and medical procedures		Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures		Female	17	47.2	0	0.0	8	50.0	1	12.5
Surgical and medical procedures	Dental implantation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures	Dental implantation	Female	17	47.2	0	0.0	8	50.0	1	12.5
Vascular disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Vascular disorders	Varicose vein	Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders	Varicose vein	Female	17	47.2	1	5.9	8	50.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Ear and labyrinth disorders	Deafness neurosensory	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Ear pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypoaacusis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		Type III	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		Type III	36	100.0	22	61.1	16	100.0	5	31.3
Gastrointestinal disorders	Abdominal discomfort	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Type III	36	100.0	6	16.7	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	Type III	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	4	11.1	16	100.0	1	6.3
Gastrointestinal disorders	Diarrhoea	Type III	36	100.0	12	33.3	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	Type III	36	100.0	5	13.9	16	100.0	4	25.0
General disorders and administration site conditions		Type III	36	100.0	10	27.8	16	100.0	3	18.8
General disorders and administration site conditions	Feeling abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Malaise	Type III	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	Type III	36	100.0	7	19.4	16	100.0	2	12.5
Immune system disorders		Type III	36	100.0	1	2.8	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations		Type III	36	100.0	35	97.2	16	100.0	13	81.3
Infections and infestations	Adenoiditis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	Type III	36	100.0	2	5.6	16	100.0	3	18.8
Infections and infestations	Folliculitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Infections and infestations	Fungal skin infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Furuncle	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	Type III	36	100.0	7	19.4	16	100.0	1	6.3
Infections and infestations	Gastroenteritis viral	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hand-foot-and-mouth disease	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Influenza	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	Type III	36	100.0	11	30.6	16	100.0	3	18.8
Infections and infestations	Otitis externa	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Otitis media	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	Type III	36	100.0	4	11.1	16	100.0	1	6.3
Infections and infestations	Pharyngitis bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	Type III	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Sinusitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tonsillitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tracheitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Type III	36	100.0	14	38.9	16	100.0	5	31.3
Infections and infestations	Upper respiratory tract infection bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Varicella	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Viral pharyngitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	10	27.8	16	100.0	3	18.8
Injury, poisoning and procedural complications	Anaemia postoperative	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		Type III	36	100.0	2	5.6	16	100.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		Type III	36	100.0	9	25.0	16	100.0	5	31.3
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Exostosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Nervous system disorders		Type III	36	100.0	18	50.0	16	100.0	4	25.0
Nervous system disorders	Amnesia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	Type III	36	100.0	12	33.3	16	100.0	4	25.0
Nervous system disorders	Migraine	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Psychiatric disorders		Type III	36	100.0	0	0.0	16	100.0	2	12.5
Psychiatric disorders	Anxiety	Type III	36	100.0	0	0.0	16	100.0	2	12.5
Renal and urinary disorders		Type III	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	9	25.0	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Type III	36	100.0	5	13.9	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		Type III	36	100.0	15	41.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Vascular disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_T3.xls
18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders		3	66.7	4	16.7	10	62.5	1	10.0	
Blood and lymphatic system disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Anaemia	2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders	Anaemia	3	24	66.7	3	12.5	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	3	24	66.7	1	4.2	10	62.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	3	24	66.7	0	0.0	10	62.5	1	10.0
Blood and lymphatic system disorders	Thrombocytopenia	4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	4	10	27.8	0	0.0	6	37.5	0	0.0
Ear and labyrinth disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders		3	24	66.7	2	8.3	10	62.5	1	10.0
Ear and labyrinth disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	3	24	66.7	1	4.2	10	62.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	4	10	27.8	0	0.0	6	37.5	0	0.0
Ear and labyrinth disorders	Ear pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Ear pain	3	24	66.7	0	0.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	3	24	66.7	1	4.2	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	4	10	27.8	0	0.0	6	37.5	0	0.0
Endocrine disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Endocrine disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Endocrine disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Endocrine disorders	Hypopituitarism	2	2	5.6	0	0.0	0	0.0	0	0.0
Endocrine disorders	Hypopituitarism	3	24	66.7	1	4.2	10	62.5	0	0.0
Endocrine disorders	Hypopituitarism	4	10	27.8	0	0.0	6	37.5	0	0.0
Eye disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders		3	24	66.7	1	4.2	10	62.5	1	10.0
Eye disorders		4	10	27.8	3	30.0	6	37.5	1	16.7
Eye disorders	Conjunctival haemorrhage	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctival haemorrhage	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctival haemorrhage	4	10	27.8	0	0.0	6	37.5	1	16.7
Eye disorders	Conjunctivitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctivitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Dry eye	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Dry eye	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Dry eye	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Eye pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Eye pain	3	24	66.7	1	4.2	10	62.5	1	10.0
Eye disorders	Eye pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Ocular hyperaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Ocular hyperaemia	3	24	66.7	1	4.2	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0

Gastrointestinal disorders		3	24	66.7	14	58.3	10	62.5	3	30.0
Gastrointestinal disorders		4	10	27.8	7	70.0	6	37.5	2	33.3
Gastrointestinal disorders	Abdominal discomfort	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal distension	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal distension	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal pain	3	24	66.7	3	12.5	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	3	24	66.7	2	8.3	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	4	10	27.8	3	30.0	6	37.5	1	16.7
Gastrointestinal disorders	Aphthous ulcer	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Constipation	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Constipation	3	24	66.7	2	8.3	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	4	10	27.8	2	20.0	6	37.5	0	0.0
Gastrointestinal disorders	Diarrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Diarrhoea	3	24	66.7	7	29.2	10	62.5	2	20.0
Gastrointestinal disorders	Diarrhoea	4	10	27.8	5	50.0	6	37.5	0	0.0
Gastrointestinal disorders	Dyspepsia	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Dyspepsia	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Faecaloma	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Faecaloma	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faecaloma	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Faeces soft	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Faeces soft	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faeces soft	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Flatulence	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Flatulence	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Nausea	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Nausea	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Tooth malformation	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Tooth malformation	3	24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Tooth malformation	4	10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Toothache	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Toothache	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	4	10	27.8	1	10.0	6	37.5	1	16.7
Gastrointestinal disorders	Vomiting	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Vomiting	3	24	66.7	2	8.3	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	4	10	27.8	2	20.0	6	37.5	1	16.7
General disorders and administration site conditions		2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions		3	24	66.7	5	20.8	10	62.5	1	10.0
General disorders and administration site conditions		4	10	27.8	5	50.0	6	37.5	2	33.3
General disorders and administration site conditions	Feeling abnormal	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	3	24	66.7	1	4.2	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	4	10	27.8	0	0.0	6	37.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Influenza like illness	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Influenza like illness	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Malaise	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Malaise	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Malaise	4	10	27.8	0	0.0	6	37.5	1	16.7

General disorders and administration site conditions	Medical device pain	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Medical device pain	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Pyrexia	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Pyrexia	3	24	66.7	4	16.7	10	62.5	1	10.0
General disorders and administration site conditions	Pyrexia	4	10	27.8	3	30.0	6	37.5	1	16.7
Immune system disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders		3	24	66.7	0	0.0	10	62.5	2	20.0
Immune system disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Immune system disorders	Hypersensitivity	2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Hypersensitivity	3	24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Hypersensitivity	4	10	27.8	0	0.0	6	37.5	0	0.0
Immune system disorders	Seasonal allergy	2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Seasonal allergy	3	24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations		2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations		3	24	66.7	24	100.0	10	62.5	8	80.0
Infections and infestations		4	10	27.8	10	100.0	6	37.5	5	83.3
Infections and infestations	Adenoiditis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Adenoiditis	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Adenoiditis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Bronchitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Bronchitis	3	24	66.7	1	4.2	10	62.5	3	30.0
Infections and infestations	Bronchitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Folliculitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Folliculitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Folliculitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Fungal skin infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Fungal skin infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Furuncle	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Furuncle	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Furuncle	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis	3	24	66.7	4	16.7	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	4	10	27.8	3	30.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis viral	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis viral	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal infection	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Genital infection fungal	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Genital infection fungal	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Genital infection fungal	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gingivitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gingivitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gingivitis	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Hand-foot-and-mouth disease	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Hordeolum	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hordeolum	3	24	66.7	1	4.2	10	62.5	1	10.0
Infections and infestations	Hordeolum	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Influenza	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Influenza	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Influenza	4	10	27.8	3	30.0	6	37.5	0	0.0
Infections and infestations	Lymph gland infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Lymph gland infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Nasopharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Nasopharyngitis	3	24	66.7	6	25.0	10	62.5	1	10.0
Infections and infestations	Nasopharyngitis	4	10	27.8	5	50.0	6	37.5	2	33.3
Infections and infestations	Otitis externa	2	2	5.6	0	0.0	0	0.0	0	0.0

Infections and infestations	Otitis externa	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis externa	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Otitis media	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Otitis media	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Otitis media acute	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media acute	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis media acute	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis	3	24	66.7	3	12.5	10	62.5	1	10.0
Infections and infestations	Pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis bacterial	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pneumonia	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pneumonia	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Pneumonia	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Respiratory tract infection	3	24	66.7	3	12.5	10	62.5	1	10.0
Infections and infestations	Respiratory tract infection	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Rhinitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Sinusitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Sinusitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Sinusitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Soft tissue infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Soft tissue infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Subcutaneous abscess	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Subcutaneous abscess	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Tonsillitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Tonsillitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Tracheitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Tracheitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Tracheitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Upper respiratory tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection	3	24	66.7	12	50.0	10	62.5	2	20.0
Infections and infestations	Upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	3	50.0
Infections and infestations	Upper respiratory tract infection bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Urinary tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Urinary tract infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Varicella	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Varicella	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Varicella	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral pharyngitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral rhinitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	3	24	66.7	3	12.5	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications		2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications		3	24	66.7	4	16.7	10	62.5	2	20.0
Injury, poisoning and procedural complications		4	10	27.8	5	50.0	6	37.5	1	16.7
Injury, poisoning and procedural complications	Anaemia postoperative	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Concussion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Concussion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Contusion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Contusion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Contusion	4	10	27.8	1	10.0	6	37.5	1	16.7

Injury, poisoning and procedural complications	Fall	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Fall	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Muscle strain	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	4	10	27.8	0	0.0	6	37.5	0	0.0
Investigations		2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations		3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations		4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Activated partial thromboplastin time shortened	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Blood bicarbonate decreased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Blood bicarbonate decreased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Blood bicarbonate decreased	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	C-reactive protein increased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	C-reactive protein increased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	C-reactive protein increased	4	10	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Dehydration	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Dehydration	3	24	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	4	10	27.8	1	10.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	24	66.7	7	29.2	10	62.5	2	20.0
Musculoskeletal and connective tissue disorders		4	10	27.8	2	20.0	6	37.5	3	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	24	66.7	2	8.3	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	10	27.8	1	10.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Back pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	10	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Exostosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	4	10	27.8	0	0.0	6	37.5	0	0.0

Musculoskeletal and connective tissue disorders	Limb discomfort	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3	24	66.7	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	3	24	66.7	2	8.3	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	3	24	66.7	2	8.3	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	4	10	27.8	0	0.0	6	37.5	1	16.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		4	10	27.8	1	10.0	6	37.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders		3	24	66.7	10	41.7	10	62.5	2	20.0
Nervous system disorders		4	10	27.8	7	70.0	6	37.5	2	33.3
Nervous system disorders	Amnesia	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Amnesia	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Amnesia	4	10	27.8	0	0.0	6	37.5	1	16.7
Nervous system disorders	Dizziness	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness	4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Dizziness postural	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness postural	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Headache	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Headache	3	24	66.7	8	33.3	10	62.5	2	20.0
Nervous system disorders	Headache	4	10	27.8	4	40.0	6	37.5	2	33.3
Nervous system disorders	Migraine	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Migraine	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Occipital neuralgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Occipital neuralgia	3	24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Paraesthesia	2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders	Paraesthesia	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	4	10	27.8	1	10.0	6	37.5	0	0.0
Psychiatric disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders		3	24	66.7	0	0.0	10	62.5	2	20.0
Psychiatric disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Psychiatric disorders	Anxiety	2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders	Anxiety	3	24	66.7	0	0.0	10	62.5	2	20.0
Psychiatric disorders	Anxiety	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders		3	24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Haematuria	2	2	5.6	0	0.0	0	0.0	0	0.0
Renal and urinary disorders	Haematuria	3	24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Renal cyst	2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Renal cyst	3	24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	4	10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Urinary incontinence	2	2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Urinary incontinence	3	24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders		3	24	66.7	3	12.5	10	62.5	1	10.0
Reproductive system and breast disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0

Reproductive system and breast disorders	Amenorrhoea	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	3	24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	3	24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	3	24	66.7	0	0.0	10	62.5	1	10.0
Reproductive system and breast disorders	Polycystic ovaries	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	24	66.7	5	20.8	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders		4	10	27.8	3	30.0	6	37.5	3	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	3	24	66.7	1	4.2	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	3	24	66.7	3	12.5	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	4	10	27.8	2	20.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	3	24	66.7	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	24	66.7	1	4.2	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	10	27.8	1	10.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	24	66.7	12	50.0	10	62.5	1	10.0
Skin and subcutaneous tissue disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	3	24	66.7	1	4.2	10	62.5	0	0.0

Skin and subcutaneous tissue disorders	Hair texture abnormal	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	24	66.7	0	0.0	10	62.5	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures		2	2	5.6	0	0.0	0	0.0	0	0.0
Surgical and medical procedures		3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures	Dental implantation	2	2	5.6	0	0.0	0	0.0	0	0.0
Surgical and medical procedures	Dental implantation	3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	4	10	27.8	0	0.0	6	37.5	0	0.0
Vascular disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Vascular disorders	Varicose vein	2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders	Varicose vein	3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	4	10	27.8	1	10.0	6	37.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 10:05

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPPOINT: AEs Grade 1-2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Blood and lymphatic system disorders	Anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	No	29	80.6	0	0.0	12	75.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Cardiac disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	No	29	80.6	1	3.4	12	75.0	0	0.0
Ear and labyrinth disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Ear and labyrinth disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Deafness neurosensory	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	No	29	80.6	0	0.0	12	75.0	0	0.0
Ear and labyrinth disorders	Ear pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Hypoacusis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	No	29	80.6	0	0.0	12	75.0	0	0.0
Endocrine disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Endocrine disorders	Hypopituitarism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders		No	29	80.6	4	13.8	12	75.0	2	16.7
Eye disorders	Conjunctival haemorrhage	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	No	29	80.6	0	0.0	12	75.0	1	8.3
Eye disorders	Conjunctivitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Dry eye	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Eye pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Eye disorders	Ocular hyperaemia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders		Yes	7	19.4	3	42.9	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	19	65.5	12	75.0	5	41.7
Gastrointestinal disorders	Abdominal discomfort	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	No	29	80.6	5	17.2	12	75.0	2	16.7
Gastrointestinal disorders	Abdominal pain upper	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	No	29	80.6	4	13.8	12	75.0	1	8.3
Gastrointestinal disorders	Aphthous ulcer	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	3	10.3	12	75.0	1	8.3
Gastrointestinal disorders	Diarrhoea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	No	29	80.6	11	37.9	12	75.0	2	16.7
Gastrointestinal disorders	Dyspepsia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Faecaloma	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Gastrointestinal disorders	Faecaloma	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Faeces soft	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Flatulence	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Nausea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Toothache	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	No	29	80.6	1	3.4	12	75.0	1	8.3
Gastrointestinal disorders	Vomiting	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	No	29	80.6	4	13.8	12	75.0	4	33.3
General disorders and administration site conditions		Yes	7	19.4	2	28.6	4	25.0	0	0.0
General disorders and administration site conditions		No	29	80.6	8	27.6	12	75.0	3	25.0
General disorders and administration site conditions	Feeling abnormal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	No	29	80.6	0	0.0	12	75.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Malaise	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	No	29	80.6	0	0.0	12	75.0	1	8.3
General disorders and administration site conditions	Medical device pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Pyrexia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	No	29	80.6	6	20.7	12	75.0	2	16.7
Immune system disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders		No	29	80.6	1	3.4	12	75.0	1	8.3
Immune system disorders	Hypersensitivity	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	No	29	80.6	0	0.0	12	75.0	0	0.0
Immune system disorders	Seasonal allergy	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations		Yes	7	19.4	6	85.7	4	25.0	4	100.0
Infections and infestations		No	29	80.6	29	100.0	12	75.0	9	75.0
Infections and infestations	Adenoiditis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Bronchitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	No	29	80.6	2	6.9	12	75.0	2	16.7
Infections and infestations	Folliculitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Fungal skin infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Furuncle	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Furuncle	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gastroenteritis	Yes	7	19.4	2	28.6	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	5	17.2	12	75.0	1	8.3
Infections and infestations	Gastroenteritis viral	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Gastrointestinal infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Genital infection fungal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gingivitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Hand-foot-and-mouth disease	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Hordeolum	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	No	29	80.6	0	0.0	12	75.0	1	8.3

Infections and infestations	Influenza	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Influenza	No	29	80.6	3	10.3	12	75.0	0	0.0
Infections and infestations	Lymph gland infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Nasopharyngitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	No	29	80.6	10	34.5	12	75.0	3	25.0
Infections and infestations	Otitis externa	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Otitis media	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Otitis media acute	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Pharyngitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	No	29	80.6	4	13.8	12	75.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Pneumonia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	No	29	80.6	3	10.3	12	75.0	1	8.3
Infections and infestations	Rhinitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Rhinitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Sinusitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Soft tissue infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Subcutaneous abscess	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Tonsillitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Tracheitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Yes	7	19.4	4	57.1	4	25.0	2	50.0
Infections and infestations	Upper respiratory tract infection	No	29	80.6	10	34.5	12	75.0	3	25.0
Infections and infestations	Upper respiratory tract infection bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Urinary tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Varicella	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations	Viral pharyngitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Viral rhinitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	No	29	80.6	4	13.8	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	2	28.6	4	25.0	1	25.0
Injury, poisoning and procedural complications		No	29	80.6	8	27.6	12	75.0	2	16.7
Injury, poisoning and procedural complications	Anaemia postoperative	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Contusion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	No	29	80.6	1	3.4	12	75.0	1	8.3
Injury, poisoning and procedural complications	Fall	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	No	29	80.6	2	6.9	12	75.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Muscle strain	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Injury, poisoning and procedural complications	Procedural pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Activated partial thromboplastin time shortened	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Blood bicarbonate decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	C-reactive protein increased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	7	24.1	12	75.0	5	41.7
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	7	19.4	2	28.6	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	29	80.6	1	3.4	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	1	3.4	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Exostosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	29	80.6	3	10.3	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Scoliosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	No	29	80.6	2	6.9	12	75.0	1	8.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		No	29	80.6	1	3.4	12	75.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders		Yes	7	19.4	5	71.4	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	13	44.8	12	75.0	4	33.3
Nervous system disorders	Amnesia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	No	29	80.6	0	0.0	12	75.0	1	8.3
Nervous system disorders	Dizziness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Dizziness postural	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	No	29	80.6	0	0.0	12	75.0	0	0.0
Nervous system disorders	Headache	Yes	7	19.4	3	42.9	4	25.0	0	0.0
Nervous system disorders	Headache	No	29	80.6	9	31.0	12	75.0	4	33.3
Nervous system disorders	Migraine	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Occipital neuralgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Paraesthesia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	No	29	80.6	2	6.9	12	75.0	0	0.0
Psychiatric disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders		No	29	80.6	0	0.0	12	75.0	2	16.7
Psychiatric disorders	Anxiety	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	No	29	80.6	0	0.0	12	75.0	2	16.7
Renal and urinary disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders		No	29	80.6	2	6.9	12	75.0	0	0.0

Renal and urinary disorders	Haematuria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	No	29	80.6	2	6.9	12	75.0	0	0.0
Renal and urinary disorders	Renal cyst	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	No	29	80.6	0	0.0	12	75.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders		Yes	7	19.4	1	14.3	4	25.0	1	25.0
Reproductive system and breast disorders		No	29	80.6	3	10.3	12	75.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	No	29	80.6	0	0.0	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	9	31.0	12	75.0	4	33.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	No	29	80.6	5	17.2	12	75.0	2	16.7
Respiratory, thoracic and mediastinal disorders	Epistaxis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	No	29	80.6	1	3.4	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	29	80.6	2	6.9	12	75.0	3	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders		Yes	7	19.4	4	57.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	11	37.9	12	75.0	1	8.3
Skin and subcutaneous tissue disorders	Alopecia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	No	29	80.6	2	6.9	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	No	29	80.6	2	6.9	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	29	80.6	0	0.0	12	75.0	1	8.3
Surgical and medical procedures		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		No	29	80.6	0	0.0	12	75.0	1	8.3
Surgical and medical procedures	Dental implantation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	No	29	80.6	0	0.0	12	75.0	1	8.3
Vascular disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Vascular disorders	Varicose vein	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	No	29	80.6	1	3.4	12	75.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG12_SE_P2_T3.xls
18DEC2020 10:05

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders		6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders		12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders		18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	4	26.7	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Vomiting	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	4	26.7	1	25.0
Immune system disorders		2 to 5 years	3	20.0	0	0.0
Immune system disorders		6 to 11 years	4	26.7	0	0.0
Immune system disorders		12 to 17 years	4	26.7	1	25.0
Immune system disorders		18 to 25 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	3	20.0	0	0.0
Immune system disorders	Hypersensitivity	6 to 11 years	4	26.7	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	4	26.7	0	0.0
Infections and infestations		2 to 5 years	3	20.0	0	0.0
Infections and infestations		6 to 11 years	4	26.7	1	25.0
Infections and infestations		12 to 17 years	4	26.7	0	0.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Subcutaneous abscess	6 to 11 years	4	26.7	1	25.0
Infections and infestations	Subcutaneous abscess	12 to 17 years	4	26.7	0	0.0

Infections and infestations	Subcutaneous abscess	18 to 25 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications		6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications		12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications		18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Contusion	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Contusion	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	12 to 17 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	18 to 25 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	2 to 5 years	3	20.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	6 to 11 years	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	12 to 17 years	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	18 to 25 years	4	26.7	0	0.0
Investigations		2 to 5 years	3	20.0	1	33.3
Investigations		6 to 11 years	4	26.7	0	0.0
Investigations		12 to 17 years	4	26.7	0	0.0
Investigations		18 to 25 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	2 to 5 years	3	20.0	1	33.3
Investigations	C-reactive protein increased	6 to 11 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	12 to 17 years	4	26.7	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders		6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	4	26.7	0	0.0
Nervous system disorders		2 to 5 years	3	20.0	0	0.0
Nervous system disorders		6 to 11 years	4	26.7	1	25.0
Nervous system disorders		12 to 17 years	4	26.7	0	0.0
Nervous system disorders		18 to 25 years	4	26.7	1	25.0
Nervous system disorders	Headache	2 to 5 years	3	20.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	4	26.7	1	25.0
Nervous system disorders	Headache	12 to 17 years	4	26.7	0	0.0
Nervous system disorders	Headache	18 to 25 years	4	26.7	1	25.0
Psychiatric disorders		2 to 5 years	3	20.0	0	0.0
Psychiatric disorders		6 to 11 years	4	26.7	0	0.0
Psychiatric disorders		12 to 17 years	4	26.7	0	0.0

Psychiatric disorders		18 to 25 years	4	26.7	1	25.0
Psychiatric disorders	Anxiety	2 to 5 years	3	20.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	12 to 17 years	4	26.7	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2 to 5 years	3	20.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6 to 11 years	4	26.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12 to 17 years	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18 to 25 years	4	26.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		n/a	15	100.0	2	13.3
Gastrointestinal disorders	Abdominal pain	n/a	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	n/a	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	n/a	15	100.0	1	6.7
Immune system disorders		n/a	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	n/a	15	100.0	1	6.7
Infections and infestations		n/a	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	n/a	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications		n/a	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	n/a	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	n/a	15	100.0	1	6.7
Investigations		n/a	15	100.0	1	6.7
Investigations	C-reactive protein increased	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		n/a	15	100.0	2	13.3
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	15	100.0	1	6.7
Nervous system disorders		n/a	15	100.0	2	13.3
Nervous system disorders	Headache	n/a	15	100.0	2	13.3
Psychiatric disorders		n/a	15	100.0	1	6.7
Psychiatric disorders	Anxiety	n/a	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		n/a	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_F2_OLE_SW_T3.xls
08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		White	12	80.0	0	0.0
Gastrointestinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders		Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Abdominal pain	White	12	80.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	2	13.3	2	100.0
Gastrointestinal disorders	Diarrhoea	White	12	80.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	2	13.3	1	50.0
Gastrointestinal disorders	Vomiting	White	12	80.0	0	0.0
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	2	13.3	1	50.0
Immune system disorders		White	12	80.0	1	8.3
Immune system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders		Unknown	2	13.3	0	0.0
Immune system disorders	Hypersensitivity	White	12	80.0	1	8.3
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Unknown	2	13.3	0	0.0
Infections and infestations		White	12	80.0	0	0.0
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations		Unknown	2	13.3	1	50.0
Infections and infestations	Gastroenteritis	White	12	80.0	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Unknown	2	13.3	1	50.0
Infections and infestations	Subcutaneous abscess	White	12	80.0	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	2	13.3	1	50.0
Injury, poisoning and procedural complications		White	12	80.0	2	16.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications		Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Contusion	White	12	80.0	1	8.3
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	2	13.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	12	80.0	1	8.3

Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	2	13.3	0	0.0
Investigations		White	12	80.0	0	0.0
Investigations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations		Unknown	2	13.3	0	0.0
Investigations	C-reactive protein increased	White	12	80.0	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	1	6.7	1	100.0
Investigations	C-reactive protein increased	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders		White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Limb discomfort	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	2	13.3	1	50.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	2	13.3	0	0.0
Nervous system disorders		White	12	80.0	1	8.3
Nervous system disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders		Unknown	2	13.3	1	50.0
Nervous system disorders	Headache	White	12	80.0	1	8.3
Nervous system disorders	Headache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Nervous system disorders	Headache	Unknown	2	13.3	1	50.0
Psychiatric disorders		White	12	80.0	0	0.0
Psychiatric disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders		Unknown	2	13.3	1	50.0
Psychiatric disorders	Anxiety	White	12	80.0	0	0.0
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Unknown	2	13.3	1	50.0
Respiratory, thoracic and mediastinal disorders		White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Unknown	2	13.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	12	80.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	2	13.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Europe	14	93.3	2	14.3
Gastrointestinal disorders		Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	14	93.3	2	14.3
Gastrointestinal disorders	Abdominal pain	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Diarrhoea	Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Vomiting	Rest of the World	1	6.7	0	0.0
Immune system disorders		Europe	14	93.3	1	7.1
Immune system disorders		Rest of the World	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	Europe	14	93.3	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	1	6.7	0	0.0
Infections and infestations		Europe	14	93.3	1	7.1
Infections and infestations		Rest of the World	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	Europe	14	93.3	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	Europe	14	93.3	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications		Europe	14	93.3	2	14.3
Injury, poisoning and procedural complications		Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	14	93.3	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	14	93.3	1	7.1
Injury, poisoning and procedural complications	Muscle strain	Rest of the World	1	6.7	0	0.0
Investigations		Europe	14	93.3	0	0.0
Investigations		Rest of the World	1	6.7	1	100.0
Investigations	C-reactive protein increased	Europe	14	93.3	0	0.0
Investigations	C-reactive protein increased	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Europe	14	93.3	2	14.3
Musculoskeletal and connective tissue disorders		Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	1	6.7	0	0.0

Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	1	6.7	0	0.0
Nervous system disorders		Europe	14	93.3	2	14.3
Nervous system disorders		Rest of the World	1	6.7	0	0.0
Nervous system disorders	Headache	Europe	14	93.3	2	14.3
Nervous system disorders	Headache	Rest of the World	1	6.7	0	0.0
Psychiatric disorders		Europe	14	93.3	1	7.1
Psychiatric disorders		Rest of the World	1	6.7	0	0.0
Psychiatric disorders	Anxiety	Europe	14	93.3	1	7.1
Psychiatric disorders	Anxiety	Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders		Rest of the World	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	14	93.3	1	7.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	1	6.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		<=Q1	1	6.7	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders		>Q3	9	60.0	2	22.2
Gastrointestinal disorders		Missing	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	9	60.0	2	22.2
Gastrointestinal disorders	Abdominal pain	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Diarrhoea	Missing	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	9	60.0	1	11.1
Gastrointestinal disorders	Vomiting	Missing	1	6.7	0	0.0
Immune system disorders		<=Q1	1	6.7	0	0.0
Immune system disorders		>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders		>Q3	9	60.0	0	0.0
Immune system disorders		Missing	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	1	6.7	0	0.0
Immune system disorders	Hypersensitivity	>Q1 to <=Q3	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	>Q3	9	60.0	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	6.7	0	0.0
Infections and infestations		<=Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations		>Q3	9	60.0	1	11.1
Infections and infestations		Missing	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	1	6.7	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	>Q3	9	60.0	1	11.1
Infections and infestations	Gastroenteritis	Missing	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	1	6.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	9	60.0	1	11.1

Infections and infestations	Subcutaneous abscess	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications		<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications		>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications		Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	1	6.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	9	60.0	1	11.1
Injury, poisoning and procedural complications	Contusion	Missing	1	6.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	1	6.7	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	4	26.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	9	60.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	6.7	0	0.0
Investigations		<=Q1	1	6.7	0	0.0
Investigations		>Q1 to <=Q3	4	26.7	0	0.0
Investigations		>Q3	9	60.0	1	11.1
Investigations		Missing	1	6.7	0	0.0
Investigations	C-reactive protein increased	<=Q1	1	6.7	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	4	26.7	0	0.0
Investigations	C-reactive protein increased	>Q3	9	60.0	1	11.1
Investigations	C-reactive protein increased	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	9	60.0	2	22.2
Musculoskeletal and connective tissue disorders		Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	6.7	0	0.0
Nervous system disorders		<=Q1	1	6.7	0	0.0
Nervous system disorders		>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders		>Q3	9	60.0	2	22.2
Nervous system disorders		Missing	1	6.7	0	0.0
Nervous system disorders	Headache	<=Q1	1	6.7	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	4	26.7	0	0.0
Nervous system disorders	Headache	>Q3	9	60.0	2	22.2
Nervous system disorders	Headache	Missing	1	6.7	0	0.0
Psychiatric disorders		<=Q1	1	6.7	0	0.0
Psychiatric disorders		>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders		>Q3	9	60.0	1	11.1

Psychiatric disorders		Missing	1	6.7	0	0.0
Psychiatric disorders	Anxiety	<=Q1	1	6.7	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	4	26.7	0	0.0
Psychiatric disorders	Anxiety	>Q3	9	60.0	1	11.1
Psychiatric disorders	Anxiety	Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Missing	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	1	6.7	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	9	60.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	6.7	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls
08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		Male	8	53.3	1	12.5
Gastrointestinal disorders		Female	7	46.7	1	14.3
Gastrointestinal disorders	Abdominal pain	Male	8	53.3	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	7	46.7	1	14.3
Gastrointestinal disorders	Diarrhoea	Male	8	53.3	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	7	46.7	0	0.0
Gastrointestinal disorders	Vomiting	Male	8	53.3	0	0.0
Gastrointestinal disorders	Vomiting	Female	7	46.7	1	14.3
Immune system disorders		Male	8	53.3	0	0.0
Immune system disorders		Female	7	46.7	1	14.3
Immune system disorders	Hypersensitivity	Male	8	53.3	0	0.0
Immune system disorders	Hypersensitivity	Female	7	46.7	1	14.3
Infections and infestations		Male	8	53.3	1	12.5
Infections and infestations		Female	7	46.7	0	0.0
Infections and infestations	Gastroenteritis	Male	8	53.3	1	12.5
Infections and infestations	Gastroenteritis	Female	7	46.7	0	0.0
Infections and infestations	Subcutaneous abscess	Male	8	53.3	1	12.5
Infections and infestations	Subcutaneous abscess	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications		Male	8	53.3	1	12.5
Injury, poisoning and procedural complications		Female	7	46.7	1	14.3
Injury, poisoning and procedural complications	Contusion	Male	8	53.3	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	7	46.7	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	8	53.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Female	7	46.7	1	14.3
Investigations		Male	8	53.3	1	12.5
Investigations		Female	7	46.7	0	0.0
Investigations	C-reactive protein increased	Male	8	53.3	1	12.5
Investigations	C-reactive protein increased	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders		Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders		Female	7	46.7	1	14.3
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	8	53.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	7	46.7	1	14.3

Musculoskeletal and connective tissue disorders	Pain in extremity	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	7	46.7	0	0.0
Nervous system disorders		Male	8	53.3	0	0.0
Nervous system disorders		Female	7	46.7	2	28.6
Nervous system disorders	Headache	Male	8	53.3	0	0.0
Nervous system disorders	Headache	Female	7	46.7	2	28.6
Psychiatric disorders		Male	8	53.3	0	0.0
Psychiatric disorders		Female	7	46.7	1	14.3
Psychiatric disorders	Anxiety	Male	8	53.3	0	0.0
Psychiatric disorders	Anxiety	Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders		Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Female	7	46.7	1	14.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	8	53.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	7	46.7	1	14.3

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Type III	15	100.0	2	13.3
Gastrointestinal disorders	Abdominal pain	Type III	15	100.0	2	13.3
Gastrointestinal disorders	Diarrhoea	Type III	15	100.0	1	6.7
Gastrointestinal disorders	Vomiting	Type III	15	100.0	1	6.7
Immune system disorders		Type III	15	100.0	1	6.7
Immune system disorders	Hypersensitivity	Type III	15	100.0	1	6.7
Infections and infestations		Type III	15	100.0	1	6.7
Infections and infestations	Gastroenteritis	Type III	15	100.0	1	6.7
Infections and infestations	Subcutaneous abscess	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications		Type III	15	100.0	2	13.3
Injury, poisoning and procedural complications	Contusion	Type III	15	100.0	1	6.7
Injury, poisoning and procedural complications	Muscle strain	Type III	15	100.0	1	6.7
Investigations		Type III	15	100.0	1	6.7
Investigations	C-reactive protein increased	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		Type III	15	100.0	2	13.3
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	15	100.0	1	6.7
Nervous system disorders		Type III	15	100.0	2	13.3
Nervous system disorders	Headache	Type III	15	100.0	2	13.3
Psychiatric disorders		Type III	15	100.0	1	6.7
Psychiatric disorders	Anxiety	Type III	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders		Type III	15	100.0	1	6.7
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	15	100.0	1	6.7

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_F2_OLE_SW_T3.xls
08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		3	10	66.7	2	20.0
Gastrointestinal disorders		4	5	33.3	0	0.0
Gastrointestinal disorders	Abdominal pain	3	10	66.7	2	20.0
Gastrointestinal disorders	Abdominal pain	4	5	33.3	0	0.0
Gastrointestinal disorders	Diarrhoea	3	10	66.7	1	10.0
Gastrointestinal disorders	Diarrhoea	4	5	33.3	0	0.0
Gastrointestinal disorders	Vomiting	3	10	66.7	1	10.0
Gastrointestinal disorders	Vomiting	4	5	33.3	0	0.0
Immune system disorders		3	10	66.7	1	10.0
Immune system disorders		4	5	33.3	0	0.0
Immune system disorders	Hypersensitivity	3	10	66.7	1	10.0
Immune system disorders	Hypersensitivity	4	5	33.3	0	0.0
Infections and infestations		3	10	66.7	1	10.0
Infections and infestations		4	5	33.3	0	0.0
Infections and infestations	Gastroenteritis	3	10	66.7	1	10.0
Infections and infestations	Gastroenteritis	4	5	33.3	0	0.0
Infections and infestations	Subcutaneous abscess	3	10	66.7	1	10.0
Infections and infestations	Subcutaneous abscess	4	5	33.3	0	0.0
Injury, poisoning and procedural complications		3	10	66.7	1	10.0
Injury, poisoning and procedural complications		4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Contusion	3	10	66.7	0	0.0
Injury, poisoning and procedural complications	Contusion	4	5	33.3	1	20.0
Injury, poisoning and procedural complications	Muscle strain	3	10	66.7	1	10.0
Injury, poisoning and procedural complications	Muscle strain	4	5	33.3	0	0.0
Investigations		3	10	66.7	0	0.0
Investigations		4	5	33.3	1	20.0
Investigations	C-reactive protein increased	3	10	66.7	0	0.0
Investigations	C-reactive protein increased	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders		3	10	66.7	2	20.0
Musculoskeletal and connective tissue disorders		4	5	33.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	5	33.3	0	0.0

Musculoskeletal and connective tissue disorders	Pain in extremity	3	10	66.7	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4	5	33.3	0	0.0
Nervous system disorders		3	10	66.7	2	20.0
Nervous system disorders		4	5	33.3	0	0.0
Nervous system disorders	Headache	3	10	66.7	2	20.0
Nervous system disorders	Headache	4	5	33.3	0	0.0
Psychiatric disorders		3	10	66.7	1	10.0
Psychiatric disorders		4	5	33.3	0	0.0
Psychiatric disorders	Anxiety	3	10	66.7	1	10.0
Psychiatric disorders	Anxiety	4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders		3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders		4	5	33.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	10	66.7	1	10.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	5	33.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 1 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event	
			n	%	n	%
Gastrointestinal disorders		Yes	4	26.7	0	0.0
Gastrointestinal disorders		No	11	73.3	2	18.2
Gastrointestinal disorders	Abdominal pain	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Abdominal pain	No	11	73.3	2	18.2
Gastrointestinal disorders	Diarrhoea	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Diarrhoea	No	11	73.3	1	9.1
Gastrointestinal disorders	Vomiting	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Vomiting	No	11	73.3	1	9.1
Immune system disorders		Yes	4	26.7	1	25.0
Immune system disorders		No	11	73.3	0	0.0
Immune system disorders	Hypersensitivity	Yes	4	26.7	1	25.0
Immune system disorders	Hypersensitivity	No	11	73.3	0	0.0
Infections and infestations		Yes	4	26.7	0	0.0
Infections and infestations		No	11	73.3	1	9.1
Infections and infestations	Gastroenteritis	Yes	4	26.7	0	0.0
Infections and infestations	Gastroenteritis	No	11	73.3	1	9.1
Infections and infestations	Subcutaneous abscess	Yes	4	26.7	0	0.0
Infections and infestations	Subcutaneous abscess	No	11	73.3	1	9.1
Injury, poisoning and procedural complications		Yes	4	26.7	1	25.0
Injury, poisoning and procedural complications		No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Contusion	Yes	4	26.7	0	0.0
Injury, poisoning and procedural complications	Contusion	No	11	73.3	1	9.1
Injury, poisoning and procedural complications	Muscle strain	Yes	4	26.7	1	25.0
Injury, poisoning and procedural complications	Muscle strain	No	11	73.3	0	0.0
Investigations		Yes	4	26.7	0	0.0
Investigations		No	11	73.3	1	9.1
Investigations	C-reactive protein increased	Yes	4	26.7	0	0.0
Investigations	C-reactive protein increased	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders		Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		No	11	73.3	2	18.2
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	11	73.3	1	9.1

Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	11	73.3	1	9.1
Nervous system disorders		Yes	4	26.7	0	0.0
Nervous system disorders		No	11	73.3	2	18.2
Nervous system disorders	Headache	Yes	4	26.7	0	0.0
Nervous system disorders	Headache	No	11	73.3	2	18.2
Psychiatric disorders		Yes	4	26.7	0	0.0
Psychiatric disorders		No	11	73.3	1	9.1
Psychiatric disorders	Anxiety	Yes	4	26.7	0	0.0
Psychiatric disorders	Anxiety	No	11	73.3	1	9.1
Respiratory, thoracic and mediastinal disorders		Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders		No	11	73.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	4	26.7	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	11	73.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_OLE_SW_T3.xls

08MAR2021 13:01

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Thrombocytopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Ear and labyrinth disorders	Ear pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Ear and labyrinth disorders	Hypoaacusis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoaacusis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoaacusis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoaacusis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Eye disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	2	50.0
Eye disorders	Conjunctival haemorrhage	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Eye disorders	Conjunctivitis allergic	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Eye disorders	Dry eye	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Eye disorders	Eye pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Eye disorders	Ocular hyperaemia	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0

Eye disorders	Ocular hyperaemia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders		6 to 11 years	11	30.6	6	54.5	4	25.0	1	25.0
Gastrointestinal disorders		12 to 17 years	15	41.7	6	40.0	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	3	50.0	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal distension	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal pain upper	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	11	30.6	3	27.3	4	25.0	1	25.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Gastrointestinal disorders	Vomiting	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0

General disorders and administration site conditions		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions		6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
General disorders and administration site conditions		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
General disorders and administration site conditions		18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
General disorders and administration site conditions	Pyrexia	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Immune system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Immune system disorders	Hypersensitivity	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Immune system disorders	Seasonal allergy	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	3	75.0	4	25.0	4	100.0
Infections and infestations		6 to 11 years	11	30.6	5	45.5	4	25.0	1	25.0
Infections and infestations		12 to 17 years	15	41.7	10	66.7	4	25.0	3	75.0
Infections and infestations		18 to 25 years	6	16.7	5	83.3	4	25.0	2	50.0
Infections and infestations	Bronchitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Bronchitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Furuncle	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Furuncle	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	3	50.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastrointestinal viral infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0

Infections and infestations	Genital infection fungal	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Gingivitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Gingivitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Influenza	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Influenza	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	4	11.1	2	50.0	4	25.0	2	50.0
Infections and infestations	Nasopharyngitis	6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Otitis externa	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis media acute	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Otitis media acute	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	12 to 17 years	15	41.7	2	13.3	4	25.0	1	25.0
Infections and infestations	Pharyngitis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Sinusitis	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Subcutaneous abscess	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Tracheitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection	12 to 17 years	15	41.7	5	33.3	4	25.0	1	25.0
Infections and infestations	Upper respiratory tract infection	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Urinary tract infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Varicella	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Injury, poisoning and procedural complications		12 to 17 years	15	41.7	3	20.0	4	25.0	1	25.0

