

Casirivimab/Imdevimab (Ronapreve®)

Roche Pharma AG

Anhang 4-G zu Modul 4 A

*Postexpositionsprophylaxe von COVID-19 bei
Erwachsenen und Jugendlichen ab 12 Jahren mit
mindestens 40 kg Körpergewicht*

Stand: 14.04.2022

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AESI	246
SOC-PT	251
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Verträglichkeit	417
Hauptdokumente	417
AESI	428
SOC-PT	433
Ergänzende Dokumente	466
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Wirksamkeit	472
Hauptdokumente	472
Ergänzende Dokumente	504
Verträglichkeit	513
Hauptdokumente	513
AESI	524
SOC-PT	529
Ergänzende Dokumente	568

KohorteA

Datenschnitt 11.03.2021 (DCO1)

bersicht:

Studie COV-2069

Kohorte A

Datenschnitt: 11.03.2021 (DCO1)

Wirksamkeit	
Hauptdokumente	
t8-3a-eff-resp-asypcrb-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t8-3a-eff-resp-asypcrb-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t9-1a-eff-smd-strat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t9-1a-eff-smd-unstrat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t9-1b-eff-smd-strat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) that has an onset during the EAP
t8-4a-eff-resp-apcrcon-strat	Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
t8-4a-eff-resp-apcrcon-unstrat	Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP (subgroup)
t9-2a-eff-smd-strat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
t9-2a-eff-smd-unstrat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP (subgroup)
t9-2b-eff-smd-strat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) that has an onset during the EAP
t8-5a-eff-resp-asypcrrc-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP
t8-5a-eff-resp-asypcrrc-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP (subgroup)
t9-3a-eff-smd-strat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP
t9-3a-eff-smd-unstrat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP (subgroup)
t9-3b-eff-smd-strat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) that has an onset during the EAP
t8-6a-eff-resp-asypcrs-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP
t8-6a-eff-resp-asypcrs-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t9-4a-eff-smd-strat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP
t9-4a-eff-smd-unstrat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t9-4b-eff-smd-strat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) that has an onset during the EAP
t8-1a-eff-resp-dth29-strat	All-cause death at EAP
t8-1a-eff-resp-dth29-unstrat	All-cause death at EAP (subgroup)
t8-2a-eff-resp-dthfu-strat	All-cause death at End of Follow-Up
t8-2a-eff-resp-dthfu-unstrat	All-cause death at End of Follow-Up (subgroup)
t8-7a-eff-resp-ahoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-7a-eff-resp-ahoer-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-7b-eff-resp-ahoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-8a-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP

t8-8a-eff-resp-hoeruc-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-8b-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-9a-eff-resp-amaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-9a-eff-resp-amaveru-unstrat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t8-9b-eff-resp-amaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-5a-eff-smd-strat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-5a-eff-smd-unstrat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t9-5b-eff-smd-strat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-10a-eff-resp-ahosp-strat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-10a-eff-resp-ahosp-unstrat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t8-10b-eff-resp-ahosp-strat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-6a-eff-smd-strat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at day 29
t9-6a-eff-smd-unstrat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at day 29 (subgroup)
t9-6b-eff-smd-strat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-7a-eff-smd-strat-ANDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-7a-eff-smd-unstrat-ANDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t9-7b-eff-smd-strat-ANDABSEN	Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
Ergänzende Dokumente	
t3-center_mFAS	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm
t4-dstat-demo	Demographic and Baseline Characteristics per arm
t5_1	Table 5.1. Summary of Overall Patient Disposition
t5_3	Number of screened patients and reason for screening failure
t2-dstat-dur_mFAS	Duration of Follow-up by domain and arm
2069-report-body-addendum_medication	Summary of Concomitant Medications
2069-116-admin-assessment-efficacy	Administrative Assessment Report
Verträglichkeit	
Hauptdokumente	
t12-1-ae-raw-anyae-unstrat-saf1	Any AEs (subgroup)
t12-2-ae-raw-anyae-nr-unstrat-saf1	Any AEs (excluding disease related events) (subgroup)
t12-3-ae-raw-toxgrgt3-unstrat-saf1	AEs Grade >= 3 (subgroup)
t12-4-ae-raw-toxgrtnr3-unstrat-saf1	AEs Grade >=3 (excluding disease related events) (subgroup)
t12-5-ae-raw-toxgr3-unstrat-saf1	AEs Grade 3 (subgroup)
t12-6-ae-raw-toxgr4-unstrat-saf1	AEs Grade 4 (subgroup)

t12-7-ae-raw-toxgr5-unstrat-saf1	AEs Grade 5 (AEs leading to death) (subgroup)
t12-8-ae-raw-anysae-unstrat-saf1	Any SAEs (subgroup)
t12-9-ae-raw-anysaenr-unstrat-saf1	Any SAEs (excluding disease related events) (subgroup)
t12-10-ae-raw-aeltdis-unstrat-saf1	AEs leading to treatment discontinuation (subgroup)
AESI	
t12-11-ae-raw-isrge3-unstrat-saf1	Injection site reactions Grade ≥ 3 (subgroup)
t12-12-ae-raw-sisr-unstrat-saf1	Serious injection site reactions (subgroup)
t12-13-ae-raw-hyprggr3-unstrat-saf1	Hypersensitivity reactions Grade ≥ 3 (subgroup)
t12-14-ae-raw-shypr-unstrat-saf1	Serious hypersensitivity reactions (subgroup)
SOC/PT	
t13-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t13-2f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade ≥ 3
t13-3f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t13-4f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t13-5f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t13-6f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t14-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Ergänzende Dokumente	
t10-ae-resolved-general	AE resolved general
t2-dstat-dur_saf	Duration of Follow-up by domain and arm Safety Analysis Set

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Wirksamkeit

Hauptdokumente

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
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Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-3a-eff-resp-asypcrb

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio			Absolute Risk Difference			Relative Risk	Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1046	100	12	1.1	1021	100	66	6.5	0.17	Algorithm converged.	0.09	0.31	-5.317	Algorithm converged.	-6.96	-3.68	0.18	Algorithm converged.	0.1	0.33	<0.0001	5.63	Algorithm converged.	3.06	10.36			
Sex	Male	479	45.8	5	1	498	48.8	26	5.2	0.19	Algorithm converged.	0.07	0.5	-4.177	Algorithm converged.	-6.33	-2.02	0.2	Algorithm converged.	0.08	0.52	0.0002	0.7359	5	Algorithm converged.	1.94	12.92		
	Female	567	54.2	7	1.2	523	51.2	40	7.6	0.15	Algorithm converged.	0.07	0.34	-6.414	Algorithm converged.	-8.87	-3.96	0.16	Algorithm converged.	0.07	0.36	<0.0001	6.2	Algorithm converged.	2.8	13.71			
Age	12-17	46	4.4	0	0	43	4.2	4	9.3	0	Algorithm converged.	NE	NE	-9.302	Algorithm converged.	-17.98	-0.62	NE	*	Algorithm not converged.	NE	NE	0.0505	0.479	NE	*	Algorithm not converged.	NE	NE
	18-49	624	59.7	6	1	606	59.4	32	5.3	0.17	Algorithm converged.	0.07	0.42	-4.319	Algorithm converged.	-6.26	-2.38	0.18	Algorithm converged.	0.08	0.43	<0.0001	5.49	Algorithm converged.	2.31	13.04			
	>=50	376	35.9	6	1.6	372	36.4	30	8.1	0.18	Algorithm converged.	0.08	0.45	-6.469	Algorithm converged.	-9.51	-3.43	0.2	Algorithm converged.	0.08	0.47	<0.0001	5.05	Algorithm converged.	2.13	12			
Region	US	959	91.7	11	1.1	939	92	59	6.3	0.17	Algorithm converged.	0.09	0.33	-5.136	Algorithm converged.	-6.83	-3.44	0.18	Algorithm converged.	0.1	0.35	<0.0001	0.7764	5.48	Algorithm converged.	2.9	10.36		
	ex-US	87	8.3	1	1.1	82	8	7	8.5	0.12	Algorithm converged.	0.01	1.04	-7.387	Algorithm converged.	-13.84	-0.94	0.13	Algorithm converged.	0.02	1.07	0.0305	7.43	Algorithm converged.	0.93	59.06			
BMI	BMI < 30 kg/m2	670	64.1	6	0.9	660	64.6	43	6.5	0.13	Algorithm converged.	0.05	0.31	-5.62	Algorithm converged.	-7.63	-3.61	0.14	Algorithm converged.	0.06	0.32	<0.0001	0.3377	7.28	Algorithm converged.	3.12	16.98		
	BMI >= 30 kg/m2	371	35.5	6	1.6	357	35	23	6.4	0.24	Algorithm converged.	0.1	0.59	-4.825	Algorithm converged.	-7.68	-1.97	0.25	Algorithm converged.	0.1	0.61	0.0009	3.98	Algorithm converged.	1.64	9.67			
	Unknown/not reported	5	0.5	0	0	4	0.4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	998	95.4	12	1.2	989	96.9	62	6.3	0.18	Algorithm converged.	0.1	0.34	-5.067	Algorithm converged.	-6.72	-3.41	0.19	Algorithm converged.	0.1	0.35	<0.0001	0.1587	5.21	Algorithm converged.	2.83	9.61		
	>=1	48	4.6	0	0	32	3.1	4	12.5	0	Algorithm converged.	NE	NE	-12.5	Algorithm converged.	-23.96	-1.04	NE	*	Algorithm not converged.	NE	NE	0.0227	NE	*	Algorithm not converged.	NE	NE	
Total household size including the household members not participating this study	2	397	38	3	0.8	367	35.9	19	5.2	0.14	Algorithm converged.	0.04	0.48	-4.421	Algorithm converged.	-6.84	-2	0.15	Algorithm converged.	0.04	0.49	0.0003	0.6701	6.85	Algorithm converged.	2.04	22.96		
	>2	649	62	9	1.4	653	64	46	7	0.19	Algorithm converged.	0.09	0.38	-5.658	Algorithm converged.	-7.82	-3.5	0.2	Algorithm converged.	0.1	0.4	<0.0001	5.08	Algorithm converged.	2.51	10.29			
Baseline high risk factor	Yes	314	30	6	1.9	306	30	26	8.5	0.21	Algorithm converged.	0.09	0.52	-6.586	Algorithm converged.	-10.06	-3.11	0.22	Algorithm converged.	0.09	0.54	0.0002	0.4922	4.45	Algorithm converged.	1.86	10.65		
	No	732	70	6	0.8	715	70	40	5.6	0.14	Algorithm converged.	0.06	0.33	-4.775	Algorithm converged.	-6.58	-2.97	0.15	Algorithm converged.	0.06	0.34	<0.0001	6.83	Algorithm converged.	2.91	16			
Race	White	879	84	9	1	856	83.8	52	6.1	0.16	Algorithm converged.	0.08	0.33	-5.051	Algorithm converged.	-6.78	-3.32	0.17	Algorithm converged.	0.08	0.34	<0.0001	0.9862	5.93	Algorithm converged.	2.94	11.96		
	Black or African American	114	10.9	1	0.9	113	11.1	6	5.3	0.16	Algorithm converged.	0.02	1.33	-4.433	Algorithm converged.	-8.91	0.04	0.17	Algorithm converged.	0.02	1.35	0.0655	6.05	Algorithm converged.	0.74	49.48			
	Other	38	3.6	1	2.6	31	3	4	12.9	0.18	Algorithm converged.	0.02	1.73	-10.272	Algorithm converged.	-23.12	2.58	0.2	Algorithm converged.	0.02	1.73	0.1662	4.9	Algorithm converged.	0.58	41.65			
	Unknown/Not Reported	15	1.4	1	6.7	21	2.1	4	19	0.3	Algorithm converged.	0.03	3.04	-12.381	Algorithm converged.	-33.39	8.63	0.35	Algorithm converged.	0.04	2.83	0.3761	2.86	Algorithm converged.	0.35	23.07			

Ethnicity	Hispanic or Latino	476	45,5	3	0,6	488	47,8	18	3,7	0,17	Algorithm converged.	0,05	0,57	-3,058	Algorithm converged.	-4,88	-1,24	0,17	Algorithm converged.	0,05	0,58	0,0014	0,978	5,85	Algorithm converged.	1,74	19,74
	Not Hispanic or Latino	567	54,2	9	1,6	527	51,6	48	9,1	0,16	Algorithm converged.	0,08	0,33	-7,521	Algorithm converged.	-10,18	-4,86	0,17	Algorithm converged.	0,09	0,35	<0.0001		5,74	Algorithm converged.	2,84	11,58
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	1	1	109	10,7	4	3,7	0,27	Algorithm converged.	0,03	2,44	-2,66	Algorithm converged.	-6,7	1,38	0,28	Algorithm converged.	0,03	2,42	0,3719	0,7008	3,63	Algorithm converged.	0,41	31,96
	No	938	89,7	11	1,2	901	88,2	61	6,8	0,16	Algorithm converged.	0,09	0,31	-5,598	Algorithm converged.	-7,38	-3,82	0,17	Algorithm converged.	0,09	0,33	<0.0001		5,77	Algorithm converged.	3,06	10,9
	Unknown/not reported	9	0,9	0	0	11	1,1	1	9,1	0	Algorithm converged.	NE	NE	-9,091	Algorithm converged.	-26,08	7,9	NE	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	1	7,7	12	1,2	2	16,7	0,42	Algorithm converged.	0,03	5,3	-8,974	Algorithm converged.	-34,56	16,61	0,46	Algorithm converged.	0,05	4,46	0,593		2,17	Algorithm converged.	0,22	20,94
	Negative	896	85,7	8	0,9	879	86,1	50	5,7	0,15	Algorithm converged.	0,07	0,32	-4,795	Algorithm converged.	-6,45	-3,15	0,16	Algorithm converged.	0,07	0,33	<0.0001		6,37	Algorithm converged.	3,04	13,36
	Unavailable	137	13,1	3	2,2	130	12,7	14	10,8	0,19	Algorithm converged.	0,05	0,66	-8,579	Algorithm converged.	-14,44	-2,71	0,2	Algorithm converged.	0,06	0,69	0,0049		4,92	Algorithm converged.	1,45	16,72
Serology status	Seropositive	235	22,5	1	0,4	222	21,7	5	2,3	0,19	Algorithm converged.	0,02	1,6	-1,827	Algorithm converged.	-3,95	0,3	0,19	Algorithm converged.	0,02	1,6	0,113	0,9898	5,29	Algorithm converged.	0,62	44,95
	Seronegative	753	72	11	1,5	752	73,7	59	7,8	0,17	Algorithm converged.	0,09	0,33	-6,385	Algorithm converged.	-8,49	-4,28	0,19	Algorithm converged.	0,1	0,35	<0.0001		5,37	Algorithm converged.	2,84	10,14
	Unclear serology status	58	5,5	0	0	47	4,6	2	4,3	0	Algorithm converged.	NE	NE	-4,255	Algorithm converged.	-10,03	1,52	NE	Algorithm not converged.	NE	NE	0,198		NE *	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-3a-eff-resp-asyprcb

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo								Difference between treatments (Casirivimab/Imdevimab - Placebo)						
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis				Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	1046	100	12	1,147	17	0,016	0,006	0,008	0,037	1021	100	66	6,464	220,571	0,216	0,036	0,207	0,038	-0,199	-0,269	-0,129	0	-0,246	-0,332	-0,16

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-1-eff-smd-ANWSYMB

POPULATION: Modified Full Analysis Set - Cohort A
 ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2069
 Template SMD

	Name	Level	Casirumab/mde19mab										Placebo										Difference between treatments (Casirumab/mde19mab - Placebo)										Interaction Test p-value (Riskhood ratio)
			Patients in analysis			Patients with Event			Total of Weeks	Statistics		ANCOVA		Patients in analysis			Patients with Event			Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference				
			n	%		n	%	w		mean (dN)	SE	LSMean	SE	LSMean	SE	LSMean	SE	LSMean	SE		LSMean	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All		n/a	1046	100	12	1.147	17	0.016	0.006	0.016	0.025	1021	100	66	6.464	220.571	0.216	0.036	0.216	0.025	-0.2	-0.27	-0.13	0	-0.267	-0.33	-0.16	NE					
Sex	Male		479	45.793	5	1.044	6,714	0.014	0.009	0.014	0.037	498	48.776	26	5.221	88.143	0.177	0.05	0.177	0.036	-0.183	-0.264	-0.061	0.002	-0.201	-0.327	-0.076	0.3133					
	Female		567	54.207	7	1.235	10,286	0.018	0.008	0.018	0.034	523	51.224	40	7.648	132.429	0.253	0.051	0.253	0.036	-0.263	-0.138	0	-0.289	-0.408	-0.17	0						
Age	12-17		46	4.398	0	0	0	0	0	0	0.171	43	4.212	4	9.302	17.857	0.415	0.205	0.415	0.177	-0.415	-0.905	0.074	0.095	-0.355	-0.773	0.063	0.0416					
	18-49		624	59.656	6	0.962	10	0.016	0.008	0.016	0.025	606	59.254	32	5.281	87.429	0.144	0.034	0.144	0.025	-0.129	-0.197	-0.06	0	-0.209	-0.323	-0.097	0					
	>=50		376	35.946	6	1.596	7	0.019	0.01	0.019	0.052	372	36.435	30	8.065	115.286	0.31	0.074	0.31	0.053	-0.291	-0.437	-0.145	0	-0.286	-0.43	-0.143	0					
Region	US		959	91.683	11	1.147	15,571	0.016	0.007	0.016	0.027	939	91.969	59	6.283	209.857	0.223	0.038	0.223	0.027	-0.207	-0.263	-0.132	0	-0.247	-0.337	-0.157	0.4754					
	Ix US		87	8.317	1	1.449	1,429	0.016	0.016	0.016	0.044	82	8.031	7	6.537	10.714	0.131	0.063	0.131	0.046	-0.114	-0.24	0.011	0.074	-0.276	-0.578	0.027	0					
BMI	BMI <= 30 kg/m2		670	64.054	6	0.896	10,857	0.016	0.008	0.016	0.032	660	64.643	43	6.515	136.714	0.207	0.045	0.207	0.032	-0.191	-0.281	-0.101	0	-0.229	-0.336	-0.121	0.7148					
	BMI >= 30 kg/m2		371	35.468	6	1.617	6,143	0.017	0.01	0.017	0.04	357	34.966	23	6.443	83.857	0.235	0.057	0.235	0.041	-0.218	-0.331	-0.106	0	-0.282	-0.428	-0.137	0					
	Unknown/not reported		5	0.478	0	0	0	0	0	0	0	NE	4	0.392	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	0				
Number of study subjects in cohort B within a household	0		998	95.411	12	1.202	17	0.017	0.006	0.017	0.026	989	96.866	62	6.269	208.857	0.211	0.036	0.211	0.026	-0.194	-0.266	-0.122	0	-0.238	-0.326	-0.15	0.3622					
	>=1		48	4.589	0	0	0	0	0	0	0.998	32	3.134	4	12.5	11.714	0.366	0.19	0.366	0.12	-0.366	-0.675	-0.057	0.021	-0.534	-0.984	-0.084	0					
Total household size including the household member(s) not participating in this study	2		397	37.954	3	0.756	1,714	0.004	0.003	0.004	0.042	367	35.945	19	5.177	65.714	0.179	0.062	0.179	0.043	-0.175	-0.292	-0.057	0.004	-0.211	-0.353	-0.069	0.6404					
	>2		649	62.046	9	1.387	15,286	0.024	0.01	0.024	0.031	653	63.957	46	7.044	152	0.233	0.043	0.233	0.031	-0.209	-0.296	-0.122	0	-0.262	-0.37	-0.153	0					
Baseline high risk factor	Yes		314	30.019	6	1.911	6	0.019	0.012	0.019	0.055	306	29.971	26	8.497	90.857	0.297	0.079	0.297	0.056	-0.278	-0.432	-0.123	0	-0.283	-0.441	-0.126	0.1523					
	No		732	69.981	6	0.82	11	0.015	0.007	0.015	0.027	715	70.029	40	5.594	129.714	0.181	0.038	0.181	0.027	-0.166	-0.241	-0.091	0	-0.229	-0.332	-0.126	0					
Race	White		879	84.034	9	1.024	11,571	0.013	0.006	0.013	0.025	856	83.839	52	6.075	164.857	0.193	0.035	0.193	0.025	-0.179	-0.248	-0.111	0	-0.246	-0.34	-0.152	0.2805					
	Black or African American		114	10.899	1	0.877	1,286	0.011	0.011	0.011	0.038	113	11.068	6	5.31	14.286	0.126	0.053	0.126	0.038	-0.115	-0.221	-0.009	0.034	-0.283	-0.543	-0.022	0.034					
	Other		38	3.633	2	0.632	1,185	0.013	0.023	0.023	0.135	34	3.236	4	12.424	14.857	0.223	0.115	0.223	0.039	-0.424	-0.887	-0.039	0.034	-0.504	-0.988	-0.026	0.034					
	Unknown/Not Reported		15	1.434	1	6.667	3,286	0.219	0.219	0.219	0.801	21	2.057	4	19.048	27.571	1.313	0.869	1.313	0.677	-1.094	-3.225	1.037	0.304	-0.345	-1.017	0.327	0					
Ethnicity	Hispanic or Latino		476	45.507	3	0.63	4,286	0.009	0.007	0.009	0.036	488	47.796	18	3.689	75.857	0.155	0.05	0.155	0.036	-0.146	-0.261	-0.047	0.004	-0.186	-0.312	-0.059	0.1408					
	Not Hispanic or Latino		567	54.207	9	1.587	12,714	0.022	0.01	0.022	0.035	527	51.616	48	9.108	144.714	0.275	0.051	0.275	0.036	-0.252	-0.354	-0.153	0	-0.303	-0.422	-0.184	0					
	Unknown/not reported		3	0.287	0	0	0	0	0	0	0	NE	6	0.588	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	0				
Healthcare worker	Yes		99	9.465	1	1.01	2,286	0.023	0.023	0.023	0.041	109	10.676	4	3.67	9.857	0.09	0.05	0.09	0.039	-0.067	-0.18	0.045	0.239	-0.163	-0.436	0.109	0.2144					
	No		938	89.675	11	1.173	14,714	0.016	0.006	0.016	0.028	901	88.247	61	6.77	208	0.231	0.04	0.231	0.028	-0.215	-0.293	-0.138	0	-0.254	-0.346	-0.163	0					
	Unknown/not reported		9	0.86	0	0	0	0	0	0	0.203	11	1.077	1	9.091	2.714	0.247	0.247	0.247	0.184	-0.823	-0.823	0.329	0.38	-0.387	-1.292	0.517	0					
Local test result of diagnostic assay for SARS-CoV-2	Positive		13	1.243	1	7.692	0.286	0.022	0.022	0.022	0.241	12	1.175	2	16.667	6.429	0.536	0.361	0.536	0.25	-0.514	-1.232	0.205	0.153	-0.573	-1.374	0.228	0.2232					
	Negative		896	85.66	8	0.893	13	0.015	0.006	0.015	0.024	879	86.092	50	5.688	155.143	0.176	0.034	0.176	0.024	-0.162	-0.228	-0.096	0	-0.227	-0.32	-0.134	0					
	Unavailable		137	13.098	3	2.19	3,714	0.027	0.024	0.027	0.108	130	12.733	14	10.769	59	0.454	0.158	0.454	0.111	-0.427	-0.733	-0.121	0.006	-0.335	-0.576	-0.095	0					
Serology status	Seropositive		235	22.467	1	0.426	4,143	0.018	0.018	0.018	0.057	222	21.743	5	2.252	0.714	0.122	0.082	0.122	0.058	-0.105	-0.265	0.055	0.199	-0.12	-0.304	0.063	0.1474					
	Seronegative		753	71.989	11	1.461	12,857	0.017	0.007	0.017	0.03	752	73.653	59	7.846	187.714	0.25	0.041	0.25	0.03	-0.233	-0.315	-0.15	0	-0.286	-0.387	-0.185	0					
	Unclear serology status		58	5.545	0	0	0	0	0	0	0.056	47	4.603	2	4.255	5.714	0.122	0.094	0.122	0.063	-0.122	-0.288	0.045	0.152	-0.281	-0.668	0.105	0					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: t9-1-eff-smd-ANWSYMB

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo												Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference							
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL					
All	n/a	12	100	12	100	17	1,417	0,368	0,554	0,942	66	100	66	100	220,571	3,342	0,382	2,569	0,551	-2,015	-3,806	-0,224	0,028	-0,697	-1,317	-0,078					

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-1-eff-smd-ANWSYMB

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
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Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-4a-eff-resp-apcrcon

POPULATION: Cohort A
ENDPOINT: Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL
All	n/a	1046	100	43	4.1	1021	100	128	12.5	0.3	Algorithm converged.	0.21	0.43	-8.426	Algorithm converged.	-10.79	-6.07	0.33	Algorithm converged.	0.23	0.46	<0.0001		3.05	Algorithm converged.	2.18	4.26
Sex	Male	479	45.8	21	4.4	498	48.8	60	12	0.33	Algorithm converged.	0.2	0.56	-7.664	Algorithm converged.	-11.06	-4.27	0.36	Algorithm converged.	0.22	0.59	<0.0001	0.5618	2.75	Algorithm converged.	1.7	4.44
	Female	567	54.2	22	3.9	523	51.2	68	13	0.27	Algorithm converged.	0.16	0.44	-9.122	Algorithm converged.	-12.41	-5.83	0.3	Algorithm converged.	0.19	0.48	<0.0001		3.35	Algorithm converged.	2.1	5.34
Age	12-17	46	4.4	2	4.3	43	4.2	10	23.3	0.15	Algorithm converged.	0.03	0.73	-18.908	Algorithm converged.	-32.84	-4.97	0.19	Algorithm converged.	0.04	0.81	0.0121	0.7045	5.35	Algorithm converged.	1.24	23.04
	18-49	624	59.7	24	3.8	606	59.4	69	11.4	0.31	Algorithm converged.	0.19	0.5	-7.54	Algorithm converged.	-10.48	-4.6	0.34	Algorithm converged.	0.22	0.53	<0.0001		2.96	Algorithm converged.	1.89	4.65
	>=50	376	35.9	17	4.5	372	36.4	49	13.2	0.31	Algorithm converged.	0.18	0.55	-8.651	Algorithm converged.	-12.68	-4.62	0.34	Algorithm converged.	0.2	0.58	<0.0001		2.91	Algorithm converged.	1.71	4.96
Region	US	959	91.7	38	4	939	92	117	12.5	0.29	Algorithm converged.	0.2	0.42	-8.498	Algorithm converged.	-10.94	-6.05	0.32	Algorithm converged.	0.22	0.45	<0.0001	0.5932	3.14	Algorithm converged.	2.21	4.48
	ex-US	87	8.3	5	5.7	82	8	11	13.4	0.39	Algorithm converged.	0.13	1.19	-7.668	Algorithm converged.	-16.52	1.18	0.43	Algorithm converged.	0.16	1.18	0.116		2.33	Algorithm converged.	0.85	6.43
BMI	BMI < 30 kg/m2	670	64.1	27	4	660	64.6	84	12.7	0.29	Algorithm converged.	0.18	0.45	-8.697	Algorithm converged.	-11.64	-5.75	0.32	Algorithm converged.	0.21	0.48	<0.0001	0.7785	3.16	Algorithm converged.	2.07	4.81
	BMI >= 30 kg/m2	371	35.5	16	4.3	357	35	44	12.3	0.32	Algorithm converged.	0.18	0.58	-8.012	Algorithm converged.	-12	-4.02	0.35	Algorithm converged.	0.2	0.61	<0.0001		2.86	Algorithm converged.	1.64	4.97
	Unknown/not reported	5	0.5	0	0	4	0.4	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	998	95.4	40	4	989	96.9	121	12.2	0.3	Algorithm converged.	0.21	0.43	-8.227	Algorithm converged.	-10.6	-5.85	0.33	Algorithm converged.	0.23	0.46	<0.0001	0.8378	3.05	Algorithm converged.	2.16	4.32
	>=1	48	4.6	3	6.3	32	3.1	7	21.9	0.24	Algorithm converged.	0.06	1	-15.625	Algorithm converged.	-31.5	0.25	0.29	Algorithm converged.	0.08	1.02	0.08		3.5	Algorithm converged.	0.98	12.54
Total household size including the household members not participating this study	2	397	38	15	3.8	367	35.9	39	10.6	0.33	Algorithm converged.	0.18	0.61	-6.848	Algorithm converged.	-10.52	-3.18	0.36	Algorithm converged.	0.2	0.63	0.0002	0.7726	2.81	Algorithm converged.	1.58	5.01
	>2	649	62	28	4.3	653	64	88	13.5	0.29	Algorithm converged.	0.19	0.45	-9.162	Algorithm converged.	-12.21	-6.11	0.32	Algorithm converged.	0.21	0.48	<0.0001		3.12	Algorithm converged.	2.07	4.71
Baseline high risk factor	Yes	314	30	14	4.5	306	30	43	14.1	0.29	Algorithm converged.	0.15	0.53	-9.594	Algorithm converged.	-14.11	-5.08	0.32	Algorithm converged.	0.18	0.57	<0.0001	0.8922	3.15	Algorithm converged.	1.76	5.64
	No	732	70	29	4	715	70	85	11.9	0.31	Algorithm converged.	0.2	0.47	-7.926	Algorithm converged.	-10.69	-5.17	0.33	Algorithm converged.	0.22	0.5	<0.0001		3	Algorithm converged.	1.99	4.52
Race	White	879	84	36	4.1	856	83.8	107	12.5	0.3	Algorithm converged.	0.2	0.44	-8.404	Algorithm converged.	-10.98	-5.83	0.33	Algorithm converged.	0.23	0.47	<0.0001	0.9559	3.05	Algorithm converged.	2.12	4.4
	Black or African American	114	10.9	3	2.6	113	11.1	10	8.8	0.28	Algorithm converged.	0.07	1.04	-6.218	Algorithm converged.	-12.22	-0.21	0.3	Algorithm converged.	0.08	1.05	0.0499		3.36	Algorithm converged.	0.95	11.9
	Other	38	3.6	2	5.3	31	3	4	12.9	0.38	Algorithm converged.	0.06	2.2	-7.64	Algorithm converged.	-21.41	6.13	0.41	Algorithm converged.	0.08	2.08	0.3974		2.45	Algorithm converged.	0.48	12.51
	Unknown/Not Reported	15	1.4	2	13.3	21	2.1	7	33.3	0.31	Algorithm converged.	0.05	1.76	-20	Algorithm converged.	-46.5	6.5	0.4	Algorithm converged.	0.1	1.66	0.2518		2.5	Algorithm converged.	0.6	10.39

Ethnicity	Hispanic or Latino	476	45,5	14	2,9	488	47,8	46	9,4	0,29	Algorithm converged.	0,16	0,54	-6,485	Algorithm converged.	-9,49	-3,48	0,31	Algorithm converged.	0,17	0,56	<0.0001	0,8858	3,2	Algorithm converged.	1,79	5,75
	Not Hispanic or Latino	567	54,2	29	5,1	527	51,6	82	15,6	0,29	Algorithm converged.	0,19	0,45	-10,445	Algorithm converged.	-14,03	-6,86	0,33	Algorithm converged.	0,22	0,49	<0.0001		3,04	Algorithm converged.	2,03	4,57
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	3	3	109	10,7	7	6,4	0,46	Algorithm converged.	0,11	1,81	-3,392	Algorithm converged.	-9,1	2,32	0,47	Algorithm converged.	0,13	1,77	0,3376	0,5734	2,12	Algorithm converged.	0,56	7,97
	No	938	89,7	39	4,2	901	88,2	119	13,2	0,29	Algorithm converged.	0,2	0,41	-9,05	Algorithm converged.	-11,6	-6,5	0,31	Algorithm converged.	0,22	0,45	<0.0001		3,18	Algorithm converged.	2,24	4,51
	Unknown/not reported	9	0,9	1	11,1	11	1,1	2	18,2	0,56	Algorithm converged.	0,04	7,44	-7,071	Algorithm converged.	-37,75	23,61	0,61	Algorithm converged.	0,07	5,7	1		1,64	Algorithm converged.	0,18	15,26
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	1	7,7	12	1,2	6	50	0,08	Algorithm converged.	0,01	0,86	-42,308	Algorithm converged.	-74,09	-10,53	0,15	Algorithm converged.	0,02	1,1	0,0302	0,423	6,5	Algorithm converged.	0,91	46,43
	Negative	896	85,7	33	3,7	879	86,1	101	11,5	0,29	Algorithm converged.	0,2	0,44	-7,807	Algorithm converged.	-10,25	-5,36	0,32	Algorithm converged.	0,22	0,47	<0.0001		3,12	Algorithm converged.	2,13	4,57
	Unavailable	137	13,1	9	6,6	130	12,7	21	16,2	0,36	Algorithm converged.	0,16	0,83	-9,585	Algorithm converged.	-17,15	-2,02	0,41	Algorithm converged.	0,19	0,85	0,0134		2,46	Algorithm converged.	1,17	5,17
Serology status	Seropositive	235	22,5	4	1,7	222	21,7	17	7,7	0,21	Algorithm converged.	0,07	0,63	-5,956	Algorithm converged.	-9,82	-2,09	0,22	Algorithm converged.	0,08	0,65	0,0029	0,4597	4,5	Algorithm converged.	1,54	13,16
	Seronegative	753	72	36	4,8	752	73,7	107	14,2	0,3	Algorithm converged.	0,2	0,45	-9,448	Algorithm converged.	-12,37	-6,52	0,34	Algorithm converged.	0,23	0,48	<0.0001		2,98	Algorithm converged.	2,07	4,28
	Unclear serology status	58	5,5	3	5,2	47	4,6	4	8,5	0,59	Algorithm converged.	0,12	2,76	-3,338	Algorithm converged.	-13,14	6,47	0,61	Algorithm converged.	0,14	2,58	0,6977		1,65	Algorithm converged.	0,39	6,99