Injury, poisoning and procedural complications		18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Injury, poisoning and procedural complications	Contusion	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Fall	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Muscle strain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Investigations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Activated partial thromboplastin time shortened	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Blood bicarbonate decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	C-reactive protein increased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0

Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2 to 5 years	4	11.1	1	25.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Pain in extremity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Nervous system disorders		12 to 17 years	15	41.7	5	33.3	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	3	50.0	4	25.0	3	75.0
Nervous system disorders	Amnesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Nervous system disorders	Dizziness	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Headache	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	11	30.6	1	9.1	4	25.0	1	25.0
Nervous system disorders	Headache	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Headache	18 to 25 years	6	16.7	3	50.0	4	25.0	2	50.0
Nervous system disorders	Migraine	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Nervous system disorders	Migraine	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Psychiatric disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0

Psychiatric disorders	Anxiety	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Renal and urinary disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders		12 to 17 years	15	41.7	3	20.0	4	25.0	1	25.0
Reproductive system and breast disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	3	50.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2 to 5 years	4	11.1	1	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Cough	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0

Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	4	11.1	2	50.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	15	41.7	5	33.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Skin exfoliation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Surgical and medical procedures	Dental implantation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	3	8.3	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		n/a	36	100.0	3	8.3	16	100.0	1	6.3
Ear and labyrinth disorders	Ear pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypoacusis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		n/a	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		n/a	36	100.0	17	47.2	16	100.0	4	25.0
Gastrointestinal disorders	Abdominal distension	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	n/a	36	100.0	5	13.9	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	n/a	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Gastrointestinal disorders	Diarrhoea	n/a	36	100.0	8	22.2	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Gastrooesophageal reflux disease	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Vomiting	n/a	36	100.0	4	11.1	16	100.0	4	25.0
General disorders and administration site conditions		n/a	36	100.0	6	16.7	16	100.0	2	12.5
General disorders and administration site conditions	Feeling abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	n/a	36	100.0	3	8.3	16	100.0	2	12.5
Immune system disorders		n/a	36	100.0	0	0.0	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations		n/a	36	100.0	23	63.9	16	100.0	10	62.5
Infections and infestations	Bronchitis	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Furuncle	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	n/a	36	100.0	6	16.7	16	100.0	1	6.3
Infections and infestations	Gastroenteritis viral	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hordeolum	n/a	36	100.0	0	0.0	16	100.0	1	6.3

Infections and infestations	Influenza	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Infections and infestations	Nasopharyngitis	n/a	36	100.0	9	25.0	16	100.0	2	12.5
Infections and infestations	Otitis externa	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Otitis media	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Infections and infestations	Sinusitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tracheitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	n/a	36	100.0	7	19.4	16	100.0	2	12.5
Infections and infestations	Urinary tract infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Varicella	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Viral rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	7	19.4	16	100.0	3	18.8
Injury, poisoning and procedural complications	Contusion	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Dehydration	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		n/a	36	100.0	7	19.4	16	100.0	2	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	36	100.0	3	8.3	16	100.0	1	6.3
Nervous system disorders		n/a	36	100.0	11	30.6	16	100.0	4	25.0
Nervous system disorders	Amnesia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	n/a	36	100.0	6	16.7	16	100.0	3	18.8
Nervous system disorders	Migraine	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Psychiatric disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Psychiatric disorders	Anxiety	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Renal and urinary disorders		n/a	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		n/a	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	n/a	36	100.0	0	0.0	16	100.0	1	6.3

Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	8	22.2	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	n/a	36	100.0	4	11.1	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		n/a	36	100.0	12	33.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Surgical and medical procedures		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	n/a	36	100.0	0	0.0	16	100.0	1	6.3

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	2	8.0	13	81.3	1	7.7
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Anaemia	White	25	69.4	2	8.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Thrombocytopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	White	25	69.4	0	0.0	13	81.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Ear and labyrinth disorders	Ear pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Ear and labyrinth disorders	Ear pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Ear and labyrinth disorders	Hypoaacusis	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Hypoaacusis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoaacusis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Eye disorders		White	25	69.4	2	8.0	13	81.3	1	7.7
Eye disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Eye disorders	Conjunctival haemorrhage	White	25	69.4	0	0.0	13	81.3	1	7.7
Eye disorders	Conjunctival haemorrhage	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Conjunctivitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Conjunctivitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Dry eye	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Dry eye	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Eye disorders	Eye pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Eye disorders	Eye pain	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders	Eye pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Eye disorders	Ocular hyperaemia	White	25	69.4	0	0.0	13	81.3	0	0.0
Eye disorders	Ocular hyperaemia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	9	36.0	13	81.3	2	15.4
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	5	71.4	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	3	75.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal distension	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	White	25	69.4	4	16.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	4	11.1	1	25.0	2	12.5	2	100.0
Gastrointestinal disorders	Abdominal pain upper	White	25	69.4	3	12.0	13	81.3	1	7.7

Gastrointestinal disorders	Abdominal pain upper	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Diarrhoea	White	25	69.4	5	20.0	13	81.3	1	7.7
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	4	11.1	2	50.0	2	12.5	1	50.0
Gastrointestinal disorders	Dyspepsia	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Faeces soft	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Flatulence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Nausea	White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders	Nausea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	White	25	69.4	2	8.0	13	81.3	2	15.4
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	4	11.1	0	0.0	2	12.5	2	100.0
General disorders and administration site conditions		White	25	69.4	3	12.0	13	81.3	0	0.0
General disorders and administration site conditions		Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	1	100.0
General disorders and administration site conditions		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	White	25	69.4	0	0.0	13	81.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	White	25	69.4	1	4.0	13	81.3	0	0.0
General disorders and administration site conditions	Pyrexia	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
General disorders and administration site conditions	Pyrexia	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Immune system disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Immune system disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Immune system disorders	Hypersensitivity	White	25	69.4	0	0.0	13	81.3	1	7.7
Immune system disorders	Hypersensitivity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	White	25	69.4	0	0.0	13	81.3	0	0.0
Immune system disorders	Seasonal allergy	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations		White	25	69.4	14	56.0	13	81.3	7	53.8

Infections and infestations		Asian/Black or African American/Multiple	7	19.4	5	71.4	1	6.3	1	100.0
Infections and infestations		Unknown	4	11.1	4	100.0	2	12.5	2	100.0
Infections and infestations	Bronchitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Furuncle	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Furuncle	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Furuncle	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Infections and infestations	Gastroenteritis viral	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis viral	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Genital infection fungal	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Genital infection fungal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Gingivitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Infections and infestations	Gingivitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Hordeolum	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Influenza	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Influenza	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	White	25	69.4	5	20.0	13	81.3	2	15.4
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Infections and infestations	Otitis externa	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Otitis externa	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Otitis media	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Otitis media acute	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	White	25	69.4	2	8.0	13	81.3	1	7.7
Infections and infestations	Pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Sinusitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Subcutaneous abscess	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Tracheitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Tracheitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	White	25	69.4	3	12.0	13	81.3	2	15.4
Infections and infestations	Upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	4	57.1	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Urinary tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Varicella	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Varicella	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Viral rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	White	25	69.4	0	0.0	13	81.3	0	0.0

Infections and infestations	Viral upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	4	16.0	13	81.3	2	15.4
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Contusion	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Contusion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Fall	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Fall	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Muscle strain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Activated partial thromboplastin time shortened	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Blood bicarbonate decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Blood bicarbonate decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Blood bicarbonate decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	C-reactive protein increased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	C-reactive protein increased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	C-reactive protein increased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Dehydration	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Musculoskeletal and connective tissue disorders	Limb discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Pain in extremity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	7	28.0	13	81.3	3	23.1
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Nervous system disorders	Amnesia	White	25	69.4	0	0.0	13	81.3	1	7.7
Nervous system disorders	Amnesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness postural	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Dizziness postural	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Headache	White	25	69.4	4	16.0	13	81.3	2	15.4
Nervous system disorders	Headache	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Nervous system disorders	Headache	Unknown	4	11.1	1	25.0	2	12.5	1	50.0
Nervous system disorders	Migraine	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Migraine	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Occipital neuralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Paraesthesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Psychiatric disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Psychiatric disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Psychiatric disorders	Anxiety	White	25	69.4	0	0.0	13	81.3	0	0.0
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Renal and urinary disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Renal and urinary disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Haematuria	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Haematuria	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Renal cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	White	25	69.4	1	4.0	13	81.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		White	25	69.4	3	12.0	13	81.3	1	7.7
Reproductive system and breast disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Reproductive system and breast disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	White	25	69.4	0	0.0	13	81.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0

Reproductive system and breast disorders	Menstrual disorder	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	White	25	69.4	1	4.0	13	81.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	White	25	69.4	0	0.0	13	81.3	1	7.7
Reproductive system and breast disorders	Polycystic ovaries	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	4	16.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	3	75.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	White	25	69.4	1	4.0	13	81.3	1	7.7
Respiratory, thoracic and mediastinal disorders	Cough	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Cough	Unknown	4	11.1	3	75.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	White	25	69.4	1	4.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	White	25	69.4	2	8.0	13	81.3	3	23.1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	7	28.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	3	42.9	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Skin and subcutaneous tissue disorders	Seborrhoea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	White	25	69.4	2	8.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		White	25	69.4	0	0.0	13	81.3	0	0.0
Surgical and medical procedures		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Surgical and medical procedures	Dental implantation	White	25	69.4	0	0.0	13	81.3	0	0.0
Surgical and medical procedures	Dental implantation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	Unknown	4	11.1	0	0.0	2	12.5	1	50.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_T3.xls

18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Europe	28	77.8	2	7.1	14	87.5	1	7.1
Blood and lymphatic system disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Thrombocytopenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Cardiac disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Ear and labyrinth disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Ear pain	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Ear and labyrinth disorders	Ear pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders		Europe	28	77.8	2	7.1	14	87.5	2	14.3
Eye disorders		Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders	Conjunctival haemorrhage	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders	Conjunctival haemorrhage	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders	Conjunctivitis allergic	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Eye disorders	Conjunctivitis allergic	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Eye disorders	Dry eye	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders	Dry eye	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Eye disorders	Eye pain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Eye disorders	Eye pain	Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Eye disorders	Ocular hyperaemia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Eye disorders	Ocular hyperaemia	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders		Europe	28	77.8	11	39.3	14	87.5	3	21.4
Gastrointestinal disorders		Rest of the World	8	22.2	6	75.0	2	12.5	1	50.0
Gastrointestinal disorders	Abdominal distension	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	28	77.8	5	17.9	14	87.5	2	14.3
Gastrointestinal disorders	Abdominal pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
Gastrointestinal disorders	Aphthous ulcer	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	28	77.8	6	21.4	14	87.5	2	14.3
Gastrointestinal disorders	Diarrhoea	Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faeces soft	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Faeces soft	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Flatulence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0

Gastrointestinal disorders	Nausea	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders	Nausea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Toothache	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	Europe	28	77.8	1	3.6	14	87.5	3	21.4
Gastrointestinal disorders	Vomiting	Rest of the World	8	22.2	3	37.5	2	12.5	1	50.0
General disorders and administration site conditions		Europe	28	77.8	4	14.3	14	87.5	1	7.1
General disorders and administration site conditions		Rest of the World	8	22.2	2	25.0	2	12.5	1	50.0
General disorders and administration site conditions	Feeling abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Europe	28	77.8	0	0.0	14	87.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	Europe	28	77.8	2	7.1	14	87.5	1	7.1
General disorders and administration site conditions	Pyrexia	Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Immune system disorders		Europe	28	77.8	0	0.0	14	87.5	2	14.3
Immune system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Immune system disorders	Hypersensitivity	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Hypersensitivity	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Immune system disorders	Seasonal allergy	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	17	60.7	14	87.5	8	57.1
Infections and infestations		Rest of the World	8	22.2	6	75.0	2	12.5	2	100.0
Infections and infestations	Bronchitis	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Infections and infestations	Bronchitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Furuncle	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Furuncle	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	6	21.4	14	87.5	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis viral	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastroenteritis viral	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastrointestinal infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastrointestinal viral infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Genital infection fungal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Genital infection fungal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gingivitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Gingivitis	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Infections and infestations	Hordeolum	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Hordeolum	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Influenza	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Influenza	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	Europe	28	77.8	6	21.4	14	87.5	1	7.1
Infections and infestations	Nasopharyngitis	Rest of the World	8	22.2	3	37.5	2	12.5	1	50.0
Infections and infestations	Otitis externa	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Otitis externa	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Otitis media	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis media acute	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Otitis media acute	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	Europe	28	77.8	3	10.7	14	87.5	1	7.1
Infections and infestations	Pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Sinusitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Sinusitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Subcutaneous abscess	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Subcutaneous abscess	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tracheitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tracheitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	Europe	28	77.8	3	10.7	14	87.5	2	14.3
Infections and infestations	Upper respiratory tract infection	Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0

Infections and infestations	Urinary tract infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Urinary tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Varicella	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Varicella	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	6	21.4	14	87.5	3	21.4
Injury, poisoning and procedural complications		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Contusion	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Injury, poisoning and procedural complications	Contusion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Fall	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Fall	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Muscle strain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Tooth fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Activated partial thromboplastin time shortened	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Blood bicarbonate decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Blood bicarbonate decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	C-reactive protein increased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	C-reactive protein increased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	6	21.4	14	87.5	2	14.3
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Limb discomfort	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Pain in extremity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders		Europe	28	77.8	7	25.0	14	87.5	4	28.6
Nervous system disorders		Rest of the World	8	22.2	4	50.0	2	12.5	0	0.0
Nervous system disorders	Amnesia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Nervous system disorders	Amnesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Dizziness	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0

Nervous system disorders	Dizziness postural	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Dizziness postural	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Headache	Europe	28	77.8	5	17.9	14	87.5	3	21.4
Nervous system disorders	Headache	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Migraine	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Nervous system disorders	Migraine	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Nervous system disorders	Occipital neuralgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Occipital neuralgia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Paraesthesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Psychiatric disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders	Anxiety	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Psychiatric disorders	Anxiety	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Renal and urinary disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Renal and urinary disorders	Haematuria	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Haematuria	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Renal and urinary disorders	Renal cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Renal cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders		Europe	28	77.8	3	10.7	14	87.5	1	7.1
Reproductive system and breast disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Reproductive system and breast disorders	Polycystic ovaries	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	6	21.4	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	2	25.0	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Rest of the World	8	22.2	1	12.5	2	12.5	2	100.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Respiratory, thoracic and mediastinal disorders	Epistaxis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe	28	77.8	2	7.1	14	87.5	3	21.4
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	9	32.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	3	37.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Skin and subcutaneous tissue disorders	Hair texture abnormal	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Surgical and medical procedures	Dental implantation	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Surgical and medical procedures	Dental implantation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Cardiac disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Ear and labyrinth disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Ear pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders		>Q3	20	55.6	3	15.0	10	62.5	2	20.0
Eye disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Eye disorders	Conjunctival haemorrhage	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Conjunctivitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Dry eye	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Dry eye	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Eye disorders	Dry eye	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Eye disorders	Eye pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Eye disorders	Eye pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Eye disorders	Ocular hyperaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Eye disorders	Ocular hyperaemia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	8	66.7	4	25.0	0	0.0
Gastrointestinal disorders		>Q3	20	55.6	8	40.0	10	62.5	3	30.0
Gastrointestinal disorders		Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Abdominal distension	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	20	55.6	1	5.0	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Gastrointestinal disorders	Abdominal pain upper	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	20	55.6	4	20.0	10	62.5	1	10.0
Gastrointestinal disorders	Diarrhoea	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Gastrointestinal disorders	Dyspepsia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faeces soft	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Faeces soft	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Nausea	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	20	55.6	1	5.0	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	Missing	1	2.8	1	100.0	1	6.3	1	100.0

General disorders and administration site conditions		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
General disorders and administration site conditions		>Q3	20	55.6	2	10.0	10	62.5	2	20.0
General disorders and administration site conditions		Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	>Q3	20	55.6	1	5.0	10	62.5	2	20.0
General disorders and administration site conditions	Pyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Immune system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Hypersensitivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Immune system disorders	Hypersensitivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations		>Q1 to <=Q3	12	33.3	8	66.7	4	25.0	4	100.0
Infections and infestations		>Q3	20	55.6	13	65.0	10	62.5	5	50.0
Infections and infestations		Missing	1	2.8	1	100.0	1	6.3	1	100.0
Infections and infestations	Bronchitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Infections and infestations	Bronchitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Furuncle	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Furuncle	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Furuncle	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	4	20.0	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Genital infection fungal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	>Q3	20	55.6	0	0.0	10	62.5	0	0.0

Infections and infestations	Genital infection fungal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gingivitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gingivitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Hordeolum	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Infections and infestations	Influenza	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Influenza	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	20	55.6	6	30.0	10	62.5	1	10.0
Infections and infestations	Nasopharyngitis	Missing	1	2.8	1	100.0	1	6.3	1	100.0
Infections and infestations	Otitis externa	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Otitis externa	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis media acute	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis media acute	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	>Q3	20	55.6	3	15.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Sinusitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Sinusitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Sinusitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Subcutaneous abscess	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tracheitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tracheitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	2	50.0
Infections and infestations	Upper respiratory tract infection	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Varicella	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	4	20.0	10	62.5	2	20.0

Injury, poisoning and procedural complications		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Contusion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Fall	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Muscle strain	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Muscle strain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Activated partial thromboplastin time shortened	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Blood bicarbonate decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Blood bicarbonate decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	C-reactive protein increased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	C-reactive protein increased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	6	30.0	10	62.5	2	20.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	>Q3	20	55.6	3	15.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	4	33.3	4	25.0	1	25.0
Nervous system disorders		>Q3	20	55.6	5	25.0	10	62.5	3	30.0
Nervous system disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Amnesia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Nervous system disorders	Amnesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Dizziness	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Dizziness postural	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	1	25.0
Nervous system disorders	Headache	>Q3	20	55.6	3	15.0	10	62.5	2	20.0
Nervous system disorders	Headache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Migraine	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Occipital neuralgia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Psychiatric disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0

Psychiatric disorders	Anxiety	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Psychiatric disorders	Anxiety	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Haematuria	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Renal cyst	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders		<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Reproductive system and breast disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	<=Q1	3	8.3	0	0.0	1	6.3	1	100.0
Reproductive system and breast disorders	Polycystic ovaries	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	2	50.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	4	20.0	10	62.5	3	30.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q3	20	55.6	3	15.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Cough	Missing	1	2.8	1	100.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	2	50.0

Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	2	66.7	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	7	35.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema	>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Papule	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoic dermatitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0

Skin and subcutaneous tissue disorders	Skin exfoliation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Surgical and medical procedures	Dental implantation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sq_AEG1_SE_P2_T3.xls
18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	1	5.9	8	50.0	1	12.5
Blood and lymphatic system disorders	Anaemia	Male	19	52.8	2	10.5	8	50.0	0	0.0
Blood and lymphatic system disorders	Anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Cardiac disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Male	19	52.8	0	0.0	8	50.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Female	17	47.2	1	5.9	8	50.0	0	0.0
Ear and labyrinth disorders		Male	19	52.8	2	10.5	8	50.0	0	0.0
Ear and labyrinth disorders		Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Ear pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Ear pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Ear and labyrinth disorders	Hypoacusis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders		Male	19	52.8	1	5.3	8	50.0	1	12.5
Eye disorders		Female	17	47.2	3	17.6	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Male	19	52.8	0	0.0	8	50.0	1	12.5
Eye disorders	Conjunctival haemorrhage	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Conjunctivitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Dry eye	Female	17	47.2	1	5.9	8	50.0	0	0.0
Eye disorders	Eye pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Eye disorders	Eye pain	Female	17	47.2	1	5.9	8	50.0	1	12.5
Eye disorders	Ocular hyperaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Eye disorders	Ocular hyperaemia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders		Male	19	52.8	10	52.6	8	50.0	1	12.5
Gastrointestinal disorders		Female	17	47.2	7	41.2	8	50.0	3	37.5
Gastrointestinal disorders	Abdominal distension	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal distension	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain	Female	17	47.2	4	23.5	8	50.0	1	12.5
Gastrointestinal disorders	Abdominal pain upper	Male	19	52.8	4	21.1	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	Female	17	47.2	1	5.9	8	50.0	1	12.5
Gastrointestinal disorders	Aphthous ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	3	15.8	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders	Diarrhoea	Male	19	52.8	6	31.6	8	50.0	1	12.5
Gastrointestinal disorders	Diarrhoea	Female	17	47.2	2	11.8	8	50.0	1	12.5
Gastrointestinal disorders	Dyspepsia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dyspepsia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Faeces soft	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Female	17	47.2	1	5.9	8	50.0	0	0.0

Gastrointestinal disorders	Nausea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Nausea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Toothache	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Toothache	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Vomiting	Male	19	52.8	3	15.8	8	50.0	1	12.5
Gastrointestinal disorders	Vomiting	Female	17	47.2	1	5.9	8	50.0	3	37.5
General disorders and administration site conditions		Male	19	52.8	4	21.1	8	50.0	2	25.0
General disorders and administration site conditions		Female	17	47.2	2	11.8	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Male	19	52.8	1	5.3	8	50.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Pyrexia	Male	19	52.8	2	10.5	8	50.0	2	25.0
General disorders and administration site conditions	Pyrexia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Immune system disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Immune system disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Hypersensitivity	Male	19	52.8	0	0.0	8	50.0	0	0.0
Immune system disorders	Hypersensitivity	Female	17	47.2	0	0.0	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Male	19	52.8	0	0.0	8	50.0	1	12.5
Immune system disorders	Seasonal allergy	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	13	68.4	8	50.0	4	50.0
Infections and infestations		Female	17	47.2	10	58.8	8	50.0	6	75.0
Infections and infestations	Bronchitis	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Bronchitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Furuncle	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Furuncle	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Male	19	52.8	3	15.8	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Female	17	47.2	3	17.6	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Gastrointestinal infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastrointestinal infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastrointestinal viral infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Genital infection fungal	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gingivitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gingivitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Hordeolum	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Hordeolum	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Influenza	Male	19	52.8	3	15.8	8	50.0	0	0.0
Infections and infestations	Influenza	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Nasopharyngitis	Male	19	52.8	4	21.1	8	50.0	0	0.0
Infections and infestations	Nasopharyngitis	Female	17	47.2	5	29.4	8	50.0	2	25.0
Infections and infestations	Otitis externa	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis externa	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Otitis media	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Otitis media acute	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis media acute	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Male	19	52.8	2	10.5	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Sinusitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Sinusitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Subcutaneous abscess	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Subcutaneous abscess	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tracheitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tracheitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Male	19	52.8	4	21.1	8	50.0	1	12.5
Infections and infestations	Upper respiratory tract infection	Female	17	47.2	3	17.6	8	50.0	1	12.5

Infections and infestations	Urinary tract infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Varicella	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Varicella	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral rhinitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	6	31.6	8	50.0	1	12.5
Injury, poisoning and procedural complications		Female	17	47.2	1	5.9	8	50.0	2	25.0
Injury, poisoning and procedural complications	Contusion	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Contusion	Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Fall	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Male	19	52.8	2	10.5	8	50.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Female	17	47.2	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Female	17	47.2	0	0.0	8	50.0	1	12.5
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Activated partial thromboplastin time shortened	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Blood bicarbonate decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Blood bicarbonate decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	C-reactive protein increased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	C-reactive protein increased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Metabolism and nutrition disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Male	19	52.8	1	5.3	8	50.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	3	15.8	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders		Female	17	47.2	4	23.5	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	17	47.2	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	19	52.8	1	5.3	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	17	47.2	2	11.8	8	50.0	0	0.0
Nervous system disorders		Male	19	52.8	7	36.8	8	50.0	2	25.0
Nervous system disorders		Female	17	47.2	4	23.5	8	50.0	2	25.0
Nervous system disorders	Amnesia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Nervous system disorders	Amnesia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Dizziness	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Dizziness	Female	17	47.2	1	5.9	8	50.0	0	0.0

Nervous system disorders	Dizziness postural	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Dizziness postural	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Headache	Male	19	52.8	4	21.1	8	50.0	1	12.5
Nervous system disorders	Headache	Female	17	47.2	2	11.8	8	50.0	2	25.0
Nervous system disorders	Migraine	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Migraine	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Occipital neuralgia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Psychiatric disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Psychiatric disorders	Anxiety	Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders	Anxiety	Female	17	47.2	0	0.0	8	50.0	1	12.5
Renal and urinary disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders		Female	17	47.2	2	11.8	8	50.0	0	0.0
Renal and urinary disorders	Haematuria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Haematuria	Female	17	47.2	2	11.8	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Renal cyst	Female	17	47.2	0	0.0	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Male	19	52.8	1	5.3	8	50.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Female	17	47.2	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders		Female	17	47.2	4	23.5	8	50.0	1	12.5
Reproductive system and breast disorders	Amenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Female	17	47.2	1	5.9	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Male	19	52.8	0	0.0	8	50.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	6	31.6	8	50.0	2	25.0
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	2	11.8	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Male	19	52.8	3	15.8	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Cough	Female	17	47.2	1	5.9	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	19	52.8	1	5.3	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	17	47.2	1	5.9	8	50.0	3	37.5
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	6	31.6	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	6	35.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Female	17	47.2	2	11.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Female	17	47.2	0	0.0	8	50.0	0	0.0

Skin and subcutaneous tissue disorders	Hair texture abnormal	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Surgical and medical procedures		Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures		Female	17	47.2	0	0.0	8	50.0	1	12.5
Surgical and medical procedures	Dental implantation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Surgical and medical procedures	Dental implantation	Female	17	47.2	0	0.0	8	50.0	1	12.5

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	3	8.3	16	100.0	1	6.3
Blood and lymphatic system disorders	Anaemia	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Cardiac disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		Type III	36	100.0	3	8.3	16	100.0	1	6.3
Ear and labyrinth disorders	Ear pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Ear and labyrinth disorders	Hypoacusis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders		Type III	36	100.0	4	11.1	16	100.0	2	12.5
Eye disorders	Conjunctival haemorrhage	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Eye disorders	Conjunctivitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Dry eye	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Eye disorders	Eye pain	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Eye disorders	Ocular hyperaemia	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders		Type III	36	100.0	17	47.2	16	100.0	4	25.0
Gastrointestinal disorders	Abdominal distension	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Type III	36	100.0	5	13.9	16	100.0	2	12.5
Gastrointestinal disorders	Abdominal pain upper	Type III	36	100.0	5	13.9	16	100.0	1	6.3
Gastrointestinal disorders	Aphthous ulcer	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Gastrointestinal disorders	Diarrhoea	Type III	36	100.0	8	22.2	16	100.0	2	12.5
Gastrointestinal disorders	Dyspepsia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Faeces soft	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Nausea	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Vomiting	Type III	36	100.0	4	11.1	16	100.0	4	25.0
General disorders and administration site conditions		Type III	36	100.0	6	16.7	16	100.0	2	12.5
General disorders and administration site conditions	Feeling abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	Type III	36	100.0	3	8.3	16	100.0	2	12.5
Immune system disorders		Type III	36	100.0	0	0.0	16	100.0	2	12.5
Immune system disorders	Hypersensitivity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Immune system disorders	Seasonal allergy	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations		Type III	36	100.0	23	63.9	16	100.0	10	62.5
Infections and infestations	Bronchitis	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Infections and infestations	Furuncle	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	Type III	36	100.0	6	16.7	16	100.0	1	6.3
Infections and infestations	Gastroenteritis viral	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Genital infection fungal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gingivitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Hordeolum	Type III	36	100.0	0	0.0	16	100.0	1	6.3

Infections and infestations	Influenza	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Infections and infestations	Nasopharyngitis	Type III	36	100.0	9	25.0	16	100.0	2	12.5
Infections and infestations	Otitis externa	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Otitis media	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Otitis media acute	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Infections and infestations	Sinusitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Subcutaneous abscess	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Tracheitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Type III	36	100.0	7	19.4	16	100.0	2	12.5
Infections and infestations	Urinary tract infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Varicella	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Viral rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	7	19.4	16	100.0	3	18.8
Injury, poisoning and procedural complications	Contusion	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Injury, poisoning and procedural complications	Fall	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Activated partial thromboplastin time shortened	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Blood bicarbonate decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	C-reactive protein increased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		Type III	36	100.0	7	19.4	16	100.0	2	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Type III	36	100.0	3	8.3	16	100.0	1	6.3
Nervous system disorders		Type III	36	100.0	11	30.6	16	100.0	4	25.0
Nervous system disorders	Amnesia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Nervous system disorders	Dizziness	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Dizziness postural	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Headache	Type III	36	100.0	6	16.7	16	100.0	3	18.8
Nervous system disorders	Migraine	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Occipital neuralgia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Paraesthesia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Psychiatric disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Psychiatric disorders	Anxiety	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Renal and urinary disorders		Type III	36	100.0	3	8.3	16	100.0	0	0.0
Renal and urinary disorders	Haematuria	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Renal and urinary disorders	Renal cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders		Type III	36	100.0	4	11.1	16	100.0	1	6.3
Reproductive system and breast disorders	Amenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Type III	36	100.0	0	0.0	16	100.0	1	6.3

Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	8	22.2	16	100.0	5	31.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Type III	36	100.0	4	11.1	16	100.0	2	12.5
Respiratory, thoracic and mediastinal disorders	Epistaxis	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Type III	36	100.0	2	5.6	16	100.0	4	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		Type III	36	100.0	12	33.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrheic dermatitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Surgical and medical procedures		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Surgical and medical procedures	Dental implantation	Type III	36	100.0	0	0.0	16	100.0	1	6.3

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders		3	24	66.7	3	12.5	10	62.5	1	10.0
Blood and lymphatic system disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Anaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Anaemia	3	24	66.7	3	12.5	10	62.5	0	0.0
Blood and lymphatic system disorders	Anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	2	2	5.6	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	3	24	66.7	0	0.0	10	62.5	1	10.0
Blood and lymphatic system disorders	Thrombocytopenia	4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	2	2	5.6	0	0.0	0	0.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	3	24	66.7	1	4.2	10	62.5	0	0.0
Cardiac disorders	Atrioventricular block first degree	4	10	27.8	0	0.0	6	37.5	0	0.0
Ear and labyrinth disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders		3	24	66.7	1	4.2	10	62.5	1	10.0
Ear and labyrinth disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Ear pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Ear pain	3	24	66.7	0	0.0	10	62.5	1	10.0
Ear and labyrinth disorders	Ear pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	2	2	5.6	0	0.0	0	0.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	3	24	66.7	1	4.2	10	62.5	0	0.0
Ear and labyrinth disorders	Hypoacusis	4	10	27.8	0	0.0	6	37.5	0	0.0
Eye disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders		3	24	66.7	1	4.2	10	62.5	1	10.0
Eye disorders		4	10	27.8	3	30.0	6	37.5	1	16.7
Eye disorders	Conjunctival haemorrhage	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctival haemorrhage	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctival haemorrhage	4	10	27.8	0	0.0	6	37.5	1	16.7
Eye disorders	Conjunctivitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Conjunctivitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Conjunctivitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Dry eye	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Dry eye	3	24	66.7	0	0.0	10	62.5	0	0.0
Eye disorders	Dry eye	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Eye pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Eye pain	3	24	66.7	1	4.2	10	62.5	1	10.0
Eye disorders	Eye pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Eye disorders	Ocular hyperaemia	2	2	5.6	0	0.0	0	0.0	0	0.0
Eye disorders	Ocular hyperaemia	3	24	66.7	1	4.2	10	62.5	0	0.0
Eye disorders	Ocular hyperaemia	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders		3	24	66.7	10	41.7	10	62.5	3	30.0
Gastrointestinal disorders		4	10	27.8	6	60.0	6	37.5	1	16.7
Gastrointestinal disorders	Abdominal distension	2	2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal distension	3	24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal distension	4	10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain	2	2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Abdominal pain	3	24	66.7	2	8.3	10	62.5	2	20.0
Gastrointestinal disorders	Abdominal pain	4	10	27.8	2	20.0	6	37.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	2	2	5.6	0	0.0	0	0.0	0	0.0

Gastrointestinal disorders	Abdominal pain upper	3		24	66.7	2	8.3	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal pain upper	4		10	27.8	3	30.0	6	37.5	1	16.7
Gastrointestinal disorders	Aphthous ulcer	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Aphthous ulcer	4		10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Constipation	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Constipation	3		24	66.7	2	8.3	10	62.5	1	10.0
Gastrointestinal disorders	Constipation	4		10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Diarrhoea	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Diarrhoea	3		24	66.7	4	16.7	10	62.5	2	20.0
Gastrointestinal disorders	Diarrhoea	4		10	27.8	4	40.0	6	37.5	0	0.0
Gastrointestinal disorders	Dyspepsia	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Dyspepsia	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Dyspepsia	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Faeces soft	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Faeces soft	3		24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faeces soft	4		10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Flatulence	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Flatulence	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Gastroesophageal reflux disease	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Mouth ulceration	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Nausea	2		2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Nausea	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Nausea	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	3		24	66.7	1	4.2	10	62.5	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	4		10	27.8	0	0.0	6	37.5	0	0.0
Gastrointestinal disorders	Toothache	2		2	5.6	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders	Toothache	3		24	66.7	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	4		10	27.8	1	10.0	6	37.5	0	0.0
Gastrointestinal disorders	Vomiting	2		2	5.6	1	50.0	0	0.0	0	0.0
Gastrointestinal disorders	Vomiting	3		24	66.7	2	8.3	10	62.5	3	30.0
Gastrointestinal disorders	Vomiting	4		10	27.8	1	10.0	6	37.5	1	16.7
General disorders and administration site conditions		2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions		3		24	66.7	3	12.5	10	62.5	1	10.0
General disorders and administration site conditions		4		10	27.8	3	30.0	6	37.5	1	16.7
General disorders and administration site conditions	Feeling abnormal	2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	3		24	66.7	1	4.2	10	62.5	0	0.0
General disorders and administration site conditions	Feeling abnormal	4		10	27.8	0	0.0	6	37.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	3		24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Hyperpyrexia	4		10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Influenza like illness	2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Influenza like illness	3		24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Influenza like illness	4		10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	3		24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Physical deconditioning	4		10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Pyrexia	2		2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Pyrexia	3		24	66.7	2	8.3	10	62.5	1	10.0
General disorders and administration site conditions	Pyrexia	4		10	27.8	1	10.0	6	37.5	1	16.7
Immune system disorders		2		2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders		3		24	66.7	0	0.0	10	62.5	2	20.0
Immune system disorders		4		10	27.8	0	0.0	6	37.5	0	0.0
Immune system disorders	Hypersensitivity	2		2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Hypersensitivity	3		24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Hypersensitivity	4		10	27.8	0	0.0	6	37.5	0	0.0
Immune system disorders	Seasonal allergy	2		2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Seasonal allergy	3		24	66.7	0	0.0	10	62.5	1	10.0
Immune system disorders	Seasonal allergy	4		10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations		2		2	5.6	1	50.0	0	0.0	0	0.0

Infections and infestations		3	24	66.7	15	62.5	10	62.5	7	70.0
Infections and infestations		4	10	27.8	7	70.0	6	37.5	3	50.0
Infections and infestations	Bronchitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Bronchitis	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Bronchitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Furuncle	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Furuncle	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Furuncle	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis	3	24	66.7	4	16.7	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	4	10	27.8	2	20.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis viral	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis viral	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal infection	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gastrointestinal infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Gastrointestinal viral infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastrointestinal viral infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Genital infection fungal	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Genital infection fungal	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Genital infection fungal	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gingivitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gingivitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gingivitis	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Hordeolum	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hordeolum	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Hordeolum	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Influenza	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Influenza	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Influenza	4	10	27.8	2	20.0	6	37.5	0	0.0
Infections and infestations	Nasopharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Nasopharyngitis	3	24	66.7	5	20.8	10	62.5	1	10.0
Infections and infestations	Nasopharyngitis	4	10	27.8	4	40.0	6	37.5	1	16.7
Infections and infestations	Otitis externa	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis externa	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis externa	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Otitis media	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Otitis media	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Otitis media acute	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis media acute	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Otitis media acute	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis	3	24	66.7	2	8.3	10	62.5	1	10.0
Infections and infestations	Pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Sinusitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Sinusitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Sinusitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Subcutaneous abscess	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Subcutaneous abscess	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Subcutaneous abscess	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Tracheitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Tracheitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Tracheitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Upper respiratory tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection	3	24	66.7	5	20.8	10	62.5	1	10.0
Infections and infestations	Upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	1	16.7
Infections and infestations	Urinary tract infection	2	2	5.6	1	50.0	0	0.0	0	0.0
Infections and infestations	Urinary tract infection	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Varicella	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Varicella	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Varicella	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Viral rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral rhinitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Viral rhinitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0

Infections and infestations	Viral upper respiratory tract infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications		2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications		3	24	66.7	2	8.3	10	62.5	2	20.0
Injury, poisoning and procedural complications		4	10	27.8	4	40.0	6	37.5	1	16.7
Injury, poisoning and procedural complications	Contusion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Contusion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Contusion	4	10	27.8	1	10.0	6	37.5	1	16.7
Injury, poisoning and procedural complications	Fall	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Fall	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Fall	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint injury	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Limb injury	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Muscle strain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Muscle strain	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	3	24	66.7	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Tooth fracture	4	10	27.8	0	0.0	6	37.5	0	0.0
Investigations		2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations		3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations		4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Activated partial thromboplastin time shortened	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Activated partial thromboplastin time shortened	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	Blood bicarbonate decreased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Blood bicarbonate decreased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	Blood bicarbonate decreased	4	10	27.8	0	0.0	6	37.5	1	16.7
Investigations	C-reactive protein increased	2	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	C-reactive protein increased	3	24	66.7	0	0.0	10	62.5	0	0.0
Investigations	C-reactive protein increased	4	10	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Dehydration	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Dehydration	3	24	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Dehydration	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	24	66.7	5	20.8	10	62.5	2	20.0
Musculoskeletal and connective tissue disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	4	10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	4	10	27.8	0	0.0	6	37.5	0	0.0

Musculoskeletal and connective tissue disorders	Limb discomfort	2		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	3		24	66.7	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Limb discomfort	4		10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	3		24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	4		10	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	2		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	3		24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	4		10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	2		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	3		24	66.7	2	8.3	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Pain in extremity	4		10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders		3		24	66.7	7	29.2	10	62.5	2	20.0
Nervous system disorders		4		10	27.8	4	40.0	6	37.5	2	33.3
Nervous system disorders	Amnesia	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Amnesia	3		24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Amnesia	4		10	27.8	0	0.0	6	37.5	1	16.7
Nervous system disorders	Dizziness	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness	3		24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness	4		10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Dizziness postural	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Dizziness postural	3		24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Dizziness postural	4		10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Headache	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Headache	3		24	66.7	5	20.8	10	62.5	2	20.0
Nervous system disorders	Headache	4		10	27.8	1	10.0	6	37.5	1	16.7
Nervous system disorders	Migraine	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Migraine	3		24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Migraine	4		10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Occipital neuralgia	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Occipital neuralgia	3		24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Occipital neuralgia	4		10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Paraesthesia	2		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Paraesthesia	3		24	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	4		10	27.8	1	10.0	6	37.5	0	0.0
Psychiatric disorders		2		2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders		3		24	66.7	0	0.0	10	62.5	1	10.0
Psychiatric disorders		4		10	27.8	0	0.0	6	37.5	0	0.0
Psychiatric disorders	Anxiety	2		2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders	Anxiety	3		24	66.7	0	0.0	10	62.5	1	10.0
Psychiatric disorders	Anxiety	4		10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders		2		2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders		3		24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders		4		10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Haematuria	2		2	5.6	0	0.0	0	0.0	0	0.0
Renal and urinary disorders	Haematuria	3		24	66.7	2	8.3	10	62.5	0	0.0
Renal and urinary disorders	Haematuria	4		10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Renal cyst	2		2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Renal cyst	3		24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Renal cyst	4		10	27.8	0	0.0	6	37.5	0	0.0
Renal and urinary disorders	Urinary incontinence	2		2	5.6	1	50.0	0	0.0	0	0.0
Renal and urinary disorders	Urinary incontinence	3		24	66.7	0	0.0	10	62.5	0	0.0
Renal and urinary disorders	Urinary incontinence	4		10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders		2		2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders		3		24	66.7	3	12.5	10	62.5	1	10.0
Reproductive system and breast disorders		4		10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	2		2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	3		24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Amenorrhoea	4		10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	2		2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	3		24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	4		10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Menstrual disorder	2		2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	3		24	66.7	1	4.2	10	62.5	0	0.0

Reproductive system and breast disorders	Menstrual disorder	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	3	24	66.7	1	4.2	10	62.5	0	0.0
Reproductive system and breast disorders	Metrorrhagia	4	10	27.8	0	0.0	6	37.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	3	24	66.7	0	0.0	10	62.5	0	0.0
Reproductive system and breast disorders	Ovarian cyst	4	10	27.8	1	10.0	6	37.5	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	2	2	5.6	0	0.0	0	0.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	3	24	66.7	0	0.0	10	62.5	1	10.0
Reproductive system and breast disorders	Polycystic ovaries	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	24	66.7	4	16.7	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders		4	10	27.8	3	30.0	6	37.5	3	50.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	3	24	66.7	1	4.2	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	3	24	66.7	2	8.3	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	4	10	27.8	2	20.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	2	5.6	1	50.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	3	24	66.7	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	24	66.7	1	4.2	10	62.5	2	20.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	4	10	27.8	1	10.0	6	37.5	2	33.3
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	24	66.7	9	37.5	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		4	10	27.8	2	20.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	3	24	66.7	2	8.3	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Erythema	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Papule	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	4	10	27.8	0	0.0	6	37.5	0	0.0

Skin and subcutaneous tissue disorders	Seborrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures		2	2	5.6	0	0.0	0	0.0	0	0.0
Surgical and medical procedures		3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures		4	10	27.8	0	0.0	6	37.5	0	0.0
Surgical and medical procedures	Dental implantation	2	2	5.6	0	0.0	0	0.0	0	0.0
Surgical and medical procedures	Dental implantation	3	24	66.7	0	0.0	10	62.5	1	10.0
Surgical and medical procedures	Dental implantation	4	10	27.8	0	0.0	6	37.5	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_AEG1_SE_P2_T3.xls