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-4a-eff-resp-apcrcon

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)								
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	1046	100	43	4,111	50	0,048	0,008	0,041	0,027	1021	100	128	12,537	271	0,265	0,025	0,258	0,027	-0,217	-0,268	-0,167	0	-0,372	-0,458	-0,286		

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-2-eff-smd-AIFNPDUR

POPULATION: Modified Full Analysis Set - Cohort A
ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

Casirivimab/Imdevimab													Placebo													Difference between treatments (Casirivimab/Imdevimab - Placebo)													Interaction Test																									
Patients in analysis													Patients with Event		Total of Weeks		Statistics		ANCOVA		Patients in analysis													Patients with Event		Total of Weeks		Statistics		ANCOVA		Mean Difference					Standardized Mean Difference				p-value													
Name													Level		n		%		n		%		w		mean (d/N)		SE		LSMean		SE		n		%		n		%		w		mean (d/N)		SE		LSMean		SE		LSMean		95% Lower CL		95% Upper CL		p-value	Hedges' g		95% Lower CL		95% Upper CL		p-value (likelihood ratio)
All	n/a													1046		100		43		4.111		50		0.048		0.008		0.048		0.018		1021		100		128		12.537		271		0.265		0.025		0.265		0.018		-0.218		-0.268		-0.167	0		-0.372		-0.459		-0.286		NE	
Sex	Male													479		45.793		21		4.384		27		0.056		0.013		0.056		0.026		498		48.776		60		12.048		119		0.239		0.033		0.239		0.025		-0.183		-0.253		-0.112	0		-0.325		-0.45		-0.199		0.1902	
	Female													567		54.207		22		3.88		23		0.041		0.009		0.041		0.025		523		51.224		68		13.002		152		0.291		0.037		0.291		0.026		-0.25		-0.322		-0.178	0		-0.414		-0.533		-0.295			
Age	12-17													46		4.398		2		4.348		2		0.043		0.03		0.043		0.108		43		4.212		10		23.256		21		0.488		0.157		0.488		0.112		-0.445		0.754		-0.136	0.005		-0.602		-1.02		-0.184		0.076	
	18-49													624		59.656		24		3.846		30		0.048		0.01		0.048		0.022		606		59.354		69		11.386		139		0.229		0.03		0.229		0.022		-0.181		-0.243		-0.12	0		-0.33		-0.442		-0.218			
	>=50													376		35.946		17		4.521		18		0.048		0.012		0.048		0.032		372		36.435		49		13.172		111		0.298		0.044		0.298		0.032		-0.251		-0.339		-0.162	0		-0.405		-0.548		-0.261			
Region	US													959		91.683		38		3.962		45		0.047		0.008		0.047		0.019		939		91.969		117		12.46		254		0.271		0.026		0.271		0.019		-0.224		-0.277		-0.17	0		-0.375		-0.465		-0.285		0.4322	
	ex-US													87		8.317		5		5.747		5		0.057		0.025		0.057		0.047		82		8.031		11		13.415		17		0.207		0.064		0.207		0.048		-0.15		-0.283		-0.016	0.028		-0.34		-0.642		-0.037			
BMI																																																																
	BMI < 30 kg/m2													670		64.054		27		4.03		30		0.045		0.009		0.045		0.022		660		64.643		84		12.727		174		0.264		0.031		0.264		0.022		-0.219		-0.281		-0.157	0		-0.379		-0.486		-0.271		0.9843	
	BMI >= 30 kg/m2													371		35.468		16		4.313		20		0.054		0.015		0.054		0.031		357		34.966		44		12.325		97		0.272		0.043		0.272		0.032		-0.218		-0.305		-0.13	0		-0.362		-0.508		-0.227			
Unknown/not reported													5		0.478		0		0		0		0		0		0		NE		4		0.392		0		0		0		0		0		0		0		0		0		0		0									
Number of study subjects in cohort B within a household													0		998		95.411		40		4.008		47		0.047		0.008		0.047		0.018		989		96.866		121		12.235		256		0.259		0.025		0.259		0.018		-0.212		-0.263		-0.161	0		-0.365		-0.453		-0.277		0.1522
>=1													48		4.589		3		6.25		3		0.063		0.035		0.063		0.099		32		3.134		7		21.875		15		0.469		0.185		0.469		0.121		-0.406		-0.718		-0.094	0.011		-0.586		-1.036		-0.136				
Total household size including the household member(s) not participating this study													2		397		37.954		15		3.778		16		0.04		0.011		0.04		0.027		367		35.945		39		10.627		82		0.223		0.038		0.223		0.028		-0.183		-0.258		-0.108	0		-0.346		-0.488		-0.204		0.3389
>2													649		62.046		28		4.314		34		0.052		0.01		0.052		0.024		653		63.957		88		13.476		187		0.286		0.032		0.286		0.024		-0.234		-0.301		-0.167	0		-0.382		-0.49		-0.273				
Baseline high risk factor	Yes													314		30.019		14		4.459		18		0.057		0.017		0.057		0.036		306		29.971		43		14.052		95		0.31		0.049		0.31		0.036		-0.253		-0.353		-0.153	0		-0.399		-0.556		-0.241		0.3661	
	No													732		69.981		29		3.962		32		0.044		0.008		0.044		0.021		715		70.029		85		11.888		176		0.246		0.029		0.246		0.021		-0.202		-0.26		-0.145	0		-0.36		-0.464		-0.257			
Race	White													879		84.034		36		4.096		40		0.046		0.008		0.046		0.02		856		83.839		107		12.5		233		0.272		0.028		0.272		0.02		-0.227		-0.282		-0.171	0		-0.383		-0.477		-0.288		0.3581	
	Black or African American													114		10.899		3		2.632		5		0.044		0.029		0.044		0.048		113		11.068		10		8.85		19		0.168		0.061		0.168		0.048		-0.124		-0.258		0.009	0.068		-0.243		-0.503		0.018			
	Other													38		3.633		2		5.263		3		0.079		0.058		0.079		31		3.036		4		12.903		13		0.194		0.108		0.194		0.087		-0.115		-0.348		0.119	0.33		-0.235		-0.712		0.243					
	Unknown/Not Reported													15		1.434		2		13.333		2		0.133		0.091		0.133		0.191		21		2.057		7		33.333		13		0.619		0.201		0.619		0.162		-0.486		-0.995		0.024	0.061		-0.641		-1.312		0.031			
Ethnicity	Hispanic or Latino													476		45.507		14		2.941		15		0.032		0.009		0.032		0.022		488		47.796		46		9.426		90		0.184		0.029		0.184		0.022		-0.153		-0.214		-0.092	0		-0.318		-0.444		-0.192		0.0125	
	Not Hispanic or Latino													567		54.207		29		5.115		35		0.062		0.012		0.062		0.028		527		51.615		82		15.56		181		0.343		0.039		0.343		0.026		-0.282		-0.36		-0.203	0		-0.427		-0.545		-0.308			
	Unknown/not reported													3		0.287		0		0		0		0		0		0		NE		6		0.588		0		0		0		0		0		0		0		0		0		0		0								
Healthcare worker	Yes													99		9.465		3		3.03		3		0.03		0.017		0.03		0.043		109		10.676		7		6.422		15		0.138		0.054		0.138		0.041		0.107		0.225		0.01	0.073		-0.249		-0.522		0.023		0.1461	
	No													938		89.675		39		4.158		46		0.049		0.008		0.049		0.02		901		88.247		119		13.208		253		0.281		0.027		0.281		0.02		-0.232		-0.287		-0.177	0		-0.387		-0.478		-0.295			
	Unknown/not reported													9		0.86		1		11.111		1		0.111		0.111		0.177		11		1.077		2		18.182		3		0.273		0.195		0.273		0.16		-0.162		-0.663		0.34	0.507		-0.292		-1.196		0.613					
Local test result of diagnostic assay for SARS-CoV-2	Positive													13		1.243		1		7.692		1		0.077		0.077		0.077		0.258		12		1.175		6		50		13		1.083		0.379		1.083		0.268		-1.006		-1.776		-0.237	0.013		-1.048		-1.849		-0.247		0.0002	
	Negative													896		85.66		33		3.683		38		0.042		0.008		0.042		0.018		879		86.092		101		11.49		204		0.232		0.025		0.232		0.018		-0.19		-0.24		-0.14	0		-0.352		-0.446		-0.259			
	Unavailable													137		13.098		9		6.569		11		0.08		0.028		0.08		0.066		130		12.733		21		16.154		54		0.415		0.093		0.415		0.068		-0.335		-0.522		-0.148	0		-0.43		-0.671		-0.19			
Serology status	Seropositive													235		22.467		4		1.702		5		0.021		0.011		0.021		0.026		222		21.743		17		7.658		31		0.14		0.037		0.14		0.027		-0.118		-0.192		-0.044	0.002		-0.294		-0.478		-0.11		0.032	
	Seronegative													753		71.989		36		4.781		41		0.054		0.009		0.054		0.023		752		73.653		107		14.229		231		0.307		0.031		0.307		0.023		-0.253		-0.317		-0.189	0		-0.4		-0.501		-0.299			
	Unclear serology status													58		5.545		3		5.172		4		0.069		0.042		0.069		0.067		47		4.603		4		8.511		9		0.191		0.099		0.191		0.075		-0.123		-0.322		0.077	0.226		-0.238		-0.624		0.149			

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: 19-2-eff-smd-AFNP04R

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) that has an onset during the EAP

ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)						
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	
All	n/a	43	100	43	100	50	1.163	0.066	0.975	0.169	128	100	128	100	271	2.117	0.093	1.915	0.129	-0.94	-1.262	-0.619	0	-1.014	-1.361	-0.668	

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-2-eff-smd-AIFNPDIR

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab						Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo												Placebo vs. Casirivimab/Imdevimab					
Patients						Event				Odds Ratio						Absolute Risk Difference						Relative Risk						Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL												
All	n/a	1046	100	7	0,7	1021	100	51	5	0,13	Algorithm converged.	0,06	0,28	-4,326	Algorithm converged.	-5,75	-2,9	0,13	Algorithm converged.	0,06	0,29	<0.0001		7,46	Algorithm converged.	3,4	16,37												

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-5a-eff-resp-asyprc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	Relative Risk	Relative Risk										
		n	%	n	%	n	%	n	%		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			Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1046	100	7	0,7	1021	100	51	5	0,13	Algorithm converged.	0,06	0,28	-4,326	Algorithm converged.	-5,75	-2,9	0,13	Algorithm converged.	0,06	0,29	<0.0001	7,46	Algorithm converged.	3,4	16,37									
Sex	Male	479	45,8	2	0,4	498	48,8	20	4	0,1	Algorithm converged.	0,02	0,43	-3,599	Algorithm converged.	-5,42	-1,78	0,1	Algorithm converged.	0,02	0,44	0,0001	0,6781	9,62	Algorithm converged.	2,26	40,93								
	Female	567	54,2	5	0,9	523	51,2	31	5,9	0,14	Algorithm converged.	0,05	0,37	-5,046	Algorithm converged.	-7,21	-2,88	0,15	Algorithm converged.	0,06	0,38	<0.0001	6,72	Algorithm converged.	2,63	17,16									
Age	12-17	46	4,4	0	0	43	4,2	2	4,7	0	Algorithm converged.	NE	NE	-4,651	Algorithm converged.	-10,95	1,64	NE	Algorithm not converged.	NE	NE	0,2306	0,7398	NE	Algorithm not converged.	NE	NE								
	18-49	624	59,7	3	0,5	606	59,4	23	3,8	0,12	Algorithm converged.	0,04	0,41	-3,315	Algorithm converged.	-4,93	-1,7	0,13	Algorithm converged.	0,04	0,42	<0.0001	7,89	Algorithm converged.	2,38	26,16									
	>=50	376	35,9	4	1,1	372	36,4	26	7	0,14	Algorithm converged.	0,05	0,41	-5,925	Algorithm converged.	-8,72	-3,13	0,15	Algorithm converged.	0,05	0,43	<0.0001	6,57	Algorithm converged.	2,32	18,64									
Region	US	959	91,7	6	0,6	939	92	47	5	0,12	Algorithm converged.	0,05	0,28	-4,38	Algorithm converged.	-5,86	-2,9	0,12	Algorithm converged.	0,05	0,29	<0.0001	0,6124	8	Algorithm converged.	3,44	18,62								
	ex-US	87	8,3	1	1,1	82	8	4	4,9	0,23	Algorithm converged.	0,02	2,07	-3,729	Algorithm converged.	-8,9	1,44	0,24	Algorithm converged.	0,03	2,06	0,2	4,24	Algorithm converged.	0,48	37,19									
BMI	BMI < 30 kg/m2	670	64,1	4	0,6	660	64,6	33	5	0,11	Algorithm converged.	0,04	0,32	-4,403	Algorithm converged.	-6,17	-2,64	0,12	Algorithm converged.	0,04	0,34	<0.0001	0,7184	8,38	Algorithm converged.	2,98	23,51								
	BMI >= 30 kg/m2	371	35,5	3	0,8	357	35	18	5	0,15	Algorithm converged.	0,04	0,53	-4,233	Algorithm converged.	-6,68	-1,79	0,16	Algorithm converged.	0,05	0,54	0,0006	6,24	Algorithm converged.	1,85	20,99									
	Unknown/not reported	5	0,5	0	0	4	0,4	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE									
Number of study subjects in cohort B within a household	0	998	95,4	7	0,7	989	96,9	48	4,9	0,14	Algorithm converged.	0,06	0,31	-4,152	Algorithm converged.	-5,59	-2,72	0,14	Algorithm converged.	0,07	0,32	<0.0001	0,2843	6,92	Algorithm converged.	3,15	15,22								
	>=1	48	4,6	0	0	32	3,1	3	9,4	0	Algorithm converged.	NE	NE	-9,375	Algorithm converged.	-19,47	0,72	NE	Algorithm not converged.	NE	NE	0,0604	NE	Algorithm not converged.	NE	NE									
Total household size including the household members not participating this study	2	397	38	1	0,3	367	35,9	15	4,1	0,06	Algorithm converged.	0,01	0,45	-3,835	Algorithm converged.	-5,92	-1,75	0,06	Algorithm converged.	0,01	0,46	0,0002	0,3111	16,23	Algorithm converged.	2,15	122,23								
	>2	649	62	6	0,9	653	64	35	5,4	0,16	Algorithm converged.	0,07	0,39	-4,435	Algorithm converged.	-6,31	-2,56	0,17	Algorithm converged.	0,07	0,41	<0.0001	5,8	Algorithm converged.	2,46	13,69									
Baseline high risk factor	Yes	314	30	3	1	306	30	20	6,5	0,14	Algorithm converged.	0,04	0,47	-5,581	Algorithm converged.	-8,55	-2,61	0,15	Algorithm converged.	0,04	0,49	0,0002	0,8552	6,84	Algorithm converged.	2,05	22,79								
	No	732	70	4	0,5	715	70	31	4,3	0,12	Algorithm converged.	0,04	0,35	-3,789	Algorithm converged.	-5,37	-2,2	0,13	Algorithm converged.	0,04	0,36	<0.0001	7,93	Algorithm converged.	2,82	22,36									
Race	White	879	84	5	0,6	856	83,8	40	4,7	0,12	Algorithm converged.	0,05	0,3	-4,104	Algorithm converged.	-5,6	-2,61	0,12	Algorithm converged.	0,05	0,31	<0.0001	0,5997	8,21	Algorithm converged.	3,26	20,72								
	Black or African American	114	10,9	1	0,9	113	11,1	5	4,4	0,19	Algorithm converged.	0,02	1,66	-3,548	Algorithm converged.	-7,71	0,61	0,2	Algorithm converged.	0,02	1,67	0,1192	5,04	Algorithm converged.	0,6	42,5									
	Other	38	3,6	0	0	31	3	3	9,7	0	Algorithm converged.	NE	NE	-9,677	Algorithm converged.	-20,08	0,73	NE	Algorithm not converged.	NE	NE	0,0858	NE	Algorithm not converged.	NE	NE									
	Unknown/Not Reported	15	1,4	1	6,7	21	2,1	3	14,3	0,43	Algorithm converged.	0,04	4,58	-7,619	Algorithm converged.	-27,2	11,96	0,47	Algorithm converged.	0,05	4,06	0,6257	2,14	Algorithm converged.	0,25	18,66									

Ethnicity	Hispanic or Latino	476	45,5	1	0,2	488	47,8	15	3,1	0,07	Algorithm converged.	0,01	0,5	-2,864	Algorithm converged.	-4,45	-1,28	0,07	Algorithm converged.	0,01	0,52	0,0005	0,429	14,63	Algorithm converged.	1,94	110,33
	Not Hispanic or Latino	567	54,2	6	1,1	527	51,6	36	6,8	0,15	Algorithm converged.	0,06	0,35	-5,773	Algorithm converged.	-8,09	-3,46	0,15	Algorithm converged.	0,07	0,36	<0.0001		6,46	Algorithm converged.	2,74	15,2
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	1	1	109	10,7	3	2,8	0,36	Algorithm converged.	0,04	3,52	-1,742	Algorithm converged.	-5,39	1,91	0,37	Algorithm converged.	0,04	3,47	0,6231	0,4092	2,72	Algorithm converged.	0,29	25,77
	No	938	89,7	6	0,6	901	88,2	47	5,2	0,12	Algorithm converged.	0,05	0,27	-4,577	Algorithm converged.	-6,12	-3,04	0,12	Algorithm converged.	0,05	0,29	<0.0001		8,16	Algorithm converged.	3,5	18,98
	Unknown/not reported	9	0,9	0	0	11	1,1	1	9,1	0	Algorithm converged.	NE	NE	-9,091	Algorithm converged.	-26,08	7,9	NE	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	1	7,7	12	1,2	2	16,7	0,42	Algorithm converged.	0,03	5,3	-8,974	Algorithm converged.	-34,56	16,61	0,46	Algorithm converged.	0,05	4,46	0,593		2,17	Algorithm converged.	0,22	20,94
	Negative	896	85,7	5	0,6	879	86,1	37	4,2	0,13	Algorithm converged.	0,05	0,33	-3,651	Algorithm converged.	-5,07	-2,24	0,13	Algorithm converged.	0,05	0,34	<0.0001		7,54	Algorithm converged.	2,98	19,1
	Unavailable	137	13,1	1	0,7	130	12,7	12	9,2	0,07	Algorithm converged.	0,01	0,56	-8,501	Algorithm converged.	-13,68	-3,32	0,08	Algorithm converged.	0,01	0,6	0,0011		12,65	Algorithm converged.	1,67	95,89
Serology status	Seropositive	235	22,5	1	0,4	222	21,7	5	2,3	0,19	Algorithm converged.	0,02	1,6	-1,827	Algorithm converged.	-3,95	0,3	0,19	Algorithm converged.	0,02	1,6	0,113	0,7588	5,29	Algorithm converged.	0,62	44,95
	Seronegative	753	72	6	0,8	752	73,7	46	6,1	0,12	Algorithm converged.	0,05	0,29	-5,32	Algorithm converged.	-7,15	-3,49	0,13	Algorithm converged.	0,06	0,3	<0.0001		7,68	Algorithm converged.	3,3	17,87
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-5a-eff-resp-asyprc

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)								
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference			
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	1046	100	7	0,669	12	0,011	0,005	0,009	0,035	1021	100	51	4,995	184,571	0,181	0,033	0,178	0,035	-0,169	-0,234	-0,104	0	-0,224	-0,31	-0,138		

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-3-eff-smd-ANWSYMC

POPULATION: Modified Full Analysis Set - Cohort A
ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

Casirivimab/Imdevimab															Placebo															Difference between treatments (Casirivimab/Imdevimab - Placebo)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
Patients in analysis															Patients with Event					Total of Weeks					Statistics					ANCOVA					Patients in analysis					Patients with Event					Total of Weeks					Statistics					ANCOVA					Mean Difference					Standardized Mean Difference					Interaction Test																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11/Mar/2021.

Program: t-efl-smd.sas
Output: t9-3-efl-smd-ANWSYMC

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo											Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	7	100	7	100	12	1,714	0,464	1,103	1,283	51	100	51	100	184,571	3,619	0,447	2,956	0,766	-1,853	-4,332	0,626	0,14	-0,597	-1,397	0,202			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-3-eff-smd-ANWSYMC

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1046	100	3	0,3	1021	100	25	2,4	0,11	Algorithm converged.	0,03	0,38	-2,162	Algorithm converged.	-3,16	-1,16	0,12	Algorithm converged.	0,04	0,39	<0.0001		8,54	Algorithm converged.	2,59	28,19		

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-6a-eff-resp-asyprcs

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
Name	Level	Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1046	100	3	0,3	1021	100	25	2,4	0,11	Algorithm converged.	0,03	0,38	-2,162	Algorithm converged.	-3,16	-1,16	0,12	Algorithm converged.	0,04	0,39	<0.0001		8,54	Algorithm converged.	2,59	28,19		
Sex	Male	479	45,8	1	0,2	498	48,8	9	1,8	0,11	Algorithm converged.	0,01	0,9	-1,598	Algorithm converged.	-2,84	-0,36	0,12	Algorithm converged.	0,01	0,91	0,0211	0,9988	8,66	Algorithm converged.	1,1	68,07		
	Female	567	54,2	2	0,4	523	51,2	16	3,1	0,11	Algorithm converged.	0,03	0,49	-2,707	Algorithm converged.	-4,26	-1,15	0,12	Algorithm converged.	0,03	0,5	0,0005		8,67	Algorithm converged.	2	37,54		
Age	12-17	46	4,4	0	0	43	4,2	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	0,8338	NE	* Algorithm not converged.	NE	NE		
	18-49	624	59,7	2	0,3	606	59,4	12	2	0,16	Algorithm converged.	0,04	0,71	-1,66	Algorithm converged.	-2,85	-0,47	0,16	Algorithm converged.	0,04	0,72	0,0064		6,18	Algorithm converged.	1,39	27,49		
	>=50	376	35,9	1	0,3	372	36,4	13	3,5	0,07	Algorithm converged.	0,01	0,57	-3,229	Algorithm converged.	-5,17	-1,29	0,08	Algorithm converged.	0,01	0,58	0,0008		13,14	Algorithm converged.	1,73	99,94		
Region	US	959	91,7	3	0,3	939	92	24	2,6	0,12	Algorithm converged.	0,04	0,4	-2,243	Algorithm converged.	-3,31	-1,17	0,12	Algorithm converged.	0,04	0,41	<0.0001	0,6244	8,17	Algorithm converged.	2,47	27,04		
	ex-US	87	8,3	0	0	82	8	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE	* Algorithm not converged.	NE	NE	0,4852		NE	* Algorithm not converged.	NE	NE		
BMI	BMI < 30 kg/m2	670	64,1	2	0,3	660	64,6	14	2,1	0,14	Algorithm converged.	0,03	0,61	-1,823	Algorithm converged.	-3	-0,65	0,14	Algorithm converged.	0,03	0,62	0,0021	0,7065	7,11	Algorithm converged.	1,62	31,14		
	BMI >= 30 kg/m2	371	35,5	1	0,3	357	35	11	3,1	0,09	Algorithm converged.	0,01	0,66	-2,812	Algorithm converged.	-4,68	-0,94	0,09	Algorithm converged.	0,01	0,67	0,0027		11,43	Algorithm converged.	1,48	88,09		
	Unknown/not reported	5	0,5	0	0	4	0,4	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE		
Number of study subjects in cohort B within a household	0	998	95,4	3	0,3	989	96,9	25	2,5	0,12	Algorithm converged.	0,03	0,39	-2,227	Algorithm converged.	-3,26	-1,19	0,12	Algorithm converged.	0,04	0,39	<0.0001		8,41	Algorithm converged.	2,55	27,76		
	>=1	48	4,6	0	0	32	3,1	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE		
Total household size including the household members not participating this study	2	397	38	1	0,3	367	35,9	8	2,2	0,11	Algorithm converged.	0,01	0,91	-1,928	Algorithm converged.	-3,5	-0,35	0,12	Algorithm converged.	0,01	0,92	0,0168	0,9477	8,65	Algorithm converged.	1,09	68,86		
	>2	649	62	2	0,3	653	64	16	2,5	0,12	Algorithm converged.	0,03	0,54	-2,142	Algorithm converged.	-3,4	-0,88	0,13	Algorithm converged.	0,03	0,54	0,0012		7,95	Algorithm converged.	1,84	34,44		
Baseline high risk factor	Yes	314	30	1	0,3	306	30	11	3,6	0,09	Algorithm converged.	0,01	0,67	-3,276	Algorithm converged.	-5,45	-1,1	0,09	Algorithm converged.	0,01	0,68	0,0028	0,7191	11,29	Algorithm converged.	1,47	86,9		
	No	732	70	2	0,3	715	70	14	2	0,14	Algorithm converged.	0,03	0,61	-1,685	Algorithm converged.	-2,77	-0,6	0,14	Algorithm converged.	0,03	0,61	0,002		7,17	Algorithm converged.	1,63	31,42		
Race	White	879	84	3	0,3	856	83,8	21	2,5	0,14	Algorithm converged.	0,04	0,46	-2,112	Algorithm converged.	-3,22	-1,01	0,14	Algorithm converged.	0,04	0,46	0,0001		7,19	Algorithm converged.	2,15	24,01		
	Black or African American	114	10,9	0	0	113	11,1	2	1,8	0	Algorithm converged.	NE	NE	-1,77	Algorithm converged.	-4,2	0,66	NE	* Algorithm not converged.	NE	NE	0,2467		NE	* Algorithm not converged.	NE	NE		
	Other	38	3,6	0	0	31	3	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE		
	Unknown/Not Reported	15	1,4	0	0	21	2,1	2	9,5	0	Algorithm converged.	NE	NE	-9,524	Algorithm converged.	-22,08	3,03	NE	* Algorithm not converged.	NE	NE	0,5		NE	* Algorithm not converged.	NE	NE		

Ethnicity	Hispanic or Latino	476	45.5	0	0	488	47.8	8	1.6	0		Algorithm converged.	NE	NE	-1.639		Algorithm converged.	-2.77	-0.51	NE	*	Algorithm not converged.	NE	NE	0.0076	0.1571	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	567	54.2	3	0.5	527	51.6	17	3.2	0.16		Algorithm converged.	0.05	0.55	-2.697		Algorithm converged.	-4.32	-1.07	0.16		Algorithm converged.	0.05	0.56	0.001		6.1		Algorithm converged.	1.8	20.68
	Unknown/not reported	3	0.3	0	0	6	0.6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9.5	1	1	109	10.7	0	0	NE	*	Algorithm not converged.	NE	NE	1.01		Algorithm converged.	-0.96	2.98	NE	*	Algorithm not converged.	NE	NE	0.476	0.0243	NE	*	Algorithm not converged.	NE	NE
	No	938	89.7	2	0.2	901	88.2	25	2.8	0.07		Algorithm converged.	0.02	0.32	-2.561		Algorithm converged.	-3.67	-1.45	0.08		Algorithm converged.	0.02	0.32	<0.0001		13.01		Algorithm converged.	3.09	54.78
	Unknown/not reported	9	0.9	0	0	11	1.1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1.2	1	7.7	12	1.2	0	0	NE	*	Algorithm not converged.	NE	NE	7.692		Algorithm converged.	-6.79	22.18	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Negative	896	85.7	2	0.2	879	86.1	18	2	0.11		Algorithm converged.	0.02	0.46	-1.825		Algorithm converged.	-2.81	-0.84	0.11		Algorithm converged.	0.03	0.47	0.0002		9.17		Algorithm converged.	2.14	39.42
	Unavailable	137	13.1	0	0	130	12.7	7	5.4	0		Algorithm converged.	NE	NE	-5.385		Algorithm converged.	-9.26	-1.5	NE	*	Algorithm not converged.	NE	NE	0.006		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	235	22.5	1	0.4	222	21.7	3	1.4	0.31		Algorithm converged.	0.03	3.02	-0.926		Algorithm converged.	-2.66	0.81	0.31		Algorithm converged.	0.03	3	0.3597	0.389	3.18		Algorithm converged.	0.33	30.3
	Seronegative	753	72	2	0.3	752	73.7	22	2.9	0.09		Algorithm converged.	0.02	0.38	-2.66		Algorithm converged.	-3.92	-1.4	0.09		Algorithm converged.	0.02	0.38	<0.0001		11.01		Algorithm converged.	2.6	46.68
	Unclear serology status	58	5.5	0	0	47	4.6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-6a-eff-resp-asyprcs

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)								
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	1046	100	3	0,287	6,714	0,006	0,005	-0,005	0,03	1021	100	25	2,449	108,143	0,106	0,028	0,094	0,03	-0,099	-0,155	-0,043	0	-0,154	-0,24	-0,067		

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-4-eff-smd-ANWSYMS

POPULATION: Modified Full Analysis Set - Cohort A
ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

Casirivimab/Indevimab										Placebo										Difference between treatments (Casirivimab/Indevimab - Placebo)										Interaction Test						
Patients in analysis										Patients in analysis										Mean Difference											Standardized Mean Difference					
Patients with Event										Patients with Event										95% Upper CL											95% Lower CL					
Total of Weeks										Total of Weeks										95% Upper CL										95% Lower CL						
Statistics										Statistics										Statistics										Statistics						
ANCOVA										ANCOVA										ANCOVA										ANCOVA						
p-value										p-value										p-value										p-value						
Hedges' g										Hedges' g										Hedges' g										Hedges' g						
p-value										p-value										p-value										p-value						
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Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: t9-4-eff-smd-ANWSYMS

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo												Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	SE	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL				
All	n/a	3	100	3	100	6,714	2,238	1,114	1,128	3,035	25	100	25	100	108,143	4,326	0,798	3,051	2,044	-1,923	-6,924	3,079	0,435	-0,473	-1,704	0,758					

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-4-eff-smd-ANWSYMS

POPULATION: Cohort A

ENDPOINT: All-cause death at EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1046	100	0	0	1021	100	0	0																						

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-1a-eff-resp-dth29

POPULATION: Cohort A
ENDPOINT: All-cause death at EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
Name	Level	Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Interaction Test p-value (likelihood ratio)						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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
All	n/a	1046	100		0 0	1021	100		0 0																												
Sex	Male	479	45,8		0 0	498	48,8		0 0																												
	Female	567	54,2		0 0	523	51,2		0 0																												
Age	12-17	46	4,4		0 0	43	4,2		0 0																												
	18-49	624	59,7		0 0	606	59,4		0 0																												
	>=50	376	35,9		0 0	372	36,4		0 0																												
Region	US	959	91,7		0 0	939	92		0 0																												
	ex-US	87	8,3		0 0	82	8		0 0																												
BMI	BMI < 30 kg/m2	670	64,1		0 0	660	64,6		0 0																												
	BMI >= 30 kg/m2	371	35,5		0 0	357	35		0 0																												
	Unknown/not reported	5	0,5		0 0	4	0,4		0 0																												
Number of study subjects in cohort B within a household	0	998	95,4		0 0	989	96,9		0 0																												
	>=1	48	4,6		0 0	32	3,1		0 0																												
Total household size including the household members not participating this study	2	397	38		0 0	367	35,9		0 0																												
	>2	649	62		0 0	653	64		0 0																												
Baseline high risk factor	Yes	314	30		0 0	306	30		0 0																												
	No	732	70		0 0	715	70		0 0																												
Race	White	879	84		0 0	856	83,8		0 0																												
	Black or African American	114	10,9		0 0	113	11,1		0 0																												
	Other	38	3,6		0 0	31	3		0 0																												
	Unknown/Not Reported	15	1,4		0 0	21	2,1		0 0																												

Ethnicity	Hispanic or Latino	476 45,5	0 0	488 47,8	0 0
	Not Hispanic or Latino	567 54,2	0 0	527 51,6	0 0
	Unknown/not reported	3 0,3	0 0	6 0,6	0 0
Healthcare worker	Yes	99 9,5	0 0	109 10,7	0 0
	No	938 89,7	0 0	901 88,2	0 0
	Unknown/not reported	9 0,9	0 0	11 1,1	0 0
Local test result of diagnostic assay for SARS-CoV-2	Positive	13 1,2	0 0	12 1,2	0 0
	Negative	896 85,7	0 0	879 86,1	0 0
	Unavailable	137 13,1	0 0	130 12,7	0 0
Serology status	Seropositive	235 22,5	0 0	222 21,7	0 0
	Seronegative	753 72	0 0	752 73,7	0 0
	Unclear serology status	58 5,5	0 0	47 4,6	0 0

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $np \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-1a-eff-resp-dth29

POPULATION: Cohort A

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-2a-eff-resp-dthfu

POPULATION: Cohort A
ENDPOINT: All-cause death at end of Follow-Up
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk		Relative Risk						
Name	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
All	n/a	1046	100	2	0.2	1021	100	1	0.1	1.95	Algorithm converged.	0.18	21.58	0.093	Algorithm converged.	-0.23	0.42	1.95	Algorithm converged.	0.18	21.5	1		0.51	Algorithm converged.	0.05	5.64							
Sex	Male	479	45.8	1	0.2	498	48.8	1	0.2	1.04	Algorithm converged.	0.06	16.67	0.008	Algorithm converged.	-0.56	0.58	1.04	Algorithm converged.	0.07	16.57	1	0.3248	0.96	Algorithm converged.	0.06	15.33							
	Female	567	54.2	1	0.2	523	51.2	0	0	NE *	Algorithm not converged.	NE	NE	0.176	Algorithm converged.	-0.17	0.52	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE							
Age	12-17	46	4.4	0	0	43	4.2	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
	18-49	624	59.7	0	0	606	59.4	1	0.2	0	Algorithm converged.	NE	NE	-0.165	Algorithm converged.	-0.49	0.16	NE *	Algorithm not converged.	NE	NE	0.4927		NE *	Algorithm not converged.	NE	NE							
	>=50	376	35.9	2	0.5	372	36.4	0	0	NE *	Algorithm not converged.	NE	NE	0.532	Algorithm converged.	-0.2	1.27	NE *	Algorithm not converged.	NE	NE	0.4993		NE *	Algorithm not converged.	NE	NE							
Region	US	959	91.7	2	0.2	939	92	1	0.1	1.96	Algorithm converged.	0.18	21.66	0.102	Algorithm converged.	-0.25	0.46	1.96	Algorithm converged.	0.18	21.56	1	1	0.51	Algorithm converged.	0.05	5.62							
	ex-US	87	8.3	0	0	82	8	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
BMI	BMI < 30 kg/m2	670	64.1	2	0.3	660	64.6	1	0.2	1.97	Algorithm converged.	0.18	21.81	0.147	Algorithm converged.	-0.36	0.66	1.97	Algorithm converged.	0.18	21.67	1	1	0.51	Algorithm converged.	0.05	5.58							
	BMI >= 30 kg/m2	371	35.5	0	0	357	35	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
	Unknown/not reported	5	0.5	0	0	4	0.4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
Number of study subjects in cohort B within a household	0	998	95.4	2	0.2	989	96.9	1	0.1	1.98	Algorithm converged.	0.18	21.91	0.099	Algorithm converged.	-0.24	0.44	1.98	Algorithm converged.	0.18	21.82	1	1	0.5	Algorithm converged.	0.05	5.56							
	>=1	48	4.6	0	0	32	3.1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
Total household size including the household members not participating this study	2	397	38	0	0	367	35.9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	1	NE *	Algorithm not converged.	NE	NE							
	>2	649	62	2	0.3	653	64	1	0.2	2.02	Algorithm converged.	0.18	22.28	0.155	Algorithm converged.	-0.37	0.68	2.01	Algorithm converged.	0.18	22.14	0.6236		0.5	Algorithm converged.	0.05	5.47							
Baseline high risk factor	Yes	314	30	2	0.6	306	30	0	0	NE *	Algorithm not converged.	NE	NE	0.637	Algorithm converged.	-0.24	1.52	NE *	Algorithm not converged.	NE	NE	0.4993	0.0506	NE *	Algorithm not converged.	NE	NE							
	No	732	70	0	0	715	70	1	0.1	0	Algorithm converged.	NE	NE	-0.14	Algorithm converged.	-0.41	0.13	NE *	Algorithm not converged.	NE	NE	0.4941		NE *	Algorithm not converged.	NE	NE							
Race	White	879	84	2	0.2	856	83.8	1	0.1	1.95	Algorithm converged.	0.18	21.54	0.111	Algorithm converged.	-0.28	0.5	1.95	Algorithm converged.	0.18	21.44	1		0.51	Algorithm converged.	0.05	5.65							
	Black or African American	114	10.9	0	0	113	11.1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
	Other	38	3.6	0	0	31	3	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							
	Unknown/Not Reported	15	1.4	0	0	21	2.1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE							

Ethnicity	Hispanic or Latino	476	45,5	0	0	488	47,8	1	0,2	0		Algorithm converged.	NE	NE	-0,205		Algorithm converged.	-0,61	0,2	NE	*	Algorithm not converged.	NE	NE	1	0,0546	NE	*	Algorithm not converged.	NE	NE	
	Not Hispanic or Latino	567	54,2	2	0,4	527	51,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,353		Algorithm converged.	-0,14	0,84	NE	*	Algorithm not converged.	NE	NE	0,5002		NE	*	Algorithm not converged.	NE	NE	
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Healthcare worker	Yes	99	9,5	0	0	109	10,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	No	938	89,7	2	0,2	901	88,2	1	0,1	1,92		Algorithm converged.	0,17	21,25	0,102		Algorithm converged.	-0,26	0,47	1,92		Algorithm converged.	0,17	21,15	1		0,52		Algorithm converged.	0,05	5,73	
	Unknown/not reported	9	0,9	0	0	11	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	0	0	12	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Negative	896	85,7	2	0,2	879	86,1	1	0,1	1,96		Algorithm converged.	0,18	21,7	0,109		Algorithm converged.	-0,27	0,49	1,96		Algorithm converged.	0,18	21,6	1		0,51		Algorithm converged.	0,05	5,61	
	Unavailable	137	13,1	0	0	130	12,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Serology status	Seropositive	235	22,5	1	0,4	222	21,7	1	0,5	0,94		Algorithm converged.	0,06	15,19	-0,025		Algorithm converged.	-1,24	1,19	0,94		Algorithm converged.	0,06	15,01	1	0,2975	1,06		Algorithm converged.	0,07	16,82	
	Seronegative	753	72	1	0,1	752	73,7	0	0	NE	*	Algorithm not converged.	NE	NE	0,133		Algorithm converged.	-0,13	0,39	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-2a-eff-resp-dthfu

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7a-eff-resp-ahoer

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1046	100		0 0	1021	100	4	0,4	0	Algorithm converged.	NE	NE	-0,392	Algorithm converged.	-0,77	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0594		NE	*	Algorithm not converged.	NE	NE
Sex	Male	479	45,8		0 0	498	48,8	2	0,4	0	Algorithm converged.	NE	NE	-0,402	Algorithm converged.	-0,96	0,15	NE	*	Algorithm not converged.	NE	NE	0,4997	1	NE	*	Algorithm not converged.	NE	NE
	Female	567	54,2		0 0	523	51,2	2	0,4	0	Algorithm converged.	NE	NE	-0,382	Algorithm converged.	-0,91	0,15	NE	*	Algorithm not converged.	NE	NE	0,23		NE	*	Algorithm not converged.	NE	NE
Age	12-17	46	4,4		0 0	43	4,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
	18-49	624	59,7		0 0	606	59,4	1	0,2	0	Algorithm converged.	NE	NE	-0,165	Algorithm converged.	-0,49	0,16	NE	*	Algorithm not converged.	NE	NE	0,4927		NE	*	Algorithm not converged.	NE	NE
	>=50	376	35,9		0 0	372	36,4	3	0,8	0	Algorithm converged.	NE	NE	-0,806	Algorithm converged.	-1,72	0,1	NE	*	Algorithm not converged.	NE	NE	0,1225		NE	*	Algorithm not converged.	NE	NE
Region	US	959	91,7		0 0	939	92	3	0,3	0	Algorithm converged.	NE	NE	-0,319	Algorithm converged.	-0,68	0,04	NE	*	Algorithm not converged.	NE	NE	0,1209		NE	*	Algorithm not converged.	NE	NE
	ex-US	87	8,3		0 0	82	8	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE	*	Algorithm not converged.	NE	NE	0,4852		NE	*	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	670	64,1		0 0	660	64,6	1	0,2	0	Algorithm converged.	NE	NE	-0,152	Algorithm converged.	-0,45	0,15	NE	*	Algorithm not converged.	NE	NE	0,4962	1	NE	*	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	371	35,5		0 0	357	35	3	0,8	0	Algorithm converged.	NE	NE	-0,84	Algorithm converged.	-1,79	0,11	NE	*	Algorithm not converged.	NE	NE	0,1174		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	5	0,5		0 0	4	0,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
Number of study subjects in cohort B within a household	0	998	95,4		0 0	989	96,9	4	0,4	0	Algorithm converged.	NE	NE	-0,404	Algorithm converged.	-0,8	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0612		NE	*	Algorithm not converged.	NE	NE
	>=1	48	4,6		0 0	32	3,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
Total household size including the household members not participating this study	2	397	38		0 0	367	35,9	2	0,5	0	Algorithm converged.	NE	NE	-0,545	Algorithm converged.	-1,3	0,21	NE	*	Algorithm not converged.	NE	NE	0,2304	1	NE	*	Algorithm not converged.	NE	NE
	>2	649	62		0 0	653	64	2	0,3	0	Algorithm converged.	NE	NE	-0,306	Algorithm converged.	-0,73	0,12	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	*	Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	314	30		0 0	306	30	4	1,3	0	Algorithm converged.	NE	NE	-1,307	Algorithm converged.	-2,58	-0,03	NE	*	Algorithm not converged.	NE	NE	0,0587		NE	*	Algorithm not converged.	NE	NE
	No	732	70		0 0	715	70	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
Race	White	879	84		0 0	856	83,8	4	0,5	0	Algorithm converged.	NE	NE	-0,467	Algorithm converged.	-0,92	-0,01	NE	*	Algorithm not converged.	NE	NE	0,059		NE	*	Algorithm not converged.	NE	NE
	Black or African American	114	10,9		0 0	113	11,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
	Other	38	3,6		0 0	31	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not Reported	15	1,4		0 0	21	2,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	

Ethnicity	Hispanic or Latino	476	45,5	0	0	488	47,8	1	0,2	0		Algorithm converged.	NE	NE	-0,205		Algorithm converged.	-0,61	0,2	NE	*	Algorithm not converged.	NE	NE	1	1	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	567	54,2	0	0	527	51,6	3	0,6	0		Algorithm converged.	NE	NE	-0,569		Algorithm converged.	-1,21	0,07	NE	*	Algorithm not converged.	NE	NE	0,1115		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	0	0	109	10,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	No	938	89,7	0	0	901	88,2	4	0,4	0		Algorithm converged.	NE	NE	-0,444		Algorithm converged.	-0,88	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0574		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,9	0	0	11	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	0	0	12	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Negative	896	85,7	0	0	879	86,1	3	0,3	0		Algorithm converged.	NE	NE	-0,341		Algorithm converged.	-0,73	0,04	NE	*	Algorithm not converged.	NE	NE	0,1212		NE	*	Algorithm not converged.	NE	NE
	Unavailable	137	13,1	0	0	130	12,7	1	0,8	0		Algorithm converged.	NE	NE	-0,769		Algorithm converged.	-2,27	0,73	NE	*	Algorithm not converged.	NE	NE	0,4869		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	235	22,5	0	0	222	21,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Seronegative	753	72	0	0	752	73,7	4	0,5	0		Algorithm converged.	NE	NE	-0,532		Algorithm converged.	-1,05	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7a-eff-resp-ahoer

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
Patients				Event				Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	43	4,1	0	0	128	12,5	4	3,1	0	Algorithm converged.	NE	NE	-3,125	Algorithm converged.	-6,14	-0,11	NE	*	Algorithm not converged.	NE	NE	0,5732		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7b-eff-resp-ahoer

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8a-eff-resp-hoeruc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio			Absolute Risk Difference			Relative Risk	Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL			95% upper CL	p-value	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	1046	100		0 0	1021	100	10	1	0	Algorithm converged.	NE	NE	-0,979	Algorithm converged.	-1,58	-0,38	NE	*	Algorithm not converged.	NE	NE	0,0008		NE	*	Algorithm not converged.	NE	NE
Sex	Male	479	45,8		0 0	498	48,8	7	1,4	0	Algorithm converged.	NE	NE	-1,406	Algorithm converged.	-2,44	-0,37	NE	*	Algorithm not converged.	NE	NE	0,0154	1	NE	*	Algorithm not converged.	NE	NE
	Female	567	54,2		0 0	523	51,2	3	0,6	0	Algorithm converged.	NE	NE	-0,574	Algorithm converged.	-1,22	0,07	NE	*	Algorithm not converged.	NE	NE	0,1101		NE	*	Algorithm not converged.	NE	NE
Age	12-17	46	4,4		0 0	43	4,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
	18-49	624	59,7		0 0	606	59,4	5	0,8	0	Algorithm converged.	NE	NE	-0,825	Algorithm converged.	-1,55	-0,1	NE	*	Algorithm not converged.	NE	NE	0,0288		NE	*	Algorithm not converged.	NE	NE
	>=50	376	35,9		0 0	372	36,4	5	1,3	0	Algorithm converged.	NE	NE	-1,344	Algorithm converged.	-2,51	-0,17	NE	*	Algorithm not converged.	NE	NE	0,03		NE	*	Algorithm not converged.	NE	NE
Region	US	959	91,7		0 0	939	92	9	1	0	Algorithm converged.	NE	NE	-0,958	Algorithm converged.	-1,58	-0,34	NE	*	Algorithm not converged.	NE	NE	0,0017		NE	*	Algorithm not converged.	NE	NE
	ex-US	87	8,3		0 0	82	8	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE	*	Algorithm not converged.	NE	NE	0,4852		NE	*	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	670	64,1		0 0	660	64,6	4	0,6	0	Algorithm converged.	NE	NE	-0,606	Algorithm converged.	-1,2	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0604	1	NE	*	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	371	35,5		0 0	357	35	6	1,7	0	Algorithm converged.	NE	NE	-1,681	Algorithm converged.	-3,01	-0,35	NE	*	Algorithm not converged.	NE	NE	0,0136		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	5	0,5		0 0	4	0,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
Number of study subjects in cohort B within a household	0	998	95,4		0 0	989	96,9	10	1	0	Algorithm converged.	NE	NE	-1,011	Algorithm converged.	-1,63	-0,39	NE	*	Algorithm not converged.	NE	NE	0,0009		NE	*	Algorithm not converged.	NE	NE
	>=1	48	4,6		0 0	32	3,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
Total household size including the household members not participating this study	2	397	38		0 0	367	35,9	4	1,1	0	Algorithm converged.	NE	NE	-1,09	Algorithm converged.	-2,15	-0,03	NE	*	Algorithm not converged.	NE	NE	0,0528	1	NE	*	Algorithm not converged.	NE	NE
	>2	649	62		0 0	653	64	6	0,9	0	Algorithm converged.	NE	NE	-0,919	Algorithm converged.	-1,65	-0,19	NE	*	Algorithm not converged.	NE	NE	0,0309		NE	*	Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	314	30		0 0	306	30	6	2	0	Algorithm converged.	NE	NE	-1,961	Algorithm converged.	-3,51	-0,41	NE	*	Algorithm not converged.	NE	NE	0,0141	1	NE	*	Algorithm not converged.	NE	NE
	No	732	70		0 0	715	70	4	0,6	0	Algorithm converged.	NE	NE	-0,559	Algorithm converged.	-1,11	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0594		NE	*	Algorithm not converged.	NE	NE
Race	White	879	84		0 0	856	83,8	8	0,9	0	Algorithm converged.	NE	NE	-0,935	Algorithm converged.	-1,58	-0,29	NE	*	Algorithm not converged.	NE	NE	0,0035		NE	*	Algorithm not converged.	NE	NE
	Black or African American	114	10,9		0 0	113	11,1	2	1,8	0	Algorithm converged.	NE	NE	-1,77	Algorithm converged.	-4,2	0,66	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	*	Algorithm not converged.	NE	NE
	Other	38	3,6		0 0	31	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not Reported	15	1,4		0 0	21	2,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE				NE	*	Algorithm not converged.	NE	NE	

Ethnicity	Hispanic or Latino	476	45,5	0	0	488	47,8	4	0,8	0		Algorithm converged.	NE	NE	-0,82		Algorithm converged.	-1,62	-0,02	NE	*	Algorithm not converged.	NE	NE	0,1243	1		NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	567	54,2	0	0	527	51,6	6	1,1	0		Algorithm converged.	NE	NE	-1,139		Algorithm converged.	-2,04	-0,23	NE	*	Algorithm not converged.	NE	NE	0,0123			NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	0	0	109	10,7	1	0,9	0		Algorithm converged.	NE	NE	-0,917		Algorithm converged.	-2,71	0,87	NE	*	Algorithm not converged.	NE	NE	1			NE	*	Algorithm not converged.	NE	NE
	No	938	89,7	0	0	901	88,2	9	1	0		Algorithm converged.	NE	NE	-0,999		Algorithm converged.	-1,65	-0,35	NE	*	Algorithm not converged.	NE	NE	0,0016			NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,9	0	0	11	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	0	0	12	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
	Negative	896	85,7	0	0	879	86,1	6	0,7	0		Algorithm converged.	NE	NE	-0,683		Algorithm converged.	-1,23	-0,14	NE	*	Algorithm not converged.	NE	NE	0,0146			NE	*	Algorithm not converged.	NE	NE
	Unavailable	137	13,1	0	0	130	12,7	4	3,1	0		Algorithm converged.	NE	NE	-3,077		Algorithm converged.	-6,05	-0,11	NE	*	Algorithm not converged.	NE	NE	0,0549			NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	235	22,5	0	0	222	21,7	2	0,9	0		Algorithm converged.	NE	NE	-0,901		Algorithm converged.	-2,14	0,34	NE	*	Algorithm not converged.	NE	NE	0,2354	1		NE	*	Algorithm not converged.	NE	NE
	Seronegative	753	72	0	0	752	73,7	8	1,1	0		Algorithm converged.	NE	NE	-1,064		Algorithm converged.	-1,8	-0,33	NE	*	Algorithm not converged.	NE	NE	0,0038			NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8a-eff-resp-hoeruc

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
										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	
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	43	4,1	0	0	128	12,5	10	7,8	0	Algorithm converged.	NE	NE	-7,813	Algorithm converged.	-12,46	-3,16	NE	*	Algorithm not converged.	NE	NE	0,0675		NE	*	Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8b-eff-resp-hoeruc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	
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Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-9a-eff-resp-amaveru

POPULATION: Cohort A

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
		Patients		Event		Patients		Event				Odds Ratio																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															

Ethnicity	Hispanic or Latino	476	45,5	0	0	488	47,8	5	1	0		Algorithm converged.	NE	NE	-1,025		Algorithm converged.	-1,92	-0,13	NE	*	Algorithm not converged.	NE	NE	0,0619	1		NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	567	54,2	0	0	527	51,6	5	0,9	0		Algorithm converged.	NE	NE	-0,949		Algorithm converged.	-1,78	-0,12	NE	*	Algorithm not converged.	NE	NE	0,0257			NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	0	0	109	10,7	1	0,9	0		Algorithm converged.	NE	NE	-0,917		Algorithm converged.	-2,71	0,87	NE	*	Algorithm not converged.	NE	NE	1			NE	*	Algorithm not converged.	NE	NE
	No	938	89,7	0	0	901	88,2	9	1	0		Algorithm converged.	NE	NE	-0,999		Algorithm converged.	-1,65	-0,35	NE	*	Algorithm not converged.	NE	NE	0,0016			NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,9	0	0	11	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	0	0	12	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE
	Negative	896	85,7	0	0	879	86,1	6	0,7	0		Algorithm converged.	NE	NE	-0,683		Algorithm converged.	-1,23	-0,14	NE	*	Algorithm not converged.	NE	NE	0,0146			NE	*	Algorithm not converged.	NE	NE
	Unavailable	137	13,1	0	0	130	12,7	4	3,1	0		Algorithm converged.	NE	NE	-3,077		Algorithm converged.	-6,05	-0,11	NE	*	Algorithm not converged.	NE	NE	0,0549			NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	235	22,5	0	0	222	21,7	2	0,9	0		Algorithm converged.	NE	NE	-0,901		Algorithm converged.	-2,14	0,34	NE	*	Algorithm not converged.	NE	NE	0,2354	1		NE	*	Algorithm not converged.	NE	NE
	Seronegative	753	72	0	0	752	73,7	8	1,1	0		Algorithm converged.	NE	NE	-1,064		Algorithm converged.	-1,8	-0,33	NE	*	Algorithm not converged.	NE	NE	0,0038			NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-9a-eff-resp-amaveru

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
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Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-9b-eff-resp-amaveru

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	1046	100	0	0	0	0	0	-0,002	0,004	1021	100	10	0,979	11	0,011	0,004	0,009	0,004	-0,011	-0,018	-0,004	0,002	-0,136	-0,222	-0,05			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-5-eff-smd-ANMAVERU

POPULATION: Modified Full Analysis Set - Cohort A
 ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2069
 Template SMD

Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)										Interaction Test				
Patients in analysis										Patients with Event		Total of visits		Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of visits		Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		p-value
Name	Level	n	%		n	%		d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value	(likelihood ratio)				
All	n/a	1046	100		0	0		0	0.002	1021	0.011	0.002	1021	100	10	0.979	11	0.011	0.004	0.011	0.002	-0.011	-0.018	-0.004	0.002	-0.136	-0.223	-0.05		NE				
Sex	Male	479	45.793	0	0	0		0	0	0	0.004	498	48.776	7	1.406	7	0.014	0.005	0.014	0.004	-0.014	-0.025	-0.003	0.009	-0.167	-0.292	-0.041		0.3575					
	Female	567	54.207	0	0	0		0	0	0	0.003	523	51.224	3	0.574	4	0.008	0.005	0.008	0.003	-0.008	-0.016	-0.103	0.089	-0.103	-0.222	0.016							
Age	12-17	46	4.398	0	0	0		0	0	0	NE	43	4.212	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE		0.7177				
	18-49	624	59.656	0	0	0		0	0	0	0.003	606	59.354	6	0.99	6	0.01	0.004	0.01	0.003	-0.01	-0.018	-0.002	0.013	-0.142	-0.254	-0.03							
	>=50	376	35.946	0	0	0		0	0	0	0.005	372	36.435	4	1.075	5	0.013	0.007	0.013	0.005	-0.013	-0.027	0	0.057	-0.139	-0.263	0.004							
Region	US	959	91.683	0	0	0		0	0	0	0.003	939	91.969	10	1.065	11	0.012	0	0.012	0	0.003	-0.012	-0.019	-0.004	0.002	-0.142	-0.232	NE	-0.052	0.3559				
	exUS	87	8.317	0	0	0		0	0	0	NE	82	8.031	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
BMI	BMI < 30 kg/m2	670	64.054	0	0	0		0	0	0	0.002	660	64.643	4	0.606	4	0.006	0.003	0.006	0.002	-0.006	-0.012	0	0.044	-0.111	-0.218	-0.003		0.0633					
	BMI >= 30 kg/m2	371	35.468	0	0	0		0	0	0	0.006	357	34.966	6	1.681	7	0.02	0.008	0.02	0.006	-0.02	-0.036	-0.004	0.017	-0.177	-0.323	-0.032							
	Unknown/not reported	5	0.478	0	0	0		0	0	0	NE	4	0.392	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Number of study subjects in cohort B within a household	0	998	95.411	0	0	0		0	0	0	0.003	989	96.866	10	1.011	11	0.011	0.004	0.011	0.003	-0.011	-0.018	-0.004	0.002	-0.138	-0.226	-0.05		0.5451					
	>=1	48	4.589	0	0	0		0	0	0	NE	32	3.134	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Total household size including the household member(s) not participating this study	2	397	37.954	0	0	0		0	0	0	0.004	367	35.945	4	1.09	4	0.011	0.005	0.011	0.004	-0.011	-0.021	-0.001	0.037	-0.151	-0.293	-0.009		0.9801					
	>2	649	62.046	0	0	0		0	0	0	0.003	653	63.957	6	0.919	7	0.011	0.005	0.011	0.003	-0.011	-0.02	-0.002	0.02	-0.129	-0.238	-0.021							
Baseline high risk factor	Yes	314	30.019	0	0	0		0	0	0	0.006	306	29.971	5	1.634	6	0.02	0.009	0.02	0.006	-0.02	-0.037	-0.002	0.031	-0.173	-0.331	-0.016		0.0961					
	No	732	69.981	0	0	0		0	0	0	0.002	715	70.029	5	0.699	5	0.007	0.003	0.007	0.002	-0.007	-0.013	-0.001	0.023	-0.119	-0.222	-0.016							
Race	White	879	84.034	0	0	0		0	0	0	0.003	856	83.839	8	0.935	9	0.011	0.004	0.011	0.003	-0.011	-0.018	-0.003	0.006	-0.132	-0.227	-0.038		0.6902					
	Black or African American	114	10.899	0	0	0		0	0	0	0.009	113	11.068	2	1.77	2	0.018	0.012	0.018	0.009	-0.018	-0.042	0.007	0.195	-0.189	-0.449	0.072							
	Other	38	3.633	0	0	0		0	0	0	0.04	31	3.006	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
	Unknown/Not Reported	15	1.434	0	0	0		0	0	0	NE	21	2.057	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Ethnicity	Hispanic or Latino	476	45.507	0	0	0		0	0	0	0.003	488	47.796	5	1.025	5	0.01	0.005	0.01	0.003	-0.01	-0.019	-0.001	0.027	-0.143	-0.269	-0.016		0.8707					
	Not Hispanic or Latino	567	54.207	0	0	0		0	0	0	0.004	527	51.516	5	0.949	6	0.011	0.005	0.011	0.004	-0.011	-0.022	-0.001	0.027	-0.133	-0.252	-0.015							
	Unknown/Not reported	3	0.287	0	0	0		0	0	0	NE	6	0.588	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Healthcare worker	Yes	99	9.465	0	0	0		0	0	0	0.007	109	10.676	1	0.917	1	0.009	0.009	0.009	0.007	-0.009	-0.028	0.01	0.342	-0.132	-0.405	0.141		0.8686					
	No	938	89.675	0	0	0		0	0	0	0.003	901	88.247	9	0.999	10	0.011	0.004	0.011	0.003	-0.011	-0.018	-0.004	0.003	-0.138	-0.229	-0.046							
	Unknown/not reported	9	0.86	0	0	0		0	0	0	NE	11	1.077	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1.243	0	0	0		0	0	0	NE	12	1.175	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE		0.7688				
	Negative	896	85.66	0	0	0		0	0	0	0.002	879	86.992	6	0.683	6	0.007	0.003	0.007	0.002	-0.007	-0.012	-0.001	0.013	-0.118	-0.211	-0.025							
	Unavailable	137	13.098	0	0	0		0	0	0	0.014	130	12.733	4	3.077	5	0.038	0.02	0.038	0.014	-0.038	-0.077	0	0.051	-0.239	-0.48	0.001							
Serology status	Seropositive	235	22.467	0	0	0		0	0	0	0.004	222	21.743	2	0.901	2	0.009	0.006	0.009	0.004	-0.009	-0.021	0.003	0.145	-0.136	-0.32	0.047		0.7328					
	Seronegative	753	71.989	0	0	0		0	0	0	0.003	752	73.653	8	1.064	9	0.012	0.004	0.012	0.003	-0.012	-0.021	-0.003	0.006	-0.141	-0.242	-0.039							
	Unclear serology status	58	5.545	0	0	0		0	0	0	NE	47	4.603	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: t9-5-eff-smd-ANMAVERU

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo					Difference between treatments (Casirivimab/Imdevimab - Placebo)											
		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	
All	n/a	43	100	0	0	0	0	0	-0,023	0,047	128	100	9	7,031	10	0,078	0,026	0,054	0,036	-0,076	-0,166	0,013	0,095	-0,295	-0,642	0,052	

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-5-eff-smd-ANMAVERU

POPULATION: Cohort A

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

										Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
										Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk											
																										Interaction Test p-value (likelihood ratio)																	
Name	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL																
All	n/a	1046	100		0/0	1021	100	1	0.1	0	Algorithm converged.	NE	NE	-0.098	Algorithm converged.	-0.29	0.09	NE	*	Algorithm not converged.	NE	NE	0.494		NE	*	Algorithm not converged.	NE	NE														

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10a-eff-resp-ahosp

POPULATION: Cohort A

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1046	100		0 0	1021	100	1	0.1	0	Algorithm converged.	NE	NE	-0.098	Algorithm converged.	-0.29	0.09	NE	*	Algorithm not converged.	NE	NE	0.494		NE	*	Algorithm not converged.	NE	NE		
Sex	Male	479	45.8		0 0	498	48.8	1	0.2	0	Algorithm converged.	NE	NE	-0.201	Algorithm converged.	-0.59	0.19	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE		
	Female	567	54.2		0 0	523	51.2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Age	12-17	46	4.4		0 0	43	4.2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	18-49	624	59.7		0 0	606	59.4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=50	376	35.9		0 0	372	36.4	1	0.3	0	Algorithm converged.	NE	NE	-0.269	Algorithm converged.	-0.79	0.26	NE	*	Algorithm not converged.	NE	NE	0.4973		NE	*	Algorithm not converged.	NE	NE		
Region	US	959	91.7		0 0	939	92	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	ex-US	87	8.3		0 0	82	8	1	1.2	0	Algorithm converged.	NE	NE	-1.22	Algorithm converged.	-3.6	1.16	NE	*	Algorithm not converged.	NE	NE	0.4852		NE	*	Algorithm not converged.	NE	NE		
BMI	BMI < 30 kg/m2	670	64.1		0 0	660	64.6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	371	35.5		0 0	357	35	1	0.3	0	Algorithm converged.	NE	NE	-0.28	Algorithm converged.	-0.83	0.27	NE	*	Algorithm not converged.	NE	NE	0.4904		NE	*	Algorithm not converged.	NE	NE		
	Unknown/not reported	5	0.5		0 0	4	0.4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	998	95.4		0 0	989	96.9	1	0.1	0	Algorithm converged.	NE	NE	-0.101	Algorithm converged.	-0.3	0.1	NE	*	Algorithm not converged.	NE	NE	0.4977		NE	*	Algorithm not converged.	NE	NE		
	>=1	48	4.6		0 0	32	3.1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	397	38		0 0	367	35.9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>2	649	62		0 0	653	64	1	0.2	0	Algorithm converged.	NE	NE	-0.153	Algorithm converged.	-0.45	0.15	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE		
Baseline high risk factor	Yes	314	30		0 0	306	30	1	0.3	0	Algorithm converged.	NE	NE	-0.327	Algorithm converged.	-0.97	0.31	NE	*	Algorithm not converged.	NE	NE	0.4935		NE	*	Algorithm not converged.	NE	NE		
	No	732	70		0 0	715	70	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Race	White	879	84		0 0	856	83.8	1	0.1	0	Algorithm converged.	NE	NE	-0.117	Algorithm converged.	-0.35	0.11	NE	*	Algorithm not converged.	NE	NE	0.4934		NE	*	Algorithm not converged.	NE	NE		
	Black or African American	114	10.9		0 0	113	11.1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Other	38	3.6		0 0	31	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Unknown/Not Reported	15	1.4		0 0	21	2.1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Ethnicity	Hispanic or Latino	476	45,5	0	0	488	47,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	567	54,2	0	0	527	51,6	1	0,2	0		Algorithm converged.	NE	NE	-0,19		Algorithm converged.	-0,56	0,18	NE	*	Algorithm not converged.	NE	NE	0,4817		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	3	0,3	0	0	6	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	99	9,5	0	0	109	10,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	No	938	89,7	0	0	901	88,2	1	0,1	0		Algorithm converged.	NE	NE	-0,111		Algorithm converged.	-0,33	0,11	NE	*	Algorithm not converged.	NE	NE	0,4899		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,9	0	0	11	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	13	1,2	0	0	12	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Negative	896	85,7	0	0	879	86,1	1	0,1	0		Algorithm converged.	NE	NE	-0,114		Algorithm converged.	-0,34	0,11	NE	*	Algorithm not converged.	NE	NE	0,4952		NE	*	Algorithm not converged.	NE	NE
	Unavailable	137	13,1	0	0	130	12,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	235	22,5	0	0	222	21,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Seronegative	753	72	0	0	752	73,7	1	0,1	0		Algorithm converged.	NE	NE	-0,133		Algorithm converged.	-0,39	0,13	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	58	5,5	0	0	47	4,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10a-eff-resp-ahosp