18DEC2020 9:47

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 1 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Blood and lymphatic system disorders	Anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Anaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Cardiac disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Cardiac disorders	Atrioventricular block first degree	No	29	80.6	1	3.4	12	75.0	0	0.0
Ear and labyrinth disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders		No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Ear pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Ear pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Ear and labyrinth disorders	Hypoacusis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Hypoacusis	No	29	80.6	0	0.0	12	75.0	0	0.0
Eye disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders		No	29	80.6	4	13.8	12	75.0	2	16.7
Eye disorders	Conjunctival haemorrhage	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctival haemorrhage	No	29	80.6	0	0.0	12	75.0	1	8.3
Eye disorders	Conjunctivitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Conjunctivitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Dry eye	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Dry eye	No	29	80.6	1	3.4	12	75.0	0	0.0
Eye disorders	Eye pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Eye pain	No	29	80.6	2	6.9	12	75.0	1	8.3
Eye disorders	Ocular hyperaemia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Eye disorders	Ocular hyperaemia	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders		Yes	7	19.4	3	42.9	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	14	48.3	12	75.0	4	33.3
Gastrointestinal disorders	Abdominal distension	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal distension	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	No	29	80.6	4	13.8	12	75.0	2	16.7
Gastrointestinal disorders	Abdominal pain upper	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain upper	No	29	80.6	4	13.8	12	75.0	1	8.3
Gastrointestinal disorders	Aphthous ulcer	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Aphthous ulcer	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	2	6.9	12	75.0	1	8.3
Gastrointestinal disorders	Diarrhoea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	No	29	80.6	7	24.1	12	75.0	2	16.7
Gastrointestinal disorders	Dyspepsia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Dyspepsia	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Faeces soft	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faeces soft	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Flatulence	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Gastrooesophageal reflux disease	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Gastrooesophageal reflux disease	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Mouth ulceration	No	29	80.6	1	3.4	12	75.0	0	0.0

Gastrointestinal disorders	Nausea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Nausea	No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Noninfective sialoadenitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Toothache	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Vomiting	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	No	29	80.6	3	10.3	12	75.0	4	33.3
General disorders and administration site conditions		Yes	7	19.4	2	28.6	4	25.0	0	0.0
General disorders and administration site conditions		No	29	80.6	4	13.8	12	75.0	2	16.7
General disorders and administration site conditions	Feeling abnormal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Feeling abnormal	No	29	80.6	0	0.0	12	75.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Hyperpyrexia	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Influenza like illness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Influenza like illness	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Physical deconditioning	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Pyrexia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	No	29	80.6	2	6.9	12	75.0	2	16.7
Immune system disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Immune system disorders	Hypersensitivity	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Immune system disorders	Hypersensitivity	No	29	80.6	0	0.0	12	75.0	0	0.0
Immune system disorders	Seasonal allergy	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations		Yes	7	19.4	5	71.4	4	25.0	3	75.0
Infections and infestations		No	29	80.6	18	62.1	12	75.0	7	58.3
Infections and infestations	Bronchitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations	Furuncle	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Furuncle	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gastroenteritis	Yes	7	19.4	2	28.6	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	4	13.8	12	75.0	1	8.3
Infections and infestations	Gastroenteritis viral	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastrointestinal infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastrointestinal viral infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Genital infection fungal	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Genital infection fungal	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gingivitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gingivitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Hordeolum	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Influenza	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Influenza	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Nasopharyngitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	No	29	80.6	8	27.6	12	75.0	2	16.7
Infections and infestations	Otitis externa	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Otitis media	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Otitis media	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Otitis media acute	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Otitis media acute	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Pharyngitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Pharyngitis	No	29	80.6	3	10.3	12	75.0	0	0.0
Infections and infestations	Sinusitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Sinusitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Subcutaneous abscess	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Subcutaneous abscess	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Tracheitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tracheitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Yes	7	19.4	2	28.6	4	25.0	1	25.0
Infections and infestations	Upper respiratory tract infection	No	29	80.6	5	17.2	12	75.0	1	8.3

Infections and infestations	Urinary tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Varicella	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Viral rhinitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Viral rhinitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	1	14.3	4	25.0	1	25.0
Injury, poisoning and procedural complications		No	29	80.6	6	20.7	12	75.0	2	16.7
Injury, poisoning and procedural complications	Contusion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Contusion	No	29	80.6	1	3.4	12	75.0	1	8.3
Injury, poisoning and procedural complications	Fall	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Fall	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint injury	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Ligament sprain	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Limb injury	No	29	80.6	2	6.9	12	75.0	0	0.0
Injury, poisoning and procedural complications	Muscle strain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Muscle strain	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Tooth fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Activated partial thromboplastin time shortened	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Activated partial thromboplastin time shortened	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Blood bicarbonate decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Blood bicarbonate decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	C-reactive protein increased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	C-reactive protein increased	No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders	Dehydration	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Dehydration	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	6	20.7	12	75.0	2	16.7
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Exostosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Haemarthrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Joint instability	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Limb discomfort	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Myalgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Pain in extremity	No	29	80.6	3	10.3	12	75.0	1	8.3
Nervous system disorders		Yes	7	19.4	4	57.1	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	7	24.1	12	75.0	4	33.3
Nervous system disorders	Amnesia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Amnesia	No	29	80.6	0	0.0	12	75.0	1	8.3
Nervous system disorders	Dizziness	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Dizziness	No	29	80.6	1	3.4	12	75.0	0	0.0

Nervous system disorders	Dizziness postural	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Dizziness postural	No	29	80.6	0	0.0	12	75.0	0	0.0
Nervous system disorders	Headache	Yes	7	19.4	3	42.9	4	25.0	0	0.0
Nervous system disorders	Headache	No	29	80.6	3	10.3	12	75.0	3	25.0
Nervous system disorders	Migraine	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Migraine	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Occipital neuralgia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Occipital neuralgia	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Paraesthesia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	No	29	80.6	1	3.4	12	75.0	0	0.0
Psychiatric disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Psychiatric disorders	Anxiety	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	No	29	80.6	0	0.0	12	75.0	1	8.3
Renal and urinary disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Renal and urinary disorders	Haematuria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Renal and urinary disorders	Haematuria	No	29	80.6	2	6.9	12	75.0	0	0.0
Renal and urinary disorders	Renal cyst	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Renal cyst	No	29	80.6	0	0.0	12	75.0	0	0.0
Renal and urinary disorders	Urinary incontinence	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Renal and urinary disorders	Urinary incontinence	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders		Yes	7	19.4	1	14.3	4	25.0	1	25.0
Reproductive system and breast disorders		No	29	80.6	3	10.3	12	75.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Amenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Dysmenorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Menstrual disorder	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Reproductive system and breast disorders	Metrorrhagia	No	29	80.6	0	0.0	12	75.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Reproductive system and breast disorders	Ovarian cyst	No	29	80.6	1	3.4	12	75.0	0	0.0
Reproductive system and breast disorders	Polycystic ovaries	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Reproductive system and breast disorders	Polycystic ovaries	No	29	80.6	0	0.0	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	8	27.6	12	75.0	4	33.3
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	No	29	80.6	4	13.8	12	75.0	2	16.7
Respiratory, thoracic and mediastinal disorders	Epistaxis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Epistaxis	No	29	80.6	1	3.4	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	No	29	80.6	2	6.9	12	75.0	3	25.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders		Yes	7	19.4	3	42.9	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	9	31.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis allergic	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dry skin	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Ecchymosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema	No	29	80.6	2	6.9	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Erythema	No	29	80.6	0	0.0	12	75.0	0	0.0

Skin and subcutaneous tissue disorders	Hair texture abnormal	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Hair texture abnormal	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Papule	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash maculo-papular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoea	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Skin exfoliation	No	29	80.6	1	3.4	12	75.0	0	0.0
Surgical and medical procedures		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures		No	29	80.6	0	0.0	12	75.0	1	8.3
Surgical and medical procedures	Dental implantation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Surgical and medical procedures	Dental implantation	No	29	80.6	0	0.0	12	75.0	1	8.3

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG1_SE_P2_T3.xls
18DEC2020 9:47

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders		6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders		12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders		18 to 25 years	4	26.7	1	25.0
Gastrointestinal disorders	Toothache	2 to 5 years	3	20.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions		2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions		6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions		12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions		18 to 25 years	4	26.7	1	25.0
General disorders and administration site conditions	Malaise	2 to 5 years	3	20.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	4	26.7	1	25.0
Infections and infestations		2 to 5 years	3	20.0	1	33.3
Infections and infestations		6 to 11 years	4	26.7	0	0.0
Infections and infestations		12 to 17 years	4	26.7	1	25.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	3	20.0	0	0.0
Infections and infestations	Bronchitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Bronchitis	12 to 17 years	4	26.7	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Nasopharyngitis	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	3	20.0	1	33.3
Musculoskeletal and connective tissue disorders		6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	3	20.0	1	33.3

Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	4	26.7	1	25.0
Skin and subcutaneous tissue disorders		2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders		6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	3	20.0	1	33.3
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	4	26.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_OLE_SW_T3.xls

08MAR2021 13:04

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		n/a	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	n/a	15	100.0	1	6.7
General disorders and administration site conditions		n/a	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	n/a	15	100.0	1	6.7
Infections and infestations		n/a	15	100.0	2	13.3
Infections and infestations	Bronchitis	n/a	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		n/a	15	100.0	2	13.3
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	n/a	15	100.0	1	6.7
Skin and subcutaneous tissue disorders		n/a	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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 08MAR2021 13:04

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		White	12	80.0	1	8.3
Gastrointestinal disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders		Unknown	2	13.3	0	0.0
Gastrointestinal disorders	Toothache	White	12	80.0	1	8.3
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Unknown	2	13.3	0	0.0
General disorders and administration site conditions		White	12	80.0	1	8.3
General disorders and administration site conditions		Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions		Unknown	2	13.3	0	0.0
General disorders and administration site conditions	Malaise	White	12	80.0	1	8.3
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Unknown	2	13.3	0	0.0
Infections and infestations		White	12	80.0	1	8.3
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations		Unknown	2	13.3	0	0.0
Infections and infestations	Bronchitis	White	12	80.0	1	8.3
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Bronchitis	Unknown	2	13.3	0	0.0
Infections and infestations	Nasopharyngitis	White	12	80.0	0	0.0
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	1	6.7	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders		White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	12	80.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders		White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0

Skin and subcutaneous tissue disorders		Unknown	2	13.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	12	80.0	1	8.3
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	2	13.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

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 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Europe	14	93.3	1	7.1
Gastrointestinal disorders		Rest of the World	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	Europe	14	93.3	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions		Europe	14	93.3	1	7.1
General disorders and administration site conditions		Rest of the World	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	Europe	14	93.3	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	1	6.7	0	0.0
Infections and infestations		Europe	14	93.3	1	7.1
Infections and infestations		Rest of the World	1	6.7	1	100.0
Infections and infestations	Bronchitis	Europe	14	93.3	1	7.1
Infections and infestations	Bronchitis	Rest of the World	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	Europe	14	93.3	0	0.0
Infections and infestations	Nasopharyngitis	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders		Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders		Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	14	93.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	1	6.7	1	100.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	14	93.3	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	1	6.7	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

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 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		<=Q1	1	6.7	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders		>Q3	9	60.0	0	0.0
Gastrointestinal disorders		Missing	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	<=Q1	1	6.7	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	4	26.7	1	25.0
Gastrointestinal disorders	Toothache	>Q3	9	60.0	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	6.7	0	0.0
General disorders and administration site conditions		<=Q1	1	6.7	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions		>Q3	9	60.0	1	11.1
General disorders and administration site conditions		Missing	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	1	6.7	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	>Q3	9	60.0	1	11.1
General disorders and administration site conditions	Malaise	Missing	1	6.7	0	0.0
Infections and infestations		<=Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations		>Q3	9	60.0	1	11.1
Infections and infestations		Missing	1	6.7	0	0.0
Infections and infestations	Bronchitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	4	26.7	1	25.0
Infections and infestations	Bronchitis	>Q3	9	60.0	0	0.0
Infections and infestations	Bronchitis	Missing	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	1	6.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	9	60.0	1	11.1
Infections and infestations	Nasopharyngitis	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	9	60.0	2	22.2
Musculoskeletal and connective tissue disorders		Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	1	6.7	0	0.0

Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		>Q3	9	60.0	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	6.7	1	100.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	1	6.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	9	60.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Missing	1	6.7	1	100.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

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 Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Male	8	53.3	1	12.5
Gastrointestinal disorders		Female	7	46.7	0	0.0
Gastrointestinal disorders	Toothache	Male	8	53.3	1	12.5
Gastrointestinal disorders	Toothache	Female	7	46.7	0	0.0
General disorders and administration site conditions		Male	8	53.3	1	12.5
General disorders and administration site conditions		Female	7	46.7	0	0.0
General disorders and administration site conditions	Malaise	Male	8	53.3	1	12.5
General disorders and administration site conditions	Malaise	Female	7	46.7	0	0.0
Infections and infestations		Male	8	53.3	1	12.5
Infections and infestations		Female	7	46.7	1	14.3
Infections and infestations	Bronchitis	Male	8	53.3	0	0.0
Infections and infestations	Bronchitis	Female	7	46.7	1	14.3
Infections and infestations	Nasopharyngitis	Male	8	53.3	1	12.5
Infections and infestations	Nasopharyngitis	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders		Male	8	53.3	2	25.0
Musculoskeletal and connective tissue disorders		Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	7	46.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	8	53.3	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	7	46.7	0	0.0
Skin and subcutaneous tissue disorders		Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders		Female	7	46.7	1	14.3
Skin and subcutaneous tissue disorders	Urticaria	Male	8	53.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	7	46.7	1	14.3

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 Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Type III	15	100.0	1	6.7
Gastrointestinal disorders	Toothache	Type III	15	100.0	1	6.7
General disorders and administration site conditions		Type III	15	100.0	1	6.7
General disorders and administration site conditions	Malaise	Type III	15	100.0	1	6.7
Infections and infestations		Type III	15	100.0	2	13.3
Infections and infestations	Bronchitis	Type III	15	100.0	1	6.7
Infections and infestations	Nasopharyngitis	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders		Type III	15	100.0	2	13.3
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	15	100.0	1	6.7
Musculoskeletal and connective tissue disorders	Back pain	Type III	15	100.0	1	6.7
Skin and subcutaneous tissue disorders		Type III	15	100.0	1	6.7
Skin and subcutaneous tissue disorders	Urticaria	Type III	15	100.0	1	6.7

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 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		3	10	66.7	0	0.0
Gastrointestinal disorders		4	5	33.3	1	20.0
Gastrointestinal disorders	Toothache	3	10	66.7	0	0.0
Gastrointestinal disorders	Toothache	4	5	33.3	1	20.0
General disorders and administration site conditions		3	10	66.7	0	0.0
General disorders and administration site conditions		4	5	33.3	1	20.0
General disorders and administration site conditions	Malaise	3	10	66.7	0	0.0
General disorders and administration site conditions	Malaise	4	5	33.3	1	20.0
Infections and infestations		3	10	66.7	1	10.0
Infections and infestations		4	5	33.3	1	20.0
Infections and infestations	Bronchitis	3	10	66.7	1	10.0
Infections and infestations	Bronchitis	4	5	33.3	0	0.0
Infections and infestations	Nasopharyngitis	3	10	66.7	0	0.0
Infections and infestations	Nasopharyngitis	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders		3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders		4	5	33.3	2	40.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Back pain	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	5	33.3	1	20.0
Skin and subcutaneous tissue disorders		3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders		4	5	33.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	10	66.7	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	5	33.3	0	0.0

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 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Gastrointestinal disorders		Yes	4	26.7	0	0.0
Gastrointestinal disorders		No	11	73.3	1	9.1
Gastrointestinal disorders	Toothache	Yes	4	26.7	0	0.0
Gastrointestinal disorders	Toothache	No	11	73.3	1	9.1
General disorders and administration site conditions		Yes	4	26.7	0	0.0
General disorders and administration site conditions		No	11	73.3	1	9.1
General disorders and administration site conditions	Malaise	Yes	4	26.7	0	0.0
General disorders and administration site conditions	Malaise	No	11	73.3	1	9.1
Infections and infestations		Yes	4	26.7	1	25.0
Infections and infestations		No	11	73.3	1	9.1
Infections and infestations	Bronchitis	Yes	4	26.7	1	25.0
Infections and infestations	Bronchitis	No	11	73.3	0	0.0
Infections and infestations	Nasopharyngitis	Yes	4	26.7	0	0.0
Infections and infestations	Nasopharyngitis	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders		Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		No	11	73.3	2	18.2
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Back pain	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	11	73.3	1	9.1
Skin and subcutaneous tissue disorders		Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders		No	11	73.3	1	9.1
Skin and subcutaneous tissue disorders	Urticaria	Yes	4	26.7	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	11	73.3	1	9.1

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
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 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Endocrine disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Gastrointestinal disorders		12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	1	16.7	4	25.0	1	25.0
Gastrointestinal disorders	Abdominal discomfort	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	18 to 25 years	6	16.7	1	16.7	4	25.0	0	0.0

Gastrointestinal disorders	Toothache	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Gastrointestinal disorders	Vomiting	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
General disorders and administration site conditions		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
General disorders and administration site conditions		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Malaise	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
General disorders and administration site conditions	Medical device pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Immune system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Immune system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	1	25.0	4	25.0	3	75.0
Infections and infestations		6 to 11 years	11	30.6	8	72.7	4	25.0	1	25.0
Infections and infestations		12 to 17 years	15	41.7	7	46.7	4	25.0	2	50.0
Infections and infestations		18 to 25 years	6	16.7	2	33.3	4	25.0	2	50.0
Infections and infestations	Adenoiditis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Adenoiditis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Bronchitis	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Bronchitis	12 to 17 years	15	41.7	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Folliculitis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Folliculitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Hordeolum	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Hordeolum	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Injury, poisoning and procedural complications		12 to 17 years	15	41.7	3	20.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Scoliosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	6 to 11 years	11	30.6	2	18.2	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Scoliosis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Nervous system disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Nervous system disorders	Headache	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Headache	6 to 11 years	11	30.6	3	27.3	4	25.0	0	0.0
Nervous system disorders	Headache	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Headache	18 to 25 years	6	16.7	2	33.3	4	25.0	1	25.0
Nervous system disorders	Paraesthesia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Psychiatric disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Psychiatric disorders	Anxiety	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Skin and subcutaneous tissue disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	15	41.7	4	26.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Skin and subcutaneous tissue disorders	Urticaria	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Vascular disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Vascular disorders	Varicose vein	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_T3.xls
18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders		n/a	36	100.0	8	22.2	16	100.0	1	6.3
Gastrointestinal disorders	Abdominal discomfort	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Diarrhoea	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions		n/a	36	100.0	4	11.1	16	100.0	1	6.3
General disorders and administration site conditions	Malaise	n/a	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	n/a	36	100.0	4	11.1	16	100.0	0	0.0
Immune system disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Immune system disorders	Seasonal allergy	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		n/a	36	100.0	18	50.0	16	100.0	8	50.0
Infections and infestations	Adenoiditis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	n/a	36	100.0	1	2.8	16	100.0	2	12.5
Infections and infestations	Folliculitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Fungal skin infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis viral	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Influenza	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Infections and infestations	Otitis externa	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	n/a	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tonsillitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	n/a	36	100.0	7	19.4	16	100.0	3	18.8
Infections and infestations	Upper respiratory tract infection bacterial	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Varicella	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral pharyngitis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	n/a	36	100.0	3	8.3	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	5	13.9	16	100.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Injury, poisoning and procedural complications	Incision site inflammation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		n/a	36	100.0	3	8.3	16	100.0	3	18.8
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		n/a	36	100.0	7	19.4	16	100.0	1	6.3
Nervous system disorders	Headache	n/a	36	100.0	6	16.7	16	100.0	1	6.3
Nervous system disorders	Paraesthesia	n/a	36	100.0	2	5.6	16	100.0	0	0.0
Psychiatric disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Psychiatric disorders	Anxiety	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		n/a	36	100.0	6	16.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Vascular disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_T3.xls
18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	White	25	69.4	1	4.0	13	81.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	White	25	69.4	0	0.0	13	81.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Endocrine disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Endocrine disorders	Hypopituitarism	White	25	69.4	1	4.0	13	81.3	0	0.0
Endocrine disorders	Hypopituitarism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	4	16.0	13	81.3	1	7.7
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	2	28.6	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	2	50.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Diarrhoea	White	25	69.4	3	12.0	13	81.3	0	0.0
Gastrointestinal disorders	Diarrhoea	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Faecaloma	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Faecaloma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Flatulence	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	White	25	69.4	0	0.0	13	81.3	1	7.7
Gastrointestinal disorders	Toothache	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	White	25	69.4	0	0.0	13	81.3	0	0.0
Gastrointestinal disorders	Vomiting	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
General disorders and administration site conditions		White	25	69.4	4	16.0	13	81.3	1	7.7
General disorders and administration site conditions		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	White	25	69.4	0	0.0	13	81.3	1	7.7
General disorders and administration site conditions	Malaise	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Medical device pain	White	25	69.4	1	4.0	13	81.3	0	0.0

General disorders and administration site conditions	Medical device pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	White	25	69.4	4	16.0	13	81.3	0	0.0
General disorders and administration site conditions	Pyrexia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Immune system disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Immune system disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	White	25	69.4	0	0.0	13	81.3	0	0.0
Immune system disorders	Seasonal allergy	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations		White	25	69.4	13	52.0	13	81.3	7	53.8
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	4	57.1	1	6.3	1	100.0
Infections and infestations		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Adenoiditis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Adenoiditis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Bronchitis	White	25	69.4	1	4.0	13	81.3	2	15.4
Infections and infestations	Bronchitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Folliculitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Folliculitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Folliculitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Fungal skin infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis viral	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Gastroenteritis viral	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	White	25	69.4	2	8.0	13	81.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Hordeolum	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Hordeolum	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Influenza	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Influenza	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Lymph gland infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Nasopharyngitis	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	1	100.0
Infections and infestations	Nasopharyngitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Otitis externa	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Otitis externa	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Pneumonia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	White	25	69.4	3	12.0	13	81.3	2	15.4
Infections and infestations	Respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Rhinitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Soft tissue infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Infections and infestations	Tonsillitis	White	25	69.4	1	4.0	13	81.3	0	0.0

Infections and infestations	Tonsillitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	White	25	69.4	6	24.0	13	81.3	3	23.1
Infections and infestations	Upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Urinary tract infection	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Varicella	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Varicella	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Viral pharyngitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	White	25	69.4	3	12.0	13	81.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	4	16.0	13	81.3	0	0.0
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Injury, poisoning and procedural complications		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	White	25	69.4	1	4.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	White	25	69.4	1	4.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	3	12.0	13	81.3	2	15.4
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	White	25	69.4	1	4.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Musculoskeletal and connective tissue disorders	Arthralgia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	White	25	69.4	2	8.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Scoliosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	White	25	69.4	1	4.0	13	81.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	6	24.0	13	81.3	1	7.7
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders	Headache	White	25	69.4	5	20.0	13	81.3	1	7.7

Nervous system disorders	Headache	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	White	25	69.4	2	8.0	13	81.3	0	0.0
Nervous system disorders	Paraesthesia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Psychiatric disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Psychiatric disorders	Anxiety	White	25	69.4	0	0.0	13	81.3	1	7.7
Psychiatric disorders	Anxiety	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	White	25	69.4	1	4.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	5	20.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	White	25	69.4	0	0.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Asian/Black or African American/Multiple	7	19.4	1	14.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	White	25	69.4	0	0.0	13	81.3	1	7.7
Skin and subcutaneous tissue disorders	Urticaria	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Vascular disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	White	25	69.4	1	4.0	13	81.3	0	0.0
Vascular disorders	Varicose vein	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Blood and lymphatic system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Ear and labyrinth disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Ear and labyrinth disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Endocrine disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Endocrine disorders	Hypopituitarism	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Endocrine disorders	Hypopituitarism	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		Europe	28	77.8	6	21.4	14	87.5	1	7.1
Gastrointestinal disorders		Rest of the World	8	22.2	2	25.0	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Abdominal pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Abdominal pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Diarrhoea	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Gastrointestinal disorders	Diarrhoea	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Gastrointestinal disorders	Faecaloma	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Faecaloma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Flatulence	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Flatulence	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Toothache	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Gastrointestinal disorders	Toothache	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Vomiting	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Vomiting	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions		Europe	28	77.8	4	14.3	14	87.5	1	7.1
General disorders and administration site conditions		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Malaise	Europe	28	77.8	0	0.0	14	87.5	1	7.1
General disorders and administration site conditions	Malaise	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Medical device pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
General disorders and administration site conditions	Medical device pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
General disorders and administration site conditions	Pyrexia	Europe	28	77.8	4	14.3	14	87.5	0	0.0
General disorders and administration site conditions	Pyrexia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Immune system disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Immune system disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Immune system disorders	Seasonal allergy	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Immune system disorders	Seasonal allergy	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	14	50.0	14	87.5	7	50.0
Infections and infestations		Rest of the World	8	22.2	4	50.0	2	12.5	1	50.0
Infections and infestations	Adenoiditis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Adenoiditis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Bronchitis	Europe	28	77.8	1	3.6	14	87.5	2	14.3
Infections and infestations	Bronchitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Folliculitis	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Folliculitis	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Fungal skin infection	Europe	28	77.8	0	0.0	14	87.5	0	0.0

Infections and infestations	Fungal skin infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis viral	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Gastroenteritis viral	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Hordeolum	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Hordeolum	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Influenza	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Influenza	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Lymph gland infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Nasopharyngitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Nasopharyngitis	Rest of the World	8	22.2	1	12.5	2	12.5	1	50.0
Infections and infestations	Otitis externa	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Otitis externa	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Pneumonia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Pneumonia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Respiratory tract infection	Europe	28	77.8	3	10.7	14	87.5	2	14.3
Infections and infestations	Respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Rhinitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Rhinitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Soft tissue infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Soft tissue infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Tonsillitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Tonsillitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection	Europe	28	77.8	6	21.4	14	87.5	3	21.4
Infections and infestations	Upper respiratory tract infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Urinary tract infection	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Infections and infestations	Urinary tract infection	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Infections and infestations	Varicella	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Varicella	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral pharyngitis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Viral pharyngitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Europe	28	77.8	3	10.7	14	87.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	4	14.3	14	87.5	0	0.0
Injury, poisoning and procedural complications		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	3	10.7	14	87.5	2	14.3
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Europe	28	77.8	2	7.1	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Scoliosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders		Europe	28	77.8	7	25.0	14	87.5	1	7.1
Nervous system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Headache	Europe	28	77.8	6	21.4	14	87.5	1	7.1
Nervous system disorders	Headache	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Paraesthesia	Europe	28	77.8	2	7.1	14	87.5	0	0.0
Nervous system disorders	Paraesthesia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Psychiatric disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Psychiatric disorders	Anxiety	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Psychiatric disorders	Anxiety	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	5	17.9	14	87.5	1	7.1
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Rest of the World	8	22.2	1	12.5	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Skin and subcutaneous tissue disorders	Urticaria	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Vascular disorders	Varicose vein	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Vascular disorders	Varicose vein	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
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18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Endocrine disorders	Hypopituitarism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Endocrine disorders	Hypopituitarism	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	2	16.7	4	25.0	1	25.0
Gastrointestinal disorders		>Q3	20	55.6	6	30.0	10	62.5	0	0.0
Gastrointestinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Abdominal pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	>Q3	20	55.6	4	20.0	10	62.5	0	0.0
Gastrointestinal disorders	Diarrhoea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Faecaloma	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Faecaloma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Flatulence	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Flatulence	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Tooth malformation	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Gastrointestinal disorders	Toothache	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Toothache	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Gastrointestinal disorders	Toothache	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Gastrointestinal disorders	Toothache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Vomiting	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Vomiting	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions		>Q3	20	55.6	3	15.0	10	62.5	1	10.0
General disorders and administration site conditions		Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Malaise	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
General disorders and administration site conditions	Malaise	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Medical device pain	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
General disorders and administration site conditions	Pyrexia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	>Q3	20	55.6	3	15.0	10	62.5	0	0.0
General disorders and administration site conditions	Pyrexia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Immune system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Immune system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Immune system disorders	Seasonal allergy	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Immune system disorders	Seasonal allergy	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Infections and infestations		>Q1 to <=Q3	12	33.3	6	50.0	4	25.0	2	50.0
Infections and infestations		>Q3	20	55.6	11	55.0	10	62.5	4	40.0
Infections and infestations		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Adenoiditis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Adenoiditis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Adenoiditis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Bronchitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Bronchitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Bronchitis	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Folliculitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Folliculitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Folliculitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Fungal skin infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Fungal skin infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis viral	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Hordeolum	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Hordeolum	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Infections and infestations	Influenza	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Influenza	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Influenza	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Influenza	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Nasopharyngitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Infections and infestations	Nasopharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Otitis externa	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Otitis externa	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis externa	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Pneumonia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Pneumonia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	<=Q1	3	8.3	1	33.3	1	6.3	1	100.0
Infections and infestations	Respiratory tract infection	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Rhinitis	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Rhinitis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Soft tissue infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Tonsillitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	1	25.0
Infections and infestations	Upper respiratory tract infection	>Q3	20	55.6	4	20.0	10	62.5	2	20.0
Infections and infestations	Upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Urinary tract infection	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Varicella	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Varicella	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral pharyngitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	>Q3	20	55.6	3	15.0	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0

Injury, poisoning and procedural complications		>Q3	20	55.6	3	15.0	10	62.5	0	0.0
Injury, poisoning and procedural complications		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Metabolism and nutrition disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	2	10.0	10	62.5	3	30.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Arthralgia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	>Q3	20	55.6	2	10.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Scoliosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Nervous system disorders		>Q3	20	55.6	3	15.0	10	62.5	1	10.0
Nervous system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Headache	>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Nervous system disorders	Headache	>Q3	20	55.6	3	15.0	10	62.5	1	10.0
Nervous system disorders	Headache	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Nervous system disorders	Paraesthesia	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Psychiatric disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Psychiatric disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Psychiatric disorders	Anxiety	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Psychiatric disorders	Anxiety	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	3	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Skin and subcutaneous tissue disorders	Alopecia	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Vascular disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Vascular disorders	Varicose vein	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_T3.xls
18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Ear and labyrinth disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Male	19	52.8	1	5.3	8	50.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Female	17	47.2	0	0.0	8	50.0	0	0.0
Endocrine disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Endocrine disorders	Hypopituitarism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders		Male	19	52.8	4	21.1	8	50.0	1	12.5
Gastrointestinal disorders		Female	17	47.2	4	23.5	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Male	19	52.8	2	10.5	8	50.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Female	17	47.2	2	11.8	8	50.0	0	0.0
Gastrointestinal disorders	Faecaloma	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Faecaloma	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Flatulence	Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Toothache	Male	19	52.8	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders	Toothache	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Vomiting	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Vomiting	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions		Male	19	52.8	2	10.5	8	50.0	1	12.5
General disorders and administration site conditions		Female	17	47.2	2	11.8	8	50.0	0	0.0
General disorders and administration site conditions	Malaise	Male	19	52.8	0	0.0	8	50.0	1	12.5
General disorders and administration site conditions	Malaise	Female	17	47.2	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
General disorders and administration site conditions	Medical device pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
General disorders and administration site conditions	Pyrexia	Male	19	52.8	2	10.5	8	50.0	0	0.0
General disorders and administration site conditions	Pyrexia	Female	17	47.2	2	11.8	8	50.0	0	0.0
Immune system disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Immune system disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Immune system disorders	Seasonal allergy	Male	19	52.8	1	5.3	8	50.0	0	0.0
Immune system disorders	Seasonal allergy	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	9	47.4	8	50.0	5	62.5
Infections and infestations		Female	17	47.2	9	52.9	8	50.0	3	37.5
Infections and infestations	Adenoiditis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Adenoiditis	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Bronchitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Bronchitis	Female	17	47.2	1	5.9	8	50.0	2	25.0
Infections and infestations	Folliculitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Folliculitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Fungal skin infection	Male	19	52.8	1	5.3	8	50.0	0	0.0

Infections and infestations	Fungal skin infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis viral	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Female	17	47.2	2	11.8	8	50.0	0	0.0
Infections and infestations	Hordeolum	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Hordeolum	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Influenza	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Influenza	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Lymph gland infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Lymph gland infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Nasopharyngitis	Male	19	52.8	1	5.3	8	50.0	1	12.5
Infections and infestations	Nasopharyngitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Otitis externa	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Otitis externa	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Pharyngitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Pneumonia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Pneumonia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Male	19	52.8	2	10.5	8	50.0	1	12.5
Infections and infestations	Respiratory tract infection	Female	17	47.2	1	5.9	8	50.0	1	12.5
Infections and infestations	Rhinitis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Rhinitis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Soft tissue infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Tonsillitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Male	19	52.8	1	5.3	8	50.0	2	25.0
Infections and infestations	Upper respiratory tract infection	Female	17	47.2	6	35.3	8	50.0	1	12.5
Infections and infestations	Upper respiratory tract infection bacterial	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Urinary tract infection	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations	Varicella	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Varicella	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral pharyngitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Female	17	47.2	2	11.8	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	4	21.1	8	50.0	0	0.0
Injury, poisoning and procedural complications		Female	17	47.2	1	5.9	8	50.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Male	19	52.8	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Female	17	47.2	1	5.9	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Male	19	52.8	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	0	0.0	8	50.0	3	37.5
Musculoskeletal and connective tissue disorders		Female	17	47.2	3	17.6	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Arthralgia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Scoliosis	Female	17	47.2	2	11.8	8	50.0	0	0.0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	17	47.2	0	0.0	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Male	19	52.8	1	5.3	8	50.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Female	17	47.2	0	0.0	8	50.0	0	0.0
Nervous system disorders		Male	19	52.8	3	15.8	8	50.0	1	12.5
Nervous system disorders		Female	17	47.2	4	23.5	8	50.0	0	0.0
Nervous system disorders	Headache	Male	19	52.8	2	10.5	8	50.0	1	12.5
Nervous system disorders	Headache	Female	17	47.2	4	23.5	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Nervous system disorders	Paraesthesia	Female	17	47.2	1	5.9	8	50.0	0	0.0
Psychiatric disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Psychiatric disorders	Anxiety	Male	19	52.8	0	0.0	8	50.0	0	0.0
Psychiatric disorders	Anxiety	Female	17	47.2	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Male	19	52.8	1	5.3	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	3	15.8	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	3	17.6	8	50.0	1	12.5
Skin and subcutaneous tissue disorders	Alopecia	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Female	17	47.2	1	5.9	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Male	19	52.8	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Female	17	47.2	0	0.0	8	50.0	1	12.5
Vascular disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Vascular disorders	Varicose vein	Male	19	52.8	0	0.0	8	50.0	0	0.0
Vascular disorders	Varicose vein	Female	17	47.2	1	5.9	8	50.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_T3.xls
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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Endocrine disorders	Hypopituitarism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders		Type III	36	100.0	8	22.2	16	100.0	1	6.3
Gastrointestinal disorders	Abdominal discomfort	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Gastrointestinal disorders	Faecaloma	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Flatulence	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Toothache	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders	Vomiting	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions		Type III	36	100.0	4	11.1	16	100.0	1	6.3
General disorders and administration site conditions	Malaise	Type III	36	100.0	0	0.0	16	100.0	1	6.3
General disorders and administration site conditions	Medical device pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
General disorders and administration site conditions	Pyrexia	Type III	36	100.0	4	11.1	16	100.0	0	0.0
Immune system disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Immune system disorders	Seasonal allergy	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		Type III	36	100.0	18	50.0	16	100.0	8	50.0
Infections and infestations	Adenoiditis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Bronchitis	Type III	36	100.0	1	2.8	16	100.0	2	12.5
Infections and infestations	Folliculitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Fungal skin infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis viral	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Infections and infestations	Hordeolum	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Influenza	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Nasopharyngitis	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Infections and infestations	Otitis externa	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Pneumonia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Respiratory tract infection	Type III	36	100.0	3	8.3	16	100.0	2	12.5
Infections and infestations	Rhinitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Soft tissue infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Tonsillitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Type III	36	100.0	7	19.4	16	100.0	3	18.8
Infections and infestations	Upper respiratory tract infection bacterial	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Urinary tract infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Varicella	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral pharyngitis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Type III	36	100.0	3	8.3	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	5	13.9	16	100.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Injury, poisoning and procedural complications	Incision site inflammation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders		Type III	36	100.0	3	8.3	16	100.0	3	18.8
Musculoskeletal and connective tissue disorders	Arthralgia	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Scoliosis	Type III	36	100.0	2	5.6	16	100.0	1	6.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		Type III	36	100.0	7	19.4	16	100.0	1	6.3
Nervous system disorders	Headache	Type III	36	100.0	6	16.7	16	100.0	1	6.3
Nervous system disorders	Paraesthesia	Type III	36	100.0	2	5.6	16	100.0	0	0.0
Psychiatric disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Psychiatric disorders	Anxiety	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders		Type III	36	100.0	6	16.7	16	100.0	1	6.3
Skin and subcutaneous tissue disorders	Alopecia	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Vascular disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Vascular disorders	Varicose vein	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

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18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)				
			Patients		Patients with Event		Patients		Patients with Event		
			n	%	n	%	n	%	n	%	
Blood and lymphatic system disorders		2									
Blood and lymphatic system disorders		3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Blood and lymphatic system disorders		4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Ear and labyrinth disorders		2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Ear and labyrinth disorders		3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Ear and labyrinth disorders		4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Ear and labyrinth disorders	Deafness neurosensory	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Ear and labyrinth disorders	Deafness neurosensory	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Ear and labyrinth disorders	Deafness neurosensory	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Endocrine disorders		2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Endocrine disorders		3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Endocrine disorders		4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Endocrine disorders	Hypopituitarism	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Endocrine disorders	Hypopituitarism	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Endocrine disorders	Hypopituitarism	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders		2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders		3	24	66.7	5	20.8	10	62.5	0	0.0	0.0
Gastrointestinal disorders		4	10	27.8	3	30.0	6	37.5	1	16.7	16.7
Gastrointestinal disorders	Abdominal discomfort	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Abdominal discomfort	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Abdominal discomfort	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Abdominal pain	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Abdominal pain	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Abdominal pain	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Constipation	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Constipation	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Constipation	4	10	27.8	1	10.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Diarrhoea	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Diarrhoea	3	24	66.7	3	12.5	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Diarrhoea	4	10	27.8	1	10.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Faecaloma	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Faecaloma	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Faecaloma	4	10	27.8	1	10.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Flatulence	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Flatulence	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Flatulence	4	10	27.8	1	10.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Tooth malformation	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Tooth malformation	3	24	66.7	1	4.2	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Tooth malformation	4	10	27.8	0	0.0	6	37.5	0	0.0	0.0
Gastrointestinal disorders	Toothache	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Toothache	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Toothache	4	10	27.8	0	0.0	6	37.5	1	16.7	16.7
Gastrointestinal disorders	Vomiting	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
Gastrointestinal disorders	Vomiting	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
Gastrointestinal disorders	Vomiting	4	10	27.8	1	10.0	6	37.5	0	0.0	0.0
General disorders and administration site conditions		2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
General disorders and administration site conditions		3	24	66.7	2	8.3	10	62.5	0	0.0	0.0
General disorders and administration site conditions		4	10	27.8	2	20.0	6	37.5	1	16.7	16.7
General disorders and administration site conditions	Malaise	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0
General disorders and administration site conditions	Malaise	3	24	66.7	0	0.0	10	62.5	0	0.0	0.0
General disorders and administration site conditions	Malaise	4	10	27.8	0	0.0	6	37.5	1	16.7	16.7
General disorders and administration site conditions	Medical device pain	2	2	5.6	0	0.0	0	0.0	0	0.0	0.0

General disorders and administration site conditions	Medical device pain	3	24	66.7	0	0.0	10	62.5	0	0.0
General disorders and administration site conditions	Medical device pain	4	10	27.8	1	10.0	6	37.5	0	0.0
General disorders and administration site conditions	Pyrexia	2	2	5.6	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions	Pyrexia	3	24	66.7	2	8.3	10	62.5	0	0.0
General disorders and administration site conditions	Pyrexia	4	10	27.8	2	20.0	6	37.5	0	0.0
Immune system disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Immune system disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Immune system disorders	Seasonal allergy	2	2	5.6	0	0.0	0	0.0	0	0.0
Immune system disorders	Seasonal allergy	3	24	66.7	0	0.0	10	62.5	0	0.0
Immune system disorders	Seasonal allergy	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations		2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations		3	24	66.7	14	58.3	10	62.5	4	40.0
Infections and infestations		4	10	27.8	4	40.0	6	37.5	4	66.7
Infections and infestations	Adenoiditis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Adenoiditis	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Adenoiditis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Bronchitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Bronchitis	3	24	66.7	1	4.2	10	62.5	2	20.0
Infections and infestations	Bronchitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Folliculitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Folliculitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Folliculitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Fungal skin infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Fungal skin infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Fungal skin infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Gastroenteritis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Gastroenteritis viral	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Gastroenteritis viral	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Gastroenteritis viral	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Hordeolum	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Hordeolum	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Hordeolum	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Influenza	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Influenza	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Influenza	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Lymph gland infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Lymph gland infection	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Nasopharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Nasopharyngitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Nasopharyngitis	4	10	27.8	1	10.0	6	37.5	1	16.7
Infections and infestations	Otitis externa	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Otitis externa	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Otitis externa	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Pharyngitis	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Pharyngitis bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pharyngitis bacterial	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Pharyngitis bacterial	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Pneumonia	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Pneumonia	3	24	66.7	0	0.0	10	62.5	1	10.0
Infections and infestations	Pneumonia	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Respiratory tract infection	3	24	66.7	3	12.5	10	62.5	1	10.0
Infections and infestations	Respiratory tract infection	4	10	27.8	0	0.0	6	37.5	1	16.7
Infections and infestations	Rhinitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Rhinitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Rhinitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Soft tissue infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Soft tissue infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Soft tissue infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Tonsillitis	2	2	5.6	0	0.0	0	0.0	0	0.0

Infections and infestations	Tonsillitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Tonsillitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Upper respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection	3	24	66.7	7	29.2	10	62.5	1	10.0
Infections and infestations	Upper respiratory tract infection	4	10	27.8	0	0.0	6	37.5	2	33.3
Infections and infestations	Upper respiratory tract infection bacterial	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Urinary tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Urinary tract infection	3	24	66.7	1	4.2	10	62.5	0	0.0
Infections and infestations	Urinary tract infection	4	10	27.8	0	0.0	6	37.5	0	0.0
Infections and infestations	Varicella	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Varicella	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Varicella	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral pharyngitis	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral pharyngitis	3	24	66.7	0	0.0	10	62.5	0	0.0
Infections and infestations	Viral pharyngitis	4	10	27.8	1	10.0	6	37.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	2	2	5.6	0	0.0	0	0.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	3	24	66.7	2	8.3	10	62.5	0	0.0
Infections and infestations	Viral upper respiratory tract infection	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications		2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications		3	24	66.7	2	8.3	10	62.5	0	0.0
Injury, poisoning and procedural complications		4	10	27.8	2	20.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	2	2	5.6	1	50.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Concussion	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Concussion	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Concussion	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	3	24	66.7	0	0.0	10	62.5	0	0.0
Injury, poisoning and procedural complications	Hand fracture	4	10	27.8	1	10.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	4	10	27.8	0	0.0	6	37.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	2	2	5.6	0	0.0	0	0.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	3	24	66.7	1	4.2	10	62.5	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	4	10	27.8	0	0.0	6	37.5	0	0.0
Metabolism and nutrition disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	2	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	3	24	66.7	1	4.2	10	62.5	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	4	10	27.8	0	0.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	24	66.7	3	12.5	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders		4	10	27.8	0	0.0	6	37.5	3	50.0
Musculoskeletal and connective tissue disorders	Arthralgia	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	3	24	66.7	1	4.2	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	4	10	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Back pain	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	24	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	10	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders	Scoliosis	2	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	3	24	66.7	2	8.3	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	4	10	27.8	0	0.0	6	37.5	1	16.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		4	10	27.8	1	10.0	6	37.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	5.6	0	0.0	0	0.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	3	24	66.7	0	0.0	10	62.5	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	4	10	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders		3	24	66.7	3	12.5	10	62.5	0	0.0
Nervous system disorders		4	10	27.8	3	30.0	6	37.5	1	16.7
Nervous system disorders	Headache	2	2	5.6	0	0.0	0	0.0	0	0.0

Nervous system disorders	Headache	3	24	66.7	3	12.5	10	62.5	0	0.0
Nervous system disorders	Headache	4	10	27.8	3	30.0	6	37.5	1	16.7
Nervous system disorders	Paraesthesia	2	2	5.6	1	50.0	0	0.0	0	0.0
Nervous system disorders	Paraesthesia	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Paraesthesia	4	10	27.8	0	0.0	6	37.5	0	0.0
Psychiatric disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders		3	24	66.7	0	0.0	10	62.5	1	10.0
Psychiatric disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Psychiatric disorders	Anxiety	2	2	5.6	0	0.0	0	0.0	0	0.0
Psychiatric disorders	Anxiety	3	24	66.7	0	0.0	10	62.5	1	10.0
Psychiatric disorders	Anxiety	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	3	24	66.7	1	4.2	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders		2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	24	66.7	4	16.7	10	62.5	1	10.0
Skin and subcutaneous tissue disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	2	2	5.6	1	50.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	3	24	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	4	10	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	3	24	66.7	1	4.2	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Rash	4	10	27.8	0	0.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	2	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	3	24	66.7	0	0.0	10	62.5	1	10.0
Skin and subcutaneous tissue disorders	Urticaria	4	10	27.8	0	0.0	6	37.5	0	0.0
Vascular disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders		4	10	27.8	1	10.0	6	37.5	0	0.0
Vascular disorders	Varicose vein	2	2	5.6	0	0.0	0	0.0	0	0.0
Vascular disorders	Varicose vein	3	24	66.7	0	0.0	10	62.5	0	0.0
Vascular disorders	Varicose vein	4	10	27.8	1	10.0	6	37.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

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18DEC2020 9:56

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	0	0.0	12	75.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Blood and lymphatic system disorders	Iron deficiency anaemia	No	29	80.6	0	0.0	12	75.0	0	0.0
Ear and labyrinth disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders		No	29	80.6	0	0.0	12	75.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Ear and labyrinth disorders	Deafness neurosensory	No	29	80.6	0	0.0	12	75.0	0	0.0
Endocrine disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Endocrine disorders	Hypopituitarism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Endocrine disorders	Hypopituitarism	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	7	24.1	12	75.0	1	8.3
Gastrointestinal disorders	Abdominal discomfort	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal discomfort	No	29	80.6	0	0.0	12	75.0	0	0.0
Gastrointestinal disorders	Abdominal pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Abdominal pain	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Diarrhoea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Diarrhoea	No	29	80.6	4	13.8	12	75.0	0	0.0
Gastrointestinal disorders	Faecaloma	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Faecaloma	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Flatulence	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Flatulence	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Tooth malformation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Tooth malformation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Toothache	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Toothache	No	29	80.6	0	0.0	12	75.0	1	8.3
Gastrointestinal disorders	Vomiting	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Vomiting	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions		Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions		No	29	80.6	4	13.8	12	75.0	1	8.3
General disorders and administration site conditions	Malaise	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Malaise	No	29	80.6	0	0.0	12	75.0	1	8.3
General disorders and administration site conditions	Medical device pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Medical device pain	No	29	80.6	1	3.4	12	75.0	0	0.0
General disorders and administration site conditions	Pyrexia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
General disorders and administration site conditions	Pyrexia	No	29	80.6	4	13.8	12	75.0	0	0.0
Immune system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Immune system disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Immune system disorders	Seasonal allergy	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Immune system disorders	Seasonal allergy	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations		Yes	7	19.4	3	42.9	4	25.0	2	50.0
Infections and infestations		No	29	80.6	15	51.7	12	75.0	6	50.0
Infections and infestations	Adenoiditis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Adenoiditis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Bronchitis	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Bronchitis	No	29	80.6	1	3.4	12	75.0	1	8.3
Infections and infestations	Folliculitis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Folliculitis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Fungal skin infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0

Infections and infestations	Fungal skin infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastroenteritis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Gastroenteritis viral	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis viral	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Hand-foot-and-mouth disease	No	29	80.6	2	6.9	12	75.0	0	0.0
Infections and infestations	Hordeolum	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Hordeolum	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Influenza	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Influenza	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Lymph gland infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Nasopharyngitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Nasopharyngitis	No	29	80.6	2	6.9	12	75.0	1	8.3
Infections and infestations	Otitis externa	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Otitis externa	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Pharyngitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Pharyngitis bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pharyngitis bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Pneumonia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Pneumonia	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	1	25.0
Infections and infestations	Respiratory tract infection	No	29	80.6	3	10.3	12	75.0	1	8.3
Infections and infestations	Rhinitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Rhinitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Soft tissue infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Soft tissue infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Tonsillitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Tonsillitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Upper respiratory tract infection	Yes	7	19.4	2	28.6	4	25.0	1	25.0
Infections and infestations	Upper respiratory tract infection	No	29	80.6	5	17.2	12	75.0	2	16.7
Infections and infestations	Upper respiratory tract infection bacterial	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Upper respiratory tract infection bacterial	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Urinary tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Urinary tract infection	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Varicella	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Varicella	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Viral pharyngitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral pharyngitis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Viral upper respiratory tract infection	No	29	80.6	3	10.3	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	2	28.6	4	25.0	0	0.0
Injury, poisoning and procedural complications		No	29	80.6	3	10.3	12	75.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Anaemia postoperative	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Concussion	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Concussion	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Hand fracture	No	29	80.6	1	3.4	12	75.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Injury, poisoning and procedural complications	Incision site inflammation	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Joint dislocation	No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Hyperinsulinism	No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	2	6.9	12	75.0	3	25.0
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Arthralgia	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Scoliosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Scoliosis	No	29	80.6	2	6.9	12	75.0	1	8.3

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		No	29	80.6	1	3.4	12	75.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	6	20.7	12	75.0	1	8.3
Nervous system disorders	Headache	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Headache	No	29	80.6	6	20.7	12	75.0	1	8.3
Nervous system disorders	Paraesthesia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Nervous system disorders	Paraesthesia	No	29	80.6	1	3.4	12	75.0	0	0.0
Psychiatric disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Psychiatric disorders	Anxiety	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Psychiatric disorders	Anxiety	No	29	80.6	0	0.0	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Cough	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders		Yes	7	19.4	3	42.9	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	3	10.3	12	75.0	1	8.3
Skin and subcutaneous tissue disorders	Alopecia	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Alopecia	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Decubitus ulcer	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Eczema nummular	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pityriasis rosea	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Pruritus	No	29	80.6	0	0.0	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Rash	No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Urticaria	No	29	80.6	0	0.0	12	75.0	1	8.3
Vascular disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Vascular disorders	Varicose vein	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Vascular disorders	Varicose vein	No	29	80.6	1	3.4	12	75.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG2_SE_P2_T3.xls
18DEC2020 9:56

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		2 to 5 years	3	20.0	1	33.3
Infections and infestations		6 to 11 years	4	26.7	0	0.0
Infections and infestations		12 to 17 years	4	26.7	0	0.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Enterovirus infection	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	4	26.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		n/a	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		White	12	80.0	1	8.3
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations		Unknown	2	13.3	0	0.0
Infections and infestations	Enterovirus infection	White	12	80.0	1	8.3
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Unknown	2	13.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Europe	14	93.3	1	7.1
Infections and infestations		Rest of the World	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Europe	14	93.3	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	1	6.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		\leq Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to \leq Q3	4	26.7	0	0.0
Infections and infestations		>Q3	9	60.0	0	0.0
Infections and infestations		Missing	1	6.7	1	100.0
Infections and infestations	Enterovirus infection	\leq Q1	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to \leq Q3	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	>Q3	9	60.0	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	6.7	1	100.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Male	8	53.3	0	0.0
Infections and infestations		Female	7	46.7	1	14.3
Infections and infestations	Enterovirus infection	Male	8	53.3	0	0.0
Infections and infestations	Enterovirus infection	Female	7	46.7	1	14.3

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade ≥ 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Type III	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	Type III	15	100.0	1	6.7

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		3	10	66.7	1	10.0
Infections and infestations		4	5	33.3	0	0.0
Infections and infestations	Enterovirus infection	3	10	66.7	1	10.0
Infections and infestations	Enterovirus infection	4	5	33.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade \geq 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Yes	4	26.7	0	0.0
Infections and infestations		No	11	73.3	1	9.1
Infections and infestations	Enterovirus infection	Yes	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	No	11	73.3	1	9.1

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_OLE_SW_T3.xls

08MAR2021 13:19

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Leukopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Neutropenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations		6 to 11 years	11	30.6	0	0.0	4	25.0	2	50.0
Infections and infestations		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Appendicitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Device related infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Enterovirus infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0

Infections and infestations	Infective thrombosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Femur fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Procedural pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Oxygen saturation decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Metabolism and nutrition disorders	Obesity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Nervous system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Partial seizures	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Presyncope	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
18DEC2020 10:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Leukopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders		n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Dental necrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		n/a	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Gastroenteritis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	0	0.0	16	100.0	2	12.5
Injury, poisoning and procedural complications	Femur fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders	Obesity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		n/a	36	100.0	2	5.6	16	100.0	0	0.0
Nervous system disorders	Partial seizures	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
 18DEC2020 10:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Leukopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Neutropenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Dental necrosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations		White	25	69.4	1	4.0	13	81.3	2	15.4
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Appendicitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Appendicitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Device related infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Device related infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Infective thrombosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Femur fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Procedural pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Oxygen saturation decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Oxygen saturation decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Oxygen saturation decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Obesity	White	25	69.4	0	0.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Obesity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders	Obesity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Partial seizures	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Presyncope	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_F2_T3.xls

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Leukopenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Neutropenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	1	3.6	14	87.5	3	21.4
Infections and infestations		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Appendicitis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Appendicitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Device related infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Device related infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Infective thrombosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Femur fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Femur fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Oxygen saturation decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Oxygen saturation decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders	Obesity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Obesity	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Nervous system disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Nervous system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Partial seizures	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Presyncope	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Leukopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Neutropenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Gastrointestinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Infections and infestations		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Appendicitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Appendicitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Device related infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Device related infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0

Infections and infestations	Infective thrombosis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Infective thrombosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Injury, poisoning and procedural complications		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Femur fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Procedural pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Oxygen saturation decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Metabolism and nutrition disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Metabolism and nutrition disorders	Obesity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Partial seizures	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Partial seizures	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Leukopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Neutropenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	1	5.3	8	50.0	2	25.0
Infections and infestations		Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Device related infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Device related infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	0	0.0	8	50.0	2	25.0
Injury, poisoning and procedural complications		Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Femur fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Oxygen saturation decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Oxygen saturation decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Metabolism and nutrition disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Obesity	Male	19	52.8	0	0.0	8	50.0	1	12.5
Metabolism and nutrition disorders	Obesity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	1	5.9	8	50.0	0	0.0

Nervous system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders		Female	17	47.2	2	11.8	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Presyncope	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Presyncope	Female	17	47.2	1	5.9	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Female	17	47.2	0	0.0	8	50.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
18DEC2020 10:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Leukopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders		Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		Type III	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Gastroenteritis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	0	0.0	16	100.0	2	12.5
Injury, poisoning and procedural complications	Femur fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders	Obesity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		Type III	36	100.0	2	5.6	16	100.0	0	0.0
Nervous system disorders	Partial seizures	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
 18DEC2020 10:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders		3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders		4	27.8	0	0.0	6	37.5	0	0.0	
Blood and lymphatic system disorders	Leukopenia	2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders	Leukopenia	3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders	Leukopenia	4	27.8	0	0.0	6	37.5	0	0.0	
Blood and lymphatic system disorders	Neutropenia	2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders	Neutropenia	3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders	Neutropenia	4	27.8	0	0.0	6	37.5	0	0.0	
Gastrointestinal disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders		3	66.7	1	4.2	10	62.5	0	0.0	
Gastrointestinal disorders		4	27.8	1	10.0	6	37.5	0	0.0	
Gastrointestinal disorders	Constipation	2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders	Constipation	3	66.7	0	0.0	10	62.5	0	0.0	
Gastrointestinal disorders	Constipation	4	27.8	1	10.0	6	37.5	0	0.0	
Gastrointestinal disorders	Dental necrosis	2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders	Dental necrosis	3	66.7	1	4.2	10	62.5	0	0.0	
Gastrointestinal disorders	Dental necrosis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations		2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations		3	66.7	0	0.0	10	62.5	2	20.0	
Infections and infestations		4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Appendicitis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Appendicitis	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Appendicitis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Device related infection	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Device related infection	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Device related infection	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Enterovirus infection	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Enterovirus infection	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Enterovirus infection	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Gastroenteritis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Gastroenteritis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Gastroenteritis	4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Infective thrombosis	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Infective thrombosis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Infective thrombosis	4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications		2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications		3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications		4	27.8	0	0.0	6	37.5	1	16.7	
Injury, poisoning and procedural complications	Femur fracture	2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications	Femur fracture	3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications	Femur fracture	4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	3	66.7	0	0.0	10	62.5	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	4	27.8	0	0.0	6	37.5	1	16.7	

Investigations		2	5.6	0	0.0	0	0.0	0	0.0
Investigations		3	66.7	0	0.0	10	62.5	0	0.0
Investigations		4	27.8	0	0.0	6	37.5	1	16.7
Investigations	Oxygen saturation decreased	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Oxygen saturation decreased	3	66.7	0	0.0	10	62.5	0	0.0
Investigations	Oxygen saturation decreased	4	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders		2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders		3	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders		4	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders	Obesity	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Obesity	3	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Obesity	4	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders		4	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders		3	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders		4	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Partial seizures	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Partial seizures	3	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Partial seizures	4	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Presyncope	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Presyncope	3	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	4	27.8	1	10.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders		4	27.8	0	0.0	6	37.5	1	16.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	3	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	4	27.8	0	0.0	6	37.5	1	16.7
Skin and subcutaneous tissue disorders		2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		4	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	3	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	4	27.8	1	10.0	6	37.5	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_F2_T3.xls

18DEC2020 10:34

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Leukopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Neutropenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Gastrointestinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations		No	29	80.6	0	0.0	12	75.0	3	25.0
Infections and infestations	Appendicitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Device related infection	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Device related infection	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Enterovirus infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Gastroenteritis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Infective thrombosis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		No	29	80.6	0	0.0	12	75.0	2	16.7
Injury, poisoning and procedural complications	Femur fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Injury, poisoning and procedural complications	Procedural pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Oxygen saturation decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders	Obesity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	1	3.4	12	75.0	0	0.0

Nervous system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Nervous system disorders	Partial seizures	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Presyncope	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	No	29	80.6	0	0.0	12	75.0	1	8.3
Skin and subcutaneous tissue disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	No	29	80.6	1	3.4	12	75.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG345_SE_P2_T3.xls
18DEC2020 10:34

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		2 to 5 years	3	20.0	1	33.3
Infections and infestations		6 to 11 years	4	26.7	0	0.0
Infections and infestations		12 to 17 years	4	26.7	0	0.0
Infections and infestations		18 to 25 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	3	20.0	1	33.3
Infections and infestations	Enterovirus infection	6 to 11 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	4	26.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

All

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		n/a	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	n/a	15	100.0	1	6.7

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		White	12	80.0	1	8.3
Infections and infestations		Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations		Unknown	2	13.3	0	0.0
Infections and infestations	Enterovirus infection	White	12	80.0	1	8.3
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Unknown	2	13.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Europe	14	93.3	1	7.1
Infections and infestations		Rest of the World	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	Europe	14	93.3	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	1	6.7	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		<=Q1	1	6.7	0	0.0
Infections and infestations		>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations		>Q3	9	60.0	0	0.0
Infections and infestations		Missing	1	6.7	1	100.0
Infections and infestations	Enterovirus infection	<=Q1	1	6.7	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to <=Q3	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	>Q3	9	60.0	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	6.7	1	100.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Sex

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Male	8	53.3	0	0.0
Infections and infestations		Female	7	46.7	1	14.3
Infections and infestations	Enterovirus infection	Male	8	53.3	0	0.0
Infections and infestations	Enterovirus infection	Female	7	46.7	1	14.3

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Type III	15	100.0	1	6.7
Infections and infestations	Enterovirus infection	Type III	15	100.0	1	6.7

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		3	10	66.7	1	10.0
Infections and infestations		4	5	33.3	0	0.0
Infections and infestations	Enterovirus infection	3	10	66.7	1	10.0
Infections and infestations	Enterovirus infection	4	5	33.3	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 3 including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Infections and infestations		Yes	4	26.7	0	0.0
Infections and infestations		No	11	73.3	1	9.1
Infections and infestations	Enterovirus infection	Yes	4	26.7	0	0.0
Infections and infestations	Enterovirus infection	No	11	73.3	1	9.1

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_OLE_SW_T3.xls

08MAR2021 13:10

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Leukopenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Blood and lymphatic system disorders	Neutropenia	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations		6 to 11 years	11	30.6	0	0.0	4	25.0	2	50.0
Infections and infestations		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Appendicitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Device related infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Enterovirus infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0

Infections and infestations	Infective thrombosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Femur fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Procedural pain	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations	Oxygen saturation decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Metabolism and nutrition disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Metabolism and nutrition disorders	Obesity	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	2	18.2	4	25.0	0	0.0
Nervous system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Partial seizures	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Presyncope	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	2 to 5 years	4	11.1	1	25.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Leukopenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders		n/a	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Dental necrosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		n/a	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Gastroenteritis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		n/a	36	100.0	0	0.0	16	100.0	2	12.5
Injury, poisoning and procedural complications	Femur fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders	Obesity	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		n/a	36	100.0	2	5.6	16	100.0	0	0.0
Nervous system disorders	Partial seizures	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	n/a	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
 18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Leukopenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	White	25	69.4	0	0.0	13	81.3	1	7.7
Blood and lymphatic system disorders	Neutropenia	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		White	25	69.4	2	8.0	13	81.3	0	0.0
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Dental necrosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations		White	25	69.4	1	4.0	13	81.3	2	15.4
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Appendicitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Appendicitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Device related infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Device related infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Enterovirus infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Infective thrombosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Femur fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	White	25	69.4	0	0.0	13	81.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Injury, poisoning and procedural complications	Procedural pain	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Oxygen saturation decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Oxygen saturation decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Oxygen saturation decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Metabolism and nutrition disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Metabolism and nutrition disorders	Obesity	White	25	69.4	0	0.0	13	81.3	0	0.0
Metabolism and nutrition disorders	Obesity	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Metabolism and nutrition disorders	Obesity	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Partial seizures	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	White	25	69.4	0	0.0	13	81.3	0	0.0
Nervous system disorders	Presyncope	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	White	25	69.4	1	4.0	13	81.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Leukopenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Blood and lymphatic system disorders	Neutropenia	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Gastrointestinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	1	3.6	14	87.5	3	21.4
Infections and infestations		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Appendicitis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Appendicitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Device related infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Device related infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Enterovirus infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Enterovirus infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Infective thrombosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Injury, poisoning and procedural complications	Femur fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Femur fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Oxygen saturation decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Oxygen saturation decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Metabolism and nutrition disorders	Obesity	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Metabolism and nutrition disorders	Obesity	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Nervous system disorders		Europe	28	77.8	2	7.1	14	87.5	0	0.0
Nervous system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Partial seizures	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Presyncope	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Presyncope	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Skin and subcutaneous tissue disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Leukopenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Leukopenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Blood and lymphatic system disorders	Neutropenia	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		>Q3	20	55.6	2	10.0	10	62.5	0	0.0
Gastrointestinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Dental necrosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Infections and infestations		Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Appendicitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Appendicitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Device related infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Device related infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Enterovirus infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Enterovirus infection	Missing	1	2.8	0	0.0	1	6.3	1	100.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0

Infections and infestations	Infective thrombosis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Infective thrombosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	0	0.0	10	62.5	2	20.0
Injury, poisoning and procedural complications		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Femur fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Procedural pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Oxygen saturation decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Metabolism and nutrition disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Metabolism and nutrition disorders	Obesity	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Metabolism and nutrition disorders	Obesity	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Partial seizures	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Partial seizures	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Presyncope	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0

Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders		Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Leukopenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Blood and lymphatic system disorders	Neutropenia	Male	19	52.8	0	0.0	8	50.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	Female	17	47.2	0	0.0	8	50.0	1	12.5
Gastrointestinal disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Male	19	52.8	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Female	17	47.2	1	5.9	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	1	5.3	8	50.0	2	25.0
Infections and infestations		Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Device related infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Device related infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Male	19	52.8	0	0.0	8	50.0	0	0.0
Infections and infestations	Enterovirus infection	Female	17	47.2	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	0	0.0	8	50.0	2	25.0
Injury, poisoning and procedural complications		Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Femur fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Procedural pain	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Oxygen saturation decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Oxygen saturation decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Metabolism and nutrition disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Metabolism and nutrition disorders	Obesity	Male	19	52.8	0	0.0	8	50.0	1	12.5
Metabolism and nutrition disorders	Obesity	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	1	5.9	8	50.0	0	0.0

Nervous system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders		Female	17	47.2	2	11.8	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Presyncope	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Presyncope	Female	17	47.2	1	5.9	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Male	19	52.8	1	5.3	8	50.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Female	17	47.2	0	0.0	8	50.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Leukopenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Blood and lymphatic system disorders	Neutropenia	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Gastrointestinal disorders		Type III	36	100.0	2	5.6	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		Type III	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Enterovirus infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Gastroenteritis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Injury, poisoning and procedural complications		Type III	36	100.0	0	0.0	16	100.0	2	12.5
Injury, poisoning and procedural complications	Femur fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Procedural pain	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Metabolism and nutrition disorders	Obesity	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders		Type III	36	100.0	2	5.6	16	100.0	0	0.0
Nervous system disorders	Partial seizures	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Presyncope	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Skin and subcutaneous tissue disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Type III	36	100.0	1	2.8	16	100.0	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
 18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders		3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders		4	27.8	0	0.0	6	37.5	0	0.0	
Blood and lymphatic system disorders	Leukopenia	2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders	Leukopenia	3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders	Leukopenia	4	27.8	0	0.0	6	37.5	0	0.0	
Blood and lymphatic system disorders	Neutropenia	2	5.6	0	0.0	0	0.0	0	0.0	
Blood and lymphatic system disorders	Neutropenia	3	66.7	0	0.0	10	62.5	1	10.0	
Blood and lymphatic system disorders	Neutropenia	4	27.8	0	0.0	6	37.5	0	0.0	
Gastrointestinal disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders		3	66.7	1	4.2	10	62.5	0	0.0	
Gastrointestinal disorders		4	27.8	1	10.0	6	37.5	0	0.0	
Gastrointestinal disorders	Constipation	2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders	Constipation	3	66.7	0	0.0	10	62.5	0	0.0	
Gastrointestinal disorders	Constipation	4	27.8	1	10.0	6	37.5	0	0.0	
Gastrointestinal disorders	Dental necrosis	2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders	Dental necrosis	3	66.7	1	4.2	10	62.5	0	0.0	
Gastrointestinal disorders	Dental necrosis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations		2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations		3	66.7	0	0.0	10	62.5	2	20.0	
Infections and infestations		4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Appendicitis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Appendicitis	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Appendicitis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Device related infection	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Device related infection	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Device related infection	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Enterovirus infection	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Enterovirus infection	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Enterovirus infection	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Gastroenteritis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Gastroenteritis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Gastroenteritis	4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Infective thrombosis	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Infective thrombosis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Infective thrombosis	4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications		2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications		3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications		4	27.8	0	0.0	6	37.5	1	16.7	
Injury, poisoning and procedural complications	Femur fracture	2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications	Femur fracture	3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications	Femur fracture	4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	3	66.7	0	0.0	10	62.5	0	0.0	
Injury, poisoning and procedural complications	Procedural pain	4	27.8	0	0.0	6	37.5	1	16.7	

Investigations		2	5.6	0	0.0	0	0.0	0	0.0
Investigations		3	66.7	0	0.0	10	62.5	0	0.0
Investigations		4	27.8	0	0.0	6	37.5	1	16.7
Investigations	Oxygen saturation decreased	2	5.6	0	0.0	0	0.0	0	0.0
Investigations	Oxygen saturation decreased	3	66.7	0	0.0	10	62.5	0	0.0
Investigations	Oxygen saturation decreased	4	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders		2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders		3	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders		4	27.8	0	0.0	6	37.5	1	16.7
Metabolism and nutrition disorders	Obesity	2	5.6	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders	Obesity	3	66.7	0	0.0	10	62.5	0	0.0
Metabolism and nutrition disorders	Obesity	4	27.8	0	0.0	6	37.5	1	16.7
Musculoskeletal and connective tissue disorders		2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders		3	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders		4	27.8	1	10.0	6	37.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	2	5.6	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	3	66.7	0	0.0	10	62.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders		2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders		3	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders		4	27.8	1	10.0	6	37.5	0	0.0
Nervous system disorders	Partial seizures	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Partial seizures	3	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Partial seizures	4	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Presyncope	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Presyncope	3	66.7	0	0.0	10	62.5	0	0.0
Nervous system disorders	Presyncope	4	27.8	1	10.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders		4	27.8	0	0.0	6	37.5	1	16.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	3	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	4	27.8	0	0.0	6	37.5	1	16.7
Skin and subcutaneous tissue disorders		2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders		3	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders		4	27.8	1	10.0	6	37.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	2	5.6	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	3	66.7	0	0.0	10	62.5	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	4	27.8	1	10.0	6	37.5	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Leukopenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Leukopenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Blood and lymphatic system disorders	Neutropenia	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	No	29	80.6	0	0.0	12	75.0	1	8.3
Gastrointestinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Dental necrosis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Dental necrosis	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations		No	29	80.6	0	0.0	12	75.0	3	25.0
Infections and infestations	Appendicitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Device related infection	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Device related infection	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Enterovirus infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Enterovirus infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Gastroenteritis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Infective thrombosis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	No	29	80.6	0	0.0	12	75.0	0	0.0
Injury, poisoning and procedural complications		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		No	29	80.6	0	0.0	12	75.0	2	16.7
Injury, poisoning and procedural complications	Femur fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Injury, poisoning and procedural complications	Procedural pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Procedural pain	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Oxygen saturation decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Metabolism and nutrition disorders	Obesity	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Metabolism and nutrition disorders	Obesity	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	1	3.4	12	75.0	0	0.0

Nervous system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	2	6.9	12	75.0	0	0.0
Nervous system disorders	Partial seizures	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Presyncope	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Presyncope	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	No	29	80.6	0	0.0	12	75.0	1	8.3
Skin and subcutaneous tissue disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Skin and subcutaneous tissue disorders	Dermatitis contact	No	29	80.6	1	3.4	12	75.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG3_SE_P2_T3.xls
18DEC2020 10:13

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 4 including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG4_SE_P2_OLE_SW_T3.xls
08MAR2021 13:13

POPULATION: SMA Type III, Safety-Evaluable Population
ENDPOINT: AEs Grade 4 including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG4_SE_P2_T3.xls
18DEC2020 10:20

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs Grade 5 (AEs leading to death) including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG5_SE_P2_OLE_SW_T3.xls
08MAR2021 13:16

POPULATION: SMA Type III, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to death) including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AEG5_SE_P2_T3.xls
18DEC2020 10:27

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, AEs leading to treatment discontinuation including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AELDIS_SE_P2_OLE_SW_T3.xls
08MAR2021 13:24

POPULATION: SMA Type III, Safety-Evaluable Population
ENDPOINT: AEs leading to treatment discontinuation including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39055 SUNFISH - Part 2
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_AELDIS_SE_P2_T3.xls
18DEC2020 10:48

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders		6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	4	26.7	1	25.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	3	20.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	4	26.7	1	25.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls
 08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

				Placebo/Risdiplam (N=15)			
				Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	
Musculoskeletal and connective tissue disorders		n/a	15	100.0	1	6.7	
Musculoskeletal and connective tissue disorders	Back pain	n/a	15	100.0	1	6.7	

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls
 08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	2	13.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	12	80.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	2	13.3	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders		Rest of the World	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	14	93.3	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	1	6.7	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population
 ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders		Missing	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	1	6.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	9	60.0	1	11.1
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	6.7	0	0.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls
 08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

Sex

				Placebo/Risdiplam (N=15)			
				Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	
Musculoskeletal and connective tissue disorders		Male	8	53.3	1	12.5	
Musculoskeletal and connective tissue disorders		Female	7	46.7	0	0.0	
Musculoskeletal and connective tissue disorders	Back pain	Male	8	53.3	1	12.5	
Musculoskeletal and connective tissue disorders	Back pain	Female	7	46.7	0	0.0	

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMA Type

				Placebo/Risdiplam (N=15)			
				Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	
Musculoskeletal and connective tissue disorders		Type III	15	100.0	1	6.7	
Musculoskeletal and connective tissue disorders	Back pain	Type III	15	100.0	1	6.7	

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders		4	5	33.3	1	20.0
Musculoskeletal and connective tissue disorders	Back pain	3	10	66.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	4	5	33.3	1	20.0

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Patients who switched from Placebo to Risdiplam, Safety-Evaluable Population

ENDPOINT: Open-Label Treatment Period and Extension Open-Label Treatment Period, Any SAEs including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39055 SUNFISH - Part 2

Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Placebo/Risdiplam (N=15)			
			Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%
Musculoskeletal and connective tissue disorders		Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders		No	11	73.3	1	9.1
Musculoskeletal and connective tissue disorders	Back pain	Yes	4	26.7	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	11	73.3	1	9.1

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_OLE_SW_T3.xls

08MAR2021 13:22

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Age (at randomization)

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations		6 to 11 years	11	30.6	0	0.0	4	25.0	2	50.0
Infections and infestations		12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Appendicitis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Device related infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Infections and infestations	Gastroenteritis	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	12 to 17 years	15	41.7	1	6.7	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Infections and infestations	Lymph gland infection	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	6 to 11 years	11	30.6	0	0.0	4	25.0	1	25.0
Injury, poisoning and procedural complications	Femur fracture	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Investigations		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0

Investigations	Oxygen saturation decreased	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Musculoskeletal and connective tissue disorders	Back pain	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	18 to 25 years	6	16.7	0	0.0	4	25.0	1	25.0
Nervous system disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders		6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	2 to 5 years	4	11.1	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	6 to 11 years	11	30.6	1	9.1	4	25.0	0	0.0
Nervous system disorders	Partial seizures	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders		6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2 to 5 years	4	11.1	0	0.0	4	25.0	1	25.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	6 to 11 years	11	30.6	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	12 to 17 years	15	41.7	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
18DEC2020 10:41

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

All

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		n/a	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Femur fracture	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	n/a	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		n/a	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	n/a	36	100.0	1	2.8	16	100.0	1	6.3
Nervous system disorders		n/a	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Partial seizures	n/a	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		n/a	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	36	100.0	0	0.0	16	100.0	1	6.3

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
 18DEC2020 10:41

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Race/ethnicity

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	White	25	69.4	1	4.0	13	81.3	0	0.0
Gastrointestinal disorders	Constipation	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations		White	25	69.4	1	4.0	13	81.3	2	15.4
Infections and infestations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations		Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Appendicitis	White	25	69.4	0	0.0	13	81.3	0	0.0
Infections and infestations	Appendicitis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	Unknown	4	11.1	0	0.0	2	12.5	1	50.0
Infections and infestations	Device related infection	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Device related infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Gastroenteritis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	White	25	69.4	1	4.0	13	81.3	0	0.0
Infections and infestations	Infective thrombosis	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	White	25	69.4	0	0.0	13	81.3	1	7.7
Infections and infestations	Lymph gland infection	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	White	25	69.4	0	0.0	13	81.3	1	7.7
Injury, poisoning and procedural complications	Femur fracture	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations		White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Investigations	Oxygen saturation decreased	White	25	69.4	0	0.0	13	81.3	0	0.0
Investigations	Oxygen saturation decreased	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Investigations	Oxygen saturation decreased	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders		White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	White	25	69.4	0	0.0	13	81.3	1	7.7
Musculoskeletal and connective tissue disorders	Back pain	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Unknown	4	11.1	1	25.0	2	12.5	0	0.0
Nervous system disorders		White	25	69.4	1	4.0	13	81.3	0	0.0

Nervous system disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	White	25	69.4	1	4.0	13	81.3	0	0.0
Nervous system disorders	Partial seizures	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders		Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders		Unknown	4	11.1	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	White	25	69.4	0	0.0	13	81.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asian/Black or African American/Multiple	7	19.4	0	0.0	1	6.3	1	100.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Unknown	4	11.1	0	0.0	2	12.5	0	0.0

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls

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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Gastrointestinal disorders	Constipation	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Gastrointestinal disorders	Constipation	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations		Europe	28	77.8	1	3.6	14	87.5	3	21.4
Infections and infestations		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Appendicitis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Appendicitis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Device related infection	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Device related infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Gastroenteritis	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Gastroenteritis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Infective thrombosis	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Infections and infestations	Infective thrombosis	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Infections and infestations	Lymph gland infection	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Infections and infestations	Lymph gland infection	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications		Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Europe	28	77.8	0	0.0	14	87.5	1	7.1
Injury, poisoning and procedural complications	Femur fracture	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Investigations		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Investigations	Oxygen saturation decreased	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Investigations	Oxygen saturation decreased	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Musculoskeletal and connective tissue disorders		Europe	28	77.8	1	3.6	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Europe	28	77.8	1	3.6	14	87.5	1	7.1
Musculoskeletal and connective tissue disorders	Back pain	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders		Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders		Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Nervous system disorders	Partial seizures	Europe	28	77.8	1	3.6	14	87.5	0	0.0
Nervous system disorders	Partial seizures	Rest of the World	8	22.2	0	0.0	2	12.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders		Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe	28	77.8	0	0.0	14	87.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Output: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Disease Severity

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Gastrointestinal disorders	Constipation	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	>Q3	20	55.6	1	5.0	10	62.5	0	0.0
Gastrointestinal disorders	Constipation	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations		<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations		>Q3	20	55.6	0	0.0	10	62.5	3	30.0
Infections and infestations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Appendicitis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Appendicitis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Device related infection	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Device related infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Device related infection	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Device related infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Gastroenteritis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Gastroenteritis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	<=Q1	3	8.3	1	33.3	1	6.3	0	0.0
Infections and infestations	Infective thrombosis	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Infections and infestations	Infective thrombosis	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Infections and infestations	Lymph gland infection	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Infections and infestations	Lymph gland infection	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Injury, poisoning and procedural complications	Femur fracture	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Investigations		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Investigations	Oxygen saturation decreased	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0

Investigations	Oxygen saturation decreased	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Investigations	Oxygen saturation decreased	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	>Q3	20	55.6	1	5.0	10	62.5	1	10.0
Musculoskeletal and connective tissue disorders	Back pain	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders		>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders		>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Nervous system disorders	Partial seizures	>Q1 to <=Q3	12	33.3	1	8.3	4	25.0	0	0.0
Nervous system disorders	Partial seizures	>Q3	20	55.6	0	0.0	10	62.5	0	0.0
Nervous system disorders	Partial seizures	Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders		Missing	1	2.8	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	<=Q1	3	8.3	0	0.0	1	6.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q1 to <=Q3	12	33.3	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>Q3	20	55.6	0	0.0	10	62.5	1	10.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Missing	1	2.8	0	0.0	1	6.3	0	0.0

Only AEs of highest severity are counted.
Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
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POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Male	19	52.8	1	5.3	8	50.0	0	0.0
Gastrointestinal disorders	Constipation	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations		Male	19	52.8	1	5.3	8	50.0	3	37.5
Infections and infestations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Appendicitis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Appendicitis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Device related infection	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Device related infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Gastroenteritis	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Gastroenteritis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Male	19	52.8	1	5.3	8	50.0	0	0.0
Infections and infestations	Infective thrombosis	Female	17	47.2	0	0.0	8	50.0	0	0.0
Infections and infestations	Lymph gland infection	Male	19	52.8	0	0.0	8	50.0	1	12.5
Infections and infestations	Lymph gland infection	Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications		Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications		Female	17	47.2	0	0.0	8	50.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	Male	19	52.8	0	0.0	8	50.0	1	12.5
Injury, poisoning and procedural complications	Femur fracture	Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations		Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations		Female	17	47.2	0	0.0	8	50.0	0	0.0
Investigations	Oxygen saturation decreased	Male	19	52.8	0	0.0	8	50.0	1	12.5
Investigations	Oxygen saturation decreased	Female	17	47.2	0	0.0	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	Male	19	52.8	0	0.0	8	50.0	1	12.5
Musculoskeletal and connective tissue disorders	Back pain	Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders		Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders		Female	17	47.2	1	5.9	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Male	19	52.8	0	0.0	8	50.0	0	0.0
Nervous system disorders	Partial seizures	Female	17	47.2	1	5.9	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders		Female	17	47.2	0	0.0	8	50.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	19	52.8	0	0.0	8	50.0	1	12.5
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	17	47.2	0	0.0	8	50.0	0	0.0

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Output: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
18DEC2020 10:41

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMA Type

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Gastrointestinal disorders	Constipation	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations		Type III	36	100.0	1	2.8	16	100.0	3	18.8
Infections and infestations	Appendicitis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Device related infection	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Gastroenteritis	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Infections and infestations	Infective thrombosis	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Infections and infestations	Lymph gland infection	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Injury, poisoning and procedural complications	Femur fracture	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Investigations	Oxygen saturation decreased	Type III	36	100.0	0	0.0	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders		Type III	36	100.0	1	2.8	16	100.0	1	6.3
Musculoskeletal and connective tissue disorders	Back pain	Type III	36	100.0	1	2.8	16	100.0	1	6.3
Nervous system disorders		Type III	36	100.0	1	2.8	16	100.0	0	0.0
Nervous system disorders	Partial seizures	Type III	36	100.0	1	2.8	16	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Type III	36	100.0	0	0.0	16	100.0	1	6.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Type III	36	100.0	0	0.0	16	100.0	1	6.3

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
 18DEC2020 10:41

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

SMN2 Copy Number

MedDRA System Organ Class	MedDRA Preferred Term	Level	Risdiplam (N=36)				Placebo (N=16)			
			Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders		3	66.7	0	0.0	10	62.5	0	0.0	
Gastrointestinal disorders		4	27.8	1	10.0	6	37.5	0	0.0	
Gastrointestinal disorders	Constipation	2	5.6	0	0.0	0	0.0	0	0.0	
Gastrointestinal disorders	Constipation	3	66.7	0	0.0	10	62.5	0	0.0	
Gastrointestinal disorders	Constipation	4	27.8	1	10.0	6	37.5	0	0.0	
Infections and infestations		2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations		3	66.7	0	0.0	10	62.5	2	20.0	
Infections and infestations		4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Appendicitis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Appendicitis	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Appendicitis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Device related infection	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Device related infection	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Device related infection	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Gastroenteritis	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Gastroenteritis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Gastroenteritis	4	27.8	0	0.0	6	37.5	1	16.7	
Infections and infestations	Infective thrombosis	2	5.6	1	50.0	0	0.0	0	0.0	
Infections and infestations	Infective thrombosis	3	66.7	0	0.0	10	62.5	0	0.0	
Infections and infestations	Infective thrombosis	4	27.8	0	0.0	6	37.5	0	0.0	
Infections and infestations	Lymph gland infection	2	5.6	0	0.0	0	0.0	0	0.0	
Infections and infestations	Lymph gland infection	3	66.7	0	0.0	10	62.5	1	10.0	
Infections and infestations	Lymph gland infection	4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications		2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications		3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications		4	27.8	0	0.0	6	37.5	0	0.0	
Injury, poisoning and procedural complications	Femur fracture	2	5.6	0	0.0	0	0.0	0	0.0	
Injury, poisoning and procedural complications	Femur fracture	3	66.7	0	0.0	10	62.5	1	10.0	
Injury, poisoning and procedural complications	Femur fracture	4	27.8	0	0.0	6	37.5	0	0.0	
Investigations		2	5.6	0	0.0	0	0.0	0	0.0	
Investigations		3	66.7	0	0.0	10	62.5	0	0.0	
Investigations		4	27.8	0	0.0	6	37.5	1	16.7	
Investigations	Oxygen saturation decreased	2	5.6	0	0.0	0	0.0	0	0.0	
Investigations	Oxygen saturation decreased	3	66.7	0	0.0	10	62.5	0	0.0	
Investigations	Oxygen saturation decreased	4	27.8	0	0.0	6	37.5	1	16.7	
Musculoskeletal and connective tissue disorders		2	5.6	0	0.0	0	0.0	0	0.0	
Musculoskeletal and connective tissue disorders		3	66.7	0	0.0	10	62.5	0	0.0	
Musculoskeletal and connective tissue disorders		4	27.8	1	10.0	6	37.5	1	16.7	
Musculoskeletal and connective tissue disorders	Back pain	2	5.6	0	0.0	0	0.0	0	0.0	
Musculoskeletal and connective tissue disorders	Back pain	3	66.7	0	0.0	10	62.5	0	0.0	
Musculoskeletal and connective tissue disorders	Back pain	4	27.8	1	10.0	6	37.5	1	16.7	
Nervous system disorders		2	5.6	0	0.0	0	0.0	0	0.0	

Nervous system disorders		3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders		4	10	27.8	0	0.0	6	37.5	0	0.0
Nervous system disorders	Partial seizures	2	2	5.6	0	0.0	0	0.0	0	0.0
Nervous system disorders	Partial seizures	3	24	66.7	1	4.2	10	62.5	0	0.0
Nervous system disorders	Partial seizures	4	10	27.8	0	0.0	6	37.5	0	0.0
Respiratory, thoracic and mediastinal disorders		2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders		3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders		4	10	27.8	0	0.0	6	37.5	1	16.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	5.6	0	0.0	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	3	24	66.7	0	0.0	10	62.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	4	10	27.8	0	0.0	6	37.5	1	16.7

Only AEs of highest severity are counted.