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference								Relative Risk				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10b-eff-resp-ahosp

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	1046	100	0	0	0	0	0	0,029	0,011	1021	100	1	0,098	11	0,011	0,011	0,04	0,011	-0,011	-0,032	0,01	0,305	-0,045	-0,131	0,041			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A
ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)										Interaction		
		Patients in analysis			Patients with Event			Total of days		Statistics		ANCOVA		Patients in analysis			Patients with Event			Total of days		Statistics		ANCOVA		Mean Difference					Standardized Mean Difference			p-value
Name		Level	n	%	n	%	d		mean (d/N)	SE	LSMean	SE	n	%	n	%	d		mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value	(likelihood ratio)			
All		n/a	1046	100	0	0	0	0	0.007	1021	100	1	0.098	11	0	0.098	11	0	0.011	0.011	0.011	0.008	-0.011	-0.032	0.01	0.312	-0.045	-0.131	0.042	NE				
Sex	Male		479	45.793	0	0	0	0	0	0	0.016	498	48.776	1	0.201	11	0	0.022	0.022	0.022	0.016	-0.022	-0.066	0.022	0.327	-0.063	-0.188	0.063	0.3005					
	Female		567	54.207	0	0	0	0	0	0	NE	523	51.224	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Age	12-17		46	4.398	0	0	0	0	0	0	NE	43	4.212	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.4104			
	18-49		624	59.656	0	0	0	0	0	0	NE	606	59.354	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE				
	>=50		376	35.946	0	0	0	0	0	0	0.021	372	36.435	1	0.269	11	0	0.03	0.03	0.03	0.021	-0.03	-0.087	0.028	0.315	-0.073	-0.217	0.07						
Region	US		959	91.683	0	0	0	0	0	0	NE	939	91.969	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.0005			
	ex-US		87	8.317	0	0	0	0	0	0	0.091	82	8.031	1	1.22	11	0	0.134	0.134	0.134	0.093	-0.134	-0.391	0.123	0.304	-0.158	-0.46	0.145						
BMI	BMI < 30 kg/m2		670	64.054	0	0	0	0	0	0	NE	660	64.643	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.1682			
	BMI >= 30 kg/m2		371	35.468	0	0	0	0	0	0	0.021	357	34.966	1	0.28	11	0	0.031	0.031	0.031	0.022	-0.031	-0.09	0.029	0.308	-0.076	-0.221	0.07						
	Unknown/not reported		5	0.478	0	0	0	0	0	0	NE	4	0.392	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Number of study subjects in cohort B within a household			0																															
	>=1		998	95.411	0	0	0	0	0	0	0.008	989	96.866	1	0.101	11	0	0.011	0.011	0.011	0.008	-0.011	-0.033	0.011	0.315	-0.045	-0.133	0.043	0.8434					
			48	4.589	0	0	0	0	0	0	NE	32	3.134	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Total household size including the household member(s) not participating this study			2																															
	>2		397	37.954	0	0	0	0	0	0	NE	367	35.945	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.4455			
			649	62.046	0	0	0	0	0	0	0.012	653	63.957	1	0.153	11	0	0.017	0.017	0.017	0.012	-0.017	-0.05	0.016	0.319	-0.055	-0.164	0.053						
Baseline high risk factor	Yes		314	30.019	0	0	0	0	0	0	0.025	306	29.971	1	0.327	11	0	0.036	0.036	0.036	0.025	-0.036	-0.106	0.034	0.311	-0.081	-0.239	0.076	0.1216					
	No		732	69.981	0	0	0	0	0	0	NE	715	70.029	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Race	White		879	84.034	0	0	0	0	0	0	0.009	856	83.839	1	0.117	11	0	0.013	0.013	0.013	0.009	-0.013	-0.038	0.012	0.311	-0.049	-0.143	0.046	0.9164					
	Black or African American		114	10.899	0	0	0	0	0	0	NE	113	11.098	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
	Other		38	3.633	0	0	0	0	0	0	NE	31	3.036	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
	Unknown/Not Reported		15	1.434	0	0	0	0	0	0	NE	21	2.057	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Ethnicity	Hispanic or Latino		476	45.507	0	0	0	0	0	0	NE	488	47.796	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.3302			
	Not Hispanic or Latino		567	54.207	0	0	0	0	0	0	0.014	527	51.616	1	0.19	11	0	0.021	0.021	0.021	0.014	-0.021	-0.06	0.019	0.3	-0.063	-0.181	0.056						
	Unknown/not reported		3	0.287	0	0	0	0	0	0	NE	6	0.588	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes		99	9.465	0	0	0	0	0	0	NE	109	10.676	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.7319			
	No		938	89.675	0	0	0	0	0	0	0.008	901	88.247	1	0.111	11	0	0.012	0.012	0.012	0.009	-0.012	-0.036	0.011	0.308	-0.048	-0.139	0.044						
	Unknown/not reported		9	0.86	0	0	0	0	0	0	NE	11	1.077	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Local test result of diagnostic assay for SARS-CoV-2			Positive	13	1.243	0	0	0	0	0	0	0	NE	12	1.175	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	0.9048		
	Negative		896	85.66	0	0	0	0	0	0	0.009	879	86.092	1	0.114	11	0	0.013	0.013	0.013	0.009	-0.013	-0.037	0.012	0.313	-0.048	-0.141	0.045						
	Unavailable		137	13.098	0	0	0	0	0	0	NE	130	12.733	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					
Serology status	Seropositive		235	22.467	0	0	0	0	0	0	NE	222	21.743	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE	NE	0.5817			
	Seronegative		753	71.989	0	0	0	0	0	0	0.01	752	73.653	1	0.133	11	0	0.015	0.015	0.015	0.01	-0.015	-0.043	0.014	0.317	-0.052	-0.153	0.05						
	Unclear serology status		58	5.545	0	0	0	0	0	0	NE	47	4.603	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: 19-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo											Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	43	100	0	0	0	0	0	0,267	0,15	128	100	1	0,781	11	0,086	0,086	0,374	0,115	-0,107	-0,394	0,179	0,459	-0,13	-0,477	0,216			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo					Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients		Patients with Event		Total of days	Time to event		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	1046	100	15	1,434	137	0,131	0,039	0,261	0,116	1021	100	44	4,31	520	0,509	0,105	0,64	0,117	-0,379	-0,596	-0,162	0,0006	-0,15	-0,237	-0,064

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-7-eff-smd-ANDABSEN

POPULATION: Modified Full Analysis Set - Cohort A
ENDPOINT: Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

										Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)										Interaction Test
		Patients in analysis				Patients with Event				Total of days		Statistics		ANCOVA		Patients		Patients with Event		Total of days		Time to event		ANCOVA		Mean Difference				Standardized Mean Difference				p-value						
Name		Level	n	%		n	%		d	mean (d/N)	SE	LSMean	SE		n	%		n	%		d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)							
All		n/a	1046			15			137	0.131		0.039	0.131	0.078	1021			100			44	0.509		0.105	0.509	0.079	-0.378	-0.596	-0.161	0.0006	-0.15	-0.236	-0.064	NE						
Sex	Male		479	45.793	8	1.67	89			0.186	0.076	0.186	0.124	498	48.776	25	5.02	283				0.568	0.154	0.568	0.122	-0.382	-0.725	-0.04	0.0285	-0.14	-0.266	-0.015	0.9498							
	Female		567	54.207	7	1.235	48			0.085	0.033	0.085	0.097	523	51.224	19	3.633	237				0.453	0.142	0.453	0.101	-0.368	-0.644	-0.093	0.0089	-0.159	-0.278	-0.04								
Age	12-17		46	4.398	0	0	0		0	0	0	0	0.056	43	4.212	2	4.651	5				0.116	0.083	0.116	0.058	-0.116	-0.276	0.043	0.1504	-0.305	-0.723	0.113	0.6188							
	18-49		624	59.656	8	1.282	100			0.16	0.061	0.16	0.111	606	59.354	23	3.795	288				0.475	0.147	0.475	0.113	-0.315	-0.625	-0.005	0.0465	-0.114	-0.225	-0.002								
	>=50		376	35.946	7	1.862	37			0.098	0.04	0.098	0.114	372	36.435	19	5.108	227				0.61	0.157	0.61	0.114	-0.512	-0.829	-0.195	0.0016	-0.232	-0.375	-0.088								
Region	US		959	91.683	11	1.147	105			0.109	0.039	0.109	0.081	939	91.969	38	4.047	453				0.482	0.11	0.482	0.082	-0.373	-0.6	-0.146	0.0013	-0.148	-0.238	-0.058	0.8503							
	ex-US		87	8.317	4	4.598	32			0.368	0.194	0.368	0.269	82	8.031	6	7.317	67				0.817	0.34	0.817	0.277	-0.449	-1.211	0.312	0.2457	-0.178	-0.481	0.124								
BMI	BMI < 30 kg/m2		670	64.054	7	1.045	55			0.082	0.033	0.082	0.102	660	64.643	26	3.939	327				0.495	0.142	0.495	0.103	-0.413	-0.697	-0.13	0.0043	-0.157	-0.264	-0.049	0.687							
	BMI >= 30 kg/m2		371	35.468	8	2.156	82			0.221	0.094	0.221	0.12	357	34.966	18	5.042	193				0.541	0.144	0.541	0.122	-0.32	-0.655	0.016	0.0617	-0.139	-0.284	0.007								
Unknown/not reported			5	0.478	0	0	0			0	0	0	NE	4	0.392	0	0	0				0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE							
Number of study subjects in cohort B within a household		0	998	95.411	14	1.403	119			0.119	0.037	0.119	0.08	989	96.866	43	4.348	510				0.516	0.108	0.516	0.08	-0.396	-0.619	-0.174	0.0005	-0.157	-0.245	-0.069	0.4334							
>=1			48	4.589	1	2.083	18			0.375	0.375	0.375	0.333	32	3.134	1	3.125	10				0.313	0.313	0.313	0.407	0.062	-0.984	1.109	0.9057	0.027	-0.423	0.477								
Total household size including the household member(s) not participating this study		2	397	37.954	4	1.008	31			0.078	0.04	0.078	0.124	367	35.945	13	3.542	168				0.458	0.18	0.458	0.128	-0.38	-0.73	-0.03	0.0335	-0.154	-0.296	-0.012	0.6624							
>2			649	62.046	11	1.695	106			0.163	0.058	0.163	0.081	653	63.957	30	4.594	297				0.455	0.098	0.455	0.08	-0.291	-0.515	-0.068	0.0107	-0.142	-0.25	-0.033								
Baseline high risk factor	Yes		314	30.019	6	1.911	75			0.239	0.109	0.239	0.187	306	29.971	18	5.882	245				0.801	0.245	0.801	0.189	-0.562	-1.084	-0.039	0.0351	-0.169	-0.327	-0.012	0.2781							
	No		732	69.981	9	1.23	62			0.085	0.031	0.085	0.077	715	70.029	26	3.636	275				0.385	0.106	0.385	0.078	-0.3	-0.515	-0.085	0.0062	-0.144	-0.247	-0.041								
Race	White		879	84.034	11	1.251	89			0.101	0.034	0.101	0.075	856	83.839	35	4.089	395				0.461	0.103	0.461	0.076	-0.36	-0.571	-0.15	0.0008	-0.161	-0.255	-0.067	0.7826							
	Black or African American		114	10.899	2	1.794	27			0.237	0.191	0.237	0.376	113	11.068	3	2.655	72				0.637	0.499	0.637	0.377	-0.4	-1.449	0.649	0.4528	-0.099	-0.36	0.161								
	Other		38	3.633	1	2.632	17			0.447	0.447	0.447	0.387	31	3.036	2	6.452	12				0.387	0.327	0.387	0.428	0.06	-1.091	1.212	0.9171	0.025	-0.453	0.503								
	Unknown/Not Reported		15	1.434	1	6.667	4			0.267	0.267	0.267	0.872	21	2.057	4	19.048	41				1.952	0.942	1.952	0.737	-1.686	-4.006	0.635	0.1491	-0.488	-1.16	0.184								
Ethnicity	Hispanic or Latino		476	45.507	3	0.63	27			0.057	0.039	0.057	0.106	488	47.796	13	2.664	180				0.369	0.142	0.369	0.105	-0.312	-0.605	-0.02	0.0365	-0.135	-0.261	-0.008	0.5328							
	Not Hispanic or Latino		567	54.207	12	2.116	110			0.194	0.065	0.194	0.113	527	51.616	31	5.882	340				0.645	0.154	0.645	0.117	-0.451	-0.771	-0.132	0.0057	-0.168	-0.286	-0.049								
	Unknown/not reported		3	0.287	0	0	0			0	0	0	0	NE	6	0.588	0	0	0				0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Healthcare worker	Yes		99	9.465	0	0	0			0	0	0	0.081	109	10.676	4	3.67	21				0.193	0.107	0.193	0.078	-0.193	-0.414	0.029	0.0879	-0.237	-0.51	0.036	0.5615							
	No		938	89.675	15	1.599	137			0.146	0.044	0.146	0.087	901	88.247	40	4.44	499				0.554	0.118	0.554	0.088	-0.408	-0.651	-0.165	0.001	-0.154	-0.245	-0.062								
Unknown/not reported			9	0.86	0	0	0			0	0	0	NE	11	1.077	0	0	0				0	0	0	NE	0	NE	NE	NE	NE	NE	NE	NE							
Local test result of diagnostic assay for SARS-CoV-2	Positive		13	1.243	1	7.692	8			0.615	0.615	0.615	0.942	12	1.175	1	8.333	15				1.25	1.25	1.25	0.98	-0.635	-3.447	2.178	0.6451	-0.181	-0.982	0.62	0.729							
	Negative		896	85.66	12	1.339	124			0.138	0.045	0.138	0.083	879	86.092	31	3.527	374				0.425	0.109	0.425	0.083	-0.287	-0.517	-0.057	0.0146	-0.116	-0.209	-0.023								
	Unavailable		137	13.098	2	1.46	5			0.036	0.03	0.036	0.23	130	12.733	12	9.231	131				1.008	0.337	1.008	0.236	-0.971	-1.62	-0.323	0.0035	-0.36	-0.6	-0.12								
Serology status	Seropositive		235	22.467	2	0.851	19			0.081	0.061	0.081	0.091	222	21.743	4	1.802	46				0.207	0.118	0.207	0.094	-0.126	-0.383	0.13	0.3333	-0.091	-0.274	0.093	0.1762							
	Seronegative		753	71.989	12	1.594	100			0.133	0.045	0.133	0.102	752	73.653	39	5.186	472				0.628	0.137	0.628	0.102	-0.495	-0.779	-0.211	0.0006	-0.176	-0.277	-0.075								
	Unclear serology status		58	5.545	1	1.724	18			0.31	0.31	0.31	0.232	47	4.603	1	2.128	2				0.043	0.043	0.043	0.258	0.268	-0.421	0.956	0.4423	0.15	-0.236	0.537								

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas
Output: 19-7-eff-smd-ANDABSEN

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)										
Patients in analysis				Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis				Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference					Standardized Mean Difference	
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL				
All	n/a	43	100	15	34,884	137	3,186	0,838	4,204	1,465	128	100	44	34,375	520	4,063	0,767	5,161	1,123	-0,957	-3,748	1,834	0,499	-0,119	-0,466	0,228				

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Program: t-eff-smd.sas

Output: t9-7-eff-smd-ANDABSEN

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Wirksamkeit

Ergänzende Dokumente

POPULATION: mFAS - Cohort A
ENDPOINT: --
MODEL: --
STUDY: R10933-10987-COV-2069
Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	106	100%	2067	100%	3	100%	2067	100%	2	100%	2067	100%
with <10 Patients per arm ¹	80	75.5%	501	24.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	26	24.5%	1566	75.8%	3	100%	2067	100%	2	100%	2067	100%

¹: ' <10 patients category' if at least one treatment arm has <10 patients.
²: ' >=10 patients ' category if all treatment arms have >=10 patients.
³: Geographical regions: US vs Ex-US (Romania; Republic of Moldova)
⁴: Number of centers, countries, or geographical regions
⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions
⁶: Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm)
⁷: % 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 cut-off: 11MAR21

Program: 0:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2069_CohortA\Analysis_MA\Programs\t3_center.sas
Output: 0:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2069_CohortA\Analysis_MA\Outputs\t3_center.xlsx

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1021)	Casirivimab/Imdevimab (N = 1046)
Age (Years)		
n	1021	1046
Mean	42.49	42.27
SD	15.67	16.06
Median	44.0	43.0
Q1	30.0	28.0
Q3	54.0	55.0
Min	12.0	12.0
Max	92.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	43 (4.2)	46 (4.4)
>=18 to <45	482 (47.2)	503 (48.1)
>=45 to <65	417 (40.8)	402 (38.4)
>=65 to <80	72 (7.1)	92 (8.8)
>=80	7 (0.7)	3 (0.3)
Age Group (Years) [n (%)]		
>=12 to <50	649 (63.6)	670 (64.1)
>=50	372 (36.4)	376 (35.9)
Sex [n (%)]		
Male	498 (48.8)	479 (45.8)
Female	523 (51.2)	567 (54.2)
Race [n (%)]		
White	856 (83.8)	879 (84.0)
Black or African American	113 (11.1)	114 (10.9)
Asian	25 (2.4)	33 (3.2)
American Indian or Alaska Native	4 (0.4)	3 (0.3)
Native Hawaiian or Other Pacific Islander	2 (0.2)	2 (0.2)
Other	21 (2.1)	15 (1.4)
Ethnicity [n (%)]		
Hispanic or Latino	488 (47.8)	476 (45.5)
Not Hispanic or Latino	527 (51.6)	567 (54.2)
Other	6 (0.6)	3 (0.3)
Weight (kg)		
n	1018	1041
Missing	3	5
Mean	81.85	81.21
SD	19.89	19.67
Median	79.1	79.0
Q1	68.0	67.1
Q3	92.0	91.8
Min	35.5	25.8
Max	164.2	180.3
Height (cm)		
n	1017	1042
Missing	4	4
Mean	168.51	168.45
SD	10.08	10.57
Median	167.6	167.6
Q1	161.5	160.4
Q3	175.3	176.0
Min	125.0	71.5
Max	195.6	200.7
BMI (kg/m2)		
n	1017	1041
Missing	4	5
Mean	28.77	28.79
SD	6.30	10.99
Median	27.7	27.6
Q1	24.4	24.0
Q3	31.8	31.7
Min	14.1	7.6
Max	58.2	320.8

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1021)	Casirivimab/Imdevimab (N = 1046)
BMI group (kg/m2) [n (%)]		
Missing	4 (0.4)	5 (0.5)
BMI < 30 kg/m2	660 (64.6)	670 (64.1)
BMI >= 30 kg/m2	357 (35.0)	371 (35.5)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	12 (1.2)	13 (1.2)
Negative	879 (86.1)	896 (85.7)
Unavailable	130 (12.7)	137 (13.1)
Randomization strata: age [n (%)]		
12-17	43 (4.2)	46 (4.4)
18-49	606 (59.4)	624 (59.7)
>=50	372 (36.4)	376 (35.9)
Region [n (%)]		
US	939 (92.0)	959 (91.7)
ex-US	82 (8.0)	87 (8.3)
Country [n (%)]		
Moldova, Republic of	52 (5.1)	51 (4.9)
Romania	30 (2.9)	36 (3.4)
United States of America	939 (92.0)	959 (91.7)
Total household size including the house members not participating this study [n (%)]		
2	367 (35.9)	397 (38.0)
>2	653 (64.0)	649 (62.0)
Others	1 (0.1)	0 (0.0)
Number of study subjects in cohort B within a household [n (%)]		
0	989 (96.9)	998 (95.4)
>=1	32 (3.1)	48 (4.6)
No one wears a mask in home [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	499 (48.9)	554 (53.0)
No	512 (50.1)	484 (46.3)
N/A	9 (0.9)	8 (0.8)
Share a bedroom [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	311 (30.5)	308 (29.4)
No	699 (68.5)	733 (70.1)
N/A	10 (1.0)	5 (0.5)
Share a common room [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	966 (94.6)	988 (94.5)
No	45 (4.4)	53 (5.1)
N/A	9 (0.9)	5 (0.5)
Symptoms in suspected infected person [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	781 (76.5)	800 (76.5)
No	221 (21.6)	231 (22.1)
N/A	18 (1.8)	15 (1.4)
Aware of any treatment [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	347 (34.0)	359 (34.3)
No	654 (64.1)	669 (64.0)
N/A	19 (1.9)	18 (1.7)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	5 (0.5)	3 (0.3)
Yes	238 (23.3)	235 (22.5)
No	778 (76.2)	808 (77.2)

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1021)	Casirivimab/Imdevimab (N = 1046)
Total household members, including index case, who participated at the R10933-10987-COV-2067 [n (%)]		
Missing	26 (2.5)	22 (2.1)
0	846 (82.9)	886 (84.7)
1	144 (14.1)	131 (12.5)
2	4 (0.4)	5 (0.5)
3	1 (0.1)	1 (0.1)
4	0 (0.0)	1 (0.1)
Subject received influenza [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	222 (21.7)	242 (23.1)
No	798 (78.2)	804 (76.9)
Subject been quarantined [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	202 (19.8)	203 (19.4)
No	818 (80.1)	843 (80.6)
First responder [n (%)]		
Missing	11 (1.1)	1 (0.1)
Yes	30 (2.9)	23 (2.2)
No	980 (96.0)	1022 (97.7)
Healthcare worker [n (%)]		
Yes	109 (10.7)	99 (9.5)
No	901 (88.2)	938 (89.7)
Unknown/not reported	11 (1.1)	9 (0.9)
Contact with a stranger [n (%)]		
Missing	2 (0.2)	0 (0.0)
Yes	344 (33.7)	343 (32.8)
No	675 (66.1)	703 (67.2)
Serology status [n (%)]		
Seropositive	222 (21.7)	235 (22.5)
Seronegative	752 (73.7)	753 (72.0)
Unclear serology status	47 (4.6)	58 (5.5)
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	10 (1.0)	16 (1.5)
-4	0 (0.0)	1 (0.1)
-1	1 (0.1)	2 (0.2)
0	1010 (98.9)	1027 (98.2)
Baseline high risk factor [n (%)]		
Yes	306 (30.0)	314 (30.0)
No	715 (70.0)	732 (70.0)

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-A

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 752)	Casirivimab/Imdevimab (N = 753)
Age (Years)		
n	752	753
Mean	42.69	43.17
SD	15.58	16.32
Median	44.0	44.0
Q1	31.0	30.0
Q3	54.0	55.0
Min	12.0	12.0
Max	92.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	34 (4.5)	34 (4.5)
>=18 to <45	346 (46.0)	346 (45.9)
>=45 to <65	317 (42.2)	297 (39.4)
>=65 to <80	51 (6.8)	73 (9.7)
>=80	4 (0.5)	3 (0.4)
Age Group (Years) [n (%)]		
>=12 to <50	472 (62.8)	459 (61.0)
>=50	280 (37.2)	294 (39.0)
Sex [n (%)]		
Male	358 (47.6)	333 (44.2)
Female	394 (52.4)	420 (55.8)
Race [n (%)]		
White	635 (84.4)	653 (86.7)
Black or African American	78 (10.4)	62 (8.2)
Asian	19 (2.5)	23 (3.1)
American Indian or Alaska Native	4 (0.5)	3 (0.4)
Native Hawaiian or Other Pacific Islander	2 (0.3)	1 (0.1)
Other	14 (1.9)	11 (1.5)
Ethnicity [n (%)]		
Hispanic or Latino	319 (42.4)	291 (38.6)
Not Hispanic or Latino	428 (56.9)	459 (61.0)
Other	5 (0.7)	3 (0.4)
Weight (kg)		
n	752	748
Missing	0	5
Mean	81.25	81.30
SD	19.72	19.92
Median	78.2	78.9
Q1	67.9	66.7
Q3	90.7	92.1
Min	40.4	25.8
Max	164.2	180.3
Height (cm)		
n	751	749
Missing	1	4
Mean	168.68	168.55
SD	10.07	10.75
Median	168.0	167.8
Q1	162.0	161.0
Q3	175.3	176.0
Min	125.0	71.5
Max	195.6	200.7
BMI (kg/m2)		
n	751	748
Missing	1	5
Mean	28.51	28.86
SD	6.28	12.35
Median	27.5	27.4
Q1	24.1	24.1
Q3	31.6	31.7
Min	14.1	7.6
Max	58.2	320.8

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-A

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 752)	Casirivimab/Imdevimab (N = 753)
BMI group (kg/m2) [n (%)]		
Missing	1 (0.1)	5 (0.7)
BMI < 30 kg/m2	501 (66.6)	487 (64.7)
BMI >= 30 kg/m2	250 (33.2)	261 (34.7)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	6 (0.8)	8 (1.1)
Negative	644 (85.6)	638 (84.7)
Unavailable	102 (13.6)	107 (14.2)
Randomization strata: age [n (%)]		
12-17	34 (4.5)	34 (4.5)
18-49	438 (58.2)	425 (56.4)
>=50	280 (37.2)	294 (39.0)
Region [n (%)]		
US	682 (90.7)	689 (91.5)
ex-US	70 (9.3)	64 (8.5)
Country [n (%)]		
Moldova, Republic of	44 (5.9)	35 (4.6)
Romania	26 (3.5)	29 (3.9)
United States of America	682 (90.7)	689 (91.5)
Total household size including the house members not participating this study [n (%)]		
2	260 (34.6)	281 (37.3)
>2	491 (65.3)	472 (62.7)
Others	1 (0.1)	0 (0.0)
Number of study subjects in cohort B within a household [n (%)]		
0	726 (96.5)	718 (95.4)
>=1	26 (3.5)	35 (4.6)
No one wears a mask in home [n (%)]		
Yes	358 (47.6)	391 (51.9)
No	385 (51.2)	354 (47.0)
N/A	9 (1.2)	8 (1.1)
Share a bedroom [n (%)]		
Yes	231 (30.7)	221 (29.3)
No	512 (68.1)	527 (70.0)
N/A	9 (1.2)	5 (0.7)
Share a common room [n (%)]		
Yes	711 (94.5)	720 (95.6)
No	33 (4.4)	28 (3.7)
N/A	8 (1.1)	5 (0.7)
Symptoms in suspected infected person [n (%)]		
Yes	572 (76.1)	577 (76.6)
No	165 (21.9)	164 (21.8)
N/A	15 (2.0)	12 (1.6)
Aware of any treatment [n (%)]		
Yes	261 (34.7)	266 (35.3)
No	475 (63.2)	474 (62.9)
N/A	16 (2.1)	13 (1.7)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	5 (0.7)	3 (0.4)
Yes	186 (24.7)	187 (24.8)
No	561 (74.6)	563 (74.8)

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-A

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 752)	Casirivimab/Imdevimab (N = 753)
Total household members, including index case, who participated the R10933-10987-COV-2067 [n (%)]		
Missing	19 (2.5)	14 (1.9)
0	614 (81.6)	624 (82.9)
1	114 (15.2)	110 (14.6)
2	4 (0.5)	3 (0.4)
3	1 (0.1)	1 (0.1)
4	0 (0.0)	1 (0.1)
Subject received influenza [n (%)]		
Yes	179 (23.8)	197 (26.2)
No	573 (76.2)	556 (73.8)
Subject been quarantined [n (%)]		
Yes	160 (21.3)	167 (22.2)
No	592 (78.7)	586 (77.8)
First responder [n (%)]		
Missing	9 (1.2)	0 (0.0)
Yes	25 (3.3)	20 (2.7)
No	718 (95.5)	733 (97.3)
Healthcare worker [n (%)]		
Yes	80 (10.6)	73 (9.7)
No	666 (88.6)	673 (89.4)
Unknown/not reported	6 (0.8)	7 (0.9)
Contact with a stranger [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	252 (33.5)	250 (33.2)
No	499 (66.4)	503 (66.8)
Serology status [n (%)]		
Seronegative	752 (100.0)	753 (100.0)
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	6 (0.8)	13 (1.7)
-4	0 (0.0)	1 (0.1)
-1	1 (0.1)	1 (0.1)
0	745 (99.1)	738 (98.0)
Baseline high risk factor [n (%)]		
Yes	221 (29.4)	238 (31.6)
No	531 (70.6)	515 (68.4)

Table 5.1. Summary of Overall Patient Disposition
Modified Full Analysis Set - Cohort A

	Placebo (N=1021)	Casirivimab/Imdevimab (N=1046)
Randomized patients	1021 (100%)	1046 (100%)
Randomized but not treated	1 (<0.1%)	2 (0.2%)
Randomized and treated	1020 (99.9%)	1044 (99.8%)
Complete the efficacy assessment period(EAP) (as derived)	1018 (99.7%)	1038 (99.2%)
Complete the end of study follow-up visit (as per CRF)	0	0
Did not complete the end of study follow-up visit	1020 (99.9%)	1044 (99.8%)
Subjects discontinued from the study during EAP	2 (0.2%)	6 (0.6%)
Reason for subjects discontinuing from the study during EAP		
Adverse Event	0	0
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	0	0
Lost To Follow-Up	1 (<0.1%)	2 (0.2%)
Subject Decision	1 (<0.1%)	4 (0.4%)

Clinical cut-off: 11MAR21

Table 14.1.1 Disposition of Screened Subjects
All Screened Subjects

	Total (N=3096)
Number of Subjects Screened	3096
Randomized Subject	3029 (97.8%)
Subjects treated but not randomized	0
Subjects randomized but not treated	27 (0.9%)
Screen phase discontinuation	83 (2.7%)
Adverse Event	1 (<0.1%)
Screen Failure	65 (2.1%)
Subject Decision	9 (0.3%)
Lost To Follow-Up	0
Death	0
Sponsor Request	0
Other	8 (0.3%)
Screen phase discontinuation and randomized	16 (0.5%)
Adverse Event	0
Screen Failure	5 (0.2%)
Subject Decision	5 (0.2%)
Lost To Follow-Up	0
Death	0
Sponsor Request	0

Note: For the first step analysis, all subjects randomized by 28Jan2021 are included. The cutoff date is 11Mar2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: % calculated using the number of subjects screened as denominator.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA_rand28Jan/Analysis_CSR/Programs/TFL/Generated/t_1011_scr.sas (bryan.zhu 04JUN2021 14:41 SAS Linux 9.4)

Table 14.1.1 Disposition of Screened Subjects
All Screened Subjects

	Total (N=3096)
Screen phase discontinuation and randomized	
Other	6 (0.2%)

Note: For the first step analysis, all subjects randomized by 28Jan2021 are included. The cutoff date is 11Mar2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: % calculated using the number of subjects screened as denominator.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA_rand28Jan/Analysis_CSR/Programs/TFL/Generated/t_1011_scr.sas (bryan.zhu 04JUN2021 14:41 SAS Linux 9.4)

Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set - Cohort A

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1021)	Casirivimab/Imdevimab (N = 1046)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Missing	1	2
Median	94.0	97.0

Table 15: Summary of Concomitant Medications Reported During TEEAP (SAF-A)

ATC Level 2 Preferred Term ¹	Seronegative		Seropositive		Undetermined	
	Placebo (N=1067)	R10933+ R10987 (N=1028)	Placebo (N=296)	R10933+ R10987 (N=337)	Placebo (N=65)	R10933+ R10987 (N=74)
Subjects using at least one concomitant medication	546 (51.2%)	534 (51.9%)	101 (34.1%)	108 (32.0%)	34 (52.3%)	35 (47.3%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM						
LISINOPRIL	65 (6.1%)	50 (4.9%)	9 (3.0%)	17 (5.0%)	6 (9.2%)	2 (2.7%)
LOSARTAN	30 (2.8%)	33 (3.2%)	11 (3.7%)	6 (1.8%)	1 (1.5%)	1 (1.4%)
LIPID MODIFYING AGENTS						
ATORVASTATIN	33 (3.1%)	40 (3.9%)	7 (2.4%)	6 (1.8%)	3 (4.6%)	2 (2.7%)
ROSUVASTATIN	14 (1.3%)	25 (2.4%)	2 (0.7%)	5 (1.5%)	3 (4.6%)	0
VITAMINS						
VITAMIN D NOS	46 (4.3%)	37 (3.6%)	3 (1.0%)	5 (1.5%)	3 (4.6%)	3 (4.1%)
COLECALCIFEROL	21 (2.0%)	14 (1.4%)	1 (0.3%)	2 (0.6%)	2 (3.1%)	1 (1.4%)
VITAMINS NOS	29 (2.7%)	36 (3.5%)	3 (1.0%)	6 (1.8%)	1 (1.5%)	1 (1.4%)
ASCORBIC ACID	31 (2.9%)	26 (2.5%)	3 (1.0%)	7 (2.1%)	3 (4.6%)	0
ANALGESICS						
PARACETAMOL	42 (3.9%)	20 (1.9%)	4 (1.4%)	5 (1.5%)	2 (3.1%)	1 (1.4%)
DRUGS USED IN DIABETES						
METFORMIN	55 (5.2%)	48 (4.7%)	12 (4.1%)	15 (4.5%)	4 (6.2%)	6 (8.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES						
SALBUTAMOL	29 (2.7%)	32 (3.1%)	4 (1.4%)	1 (0.3%)	3 (4.6%)	3 (4.1%)
THYROID THERAPY						
LEVOTHYROXINE	29 (2.7%)	32 (3.1%)	6 (2.0%)	7 (2.1%)	1 (1.5%)	1 (1.4%)
LEVOTHYROXINE SODIUM	18 (1.7%)	22 (2.1%)	2 (0.7%)	1 (0.3%)	2 (3.1%)	1 (1.4%)
DIURETICS						
HYDROCHLOROTHIAZIDE	29 (2.7%)	29 (2.8%)	9 (3.0%)	3 (0.9%)	4 (6.2%)	2 (2.7%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS						
IBUPROFEN	40 (3.7%)	22 (2.1%)	5 (1.7%)	4 (1.2%)	1 (1.5%)	6 (8.1%)
BETA BLOCKING AGENTS						

ATC Level 2 Preferred Term ¹	Seronegative		Seropositive		Undetermined	
	Placebo (N=1067)	R10933+ R10987 (N=1028)	Placebo (N=296)	R10933+ R10987 (N=337)	Placebo (N=65)	R10933+ R10987 (N=74)
METOPROLOL	23 (2.2%)	18 (1.8%)	5 (1.7%)	5 (1.5%)	1 (1.5%)	3 (4.1%)
DRUGS FOR ACID RELATED DISORDERS						
OMEPRazole	25 (2.3%)	25 (2.4%)	6 (2.0%)	4 (1.2%)	5 (7.7%)	2 (2.7%)
ANTITHROMBOTIC AGENTS						
ACETYLSALICYLIC ACID	30 (2.8%)	35 (3.4%)	9 (3.0%)	12 (3.6%)	3 (4.6%)	5 (6.8%)
CALCIUM CHANNEL BLOCKERS						
AMLODIPINE	29 (2.7%)	22 (2.1%)	9 (3.0%)	8 (2.4%)	5 (7.7%)	1 (1.4%)

Note: Data from all treated participants by the 01Jul2021 cutoff date are included.

TEEAP is defined as the day from first dose of study drug to 28 days after the last dose of study drug.

1. Concomitant medications are shown for PTs >2% in either treatment group in baseline-seronegative participants

Source: PTT 14.4.6.2.1

Table 16: Summary of Concomitant Medications Reported During TEEAP (SAF-B)

ATC Level 2 Preferred Term ¹	Seronegative		Seropositive		Other	
	Placebo (N=114)	R10933+ R10987 (N=109)	Placebo (N=43)	R10933+ R10987 (N=48)	Placebo (N=13)	R10933+ R10987 (N=8)
Subjects using at least one concomitant medication	81 (71.1%)	64 (58.7%)	18 (41.9%)	19 (39.6%)	12 (92.3%)	4 (50.0%)
VITAMINS						
COLECALCIFEROL	5 (4.4%)	7 (6.4%)	0	1 (2.1%)	1 (7.7%)	0
VITAMIN D NOS	8 (7.0%)	5 (4.6%)	1 (2.3%)	0	1 (7.7%)	1 (12.5%)
ERGOCALCIFEROL	1 (0.9%)	2 (1.8%)	0	0	0	0
ASCORBIC ACID	8 (7.0%)	8 (7.3%)	2 (4.7%)	0	0	0
ANALGESICS						
PARACETAMOL	17 (14.9%)	11 (10.1%)	2 (4.7%)	4 (8.3%)	3 (23.1%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS						
IBUPROFEN	6 (5.3%)	4 (3.7%)	0	2 (4.2%)	2 (15.4%)	0
MELOXICAM	1 (0.9%)	3 (2.8%)	1 (2.3%)	0	0	0
PSYCHOANALEPTICS						
LISDEXAMFETAMINE MESILATE	1 (0.9%)	3 (2.8%)	0	0	0	0
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE	3 (2.6%)	0	0	0	0	0
SERTRALINE HYDROCHLORIDE	3 (2.6%)	0	0	0	0	0
ANTITHROMBOTIC AGENTS						
ACETYLSALICYLIC ACID	8 (7.0%)	6 (5.5%)	0	2 (4.2%)	2 (15.4%)	0
BETA BLOCKING AGENTS						
METOPROLOL	1 (0.9%)	5 (4.6%)	0	1 (2.1%)	0	0
LIPID MODIFYING AGENTS						
ATORVASTATIN	8 (7.0%)	4 (3.7%)	1 (2.3%)	0	1 (7.7%)	0
PSYCHOLEPTICS						
MELATONIN	3 (2.6%)	5 (4.6%)	1 (2.3%)	0	0	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM						
LISINOPRIL	3 (2.6%)	3 (2.8%)	1 (2.3%)	2 (4.2%)	1 (7.7%)	0
CALCIUM CHANNEL BLOCKERS						
AMLODIPINE	6 (5.3%)	4 (3.7%)	0	1 (2.1%)	0	0
AMLODIPINE BESILATE	0	4 (3.7%)	0	0	0	0
DRUGS USED IN DIABETES						
METFORMIN	7 (6.1%)	6 (5.5%)	2 (4.7%)	1 (2.1%)	1 (7.7%)	0
INSULIN LISPRO	3 (2.6%)	0	0	0	0	0

ATC Level 2 Preferred Term ¹	Seronegative		Seropositive		Other	
	Placebo (N=114)	R10933+ R10987 (N=109)	Placebo (N=43)	R10933+ R10987 (N=48)	Placebo (N=13)	R10933+ R10987 (N=8)
ANTIHISTAMINES FOR SYSTEMIC USE						
LORATADINE	4 (3.5%)	2 (1.8%)	0	0	0	0
MINERAL SUPPLEMENTS						
ZINC	6 (5.3%)	2 (1.8%)	0	0	0	0
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM						
MEDROXYPROGESTERONE ACETATE	2 (1.8%)	0	0	0	0	0
DRUGS FOR ACID RELATED DISORDERS						
OMEPRAZOLE	6 (5.3%)	1 (0.9%)	2 (4.7%)	1 (2.1%)	0	0
PANTOPRAZOLE	3 (2.6%)	1 (0.9%)	1 (2.3%)	0	0	0
FAMOTIDINE	3 (2.6%)	2 (1.8%)	0	0	1 (7.7%)	0
NASAL PREPARATIONS						
FLUTICASONE PROPIONATE	1 (0.9%)	3 (2.8%)	0	0	0	0
THYROID THERAPY						
LEVOTHYROXINE	5 (4.4%)	2 (1.8%)	1 (2.3%)	1 (2.1%)	0	0
ANTIBACTERIALS FOR SYSTEMIC USE						
AZITHROMYCIN	4 (3.5%)	1 (0.9%)	0	1 (2.1%)	0	0
AMOXICILLIN	3 (2.6%)	0	0	0	0	0
DOXYCYCLINE	3 (2.6%)	0	0	0	0	0
CORTICOSTEROIDS FOR SYSTEMIC USE						
DEXAMETHASONE	5 (4.4%)	1 (0.9%)	0	1 (2.1%)	0	0
PREDNISONE	4 (3.5%)	1 (0.9%)	0	0	0	0
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS						
HYDROCORTISONE	3 (2.6%)	0	0	0	0	0
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES						
SALBUTAMOL	7 (6.1%)	1 (0.9%)	2 (4.7%)	0	1 (7.7%)	0

Note: Data from all treated participants by the 01Jul2021cutoff date are included.

TEEAP is defined as the day from first dose of study drug to 28 days after the last dose of study drug.

1. Concomitant medications are shown for PTs >2% in either treatment group in baseline-seronegative participants

Source: PTT 14.4.6.2.4

Table 1: Demographics and Baseline Characteristics by Baseline Serostatus (Cohort A)

	SERONEGATIVE			SEROPOSITIVE			OTHER*		
Parameter	Placebo (n=223)	REGEN-COV (n=186)	Total (n=409)	Placebo (n=46)	REGEN-COV (n=60)	Total (n=106)	Placebo (n=18)	REGEN-COV (n=21)	Total (n=39)
Mean age years (SD)	43.5 (15.79)	42.6 (15.63)	43.1 (15.71)	43.4 (19.08)	41.8 (17.92)	42.5 (18.36)	47.1 (13.28)	48.0 (19.76)	47.6 (16.87)
% ≥50 years	86 (38.6%)	74 (39.8%)	160 (39.1%)	16 (34.8%)	19 (31.7%)	35 (33.0%)	7 (38.9%)	10 (47.6%)	17 (43.6%)
% Female	116 (52.0%)	106 (57.0%)	222 (54.3%)	23 (50.0%)	27 (45.0%)	50 (47.2%)	11 (61.1%)	12 (57.1%)	23 (59.0%)
% White	174 (78.0%)	146 (78.5%)	320 (78.2%)	38 (82.6%)	47 (78.3%)	85 (80.2%)	17 (94.4%)	12 (57.1%)	29 (74.4%)
% Black	31 (13.9%)	21 (11.3%)	52 (12.7%)	6 (13.0%)	11 (18.3%)	17 (16.0%)	1 (5.6%)	3 (14.3%)	4 (10.3%)
% Hispanic or Latino Ethnicity	103 (46.2%)	96 (51.6%)	199 (48.7%)	33 (71.7%)	34 (56.7%)	67 (63.2%)	5 (27.8%)	10 (47.6%)	15 (38.5%)
% BMI >30 kg/m ²	85 (38.1%)	74 (39.8%)	159 (38.9%)	15 (32.6%)	16 (26.7%)	31 (29.2%)	9 (50.0%)	7 (33.3%)	16 (41.0%)

BMI, body mass index; REGN10933, casirivimab; REGN10987, imdevimab; SD, standard deviation

*Other indicates indeterminate serostatus (neither seronegative nor seropositive).

Source: Table 14.4.1.1

Table 2: Summary of All SARS-CoV-2 Infections Among Subjects Who Were Seronegative at Baseline (Primary Endpoint)

Endpoint	Placebo n/N (%)	REGEN-COV n/N (%)	Relative Risk (95% CI) [REGEN-COV/PBO]	Odds Ratio (95% CI) [REGEN-COV/PBO]
PCR + All Infections (All Swab Types)	23/223 (10.3%)	10/186 (5.4%)	0.52 (0.25, 1.07)	0.49 (0.20, 1.12) [†]
PCR + All Infections (NP Swab Only)	21/212 (9.9%)	9/179 (5.0%)	0.51 (0.24, 1.08)	0.48 (0.19, 1.13) [†]

CI, confidence interval; PBO, placebo; REGEN-COV, casirivimab+imdevimab; PCR, polymerase chain reaction

Exploratory/ad hoc p-values using Fisher's Exact Test: [†]p < 0.10 (but >0.05); *p < 0.05; **p < 0.01; ***p < 0.001.

Source: Tables 14.6.1.2.1, Table 14.6.1.2.1a.

Table 3: Summary of Symptomatic SARS-CoV-2 Infections Among Subjects Who Were Seronegative at Baseline (Key Secondary Endpoint)

Endpoint	Placebo n/N (%)	REGEN-COV n/N (%)	Odds Ratio (95% CI) [REGEN-COV/PBO]
Broad term ¹ symptomatic infections	8/223 (3.6%)	0/186 (0%)	0 (0, 0.69)**
CDC term ² symptomatic infections	7/223 (3.1%)	0/186 (0%)	0 (0, 0.82)*
Strict term ³ symptomatic infections	5/223 (2.2%)	0/186 (0%)	0 (0, 1.29) [†]

CDC, US Centers for Disease Control and Prevention; CI, confidence interval; PBO, placebo; REGEN-COV,

casirivimab+imdevimab; RT-qPCR, reverse transcription polymerase chain reaction

Exploratory/ad hoc p-values using Fisher's Exact Test: [†]p < 0.10 (but >0.05); *p < 0.05; **p < 0.01; ***p < 0.001. Based on observed data without any imputations applied.

¹Broad term symptoms: Feverish, Sore throat, Cough, Shortness of breath/difficulty breathing, Chills, Nausea, Vomiting, Diarrhea, Headache, Red or watery eyes, Body aches such as muscle pain or joint pain, Loss of taste/smell, Fatigue, Loss of appetite or poor eating/feeding, Confusion, Dizziness, Pressure/tightness in chest, Chest pain, Stomachache, Rash, Sneezing, Runny nose, Sputum/phlegm.

²CDC defined symptoms: at least 2 of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, nausea or vomiting, diarrhea, fatigue, congestion or runny nose OR Any 1 of the following symptoms: cough, shortness of breath, difficulty breathing, new olfactory disorder, new taste disorder OR Severe respiratory illness with at least 1 of the following, clinical or radiographic evidence of pneumonia, acute respiratory distress syndrome (ARDS).

³Strict term symptoms: fever PLUS ≥1 respiratory symptoms (sore throat, cough, shortness of breath), OR 2 respiratory symptoms, OR 1 respiratory symptom PLUS ≥2 non-respiratory symptoms (chills, nausea, vomiting, diarrhea, headache, conjunctivitis, myalgia, arthralgia, loss of taste or smell, fatigue or general malaise).

Source: Table 14.6.2.1.9a, Table 14.6.2.1.15a, and Table 14.6.2.1.12a

Table 5: Measures of Virus Transmission Potential (FAS-A)

Endpoint	Placebo	REGEN-COV
Symptomatic weeks ¹	21 weeks (Mean: 2.6 weeks)	0
Viral shedding weeks	44 weeks (Mean: 2.1 weeks)	9 (Mean: 1.0 weeks)
High viral shedding weeks ²	22 weeks (Mean 1.7 weeks)	0

FAS-A, full analysis set for cohort A; REGN10933, casirivimab; REGN10987, imdevimab

¹Symptoms COVID-19 as defined by broad symptoms.

²>10⁴ copies/mL.

Source: Table 14.6.2.1.68, Table 14.6.2.5.66, Table 14.6.2.5.67.

Table 6: SARS-CoV-2 Viral Loads as Assessed by RT-qPCR in the First Positive Nasopharyngeal Swab

Viral Load by RT-qPCR at Time of Infection	Placebo n/N (%) (n=212)	REGEN-COV n/N (%)	Relative Risk (95% CI) [REGEN-COV/PBO]	Odds Ratio (95% CI) [REGEN-COV/PBO]
All	21/212 (9.9%)	9/179 (5.0%)	0.51 (0.24, 1.08)	0.48 (0.19, 1.13) [†]
>10 ³ copies/mL	19/212 (9.0%)	8/179 (4.5%)	0.50 (0.22, 1.11)	0.48 (0.18, 1.17)
>10 ⁴ copies/mL	13/212 (6.1%)	0/179 (0%)	0	0 (0, 0.37) ***
>10 ⁵ copies/mL	12/212 (5.7%)	0/179 (0%)	0	0 (0, 0.41) ***

CI, confidence interval; PBO, placebo; REGEN-COV, casirivimab+imdevimab; RT-qPCR, reverse transcription polymerase chain reaction

Exploratory/ad hoc p-values using Fisher's Exact Test: [†]p < 0.10 (but >0.05); *p < 0.05; **p < 0.01; ***p < 0.001.

Data from subjects with available NP swab samples only.

Source: Table 14.6.2.5.40

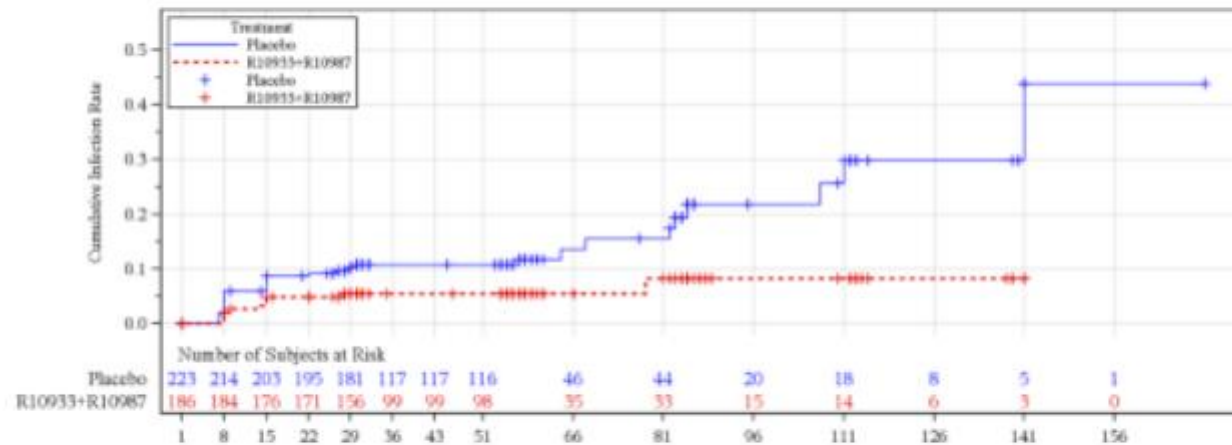
Table 9: Proportion of Subjects Who Have a RT-qPCR-Confirmed SARS-CoV-2 Infection Based on Nasopharyngeal Swabs (Either Symptomatic or Asymptomatic) During the Efficacy Assessment Period, by the State of Household Members Receiving REGEN-COV in COV-2067: Raw Data Descriptive (FAS-A).

State of Index Case in the Household Members With the 2069 Subject	Placebo (n=212) n/N1 (%)	REGEN-COV (n=179) n/N1 (%)
Index Case Treated with REGEN-COV in 2067	1/17 (5.9%)	0/13 (0.0%)
95% CI	0.1%, 28.7%	0.0%, 24.7%
Index Case Not in 2067 or Not Treated with REGEN-COV in 2067	18/158 (11.4%)	7/143 (4.9%)
95% CI	6.9%, 17.4%	2.0%, 9.8%
Index Case Information Not available	2/37 (5.4%)	2/23 (8.7%)
95% CI	0.7%, 18.2%	1.1%, 28.0%

2067, study R10933-10987-COV-2067; CI, confidence interval; FAS-A, full analysis set for cohort A; REGEN-COV, casirivimab+imdevimab

Source: 14.6.2.5.31

Figure 5: Kaplan-Meier Cumulative Incidence Curve of Time to First RT-qPCR Confirmed SARS-CoV-2 Infection (Either Asymptomatic or Symptomatic) Long Term: Raw Data Descriptive (FAS-A)



FAS-A, full analysis set for cohort A; R10933, casirivimab; R10987, imdevimab

Based on observed data without any imputations applied. 95% exact confidence interval shown.

Source: Figure 14.6.1.2.3x

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

Hauptdokumente

POPULATION: Safety - Cohort A
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
All	n/a	1311	100	265	20,2	1306	100	379	29	0,62	Algorithm converged.	0,52	0,74	-8,806	Algorithm converged.	-12,09	-5,52	0,7	Algorithm converged.	0,61	0,8	<0.0001		1,44	Algorithm converged.	1,25	1,65							
Sex	Male	601	45,8	118	19,6	633	48,5	180	28,4	0,61	Algorithm converged.	0,47	0,8	-8,802	Algorithm converged.	-13,54	-4,07	0,69	Algorithm converged.	0,56	0,85	0,0003	0,9205	1,45	Algorithm converged.	1,18	1,78							
	Female	710	54,2	147	20,7	673	51,5	199	29,6	0,62	Algorithm converged.	0,49	0,8	-8,865	Algorithm converged.	-13,42	-4,31	0,7	Algorithm converged.	0,58	0,84	0,0001		1,43	Algorithm converged.	1,19	1,72							
Age	12-17	45	3,4	8	17,8	43	3,3	14	32,6	0,45	Algorithm converged.	0,17	1,21	-14,78	Algorithm converged.	-32,7	3,13	0,55	Algorithm converged.	0,25	1,17	0,1115	0,3735	1,83	Algorithm converged.	0,86	3,92							
	18-49	787	60	170	21,6	782	59,9	225	28,8	0,68	Algorithm converged.	0,54	0,86	-7,171	Algorithm converged.	-11,45	-2,89	0,75	Algorithm converged.	0,63	0,89	0,0011	-2,33	1,33	Algorithm converged.	1,12	1,58							
	>=50	479	36,5	87	18,2	481	36,8	140	29,1	0,54	Algorithm converged.	0,4	0,73	-10,943	Algorithm converged.	-16,27	-5,61	0,62	Algorithm converged.	0,49	0,79	<0.0001		1,6	Algorithm converged.	1,27	2,03							
Region	US	1220	93,1	254	20,8	1217	93,2	356	29,3	0,64	Algorithm converged.	0,53	0,77	-8,433	Algorithm converged.	-11,86	-5,01	0,71	Algorithm converged.	0,62	0,82	<0.0001	0,2074	1,41	Algorithm converged.	1,22	1,62							
	ex-US	91	6,9	11	12,1	89	6,8	23	25,8	0,39	Algorithm converged.	0,18	0,87	-13,755	Algorithm converged.	-25,05	-2,46	0,47	Algorithm converged.	0,24	0,9	0,0187		2,14	Algorithm converged.	1,11	4,12							

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-1-ae-raw-anyae

POPULATION: Safety - Cohort A

ENDPOINT: Any AEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1311	100	210	16	1306	100	215	16,5	0,97	Algorithm converged.	0,79	1,19	-0,444	Algorithm converged.	-3,27	2,38	0,97	Algorithm converged.	0,82	1,16	0,7581		1,03		Algorithm converged.	0,86	1,22							
Sex	Male	601	45,8	89	14,8	633	48,5	100	15,8	0,93	Algorithm converged.	0,68	1,26	-0,989	Algorithm converged.	-5,01	3,03	0,94	Algorithm converged.	0,72	1,22	0,6298	0,7291	1,07		Algorithm converged.	0,82	1,39							
	Female	710	54,2	121	17	673	51,5	115	17,1	1	Algorithm converged.	0,75	1,32	-0,045	Algorithm converged.	-4,01	3,92	1	Algorithm converged.	0,79	1,26	0,9821		1		Algorithm converged.	0,79	1,27							
Age	12-17	45	3,4	6	13,3	43	3,3	8	18,6	0,67	Algorithm converged.	0,21	2,13	-5,271	Algorithm converged.	-20,57	10,02	0,72	Algorithm converged.	0,27	1,9	0,5016	0,4114	1,4		Algorithm converged.	0,53	3,69							
	18-49	787	60	137	17,4	782	59,9	128	16,4	1,08	Algorithm converged.	0,83	1,4	1,04	Algorithm converged.	-2,67	4,75	1,06	Algorithm converged.	0,85	1,32	0,5828		0,94		Algorithm converged.	0,75	1,17							
	>=50	479	36,5	67	14	481	36,8	79	16,4	0,83	Algorithm converged.	0,58	1,18	-2,437	Algorithm converged.	-6,98	2,1	0,85	Algorithm converged.	0,63	1,15	0,2934		1,17		Algorithm converged.	0,87	1,58							
Region	US	1220	93,1	202	16,6	1217	93,2	207	17	0,97	Algorithm converged.	0,78	1,2	-0,452	Algorithm converged.	-3,42	2,52	0,97	Algorithm converged.	0,82	1,16	0,7655	0,9923	1,03		Algorithm converged.	0,86	1,23							
	ex-US	91	6,9	8	8,8	89	6,8	8	9	0,98	Algorithm converged.	0,35	2,72	-0,198	Algorithm converged.	-8,51	8,12	0,98	Algorithm converged.	0,38	2,49	0,963		1,02		Algorithm converged.	0,4	2,61							

Test for action based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas

Output: t12-2-ae-raw-anyaenr

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
Patients				Event								Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1311	100	11	0,8	1306	100	22	1,7	0,49		Algorithm converged.	0,24	1,02	-0,845		Algorithm converged.	-1,7	0,01	0,5		Algorithm converged.	0,24	1,02	0,0527		2,01		Algorithm converged.	0,98	4,12
Sex	Male	601	45,8	5	0,8	633	48,5	9	1,4	0,58		Algorithm converged.	0,19	1,75	-0,59		Algorithm converged.	-1,76	0,58	0,59		Algorithm converged.	0,2	1,74	0,4235	0,695	1,71		Algorithm converged.	0,58	5,07
	Female	710	54,2	6	0,8	673	51,5	13	1,9	0,43		Algorithm converged.	0,16	1,15	-1,087		Algorithm converged.	-2,33	0,15	0,44		Algorithm converged.	0,17	1,14	0,0828		2,29		Algorithm converged.	0,87	5,98
Age	12-17	45	3,4	0	0	43	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,7653	NE	*	Algorithm not converged.	NE	NE
	18-49	787	60	6	0,8	782	59,9	9	1,2	0,66		Algorithm converged.	0,23	1,86	-0,389		Algorithm converged.	-1,35	0,57	0,66		Algorithm converged.	0,24	1,85	0,4292		1,51		Algorithm converged.	0,54	4,22
	>=50	479	36,5	5	1	481	36,8	13	2,7	0,38		Algorithm converged.	0,13	1,07	-1,659		Algorithm converged.	-3,37	0,05	0,39		Algorithm converged.	0,14	1,07	0,0932		2,59		Algorithm converged.	0,93	7,21
Region	US	1220	93,1	11	0,9	1217	93,2	19	1,6	0,57		Algorithm converged.	0,27	1,21	-0,66		Algorithm converged.	-1,54	0,22	0,58		Algorithm converged.	0,28	1,21	0,1399	0,1039	1,73		Algorithm converged.	0,83	3,62
	ex-US	91	6,9	0	0	89	6,8	3	3,4	0		Algorithm converged.	NE	NE	-3,371		Algorithm converged.	-7,12	0,38	NE	*	Algorithm not converged.	NE	NE	0,1188		NE	*	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-3-ae-raw-toxgrt3

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade >=3 (excluding disease related events)
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1311	100	11	0,8	1306	100	17	1,3	0,64	Algorithm converged.	0,3	1,38	-0,463	Algorithm converged.	-1,25	0,33	0,64	Algorithm converged.	0,3	1,37	0,2502		1,55	Algorithm converged.	0,73	3,3								
Sex	Male	601	45,8	5	0,8	633	48,5	6	0,9	0,88	Algorithm converged.	0,27	2,89	-0,116	Algorithm converged.	-1,16	0,93	0,88	Algorithm converged.	0,27	2,86	1	0,5009	1,14	Algorithm converged.	0,35	3,71								
	Female	710	54,2	6	0,8	673	51,5	11	1,6	0,51	Algorithm converged.	0,19	1,39	-0,789	Algorithm converged.	-1,96	0,38	0,52	Algorithm converged.	0,19	1,39	0,1831		1,93	Algorithm converged.	0,72	5,2								
Age	12-17	45	3,4	0	0	43	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	0,9319	NE	*	Algorithm not converged.	NE	NE								
	18-49	787	60	6	0,8	782	59,9	8	1	0,74	Algorithm converged.	0,26	2,15	-0,261	Algorithm converged.	-1,19	0,67	0,75	Algorithm converged.	0,26	2,14	0,5832		1,34	Algorithm converged.	0,47	3,85								
	>=50	479	36,5	5	1	481	36,8	9	1,9	0,55	Algorithm converged.	0,18	1,66	-0,827	Algorithm converged.	-2,34	0,69	0,56	Algorithm converged.	0,19	1,65	0,4205		1,79	Algorithm converged.	0,61	5,31								
Region	US	1220	93,1	11	0,9	1217	93,2	16	1,3	0,68	Algorithm converged.	0,32	1,48	-0,413	Algorithm converged.	-1,24	0,42	0,69	Algorithm converged.	0,32	1,47	0,3301	0,3075	1,46	Algorithm converged.	0,68	3,13								
	ex-US	91	6,9	0	0	89	6,8	1	1,1	0	Algorithm converged.	NE	NE	-1,124	Algorithm converged.	-3,31	1,07	NE	Algorithm not converged.	NE	NE	0,4944		NE	*	Algorithm not converged.	NE	NE							

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-4-ae-raw-toxgtnr3

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1311	100	9	0,7	1306	100	19	1,5	0,47	Algorithm converged.	0,21	1,04	-0,768	Algorithm converged.	-1,56	0,02	0,47	Algorithm converged.	0,21	1,04	0,0562		2,12	Algorithm converged.	0,96	4,67				
Sex	Male	601	45,8	4	0,7	633	48,5	7	1,1	0,6	Algorithm converged.	0,17	2,06	-0,44	Algorithm converged.	-1,48	0,6	0,6	Algorithm converged.	0,18	2,05	0,5485	0,6078	1,66	Algorithm converged.	0,49	5,65				
	Female	710	54,2	5	0,7	673	51,5	12	1,8	0,39	Algorithm converged.	0,14	1,11	-1,079	Algorithm converged.	-2,25	0,1	0,39	Algorithm converged.	0,14	1,12	0,0874		2,53	Algorithm converged.	0,9	7,15				
Age	12-17	45	3,4	0	0	43	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	0,4775	NE	*	Algorithm not converged.	NE	NE	
	18-49	787	60	6	0,8	782	59,9	8	1	0,74	Algorithm converged.	0,26	2,15	-0,261	Algorithm converged.	-1,19	0,67	0,75	Algorithm converged.	0,26	2,14	0,5832		1,34	Algorithm converged.	0,47	3,85				
	>=50	479	36,5	3	0,6	481	36,8	11	2,3	0,27	Algorithm converged.	0,07	0,97	-1,661	Algorithm converged.	-3,17	-0,15	0,27	Algorithm converged.	0,08	0,98	0,0556		3,65	Algorithm converged.	1,03	13,01				
Region	US	1220	93,1	9	0,7	1217	93,2	17	1,4	0,52	Algorithm converged.	0,23	1,18	-0,659	Algorithm converged.	-1,47	0,16	0,53	Algorithm converged.	0,24	1,18	0,1133	0,1978	1,89	Algorithm converged.	0,85	4,23				
	ex-US	91	6,9	0	0	89	6,8	2	2,2	0	Algorithm converged.	NE	NE	-2,247	Algorithm converged.	-5,33	0,83	NE	*	Algorithm not converged.	NE	NE	0,2431		NE	*	Algorithm not converged.	NE	NE		