Clinical cut-off: 30SEP2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls

18DEC2020 10:41

POPULATION: SMA Type III, Safety-Evaluable Population
 ENDPOINT: Any SAEs including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39055 SUNFISH - Part 2
 Dichotomous Analysis by Subgroups (Safety)

History of scoliosis surgery or hip surgery

			Risdiplam (N=36)				Placebo (N=16)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Gastrointestinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Gastrointestinal disorders	Constipation	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Gastrointestinal disorders	Constipation	No	29	80.6	1	3.4	12	75.0	0	0.0
Infections and infestations		Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations		No	29	80.6	0	0.0	12	75.0	3	25.0
Infections and infestations	Appendicitis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Appendicitis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Device related infection	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Device related infection	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Gastroenteritis	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Gastroenteritis	No	29	80.6	0	0.0	12	75.0	1	8.3
Infections and infestations	Infective thrombosis	Yes	7	19.4	1	14.3	4	25.0	0	0.0
Infections and infestations	Infective thrombosis	No	29	80.6	0	0.0	12	75.0	0	0.0
Infections and infestations	Lymph gland infection	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Infections and infestations	Lymph gland infection	No	29	80.6	0	0.0	12	75.0	1	8.3
Injury, poisoning and procedural complications		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications		No	29	80.6	0	0.0	12	75.0	1	8.3
Injury, poisoning and procedural complications	Femur fracture	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Injury, poisoning and procedural complications	Femur fracture	No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations		No	29	80.6	0	0.0	12	75.0	1	8.3
Investigations	Oxygen saturation decreased	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Investigations	Oxygen saturation decreased	No	29	80.6	0	0.0	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders		No	29	80.6	1	3.4	12	75.0	1	8.3
Musculoskeletal and connective tissue disorders	Back pain	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Musculoskeletal and connective tissue disorders	Back pain	No	29	80.6	1	3.4	12	75.0	1	8.3
Nervous system disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders		No	29	80.6	1	3.4	12	75.0	0	0.0
Nervous system disorders	Partial seizures	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Nervous system disorders	Partial seizures	No	29	80.6	1	3.4	12	75.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders		No	29	80.6	0	0.0	12	75.0	1	8.3
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Yes	7	19.4	0	0.0	4	25.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	No	29	80.6	0	0.0	12	75.0	1	8.3

Only AEs of highest severity are counted.
 Clinical cut-off: 30SEP2020

Output: root/clinical_studies/R07034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2_2y/prod/output/t_saf_ae_raw_soc_sg_ASAE_SE_P2_T3.xls
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Population: Type III SMA.
 Endpoint: Change from Baseline in Total score of the RULM (Analysis of MMRM).
 Model: Stratified analysis.
 Study: BP39055 SUNFRIS - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics				Placebo Statistics				Difference between treatments (Risdiplam - placebo)			p-value (interaction)	Population/Method (4)			
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (CI)	95% CI Hedges g (CI)					
Sex	male	n/a	19	19	19	8	8														0.0015	ITT	Adjusted	
		Week 17						0.59	0.45	1.38	0.69	-0.79	0.83	-2.46	0.87	-0.39	0.42						ITT	Adjusted
		Week 35						0.97	0.59	-0.96	0.90	1.93	1.08	-0.25	4.11	0.73	-0.10	1.56					ITT	Adjusted
		Week 52						1.18	0.58	-0.35	0.87	1.81	1.04	-0.60	3.61	0.58	-0.23	1.41					ITT	Adjusted
	female	n/a	17	17	15	8	8															ITT	Adjusted	
		Week 17						0.73	0.47	-1.27	0.69	2.00	0.84	0.30	3.69	0.98	0.12	1.84					ITT	Adjusted
		Week 35						0.68	0.61	-0.67	0.90	1.35	1.10	-0.86	3.57	0.51	-0.31	1.34					ITT	Adjusted
		Week 52						2.01	0.61	-0.64	0.90	2.65	1.09	0.45	4.85	1.01	0.15	1.99					ITT	Adjusted
Age at randomization	2 to 5 years	n/a	4	4	3	4	4															ITT	Adjusted	
		Week 17						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 35						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 52						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
	6 to 11 years	n/a	11	11	11	4	4																ITT	Adjusted
		Week 17						1.35	0.60	0.88	1.00	0.47	1.16	-1.88	2.83	0.22	-0.86	1.30					ITT	Adjusted
		Week 35						1.94	0.70	0.55	1.24	1.39	1.44	-1.54	4.32	0.53	-0.56	1.62					ITT	Adjusted
		Week 52						2.90	0.74	-1.13	1.22	4.02	1.42	-1.15	6.90	1.56	0.34	2.77					ITT	Adjusted
	12 to 17 years	n/a	15	15	14	4	4																ITT	Adjusted
		Week 17						-0.31	0.51	-1.21	1.06	0.90	1.18	-1.50	3.29	0.41	-0.65	1.47					ITT	Adjusted
		Week 35						0.07	0.44	-0.66	1.32	0.74	1.47	-2.24	3.72	0.27	-0.79	1.33					ITT	Adjusted
		Week 52						0.27	0.63	-0.05	1.29	0.22	1.44	-2.71	3.15	0.08	-0.98	1.14					ITT	Adjusted
18 to 25 years	n/a	6	6	6	4	4																ITT	Adjusted	
	Week 17						0.56	0.82	-0.95	1.01	-0.40	1.31	-3.05	2.25	-0.18	-1.32	0.97					ITT	Adjusted	
	Week 35						0.29	1.02	-1.93	1.23	2.22	1.63	-1.07	3.51	0.85	-0.40	1.99					ITT	Adjusted	
	Week 52						1.39	1.00	-1.05	1.23	2.44	1.60	-0.79	5.68	0.89	-0.32	2.10					ITT	Adjusted	
Geographic region	Europe	n/a	28	28	27	14	14																ITT	Adjusted
		Week 17						0.76	0.39	-0.24	0.55	0.52	0.67	-0.83	1.88	0.25	-0.38	0.88					ITT	Adjusted
		Week 35						1.12	0.47	-0.82	0.66	1.79	0.81	0.11	3.36	0.69	0.04	1.34					ITT	Adjusted
		Week 52						1.85	0.45	-0.57	0.64	2.42	0.78	0.85	3.99	1.00	0.33	1.67					ITT	Adjusted
Rest of the World	n/a	8	8	7	2	2																ITT	Adjusted	
	Week 17						0.27	0.74	-1.34	1.55	1.62	1.47	-1.75	4.98	0.69	-0.74	2.12					ITT	Adjusted	
	Week 35						-0.24	0.91	-2.16	1.82	2.12	2.00	-1.91	6.15	0.76	-0.68	2.19					ITT	Adjusted	
	Week 52						0.41	0.87	-1.42	2.02	-1.01	2.17	-5.35	3.33	-0.43	-2.27	1.40					ITT	Adjusted	
Race / ethnicity	White	n/a	25	25	24	13	13																ITT	Adjusted
		Week 17						0.83	0.41	-0.20	0.58	1.06	0.71	-0.39	2.50	0.50	-0.17	1.16					ITT	Adjusted
		Week 35						1.02	0.45	-0.66	0.62	1.68	0.77	0.12	3.25	0.74	0.06	1.42					ITT	Adjusted
		Week 52						1.81	0.49	-0.69	0.69	2.51	0.85	0.79	4.23	1.02	0.31	1.74					ITT	Adjusted
	Asian / Black or African American / Multiple	n/a	7	7	6	1	1																ITT	Adjusted
		Week 17						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 35						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 52						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
	Unknown	n/a	4	4	4	2	2																ITT	Adjusted
		Week 17						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 35						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 52						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
History of scoliosis surgery or hip surgery	Yes	n/a	7	7	7	4	4																ITT	Adjusted
		Week 17						0.03	0.84	-1.26	1.08	1.29	1.28	-1.29	3.87	0.58	-0.37	1.73					ITT	Adjusted
		Week 35						0.31	1.03	-0.78	1.35	1.09	1.60	-2.13	4.31	0.39	-0.74	1.52					ITT	Adjusted
		Week 52						1.08	1.01	0.08	1.32	1.00	1.56	-2.14	4.15	0.37	-0.77	1.50					ITT	Adjusted
	No	n/a	29	29	27	12	12																ITT	Adjusted
		Week 17						0.80	0.38	0.51	0.60	0.29	0.70	-1.12	1.69	0.14	-0.52	0.80					ITT	Adjusted
		Week 35						0.94	0.48	-0.81	0.75	1.75	0.87	-0.01	3.51	0.68	0.00	1.36					ITT	Adjusted
		Week 52						1.63	0.47	-0.72	0.74	2.35	0.86	0.61	4.08	0.95	0.23	1.67					ITT	Adjusted
Disease Severity	NPM22 baseline <= 37.5 (Q1)	n/a	3	3	3	1	1																ITT	Adjusted
		Week 17						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 35						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 52						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
	NPM22 baseline >37.5 (Q1) to <= 54.17 (Q3)	n/a	13	13	13	5	5																ITT	Adjusted
		Week 17						0.13	0.65	-0.36	1.10	1.09	1.10	-1.14	3.31	0.49	-0.50	1.49					ITT	Adjusted
		Week 35						-0.88	0.80	-0.61	1.33	-0.27	1.34	-2.97	2.44	-0.10	-1.09	0.89					ITT	Adjusted
		Week 52						0.28	0.80	-0.38	1.35	1.46	1.36	-1.28	4.20	0.54	-0.46	1.54					ITT	Adjusted
	NPM22 baseline >54.17 (Q3)	n/a	20	20	18	10	10																ITT	Adjusted
		Week 17						1.04	0.51	0.90	0.69	0.13	0.78	-1.44	1.71	0.07	-0.67	0.80					ITT	Adjusted
		Week 35						1.90	0.62	-0.88	0.84	2.89	0.95	0.92	4.75	1.13	0.24	1.92					ITT	Adjusted
		Week 52						2.33	0.65	-0.41	0.86	2.74	0.88	0.77	4.72	1.13	0.28	1.94					ITT	Adjusted
BM22 cov number	2	n/a	2	2	2	0	0																ITT	Adjusted
		Week 17						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 35						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
		Week 52						NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted
	3	n/a	24	24	23	10	10																	

Covariance matrix: unstructured. Data as observed (no imputation of missing values). Clinical Cutoff Date: 06SEP2019. NR when shown, means Not Reported. NE when shown, means Not Estimable. Inferential statistics of subgroup categories with N<10 not reported. Category Unknown not used and SMN copy nr 1+2 combined for calculation of the interaction tests.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/program/t_eff_mrm_sg.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/output/t_eff_mrm_sg_IT_T3_CS_NULM.xls
15SEP2020 12:28

Covariance matrix: unstructured. Data as observed (no imputation of missing values). Clinical Cutoff Date: 06SEP2019. NR when shown, means Not Reported. NE when shown, means Not Estimable.
Inferential statistics of subgroup categories with N<10 not reported. Category Unknown not used and SMM copy nr 1+2 combined for calculation of the interaction tests.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/program/t_eff_mrm_sg.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/output/t_eff_mrm_sg_IT_T3_CS_HFMSE.xls
15SEP2020 12:27

Population: Type III BMA.
 Endpoint: Change from Baseline in Total score of the MPK-32 (Analysis of M66M).
 Model: Stratified analysis.
 Study: BPS9055 SUNFRIS - Part 2.

Subgroup	Level	Visit	Risdiplam N			Placebo N			Risdiplam Statistics				Placebo Statistics				Difference between treatments (Risdiplam - placebo)			p-value (interaction)	Population/Method (4)			
			Total	with baseline value	included in analysis (1)	Total	with baseline value	included in analysis (1)	LSMeans (2)	SE (LSMeans)	LSMeans (2)	SE (LSMeans)	LSMeans (3)	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Hedges g	95% CI Hedges g (CI)	95% CI Hedges g (CI)					
Sex	male	n/a	19	19	18	8	8													0.1980	ITT	Adjusted		
		Week 17			0.57	0.51	1.04	0.78	-0.47	0.95	-2.38	1.44	-0.20	-1.01	0.60							ITT	Adjusted	
		Week 35			0.34	0.73	-0.79	1.11	1.14	1.36	-1.60	3.87	0.34	-0.47	1.16							ITT	Adjusted	
		Week 52			0.72	0.70	-0.07	1.06	0.79	1.29	-1.80	3.38	0.25	-0.56	1.06							ITT	Adjusted	
	female	n/a	17	17	17	8	7														ITT	Adjusted		
		Week 17			0.26	0.52	-0.62	0.82	0.89	0.99	-1.10	2.88	0.39	-0.47	1.25							ITT	Adjusted	
		Week 35			0.37	0.75	-0.29	1.18	0.66	1.42	-2.19	3.51	0.20	-0.65	1.05							ITT	Adjusted	
		Week 52			0.46	0.71	-1.49	1.47	1.95	1.38	-0.84	4.73	0.64	-0.27	1.36							ITT	Adjusted	
Age at randomization	2 to 5 years	n/a	4	3	3	4	3														ITT	Adjusted		
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
	6 to 11 years	n/a	11	11	11	4	4															ITT	Adjusted	
		Week 17			0.05	0.59	-0.13	0.94	0.18	1.07	-1.99	2.35	0.09	-0.99	1.17							ITT	Adjusted	
		Week 35			0.88	0.89	0.37	1.58	0.51	1.81	-3.16	4.18	0.15	-0.92	1.23							ITT	Adjusted	
		Week 52			-0.21	0.86	-0.28	1.37	0.97	1.97	-3.11	3.25	0.02	-1.05	1.10							ITT	Adjusted	
	12 to 17 years	n/a	15	15	15	4	4															ITT	Adjusted	
		Week 17			0.58	0.48	-1.09	1.01	1.67	1.09	-0.54	3.88	0.82	-0.26	1.91							ITT	Adjusted	
		Week 35			0.43	0.81	-0.85	1.31	1.48	1.84	-2.26	5.22	0.43	-0.43	1.49							ITT	Adjusted	
		Week 52			0.40	0.70	-1.86	1.48	2.26	1.60	-0.99	5.50	0.76	-0.32	1.84							ITT	Adjusted	
18 to 25 years	n/a	6	6	6	4	4															ITT	Adjusted		
	Week 17			-0.65	0.77	1.71	0.94	-2.36	1.24	-4.88	0.16	-1.11	-2.35	0.13							ITT	Adjusted		
	Week 35			-1.19	1.20	-0.80	1.59	-0.50	2.10	-4.75	3.76	-0.14	-1.28	1.01							ITT	Adjusted		
	Week 52			-0.06	1.13	-0.26	1.38	0.20	1.82	-3.49	3.89	0.08	-1.08	1.21							ITT	Adjusted		
Geographic region	Europe	n/a	28	28	28	14	13														ITT	Adjusted		
		Week 17			0.24	0.39	0.15	0.57	0.20	0.69	-1.20	1.59	0.08	-0.55	0.74						NR	ITT	Adjusted	
		Week 35			0.67	0.55	-0.39	0.81	1.06	0.98	-0.93	3.04	0.35	-0.30	1.00							ITT	Adjusted	
		Week 52			0.85	0.49	-0.70	0.72	1.55	0.88	-0.23	3.32	0.58	-0.08	1.24							ITT	Adjusted	
	Rest of the World	n/a	8	7	7	2	2															ITT	Adjusted	
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
Race / ethnicity	White	n/a	25	24	24	13	12														NR	ITT	Adjusted	
		Week 17			0.70	0.36	0.24	0.51	0.46	0.62	-0.80	1.72	0.26	-0.42	0.94							ITT	Adjusted	
		Week 35			1.00	0.59	-0.77	0.84	1.77	1.02	-0.32	3.85	0.60	-0.10	1.29							ITT	Adjusted	
		Week 52			1.00	0.56	-0.79	0.80	1.79	0.98	-0.20	3.77	0.65	-0.06	1.36							ITT	Adjusted	
	Asian / Black or African American / Multiple	n/a	7	7	7	1	1															ITT	Adjusted	
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
	Unknown	n/a	4	4	4	2	2															ITT	Adjusted	
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
History of scoliosis surgery or hip surgery	Yes	n/a	7	7	7	4	4														0.0693	ITT	Adjusted	
		Week 17			0.07	0.97	-0.98	1.20	1.05	1.36	-1.69	3.80	0.44	-0.69	1.58							ITT	Adjusted	
		Week 35			-1.61	1.32	-0.93	1.66	-0.68	1.88	-4.46	3.11	-0.21	-1.33	0.92							ITT	Adjusted	
		Week 52			-0.89	1.27	-2.37	1.59	1.39	1.80	-2.24	5.02	0.44	-0.70	1.58							ITT	Adjusted	
	No	n/a	29	28	28	12	11																ITT	Adjusted
		Week 17			0.50	0.42	0.73	0.69	-0.23	0.78	-1.80	1.33	-0.10	-0.79	0.58							ITT	Adjusted	
		Week 35			0.83	0.58	-0.38	0.95	1.01	1.07	-0.96	3.37	0.39	-0.30	1.08							ITT	Adjusted	
		Week 52			0.97	0.56	-0.02	0.93	0.89	1.05	-1.12	3.09	0.34	-0.37	1.05							ITT	Adjusted	
Disease Severity	MPM32 baseline <= 37.5 (Q1)	n/a	3	3	3	1	1															ITT	Adjusted	
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
	MPM32 baseline >37.5 (Q1) to <= 54.17 (Q3)	n/a	13	12	12	5	4															ITT	Adjusted	
		Week 17			0.16	0.92	-0.47	1.47	0.64	1.34	-2.08	3.35	0.26	-0.81	1.33							ITT	Adjusted	
		Week 35			-1.00	1.25	-1.12	2.00	0.12	1.86	-3.64	3.87	0.03	-1.04	1.10							ITT	Adjusted	
		Week 52			-0.03	1.22	-1.31	1.94	1.46	1.80	-2.16	5.12	0.45	-0.63	1.53							ITT	Adjusted	
	MPM32 baseline >54.17 (Q3)	n/a	20	20	20	10	10															ITT	Adjusted	
		Week 17			0.58	0.63	0.70	0.82	-0.12	0.88	-1.91	1.66	-0.05	-0.79	0.69							ITT	Adjusted	
		Week 35			1.22	0.87	-0.48	1.13	1.59	1.22	-0.87	4.06	0.49	-0.26	1.24							ITT	Adjusted	
		Week 52			0.85	0.84	-0.32	1.12	1.17	1.20	-1.25	3.60	0.38	-0.39	1.15							ITT	Adjusted	
BM22 cov number	2	n/a	2	2	2	0	0															ITT	Adjusted	
		Week 17			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 35			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
		Week 52			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	ITT	Adjusted	
	3	n/a	24	24	24	10	9															ITT	Adjusted	
		Week 17			0.40	0.44	-0.50	0.73	0.89	0.85	-0.82	2.61	0.40	-0.35	1.16							ITT	Adjusted	
		Week 35			0.16	0.62	0.28	1.02	-0.22															

Covariance matrix: unstructured. Data as observed (no imputation of missing values). Clinical Cutoff Date: 06SEP2019. NR when shown, means Not Reported. NE when shown, means Not Estimable.
Inferential statistics of subgroup categories with N<10 not reported. Category Unknown not used and SMN copy nr 1+2 combined for calculation of the interaction tests.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/program/t_eff_mmrn_sg.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/output/t_eff_mmrn_sg_IT_T3_DB_MFM.xls
23SEP2020 14:25

Population: Type III SMO.
 Endpoint: Patients who Experienced at Least One Adverse Event Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: RP39055 S0M728 - Part 2.

Subgroup	Level	Randomized			Patients with Event			Odds Ratio			Relative Risk Difference			Relative Risk			Relative Risk											
		n	%	n	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (Likelihood Ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI						
Sex	Male	19	82.8	17	89.5	6	100.0	7	87.5	1.21	Algorithm converged.	0.00	16.73	0.020	Algorithm converged.	-0.235	0.294	1.02	Algorithm converged.	0.75	1.39	0.887	<.0001	0.98	Algorithm converged.	0.72	1.34	
	Female	17	67.2	16	94.1	6	100.0	8	100	0.00	Algorithm converged.	0.00	NR	<0.010	Algorithm converged.	-0.333	0.216	0.94	Algorithm converged.	0.69	1.28	0.6929		1.06	Algorithm converged.	0.78	1.47	
	Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0.00	Algorithm converged.	0.00	NR	0.000	Algorithm converged.	0.000	NR	NR	Algorithm converged.	NR	NR	NR		NR	Algorithm converged.	NR	NR	
Age at randomization	2 to 5 years	4	11.1	4	100	4	25.0	4	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
	6 to 11 years	11	40.8	10	90.9	4	25.0	4	100	0.00	Algorithm converged.	0.00	NR	<0.001	Algorithm converged.	-0.582	0.380	0.91	Algorithm converged.	0.66	1.26	0.3495		1.09	Algorithm converged.	0.77	1.34	
	12 to 17 years	15	61.7	13	86.0	4	25.0	4	100	0.00	Algorithm converged.	0.00	NR	<0.100	Algorithm converged.	-0.404	0.337	0.87	Algorithm converged.	0.64	1.21	0.4649		1.14	Algorithm converged.	0.89	1.43	
	18 to 25 years	6	16.7	6	100	4	25.0	3	75.0	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity	Infinity		Infinity	Infinity	Infinity	Infinity	
Geographic region	Europe	28	87.9	23	89.3	14	87.5	13	92.9	0.84	Algorithm converged.	0.56	7.22	<0.010	Algorithm converged.	-0.217	0.149	0.98	Algorithm converged.	0.79	1.17	0.6997	<.0001	1.00	Algorithm converged.	0.85	1.24	
	Rest of the World	4	15.2	3	75.0	2	100	2	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
Race / ethnicity	White	25	89.4	22	88.0	13	81.3	12	92.3	0.61	Algorithm converged.	0.03	6.97	<0.010	Algorithm converged.	-0.241	0.155	0.86	Algorithm converged.	0.77	1.20	0.7203		1.04	Algorithm converged.	0.84	1.28	
	Black or African American / Multiracial	7	28.4	7	100	1	6.3	1	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
	Unknown	4	11.1	4	100	2	12.5	2	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
History of neovascular surgery of hip	Yes	7	18.4	6	85.7	4	25.0	4	100	0.00	Algorithm converged.	0.00	NR	<0.100	Algorithm converged.	-0.329	0.043	0.86	Algorithm converged.	0.70	1.05	0.1332	<.0001	1.17	Algorithm converged.	0.95	1.43	
	No	19	80.6	27	93.1	17	75.0	11	81.7	1.29	Algorithm converged.	0.00	15.94	0.014	Algorithm converged.	-0.171	0.207	1.02	Algorithm converged.	0.83	1.24	0.6734		0.98	Algorithm converged.	0.80	1.27	
Disease severity	DM2 baseline <=0.50 (Q1)	5	18.5	3	66.7	1	6.0	1	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
	DM2 baseline >0.50 (Q1) to <=0.17 (Q2)	13	50.1	12	100	5	31.3	5	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
	DM2 baseline >0.17 (Q2) to <=0.33 (Q3)	20	75.6	18	90.0	10	50.0	9	90.0	1.00	Algorithm converged.	0.07	13.45	0.010	Algorithm converged.	-0.234	0.234	0.99	Algorithm converged.	0.77	1.27	0.3160		NR	NR	NR	NR	
	DM2 copy number	2	6.6	1	50.0	0	0.0	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
Age	2	24	66.7	23	95.8	10	62.5	10	100	0.00	Algorithm converged.	0.00	NR	<0.001	Algorithm converged.	-0.402	0.319	0.96	Algorithm converged.	0.70	1.31	0.7894		1.05	Algorithm converged.	0.75	1.44	
	3	10	37.5	9	90.0	4	37.5	5	83.3	1.80	Algorithm converged.	0.08	38.33	0.067	Algorithm converged.	-0.234	0.427	0.88	Algorithm converged.	0.72	1.35	0.3183		1.02	Algorithm converged.	0.73	1.43	
	4	0	0.0	0	0.0	0	0.0	0	0.0	0.00	Algorithm converged.	0.00	NR	0.000	Algorithm converged.	0.000	NR	NR	Algorithm converged.	NR	NR	NR		NR	NR	NR	NR	

Text for interaction based on RR (Log-binomial regression), DM2 copy numbers 2 and 3 are combined. * When above, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 10/20/2019. Inferential statistics for subgroups with N=0 patients are not reported.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, estimates for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NR when above, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: /rsof/clinical_studies/20703467/CDPT916/RP39055/data_analysis/ACR_CSB_part2/prod/program/1_naf_m_raw_03_naf
 Output: /rsof/clinical_studies/20703467/CDPT916/RP39055/data_analysis/ACR_CSB_part2/prod/output/1_naf_m_raw_03_naf_01_01_2020_1514

Population: Type III SMO.
 Endpoint: Patients who Experienced at Least One Adverse Event of Grade 3 Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: RP39055 S0M728 - Part 2.

Subgroup	Level	Stratum				Patients				Odds Ratio			Relative Risk			Relative Risk			Relative Risk							
		n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value (Mid)	Interaction Test p-value (Likelihood Ratio)	Relative Risk	95% Lower CI	95% Upper CI					
Sex	Male	19	52.8	1	5.3	8	50.0	3	37.5	0.29	Algorithm converged	0.01	1.17	<0.100	Algorithm converged	<0.402	0.037	0.14	Algorithm converged	0.02	1.22	0.0740	1.13	Algorithm converged	0.82	0.47
	Female	17	47.2	2	11.8	4	50.0	1	12.5	0.83	Algorithm converged	0.07	12.93	<0.001	Algorithm converged	<0.205	0.273	0.04	Algorithm converged	0.09	0.45	0.0921	1.06	Algorithm converged	0.11	10.47
Age at randomization	2 to 5 years	4	11.1	0	0.0	4	25.0	2	50.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	5 to 11 years	11	30.6	1	9.1	4	25.0	2	50.0	0.10	Algorithm converged	0.01	1.88	<0.409	Algorithm converged	<0.885	0.127	0.18	Algorithm converged	0.02	1.41	0.1216	5.56	Algorithm converged	0.02	48.63
	12 to 17 years	15	41.7	2	13.3	4	25.0	0	0.0	Infinity	Algorithm converged	0.00	Infinity	0.133	Algorithm converged	<0.402	0.668	Infinity	Algorithm converged	0.00	Infinity	0.8843	0.00	Algorithm converged	0.00	NR
	18 to 25 years	6	16.7	0	0.0	4	25.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Geographic region	Europe	28	77.8	3	10.7	14	87.5	3	21.4	0.44	Algorithm converged	0.07	2.65	<0.100	Algorithm converged	<0.357	0.143	0.30	Algorithm converged	0.11	2.25	0.3587	2.00	Algorithm converged	0.44	0.05
	Rest of the World	8	22.2	0	0.0	2	12.5	1	50.0	0.00	Algorithm converged	0.00	NR	<0.100	Algorithm converged	<0.710	<0.250	0.00	Algorithm converged	0.00	NR	0.8734	Infinity	Algorithm converged	0.00	Infinity
Race / ethnicity	White	25	69.4	2	8.0	13	81.1	2	15.4	0.48	Algorithm converged	0.06	4.10	<0.074	Algorithm converged	<0.303	0.157	0.02	Algorithm converged	0.08	1.50	0.4910	1.02	Algorithm converged	0.29	12.93
	Black or African American / Multiracial	7	19.4	0	0.0	1	6.3	1	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Unknown	4	11.1	1	25.0	1	12.5	1	50.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
History of previous surgery of hip	Yes	7	19.4	0	0.0	4	25.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	No	19	50.6	1	10.0	10	75.0	4	33.3	0.27	Algorithm converged	0.04	1.31	<0.100	Algorithm converged	<0.524	0.064	0.31	Algorithm converged	0.04	1.22	0.0204	1.22	Algorithm converged	0.81	11.70
Disease severity	DM2 baseline <40.50 (Q1)	5	13.9	0	0.0	1	6.3	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	DM2 baseline >37.50 (Q3) to <=41.17 (Q2)	13	36.1	0	0.0	5	31.3	1	20.0	0.00	Algorithm converged	0.00	NR	<0.100	Algorithm converged	<0.533	0.133	0.00	Algorithm converged	0.00	7.8232	0.9707	Infinity	Algorithm converged	0.00	Infinity
	DM2 baseline >34.17 (Q3)	20	55.6	3	15.0	10	62.5	1	50.0	0.41	Algorithm converged	0.06	2.69	<0.100	Algorithm converged	<0.483	0.181	0.10	Algorithm converged	0.12	2.13	0.1402	2.00	Algorithm converged	0.47	0.51
		2	5.6	0	0.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
DM2 copy number	2	24	66.7	1	4.2	10	62.5	3	50.0	0.10	Algorithm converged	0.01	1.21	<0.258	Algorithm converged	<0.561	0.045	0.14	Algorithm converged	0.02	1.25	0.0711	1.20	Algorithm converged	0.80	44.81
	3	10	27.8	2	20.0	4	37.5	1	16.7	1.25	Algorithm converged	0.08	18.96	0.033	Algorithm converged	<0.345	0.432	1.20	Algorithm converged	0.13	11.22	0.8703	0.83	Algorithm converged	0.29	1.78
	4																									

Test for interaction based on RR (Log-binomial regression). DM2 copy numbers 2 and 3 are combined. * When shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 10/22/2019. Inferential statistics for subgroups with N=0 patients are not reported.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, estimates for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: rse/clinical_studies/20703467/CDPT7916/RP39055/data_analysis/ACR_CSB_part2/prod/program/1_naf_m_raw_ug_sas
 Output: rse/clinical_studies/20703467/CDPT7916/RP39055/data_analysis/ACR_CSB_part2/prod/output/1_naf_m_raw_ug_R1_08_083.sas
 15M02020 16:10

Population: Type III SMO.
 Endpoint: Patients who Experienced at Least One Adverse Event of Grade Greater than or Equal to 3 Including Disease Related Adverse Events.
 Model: Unstratified Analysis.
 Study: RP39055 S0M728 - Part 2.

Subgroup	Level	Stratum			Patients			Odds Ratio	Relative Risk			Relative Risk			Relative Risk			Relative Risk							
		n	%	n	%	n	%		95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (Likelihood Ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
Sex	Male	19	52.8	1	5.3	8	50.0	0.09	Algorithm converged	0.01	1.17	<0.100	Algorithm converged	<0.402	0.037	0.14	Algorithm converged	0.02	1.22	0.0740		1.13	Algorithm converged	0.82	61.47
	Female	17	47.2	2	11.8	4	50.0	0.83	Algorithm converged	0.07	12.93	<0.001	Algorithm converged	<0.205	0.273	0.04	Algorithm converged	0.09	8.45	0.0092		1.06	Algorithm converged	0.11	10.47
Age at randomization	2 to 5 years	4	11.1	0	0.0	4	25.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
	5 to 11 years	11	30.6	1	9.1	4	25.0	0.10	Algorithm converged	0.01	1.88	<0.409	Algorithm converged	<0.885	0.127	0.18	Algorithm converged	0.02	1.41	0.1216		5.56	Algorithm converged	0.02	48.63
	12 to 17 years	15	41.7	2	13.3	4	25.0	0.0	Algorithm converged	0.00	Infinity	0.133	Algorithm converged	<0.402	0.668	Infinity	Algorithm converged	0.00	Infinity	0.8843		0.00	Algorithm converged	0.00	NR
	18 to 25 years	6	16.3	0	0.0	4	25.0	0.0	Algorithm converged	0.00	NR	0.000	Algorithm converged	NR	NR	NR	Algorithm converged	NR	NR	NR		0.00	Algorithm converged	NR	NR
Geographic region	Europe	28	77.8	3	10.7	14	87.5	0.44	Algorithm converged	0.07	2.65	<0.100	Algorithm converged	<0.357	0.143	0.30	Algorithm converged	0.11	2.25	0.3587		2.00	Algorithm converged	0.44	0.00
	Rest of the World	8	22.2	0	0.0	2	12.5	0.00	Algorithm converged	0.00	NR	<0.100	Algorithm converged	<0.710	<0.250	0.00	Algorithm converged	0.00	NR	0.8734		Infinity	Algorithm converged	0.00	Infinity
Race / ethnicity	White	25	69.4	2	8.0	13	81.3	0.48	Algorithm converged	0.06	4.15	<0.074	Algorithm converged	<0.303	0.157	0.02	Algorithm converged	0.08	1.50	0.4910		1.02	Algorithm converged	0.29	12.93
	Black or African American / Multiracial	7	19.4	0	0.0	1	6.3	1.00	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
	Unknown	4	11.1	1	25.0	1	50.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
History of previous surgery of hip	Yes	7	19.4	0	0.0	4	25.0	0.0	Algorithm converged	0.00	NR	0.000	Algorithm converged	NR	NR	NR	Algorithm converged	NR	NR	NR		0.00	Algorithm converged	NR	NR
	No	19	50.6	2	10.5	10	62.5	0.27	Algorithm converged	0.04	1.31	<0.100	Algorithm converged	<0.524	0.064	0.31	Algorithm converged	0.04	1.22	0.0208		1.22	Algorithm converged	0.41	11.70
Disease severity	DM2 baseline <40.50 (Q1)	5	13.5	0	0.0	1	6.3	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
	DM2 baseline >40.50 (Q1) to <64.17 (Q2)	13	36.1	0	0.0	5	31.3	0.00	Algorithm converged	0.00	NR	<0.100	Algorithm converged	<0.533	0.133	0.00	Algorithm converged	0.00	7.8232	0.9707		Infinity	Algorithm converged	0.00	Infinity
	DM2 baseline >64.17 (Q2)	20	55.6	3	15.0	10	62.5	0.41	Algorithm converged	0.06	2.69	<0.100	Algorithm converged	<0.483	0.181	0.10	Algorithm converged	0.12	2.13	0.1402		2.00	Algorithm converged	0.47	8.51
		2	5.6	0	0.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR
DM2 copy number	1	24	66.7	1	4.2	10	62.5	0.10	Algorithm converged	0.01	1.21	<0.258	Algorithm converged	<0.561	0.045	0.14	Algorithm converged	0.02	1.25	0.0711		1.20	Algorithm converged	0.80	44.81
	2	10	27.8	2	20.0	4	37.5	1.25	Algorithm converged	0.08	18.96	0.003	Algorithm converged	<0.345	0.432	1.20	Algorithm converged	0.13	11.22	0.8703		0.83	Algorithm converged	0.29	1.78
	3																								
	4																								

Test for interaction based on RR (Log-binomial regression), DM2 copy numbers 2 and 3 are combined. * When shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 10/22/2019. Inferential statistics for subgroups with N=0 patients are not reported.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: /rso/clinical_studies/20703467/CDPT7916/RP39055/data_analysis/ACR_CSR_part2/prod/program/1_naf_m_raw_0g_sas
 Output: /rso/clinical_studies/20703467/CDPT7916/RP39055/data_analysis/ACR_CSR_part2/prod/output/1_naf_m_raw_0g_01_00_000220_1613

Population: Type III SMO.
 Endpoint: Patients who Experienced at Least One Serious Adverse Event Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: RP39055 S0M728 - Part 2.

Subgroup	Level	Flavipim				Flavim				Relative vs. Placebo																	
		n	k	n	k	n	k	n	k	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
Sex	Male	19	42.6	1	5.3	8	10.0	5	42.5	0.03	Algorithm converged.	0.00	0.47	-0.572	Algorithm converged.	-0.512	-0.213	0.08	Algorithm converged.	0.01	0.44	0.0181		11.48	Algorithm converged.	1.55	40.43
	Female	17	49.2	0	0.0	8	10.0	0	0.0	NR	NR	NR	0.000	NR	NR	NR	NR	NR	NR	NR	NR		0.00	NR	NR	NR	
Age at randomization	7 to 9 years	4	11.3	0	0.0	4	25.0	2	50.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
	9 to 11 years	11	40.4	0	0.0	4	25.0	3	75.0	0.00	Algorithm converged.	0.00	NR	-0.750	Algorithm converged.	-1.207	-0.293	0.00	Algorithm converged.	0.00	NR	0.8827		Infinity	Algorithm converged.	0.00	Infinity
	12 to 17 years	13	41.7	1	6.7	4	25.0	0	0.0	Infinity	Algorithm converged.	0.00	Infinity	0.047	Algorithm converged.	-0.391	0.524	Infinity	Algorithm converged.	0.00	Infinity	0.8902		0.00	Algorithm converged.	0.00	NR
18 to 24 years	6	16.7	0	0.0	4	25.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		0.00	NR	NR	NR		
Geographic region	Europe	28	47.9	1	3.4	12	47.3	4	28.6	0.09	Algorithm converged.	0.01	0.40	-0.230	Algorithm converged.	-0.303	0.003	0.13	Algorithm converged.	0.01	1.07	0.0322		0.00	Algorithm converged.	0.41	48.44
	Rest of the World	8	42.2	0	0.0	2	12.5	1	50.0	0.00	Algorithm converged.	0.00	NR	-0.500	Algorithm converged.	-0.703	-0.247	0.00	Algorithm converged.	0.00	NR	0.9784		Infinity	Algorithm converged.	0.00	Infinity
Race / ethnicity	White	21	49.4	1	4.0	11	41.7	7	21.7	0.14	Algorithm converged.	0.01	1.47	-0.120	Algorithm converged.	-0.441	0.003	0.17	Algorithm converged.	0.01	1.40	0.1028		0.27	Algorithm converged.	0.40	14.02
	Asian / Black or African American / Hispanic	1	42.4	0	0.0	1	42.4	1	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
History of scoliosis surgery or hip surgery	Yes	7	49.4	0	0.0	4	25.0	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		0.00	NR	NR	NR	
	No	23	49.6	1	3.4	12	41.7	5	41.7	0.05	Algorithm converged.	0.00	0.33	-0.382	Algorithm converged.	-0.406	-0.088	0.08	Algorithm converged.	0.01	0.47	0.0206		12.03	Algorithm converged.	1.43	47.83
Disease severity	BM12 baseline <=3-10 (Q1)	3	49.3	0	0.0	1	4.3	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
	BM12 baseline >7-10 (Q1 to <=4-17 (Q3))	13	46.1	0	0.0	5	31.1	0	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		0.00	NR	NR	NR	
	BM12 baseline >4-17 (Q3)	20	45.4	1	4.0	10	42.4	5	40.0	0.03	Algorithm converged.	0.00	0.40	-0.450	Algorithm converged.	-0.783	-0.117	0.10	Algorithm converged.	0.01	0.74	0.0297		10.00	Algorithm converged.	1.27	34.82
BM2 copy number	2	2	16.4	0	0.0	0	0.0	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	
	3	24	46.7	0	0.0	10	42.3	2	30.0	0.00	Algorithm converged.	0.00	NR	-0.300	Algorithm converged.	-0.702	0.132	0.00	Algorithm converged.	0.00	NR	0.9702		Infinity	Algorithm converged.	0.00	Infinity
	4	10	47.9	1	10.0	4	37.3	2	33.3	0.22	Algorithm converged.	0.01	3.44	-0.221	Algorithm converged.	-0.483	0.192	0.10	Algorithm converged.	0.03	3.41	0.2840		3.33	Algorithm converged.	0.34	31.17

Test for interaction based on OR (log-binomial regression). BM2 copy numbers 2 and 3 are combined. * when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff Date: 06/22/2019. Inferential statistics for subgroups with 0/10 patients are not reported.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NR when shown, means Not Estimable.
 Disease related events are defined as those under the broad perspective-PT basket. Only AEs of highest severity are counted.