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-5-ae-raw-toxgr3

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1311	100	0	0	1306	100	1	0.1	0	Algorithm converged.	NE	NE	-0.077	Algorithm converged.	-0.23	0.07	NE	*	Algorithm not converged.	NE	NE	0.499		NE	*	Algorithm not converged.	NE	NE		
Sex	Male	601	45.8	0	0	633	48.5	1	0.2	0	Algorithm converged.	NE	NE	-0.158	Algorithm converged.	-0.47	0.15	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE		
	Female	710	54.2	0	0	673	51.5	0	0	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Age	12-17	45	3.4	0	0	43	3.3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	18-49	787	60	0	0	782	59.9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=50	479	36.5	0	0	481	36.8	1	0.2	0	Algorithm converged.	NE	NE	-0.208	Algorithm converged.	-0.61	0.2	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE		
Region	US	1220	93.1	0	0	1217	93.2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	ex-US	91	6.9	0	0	89	6.8	1	1.1	0	Algorithm converged.	NE	NE	-1.124	Algorithm converged.	-3.31	1.07	NE	*	Algorithm not converged.	NE	NE	0.4944		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-6-ae-raw-toxgr4-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	1311	100	2	0,2	1306	100	2	0,2	1	Algorithm converged.	0,14	7,08	-0,001	Algorithm converged.	-0,3	0,3	1	Algorithm converged.	0,14	7,06	1		1	Algorithm converged.	0,14	7,12						
Sex	Male	601	45,8	1	0,2	633	48,5	1	0,2	1,05	Algorithm converged.	0,07	16,88	0,008	Algorithm converged.	-0,44	0,46	1,05	Algorithm converged.	0,07	16,8	1	0,9579	0,95	Algorithm converged.	0,06	15,15						
	Female	710	54,2	1	0,1	673	51,5	1	0,1	0,95	Algorithm converged.	0,06	15,18	-0,008	Algorithm converged.	-0,41	0,39	0,95	Algorithm converged.	0,06	15,12	1		1,05	Algorithm converged.	0,07	16,83						
Age	12-17	45	3,4	0	0	43	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE						
	18-49	787	60	0	0	782	59,9	1	0,1	0	Algorithm converged.	NE	NE	-0,128	Algorithm converged.	-0,38	0,12	NE	*	Algorithm not converged.	NE	NE	0,4984	NE	*	Algorithm not converged.	NE	NE					
	>=50	479	36,5	2	0,4	481	36,8	1	0,2	2,01	Algorithm converged.	0,18	22,27	0,21	Algorithm converged.	-0,5	0,92	2,01	Algorithm converged.	0,18	22,07	0,6238		0,5	Algorithm converged.	0,05	5,47						
Region	US	1220	93,1	2	0,2	1217	93,2	2	0,2	1	Algorithm converged.	0,14	7,09	0	Algorithm converged.	-0,32	0,32	1	Algorithm converged.	0,14	7,07	1	1	1	Algorithm converged.	0,14	7,11						
	ex-US	91	6,9	0	0	89	6,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE						

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-7-ae-raw-toxgr5

POPULATION: Safety - Cohort A
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab													
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk															
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason			95% Lower CL	95% upper CL				
All	n/a	1311	100		10 0,8	1306	100	15	1,1	0,66	Algorithm converged.			0,3	1,48	-0,386	Algorithm converged.			-1,13	0,36	0,66	Algorithm converged.			0,3	1,47	0,3105		1,51	Algorithm converged.			0,68	3,34				
Sex	Male	601	45,8		4 0,7	633	48,5	5	0,8	0,84	Algorithm converged.			0,22	3,15	-0,124	Algorithm converged.			-1,07	0,82	0,84	Algorithm converged.			0,23	3,12	1	0,6415	1,19	Algorithm converged.			0,32	4,4				
	Female	710	54,2		6 0,8	673	51,5	10	1,5	0,57	Algorithm converged.			0,2	1,56	-0,641	Algorithm converged.			-1,78	0,49	0,57	Algorithm converged.			0,21	1,56	0,2655		1,76	Algorithm converged.			0,64	4,81				
Age	12-17	45	3,4		0 0	43	3,3	0	0	NE	*	Algorithm not converged.			NE	NE	NE	*	Algorithm not converged.			NE	NE	NE	*	Algorithm not converged.			NE	NE	NE	0,5129	NE	*	Algorithm not converged.			NE	NE
	18-49	787	60		7 0,9	782	59,9	7	0,9	0,99	Algorithm converged.			0,35	2,85	-0,006	Algorithm converged.			-0,94	0,92	0,99	Algorithm converged.			0,35	2,82	0,9904		1,01	Algorithm converged.			0,35	2,86				
	>=50	479	36,5		3 0,6	481	36,8	8	1,7	0,37	Algorithm converged.			0,1	1,41	-1,037	Algorithm converged.			-2,38	0,31	0,38	Algorithm converged.			0,1	1,41	0,2239		2,66	Algorithm converged.			0,71	9,95				
Region	US	1220	93,1		9 0,7	1217	93,2	12	1	0,75	Algorithm converged.			0,31	1,78	-0,248	Algorithm converged.			-0,98	0,49	0,75	Algorithm converged.			0,32	1,77	0,5073	0,4782	1,34	Algorithm converged.			0,57	3,16				
	ex-US	91	6,9		1 1,1	89	6,8	3	3,4	0,32	Algorithm converged.			0,03	3,12	-2,272	Algorithm converged.			-6,59	2,05	0,33	Algorithm converged.			0,03	3,08	0,3652		3,07	Algorithm converged.			0,33	28,94				

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-8-ae-raw-anyxae

POPULATION: Safety - Cohort A

ENDPOINT: Any SAEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1311	100	10	0,8	1306	100	10	0,8	1	Algorithm converged.	0,41	2,4	-0,003	Algorithm converged.	-0,67	0,66	1	Algorithm converged.	0,42	2,39	0,9932		1	Algorithm converged.	0,42	2,4								
Sex	Male	601	45,8	4	0,7	633	48,5	2	0,3	2,11	Algorithm converged.	0,39	11,58	0,35	Algorithm converged.	-0,43	1,13	2,11	Algorithm converged.	0,39	11,46	0,4408	0,274	0,47	Algorithm converged.	0,09	2,58								
	Female	710	54,2	6	0,8	673	51,5	8	1,2	0,71	Algorithm converged.	0,24	2,05	-0,344	Algorithm converged.	-1,4	0,72	0,71	Algorithm converged.	0,25	2,04	0,5236		1,41	Algorithm converged.	0,49	4,03								
Age	12-17	45	3,4	0	0	43	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,9999	NE	*	Algorithm not converged.	NE	NE				
	18-49	787	60	7	0,9	782	59,9	7	0,9	0,99	Algorithm converged.	0,35	2,85	-0,006	Algorithm converged.	-0,94	0,92	0,99	Algorithm converged.	0,35	2,82	0,9904		1,01	Algorithm converged.	0,35	2,86								
	>=50	479	36,5	3	0,6	481	36,8	3	0,6	1	Algorithm converged.	0,2	5	0,003	Algorithm converged.	-0,99	1	1	Algorithm converged.	0,2	4,95	1		1	Algorithm converged.	0,2	4,91								
Region	US	1220	93,1	9	0,7	1217	93,2	10	0,8	0,9	Algorithm converged.	0,36	2,22	-0,084	Algorithm converged.	-0,78	0,61	0,9	Algorithm converged.	0,37	2,2	0,8137	0,2326	1,11	Algorithm converged.	0,45	2,73								
	ex-US	91	6,9	1	1,1	89	6,8	0	0	NE	*	Algorithm not converged.	NE	NE	1,099	Algorithm converged.	-1,04	3,24	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE					

Test for action based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas

Output: t12-9-ae-raw-anyrsaenr

POPULATION: Safety - Cohort A
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk							Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1311	100		0 0	1306	100		0 0																						
Sex	Male	601	45,8		0 0	633	48,5		0 0																						
	Female	710	54,2		0 0	673	51,5		0 0																						
Age	12-17	45	3,4		0 0	43	3,3		0 0																						
	18-49	787	60		0 0	782	59,9		0 0																						
	>=50	479	36,5		0 0	481	36,8		0 0																						
Region	US	1220	93,1		0 0	1217	93,2		0 0																						
	ex-US	91	6,9		0 0	89	6,8		0 0																						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-10-ae-raw-aeltdis-unstrat-saf1

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

AESI

POPULATION: Safety - Cohort A
ENDPOINT: Injection site reactions Grade >=3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1311	100		0 0	1306	100		0 0																						
Sex	Male	601	45,8		0 0	633	48,5		0 0																						
	Female	710	54,2		0 0	673	51,5		0 0																						
Age	12-17	45	3,4		0 0	43	3,3		0 0																						
	18-49	787	60		0 0	782	59,9		0 0																						
	>=50	479	36,5		0 0	481	36,8		0 0																						
Region	US	1220	93,1		0 0	1217	93,2		0 0																						
	ex-US	91	6,9		0 0	89	6,8		0 0																						

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-11-ae-raw-isrge3

POPULATION: Safety - Cohort A
ENDPOINT: Serious injection site reactions
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	1311	100		0 0	1306	100		0 0																							
Sex	Male	601	45,8		0 0	633	48,5		0 0																							
	Female	710	54,2		0 0	673	51,5		0 0																							
Age	12-17	45	3,4		0 0	43	3,3		0 0																							
	18-49	787	60		0 0	782	59,9		0 0																							
	>=50	479	36,5		0 0	481	36,8		0 0																							
Region	US	1220	93,1		0 0	1217	93,2		0 0																							
	ex-US	91	6,9		0 0	89	6,8		0 0																							

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-12-ae-raw-sisr

POPULATION: Safety - Cohort A
ENDPOINT: Hypersensitivity reactions Grade >=3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk							Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1311	100		0 0	1306	100		0 0																						
Sex	Male	601	45,8		0 0	633	48,5		0 0																						
	Female	710	54,2		0 0	673	51,5		0 0																						
Age	12-17	45	3,4		0 0	43	3,3		0 0																						
	18-49	787	60		0 0	782	59,9		0 0																						
	>=50	479	36,5		0 0	481	36,8		0 0																						
Region	US	1220	93,1		0 0	1217	93,2		0 0																						
	ex-US	91	6,9		0 0	89	6,8		0 0																						

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-13-ae-raw-hyprggr3

POPULATION: Safety - Cohort A
ENDPOINT: Serious hypersensitivity reactions
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk							Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1311	100		0 0	1306	100		0 0																						
Sex	Male	601	45,8		0 0	633	48,5		0 0																						
	Female	710	54,2		0 0	673	51,5		0 0																						
Age	12-17	45	3,4		0 0	43	3,3		0 0																						
	18-49	787	60		0 0	782	59,9		0 0																						
	>=50	479	36,5		0 0	481	36,8		0 0																						
Region	US	1220	93,1		0 0	1217	93,2		0 0																						
	ex-US	91	6,9		0 0	89	6,8		0 0																						

Test for action based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-14-ae-raw-shypr

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

SOC-PT

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	

	Asymptomatic bacteremia	-	1311	100	2	0.153	1306	100	3	0.23	0.964	Algorithm converged.	0.111	3.978	-0.077	Algorithm converged.	0.412	NE	0.654	Algorithm converged.	0.111	3.968	0.8667	1.508	Algorithm converged.	0.252	8.897
	Bacterial vaginosis	-	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.943	1	1.004	Algorithm converged.	0.063	16.032
	Bacteriuria	-	1311	100	2	0.153	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.153	Algorithm converged.	-0.059	NE	NE *	Algorithm not converged.	NE	NE	0.998	NE	Algorithm not converged.	NE	NE
	Bronchitis	-	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.943	1	1.004	Algorithm converged.	0.063	16.032
	COVID-19	-	1311	100	15	1.144	1306	100	112	0.32	0.656	Algorithm converged.	0.078	0.123	-7.432	Algorithm converged.	0.078	0.123	-7.432	Algorithm converged.	0.078	0.123	-7.432	1.001	Algorithm converged.	0.437	12.777
	COVID-19 pneumonia	-	1311	100	1	0.076	1306	100	3	0.23	0.332	Algorithm converged.	0.034	3.192	-0.153	Algorithm converged.	-0.453	NE	0.332	Algorithm converged.	0.035	3.188	0.3738	3.011	Algorithm converged.	0.314	28.913
	Campylobacter gastroenteritis	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Cellulitis	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Cystitis	-	1311	100	1	0.076	1306	100	2	0.153	0.996	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114
	Ear infection	-	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.943	1	1.004	Algorithm converged.	0.063	16.032
	Gastrointestinal viral infection	-	1311	100	0	0	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114
	Gonorrhoea	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Helicobacter infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Influenza	-	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.943	1	1.004	Algorithm converged.	0.063	16.032
	Kidney infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Laryngitis	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Nasopharyngitis	-	1311	100	0	0	1306	100	6	0.459	NE *	Algorithm not converged.	NE	NE	0.459	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	0.0154	NE	Algorithm not converged.	NE	NE
	Oral herpes	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Paronychia	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Pelvic inflammatory disease	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Pharyngitis	-	1311	100	0	0	1306	100	2	0.153	0.996	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114
	Pneumonia	-	1311	100	2	0.153	1306	100	1	0.077	1.994	Algorithm converged.	0.181	22.016	0	Algorithm converged.	-0.183	NE	1.992	Algorithm converged.	0.181	21.945	1	0.502	Algorithm converged.	0.046	5.528
	Respiratory tract infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Rhinitis	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Scrotal abscess	-	1311	100	0	0	1306	100	2	0.153	0.996	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114
	Sepsis	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Sinusitis	-	1311	100	3	0.229	1306	100	2	0.153	1.495	Algorithm converged.	0.249	8.964	0.076	Algorithm converged.	-0.259	NE	1.494	Algorithm converged.	0.25	8.928	1	0.669	Algorithm converged.	0.112	3.998
	Soft tissue infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Staphylococcal infection	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Subcutaneous abscess	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Tooth abscess	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Tooth infection	-	1311	100	3	0.229	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.229	Algorithm converged.	-0.03	NE	NE *	Algorithm not converged.	NE	NE	0.2497	NE	Algorithm not converged.	NE	NE
	Upper respiratory tract infection	-	1311	100	3	0.229	1306	100	1	0.077	1.526	Algorithm converged.	0.249	8.964	0.076	Algorithm converged.	-0.259	NE	1.494	Algorithm converged.	0.25	8.928	1	0.669	Algorithm converged.	0.112	3.998
	Urinary tract infection	-	1311	100	14	1.068	1306	100	19	1.455	0.731	Algorithm converged.	0.365	1.465	-0.387	Algorithm converged.	-1.242	NE	0.734	Algorithm converged.	0.37	1.458	0.3752	1.362	Algorithm converged.	0.686	2.705
	Viral infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Wound infection	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Injury, poisoning and procedural complications	-	-	1311	100	6	0.458	1306	100	12	0.919	0.496	Algorithm converged.	0.186	1.325	-0.461	Algorithm converged.	-1.095	NE	0.498	Algorithm converged.	0.188	1.323	0.1536	2.008	Algorithm converged.	0.756	5.333
	Ankle fracture	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Concussion	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Contusion	-	1311	100	0	0	1306	100	3	0.23	NE *	Algorithm not converged.	NE	NE	-0.23	Algorithm converged.	-0.489	NE	NE *	Algorithm not converged.	NE	NE	0.1241	NE	Algorithm not converged.	NE	NE
	Epididymitis	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Fall	-	1311	100	0	0	1306	100	2	0.153	NE *	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE *	Algorithm not converged.	NE	NE	0.249	NE	Algorithm not converged.	NE	NE
	Foot fracture	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Gun shot wound	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Injection related reaction	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Ligament sprain	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Neck injury	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
	Road traffic accident	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Skin abrasion	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Thermal burn	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Tibia fracture	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Tooth fracture	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Upper limb fracture	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
Investigations	-	-	1311	100	23	1.754	1306	100	18	1.378	1.278	Algorithm converged.	0.686	2.379	0.376	Algorithm converged.	-0.575	NE	1.273	Algorithm converged.	0.69	2.347	0.4386	0.786	Algorithm converged.	0.426	1.449
	Alanine aminotransferase increased	-	1311	100	5	0.381	1306	100	2	0.153	2.496	Algorithm converged.	0.163	12.889	0.228	Algorithm converged.	-0.167	NE	2.49	Algorithm converged.	0.484	12.814	0.4525	1.402	Algorithm converged.	0.078	2.066
	Aspartate aminotransferase increased	-	1311	100	5	0.381	1306	100	2	0.153	2.496	Algorithm converged.	0.163	12.889	0.228	Algorithm converged.	-0.167	NE	2.49	Algorithm converged.	0.484	12.814	0.4525	1.402	Algorithm converged.	0.078	2.066
	Blood bilirubin increased	-	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.062	NE	0.996	Algorithm converged.	0.062	15.943	1	1.004	Algorithm converged.	0.063	16.032
	Blood cholesterol increased	-	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE														

	Trigger finger	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	1311	100	1	0.076	1306	100	2	0.153	0.498			Algorithm converged.	0.045	5.496	-0.077		Algorithm converged.	-0.336	NE	0.498			Algorithm converged.	0.045	5.496	0.6241	2.008		Algorithm converged.	0.182	22.114	
	Breast cancer	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Cervix carcinoma recurrent	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Prostate cancer	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
Nervous system disorders	--	1311	100	33	2.517	1306	100	56	4.288	0.576			Algorithm converged.	0.372	0.892	-1.771		Algorithm converged.	-3.159	NE	0.587			Algorithm converged.	0.384	0.896	0.0125	1.703		Algorithm converged.	1.116	2.601	
	Agnesia	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Anosmia	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Cerebral infarction	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Dizziness	--	1311	100	5	0.381	1306	100	4	0.306	1.246			Algorithm converged.	0.334	4.651	0.076		Algorithm converged.	-0.373	NE	1.245			Algorithm converged.	0.335	4.627	1	0.803		Algorithm converged.	0.216	2.984
	Headache	--	1311	100	24	1.831	1306	100	46	3.522	0.511			Algorithm converged.	0.31	0.842	-1.692		Algorithm converged.	-2.927	NE	0.52			Algorithm converged.	0.319	0.846	0.0073	1.924		Algorithm converged.	1.182	3.133
	Hypoesthesia	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Migraine	--	1311	100	4	0.305	1306	100	2	0.153	1.995			Algorithm converged.	0.365	10.913	0.152		Algorithm converged.	-0.214	NE	1.992			Algorithm converged.	0.366	10.859	0.6871	0.502		Algorithm converged.	0.092	2.736
	Presyncope	--	1311	100	1	0.076	1306	100	2	0.153	0.498			Algorithm not converged.	0.045	5.498	-0.077		Algorithm converged.	-0.336	NE	0.498			Algorithm converged.	0.045	5.498	0.6241	2.008		Algorithm converged.	0.182	22.114
	Syncope	--	1311	100	2	0.153	1306	100	2	0.153	0.996			Algorithm converged.	0.14	7.083	-0.001		Algorithm converged.	-0.3	NE	0.996			Algorithm converged.	0.141	7.061	1	1.004		Algorithm converged.	0.142	7.116
Pregnancy, puerperium and perinatal conditions	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
	Abortion spontaneous	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
Psychiatric disorders	--	1311	100	5	0.381	1306	100	12	0.919	0.413			Algorithm converged.	0.145	1.175	-0.537		Algorithm converged.	-1.153	NE	0.415			Algorithm converged.	0.147	1.175	0.0946	2.409		Algorithm converged.	0.851	6.819	
	Anxiety	--	1311	100	2	0.153	1306	100	6	0.459	0.331			Algorithm converged.	0.067	1.643	-0.307		Algorithm converged.	-0.73	NE	0.332			Algorithm converged.	0.067	1.642	0.1783	3.011		Algorithm converged.	0.609	14.893
	Confusional state	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Depression	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Initial insomnia	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Insomnia	--	1311	100	1	0.076	1306	100	3	0.23	0.332			Algorithm converged.	0.034	3.192	-0.153		Algorithm converged.	-0.453	NE	0.332			Algorithm converged.	0.035	3.188	0.3738	3.011		Algorithm converged.	0.314	28.913
	Mania	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Panic attack	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Suicidal ideation	--	1311	100	0	0	1306	100	2	0.153	NE	*	Algorithm not converged.	NE	NE	-0.153		Algorithm converged.	-0.365	NE	NE	*	Algorithm not converged.	NE	NE	0.249	NE	NE	NE	Algorithm not converged.	NE	NE	
Renal and urinary disorders	--	1311	100	3	0.229	1306	100	5	0.383	0.597			Algorithm converged.	0.142	2.502	-0.154		Algorithm converged.	-0.577	NE	0.598			Algorithm converged.	0.143	2.496	0.5064			Algorithm converged.	0.401	6.986	
	Chronic kidney disease	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Glycosuria	--	1311	100	0	0	1306	100	2	0.153	NE	*	Algorithm not converged.	NE	NE	-0.153		Algorithm converged.	-0.365	NE	NE	*	Algorithm not converged.	NE	NE	0.249	NE	NE	NE	Algorithm not converged.	NE	NE	
	Haematuria	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Ketonuria	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Leukocyturia	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Proteinuria	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
	Renal failure	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Urinary retention	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077		Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	NE	NE	Algorithm not converged.	NE	NE	
Reproductive system and breast disorders	--	1311	100	5	0.381	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.381		Algorithm converged.	0.048	NE	NE	*	Algorithm not converged.	NE	NE	0.0623	NE		NE		Algorithm not converged.	NE	NE	
	Breast mass	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Erectile dysfunction	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Menstruation irregular	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Pelvic pain	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Prostatitis	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	--	1311	100	53	4.043	1306	100	54	4.135	0.977			Algorithm converged.	0.663	1.438	-0.092		Algorithm converged.	-1.609	NE	0.978			Algorithm converged.	0.675	1.417	0.9054			Algorithm converged.	1.023	1.482	
	Chronic obstructive pulmonary disease	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076		Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	Algorithm not converged.	NE	NE	
	Cough	--	1311	100	17	1.297	1306	100	15	1.149	1.131			Algorithm converged.	0.562	2.274	0.148		Algorithm converged.	-0.694	NE	1.129			Algorithm converged.	0.5666							

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						

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Immune system disorders	--	Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
		Male	601	45.843	0	0	633	48.469	0	0	0.948	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE	0.948	*	Algorithm not converged.	NE	NE	1	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	0	0.149	0.948	*	Algorithm not converged.	NE	NE	NE	-0.008	*	Algorithm not converged.	NE	NE	NE	0.948	*	Algorithm not converged.	0.059	15.124	1		NE	1.055	Algorithm not converged.	NE	0.066	16.833
Drug hypersensitivity		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.141	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
Seasonal allergy		Female	710	54.157	0	0	633	48.469	0	0.149	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	NE	-0.149	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	0.4866		NE		Algorithm not converged.	NE	NE
Infections and infestations	--	Male	601	45.843	48	7.987	633	48.469	112	17.894	0.404	*	Algorithm converged.	0.282	0.578	-9.707		Algorithm converged.	-13.386	NE	0.451		Algorithm converged.	0.328	0.621	<-0.001	0.9945	2.215		Algorithm converged.	1.61	3.048			
		Female	710	54.157	62	8.732	673	51.531	130	19.316	0.4	*	Algorithm converged.	0.289	0.562	-10.584		Algorithm converged.	-14.218	NE	0.452		Algorithm converged.	0.34	0.6	<-0.001	2.212		Algorithm converged.	1.666	2.937				
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
Acute sinusitis		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	NE	-0.149	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	0.4866		NE		Algorithm not converged.	NE	NE
Appendicitis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	NE	-0.149	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	0.4866		NE		Algorithm not converged.	NE	NE
		Male	601	45.843	32	5.324	633	48.469	60	9.479	0.537	Algorithm converged.	0.344	0.838	-4.154		Algorithm converged.	-7.058	NE	0.562		Algorithm converged.	0.371	0.85	0.0055	0.4331	1.78		Algorithm converged.	1.176	2.694				
Asymptomatic COVID-19		Female	710	54.157	22	3.099	673	51.531	48	7.132	0.416	Algorithm converged.	0.249	0.698	-4.034		Algorithm converged.	-6.359	NE	0.434		Algorithm converged.	0.285	0.712	0.0006		2.302		Algorithm converged.	1.405	3.77				
		Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487	0.1243	NE		Algorithm not converged.	NE	NE			
		Female	710	54.157	1	0.141	673	51.531	3	0.446	0.315	Algorithm converged.	0.033	0.036	-0.305		Algorithm converged.	-0.879	NE	0.316		Algorithm converged.	0.033	3.03	0.3616		3.165		Algorithm not converged.	0.33	30.351				
Bacterial vaginosis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	1	0.149	0.948	Algorithm converged.	0.059	15.184	-0.008		Algorithm converged.	-0.409	NE	0.948		Algorithm converged.	0.059	15.124	1		1.055		Algorithm converged.	0.066	16.833				
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	-0.108	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
Bacteriuria		Female	710	54.157	2	0.282	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.282		Algorithm converged.	-0.108	NE	NE	*	Algorithm not converged.	NE	NE	0.5		NE		Algorithm not converged.	NE	NE			
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	2	0.282	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.282		Algorithm converged.	-0.108	NE	NE	*	Algorithm not converged.	NE	NE	0.5		NE		Algorithm not converged.	NE	NE			
Bronchitis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	1	0.149	0.948	Algorithm converged.	0.059	15.184	-0.008		Algorithm converged.	-0.409	NE	0.948		Algorithm converged.	0.059	15.124	1		1.055		Algorithm converged.	0.066	16.833				
		Male	601	45.843	6	0.998	633	48.469	45	7.109	0.132	Algorithm converged.	0.056	0.311	-6.611		Algorithm converged.	-8.265	NE	0.14		Algorithm converged.	0.06	0.327	<-0.001	0.8604	7.121		Algorithm converged.	3.06	16.569				
COVID-19		Female	710	54.157	9	1.269	673	51.531	67	9.955	0.116	Algorithm converged.	0.057	0.235	-8.688		Algorithm converged.	-11.095	NE	0.127		Algorithm converged.	0.064	0.253	<-0.001		7.854		Algorithm converged.	3.948	15.623				
		Male	601	45.843	1	0.166	633	48.469	2	0.316	0.626	Algorithm converged.	0.048	5.814	-0.15		Algorithm converged.	-0.695	NE	0.527		Algorithm converged.	0.048	5.793	1	0.3915	1.899		Algorithm converged.	0.173	20.887				
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.4866		NE		Algorithm not converged.	NE	NE			
Campylobacter gastroenteritis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.141	*	Algorithm not converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158		Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
Cellulitis		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
Cystitis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	2	0.297	0.473	Algorithm converged.	0.043	5.231	-0.156		Algorithm converged.	-0.652	NE	0.474		Algorithm converged.	0.043	5.215	0.615		2.11		Algorithm converged.	0.192	23.215				
		Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158		Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1	0.1023	NE		Algorithm not converged.	NE	NE			
Ear infection		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
		Male	601	45.843	0	0	633	48.469	2	0.316	NE	*	Algorithm not converged.	NE	NE	-0.316		Algorithm converged.	-0.753	NE	NE	*	Algorithm not converged.	NE	NE	1	0.4999	0.055	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
Gastroenteritis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	-0.316		Algorithm converged.	-0.753	NE	NE	*	Algorithm not converged.	NE	NE	1	0.4999	0.055	NE		Algorithm not converged.	NE	NE		
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
Gastrointestinal viral infection		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
		Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
Gonorrhea		Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE			
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
Helicobacter infection		Female	71																																

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[illegible]

			Female	710	54.157	0	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.866	NE	Algorithm not converged.	NE	NE			
		Cervix carcinoma recurrent	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0.141	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	0.141	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Prostate cancer	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Nervous system disorders	--	Male	601	45.843	7	1.165	633	48.469	25	3.949	0.287	Algorithm converged.	Algorithm converged.	0.123	0.668	-2.785	Algorithm converged.	-4.528	NE	0.295	Algorithm converged.	0.129	0.677	0.0021	0.0378	3.391	Algorithm converged.	1.478	7.781			
			Female	710	54.157	26	3.662	673	51.531	31	4.806	0.787	Algorithm converged.	Algorithm converged.	0.462	1.34	-0.944	Algorithm converged.	-3.046	NE	0.795	Algorithm converged.	0.477	1.324	0.3774	1.258	Algorithm converged.	0.785	2.096					
		Agusia	Male	601	45.843	1	0	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Anosmia	Male	601	45.843	1	0	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Cerebral infarction	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Dizziness	Male	601	45.843	1	0	0.166	633	48.469	1	0	0.158	1.053	Algorithm converged.	0.066	16.878	0.008	Algorithm converged.	-0.441	NE	1.053	Algorithm converged.	0.066	16.801	1	0	0.9096	0.949	Algorithm converged.	0.06	15.145		
			Female	710	54.157	4	0.563	673	51.531	3	0.446	1.265	Algorithm converged.	0.282	5.675	0.118	Algorithm converged.	-0.628	NE	1.264	Algorithm converged.	0.284	5.626	1	0	0.791	Algorithm converged.	0.178	3.522					
		Headache	Male	601	45.843	2	0	0.333	633	48.469	22	3.476	0.093	Algorithm converged.	0.022	0.396	-3.143	Algorithm converged.	-4.642	NE	0.096	Algorithm converged.	0.023	0.405	<0.001	0.0007	10.444	Algorithm converged.	2.467	44.223				
			Female	710	54.157	22	3.099	673	51.531	24	3.566	0.865	Algorithm converged.	0.48	1.557	-0.468	Algorithm converged.	-2.362	NE	0.869	Algorithm converged.	0.492	1.535	0.6281	1.151	Algorithm converged.	0.652	2.033						
		Hypoesthesia	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Migraine	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	4	0.563	673	51.531	2	0.297	1.901	Algorithm converged.	0.347	10.412	0.266	Algorithm converged.	-0.421	NE	1.896	Algorithm converged.	0.348	10.316	0.6875	0.527	Algorithm converged.	0.097	2.87						
		Presyncope	Male	601	45.843	1	0	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487	0.0495	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	2	0.297	NE	*	Algorithm not converged.	NE	NE	-0.297	Algorithm converged.	-0.708	NE	NE	*	Algorithm not converged.	NE	NE	0.2366	NE	Algorithm not converged.	NE	NE			
		Syncope	Male	601	45.843	2	0	0.333	633	48.469	1	0	0.158	2.11	Algorithm converged.	0.191	23.332	0.175	Algorithm converged.	-0.38	NE	2.106	Algorithm converged.	0.192	23.171	0.6152	0.1755	0.475	Algorithm converged.	0.043	9.222			
			Female	710	54.157	0	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.866	NE	Algorithm not converged.	NE	NE			
		Pregnancy, puerperium and perinatal conditions	--	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	1	0.141	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
		Abortion spontaneous	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	1	0.141	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Psychiatric disorders	--	Male	601	45.843	1	0.166	633	48.469	6	0.948	0.174	Algorithm converged.	0.021	1.451	-0.781	Algorithm converged.	-1.604	NE	0.176	Algorithm converged.	0.021	1.454	0.1248	0.2759	5.697	Algorithm converged.	0.688	47.179				
			Female	710	54.157	4	0.563	673	51.531	6	0.892	0.63	Algorithm converged.	0.177	2.242	-0.328	Algorithm converged.	-1.227	NE	0.632	Algorithm converged.	0.179	2.229	0.5378	1.562	Algorithm converged.	0.449	5.583						
		Anxiety	Male	601	45.843	0	0	0	633	48.469	4	0.632	NE	*	Algorithm not converged.	NE	NE	-0.632	Algorithm converged.	-1.249	NE	NE	*	Algorithm not converged.	NE	NE	0.1249	0.0714	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	2	0.282	673	51.531	2	0.297	0.948	Algorithm converged.	0.133	6.747	-0.015	Algorithm converged.	-0.582	NE	0.948	Algorithm converged.	0.134	6.71	1	1.055	Algorithm converged.	0.149	7.468						
		Confusional state	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE			
		Depression	Male	601	45.843	1	0	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Initial insomnia	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Insomnia	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	0.4278	NE	Algorithm not converged.	NE	NE
			Female	710	54.157	1	0.141	673	51.531	2	0.297	0.473	Algorithm converged.	0.043	5.231	-0.156	Algorithm converged.	-0.652	NE	0.474	Algorithm converged.	0.043	5.215	0.615	2.11	Algorithm converged.	0.192	23.215						
		Mania	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm not converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4866	NE	Algorithm not converged.	NE	NE		
		Panic attack	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Suicidal ideation	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.708	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	0	0	0	673	51.531	2	0.297	NE	*	Algorithm not converged.	NE	NE	-0.297	Algorithm converged.	-0.708	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2366	NE	Algorithm not converged.	NE	NE		
		Renal and urinary disorders	--	Male	601	45.843	2	0.333	633	48.469	2	0.316	1.053	Algorithm converged.	0.148	7.502	0.017	Algorithm converged.	-0.618	NE	1.053	Algorithm converged.	0.149	7.453	1	0.4188	0.949	Algorithm converged.	0.134	6.719				
			Female	710	54.157	1	0.141	673	51.531	3	0.446	0.315	Algorithm converged.	0.033	3.036	-0.305	Algorithm converged.	-0.879	NE	0.316	Algorithm converged.	0.033	3.03	0.3616	3.165	Algorithm converged.	0.33	30.351						
		Chronic kidney disease	Male	601	45.843	0	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	-0.135	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
		Glycosuria	Male	601	45.843	0	0	0	633	48.469	1	0	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	710	54.157	0	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.486						

Respiratory, thoracic and mediastinal disorders	Prostatitis	Male	601	45.843	1	0	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
	--	Male	601	45.843	27	4.493	633	48.469	26	4.107	1.098			Algorithm converged.	0.633	1.904	0.385		Algorithm converged.	-1.88	NE	1.094		Algorithm converged.	0.646	1.852	0.7389	0.5663	0.914		Algorithm converged.	0.54	1.548
		Female	710	54.157	27	3.662	673	51.531	28	4.16	0.876			Algorithm converged.	0.508	1.909	-0.499		Algorithm converged.	-2.544	NE	0.88		Algorithm converged.	0.522	1.485	0.6325	1.136		Algorithm converged.	0.673	1.917	
	Chronic obstructive pulmonary disease	Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cough	Male	601	45.843	11	1.83	633	48.469	6	0.948	1.948			Algorithm converged.	0.716	5.302	0.882		Algorithm converged.	-0.428	NE	1.931		Algorithm converged.	0.719	5.189	0.1839	0.1184	0.518		Algorithm converged.	0.193	1.292
		Female	710	54.157	6	0.845	673	51.531	9	1.337	0.629			Algorithm converged.	0.223	1.776	-0.492		Algorithm converged.	-1.591	NE	0.632		Algorithm converged.	0.226	1.766	0.3772	1.562		Algorithm converged.	0.566	4.422	
	Dyspnoea	Male	601	45.843	3	0.499	633	48.469	2	0.316	1.583			Algorithm converged.	0.264	9.505	0.183		Algorithm converged.	-0.53	NE	1.58		Algorithm converged.	0.265	9.422	0.6793	0.7049	0.633		Algorithm converged.	0.106	3.775
		Female	710	54.157	2	0.282	673	51.531	2	0.297	0.948			Algorithm converged.	0.133	6.747	-0.015		Algorithm converged.	-0.582	NE	0.948		Algorithm converged.	0.134	6.71	1		1.055		Algorithm converged.	0.149	7.468
	Epistaxis	Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487	0.3915	NE		Algorithm not converged.	NE	NE
		Female	710	54.157	2	0.282	673	51.531	1	0.149	1.898			Algorithm converged.	0.172	20.984	0.133		Algorithm converged.	-0.353	NE	1.896		Algorithm converged.	0.172	20.859	1		0.527		Algorithm not converged.	0.048	5.804
	Haemoptysis	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Nasal congestion	Male	601	45.843	8	1.331	633	48.469	9	1.422	0.935			Algorithm converged.	0.359	2.44	-0.091		Algorithm converged.	-1.391	NE	0.936		Algorithm converged.	0.364	2.411	0.8914	0.6162	1.068		Algorithm converged.	0.415	2.75
		Female	710	54.157	7	0.986	673	51.531	10	1.486	0.66			Algorithm converged.	0.25	1.744	-0.5		Algorithm converged.	-1.668	NE	0.664		Algorithm converged.	0.254	1.733	0.3992	1.507		Algorithm converged.	0.577	3.937	
	Oropharyngeal pain	Male	601	45.843	3	0.499	633	48.469	12	1.896	0.26			Algorithm converged.	0.073	0.925	-1.397		Algorithm converged.	-1.569	NE	0.263		Algorithm converged.	0.073	0.929	0.025	0.0644	3.798		Algorithm converged.	1.077	13.392
		Female	710	54.157	10	1.408	673	51.531	9	1.337	1.054			Algorithm converged.	0.426	2.61	0.071		Algorithm converged.	-1.155	NE	1.053		Algorithm converged.	0.431	2.576	0.9096	0.949		Algorithm converged.	0.388	2.322	
	Pleuritic pain	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Productive cough	Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Respiratory failure	Male	601	45.843	1	0.166	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Rhinothorax	Male	601	45.843	5	0.832	633	48.469	3	0.474	1.762			Algorithm converged.	0.419	7.404	0.358		Algorithm converged.	-0.544	NE	1.755		Algorithm converged.	0.421	7.313	0.4962	0.5412	0.57		Algorithm converged.	0.57	2.373
		Female	710	54.157	4	0.563	673	51.531	4	0.594	0.948			Algorithm converged.	0.236	3.804	-0.031		Algorithm converged.	-0.831	NE	0.948		Algorithm converged.	0.238	3.775	1		1.055		Algorithm converged.	0.265	4.201
	Sinus congestion	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Sneezing	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Throat tightness	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
	Upper-airway cough syndrome	Male	601	45.843	1	0.166	633	48.469	1	0.158	1.053			Algorithm converged.	0.066	16.878	0.008		Algorithm converged.	-0.441	NE	1.053		Algorithm converged.	0.066	16.801	1	1	0.949		Algorithm converged.	0.06	15.145
		Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Wheezing	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
Skin and subcutaneous tissue disorders	--	Male	601	45.843	0	0	633	48.469	4	0.632	NE	*	Algorithm not converged.	NE	NE	-0.632		Algorithm converged.	-1.249	NE	NE	*	Algorithm not converged.	NE	NE	0.1249	0.0638	NE		Algorithm not converged.	NE	NE	
		Female	710	54.157	7	0.986	673	51.531	10	1.486	0.66			Algorithm converged.	0.25	1.744	-0.5		Algorithm converged.	-1.668	NE	0.664		Algorithm converged.	0.254	1.733	0.3992	1.507		Algorithm not converged.	0.577	3.937	
	Acne	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Cold sweat	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44														

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t13-1f-ae-row-soc.sas
Output: t13-1f-ae-row-soc-anyse-fs

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casimivab/Indevab										Placebo										Casimivab/Indevab vs. Placebo										Placebo vs. Casimivab/Indevab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
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Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t13-11-ae-row-soc.sas
Output: t13-11-ae-row-soc-amvse-fs

POPULATION: SAFETY
ENDPOINT: Any AE
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirumab/Indinavir								Placebo								Casirumab/Indinavir vs. Placebo								Placebo vs. Casirumab/Indinavir																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
Name	Region	SOC	PT	Level	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% upper CI																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												

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Respiratory, thoracic and mediastinal disorders	Prostatitis	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	--	US	1220	93.059	51	4.18	1217	93.185	53	4.355	0.958	Algorithm converged.		0.647	1.419	-0.175	Algorithm converged.		-1.78	NE	0.96	Algorithm converged.		0.659	1.398	0.8312	1	0.5513	1.042	Algorithm converged.		0.715	1.518		
		exUS	91	6.941	2	2.198	89	6.815	1	1.124	1.978	Algorithm converged.		0.176	22.205	1.074	Algorithm converged.		-2.65	NE	1.956	Algorithm converged.		0.181	21.19	1		0.511	Algorithm converged.		0.047	5.538			
	Chronic obstructive pulmonary disease	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Cough	US	1220	93.059	17	0	1.393	1217	93.185	15	0	1.233	1.132	Algorithm converged.		0.563	2.278	0.161	Algorithm converged.		-0.743	NE	1.131	Algorithm converged.		0.567	2.253	0.7272	1	0.885	Algorithm converged.		0.444	1.763	
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Dyspnoea	US	1220	93.059	4	0	0.328	1217	93.185	4	0	0.329	0.998	Algorithm converged.		0.249	3.998	0.001	Algorithm converged.		-0.455	NE	0.998	Algorithm converged.		0.25	3.98	1	0.2613	1.002	Algorithm converged.		0.251	3.999	
		exUS	91	6.941	1	1.099	89	6.815	0	0	0	NE	*	Algorithm not converged.	NE	NE	1.099	Algorithm converged.		-1.043	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
	Epistaxis	US	1220	93.059	3	0	0.246	1217	93.185	1	0	0.289	2.998	Algorithm converged.		0.311	28.857	0.164	Algorithm converged.		-0.157	NE	2.993	Algorithm converged.		0.312	28.73	0.6247	1	0.334	Algorithm converged.		0.035	3.208	
		exUS	91	6.941	0	0	0	89	6.815	0	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Haemophysis	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Nasal congestion	US	1220	93.059	14	1	1.148	1217	93.185	19	1	1.561	0.732	Algorithm converged.		0.365	1.467	-0.414	Algorithm converged.		-1.331	NE	0.735	Algorithm converged.		0.37	1.459	0.3771	0	1.9375	1.36	Algorithm converged.		0.685	2.701
		exUS	91	6.941	1	1.099	89	6.815	0	0	0	NE	*	Algorithm not converged.	NE	NE	1.099	Algorithm converged.		-1.043	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
	Oropharyngeal pain	US	1220	93.059	13	1	0.666	1217	93.185	20	1	0.643	0.645	Algorithm converged.		0.319	1.302	-0.578	Algorithm converged.		-1.496	NE	0.648	Algorithm converged.		0.324	1.298	0.2173	0	3.017	1.542	Algorithm converged.		0.771	3.086
		exUS	91	6.941	0	0	0	89	6.815	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.		-3.313	NE	NE	*	Algorithm not converged.	NE	NE	0.4944		NE		Algorithm not converged.	NE	NE		
	Pleuritic pain	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Productive cough	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.079	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Respiratory failure	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.079	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Rhinorrhoea	US	1220	93.059	9	0	0.738	1217	93.185	7	0.575	1.285	Algorithm converged.		0.477	3.461	0.163	Algorithm converged.		-0.479	NE	1.283	Algorithm converged.		0.479	3.433	0.6195	1	0.78	Algorithm converged.		0.291	2.087		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Sinus congestion	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Sneezing	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Throat tightness	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.079	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Upper-airway cough syndrome	US	1220	93.059	1	0	0.082	1217	93.185	1	0.082	0.998	Algorithm converged.		0.062	15.966	0	Algorithm converged.		-0.228	NE	0.998	Algorithm converged.		0.062	15.93	1	1	1.002	Algorithm converged.		0.063	16.009		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Wheezing	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.079	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
Skin and subcutaneous tissue disorders	--	US	1220	93.059	7	0.574	1217	93.185	14	1.15	0.496	Algorithm converged.		0.199	1.233	-0.577	Algorithm converged.		-1.31	NE	0.499	Algorithm converged.		0.202	1.231	0.1237	1	2.005	Algorithm converged.		0.812	4.95			
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Acne	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Cold sweat	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Drug eruption	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Eczema	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Erythema	US	1220	93.059	1	0	0.082	1217	93.185	0	0.082	0.998	Algorithm converged.		0.062	15.966	0	Algorithm converged.		-0.228	NE	0.998	Algorithm converged.		0.062	15.93	1	1	1.002	Algorithm converged.		0.063	16.009		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Night sweats	US	1220	93.059	1	0	0.082	1217	93.185	1	0.082	0.998	Algorithm converged.		0.062	15.966	0	Algorithm converged.		-0.228	NE	0.998	Algorithm converged.		0.062	15.93	1	1	1.002	Algorithm converged.		0.063	16.009		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Oncychiasis	US	1220	93.059	0	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE		Algorithm not converged.	NE	NE		
		exUS	91	6.941	0	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Pruritus	US	1220	93.059	1	0	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.		-0															

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If p < .05 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-suc.sas
Output: t13-1f-ae-raw-soc-anyae-1s

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

Casirivimab/Imdevimab										Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab															
Patients										Patients with Event				Patients				Patients with Event				Odds Ratio		Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% upper lower	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	n	%	n	%	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% lower CL	95% upper CL								
All	Cardiac disorders	--	--	1311	100	1	0.076	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE						
		--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
		--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE										
		--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE										
		--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
		--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
		--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
Gastrointestinal disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032											
	--	Abdominal pain	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Abdominal pain upper	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
General disorders and administration site conditions	--	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Sudden death	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE								
Hepatobiliary disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032											
	--	Cholecystitis	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Cholecystitis acute	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Portal hypertension	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
Infections and infestations	--	--	1311	100	3	0.229	1306	100	10	0.766	0.297	Algorithm converged.	0.082	1.083	-0.537	Algorithm converged.	-1.076	NE	0.299	Algorithm converged.	0.082	1.083	0.0564		3.346	Algorithm converged.	0.923	12.13											
	--	Appendicitis	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	COVID-19	--	1311	100	0	0	1306	100	4	0.306	NE	*	Algorithm not converged.	NE	NE	-0.306	Algorithm converged.	-0.606	NE	NE	*	Algorithm not converged.	NE	NE	0.0619	NE	Algorithm not converged.	NE	NE									
	--	COVID-19 pneumonia	--	1311	100	0	0	1306	100	2	0.153	NE	*	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE	*	Algorithm not converged.	NE	NE	0.249	NE	Algorithm not converged.	NE	NE									
	--	Gastroenteritis	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Pneumonia	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Scrootal abscess	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Sepsis	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Subcutaneous abscess	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Tooth abscess	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Urinary tract infection	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	Injury, poisoning and procedural complications	--	--	1311	100	1	0.076	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE						
--		Ankle fracture	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
--		Epicondylitis	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
--		Foot fracture	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
--		Gun shot wound	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
--		Tibia fracture	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
--			--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
Investigations	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032											
	--	Blood creatine phosphokinase increased	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Blood glucose increased	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032											
	--	Breast cancer	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
Nervous system disorders	--	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
	--	Cerebral infection	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
Psychiatric disorders	--	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE										
	--	Syncope	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
Renal and urinary disorders	--	--	1311	100	0	0	1306	100	2	0.153	NE	*	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE	*	Algorithm not converged.	NE	NE	0.249	NE	Algorithm not converged.	NE	NE										
	--	Suicidal ideation	--	1311	100	0	0	1306	100	2	0.153	NE	*	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE	*	Algorithm not converged.	NE	NE	0.249	NE	Algorithm not converged.	NE	NE									
Respiratory, thoracic and mediastinal disorders	--	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Chronic kidney disease	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
Respiratory, thoracic and mediastinal disorders	--	--	1311	100	1	0.076	1306	100	0	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
	--	Respiratory failure	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									
Vascular disorders	--	--	1311	100	1	0.076	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE							
	--	Essential hypertension	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Hypertensive urgency	--	1311	100	0	0	1306	100	1	0.077	NE	*	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE									
	--	Peripheral vascular disorder	--	1311	100	1	0.076	1306	100	0	0	NE	*	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE									

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
				Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Convergence Reason					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk					Convergence Reason					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
				Level	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t13-2f-ae-row-soc.sas
Output: t13-2f-ae-row-soc-toxgrg13-6

		Casimivab/indecavab						Placebo						Casimivab/indecavab vs. Placebo						Relative Risk						Placebo vs. Casimivab/indecavab											
		Patients			Patients with Event			Patients			Patients with Event			Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)			Relative Risk			Convergence Reason			95% Lower CL			95% upper CL		
Name	SOC	PT	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
Age	Cardiac disorders	--	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE							
			18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE							
			>=50	479	36.537	1	0.209	481	36.83	2	0.416	NE *	Algorithm converged.	0.045	5.544	-0.207	Algorithm converged.	-0.913	NE	0.502	Algorithm converged.	0.046	5.519	1	1.992	NE	Algorithm converged.	0.181	21.892								
			Acute myocardial infarction	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				>=50	479	36.537	1	0.209	481	36.83	0	0	NE *	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	0.502	Algorithm converged.	NE	NE	0.499		NE	Algorithm not converged.	NE	NE							
			Angina pectoris	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				>=50	479	36.537	0	0	481	36.83	1	0.208	NE *	Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE									
			Cardiac arrest	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				>=50	479	36.537	0	0	481	36.83	1	0.208	NE *	Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE									
			Cardiac failure congestive	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				>=50	479	36.537	1	0.209	481	36.83	0	0	NE *	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	NE	0.499		NE	Algorithm not converged.	NE	NE									
			Hypertensive cardiomyopathy	12-17	45	3.432	0	0	43	3.292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				18-49	787	60.031	0	0	782	59.877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE						
				>=50	479	36.537	1	0.209	481																												

* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p \leq 0.05$ in any treatment group, p -value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas

Output: t13-2f-se-raw-soc-toxgrt3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Inmovimab				Placebo				Casirivimab/Inmovimab vs. Placebo				Casirivimab/Inmovimab vs. Placebo				Placebo vs. Casirivimab/Inmovimab			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk			
Name	SOC	Level	n	%	n	%	n	%	n	%	Lower CI	upper CI	Absolute Risk	Lower CI	upper CI	Relative Risk	Lower CI	upper CI			
Region	Cardiac disorders	--	US 1220 93.059 1 0.082 1217 93.185 1 0.082 0.998	ex-US 91 6.941 0 0 89 6.815 1 1.124 NE *	Algorithm converged.	0.062 15.966 0	Algorithm converged.	-0.228 NE 0.998	Algorithm converged.	0.062 15.93 1 0.3027	1.002	Algorithm converged.	0.063 16.009								
	Acute myocardial infarction	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Angina pectoris	US 1220 93.059 0 0 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 1 1.124 NE *	Algorithm not converged.	NE NE NE *	Algorithm not converged.	NE NE NE *	Algorithm not converged.	NE NE NE 0.4944	NE	Algorithm not converged.	NE NE									
	Cardiac arrest	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Cardiac failure congestive	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Hypertensive cardiomyopathy	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE NE *	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Mitral valve stenosis	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Gastrointestinal disorders	--	US 1220 93.059 1 0.082 1217 93.185 1 0.082 0.998	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm converged.	0.062 15.966 0	Algorithm converged.	-0.228 NE 0.998	Algorithm converged.	0.062 15.93 1 1 1.002	Algorithm converged.	0.063 16.009									
	Abdominal pain	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Abdominal pain upper	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	General disorders and administration site conditions	--	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE								
	Sudden death	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Hepatobiliary disorders	--	US 1220 93.059 1 0.082 1217 93.185 1 0.082 0.998	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm converged.	0.062 15.966 0	Algorithm converged.	-0.228 NE 0.998	Algorithm converged.	0.062 15.93 1 1 1.002	Algorithm converged.	0.063 16.009									
	Cholecystitis	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Cholecystitis acute	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Portal hypertension	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Infections and infestations	--	US 1220 93.059 3 0.246 1217 93.185 8 0.657 0.373	ex-US 91 6.941 0 0 89 6.815 2 2.247 NE *	Algorithm converged.	0.099 1.408 -0.411	Algorithm converged.	-0.944 NE 0.374	Algorithm converged.	0.099 1.407 0.1447 0.2778	2.673	Algorithm converged.	0.711 10.052								
	Appendicitis	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	COVID-19	US 1220 93.059 0 0 1217 93.185 3 0.247 NE *	ex-US 91 6.941 0 0 89 6.815 1 1.124 NE *	Algorithm not converged.	NE NE -0.247	Algorithm converged.	-0.525 NE NE *	Algorithm not converged.	NE NE 0.1244	NE	Algorithm not converged.	NE NE									
	COVID-19 pneumonia	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 1 1.124 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Gastroenteritis	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Pneumonia	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Scrotal abscess	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Sepsis	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Subcutaneous abscess	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Tooth abscess	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Urinary tract infection	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Injury, poisoning and procedural complications	--	US 1220 93.059 1 0.082 1217 93.185 2 0.164 0.498	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm converged.	0.045 5.503 -0.082	Algorithm converged.	-0.361 NE 0.499	Algorithm converged.	0.045 5.493 0.6244 1 2.005	Algorithm converged.	0.182 22.082									
	Ankle fracture	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									
	Epicondylitis	US 1220 93.059 0 0 1217 93.185 1 0.082 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE -0.082	Algorithm converged.	-0.243 NE NE *	Algorithm not converged.	NE NE 0.4994	NE	Algorithm not converged.	NE NE									
	Foot fracture	US 1220 93.059 1 0.082 1217 93.185 0 0 NE *	ex-US 91 6.941 0 0 89 6.815 0 0 NE *	Algorithm not converged.	NE NE 0.082	Algorithm converged.	-0.079 NE NE *	Algorithm not converged.	NE NE 1	NE	Algorithm not converged.	NE NE									

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Program: t13-2f-ae-row-soc.sas
Output: t13-2f-ae-row-soc-toxgrg13-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade ≥ 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

Casimir/driver/bv													Pseudo													Casimir/driver/bv vs. Pseudo													Casimir/driver/bv vs. Pseudo																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															
Patients with Event													Patients with Event													Odds Ratio													Absolute Risk Difference													Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
Name	SOC	PT	Level	n			%			n			%			n			%			n			%			n			%			n			%			p-value			Interaction Test (p-value (likelihood ratio))			Relative Risk			n			%			n			%																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
				CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U	L	CL	U

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: i-ae-raw-soc.sas
Output: t13-2f-ae-raw-soc-toxgrg3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdeviab										Placebo										Casirivimab/Imdeviab vs. Placebo										Placebo vs. Casirivimab/Imdeviab														
			Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL															
Age	Cardiac disorders	..	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	2	0.416	0.501	Algorithm converged.	0.045	5,544	-0.207	Algorithm converged.	-0.913	0.502	Algorithm converged.	0.046	5,519	1	1.992	Algorithm converged.	0.181	22,892																				
	Acute myocardial infarction		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Angina pectoris		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	0	0	481	36,83	1	0.208	NE	*	Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																		
	Cardiac arrest		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	0	0	481	36,83	1	0.208	NE	*	Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																		
	Cardiac failure congestive		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Hypertensive cardiomyopathy		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Mitral valve stenosis		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Gastrointestinal disorders	..	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	1	0.127	782	59,877	1	0.128	0.994	Algorithm converged.	0.062	15,914	-0.001	Algorithm converged.	-0.354	NE	* Algorithm not converged.	0.062	15,858	1	1.006	Algorithm converged.	0.063	16,061																				
			>=50	479	36,537	0	0	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
	Abdominal pain		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	1	0.128	NE	*	Algorithm not converged.	NE	NE	-0.128	Algorithm converged.	-0.378	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE																		
			>=50	479	36,537	0	0	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
	Abdominal pain upper		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	1	0.127	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																		
			>=50	479	36,537	0	0	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
	General disorders and administration site conditions	..	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Sudden death		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Hepatobiliary disorders	..	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	1	0.208	1.004	Algorithm converged.	0.083	16,101	0.001	Algorithm converged.	-0.678	NE	* Algorithm not converged.	0.083	16,008	1	0.996	Algorithm converged.	0.082	15,875																				
	Cholecystitis		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	0	0	481	36,83	1	0.208	NE	*	Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																		
	Cholecystitis acute		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Portal hypertension		12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	*	Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE																		
	Infections and infestations	..	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			18-49	787	60,031	3	0.381	782	59,877	5	0.639	0.595	Algorithm converged.	0.142	2,487	-0.258	Algorithm converged.	-0.963	NE	* Algorithm not converged.	0.143	2,486	0.5054	1.677	Algorithm converged.	0.402	6,995																				
			>=50	479	36,537	0	0	481	36,83	5	1.04																																				

[illegible]

		Hypertensive urgency	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=50	479	36,537	0	0	481	36,63	1	0,208	NE	*	Algorithm not converged.	NE	NE	-0,208		Algorithm converged.	-0,633	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Peripheral vascular disorder	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-49	787	60,031	0	0	782	59,877	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=50	479	36,537	1	0,209	481	36,63	0	0	NE	*	Algorithm not converged.	NE	NE	0,209		Algorithm converged.	-0,2	NE	NE	*	Algorithm not converged.	NE	NE	0,499		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < 15 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program t-ae-raw -soc sas
Output: t13-2f-ae-raw -soc toxgrg5-ts

						Casirivimab/divinmab	Patients	%	n	%	n	Patients w/ th Event	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk Difference	Convergence Reason	Relative Risk	95% Lower CI	95% Upper CI	Relative Risk	Interaction Test p-value (beta-hood test)	P-value	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
Name Region	SOC	FT	Level	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	Low or CL	High or UCL	
	Cardiac disorders	--	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	1 0	0.082 1.124	0.998 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15.966 NE	-1.124	Algorithm converged. Algorithm converged.	0.228 -3.313	NE NE	0.998 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15.93 0.4944	1 0.3027	1.002 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.009 NE
		Acute myocardial infarction	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	1 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	* *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Angina pectoris	US ex-US	1220 91	93.059 6.941	0 0	0 89	1217 89	93.185 6.815	0 1	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	* -	Algorithm not converged. Algorithm converged.	-0.243 -3.313	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 0.4944	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Cardiac arrest	US ex-US	1220 91	93.059 6.941	0 0	0 89	1217 89	93.185 6.815	0 1	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	* -	Algorithm converged. Algorithm not converged.	-0.243 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 0.4994	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Cardiac failure congestive	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Hypertensive cardiomyopathy	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Mitral valve stenosis	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
	Gastrointestinal disorders	--	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	1 0	0.082 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15.966 NE	*	Algorithm converged. Algorithm not converged.	-0.228 NE	NE NE	0.998 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15.93 NE	1 NE	1.002 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.009 NE	
		Abdominal pain	US ex-US	1220 91	93.059 6.941	0 0	0 89	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.082 *	Algorithm converged. Algorithm not converged.	-0.243 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4994 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Abdominal pain upper	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
	General disorders and administration site conditions	--	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Sudden death	US ex-US	1220 91	93.059 6.941	1 0	0.082 0	1217 89	93.185 6.815	0 0	0 NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.082 *	Algorithm converged. Algorithm not converged.	-0.079 NE	NE NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE							

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

```
Program t1-ae-raw-soc.sas
Output: t13-2f-ae-raw-soc-toxgrg3-fs
```


Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $n_{ij} < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Program t13-ae-row-soc.sas
Output: t13-2f-ae-row-soc-toxgrg3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivabimab/devedimab										Placebo										Casirivabimab/devedimab vs. Placebo										Placebo vs. Casirivabimab/devedimab														
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk				
Name	SOC	PT	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL																	
All	Cardiac disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Gastrointestinal disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Hepatobiliary disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Infections and infestations	--	--	1311	100	3	0.229	1306	100	9	0.689	0.331	Algorithm converged.	0.089	1.224	-0.46	Algorithm converged.	-0.978	NE	0.332	Algorithm converged.	0.09	1.224	0.091		3.011	Algorithm converged.	0.817	11.099																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	4	0.306	NE *	Algorithm not converged.	NE	NE	-0.306	Algorithm converged.	-0.606	NE	NE *	Algorithm not converged.	NE	NE	0.0619	NE	NE	Algorithm not converged.	NE	NE																		
	COVID-19	--	--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																	
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
	Pneumonia	--	--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Subcutaneous abscess	--	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Urinary tract infection	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Injury, poisoning and procedural complications	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
	Investigations	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032																	
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Nervous system disorders	--	--	1311	100	1	0.076	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Psychiatric disorders	--	--	1311	100	0	0	1306	100	2	0.153	NE *	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE *	Algorithm not converged.	NE	NE	0.249	NE	NE	Algorithm not converged.	NE	NE																	
		--	1311	100	0	0	1306	100	2	0.153	NE *	Algorithm not converged.	NE	NE	-0.153	Algorithm converged.	-0.365	NE	NE *	Algorithm not converged.	NE	NE	0.249	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Renal and urinary disorders	--	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																	
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
	Respiratory, thoracic and mediastinal disorders	--	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE																	
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE																		
		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE																		
	Vascular disorders	--	--	1311	100	1	0.076	1306	100	2	0.153	0.498	Algorithm converged.	0.045	5.496	-0.077	Algorithm converged.	-0.336	NE	0.498	Algorithm converged.	0.045	5.496	0.6241	2.008	Algorithm converged.	0.182	22.114																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
		--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE *	Algorithm not converged.	NE	NE	0.499	NE	NE	Algorithm not converged.	NE	NE																		
	Peripheral vascular disorder		--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																	

Test for interaction based on RRR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t3-3f-ae-raw-soc-tmg3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
				Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
				Level		n		%		n		%		n		%		n		%		n		%		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		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
Name	Sex	SOC	PT	Male	Female	601	710	45,843	54,157	0	1	0	0.141	633	673	48,469	51,531	1	0	0.158	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

						Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	1	0.166	633	48,469	1	0.158	1,053		Algorithm converged.	0.066	16,879	0.008		Algorithm converged.	-0.441	NE	1,053		Algorithm converged.	0.066	16,801	1	0.2901	0.949		Algorithm converged.	0.06	15,145
						Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.4866				Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158		Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.4866				Algorithm not converged.	NE	NE
						Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	2	0.297	NE	*	Algorithm not converged.	NE	NE	-0.297		Algorithm converged.	-0.708	NE	NE	*	Algorithm not converged.	NE	NE	0.2366		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	2	0.297	NE	*	Algorithm not converged.	NE	NE	-0.297		Algorithm converged.	-0.708	NE	NE	*	Algorithm not converged.	NE	NE	0.2366		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166		Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158		Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1	0.3226	NE		Algorithm not converged.	NE	NE
						Female	710	54,157	1	0.141	673	51,531	1	0.149	0.948		Algorithm converged.	0.059	15,184	-0.008		Algorithm converged.	-0.409	NE	0.948		Algorithm converged.	0.059	15,124	1		1.055		Algorithm converged.	0.066	16,833
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149		Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.4866				Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158		Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
						Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141		Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on R/R (Log binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If p < .05 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: 1-ae-raw-soc.sas
 Output: 113-3f-ae-raw-soc-logp3-ls

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casimirab/mdevimab										Placebo										Casimirab/mdevimab vs. Placebo										Placebo vs. Casimirab/mdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk					Convergence Reason					95% Lower CL					95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
Name	SOC	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	95% Lower CL	95% upper CL	Relative Risk	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
Age	Cardiac disorders	PT	12-17	45	3,432	0	0	43	3,292	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison on values is derived on Cochran-Mantel-Haenszel (CMH) method
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t1-ae-row-soc.sas
Output: t13-3f-ae-row-soc-toxgr3-fts

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab						Placebo						Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
		Patients			Patients with Event			Patients			Patients with Event			Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)			Relative Risk			Convergence Reason			95% Lower CL		95% upper CL	
Name	Region	SOC	PT	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
Cardiac disorders			--	US	1220	93.185	0	0.082	1217	93.185	0	0	NE	* Algorithm not converged.	NE	NE	0.079	NE	NE	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	NE	NE	*	Algorithm not converged.	NE	NE	0.4944	NE	Algorithm not converged.	NE	NE				
			Angina pectoris	US	1220	93.059	0	0	1217	93.185	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	NE	NE	*	Algorithm not converged.	NE	NE	0.4944	NE	Algorithm not converged.	NE	NE				
			Hypertensive cardiomyopathy	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
Gastrointestinal disorders		--	US	1220	93.059	1	0.082	1217	93.185	1	0.082	0.998	Algorithm converged.	0.062	15.966	0	*	Algorithm converged.	0.228	NE	0.998	*	Algorithm converged.	0.062	15.93	1	1	1.002	Algorithm converged.	0.063	16.009				
			ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
			Abdominal pain	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Abdominal pain upper	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
Hepatobiliary disorders		--	US	1220	93.059	1	0.082	1217	93.185	1	0.082	0.998	Algorithm converged.	0.062	15.966	0	*	Algorithm converged.	0.228	NE	0.998	*	Algorithm converged.	0.062	15.93	1	1	1.002	Algorithm converged.	0.063	16.009				
			ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
			Cholecystitis	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Cholecystitis acute	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
Infections and infestations		--	US	1220	93.059	3	0.246	1217	93.185	8	0.657	0.373	Algorithm converged.	0.099	1.408	0.411	*	Algorithm converged.	0.944	NE	0.374	*	Algorithm converged.	0.099	1.407	0.1447	0.4323	2.673	Algorithm converged.	0.711	10.052				
			ieUS	91	6.941	0	0	89	6.815	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	NE	NE	*	Algorithm not converged.	NE	NE	0.4944	NE	Algorithm not converged.	NE	NE					
			Appendicitis	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			COVID-19	US	1220	93.059	0	0	1217	93.185	3	0.247	NE	*	Algorithm not converged.	NE	NE	-0.247	Algorithm converged.	0.555	NE	NE	*	Algorithm not converged.	NE	NE	0.1344	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	NE	NE	*	Algorithm not converged.	NE	NE	0.4944	NE	Algorithm not converged.	NE	NE				
			COVID-19 pneumonia	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Gastroenteritis	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Pneumonia	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Scrotal abscess	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Sepsis	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Subcutaneous abscess	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Tooth abscess	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
			Urinary tract infection	US	1220	93.059	0	0	1217	93.185	1	0.082	NE	*	Algorithm not converged.	NE	NE	-0.082	Algorithm converged.	0.243	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE				
				ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE			
Injury, poisoning and procedural complications		--	US	1220	93.059	1	0.082	1217	93.185	1	0.082	0.998	Algorithm converged.	0.062	15.966	0	*	Algorithm converged.	0.228	NE	0.998	*	Algorithm converged.	0.062	15.93	1	1	1.002	Algorithm converged.	0.063	16.009				
			ieUS	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
			Ankle fracture	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	0.079	NE														

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p-value is based on Fisher Exact Test.