Program: root/clinical_studies/R07034067/CDPT7916/RP39055/data_analysis/ACE_CDR_part2/prod/program/0_naf_wt_raw_cp_max
 Output: root/clinical_studies/R07034067/CDPT7916/RP39055/data_analysis/ACE_CDR_part2/prod/output/0_naf_wt_raw_cp_max_7_04M_0B.xlsx
 10/02/2020 16:39

General Information		Country		Year		Age		Sex		Ethnicity		Religion		Marital Status		Education		Occupation		Income		Health Status		Mental Health		Substance Use		Social Support		Life Satisfaction		Quality of Life		Overall Well-being				
ID	Name	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value	Code	Value			
1	John Doe	US	35	M	White	Protestant	Married	High School	Teacher	\$50,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low			
2	Jane Smith	US	30	F	Black	Catholic	Single	College	Engineer	\$75,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low			
3	Michael Johnson	US	40	M	Hispanic	Evangelical	Married	High School	Construction Worker	\$30,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low		
4	Sarah Lee	US	25	F	Asian	Buddhist	Single	College	Software Engineer	\$90,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low		
5	David Brown	US	55	M	White	Methodist	Married	High School	Retired	\$40,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low		
6	Emily White	US	20	F	Black	Catholic	Single	College	Student	\$15,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
7	Robert Green	US	60	M	Hispanic	Evangelical	Married	High School	Retired	\$35,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
8	Laura Black	US	38	F	Asian	Buddhist	Single	College	Marketing Executive	\$80,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
9	Christopher King	US	45	M	White	Methodist	Married	High School	Construction Worker	\$35,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
10	Amanda Hill	US	28	F	Black	Catholic	Single	College	Teacher	\$55,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
11	Matthew Young	US	50	M	Hispanic	Evangelical	Married	High School	Retired	\$45,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
12	Olivia Taylor	US	22	F	Asian	Buddhist	Single	College	Student	\$18,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
13	Benjamin Adams	US	65	M	White	Methodist	Married	High School	Retired	\$38,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
14	Isabella Baker	US	32	F	Black	Catholic	Single	College	Software Engineer	\$70,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
15	Ethan Clark	US	48	M	Hispanic	Evangelical	Married	High School	Construction Worker	\$32,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
16	Sophia Evans	US	26	F	Asian	Buddhist	Single	College	Marketing Executive	\$78,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
17	Lucas Foster	US	52	M	White	Methodist	Married	High School	Retired	\$42,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	
18	Mia Garcia	US	30	F	Black	Catholic	Single	College	Teacher	\$58,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
19	Noah Harris	US	58	M	Hispanic	Evangelical	Married	High School	Retired	\$48,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
20	Charlotte King	US	24	F	Asian	Buddhist	Single	College	Student	\$20,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
21	Leo Lopez	US	62	M	White	Methodist	Married	High School	Retired	\$40,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
22	Aria Miller	US	34	F	Black	Catholic	Single	College	Software Engineer	\$72,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
23	Isaac Nelson	US	46	M	Hispanic	Evangelical	Married	High School	Construction Worker	\$34,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
24	Amelia Owen	US	28	F	Asian	Buddhist	Single	College	Marketing Executive	\$82,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
25	Samuel Parker	US	54	M	White	Methodist	Married	High School	Retired	\$44,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
26	Harper Quinn	US	31	F	Black	Catholic	Single	College	Teacher	\$60,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
27	Oliver Reed	US	56	M	Hispanic	Evangelical	Married	High School	Retired	\$46,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
28	Evelyn Scott	US	29	F	Asian	Buddhist	Single	College	Marketing Executive	\$84,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
29	Wyatt Turner	US	51	M	White	Methodist	Married	High School	Retired	\$41,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
30	Madison Vance	US	33	F	Black	Catholic	Single	College	Software Engineer	\$74,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
31	Grayson Webb	US	49	M	Hispanic	Evangelical	Married	High School	Construction Worker	\$36,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
32	Skylar Wood	US	27	F	Asian	Buddhist	Single	College	Marketing Executive	\$86,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
33	Julian York	US	53	M	White	Methodist	Married	High School	Retired	\$43,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
34	Alaina Zane	US	35	F	Black	Catholic	Single	College	Teacher	\$62,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
35	Maxwell Bell	US	57	M	Hispanic	Evangelical	Married	High School	Retired	\$47,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
36	Brooklyn Boyd	US	30	F	Asian	Buddhist	Single	College	Marketing Executive	\$88,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
37	Easton Cole	US	50	M	White	Methodist	Married	High School	Retired	\$45,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
38	Delaney Evans	US	32	F	Black	Catholic	Single	College	Software Engineer	\$76,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
39	Lincoln Fox	US	47	M	Hispanic	Evangelical	Married	High School	Construction Worker	\$38,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
40	Leah Gibson	US	29	F	Asian	Buddhist	Single	College	Marketing Executive	\$90,000	Good	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
41	Robert Hall	US	54	M	White	Methodist	Married	High School	Retired	\$49,000	Fair	Stable	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
42	Madelyn Ives	US	34	F	Black	Catholic	Single	College	Teacher	\$6																												

Population: Type III SGA.
 Endpoint: Patients who Experienced at least One Adverse Event of Special Interest Including Disease Related Adverse Events.
 Model: Unstratified analysis.
 Study: BP39055 SUNFISH - Part 2.

Subgroup	SOC	PT	Level	Ridiplan				Placebo				Ridiplan vs. Placebo				Placebo vs. Ridiplan													
				Patients with Event		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
CC	CC	CC	CC	0	0	0	0	0	0	0	0	NR		NR	NR	NR	NR	NR	NR	NR	NR	NR	NR			NR		NR	NR

Test for interaction based on RR (Log-binomial regression), SMD copy numbers 2 and 3 are combined. * when shown, indicates convergence problem. Result is uninterpretable.
 Clinical Cutoff date: 04SEP2019. Inferential statistics for subgroups with NCI0 patients are not reported.
 When there are no adverse events in either arm, estimates and confidence limits for odds ratio and relative risk are reported as 0 or Infinity as appropriate.
 When there are no adverse events in both arms, the estimate for absolute risk difference is set to 0 and all other model estimates are set to "NR" (Not Reported).
 NE when shown, means Not Estimable. Disease related events are defined as those under the broad perspective-PT basket.
 AEs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.
 Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/program/t_saf_ae_raw_soc_sq.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/qa/output/t_saf_ae_raw_soc_sq_T3_SPT_DB.xls
 25SEP2020 13:31

Population: Type II SMA.

Endpoint: Demographics and baseline characteristics.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo	Total
N		84	44	128
Age [years] at screening	n	84	44	128
	Mean (SD)	8.7 (5.5)	9.6 (5.7)	9.0 (5.5)
	Median	8.0	8.0	8.0
	IQR	4 - 12	5 - 14	5 - 13
	Min - Max	2 - 25	2 - 24	2 - 25
Age group [years]	n	84	44	128
	2 - <6	33 (39.3%)	14 (31.8%)	47 (36.7%)
	6 - 11	28 (33.3%)	14 (31.8%)	42 (32.8%)
	12 - 17	15 (17.9%)	12 (27.3%)	27 (21.1%)
	18 - 25	8 (9.5%)	4 (9.1%)	12 (9.4%)
Sex	n	84	44	128
	Male	40 (47.6%)	22 (50.0%)	62 (48.4%)
	Female	44 (52.4%)	22 (50.0%)	66 (51.6%)
Race	n	84	44	128
	Asian	18 (21.4%)	11 (25.0%)	29 (22.7%)
	White	55 (65.5%)	28 (63.6%)	83 (64.8%)
	Multiple	1 (1.2%)	0	1 (0.8%)
	Unknown	10 (11.9%)	5 (11.4%)	15 (11.7%)
Ethnicity	n	84	44	128

	Hispanic or Latino	5 (6.0%)	2 (4.5%)	7 (5.5%)
	Not Hispanic or Latino	78 (92.9%)	41 (93.2%)	119 (93.0%)
	Not Stated	0	1 (2.3%)	1 (0.8%)
	Unknown	1 (1.2%)	0	1 (0.8%)

Patients are grouped by initial treatment received.

Clinical Cutoff Date: 06SEP2019.

Subgroup categories with 0 patients not reported.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_IT_T2.xls

12JUN2020 10:37

Population: Type II SMA.

Endpoint: Motor Function Scale Scores by Treatment Arm Group at Baseline.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo
N		84	44
MFM32 total score	n	80	44
	Median (min-max)	44.27 (16.7-65.6)	46.35 (17.7-59.4)
	Mean (SD)	41.60 (11.00)	44.70 (8.92)
RULM total score	n	83	42
	Median (min-max)	17.00 (3.0-31.0)	18.00 (9.0-30.0)
	Mean (SD)	17.08 (5.88)	19.24 (5.29)
HFMSE total score	n	84	44
	Median (min-max)	9.00 (0.0-45.0)	11.00 (2.0-38.0)
	Mean (SD)	12.07 (9.92)	13.64 (10.13)

Patients are grouped by initial treatment. HFMSE=Hammersmith Functional Motor Scale Expanded; MFM32=Motor Function Measure 32; RULM=Revised Upper Limb Module.
Clinical Cutoff Date: 06SEP2019.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm_mfss.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_mfss_IT_P2_T2.xls

26OCT2020 9:07

Population: Type II SMA.

Endpoint: SMA Baseline Disease Characteristics.

Model: --.

Study: BP39055 SUNFISH - Part 2.

		Risdiplam	Placebo	Total
N		84	44	128
SMN2 copy number	2	1 (1.2%)	1 (2.3%)	2 (1.6%)
	3	83 (98.8%)	40 (90.9%)	123 (96.1%)
	4	0	2 (4.5%)	2 (1.6%)
	Unknown	0	1 (2.3%)	1 (0.8%)
SMA type	TYPE II	84 (100%)	44 (100%)	128 (100%)
Age of onset of initial symptoms (in Months)	n	84	44	128
	Mean (SD)	11.6 (5.6)	13.1 (5.0)	12.1 (5.4)
	Median	11.2	12.0	12.0
	Min - Max	0 - 29	6 - 27	0 - 29
Time between onset of initial SMA symptoms to first treatment (in Months)	n	84	44	128
	Mean (SD)	99.7 (64.6)	108.6 (66.2)	102.7 (65.1)
	Median	92.6	90.0	91.4
	Min - Max	17 - 275	23 - 271	17 - 275
Number and percentage of patients that could or could not stand	Standing	2 (2.4%)	2 (4.5%)	4 (3.1%)
	Could not stand	82 (97.6%)	42 (95.5%)	124 (96.9%)
Number and percentage of patients that could or could not walk (walkers and non-walkers)	Could not walk	84 (100%)	44 (100%)	128 (100%)
Number of fractures (None, 1-2, 3-5 or >= 6)	NONE	67 (79.8%)	39 (88.6%)	106 (82.8%)
	1-2	11 (13.1%)	5 (11.4%)	16 (12.5%)
	3-5	5 (6.0%)	0	5 (3.9%)
Scoliosis (yes/no)	Yes	52 (61.9%)	33 (75.0%)	85 (66.4%)
	No	32 (38.1%)	11 (25.0%)	43 (33.6%)
Degree of curvature due to scoliosis (<10, 10-40, >40)	0-10	8 (9.5%)	5 (11.4%)	13 (10.2%)
	10-40	18 (21.4%)	8 (18.2%)	26 (20.3%)
	>40	25 (29.8%)	19 (43.2%)	44 (34.4%)
Surgery for scoliosis before screening (yes/no)	Yes	24 (28.6%)	13 (29.5%)	37 (28.9%)
	No	40 (47.6%)	23 (52.3%)	63 (49.2%)
Hip subluxation or dislocation (yes/no)	Yes	20 (23.8%)	7 (15.9%)	27 (21.1%)
	No	64 (76.2%)	37 (84.1%)	101 (78.9%)
Hip surgery (yes/no)	Yes	2 (2.4%)	1 (2.3%)	3 (2.3%)
	No	82 (97.6%)	43 (97.7%)	125 (97.7%)

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Patients are grouped by initial treatment received. Standing is defined as with MFM item 25 score ≥ 1 at baseline. Walking is defined as with HFMSE item 20 score ≥ 2 at baseline. Ambulatory is defined as having the ability to walk unassisted for 10 metres or more.

Clinical Cutoff Date: 06SEP2019.

Subgroup categories with 0 patients not reported.

Program: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/program/t_dm_sma.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39055/data_analysis/ACE_CSR_part2/prod/output/t_dm_sma_IT_P2_T2.xls

30JUL2020 15:16

bp39056_ENDEAR_MAIC_demographics_NusiMatch

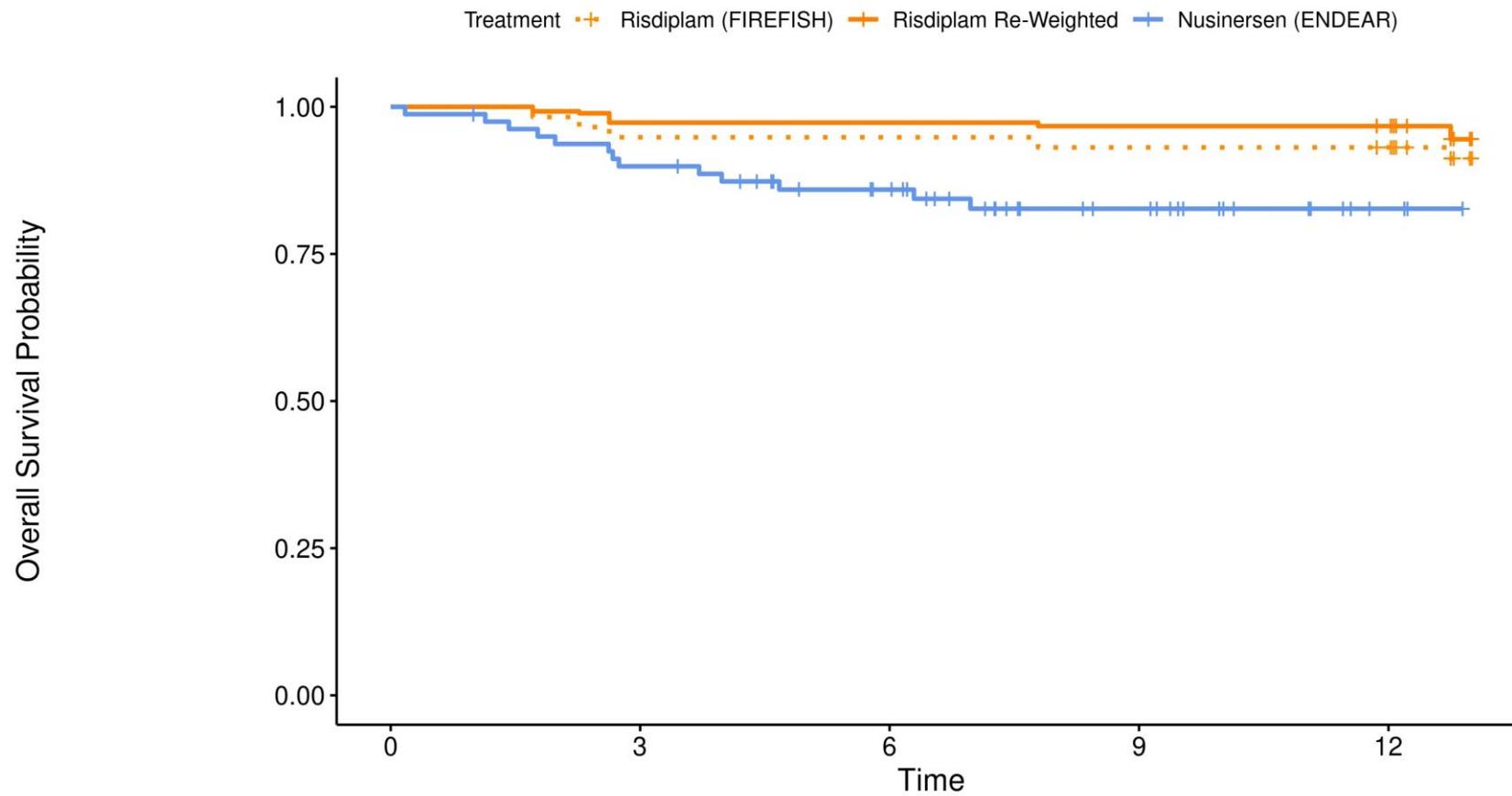
Study	Risdiplam	Risdiplam Reweighted	ENDEAR (Nusinersen)
N	58	40.12121575	80
Female (%)	57%	66%	54%
Mean Age First Dose (days)	162.67	163	163
Mean Age Symptom Onset (weeks)	50.57	51.01	55.3
Mean Symptoms duration (days)	90.78	92	92.4
Mean Age at Diagnosis (weeks)	12.66	13.31	14.3
Mean CHOP INTEND total score	22.47	26.63	26.63
Mean HINE total score	0.93	1.18	1.29
Unable to swallow/Gastrointestinal Tube Feeding (%)	9%	6%	9%
Ventilatory support (%)	29%	20%	26%
CMAP - ulnar	0.2	0.24	0.226
Age at screening (days)	140.34	142.01	147.2
Race: White (%)	53%	45%	85%
Race: Asian (%)	31%	32%	6%
Race: Unknown (%)	16%	23%	0%
Region: North America (%)	7%	10%	48%
Region: Europe (%)	66%	60%	38%
Region: Rest of the World (%)	28%	29%	15%
Disease duration <= 12 weeks (%)	52%	54%	43%
Disease duration > 12 weeks (%)	48%	46%	57%
SMN2 copy number: 2 (%)	100%	100%	100%

bp39056_eff_ITC_OS_Results_NusiMatch

	Results.Nusi.naive	Results.Nusi.maic
Comparator	Nusinersen	Nusinersen
Analysis	Naive ITC	MAIC
Method	Regular	Regular
HR	0.44	0.27
95% CI Lower	0.09	0.03
95% CI Upper	1.02	0.68
N.Boot	1000	1000

bp39056_eff_OS_maic_KM_Summary_NusiMatch

	Risdiplam	Risdiplam.weighted	Nusinersen
records	58	58	80
n.max	58	47.4	80
n.start	58	47.4	80
events	5	2.5	13
events (%)	8.6	5.3	16.3
*rmean	12.3	12.7	11.2
*se(rmean)	0.3	0.3	0.4
median	NA	NA	NA
0.95LCL	NA	NA	NA
0.95UCL	NA	NA	NA



Number at risk

Treatment	0	3	6	9	12
Risdiplam (FIREFISH)	58	55	55	54	53
Risdiplam Re-Weighted	47	46	46	46	45
Nusinersen (ENDEAR)	80	71	58	41	28

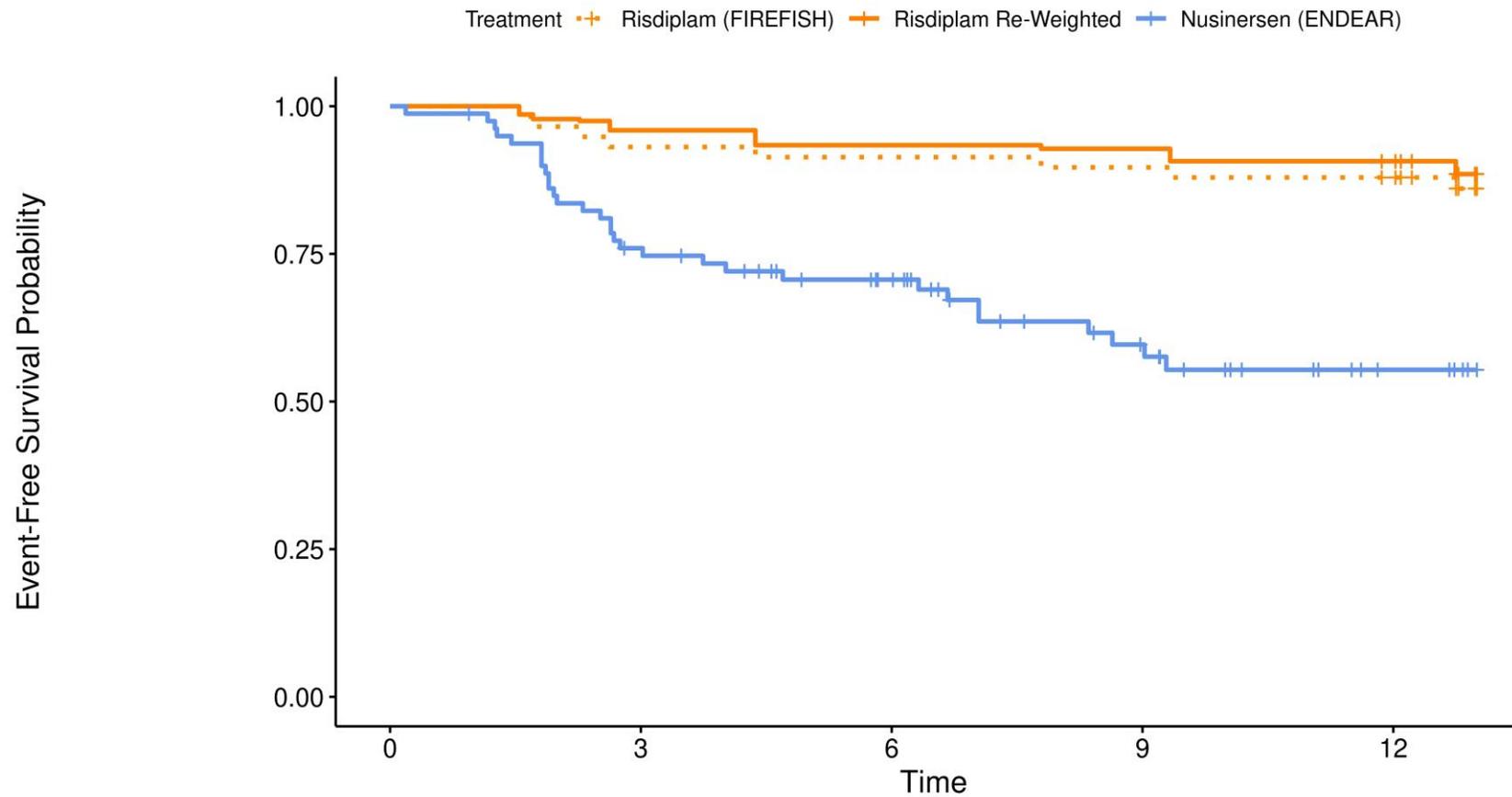
Time

bp39056_eff_ITC_EFS_Results_NusiMatch

	Results.Nusi.naive	Results.Nusi.maic
Comparator	Nusinersen	Nusinersen
Analysis	Naive ITC	MAIC
HR	0.24	0.19
95% CI Lower	0.09	0.06
95% CI Upper	0.46	0.40
N.Boot	1000	1000

bp39056_eff_EFS_maic_KM_Summary_NusiMatch

	Risdiplam	Risdiplam.maic	Nusinersen
records	58	58	80
n.max	58	47.4	80
n.start	58	47.4	80
events	8	5.4	31
events (%)	13.8	11.3	38.8
*rmean	11.9	12.2	9.1
*se(rmean)	0.4	0.4	0.6
median	NA	NA	NA
0.95LCL	NA	NA	8.64
0.95UCL	NA	NA	NA



Number at risk

Treatment	0	3	6	9	12
Risdiplam (FIREFISH)	58	54	53	52	50
Risdiplam Re-Weighted	47	45	44	44	43
Nusinersen (ENDEAR)	80	59	46	29	16

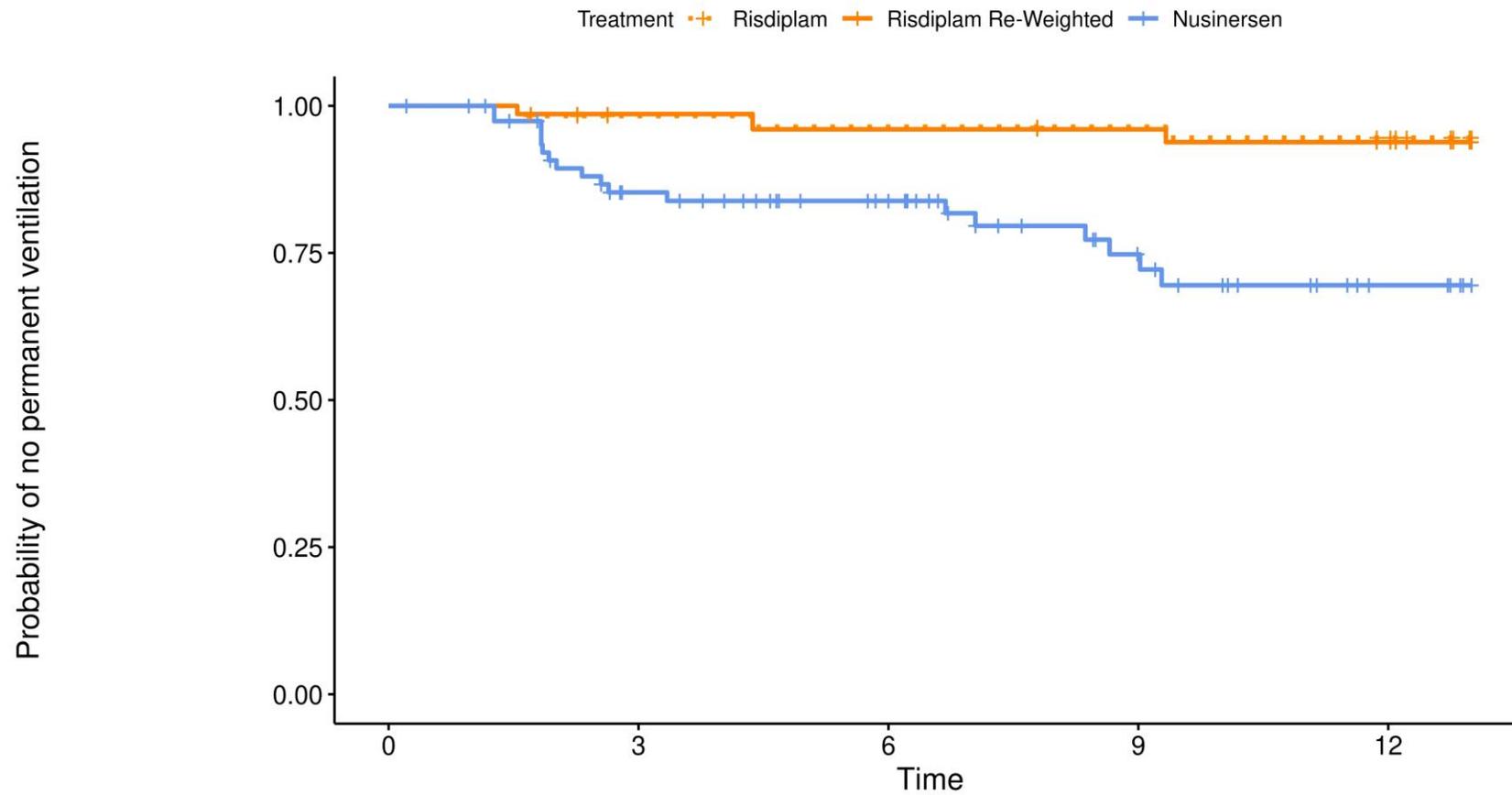
Time

bp39056_eff_ITC_PV_Results_NusiMatch

	Results.Nusi.naive	Results.Nusi.maic
Comparator	Nusinersen	Nusinersen
Analysis	Naive ITC	MAIC
Method	Regular	Regular
HR	0.15	0.17
95% CI Lower	0.00	0.00
95% CI Upper	0.41	0.48
N.Boot	1000	1000

bp39056_eff_PV_maic_KM_Summary_NusiMatch

	Risdiplam	Risdiplam.maic	Nusinersen
records	58	58	80
n.max	58	47.4	80
n.start	58	47.4	80
events	3	2.85	18
events (%)	5.17	6.02	22.50
*rmean	12.58	12.54	10.56
*se(rmean)	0.26	0.29	0.50
median	NA	NA	NA
0.95LCL	NA	NA	NA
0.95UCL	NA	NA	NA



Number at risk

Treatment	0	3	6	9	12
Risdiplam	58	54	53	52	50
Risdiplam Re-Weighted	47	45	44	44	43
Nusinersen	80	59	46	29	16

bp39056_eff_CHOPTOT_MAIC_Results_9mFU_ITT_NusiMatch_HedgG

	Risdiplam change from baseline	Weighted risdiplam change from baseline	Nusinersen change from baseline	Naive mean difference vs Nusinersen	MAIC mean difference vs Nusinersen
Number of patients	58	58	80	-	-
Number of patients included in analysis/ Sum of weights	58	47.4093	80	-	-
Mean	15.29	14.90	9.46	5.83	5.44
Boot.p50	15.24	14.92	NA	5.91	5.54
Boot.Lower	13.29	13.20	NA	3.02	2.95
Boot.Upper	17.29	16.71	NA	8.47	8.05
N.Boot	1000	1000	NA	1000	1000
g				0.72	0.76
l.g				0.37	0.39
u.g				1.07	1.13

bp39056_eff_CHOPTOT_MAIC_Results_9mFU_ES_NusiMatch_HedgG

	Risdiplam change from baseline	Weighted risdiplam change from baseline	Nusinersen change from baseline	Naive mean difference vs Nusinersen	MAIC mean difference vs Nusinersen
Number of patients	58	58	73	-	-
Number of patients included in analysis/ Sum of weights	58	47.4093	58	-	-
Mean	15.29	14.90	12.24	3.05	2.66
Boot.p50	15.24	14.92	NA	3.15	2.77
Boot.Lower	13.29	13.20	NA	0.11	-0.01
Boot.Upper	17.29	16.71	NA	5.75	5.38
N.Boot	1000	1000	NA	1000	1000
g				0.39	0.38
l.g				0.02	-0.01
u.g				0.76	0.76

bp39056_eff_CHOP_maic_vsNusinersen_9mFU_NusiMatch_ITT

	1
Response	chop4
Responder	52
Total	58
Response.rate	0.897
Response.rate.lower.Boot	0.810
Response.rate.upper.Boot	0.966
Response.rate.lower.ClopperPearson	0.788
Response.rate.upper.ClopperPearson	0.961
Responder.comparator	58
Total.comparator	80
Response.rate.comparator	0.725
Response.rate.comparator.lower.Boot	0.625
Response.rate.comparator.upper.Boot	0.812
Response.rate.comparator.lower.ClopperPearson	0.614
Response.rate.comparator.upper.ClopperPearson	0.819
naive.RR	1.237
naive.RR.lower	1.061
naive.RR.upper	1.460
naive.OR	3.287
naive.OR.lower	1.394
naive.OR.upper	11.007
naive.ARR	0.172
naive.ARR.lower	0.050
naive.ARR.upper	0.292
Responder.weighted	44.444
Total.weighted	47.409
Response.rate.weighted	0.937
Response.rate.weighted.lower.Boot	0.875
Response.rate.weighted.upper.Boot	0.985
Response.rate.weighted.lower.ClopperPearson	0.825
Response.rate.weighted.upper.ClopperPearson	0.987
maic.RR	1.293
maic.RR.lower	1.123
maic.RR.upper	1.517
maic.OR	5.685

bp39056_eff_CHOP_maic_vsNusinersen_9mFU_NusiMatch

	1	2
Response	chop4	chop40
Responder	52	27
Total	58	58
Response.rate	0.897	0.466
Response.rate.lower.Boot	0.810	0.328
Response.rate.upper.Boot	0.966	0.586
Response.rate.lower.ClopperPearson	0.788	0.333
Response.rate.upper.ClopperPearson	0.961	0.601
Responder.comparator	52	30
Total.comparator	73	73
Response.rate.comparator	0.712	0.411
Response.rate.comparator.lower.Boot	0.602	0.301
Response.rate.comparator.upper.Boot	0.808	0.521
Response.rate.comparator.lower.ClopperPearson	0.594	0.297
Response.rate.comparator.upper.ClopperPearson	0.812	0.532
naive.RR	1.26	1.13
naive.RR.lower	1.07	0.74
naive.RR.upper	1.52	1.68
naive.OR	3.50	1.25
naive.OR.lower	1.48	0.59
naive.OR.upper	12.08	2.51
naive.ARR	0.18	0.06
naive.ARR.lower	0.06	-0.13
naive.ARR.upper	0.31	0.22
Responder.weighted	44.44	30.12
Total.weighted	47.41	47.41
Response.rate.weighted	0.937	0.635
Response.rate.weighted.lower.Boot	0.875	0.52
Response.rate.weighted.upper.Boot	0.985	0.75
Response.rate.weighted.lower.ClopperPearson	0.825	0.485
Response.rate.weighted.upper.ClopperPearson	0.987	0.773
maic.RR	1.32	1.55
maic.RR.lower	1.14	1.12
maic.RR.upper	1.57	2.24
maic.OR	6.05	2.50

maic.OR.lower	2.34	1.26
maic.OR.upper	28.78	5.15
maic.ARR	0.23	0.22
maic.ARR.lower	0.11	0.06
maic.ARR.upper	0.35	0.38

bp39056_eff_HINETOT_MAIC_Results_9mFU_ITT_NusiMatch_HedgG

	Risdiplam change from baseline	Weighted risdiplam change from baseline	Nusinersen change from baseline	Naive mean difference vs Nusinersen	MAIC mean difference vs Nusinersen
Number of patients	58	58	80	-	-
Number of patients included in analysis/ Sum of weights	58	47.4093	80	-	-
Mean	3.28	4.26	3.43	-0.15	0.83
Boot.p50	3.28	4.26	NA	-0.12	0.85
Boot.Lower	2.50	3.42	NA	-1.26	-0.37
Boot.Upper	4.10	5.18	NA	1.13	2.10
N.Boot	1000	1000	NA	1000	1000
g				-0.04	0.24
l.g				-0.38	-0.12
u.g				0.30	0.60

bp39056_eff_HINETOT_MAIC_Results_9mFU_ES_NusiMatch_HedgG

	Risdiplam change from baseline	Weighted risdiplam change from baseline	Nusinersen change from baseline	Naive mean difference vs Nusinersen	MAIC mean difference vs Nusinersen
Number of patients	58	58	73	-	-
Number of patients included in analysis/ Sum of weights	58	47.4093	58	-	-
Mean	3.28	4.26	4.38	-1.10	-0.12
Boot.p50	3.28	4.26	NA	-1.07	-0.10
Boot.Lower	2.50	3.42	NA	-2.36	-1.50
Boot.Upper	4.10	5.18	NA	0.33	1.32
N.Boot	1000	1000	NA	1000	1000
g				-0.30	-0.03
l.g				-0.66	-0.42
u.g				0.07	0.35

bp39056_eff_HINE_maic_vsNusinersen_9mFU_NusiMatch_ITT

	1
Response	hineMMR
Responder	37
Total	58
Response.rate	0.638
Response.rate.lower.Boot	0.517
Response.rate.upper.Boot	0.759
Response.rate.lower.ClopperPearson	0.501
Response.rate.upper.ClopperPearson	0.76
Responder.comparator	41
Total.comparator	80
Response.rate.comparator	0.512
Response.rate.comparator.lower.Boot	0.412
Response.rate.comparator.upper.Boot	0.625
Response.rate.comparator.lower.ClopperPearson	0.398
Response.rate.comparator.upper.ClopperPearson	0.626
naive.RR	1.25
naive.RR.lower	0.93
naive.RR.upper	1.65
naive.OR	1.68
naive.OR.lower	0.82
naive.OR.upper	3.38
naive.ARR	0.13
naive.ARR.lower	-0.05
naive.ARR.upper	0.29
Responder.weighted	36.65
Total.weighted	47.41
Response.rate.weighted	0.773
Response.rate.weighted.lower.Boot	0.68
Response.rate.weighted.upper.Boot	0.865
Response.rate.weighted.lower.ClopperPearson	0.643
Response.rate.weighted.upper.ClopperPearson	0.893
maic.RR	1.51
maic.RR.lower	1.19
maic.RR.upper	1.94
maic.OR	3.24

maic.OR.lower	1.67
maic.OR.upper	6.72
maic.ARR	0.26
maic.ARR.lower	0.12
maic.ARR.upper	0.40

bp39056_eff_HINE_maic_vsNusinersen_9mFU_NusiMatch

	1	2	3	4	5
Response	hineMMR	HeadControl	Rolling	SittingWS	Standing
Responder	37	17	0	8	0
Total	58	58	58	58	58
Response.rate	0.638	0.293	0	0.138	0
Response.rate.lower.Boot	0.517	0.172	0	0.052	0
Response.rate.upper.Boot	0.759	0.414	0	0.224	0
Response.rate.lower.ClopperPearson	0.501	0.181	0	0.061	0
Response.rate.upper.ClopperPearson	0.76	0.427	0.062	0.254	0.062
Responder.comparator	37	16	7	6	1
Total.comparator	73	73	73	73	73
Response.rate.comparator	0.507	0.219	0.096	0.082	0.014
Response.rate.comparator.lower.Boot	0.397	0.123	0.041	0.027	0
Response.rate.comparator.upper.Boot	0.63	0.315	0.164	0.151	0.041
Response.rate.comparator.lower.ClopperPearson	0.387	0.131	0.039	0.031	0
Response.rate.comparator.upper.ClopperPearson	0.626	0.331	0.188	0.17	0.074
naive.RR	1.26	1.34	0.08	1.68	0.42
naive.RR.lower	0.93	0.71	0.05	0.56	0.18
naive.RR.upper	1.69	2.52	0.18	5.66	1.25
naive.OR	1.71	1.48	0.08	1.79	0.41
naive.OR.lower	0.85	0.65	0.04	0.53	0.17
naive.OR.upper	3.56	3.32	0.17	6.53	1.26
naive.ARR	0.13	0.07	-0.10	0.06	-0.01
naive.ARR.lower	-0.04	-0.08	-0.16	-0.05	-0.04
naive.ARR.upper	0.29	0.22	-0.04	0.17	0.00
Responder.weighted	36.7	18.7	0.0	11.9	0.0
Total.weighted	47.4	47.4	47.4	47.4	47.4
Response.rate.weighted	0.773	0.395	0	0.251	0
Response.rate.weighted.lower.Boot	0.68	0.248	0	0.095	0
Response.rate.weighted.upper.Boot	0.865	0.53	0	0.361	0
Response.rate.weighted.lower.ClopperPearson	0.643	0.264	0	0.139	0
Response.rate.weighted.upper.ClopperPearson	0.893	0.557	0.075	0.403	0.075
maic.RR	1.53	1.80	0.10	3.06	0.51
maic.RR.lower	1.19	1.02	0.06	1.01	0.20
maic.RR.upper	2.01	3.37	0.27	9.48	1.93
maic.OR	3.32	2.33	0.09	3.75	0.50

maic.OR.lower	1.64	1.03	0.05	1.01	0.20
maic.OR.upper	7.22	5.43	0.26	13.34	1.94
maic.ARR	0.27	0.18	-0.10	0.17	-0.01
maic.ARR.lower	0.11	0.01	-0.16	0.00	-0.04
maic.ARR.upper	0.41	0.34	-0.04	0.30	0.00

bp39056_eff_Hospital_MAIC_Results_NusiMatch

	Risdiplam rate (adjusted)	Weighted risdiplam rate (adjusted)	Nusinersen rate (adjusted)	Naive rate ratio vs Nusinersen	MAIC rate ratio vs Nusinersen
Number of patients	58	58	80	-	-
Number of patients included in analysis/ Sum of weights	58	47.4	80	-	-
Mean	2.31	3.77	4.78	0.48	0.79
Boot.p50	2.41	4.06	NA	0.51	0.86
Boot.Lower	0.58	0.37	NA	0.13	0.08
Boot.Upper	7.91	18.93	NA	1.73	4.08
N.Boot	997	997	NA	997	997

bp39056_eff_AE_maic_vsNusinersen_9mFU_NusiMatch

	1	2	3
Response	any_ae	any_serae	any_aedisc
Responder	56	27	4
Total	58	58	58
Response.rate	0.966	0.466	0.069
Response.rate.lower.Boot	0.914	0.345	0.017
Response.rate.upper.Boot	1.000	0.586	0.138
Response.rate.lower.ClopperPearson	0.881	0.333	0.019
Response.rate.upper.ClopperPearson	0.996	0.601	0.167
Responder.comparator	77	61	13
Total.comparator	80	80	80
Response.rate.comparator	0.962	0.762	0.162
Response.rate.comparator.lower.Boot	0.925	0.662	0.088
Response.rate.comparator.upper.Boot	1.000	0.850	0.250
Response.rate.comparator.lower.ClopperPearson	0.894	0.654	0.089
Response.rate.comparator.upper.ClopperPearson	0.992	0.851	0.262
naive.RR	1.00	0.61	0.42
naive.RR.lower	0.93	0.43	0.09
naive.RR.upper	1.06	0.81	1.10
naive.OR	1.09	0.27	0.38
naive.OR.lower	0.13	0.12	0.08
naive.OR.upper	6.88	0.57	1.12
naive.ARR	0.00	-0.30	-0.09
naive.ARR.lower	-0.07	-0.46	-0.20
naive.ARR.upper	0.06	-0.13	0.01
Responder.weighted	45.4	20.9	1.6
Total.weighted	47.4	47.4	47.4
Response.rate.weighted	0.958	0.441	0.033
Response.rate.weighted.lower.Boot	0.890	0.278	0.003
Response.rate.weighted.upper.Boot	1.000	0.605	0.074
Response.rate.weighted.lower.ClopperPearson	0.855	0.302	0.005
Response.rate.weighted.upper.ClopperPearson	0.995	0.599	0.145
maic.RR	1.00	0.58	0.20
maic.RR.lower	0.91	0.35	0.03
maic.RR.upper	1.06	0.81	0.56

maic.OR	0.90	0.25	0.18
maic.OR.lower	0.10	0.10	0.03
maic.OR.upper	6.04	0.55	0.53
maic.ARR	0.00	-0.32	-0.13
maic.ARR.lower	-0.09	-0.51	-0.22
maic.ARR.upper	0.06	-0.14	-0.04

POPULATION: Intent-to-Treat Population
 ENDPOINT: --
 MODEL: descriptive
 STUDY: BP39056
 Demographics and Baseline Characteristics

	Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Age at Enrollment (Months)			
n	17	41	58
Mean (SD)	5.56 (1.43)	5.20 (1.47)	5.31 (1.46)
Median	6.28	5.32	5.52
IQR	3.8 - 6.8	4.2 - 6.8	4.0 - 6.8
Min - Max	3.3 - 6.9	2.2 - 6.9	2.2 - 6.9
Age Group at Enrollment (Months)			
n	17	41	58
<=5	6 (35.3%)	19 (46.3%)	25 (43.1%)
>5	11 (64.7%)	22 (53.7%)	33 (56.9%)
Sex			
n	17	41	58
Male	6 (35.3%)	19 (46.3%)	25 (43.1%)
Female	11 (64.7%)	22 (53.7%)	33 (56.9%)
Race			
n	17	41	58
Asian	4 (23.5%)	14 (34.1%)	18 (31.0%)
White	9 (52.9%)	22 (53.7%)	31 (53.4%)
Unknown	4 (23.5%)	5 (12.2%)	9 (15.5%)
Ethnicity			
n	17	41	58
Hispanic or Latino	0	5 (12.2%)	5 (8.6%)
Not Hispanic or Latino	17 (100%)	36 (87.8%)	53 (91.4%)
Country			
n	17	41	58
Belgium	1 (5.9%)	0	1 (1.7%)
Brazil	0	3 (7.3%)	3 (5.2%)
Switzerland	1 (5.9%)	0	1 (1.7%)
China	0	11 (26.8%)	11 (19.0%)
France	4 (23.5%)	1 (2.4%)	5 (8.6%)

Croatia	0	1 (2.4%)	1 (1.7%)
Italy	8 (47.1%)	6 (14.6%)	14 (24.1%)
Japan	0	1 (2.4%)	1 (1.7%)
Poland	0	6 (14.6%)	6 (10.3%)
Russian Federation	0	7 (17.1%)	7 (12.1%)
Turkey	0	1 (2.4%)	1 (1.7%)
Ukraine	0	3 (7.3%)	3 (5.2%)
United States	3 (17.6%)	1 (2.4%)	4 (6.9%)
Region			
n	17	41	58
Europe	14 (82.4%)	24 (58.5%)	38 (65.5%)
Rest of the World	0	16 (39.0%)	16 (27.6%)
US	3 (17.6%)	1 (2.4%)	4 (6.9%)
Age at Onset of Symptoms (Months)			
n	17	41	58
Mean (SD)	1.70 (0.67)	1.64 (0.70)	1.66 (0.69)
Median	1.48	1.45	1.48
IQR	1.0 - 2.0	1.0 - 2.0	1.0 - 2.0
Min - Max	0.9 - 3.0	1.0 - 3.0	0.9 - 3.0
Age at Diagnosis (Months)			
n	17	41	58
Mean (SD)	3.19 (1.41)	2.81 (1.38)	2.92 (1.39)
Median	2.96	2.79	2.83
IQR	2.1 - 4.0	1.8 - 4.0	1.9 - 4.0
Min - Max	0.9 - 5.4	0.9 - 6.1	0.9 - 6.1
Disease Duration (Months)			
n	17	41	58
Mean (SD)	3.90 (1.29)	3.59 (1.35)	3.68 (1.33)
Median	4.01	3.38	3.43
IQR	2.9 - 4.9	2.5 - 4.9	2.5 - 4.9
Min - Max	2.0 - 5.8	1.0 - 6.0	1.0 - 6.0
n	17	41	58
<=3 Months	6 (35.3%)	14 (34.1%)	20 (34.5%)
>3 Months	11 (64.7%)	27 (65.9%)	38 (65.5%)
SMN2 Copy Number			
n	17	41	58
2	17 (100%)	41 (100%)	58 (100%)
Initial SMA Symptoms			
n	17	41	58

ABSENT DEEP TENDON REFLEXES	1 (5.9%)	1 (2.4%)	2 (3.4%)
DECREASE OF ANTI GRAVITY MOVEMENT	0	1 (2.4%)	1 (1.7%)
DECREASED LEG MOVEMENT, DIFFICULTY SWALLOWING, INCREASED SECRETIONS	1 (5.9%)	0	1 (1.7%)
DELAY IN HEAD CONTROL, ARMS AND LEGS UTILIZATION, HANDLING OF OBJECTS	1 (5.9%)	0	1 (1.7%)
DEVELOPMENTAL MOTOR DELAY	1 (5.9%)	4 (9.8%)	5 (8.6%)
DON'T RAISE THE HEAD WHEN ON THE STOMACH	0	1 (2.4%)	1 (1.7%)
HYPOTONIA	6 (35.3%)	23 (56.1%)	29 (50.0%)
LIMB WEAKNESS	5 (29.4%)	7 (17.1%)	12 (20.7%)
PNEUMONIA OR RESPIRATORY SYMPTOMS	2 (11.8%)	0	2 (3.4%)
SPONTANEOUS MOTILITY OF THE LOWER LIMBS	0	1 (2.4%)	1 (1.7%)
SWALLOWING OR FEEDING DIFFICULTIES	0	1 (2.4%)	1 (1.7%)
THE WAY SHE WAS HOLDING HER HEAD UP	0	1 (2.4%)	1 (1.7%)
UNABLE TO HOLD THE HEAD UP	0	1 (2.4%)	1 (1.7%)
Tracheostomy			
n	17	41	58
Yes	1 (5.9%)	0	1 (1.7%)
No	16 (94.1%)	41 (100%)	57 (98.3%)
CHOP-INTEND Score			
n	17	41	58
Mean (SD)	24.29 (5.75)	21.71 (7.10)	22.47 (6.79)
Median	24	22	23
IQR	21.0 - 27.0	15.0 - 28.0	16.0 - 28.0
Min - Max	16.0 - 34.0	8.0 - 37.0	8.0 - 37.0
BSID-III Gross Motor Scale Total Raw Score			
n	17	41	58
Mean (SD)	2.12 (1.36)	1.85 (1.61)	1.93 (1.53)
Median	3	2	2
IQR	1.0 - 3.0	1.0 - 2.0	1.0 - 3.0
Min - Max	0.0 - 4.0	0.0 - 8.0	0.0 - 8.0
HINE-2 Score			
n	17	41	58
Mean (SD)	0.94 (0.56)	0.93 (1.08)	0.93 (0.95)
Median	1	1	1
IQR	1.0 - 1.0	0.0 - 1.0	0.0 - 1.0
Min - Max	0.0 - 2.0	0.0 - 5.0	0.0 - 5.0
CMAP Negative Peak Amplitude (mV)			
n	17	41	58
Mean (SD)	0.18 (0.10)	0.21 (0.17)	0.20 (0.15)
Median	0.2	0.19	0.2
IQR	0.1 - 0.3	0.1 - 0.3	0.1 - 0.3
Min - Max	0.0 - 0.3	0.0 - 0.8	0.0 - 0.8

n	17	41	58
<= 1mV	17 (100%)	41 (100%)	58 (100%)
> 1mV	0	0	0
Current level of motor function			
n	17	41	58
HEAD CONTROL CARRIED UPRIGHT	1 (5.9%)	1 (2.4%)	2 (3.4%)
HEAD CONTROL VENTRAL	1 (5.9%)	1 (2.4%)	2 (3.4%)
NO APPROPRIATE FUNCTION LISTED	14 (82.4%)	39 (95.1%)	53 (91.4%)
ROLLED SIDE TO BACK	1 (5.9%)	0	1 (1.7%)
Highest motor function achieved			
n	17	41	58
CONTROLS HEAD UPRIGHT	1 (5.9%)	2 (4.9%)	3 (5.2%)
KICKING HORIZONTALLY	0	2 (4.9%)	2 (3.4%)
KICKING VERTICALLY	1 (5.9%)	2 (4.9%)	3 (5.2%)
NO APPROPRIATE FUNCTION LISTED	15 (88.2%)	35 (85.4%)	50 (86.2%)
n	17	41	58
Current Level of Respiratory Support			
No Pulmonary Care	12 (70.6%)	29 (70.7%)	41 (70.7%)
BiPAP Support < 16 Hours Per Day	3 (17.6%)	10 (24.4%)	13 (22.4%)
BiPAP Support >= 16 Hours Per Day	0	0	0
Cough Assist - Used Daily for Therapy, Not Illness Related	1 (5.9%)	3 (7.3%)	4 (6.9%)
Cough Assist - Used With An Illness	0	1 (2.4%)	1 (1.7%)
Ventilation Provided Prophylactically			
Yes	4 (23.5%)	11 (26.8%)	15 (25.9%)
No	13 (76.5%)	30 (73.2%)	43 (74.1%)
Awake Assisted Ventilation	0	0	0
Night-time Assisted Ventilation	4 (23.5%)	9 (22.0%)	13 (22.4%)
Nap-time Assisted Ventilation	0	2 (4.9%)	2 (3.4%)
>16h Assisted Ventilation	0	0	0
Airway Clearance Through Cough Assistance	0	3 (7.3%)	3 (5.2%)
BiPAP Support >=16 Hours per Day for >21 Consecutive Days			
Yes	0	0	0
No	17 (100%)	41 (100%)	58 (100%)
Intubation for >21 Consecutive Days			
Yes	0	0	0
No	17 (100%)	41 (100%)	58 (100%)
Able to Swallow			
n	17	41	58

Yes	16 (94.1%)	39 (95.1%)	55 (94.8%)
No	1 (5.9%)	1 (2.4%)	2 (3.4%)
Missing	0	1 (2.4%)	1 (1.7%)
Age Ability to Swallow Lost (Months)			
n	1	1	2
Mean (SD)	0.56 (NE)	1.58 (NE)	1.07 (0.72)
Median	0.56	1.58	1.07
IQR	0.6 - 0.6	1.6 - 1.6	0.6 - 1.6
Min - Max	0.6 - 0.6	1.6 - 1.6	0.6 - 1.6
Primary Food Intake Type			
n	17	41	58
Oral Fluid (Milk) Food Intake	10 (58.8%)	30 (73.2%)	40 (69.0%)
Mixed (Fluid/Pureed Food) Oral Intake	6 (35.3%)	4 (9.8%)	10 (17.2%)
Modified Oral Food Intake	0	0	0
Solid Food	0	0	0
Nasogastric Food Intake	1 (5.9%)	7 (17.1%)	8 (13.8%)
Gastrostomy Tube Fed	0	0	0
Missing	0	0	0
Feeding Route			
n	17	41	58
Fed Orally	6 (35.3%)	33 (80.5%)	39 (67.2%)
Fed via a Feeding Tube	0	4 (9.8%)	4 (6.9%)
Fed via a Combination of Oral and Tube Feeding	0	2 (4.9%)	2 (3.4%)
Missing	11 (64.7%)	2 (4.9%)	13 (22.4%)
Able to Swallow Water			
n	17	41	58
Yes	6 (35.3%)	36 (87.8%)	42 (72.4%)
No	0	2 (4.9%)	2 (3.4%)
Missing	11 (64.7%)	3 (7.3%)	14 (24.1%)
Able to Swallow Nectar (or Similar)			
n	17	41	58
Yes	4 (23.5%)	13 (31.7%)	17 (29.3%)
No	2 (11.8%)	24 (58.5%)	26 (44.8%)
Missing	11 (64.7%)	4 (9.8%)	15 (25.9%)
Able to Swallow Rice Pudding (or Similar)			
n	17	41	58
Yes	3 (17.6%)	4 (9.8%)	7 (12.1%)
No	3 (17.6%)	33 (80.5%)	36 (62.1%)
Missing	11 (64.7%)	4 (9.8%)	15 (25.9%)

Able to Swallow Purees			
n	17	41	58
Yes	3 (17.6%)	8 (19.5%)	11 (19.0%)
No	3 (17.6%)	29 (70.7%)	32 (55.2%)
Missing	11 (64.7%)	4 (9.8%)	15 (25.9%)
Able to Swallow Solid Food			
n	17	41	58
Yes	0	0	0
No	6 (35.3%)	38 (92.7%)	44 (75.9%)
Missing	11 (64.7%)	3 (7.3%)	14 (24.1%)

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_dm.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_dm_IT.xls
02FEB2021 14:12

POPULATION: Safety-Evaluable Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39056

Number of Patients who Died including Primary Reason

	Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Primary reason of death			
All deaths	2 (11.8%)	3 (7.3%)	5 (8.6%)
Adverse Event	0	1 (2.4%)	1 (1.7%)
Progressive Disease	2 (11.8%)	2 (4.9%)	4 (6.9%)

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_dd.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_dd_SE.xls

11MAR2021 12:24

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39056

Number of Patients by Country and Study Site

	Part 1 (N=21)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=62)
Country			
n	21	41	62
Belgium	2 (9.5%)	0	2 (3.2%)
Brazil	0	3 (7.3%)	3 (4.8%)
Switzerland	1 (4.8%)	0	1 (1.6%)
China	0	11 (26.8%)	11 (17.7%)
France	4 (19.0%)	4 (9.8%)	8 (12.9%)
Croatia	0	1 (2.4%)	1 (1.6%)
Italy	11 (52.4%)	10 (24.4%)	21 (33.9%)
Japan	0	1 (2.4%)	1 (1.6%)
Poland	0	4 (9.8%)	4 (6.5%)
Russian Federation	0	5 (12.2%)	5 (8.1%)
Turkey	0	1 (2.4%)	1 (1.6%)
United States	3 (14.3%)	1 (2.4%)	4 (6.5%)
Study Site by country			
Belgium			
n	2	0	2
21818	2 (100%)	0	2 (100%)
Brazil			
n	0	3	3
75261	0	3 (100%)	3 (100%)
Switzerland			
n	1	0	1
101486	1 (100%)	0	1 (100%)

China			
n	0	11	11
119348	0	6 (54.5%)	6 (54.5%)
94105	0	5 (45.5%)	5 (45.5%)
France			
n	4	4	8
54061	4 (100%)	4 (100%)	8 (100%)
Croatia			
n	0	1	1
119476	0	1 (100%)	1 (100%)
Italy			
n	11	10	21
105090	1 (9.1%)	1 (10.0%)	2 (9.5%)
107431	10 (90.9%)	2 (20.0%)	12 (57.1%)
111203	0	5 (50.0%)	5 (23.8%)
113484	0	2 (20.0%)	2 (9.5%)
Japan			
n	0	1	1
96007	0	1 (100%)	1 (100%)
Poland			
n	0	4	4
118493	0	4 (100%)	4 (100%)
Russian Federation			
n	0	5	5
119495	0	5 (100%)	5 (100%)
Turkey			
n	0	1	1
107710	0	1 (100%)	1 (100%)
United States			
n	3	1	4
48342	2 (66.7%)	0	2 (50.0%)
67462	1 (33.3%)	1 (100%)	2 (50.0%)

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_dm2.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_dm2_IT_AP.xls
12MAR2021 15:46

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39056

Number of Patients by Country and Study Site

	Part 1 (N=21)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=62)
Country			
n	21	41	62
Belgium	2 (9.5%)	0	2 (3.2%)
Brazil	0	3 (7.3%)	3 (4.8%)
Switzerland	1 (4.8%)	0	1 (1.6%)
China	0	11 (26.8%)	11 (17.7%)
France	4 (19.0%)	1 (2.4%)	5 (8.1%)
Croatia	0	1 (2.4%)	1 (1.6%)
Italy	11 (52.4%)	6 (14.6%)	17 (27.4%)
Japan	0	1 (2.4%)	1 (1.6%)
Poland	0	6 (14.6%)	6 (9.7%)
Russian Federation	0	7 (17.1%)	7 (11.3%)
Turkey	0	1 (2.4%)	1 (1.6%)
Ukraine	0	3 (7.3%)	3 (4.8%)
United States	3 (14.3%)	1 (2.4%)	4 (6.5%)
Study Site by country			
Belgium			
n	2	0	2
21818	2 (100%)	0	2 (100%)
Brazil			
n	0	3	3
75261	0	3 (100%)	3 (100%)
Switzerland			
n	1	0	1

101486	1 (100%)	0	1 (100%)
China			
n	0	11	11
119348	0	6 (54.5%)	6 (54.5%)
94105	0	5 (45.5%)	5 (45.5%)
France			
n	4	1	5
54061	4 (100%)	1 (100%)	5 (100%)
Croatia			
n	0	1	1
119476	0	1 (100%)	1 (100%)
Italy			
n	11	6	17
105090	1 (9.1%)	0	1 (5.9%)
107431	10 (90.9%)	1 (16.7%)	11 (64.7%)
111203	0	3 (50.0%)	3 (17.6%)
113484	0	2 (33.3%)	2 (11.8%)
Japan			
n	0	1	1
96007	0	1 (100%)	1 (100%)
Poland			
n	0	6	6
118493	0	6 (100%)	6 (100%)
Russian Federation			
n	0	7	7
119495	0	7 (100%)	7 (100%)
Turkey			
n	0	1	1
127885	0	1 (100%)	1 (100%)
Ukraine			
n	0	3	3
39380	0	3 (100%)	3 (100%)
United States			
n	3	1	4
48342	2 (66.7%)	0	2 (50.0%)
67462	1 (33.3%)	1 (100%)	2 (50.0%)

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_dm2.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_dm2_IT_AP.xls

12MAR2021 16:21

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39056

Patient Disposition

	Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Enrolled	17 (100%)	41 (100%)	58 (100%)
Treatment Ongoing	14 (82.4%)	38 (92.7%)	52 (89.7%)
Completed 12 months of treatment	16 (94.1%)	38 (92.7%)	54 (93.1%)
Completed 24 months of treatment	14 (82.4%)	38 (92.7%)	52 (89.7%)
Discontinued between 0 and 12 months of treatment	1 (5.9%)	3 (7.3%)	4 (6.9%)
Death	0	2 (4.9%)	2 (3.4%)
Progressive disease	1 (5.9%)	1 (2.4%)	2 (3.4%)
Discontinued between 12 and 24 months of treatment	2 (11.8%)	0	2 (3.4%)
Death	1 (5.9%)	0	1 (1.7%)
Withdrawal by subject	1 (5.9%)	0	1 (1.7%)
Entered open-label extension phase	8 (47.1%)	38 (92.7%)	46 (79.3%)
Discontinued from open-label extension phase	0	0	0
Entered safety follow-up	1 (5.9%)	0	1 (1.7%)
Discontinued from safety follow-up	0	0	0

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_ds.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_ds_IT.xls

12MAR2021 17:12

POPULATION: Intent-to-Treat Population
 ENDPOINT: --
 MODEL: descriptive
 STUDY: BP39056 FIREFISH - Part 1
 Patient Disposition

	Cohort 1 (N=4)
Enrolled	4 (100%)
Treatment Ongoing	3 (75.0%)
Completed 12 months of treatment	3 (75.0%)
Completed 24 months of treatment	3 (75.0%)
Discontinued between 0 and 12 months of treatment	1 (25.0%)
Progressive disease	1 (25.0%)
Entered open-label extension phase	3 (75.0%)
Discontinued from open-label extension phase	0
Entered safety follow-up	0
Discontinued from safety follow-up	0

Cohort 1 includes the first three infants enrolled in the study who received Dose Level 1 for at least 12 months and the infant enrolled at Dose Level 1 who discontinued from the study on Study Day 19.
 Clinical cut-off: 03MAR2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_Part1_24months/prod/program/t_ds.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_Part1_24months/prod/output/t_ds_IT_P1_COH1.xls
 10MAR2021 18:04

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BP39056

Patients who Discontinued Study including Reason

	Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Discontinued study			
n	2 (11.8%)	3 (7.3%)	5 (8.6%)
Death	1 (5.9%)	2 (4.9%)	3 (5.2%)
Progressive disease	1 (5.9%)	1 (2.4%)	2 (3.4%)

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_dsstu.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_dsstu_IT.xls
10MAR2021 17:10

POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Death
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)															
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					
Name	Level	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median			
All	n/a	17	100.0	2	11.8	15	88.2	NE	12.75	NE	NE	NE	41	100.0	3	7.3	38	92.7	NE	NE	NE	NE	NE	58	100.0	5	8.6	53	91.4	NE	NE	NE	NE	NE			

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_tte_DTH_IT.xls
 26JAN2021 11:20

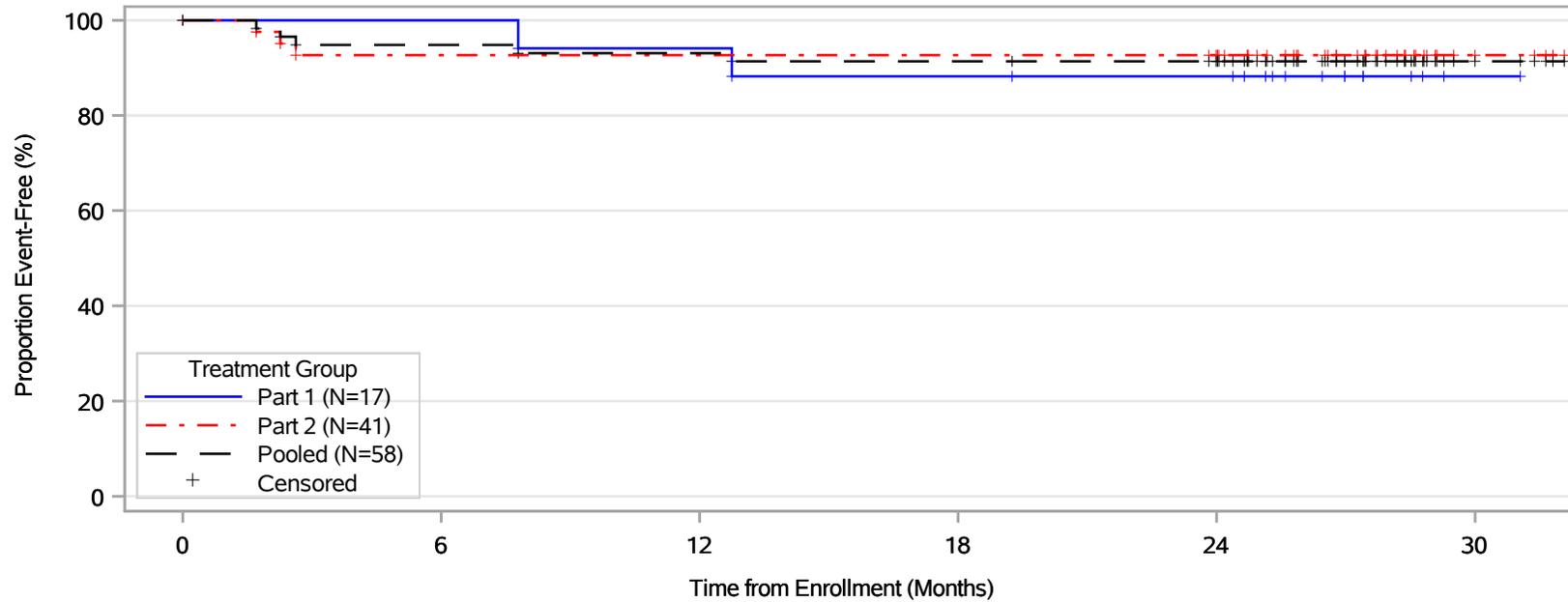
POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Death
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)												
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event				
Name	Level	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	17	100.0	2	11.8	15	88.2	NE	12.75	NE	NE	NE	41	100.0	3	7.3	38	92.7	NE	NE	NE	NE	NE	58	100.0	5	8.6	53	91.4	NE	NE	NE	NE	NE

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_tte_DTH_IT.xls
 04FEB2021 9:33

POPULATION: Intent-to-Treat Population
ENDPOINT: Time to Death
STUDY: BP39056



Patients at risk						
	0	6	12	18	24	30
Part 1	17	17	16	15	14	1
Part 2	41	38	38	38	36	4
Pooled	58	55	54	53	50	5
Patients censored						
Part 1	0	0	0	0	1	14
Part 2	0	0	0	0	2	34
Pooled	0	0	0	0	3	48

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: ..34067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/g_km.sas
 Output: ../CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/g_km_DTH_IT.pdf
 04FEB2021 9:36

POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Death or Permanent Ventilation
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)															
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					
Name	Level	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median			
All	n/a	17	100.0	2	11.8	15	88.2	NE	12.75	NE	NE	NE	41	100.0	6	14.6	35	85.4	NE	9.33	NE	NE	NE	58	100.0	8	13.8	50	86.2	NE	NE	NE	NE	NE			

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_tte_PVDTR_IT.xls
 26JUN2021 11:22

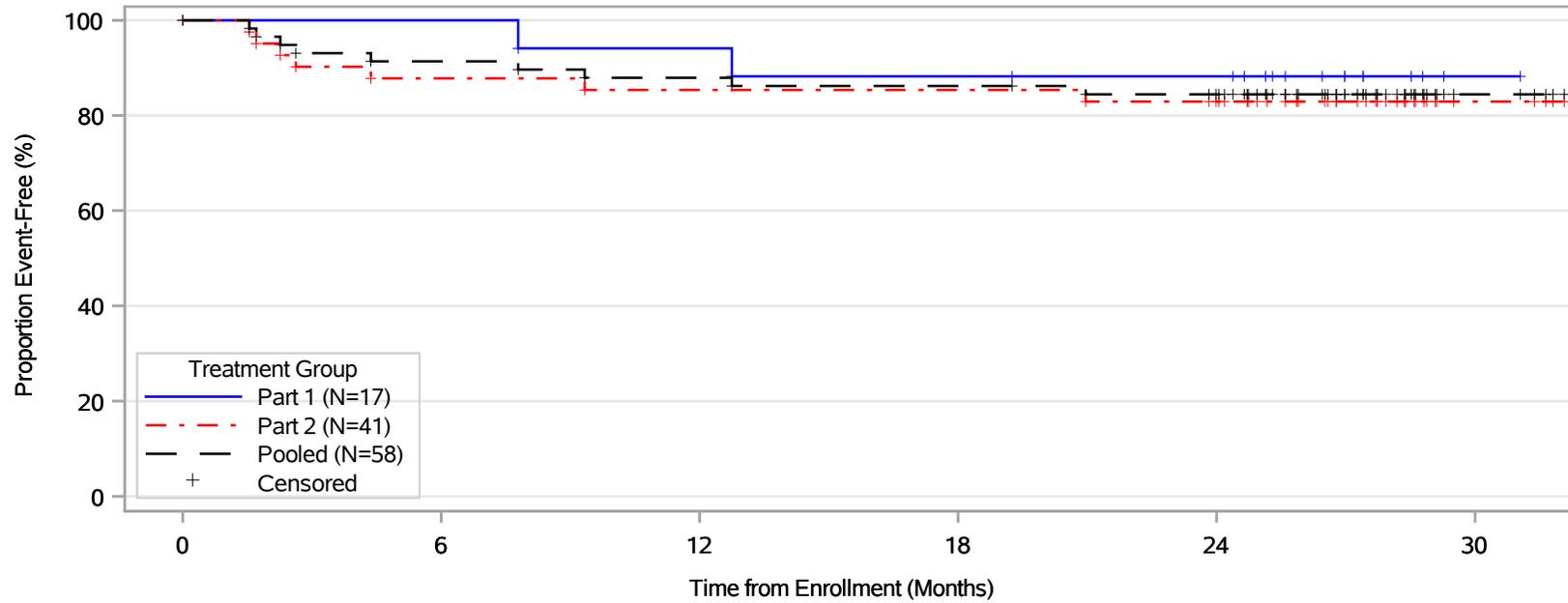
POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Death or Permanent Ventilation
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)												
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event				
Name	Level	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	95% Lower CL for Q1 (months)	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	17	100.0	2	11.8	15	88.2	NE	12.75	NE	NE	NE	41	100.0	7	17.1	34	82.9	NE	9.33	NE	NE	NE	58	100.0	9	15.5	49	84.5	NE	NE	NE	NE	NE

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_tte_FVDTH_IT.xls
 04FEB2021 9:34

POPULATION: Intent-to-Treat Population
ENDPOINT: Time to Death or Permanent Ventilation
STUDY: BP39056



Patients at risk						
	0	6	12	18	24	30
Part 1	17	17	16	15	14	1
Part 2	41	36	35	35	32	4
Pooled	58	53	51	50	46	5
Patients censored						
Part 1	0	0	0	0	1	14
Part 2	0	0	0	0	2	30
Pooled	0	0	0	0	3	44

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: ..34067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/g_km.sas
 Output: ..DPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/g_km_PVDTH_IT.pdf
 04FEB2021 9:37

POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Permanent Ventilation
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)															
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	17	100.0	0	0	17	100.0	NE	NE	NE	NE	NE	NE	41	100.0	3	7.3	38	92.7	NE	NE	NE	NE	NE	NE	58	100.0	3	5.2	55	94.8	NE	NE	NE	NE	NE	NE

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_tte_PV_IT.xls
 26JAN2021 11:21

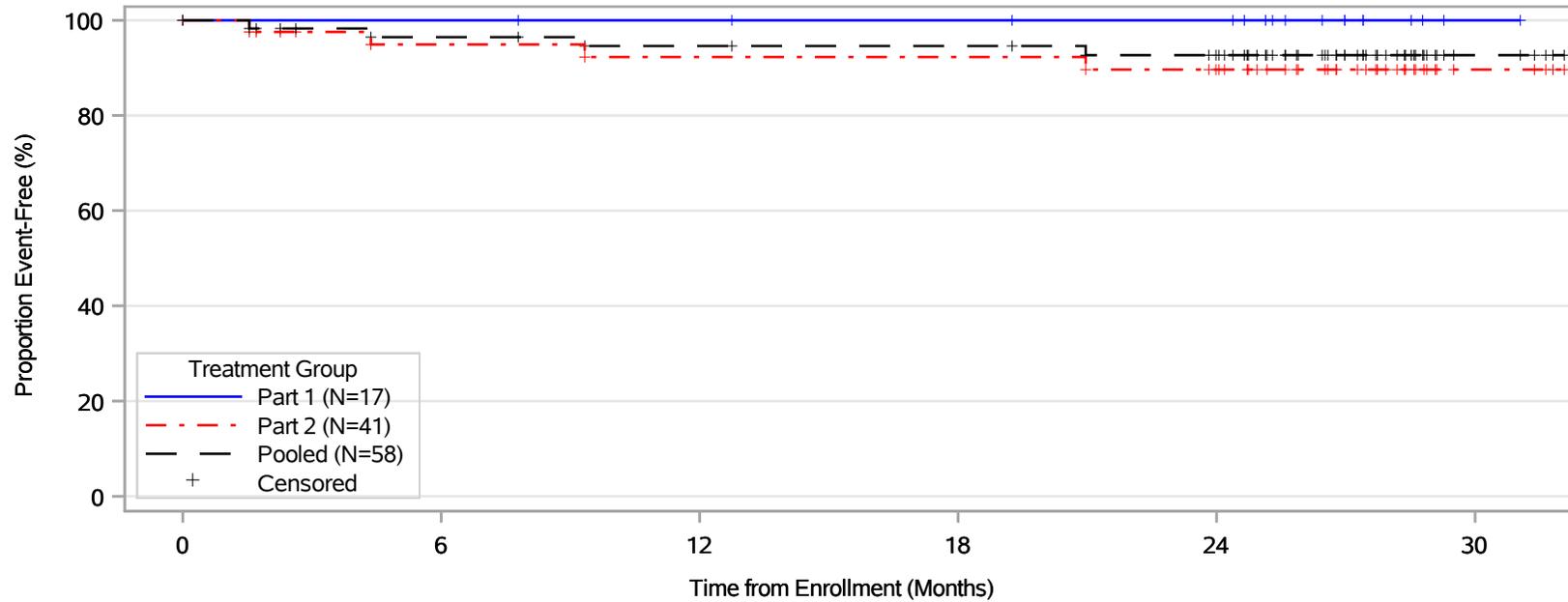
POPULATION: Intent-to-Treat Population
 ENDPOINT: Time to Permanent Ventilation
 MODEL: Unstratified Analysis
 STUDY: BP39056
 Time to Event Analysis (Efficacy)

		Part 1 (N=17)										Part 2 (N=41)										Pooled Population (Part 1 + Part 2) (N=58)															
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	17	100.0	0	0	17	100.0	NE	NE	NE	NE	NE	NE	41	100.0	4	9.8	37	90.2	NE	NE	NE	NE	NE	NE	58	100.0	4	6.9	54	93.1	NE	NE	NE	NE	NE	NE

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_tte_FV_IT.xls
 04FEB2021 9:33

POPULATION: Intent-to-Treat Population
ENDPOINT: Time to Permanent Ventilation
STUDY: BP39056



Patients at risk						
	0	6	12	18	24	30
Part 1	17	17	16	15	14	1
Part 2	41	36	35	35	32	4
Pooled	58	53	51	50	46	5
Patients censored						
Part 1	0	0	1	2	3	16
Part 2	0	3	3	3	5	33
Pooled	0	3	4	5	8	49

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: ..34067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/g_km.sas
 Output: ../CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/g_km_PV_IT.pdf
 04FEB2021 9:37

POPULATION: Intent-to-Treat Population
 ENDPOINT: CHOP-INTEND total score up to Month 12
 MODEL: Unadjusted Analysis
 STUDY: BP39056
 Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 2	All	n/a	17	17	17	6.13	1.09	34	34	34	7.64	1.14	51	51	51	7.13	0.85
Month 4	All	n/a	17	17	17	11.58	1.23	36	36	36	11.43	1.14	53	53	53	11.49	0.86
Month 6	All	n/a	17	17	17	12.82	1.37	38	38	38	12.88	1.55	55	55	55	12.85	1.14
Month 8	All	n/a	16	16	16	15.74	1.46	37	37	37	16.99	1.17	53	53	53	16.67	0.90
Month 10	All	n/a	16	16	16	16.99	1.34	38	38	38	18.50	1.32	54	54	54	18.08	0.99
Month 12	All	n/a	16	16	16	15.50	2.87	38	38	38	19.99	1.41	54	54	54	18.54	1.29

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMMeans of change from baseline from MMRM (including all available records from all visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_mmrn_CHOP_IT.xls

26JAN2021 11:42

POPULATION: Intent-to-Treat Population
 ENDPOINT: CHOP-INTEND total score up to Month 24
 MODEL: --
 STUDY: BP39056
 Compliance and Mean

		Part 1 (N=17)						Part 2 (N=41)						Pooled Population (Part1 + Part 2) (N=58)						
		Patients				Statistics		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All																				
Baseline		n/a	17	100.0	17	100.0	24.29	5.75	41	100.0	41	100.0	21.71	7.10	58	100.0	58	100.0	22.47	6.79
Day 2		n/a	17	100.0	0	NE	NE	NE	41	100.0	0	NE	NE	NE	58	100.0	0	NE	NE	NE
Month 2		n/a	17	100.0	17	100.0	30.41	7.46	40	100.0	34	85.0	29.32	8.45	57	100.0	51	89.5	29.69	8.07
Month 4		n/a	17	100.0	17	100.0	35.94	6.53	38	100.0	36	94.7	33.42	8.57	55	100.0	53	96.4	34.23	8.00
Month 6		n/a	17	100.0	17	100.0	37.18	6.90	38	100.0	38	100.0	35.03	10.35	55	100.0	55	100.0	35.69	9.41
Month 8		n/a	16	100.0	16	100.0	41.13	6.60	38	100.0	37	97.4	39.00	8.46	54	100.0	53	98.1	39.64	7.94
Month 10		n/a	16	100.0	16	100.0	42.31	6.24	38	100.0	38	100.0	40.63	8.68	54	100.0	54	100.0	41.13	8.01
Month 12		n/a	16	100.0	16	100.0	40.19	10.99	38	100.0	38	100.0	42.13	9.25	54	100.0	54	100.0	41.56	9.74
Month 14		n/a	15	100.0	15	100.0	45.93	6.86	38	100.0	38	100.0	42.82	9.18	53	100.0	53	100.0	43.70	8.64
Month 16		n/a	15	100.0	14	93.3	46.21	3.93	38	100.0	29	76.3	43.03	10.94	53	100.0	43	81.1	44.07	9.32
Month 18		n/a	15	100.0	14	93.3	47.79	6.17	38	100.0	26	68.4	41.73	9.64	53	100.0	40	75.5	43.85	8.99
Month 20		n/a	15	100.0	15	100.0	47.33	7.77	38	100.0	22	57.9	42.59	10.65	53	100.0	37	69.8	44.51	9.76
Month 22		n/a	14	100.0	13	92.9	49.62	8.27	38	100.0	23	60.5	47.65	7.29	52	100.0	36	69.2	48.36	7.60
Month 24		n/a	14	100.0	14	100.0	50.57	7.79	38	100.0	38	100.0	47.34	10.31	52	100.0	52	100.0	48.21	9.73

¹ in study: number of subjects in study at respective visit;

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mean_CHOP_IT.xls

04FEB2021 9:41

POPULATION: Intent-to-Treat Population
 ENDPOINT: CHOP-INTEND total score up to Month 24
 MODEL: Unadjusted Analysis
 STUDY: BP39056
 Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 2	All	n/a	17	17	17	NE	NE	34	34	34	NE	NE	51	51	51	7.10	0.85
Month 4	All	n/a	17	17	17	NE	NE	36	36	36	NE	NE	53	53	53	11.49	0.87
Month 6	All	n/a	17	17	17	NE	NE	38	38	38	NE	NE	55	55	55	12.78	1.14
Month 8	All	n/a	16	16	16	NE	NE	37	37	37	NE	NE	53	53	53	16.60	0.90
Month 10	All	n/a	16	16	16	NE	NE	38	38	38	NE	NE	54	54	54	17.99	0.99
Month 12	All	n/a	16	16	16	NE	NE	38	38	38	NE	NE	54	54	54	18.42	1.29
Month 14	All	n/a	15	15	15	NE	NE	38	38	38	NE	NE	53	53	53	20.62	1.01
Month 16	All	n/a	14	14	14	NE	NE	29	29	29	NE	NE	43	43	43	21.19	1.17
Month 18	All	n/a	14	14	14	NE	NE	26	26	26	NE	NE	40	40	40	21.63	1.17
Month 20	All	n/a	15	15	15	NE	NE	22	22	22	NE	NE	37	37	37	21.86	1.24
Month 22	All	n/a	13	13	13	NE	NE	23	23	23	NE	NE	36	36	36	22.90	1.27
Month 24	All	n/a	14	14	14	NE	NE	38	38	38	NE	NE	52	52	52	25.01	1.20

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from all visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mmrn_CHOP_IT.xls

04FEB2021 9:43

POPULATION: Intent-to-Treat Population
 ENDPOINT: HINE-2 total score up to Month 12
 MODEL: Unadjusted Analysis
 STUDY: BP39056
 Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 4	All	n/a	17	17	17	1.65	0.39	36	36	36	1.87	0.26	53	53	53	1.80	0.22
Month 8	All	n/a	16	16	16	4.34	0.98	37	37	37	4.02	0.50	53	53	53	4.11	0.45
Month 12	All	n/a	16	16	16	6.44	1.23	38	38	38	6.37	0.63	54	54	54	6.39	0.57

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from scheduled visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_mmrms.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_mmrms_HINE_IT.xls

23FEB2021 13:39

POPULATION: Intent-to-Treat Population
 ENDPOINT: HINE-2 total score up to Month 24
 MODEL: --
 STUDY: BP39056
 Compliance and Mean

		Part 1 (N=17)						Part 2 (N=41)						Pooled Population (Part1 + Part 2) (N=58)						
		Patients				Statistics		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All																				
Baseline		n/a	17	100.0	17	100.0	0.94	0.56	41	100.0	41	100.0	0.93	1.08	58	100.0	58	100.0	0.93	0.95
Day 2		n/a	17	100.0	0	NE	NE	NE	41	100.0	0	NE	NE	NE	58	100.0	0	NE	NE	NE
Month 2		n/a	17	100.0	0	NE	NE	NE	40	100.0	0	NE	NE	NE	57	100.0	0	NE	NE	NE
Month 4		n/a	17	100.0	17	100.0	2.59	1.58	38	100.0	36	94.7	2.86	2.24	55	100.0	53	96.4	2.77	2.04
Month 6		n/a	17	100.0	0	NE	NE	NE	38	100.0	1	2.6	7.00	NE	55	100.0	1	1.8	7.00	NE
Month 8		n/a	16	100.0	16	100.0	5.44	3.86	38	100.0	37	97.4	4.97	3.42	54	100.0	53	98.1	5.11	3.53
Month 10		n/a	16	100.0	0	NE	NE	NE	38	100.0	0	NE	NE	NE	54	100.0	0	NE	NE	NE
Month 12		n/a	16	100.0	16	100.0	7.56	4.77	38	100.0	38	100.0	7.29	4.57	54	100.0	54	100.0	7.37	4.59
Month 14		n/a	15	100.0	0	NE	NE	NE	38	100.0	0	NE	NE	NE	53	100.0	0	NE	NE	NE
Month 16		n/a	15	100.0	14	93.3	8.86	4.88	38	100.0	29	76.3	8.10	4.86	53	100.0	43	81.1	8.35	4.82
Month 18		n/a	15	100.0	0	NE	NE	NE	38	100.0	1	2.6	12.00	NE	53	100.0	1	1.9	12.00	NE
Month 20		n/a	15	100.0	15	100.0	11.00	5.83	38	100.0	22	57.9	9.50	6.35	53	100.0	37	69.8	10.11	6.11
Month 22		n/a	14	100.0	14	100.0	11.71	5.47	38	100.0	10	26.3	9.70	6.07	52	100.0	24	46.2	10.88	5.69
Month 24		n/a	14	100.0	14	100.0	12.64	5.47	38	100.0	38	100.0	11.16	5.92	52	100.0	52	100.0	11.56	5.79

¹ in study: number of subjects in study at respective visit;

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mean_HINE_IT.xls

04FEB2021 9:42

POPULATION: Intent-to-Treat Population
 ENDPOINT: HINE-2 total score up to Month 24
 MODEL: Unadjusted Analysis
 STUDY: BP39056
 Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 4	All	n/a	17	17	17	1.65	0.39	36	36	36	1.86	0.26	53	53	53	1.79	0.22
Month 8	All	n/a	16	16	16	4.34	0.98	37	37	37	4.01	0.50	53	53	53	4.11	0.45
Month 12	All	n/a	16	16	16	6.45	1.23	38	38	38	6.32	0.63	54	54	54	6.35	0.57
Month 16	All	n/a	14	14	14	7.27	1.26	29	29	29	7.61	0.67	43	43	43	7.47	0.60
Month 20	All	n/a	15	15	15	9.86	1.43	22	22	22	8.95	0.93	37	37	37	9.22	0.79
Month 24	All	n/a	14	14	14	11.02	1.41	38	38	38	10.20	0.94	52	52	52	10.43	0.78

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMMeans of change from baseline from MMRM (including all available records from scheduled visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mmrn_HINE_IT.xls

23FEB2021 15:43

POPULATION: Intent-to-Treat Population

ENDPOINT: total raw score of the modified BSID-III gross motor scale up to Month 12

MODEL: Unadjusted Analysis

STUDY: BP39056

Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 4	All	n/a	16	16	16	2.18	0.66	36	36	36	2.28	0.56	52	52	52	2.24	0.43
Month 8	All	n/a	16	16	16	4.44	1.09	37	37	37	5.29	0.75	53	53	53	5.09	0.62
Month 12	All	n/a	16	16	16	5.58	1.20	38	38	38	7.23	0.90	54	54	54	6.80	0.73

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMeans of change from baseline from MMRM (including all available records from scheduled visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_mmrn_BSID_IT.xls

23FEB2021 13:39

POPULATION: Intent-to-Treat Population

ENDPOINT: total raw score of the modified BSID-III gross motor scale up to Month 24

MODEL: --

STUDY: BP39056

Compliance and Mean

		Part 1 (N=17)						Part 2 (N=41)						Pooled Population (Part1 + Part 2) (N=58)						
		Patients				Statistics		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All																				
Baseline		n/a	17	100.0	17	100.0	2.12	1.36	41	100.0	41	100.0	1.85	1.61	58	100.0	58	100.0	1.93	1.53
Day 2		n/a	17	100.0	0	NE	NE	NE	41	100.0	0	NE	NE	NE	58	100.0	0	NE	NE	NE
Month 2		n/a	17	100.0	0	NE	NE	NE	40	100.0	0	NE	NE	NE	57	100.0	0	NE	NE	NE
Month 4		n/a	17	100.0	16	94.1	4.19	2.90	38	100.0	36	94.7	4.19	3.88	55	100.0	52	94.5	4.19	3.58
Month 6		n/a	17	100.0	0	NE	NE	NE	38	100.0	1	2.6	8.00	NE	55	100.0	1	1.8	8.00	NE
Month 8		n/a	16	100.0	16	100.0	6.94	4.17	38	100.0	37	97.4	7.19	5.82	54	100.0	53	98.1	7.11	5.33
Month 10		n/a	16	100.0	0	NE	NE	NE	38	100.0	0	NE	NE	NE	54	100.0	0	NE	NE	NE
Month 12		n/a	16	100.0	16	100.0	8.13	4.65	38	100.0	38	100.0	9.11	6.37	54	100.0	54	100.0	8.81	5.89
Month 14		n/a	15	100.0	0	NE	NE	NE	38	100.0	0	NE	NE	NE	53	100.0	0	NE	NE	NE
Month 16		n/a	15	100.0	14	93.3	11.21	6.36	38	100.0	29	76.3	10.21	6.61	53	100.0	43	81.1	10.53	6.47
Month 18		n/a	15	100.0	0	NE	NE	NE	38	100.0	2	5.3	7.50	3.54	53	100.0	2	3.8	7.50	3.54
Month 20		n/a	15	100.0	15	100.0	12.93	7.32	38	100.0	22	57.9	10.68	6.19	53	100.0	37	69.8	11.59	6.67
Month 22		n/a	14	100.0	0	NE	NE	NE	38	100.0	3	7.9	13.33	8.33	52	100.0	3	5.8	13.33	8.33
Month 24		n/a	14	100.0	14	100.0	14.71	6.59	38	100.0	38	100.0	14.79	7.25	52	100.0	52	100.0	14.77	7.01

¹ in study: number of subjects in study at respective visit;

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mean_BSID_IT.xls

04FEB2021 9:41

POPULATION: Intent-to-Treat Population

ENDPOINT: total raw score of the modified BSID-III gross motor scale up to Month 24

MODEL: Unadjusted Analysis

STUDY: BP39056

Change from Baseline (Analysis of MMRM)

			Part 1 (N=17)					Part 2 (N=41)					Pooled Population (Part1 + Part 2) (N=58)				
Visit	Name	Level	N		Statistics			N		Statistics			N		Statistics		
			Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)
Baseline	All	n/a	17	17	0	NE	NE	41	41	0	NE	NE	58	58	0	NE	NE
Month 4	All	n/a	16	16	16	2.16	0.66	36	36	36	2.27	0.56	52	52	52	2.21	0.43
Month 8	All	n/a	16	16	16	4.43	1.09	37	37	37	5.15	0.75	53	53	53	5.05	0.62
Month 12	All	n/a	16	16	16	5.57	1.20	38	38	38	7.13	0.90	54	54	54	6.76	0.73
Month 16	All	n/a	14	14	14	7.49	1.69	29	29	29	9.26	1.04	43	43	43	8.87	0.85
Month 20	All	n/a	15	15	15	10.10	1.85	22	22	22	10.62	0.99	37	37	37	10.76	0.88
Month 24	All	n/a	14	14	14	11.08	1.81	38	38	38	12.86	1.13	52	52	52	12.45	0.94

[1] Patients with a value at baseline and at least one post-baseline value

[2] LSMMeans of change from baseline from MMRM (including all available records from scheduled visits)

Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value, baseline-by-visit interaction.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_mmrn_BSID_IT.xls

23FEB2021 15:37

POPULATION: Intent-to-Treat Population

ENDPOINT: Proportion of infants sitting without support for 5 seconds at Month 12

MODEL: Unstratified Analysis

STUDY: BP39056

Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	7	41.2	41	100.0	12	29.3	58	100.0	19	32.8

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_resp_BSIDWS_IT.xls

26JAN2021 11:26

POPULATION: Intent-to-Treat Population

ENDPOINT: Proportion of infants sitting without support for 5 seconds at Month 24

MODEL: Unstratified Analysis

STUDY: BP39056

Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	10	58.8	41	100.0	25	61.0	58	100.0	35	60.3

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_resp_BSIDWS_IT.xls

04FEB2021 9:36

POPULATION: Intent-to-Treat Population
ENDPOINT: Proportion of infants with the ability to swallow at Month 12
MODEL: Unstratified Analysis
STUDY: BP39056
Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	15	88.2	41	100.0	36	87.8	58	100.0	51	87.9

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_resp_AS LW_IT.xls
 26JAN2021 11:24

POPULATION: Intent-to-Treat Population

ENDPOINT: Proportion of infants with the ability to swallow at Month 24

MODEL: Unstratified Analysis

STUDY: BP39056

Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	14	82.4	41	100.0	35	85.4	58	100.0	49	84.5

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_resp_AS LW_IT.xls

04FEB2021 9:33

POPULATION: Intent-to-Treat Population
ENDPOINT: Proportion of infants with the ability to feed orally at Month 12
MODEL: Unstratified Analysis
STUDY: BP39056
Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	15	88.2	41	100.0	34	82.9	58	100.0	49	84.5

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_resp_FEED_IT.xls
 26JAN2021 11:24

POPULATION: Intent-to-Treat Population
ENDPOINT: Proportion of infants with the ability to feed orally at Month 24
MODEL: Unstratified Analysis
STUDY: BP39056
Dichotomous Analysis (Efficacy)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	13	76.5	41	100.0	35	85.4	58	100.0	48	82.8

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_resp_FEED_IT.xls
 04FEB2021 9:34

POPULATION: Intent-to-Treat Population

ENDPOINT: Number of Hospitalizations (for any reason) per Patient-Year at Month 12.

MODEL: --

STUDY: BP39056

			Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Name	Level		Statistics	Statistics	Statistics
All	n/a	Total patient-years at risk	16.6	38.3	54.9
		Number of hospitalizations	17	50	67
		Number of hospitalizations per patient-year	1.03	1.3	1.22
		95% CI	(0.54, 1.51)	(0.94, 1.67)	(0.93, 1.51)

Total patient-years at risk is the sum over all patients of the time intervals (in years) from the start of study treatment to the earliest date of study withdrawal or completion of 12 months of treatment (Month 12 visit).

Includes all hospital admissions observed by Month 12 which span at least two days.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_eff_hosp.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_eff_hosp_IT.xls

26JAN2021 11:27

POPULATION: Intent-to-Treat Population

ENDPOINT: Number of Hospitalizations (for any reason) per Patient-Year at Month 24.

MODEL: --

STUDY: BP39056

			Part 1 (N=17)	Part 2 (N=41)	Pooled Population (Part1 + Part 2) (N=58)
Name	Level		Statistics	Statistics	Statistics
All	n/a	Total patient-years at risk	31.4	76.7	108.1
		Number of hospitalizations	27	72	99
		Number of hospitalizations per patient-year	0.86	0.94	0.92
		95% CI	(0.54, 1.18)	(0.72, 1.16)	(0.74, 1.10)

Total patient-years at risk is the sum over all patients of the time intervals (in years) from the start of study treatment to the earliest date of study withdrawal or completion of 24 months of treatment (Month 24 visit).

Includes all hospital admissions observed by Month 24 which span at least two days.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_eff_hosp.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_eff_hosp_IT.xls

04FEB2021 9:39

POPULATION: Safety-Evaluable Population
ENDPOINT: Any AEs Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	41	100.0	58	100.0	58	100.0

Only AEs of highest severity are counted. One patient from Part 1 is included despite of missing toxicity grade information.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AAE_SE.xls
 26JAN2021 11:20

POPULATION: Safety-Evaluable Population

ENDPOINT: Any AEs Excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	39	95.1	58	100.0	56	96.6

Only AEs of highest severity are counted. One patient from Part 1 is included despite of missing toxicity grade information.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AAE_SE_EXCL.xls

05NOV2020 13:44

POPULATION: Safety-Evaluable Population

ENDPOINT: Any AEs Excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	40	97.6	58	100.0	57	98.3

Only AEs of highest severity are counted. One patient from Part 1 is included despite of missing toxicity grade information.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AAE_SE_EXCLN.xls

05NOV2020 13:44

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 1-2 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	10	58.8	41	100.0	19	46.3	58	100.0	29	50.0

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG12_SE.xls

26JAN2021 11:22

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 1 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	11	26.8	58	100.0	11	19.0

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG1_SE.xls

26JAN2021 11:21

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 2 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	10	58.8	41	100.0	8	19.5	58	100.0	18	31.0

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG2_SE.xls

26JAN2021 11:21

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade >= 3 Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	6	35.3	41	100.0	22	53.7	58	100.0	28	48.3

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG345_SE.xls

26JAN2021 11:23

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade >= 3 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	8	19.5	58	100.0	11	19.0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG345_SE_EXCL.xls

05NOV2020 13:48

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade >= 3 Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	5	29.4	41	100.0	14	34.1	58	100.0	19	32.8

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG345_SE_EXCLN.xls

05NOV2020 13:48

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	13	31.7	58	100.0	15	25.9

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG3_SE.xls

26JAN2021 11:22

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	8	19.5	58	100.0	10	17.2

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG3_SE_EXCL.xls

05NOV2020 13:46

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	1	5.9	41	100.0	10	24.4	58	100.0	11	19.0

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG3_SE_EXCLN.xls

05NOV2020 13:47

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 4 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	6	14.6	58	100.0	8	13.8

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG4_SE.xls

26JAN2021 11:22

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 4 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG4_SE_EXCL.xls

05NOV2020 13:47

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 4 Excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG4_SE_EXCLN.xls

05NOV2020 13:47

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG5_SE.xls

26JAN2021 11:23

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	1	5.9	41	100.0	0	0	58	100.0	1	1.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG5_SE_EXCL.xls

05NOV2020 13:47

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AEG5_SE_EXCLN.xls

05NOV2020 13:48

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs leading to treatment discontinuation Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AELDIS_SE.xls

26JAN2021 11:24

POPULATION: Safety-Evaluable Population
 ENDPOINT: AESI Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

Only AEs of highest severity are counted.

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_AESI_SE.xls
 26JAN2021 11:25

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	7	41.2	41	100.0	24	58.5	58	100.0	31	53.4

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_ASAE_SE.xls

26JAN2021 11:24

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	9	22.0	58	100.0	12	20.7

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_ASAE_SE_EXCL.xls

05NOV2020 13:48

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	6	35.3	41	100.0	16	39.0	58	100.0	22	37.9

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_ASAE_SE_EXCLN.xls

05NOV2020 13:49

POPULATION: Safety-Evaluable Population
 ENDPOINT: Any AEs Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	2	11.8	41	100.0	5	12.2	58	100.0	7	12.1
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Cardiac disorders	Bradycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	11	64.7	41	100.0	18	43.9	58	100.0	29	50.0
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	3	17.6	41	100.0	8	19.5	58	100.0	11	19.0
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	4	9.8	58	100.0	10	17.2
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
General disorders and administration site conditions		n/a	17	100.0	10	58.8	41	100.0	16	39.0	58	100.0	26	44.8
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	8	47.1	41	100.0	16	39.0	58	100.0	24	41.4
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatocellular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	14	82.4	41	100.0	37	90.2	58	100.0	51	87.9

Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Coxsackie viral infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Myocarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	3	17.6	41	100.0	5	12.2	58	100.0	8	13.8
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Pneumonia	n/a	17	100.0	2	11.8	41	100.0	16	39.0	58	100.0	18	31.0
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Rhinitis	n/a	17	100.0	3	17.6	41	100.0	5	12.2	58	100.0	8	13.8
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	8	47.1	41	100.0	19	46.3	58	100.0	27	46.6
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Viral infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications		n/a	17	100.0	6	35.3	41	100.0	1	2.4	58	100.0	7	12.1
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	4	23.5	41	100.0	1	2.4	58	100.0	5	8.6
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	4	9.8	58	100.0	5	8.6
Nervous system disorders	Drooling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4

Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	9	52.9	41	100.0	13	31.7	58	100.0	22	37.9
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	5	29.4	41	100.0	0	0.0	58	100.0	5	8.6
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	7	41.2	41	100.0	16	39.0	58	100.0	23	39.7
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Surgical and medical procedures		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Surgical and medical procedures	Mechanical ventilation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

Only AEs of highest severity are counted. One patient from Part 1 is included despite of missing toxicity grade information.
From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
Clinical cut-off Part 1: 27/FEB2019, Part 2: 14/NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AAE_SE.xls
26JAN2021 11:26

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 1-2 Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	2	11.8	41	100.0	5	12.2	58	100.0	7	12.1
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Cardiac disorders	Bradycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	11	64.7	41	100.0	18	43.9	58	100.0	29	50.0
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	3	17.6	41	100.0	8	19.5	58	100.0	11	19.0
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	4	9.8	58	100.0	10	17.2
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	4	23.5	41	100.0	2	4.9	58	100.0	6	10.3
General disorders and administration site conditions		n/a	17	100.0	10	58.8	41	100.0	16	39.0	58	100.0	26	44.8
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	8	47.1	41	100.0	16	39.0	58	100.0	24	41.4
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatocellular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	14	82.4	41	100.0	33	80.5	58	100.0	47	81.0
Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Coxsackie viral infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Myocarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	3	17.6	41	100.0	5	12.2	58	100.0	8	13.8
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Pneumonia	n/a	17	100.0	0	0.0	41	100.0	5	12.2	58	100.0	5	8.6
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Rhinitis	n/a	17	100.0	3	17.6	41	100.0	5	12.2	58	100.0	8	13.8
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	8	47.1	41	100.0	17	41.5	58	100.0	25	43.1
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Viral infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	6	35.3	41	100.0	1	2.4	58	100.0	7	12.1
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	4	23.5	41	100.0	0	0.0	58	100.0	4	6.9
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders	Droling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	7	41.2	41	100.0	8	19.5	58	100.0	15	25.9
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	5	29.4	41	100.0	0	0.0	58	100.0	5	8.6
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4

Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	7	41.2	41	100.0	16	39.0	58	100.0	23	39.7
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG12_SE.xls

26JAN2021 11:28

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 1 Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Bradycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	10	58.8	41	100.0	17	41.5	58	100.0	27	46.6
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	2	11.8	41	100.0	8	19.5	58	100.0	10	17.2
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	3	7.3	58	100.0	9	15.5
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
General disorders and administration site conditions		n/a	17	100.0	6	35.3	41	100.0	13	31.7	58	100.0	19	32.8
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	4	23.5	41	100.0	13	31.7	58	100.0	17	29.3
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatocellular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	7	41.2	41	100.0	26	63.4	58	100.0	33	56.9
Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Conjunctivitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Coxsackie viral infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4

Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Myocarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	2	11.8	41	100.0	4	9.8	58	100.0	6	10.3
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Pneumonia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rhinitis	n/a	17	100.0	3	17.6	41	100.0	4	9.8	58	100.0	7	12.1
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	12	29.3	58	100.0	13	22.4
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Viral infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	4	23.5	41	100.0	1	2.4	58	100.0	5	8.6
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Drooling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	7	41.2	41	100.0	7	17.1	58	100.0	14	24.1
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	5	29.4	41	100.0	0	0.0	58	100.0	5	8.6
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	6	35.3	41	100.0	14	34.1	58	100.0	20	34.5
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BF39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BF39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEGl_SE.xls
26JAN2021 11:27

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	4	23.5	41	100.0	1	2.4	58	100.0	5	8.6
Gastrointestinal disorders	Constipation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Gastrointestinal disorders	Vomiting	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
General disorders and administration site conditions		n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	9	52.9	41	100.0	16	39.0	58	100.0	25	43.1
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Nasopharyngitis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Pneumonia	n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Rhinitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	7	41.2	41	100.0	5	12.2	58	100.0	12	20.7
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	4	23.5	41	100.0	0	0.0	58	100.0	4	6.9
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG2_SE.xls

26JAN2021 11:28

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	5	29.4	41	100.0	17	41.5	58	100.0	22	37.9
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	2	11.8	41	100.0	11	26.8	58	100.0	13	22.4
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	4	23.5	41	100.0	7	17.1	58	100.0	11	19.0
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/R07034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/R07034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG345_SE.xls
26JAN2021 11:31

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	3	17.6	41	100.0	11	26.8	58	100.0	14	24.1
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	6	14.6	58	100.0	7	12.1
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	2	11.8	41	100.0	4	9.8	58	100.0	6	10.3
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG3_SE.xls
 26JAN2021 11:29

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 4 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	1	5.9	41	100.0	4	9.8	58	100.0	5	8.6
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG4_SE.xls
 26JAN2021 11:29

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Pneumonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AEG5_SE.xls

26JAN2021 11:30

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs leading to treatment discontinuation Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AELDIS_SE.xls

26JAN2021 11:32

POPULATION: Safety-Evaluable Population
ENDPOINT: AESI Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

Null Report: No results could be derived for this output.

Only AEs of highest severity are counted.

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_AESI_SE.xls

26JAN2021 11:33

POPULATION: Safety-Evaluable Population
 ENDPOINT: Any SAEs Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	4	23.5	41	100.0	19	46.3	58	100.0	23	39.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	13	31.7	58	100.0	14	24.1
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	4	23.5	41	100.0	6	14.6	58	100.0	10	17.2
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Only AEs of highest severity are counted.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
 Clinical cut-off Part 1: 27FEB2019, Part 2: 14NOV2019

Program: root/clinical_studies/R07034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/R07034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled/prod/output/t_saf_ae_raw_soc_ASAE_SE.xls
26JAN2021 11:31

POPULATION: Safety-Evaluable Population
ENDPOINT: Any AEs Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	41	100.0	58	100.0	58	100.0

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AAE_SE.xls

10MAR2021 17:19

POPULATION: Safety-Evaluable Population
ENDPOINT: Any AEs Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	39	95.1	58	100.0	56	96.6

<30 days in Safety Follow-up (according to protocol).

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AAE_SE_EXCL.xls

10MAR2021 17:12

POPULATION: Safety-Evaluable Population

ENDPOINT: Any AEs Excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	17	100.0	41	100.0	40	97.6	58	100.0	57	98.3

<30 days in Safety Follow-up (according to protocol).

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AAE_SE_EXCLN.xls

10MAR2021 17:12

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 1-2 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	9	52.9	41	100.0	16	39.0	58	100.0	25	43.1

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG12_SE.xls

10MAR2021 17:20

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 1 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	8	19.5	58	100.0	8	13.8

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG1_SE.xls

10MAR2021 17:19

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 2 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	9	52.9	41	100.0	8	19.5	58	100.0	17	29.3

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG2_SE.xls

10MAR2021 17:20

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade >= 3 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	8	47.1	41	100.0	25	61.0	58	100.0	33	56.9

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG345_SE.xls

10MAR2021 17:22

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade >= 3 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	4	23.5	41	100.0	11	26.8	58	100.0	15	25.9

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG345_SE_EXCL.xls
 10MAR2021 17:16

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade >= 3 Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	6	35.3	41	100.0	17	41.5	58	100.0	23	39.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG345_SE_EXCLN.xls
 10MAR2021 17:15

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	15	36.6	58	100.0	18	31.0

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG3_SE.xls

10MAR2021 17:21

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	11	26.8	58	100.0	14	24.1

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG3_SE_EXCL.xls
 10MAR2021 17:14

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 3 Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	14	34.1	58	100.0	16	27.6

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG3_SE_EXCLN.xls
 10MAR2021 17:14

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 4 Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	7	17.1	58	100.0	10	17.2

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG4_SE.xls

10MAR2021 17:21

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 4 Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG4_SE_EXCL.xls

10MAR2021 17:15

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs Grade 4 Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG4_SE_EXCLN.xls
 10MAR2021 17:14

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG5_SE.xls

10MAR2021 17:22

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Excluding Broad Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	1	5.9	41	100.0	0	0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG5_SE_EXCL.xls

10MAR2021 17:15

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Excluding Narrow Basket Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	1	5.9	41	100.0	0	0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AEG5_SE_EXCLN.xls

10MAR2021 17:15

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs leading to treatment discontinuation Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AELDIS_SE.xls

10MAR2021 17:23

POPULATION: Safety-Evaluable Population
 ENDPOINT: AESI Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	0	0	41	100.0	0	0	58	100.0	0	0

<30 days in Safety Follow-up (according to protocol).

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.
 From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas
 Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_AESI_SE.xls
 10MAR2021 17:24

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	11	64.7	41	100.0	28	68.3	58	100.0	39	67.2

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_ASAE_SE.xls

10MAR2021 17:23

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Excluding Broad Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	5	29.4	41	100.0	12	29.3	58	100.0	17	29.3

<30 days in Safety Follow-up (according to protocol).

Disease related events are defined as those under the broad prospective-PT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_ASAE_SE_EXCL.xls

10MAR2021 17:16

POPULATION: Safety-Evaluable Population
ENDPOINT: Any SAEs Excluding Narrow Basket Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

		Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
		Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%
All	n/a	17	100.0	8	47.1	41	100.0	17	41.5	58	100.0	25	43.1

<30 days in Safety Follow-up (according to protocol).

Disease related events are defined as those under the narrow prospective-LLT basket.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_ASAE_SE_EXCLN.xls

10MAR2021 17:16

POPULATION: Safety-Evaluable Population
 ENDPOINT: Any AEs Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	2	11.8	41	100.0	6	14.6	58	100.0	8	13.8
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Splenomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Cardiac disorders	Bradycarrhythmia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	2	11.8	41	100.0	5	12.2	58	100.0	7	12.1
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Intestinal malrotation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Phimosi	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Ear and labyrinth disorders	Cerumen impaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Retinal exudates	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Strabismus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	13	76.5	41	100.0	21	51.2	58	100.0	34	58.6
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	3	17.6	41	100.0	12	29.3	58	100.0	15	25.9
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	6	14.6	58	100.0	12	20.7
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	3	17.6	41	100.0	2	4.9	58	100.0	5	8.6
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Intestinal dilatation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	5	29.4	41	100.0	3	7.3	58	100.0	8	13.8
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	6	35.3	41	100.0	4	9.8	58	100.0	10	17.2
General disorders and administration site conditions		n/a	17	100.0	14	82.4	41	100.0	19	46.3	58	100.0	33	56.9
General disorders and administration site conditions	Application site reaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Hyperthermia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	12	70.6	41	100.0	18	43.9	58	100.0	30	51.7

Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatoceleular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Immune system disorders	Allergy to arthropod bite	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	17	100.0	41	100.0	38	92.7	58	100.0	55	94.8
Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	6	14.6	58	100.0	6	10.3
Infections and infestations	COVID-19	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Ear infection	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Fungal skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Infections and infestations	Gastroenteritis adenovirus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Infections and infestations	Lower respiratory tract infection viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Mycarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	5	29.4	41	100.0	7	17.1	58	100.0	12	20.7
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Pneumonia	n/a	17	100.0	3	17.6	41	100.0	19	46.3	58	100.0	22	37.9
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Respiratory syncytial virus bronchiolitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Respiratory tract infection	n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Rhinitis	n/a	17	100.0	4	23.5	41	100.0	5	12.2	58	100.0	9	15.5
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Sepsis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Stoma site infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	10	58.8	41	100.0	22	53.7	58	100.0	32	55.2
Infections and infestations	Upper respiratory tract infection bacterial	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Viral infection	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Infections and infestations	Viral skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Injury, poisoning and procedural complications		n/a	17	100.0	6	35.3	41	100.0	5	12.2	58	100.0	11	19.0
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications	Humerus fracture	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Injury, poisoning and procedural complications	Near drowning	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation abnormal	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Investigations	Weight decreased	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Metabolism and nutrition disorders		n/a	17	100.0	4	23.5	41	100.0	4	9.8	58	100.0	8	13.8
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Hypoglycaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Malnutrition	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Joint instability	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphoscoliosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Osteoporosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	5	12.2	58	100.0	6	10.3
Nervous system disorders	Droling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders	Seizure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Vocal cord paralysis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders	Tic	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Renal and urinary disorders	Calculus urinary	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Dysuria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	10	58.8	41	100.0	15	36.6	58	100.0	25	43.1
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	7	41.2	41	100.0	1	2.4	58	100.0	8	13.8
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	7	41.2	41	100.0	19	46.3	58	100.0	26	44.8
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatosis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Vascular disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Vascular disorders	Haematoma	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AAE_SE.xls

10MAR2021 17:27

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 1-2 Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	2	11.8	41	100.0	6	14.6	58	100.0	8	13.8
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Splenomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Cardiac disorders	Bradycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Phimosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Ear and labyrinth disorders	Cerumen impaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Retinal exudates	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Strabismus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	13	76.5	41	100.0	20	48.8	58	100.0	33	56.9
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	3	17.6	41	100.0	10	24.4	58	100.0	13	22.4
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	5	12.2	58	100.0	11	19.0
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Intestinal dilatation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	5	29.4	41	100.0	3	7.3	58	100.0	8	13.8
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	6	35.3	41	100.0	3	7.3	58	100.0	9	15.5
General disorders and administration site conditions		n/a	17	100.0	14	82.4	41	100.0	19	46.3	58	100.0	33	56.9
General disorders and administration site conditions	Application site reaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Hyperthermia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	12	70.6	41	100.0	18	43.9	58	100.0	30	51.7
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Hepatobiliary disorders	Hepatocellular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Immune system disorders	Allergy to arthropod bite	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	16	94.1	41	100.0	36	87.8	58	100.0	52	89.7
Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	5	12.2	58	100.0	5	8.6
Infections and infestations	COVID-19	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Ear infection	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Fungal skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Infections and infestations	Gastroenteritis adenovirus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Myocarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	5	29.4	41	100.0	7	17.1	58	100.0	12	20.7
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	5	12.2	58	100.0	6	10.3
Infections and infestations	Respiratory tract infection	n/a	17	100.0	3	17.6	41	100.0	2	4.9	58	100.0	5	8.6
Infections and infestations	Rhinitis	n/a	17	100.0	4	23.5	41	100.0	5	12.2	58	100.0	9	15.5
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Stoma site infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	10	58.8	41	100.0	20	48.8	58	100.0	30	51.7
Infections and infestations	Upper respiratory tract infection bacterial	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Viral infection	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Infections and infestations	Viral skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	6	35.3	41	100.0	4	9.8	58	100.0	10	17.2
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Injury, poisoning and procedural complications	Humerus fracture	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation abnormal	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Metabolism and nutrition disorders		n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Malnutrition	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Joint instability	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

Musculoskeletal and connective tissue disorders	Kyphoscoliosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Osteoporosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders	Drooling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders	Tic	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Renal and urinary disorders	Calculus urinary	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Dysuria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	9	52.9	41	100.0	10	24.4	58	100.0	19	32.8
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	7	41.2	41	100.0	0	0.0	58	100.0	7	12.1
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	7	41.2	41	100.0	19	46.3	58	100.0	26	44.8
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatosis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Vascular disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Vascular disorders	Haematoma	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG12_SE.xls

10MAR2021 17:29

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 1 Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	1	5.9	41	100.0	4	9.8	58	100.0	5	8.6
Blood and lymphatic system disorders	Eosinophilia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Lymphadenopathy	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Blood and lymphatic system disorders	Splenomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Bradyarrhythmia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	1	5.9	41	100.0	3	7.3	58	100.0	4	6.9
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Congenital, familial and genetic disorders	Hydrocele	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders	Phimosi	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Ear and labyrinth disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Ear and labyrinth disorders	Cerumen impaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Ear and labyrinth disorders	Ear pain	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders		n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Eye disorders	Conjunctival hyperaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Macular cyst	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Eye disorders	Retinal exudates	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	13	76.5	41	100.0	19	46.3	58	100.0	32	55.2
Gastrointestinal disorders	Abnormal faeces	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Allergic gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	2	11.8	41	100.0	10	24.4	58	100.0	12	20.7
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	6	35.3	41	100.0	3	7.3	58	100.0	9	15.5
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Faeces discoloured	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Flatulence	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastrooesophageal reflux disease	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Haematochezia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Infrequent bowel movements	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Intestinal dilatation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Salivary hypersecretion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Gastrointestinal disorders	Teething	n/a	17	100.0	5	29.4	41	100.0	3	7.3	58	100.0	8	13.8
Gastrointestinal disorders	Toothache	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Vomiting	n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
General disorders and administration site conditions		n/a	17	100.0	9	52.9	41	100.0	15	36.6	58	100.0	24	41.4
General disorders and administration site conditions	Application site reaction	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Crying	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Discomfort	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
General disorders and administration site conditions	Hyperthermia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Ill-defined disorder	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
General disorders and administration site conditions	Oedema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	7	41.2	41	100.0	13	31.7	58	100.0	20	34.5
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Hepatobiliary disorders	Hepatocellular injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Hepatomegaly	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Immune system disorders	Allergy to arthropod bite	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Immune system disorders	Drug hypersensitivity	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Infections and infestations		n/a	17	100.0	9	52.9	41	100.0	26	63.4	58	100.0	35	60.3
Infections and infestations	Acarodermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	COVID-19	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Conjunctivitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Exanthema subitum	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Folliculitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Fungal skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis adenovirus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Myocarditis infectious	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Nasopharyngitis	n/a	17	100.0	4	23.5	41	100.0	5	12.2	58	100.0	9	15.5
Infections and infestations	Oral candidiasis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Otitis media acute	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Rhinitis	n/a	17	100.0	4	23.5	41	100.0	4	9.8	58	100.0	8	13.8
Infections and infestations	Rotavirus infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	2	11.8	41	100.0	12	29.3	58	100.0	14	24.1
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Viral infection	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Infections and infestations	Viral skin infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	4	23.5	41	100.0	3	7.3	58	100.0	7	12.1
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Injury, poisoning and procedural complications	Stoma site hypergranulation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Investigations		n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Investigations	Aspartate aminotransferase increased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Neutrophil count decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Oxygen saturation abnormal	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Investigations	Weight decreased	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders	Deformity thorax	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Osteoporosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Scoliosis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Nervous system disorders	Drooling	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Irritability	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Renal and urinary disorders	Calculus urinary	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Dysuria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	9	52.9	41	100.0	7	17.1	58	100.0	16	27.6
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	7	41.2	41	100.0	0	0.0	58	100.0	7	12.1
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Skin and subcutaneous tissue disorders		n/a	17	100.0	6	35.3	41	100.0	16	39.0	58	100.0	22	37.9
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis diaper	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Eczema	n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Eczema nummular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Erythema	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Miliaria	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Petechiae	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Skin and subcutaneous tissue disorders	Rash papular	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Skin discolouration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Vascular disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Vascular disorders	Haematoma	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG1_SE.xls

10MAR2021 17:28

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 2 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Blood and lymphatic system disorders	Anaemia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Blood and lymphatic system disorders	Leukocytosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Blood and lymphatic system disorders	Neutropenia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Congenital, familial and genetic disorders		n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Eye disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Eye disorders	Heterophoria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Eye disorders	Strabismus	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	3	17.6	41	100.0	2	4.9	58	100.0	5	8.6
Gastrointestinal disorders	Constipation	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Gastrointestinal disorders	Dysphagia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Gastrointestinal disorders	Vomiting	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
General disorders and administration site conditions		n/a	17	100.0	5	29.4	41	100.0	5	12.2	58	100.0	10	17.2
General disorders and administration site conditions	Pyrexia	n/a	17	100.0	5	29.4	41	100.0	5	12.2	58	100.0	10	17.2
Hepatobiliary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Hepatobiliary disorders	Biliary dyskinesia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	11	64.7	41	100.0	21	51.2	58	100.0	32	55.2
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2
Infections and infestations	Conjunctivitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Ear infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Herpangina	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Influenza	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Infections and infestations	Nasopharyngitis	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Otitis media	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	5	12.2	58	100.0	6	10.3
Infections and infestations	Respiratory tract infection	n/a	17	100.0	3	17.6	41	100.0	0	0.0	58	100.0	3	5.2
Infections and infestations	Rhinitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Rubella	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Stoma site infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	8	47.1	41	100.0	8	19.5	58	100.0	16	27.6
Infections and infestations	Upper respiratory tract infection bacterial	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Varicella post vaccine	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations	Viral infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications		n/a	17	100.0	3	17.6	41	100.0	1	2.4	58	100.0	4	6.9
Injury, poisoning and procedural complications	Fall	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Head injury	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Humerus fracture	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Injury, poisoning and procedural complications	Joint dislocation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

Injury, poisoning and procedural complications	Thermal burn	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	3	17.6	41	100.0	3	7.3	58	100.0	6	10.3
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Iron deficiency	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Malnutrition	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders		n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Musculoskeletal and connective tissue disorders	Joint instability	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphoscoliosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Musculoskeletal and connective tissue disorders	Kyphosis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Nervous system disorders	Loss of consciousness	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Psychiatric disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Psychiatric disorders	Sleep disorder	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Psychiatric disorders	Tic	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Renal and urinary disorders	Urinary retention	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	2	11.8	41	100.0	4	9.8	58	100.0	6	10.3
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders		n/a	17	100.0	1	5.9	41	100.0	4	9.8	58	100.0	5	8.6
Skin and subcutaneous tissue disorders	Dermatitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis allergic	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatitis atopic	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Dermatosis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Urticaria	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG2_SE.xls

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POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade >= 3 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)						Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event			
			n	%	n	%	n	%	n	%	n	%	n	%		
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Congenital, familial and genetic disorders	Intestinal malrotation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	5	12.2	58	100.0	5	8.6		
Gastrointestinal disorders	Constipation	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations		n/a	17	100.0	6	35.3	41	100.0	19	46.3	58	100.0	25	43.1		
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Lower respiratory tract infection viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia	n/a	17	100.0	2	11.8	41	100.0	14	34.1	58	100.0	16	27.6		
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Respiratory syncytial virus bronchiolitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Sepsis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Injury, poisoning and procedural complications		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Injury, poisoning and procedural complications	Near drowning	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Metabolism and nutrition disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Metabolism and nutrition disorders	Hypoglycaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9		
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Nervous system disorders	Seizure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders	Vocal cord paralysis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	4	23.5	41	100.0	8	19.5	58	100.0	12	20.7		
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2		

Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	2	11.8	41	100.0	0	0.0	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Skin and subcutaneous tissue disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG345_SE.xls

10MAR2021 17:32

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 3 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)						Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event			
			n	%	n	%	n	%	n	%	n	%	n	%		
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Congenital, familial and genetic disorders	Intestinal malrotation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9		
Gastrointestinal disorders	Constipation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations		n/a	17	100.0	5	29.4	41	100.0	12	29.3	58	100.0	17	29.3		
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Lower respiratory tract infection viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	8	19.5	58	100.0	9	15.5		
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia staphylococcal	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Respiratory syncytial virus bronchiolitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Sepsis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Injury, poisoning and procedural complications		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Injury, poisoning and procedural complications	Near drowning	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations	Oxygen saturation decreased	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Metabolism and nutrition disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9		
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Nervous system disorders	Seizure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders	Vocal cord paralysis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	3	17.6	41	100.0	5	12.2	58	100.0	8	13.8		
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	2	11.8	41	100.0	1	2.4	58	100.0	3	5.2		
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		

Skin and subcutaneous tissue disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG3_SE.xls

10MAR2021 17:30

POPULATION: Safety-Evaluable Population
 ENDPOINT: AEs Grade 4 Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Gastrointestinal disorders	Constipation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	1	5.9	41	100.0	5	12.2	58	100.0	6	10.3
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Infections and infestations	Pneumonia	n/a	17	100.0	1	5.9	41	100.0	4	9.8	58	100.0	5	8.6
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Metabolism and nutrition disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Metabolism and nutrition disorders	Hypoglycaemia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG4_SE.xls

10MAR2021 17:30

POPULATION: Safety-Evaluable Population

ENDPOINT: AEs Grade 5 (AEs leading to death) Including Disease Related Adverse Events

MODEL: Unstratified analysis

STUDY: BP39056

Dichotomous Analysis (Safety)

			Part 1 (N=17)				Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Infections and infestations		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Infections and infestations	Pneumonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

Only AEs of highest severity are counted.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas

Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AEG5_SE.xls

10MAR2021 17:31

POPULATION: Safety-Evaluable Population
ENDPOINT: AEs leading to treatment discontinuation Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

Null Report: No results could be derived for this output.

<30 days in Safety Follow-up (according to protocol).
From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.
Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AELDIS_SE.xls
10MAR2021 17:33

POPULATION: Safety-Evaluable Population
ENDPOINT: AESI Including Disease Related Adverse Events
MODEL: Unstratified analysis
STUDY: BP39056
Dichotomous Analysis (Safety)

Null Report: No results could be derived for this output.

<30 days in Safety Follow-up (according to protocol).

AESIs include the following: (1) cases of an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice; (2) suspected transmission of an infectious agent by the study drug.

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

Program: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/program/t_saf_ae_raw_soc.sas
Output: root/clinical_studies/RO7034067/CDPT7916/BP39056/data_analysis/ACE_CSR_pooled_24months/prod/output/t_saf_ae_raw_soc_AESI_SE.xls
10MAR2021 17:34

POPULATION: Safety-Evaluable Population
 ENDPOINT: Any SAEs Including Disease Related Adverse Events
 MODEL: Unstratified analysis
 STUDY: BP39056
 Dichotomous Analysis (Safety)

MedDRA System Organ Class	MedDRA Preferred Term	Level	Part 1 (N=17)						Part 2 (N=41)				Pooled Population (Part1 + Part 2) (N=58)			
			Patients		Patients with Event		Patients		Patients with Event		Patients		Patients with Event			
			n	%	n	%	n	%	n	%	n	%	n	%		
Cardiac disorders		n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2		
Cardiac disorders	Cardiac arrest	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Cardiac disorders	Sinus tachycardia	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Congenital, familial and genetic disorders		n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Congenital, familial and genetic disorders	Cryptorchism	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Congenital, familial and genetic disorders	Intestinal malrotation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders		n/a	17	100.0	0	0.0	41	100.0	4	9.8	58	100.0	4	6.9		
Gastrointestinal disorders	Constipation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Diarrhoea	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Gastrointestinal disorders	Vomiting	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations		n/a	17	100.0	8	47.1	41	100.0	21	51.2	58	100.0	29	50.0		
Infections and infestations	Bronchiolitis	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Infections and infestations	Bronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Escherichia urinary tract infection	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Gastroenteritis rotavirus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Influenza	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Lower respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Infections and infestations	Pharyngitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia	n/a	17	100.0	3	17.6	41	100.0	16	39.0	58	100.0	19	32.8		
Infections and infestations	Pneumonia bacterial	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Pneumonia viral	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Respiratory syncytial virus bronchiolitis	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Infections and infestations	Respiratory tract infection viral	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Sepsis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Tracheitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Tracheobronchitis	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Infections and infestations	Upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Infections and infestations	Viral upper respiratory tract infection	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Injury, poisoning and procedural complications		n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Injury, poisoning and procedural complications	Near drowning	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations		n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4		
Investigations	Oxygen saturation abnormal	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Investigations	Weight decreased	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Metabolism and nutrition disorders		n/a	17	100.0	2	11.8	41	100.0	2	4.9	58	100.0	4	6.9		
Metabolism and nutrition disorders	Decreased appetite	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Metabolism and nutrition disorders	Dehydration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Metabolism and nutrition disorders	Failure to thrive	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7		
Nervous system disorders		n/a	17	100.0	0	0.0	41	100.0	3	7.3	58	100.0	3	5.2		
Nervous system disorders	Hydrocephalus	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7		
Nervous system disorders	Hypotonia	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		
Respiratory, thoracic and mediastinal disorders		n/a	17	100.0	4	23.5	41	100.0	9	22.0	58	100.0	13	22.4		
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2		
Respiratory, thoracic and mediastinal disorders	Aspiration	n/a	17	100.0	0	0.0	41	100.0	2	4.9	58	100.0	2	3.4		

Respiratory, thoracic and mediastinal disorders	Atelectasis	n/a	17	100.0	1	5.9	41	100.0	1	2.4	58	100.0	2	3.4
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Cough	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Pneumothorax	n/a	17	100.0	1	5.9	41	100.0	0	0.0	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Respiratory distress	n/a	17	100.0	2	11.8	41	100.0	3	7.3	58	100.0	5	8.6
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	17	100.0	1	5.9	41	100.0	2	4.9	58	100.0	3	5.2
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	17	100.0	0	0.0	41	100.0	1	2.4	58	100.0	1	1.7

<30 days in Safety Follow-up (according to protocol).

From Part 1 only patients with the correct dose (pivotal dose) are included in the analyses.

Clinical cut-off Part 1: 03MAR2020, Part 2: 12NOV2020

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