Program: t13-3f-ae-raw-soc.sas
Output: t13-3f-ae-raw-soc-toxgr3-ft

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Odds Ratio				Casirivimab/Imdevimab vs. Placebo				Absolute Risk Difference								Casirivimab/Imdevimab vs. Placebo				Relative Risk				Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event																													
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
All	Cardiac disorders	--	--	1311	100	1	0.076	1306	100	0	0	NE	* Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE									
	Acute myocardial infarction	--	--	1311	100	1	0.076	1306	100	0	0	NE	* Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE									
	Mitral valve stenosis	--	--	1311	100	1	0.076	1306	100	0	0	NE	* Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE									
	Hepatobiliary disorders	--	--	1311	100	1	0.076	1306	100	0	0	NE	* Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE									
	Portal hypertension	--	--	1311	100	1	0.076	1306	100	0	0	NE	* Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE									
	Infections and infestations	--	--	1311	100	0	0	1306	100	1	0.077	NE	* Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499		NE	Algorithm not converged.	NE	NE									
	COVID-19 pneumonia	--	--	1311	100	0	0	1306	100	1	0.077	NE	* Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499		NE	Algorithm not converged.	NE	NE									

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toigr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Indevimab								Placebo				Casirivimab/Indevimab vs. Placebo								Placebo vs. Casirivimab/Indevimab																							
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Casirivimab/Indevimab vs. Placebo				Relative Risk				Placebo vs. Casirivimab/Indevimab											
			Test		Level		n		%		n		%		n		%		Odds Ratio		Convergence Reason		95% Lower CL		95% upper CL		Absolute Risk		Convergence Reason		95% Lower CL		95% upper CL		p-value		Interaction Test (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL	
Name	SOC	PT	Test	Level	n	%	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	Interaction Test (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL														
Sex	Cardiac disorders	--	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE													
	Acute myocardial infarction		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE													
	Mitral valve stenosis		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE													
	Hepatobiliary disorders	--	Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE													
	Portal hypertension		Male	601	45.843	0	0	633	48.469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE													
	Infections and infestations	--	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE														
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													
	COVID-19 pneumonia		Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE														
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE													

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toigr4-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab								Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk			
Name	SOC	PT	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL													
Age	Cardiac disorders	--	12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE											
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	* Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	* Algorithm not converged.	NE	NE	NE	0.499	NE	NE	NE	NE	NE	NE	NE										
	Acute myocardial infarction		12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	* Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	* Algorithm not converged.	NE	NE	NE	0.499	NE	NE	NE	NE	NE	NE	NE										
	Mitral valve stenosis		12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	* Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	* Algorithm not converged.	NE	NE	NE	0.499	NE	NE	NE	NE	NE	NE	NE										
	Hepatobiliary disorders	--	12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	* Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	* Algorithm not converged.	NE	NE	NE	0.499	NE	NE	NE	NE	NE	NE	NE										
	Portal hypertension		12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	1	0.209	481	36,83	0	0	NE	* Algorithm not converged.	NE	NE	0.209	Algorithm converged.	-0.2	NE	NE	* Algorithm not converged.	NE	NE	NE	0.499	NE	NE	NE	NE	NE	NE	NE										
	Infections and infestations	--	12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	0	0	481	36,83	1	0.208	NE	* Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	NE	* Algorithm not converged.	NE	NE	NE	1	NE	NE	NE	NE	NE	NE	NE										
	COVID-19 pneumonia		12-17	45	3,432	0	0	43	3,292	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			18-49	787	60,031	0	0	782	59,877	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>=50	479	36,537	0	0	481	36,83	1	0.208	NE	* Algorithm not converged.	NE	NE	-0.208	Algorithm converged.	-0.615	NE	NE	* Algorithm not converged.	NE	NE	NE	1	NE	NE	NE	NE	NE	NE	NE										

Test for interaction based on RR (Log-bimomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-togr4-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Region	Cardiac disorders	--	US	1220	93.059	1	0.082	1217	93.185	0	0	NE	*	Algorithm not converged.	NE	NE	0.082	Algorithm converged.	-0.079	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			ex-US	91	6.941	0	0	89	6.815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	Cardiac disorders	--	--	1311	100	1	0.076	1306	100	1	0.077	0.996	Algorithm converged.	0.062	15.943	0	Algorithm converged.	-0.212	NE	0.996	Algorithm converged.	0.062	15.91	1		1.004	Algorithm converged.	0.063	16.032
		Cardiac arrest	--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Sudden death	--	1311	100	1	0.076	1306	100	0	0	NE *	Algorithm not converged.	NE	NE	0.076	Algorithm converged.	-0.073	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE
		Gun shot wound	--	1311	100	0	0	1306	100	1	0.077	NE *	Algorithm not converged.	NE	NE	-0.077	Algorithm converged.	-0.227	NE	NE	*	Algorithm not converged.	NE	NE	0.499	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: 1-ae-raw-soc.sas
Output: 133-5f-ae-raw-soc-tovg5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Indinavir										Placebo										Casirivimab/Indinavir vs. Placebo										Placebo vs. Casirivimab/Indinavir									
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
			Level	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% upper CI													
Name	Sex	SOC	PT	Male	601	45.843	0	0	633	48.469	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE												
				Female	710	54.157	1	0.141	673	51.531	1	0.149	0.948	Algorithm converged.	0.059	15.184	-0.008	Algorithm converged.	-0.409	NE	0.948	Algorithm converged.	0.059	15.124	1		1.055	Algorithm converged.	0.066	16.833												
			Cardiac arrest	Male	601	45.843	0	0	633	48.469	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE												
				Female	710	54.157	0	0	673	51.531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	*	Algorithm not converged.	NE	NE	0.4866	NE	Algorithm not converged.	NE	NE											
			Cardiac failure congestive	Male	601	45.843	0	0	633	48.469	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE												
				Female	710	54.157	1	0.141	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE											
			General disorders and administration site conditions	Male	601	45.843	1	0.166	633	48.469	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE	Algorithm not converged.	NE	NE												
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			Sudden death	Male	601	45.843	1	0.166	633	48.469	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	*	Algorithm not converged.	NE	NE	0.487	NE	Algorithm not converged.	NE	NE												
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			Injury, poisoning and procedural complications	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE											
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											
			Gun shot wound	Male	601	45.843	0	0	633	48.469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE											
				Female	710	54.157	0	0	673	51.531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE											

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program: t-ae-raw-soc.sas
Output: 1135Hae-raw-soc-toxgr5-5

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Indevimab										Placebo				Casirivimab/Indevimab vs. Placebo										Casirivimab/Indevimab vs. Placebo										Placebo vs. Casirivimab/Indevimab												
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test (likelihood ratio)					Relative Risk						
Name	SOC	PT	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL															
Age	Cardiac disorders	--	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE												
			18-49	787	60,031	0	0	782	59,877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE											
			>=50	479	36,537	1	0,209	481	36,83	1	0,208	1,004	Algorithm converged.	0,063	16,101	0,001	Algorithm converged.	-0,576	NE	1,004	Algorithm converged.	0,063	16,008	1		0,996	Algorithm converged.	0,062	15,875			Algorithm converged.																
		Cardiac arrest	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
			18-49	787	60,031	0	0	782	59,877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
			>=50	479	36,537	0	0	481	36,83	1	0,208	NE *	Algorithm not converged.	NE	NE	-0,208	Algorithm converged.	-0,615	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
		Cardiac failure congestive	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
			18-49	787	60,031	0	0	782	59,877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>=50	479	36,537	1	0,209	481	36,83	0	0	NE *	Algorithm not converged.	NE	NE	0,209	Algorithm converged.	-0,2	NE	NE	*	Algorithm not converged.	NE	NE	0,499		NE	Algorithm not converged.			NE	NE	0,499			NE	NE	0,499			NE	NE	0,499			NE	NE	
		General disorders and administration site conditions	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			18-49	787	60,031	0	0	782	59,877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>=50	479	36,537	1	0,209	481	36,83	0	0	NE *	Algorithm not converged.	NE	NE	0,209	Algorithm converged.	-0,2	NE	NE	*	Algorithm not converged.	NE	NE	0,499		NE	Algorithm not converged.			NE	NE	0,499			NE	NE	0,499			NE	NE	0,499			NE	NE	
		Sudden death	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			18-49	787	60,031	0	0	782	59,877	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>=50	479	36,537	1	0,209	481	36,83	0	0	NE *	Algorithm not converged.	NE	NE	0,209	Algorithm converged.	-0,2	NE	NE	*	Algorithm not converged.	NE	NE	0,499		NE	Algorithm not converged.			NE	NE	0,499			NE	NE	0,499			NE	NE	0,499			NE	NE	
		Injury, poisoning and procedural complications	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			18-49	787	60,031	0	0	782	59,877	1	0,128	NE *	Algorithm not converged.	NE	NE	-0,128	Algorithm converged.	-0,378	NE	NE	*	Algorithm not converged.	NE	NE	0,4984		NE	Algorithm not converged.			NE	NE	0,4984			NE	NE	0,4984			NE	NE	0,4984			NE	NE	
			>=50	479	36,537	0	0	481	36,83	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Gun shot wound	12-17	45	3,432	0	0	43	3,292	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			18-49	787	60,031	0	0	782	59,877	1	0,128	NE *	Algorithm not converged.	NE	NE	-0,128	Algorithm converged.	-0,378	NE	NE	*	Algorithm not converged.	NE	NE	0,4984		NE	Algorithm not converged.			NE	NE	0,4984			NE	NE	0,4984			NE	NE	0,4984			NE	NE	
			>=50	479	36,537	0	0	481	36,83	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: 1-ae-raw-soc.sas
Output: 113-SI-ae-raw-soc-toxgr5-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

					Casi/mab/rnd/mab				Placebo				Casi/mab/rnd/mab vs. Placebo				Casi/mab/rnd/mab vs. Placebo				Placebo vs. Casi/mab/rnd/mab											
					Patients				Patients with Event				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)			
Name	Region	SOC	PT	Level	n	95% Lower CI	95% Upper CI	n	%	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	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI							
Cardiac disorders			--	US ex-US	1220 91	93.059 6.941	0 0	0.082 89	93.185 6.815	0 0	0.998 NE *	0.002 NE	15.966 NE	Algorithm converged. Algorithm not converged.	-0.228 NE	0.998 NE	* Algorithm not converged.	0.062 NE	15.93 NE	1 NE	1 NE	1.002 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.009 NE							
			Cardiac arrest	US ex-US	1220 91	93.059 6.941	0 0	0.082 89	93.185 6.815	0 0	NE *	Algorithm not converged. Algorithm not converged.	-0.243 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE	0.4994 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE							
			Cardiac failure congestive	US ex-US	1220 91	93.059 6.941	1 0	0.082 89	93.185 6.815	0 0	NE *	Algorithm not converged. Algorithm not converged.	-0.079 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	1 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE								
General disorders and administration site conditions			--	US ex-US	1220 91	93.059 6.941	1 0	0.082 89	93.185 6.815	0 0	NE *	Algorithm not converged. Algorithm not converged.	-0.079 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	1 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE								
			Sudden death	US ex-US	1220 91	93.059 6.941	1 0	0.082 89	93.185 6.815	0 0	NE *	Algorithm not converged. Algorithm not converged.	-0.079 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	1 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE								
Injury, poisoning and procedural complications			--	US ex-US	1220 91	93.059 6.941	0 0	0.082 89	93.185 6.815	1 0	NE *	Algorithm not converged. Algorithm not converged.	-0.243 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE	0.4994 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE							
			Gun shot wound	US ex-US	1220 91	93.059 6.941	0 0	0.082 89	93.185 6.815	1 0	NE *	Algorithm not converged. Algorithm not converged.	-0.243 NE	0.998 NE	* Algorithm not converged.	NE NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE	0.4994 NE	NE	Algorithm not converged. Algorithm not converged.	NE NE	NE							

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas

Output: t13-5f-ae-raw-soc-toxgr5-ts

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
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Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If p < = 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off 11Mar2021

Program: t-ae-raw-soc.sas
Output: 113-6f-ae-raw-soc-any-sae-fs

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo						Odds Ratio		Casirivimab/Imdevimab vs. Placebo				Absolute Risk Difference								Casirivimab/Imdevimab vs. Placebo				Relative Risk				Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event																													
				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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)							
Name	Sex	SOC		PT																																			
Cardiac disorders	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	1	0.149	0.948	Algorithm converged.	0.059	15,184	-0.008	Algorithm converged.	-0.409	NE	0.948	Algorithm converged.	0.059	15,124	1	1.055	Algorithm converged.	0.066	16,833													
Acute myocardial infarction	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Cardiac arrest	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4866	NE	Algorithm not converged.	NE	NE	NE	NE							
Cardiac failure congestive	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Gastrointestinal disorders	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	1	0.149	0.948	Algorithm converged.	0.059	15,184	-0.008	Algorithm converged.	-0.409	NE	0.948	Algorithm converged.	0.059	15,124	1	1.055	Algorithm converged.	0.066	16,833													
Abdominal pain	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4866	NE	Algorithm not converged.	NE	NE	NE	NE							
Abdominal pain upper	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
General disorders and administration site conditions	Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.487	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
Sudden death	Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.487	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
Hepatobiliary disorders	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Cholecystitis acute	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Infections and infestations	Male	601	45,843	1	0.166	633	48,469	4	0.632	0.262	Algorithm converged.	0.029	2,362	-0.466	Algorithm converged.	-1.164	NE	0.263	Algorithm converged.	0.03	2,349	0.3748	0.5517	3.798	Algorithm converged.	0.426	33,882												
	Female	710	54,157	3	0.423	673	51,531	5	0.743	0.567	Algorithm converged.	0.135	2,381	-0.32	Algorithm converged.	-1.126	NE	0.569	Algorithm converged.	0.136	2,371	0.496		1.758	Algorithm converged.	0.422	7,329												
Appendicitis	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4866	NE	Algorithm not converged.	NE	NE	NE	NE							
COVID-19	Male	601	45,843	0	0	633	48,469	2	0.316	NE	*	Algorithm not converged.	NE	NE	-0.316	Algorithm converged.	-0.753	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4999	1	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	2	0.297	NE	*	Algorithm not converged.	NE	NE	-0.297	Algorithm converged.	-0.708	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2366		NE	Algorithm not converged.	NE	NE	NE	NE							
COVID-19 pneumonia	Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	1	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.44	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4866		NE	Algorithm not converged.	NE	NE	NE	NE							
Gastroenteritis	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Pneumonia	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	1	0.149	0.948	Algorithm converged.	0.059	15,184	-0.008	Algorithm converged.	-0.409	NE	0.948	Algorithm converged.	0.059	15,124	1	1.055	Algorithm converged.	0.066	16,833													
Scrotal abscess	Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
Sepsis	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	1	0.141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0.141	Algorithm converged.	-0.135	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Soft tissue infection	Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.487		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
Urinary tract infection	Male	601	45,843	0	0	633	48,469	1	0.158	NE	*	Algorithm not converged.	NE	NE	-0.158	Algorithm converged.	-0.467	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE							
Injury, poisoning and procedural complications	Male	601	45,843	1	0.166	633	48,469	1	0.158	1.053	Algorithm converged.	0.066	16,878	0.008	Algorithm converged.	-0.441	NE	1.053	Algorithm converged.	0.066	16,801	1	1	0.949	Algorithm converged.	0.06	15,145												
	Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE							
Ankle fracture	Male	601	45,843	1	0.166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0.166	Algorithm converged.	-0.159																						

		Female	710	54,157	1	0,141	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	0,141		Algorithm converged.	-0,135	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
Psychiatric disorders	--	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	2	0,297	NE	*	Algorithm not converged.	NE	NE	-0,297		Algorithm converged.	-0,708	NE	NE	*	Algorithm not converged.	NE	NE	0,2366		NE		Algorithm not converged.	NE	NE
Mania		Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	1	0,149	NE	*	Algorithm not converged.	NE	NE	-0,149		Algorithm converged.	-0,44	NE	NE	*	Algorithm not converged.	NE	NE	0,4866		NE		Algorithm not converged.	NE	NE
Suicidal ideation		Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	1	0,149	NE	*	Algorithm not converged.	NE	NE	-0,149		Algorithm converged.	-0,44	NE	NE	*	Algorithm not converged.	NE	NE	0,4866		NE		Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--	Male	601	45,843	1	0,166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0,166		Algorithm converged.	-0,159	NE	NE	*	Algorithm not converged.	NE	NE	0,487		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Respiratory failure		Male	601	45,843	1	0,166	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	0,166		Algorithm converged.	-0,159	NE	NE	*	Algorithm not converged.	NE	NE	0,487		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Vascular disorders	--	Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	1	0,149	NE	*	Algorithm not converged.	NE	NE	-0,149		Algorithm converged.	-0,44	NE	NE	*	Algorithm not converged.	NE	NE	0,4866		NE		Algorithm not converged.	NE	NE
Essential hypertension		Male	601	45,843	0	0	633	48,469	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Female	710	54,157	0	0	673	51,531	1	0,149	NE	*	Algorithm not converged.	NE	NE	-0,149		Algorithm converged.	-0,44	NE	NE	*	Algorithm not converged.	NE	NE	0,4866		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off 11Mar2021
 Program: t-ae-raw-soc.sas
 Output: 113-6f-ae-raw-soc-any-sae-6s

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

[illegible]

Program: t-ae-row-soc.sas
Output: t13-6f-ae-row-soc-anysae-fs

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab								Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test (likelihood ratio)				Relative Risk			
Name Region	SOC	PT	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	Interaction Test (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	95% Lower CL	95% upper CL						
																																US	ex-US	US	ex-US	US	ex-US
	Cardiac disorders	--																																			

				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
Psychiatric disorders	--			US	1220	93,059	0	0	1217	93,185	2	0,164	NE	*	Algorithm not converged.	NE	NE	-0,164		Algorithm converged.	-0,392	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,2493		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Mania			US	1220	93,059	0	0	1217	93,185	1	0,082	NE	*	Algorithm not converged.	NE	NE	-0,082		Algorithm converged.	-0,243	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Suicidal ideation			US	1220	93,059	0	0	1217	93,185	1	0,082	NE	*	Algorithm not converged.	NE	NE	-0,082		Algorithm converged.	-0,243	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	--			US	1220	93,059	1	0,082	1217	93,185	0	0	NE	*	Algorithm not converged.	NE	NE	0,082		Algorithm converged.	-0,079	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Respiratory failure			US	1220	93,059	1	0,082	1217	93,185	0	0	NE	*	Algorithm not converged.	NE	NE	0,082		Algorithm converged.	-0,079	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
Vascular disorders	--			US	1220	93,059	0	0	1217	93,185	1	0,082	NE	*	Algorithm not converged.	NE	NE	-0,082		Algorithm converged.	-0,243	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Essential hypertension			US	1220	93,059	0	0	1217	93,185	1	0,082	NE	*	Algorithm not converged.	NE	NE	-0,082		Algorithm converged.	-0,243	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,941	0	0	89	6,815	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off 11Mar2021

Program: t-ae-raw-soc.sas
Output: 113-6f-ae-raw-soc-any-sae-fs

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	--	--	--	1311	100	0	0	1306	100	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	--	--	Male	601	45,843	0	0	633	48,469	0	0
			Female	710	54,157	0	0	673	51,531	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Age	--	--	12-17	45	3,432	0	0	43	3,292	0	0
			18-49	787	60,031	0	0	782	59,877	0	0
			>=50	479	36,537	0	0	481	36,83	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Region	--	--	US	1220	93,059	0	0	1217	93,185	0	0
			ex-US	91	6,941	0	0	89	6,815	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

KohorteA

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

Ergänzende Dokumente

POPULATION: SAFETY - Cohort A

ENDPOINT: All patients

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Outcome of Adverse Events

Category of Adverse Events	Casirivimab/Imdevimab (N=1311)																Placebo (N=1306)															
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING			
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Any AEs	556	423	76,079	0	0	86	15,468	2	0,36	39	7,014	2	0,36	4	0,719	709	547	77,151	2	0,282	83	11,707	2	0,282	61	8,604	5	0,705	9	1,269		
All	461	361	78,308	0	0	64	13,883	0	0	32	6,941	1	0,217	3	0,651	587	453	77,172	2	0,341	71	12,095	0	0	52	8,859	3	0,511	6	1,022		
Grade 1	74	54	72,973	0	0	13	17,568	0	0	6	8,108	0	0	1	1,351	97	77	79,381	0	0	11	11,34	0	0	6	6,186	1	1,031	2	2,062		
Grade 2	16	7	43,75	0	0	7	43,75	0	0	1	6,25	1	6,25	0	0	22	16	72,727	0	0	1	4,545	0	0	3	13,636	1	4,545	1	4,545		
Grade 3	3	1	33,333	0	0	2	66,667	0	0	0	0	0	0	0	0	1	1	100	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 4	2	0	0	0	0	0	0	2	100	0	0	0	0	0	0	2	0	0	0	0	0	2	100	0	0	0	0	0	0	0		
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Any SAEs	14	8	57,143	0	0	3	21,429	2	14,286	1	7,143	0	0	0	0	17	11	64,706	0	0	1	5,882	2	11,765	0	0	1	5,882	2	11,765		
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 1	2	2	100	0	0	0	0	0	0	0	0	0	0	0	0	3	2	66,667	0	0	0	0	0	0	0	0	0	0	1	33,333		
Grade 2	9	5	55,556	0	0	3	33,333	0	0	1	11,111	0	0	0	0	11	8	72,727	0	0	1	9,091	0	0	0	0	1	9,091	1	9,091		
Grade 3	1	1	100	0	0	0	0	0	0	0	0	0	0	0	0	1	1	100	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 4	2	0	0	0	0	0	0	2	100	0	0	0	0	0	0	2	0	0	0	0	0	2	100	0	0	0	0	0	0	0		
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Any AESIs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Clinical cut-off: 11Mar2021

Program: t-ae-resolved-general.sas

Output: t10-ae-resolved-general

Clinical cut-off: 11MAR21

**Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1306)	Casirivimab/Imdevimab (N = 1311)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Median	108.0	107.0

KohorteA

Datenschnitt 01.07.2021 (DCO2)

bersicht:

Studie COV-2069

Kohorte A

Datenschnitt: 01.07.2021 (DCO2)

Wirksamkeit	
Hauptdokumente	
t8-3a-eff-resp-asypcrb-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t8-3a-eff-resp-asypcrb-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t9-1a-eff-smd-strat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t9-1a-eff-smd-unstrat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t9-1b-eff-smd-strat-ANWSYMB	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) that has an onset during the EAP
t8-4a-eff-resp-apcrcon-strat	Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
t8-4a-eff-resp-apcrcon-unstrat	Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP (subgroup)
t9-2a-eff-smd-strat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP
t9-2a-eff-smd-unstrat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP (subgroup)
t9-2b-eff-smd-strat-AIFNPDUR	Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) that has an onset during the EAP
t8-5a-eff-resp-asypcrrc-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP
t8-5a-eff-resp-asypcrrc-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP (subgroup)
t9-3a-eff-smd-strat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP
t9-3a-eff-smd-unstrat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP (subgroup)
t9-3b-eff-smd-strat-ANWSYMC	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) that has an onset during the EAP
t8-6a-eff-resp-asypcrs-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP
t8-6a-eff-resp-asypcrs-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t9-4a-eff-smd-strat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP
t9-4a-eff-smd-unstrat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t9-4b-eff-smd-strat-ANWSYMS	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP at Day 29 - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) that has an onset during the EAP
t8-1a-eff-resp-dth29-strat	All-cause death at EAP
t8-1a-eff-resp-dth29-unstrat	All-cause death at EAP (subgroup)
t8-2a-eff-resp-dthfu-strat	All-cause death at End of Follow-Up
t8-2a-eff-resp-dthfu-unstrat	All-cause death at End of Follow-Up (subgroup)
t8-7a-eff-resp-ahoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-7a-eff-resp-ahoer-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-7b-eff-resp-ahoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-8a-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP

t8-8a-eff-resp-hoeruc-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-8b-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-9a-eff-resp-amaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-9a-eff-resp-amaveru-unstrat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t8-9b-eff-resp-amaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-5a-eff-smd-strat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-5a-eff-smd-unstrat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t9-5b-eff-smd-strat-ANMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-10a-eff-resp-ahosp-strat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-10a-eff-resp-ahosp-unstrat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t8-10b-eff-resp-ahosp-strat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-6a-eff-smd-strat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at day 29
t9-6a-eff-smd-unstrat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at day 29 (subgroup)
t9-6b-eff-smd-strat-ANDHOSP	Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-7a-eff-smd-strat-ANDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-7a-eff-smd-unstrat-ANDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
t9-7b-eff-smd-strat-ANDABSEN	Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP at Day 29 - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
Ergänzende Dokumente	
t3-center_mFAS	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm
t4-dstat-demo_mFAS	Demographic and Baseline Characteristics per arm
t5_1	Table 5.1. Summary of Overall Patient Disposition
t5_3	Table 5.2. Number of screened patients and reason for screening failure
t2-dstat-dur_mFAS	Duration of Follow-up by domain and arm
Household_characteristics	Table 14.4.3.5.1 Index Case Interaction at Baseline
Verträglichkeit	
Hauptdokumente	
t12-1-ae-raw-anyae-unstrat-saf1	Any AEs (subgroup)
t12-2-ae-raw-anyae-unstrat-saf1	Any AEs (excluding disease related events) (subgroup)
t12-3-ae-raw-toxgrt3-unstrat-saf1	AEs Grade >= 3 (subgroup)
t12-4-ae-raw-toxgrt3-unstrat-saf1	AEs Grade >=3 (excluding disease related events) (subgroup)
t12-5-ae-raw-toxgr3-unstrat-saf1	AEs Grade 3 (subgroup)
t12-6-ae-raw-toxgr4-unstrat-saf1	AEs Grade 4 (subgroup)
t12-7-ae-raw-toxgr5-unstrat-saf1	AEs Grade 5 (AEs leading to death) (subgroup)
t12-8-ae-raw-anysae-unstrat-saf1	Any SAEs (subgroup)
t12-9-ae-raw-anysaenr-unstrat-saf1	Any SAEs (excluding disease related events) (subgroup)

t12-10-ae-raw-aeltdis-unstrat-saf1	AEs leading to treatment discontinuation(subgroup)
AESI	
t12-11-ae-raw-isrge3-unstrat-saf1	Injection site reactions Grade >=3 (subgroup)
t12-12-ae-raw-sisr-unstrat-saf1	Serious injection site reactions(subgroup)
t12-13-ae-raw-hyprggr3-unstrat-saf1	Hypersensitivity reactions Grade >=3 (subgroup)
t12-14-ae-raw-shypr-unstrat-saf1	Serious hypersensitivity reactions (subgroup)
SOC/PT	
t13-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t13-2f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade >= 3
t13-3f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t13-4f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t13-5f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t13-6f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t14-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Ergänzende Dokumente	
t10-ae-resolved-general	AE resolved general
t2-dstat-dur_saf	Duration of Follow-up by domain and arm Safety Analysis Set

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Wirksamkeit

Hauptdokumente

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
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Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-3a-eff-resp-asyprb

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1174	100	15	1.3	1143	100	78	6.8	0.18	Algorithm converged.	0.1	0.31	-5,546	Algorithm converged.	-7.14	-3.95	0.19	Algorithm converged.	0.11	0.32	<0.0001		5.34	Algorithm converged.	3.09	9.23		
Sex	Male	539	45.9	7	1.3	555	48.6	30	5.4	0.23	Algorithm converged.	0.1	0.53	-4,107	Algorithm converged.	-6.22	-2	0.24	Algorithm converged.	0.11	0.54	0.0002	0.433	4.16	Algorithm converged.	1.84	9.39		
	Female	635	54.1	8	1.3	588	51.4	48	8.2	0.14	Algorithm converged.	0.07	0.31	-6,903	Algorithm converged.	-9.28	-4.53	0.15	Algorithm converged.	0.07	0.32	<0.0001		6.48	Algorithm converged.	3.09	13.58		
Age	12-17	52	4.4	0	0	47	4.1	4	8.5	0	Algorithm converged.	NE	NE	-8,511	Algorithm converged.	-16.49	-0.53	NE	*	Algorithm not converged.	NE	NE	0.0474	0.446	NE	*	Algorithm not converged.	NE	NE
	18-49	711	60.6	8	1.1	692	60.5	37	5.3	0.2	Algorithm converged.	0.09	0.44	-4,222	Algorithm converged.	-6.07	-2.37	0.21	Algorithm converged.	0.1	0.45	<0.0001		4.75	Algorithm converged.	2.23	10.13		
	>=50	411	35	7	1.7	404	35.3	37	9.2	0.17	Algorithm converged.	0.08	0.39	-7,455	Algorithm converged.	-10.53	-4.38	0.19	Algorithm converged.	0.08	0.41	<0.0001		5.38	Algorithm converged.	2.43	11.92		
Region	US	1087	92.6	14	1.3	1061	92.8	71	6.7	0.18	Algorithm converged.	0.1	0.32	-5,404	Algorithm converged.	-7.05	-3.76	0.19	Algorithm converged.	0.11	0.34	<0.0001	0.7347	5.2	Algorithm converged.	2.95	9.16		
	ex-US	87	7.4	1	1.1	82	7.2	7	8.5	0.12	Algorithm converged.	0.01	1.04	-7,387	Algorithm converged.	-13.84	-0.94	0.13	Algorithm converged.	0.02	1.07	0.0305		7.43	Algorithm converged.	0.93	59.06		
BMI	BMI < 30 kg/m2	752	64.1	6	0.8	736	64.4	52	7.1	0.11	Algorithm converged.	0.05	0.25	-6,267	Algorithm converged.	-8.22	-4.31	0.11	Algorithm converged.	0.05	0.26	<0.0001	0.0569	8.86	Algorithm converged.	3.83	20.49		
	BMI >= 30 kg/m2	418	35.6	9	2.2	400	35	26	6.5	0.32	Algorithm converged.	0.15	0.68	-4,347	Algorithm converged.	-7.13	-1.56	0.33	Algorithm converged.	0.16	0.7	0.0021		3.02	Algorithm converged.	1.43	6.36		
	Unknown/not reported	4	0.3	0	0	7	0.6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	1123	95.7	15	1.3	1110	97.1	74	6.7	0.19	Algorithm converged.	0.11	0.33	-5,331	Algorithm converged.	-6.94	-3.72	0.2	Algorithm converged.	0.12	0.35	<0.0001	0.1442	4.99	Algorithm converged.	2.88	8.64		
	>=1	51	4.3	0	0	33	2.9	4	12.1	0	Algorithm converged.	NE	NE	-12,121	Algorithm converged.	-23.26	-0.99	NE	*	Algorithm not converged.	NE	NE	0.0212		NE	*	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	446	38	5	1.1	413	36.1	26	6.3	0.17	Algorithm converged.	0.06	0.44	-5,174	Algorithm converged.	-7.71	-2.64	0.18	Algorithm converged.	0.07	0.46	<0.0001	0.8945	5.62	Algorithm converged.	2.18	14.49		
	>2	728	62	10	1.4	729	63.8	52	7.1	0.18	Algorithm converged.	0.09	0.36	-5,759	Algorithm converged.	-7.81	-3.71	0.19	Algorithm converged.	0.1	0.38	<0.0001		5.19	Algorithm converged.	2.66	10.14		
Baseline high risk factor	Yes	315	26.8	6	1.9	307	26.9	27	8.8	0.2	Algorithm converged.	0.08	0.49	-6,89	Algorithm converged.	-10.4	-3.38	0.22	Algorithm converged.	0.09	0.52	0.0001	0.6862	4.62	Algorithm converged.	1.93	11.03		
	No	859	73.2	9	1	836	73.1	51	6.1	0.16	Algorithm converged.	0.08	0.33	-5,053	Algorithm converged.	-6.81	-3.29	0.17	Algorithm converged.	0.09	0.35	<0.0001		5.82	Algorithm converged.	2.89	11.75		
Race	White	990	84.3	12	1.2	962	84.2	62	6.4	0.18	Algorithm converged.	0.1	0.33	-5,233	Algorithm converged.	-6.93	-3.54	0.19	Algorithm converged.	0.1	0.35	<0.0001	0.9572	5.32	Algorithm converged.	2.88	9.8		
	Black or African American	128	10.9	1	0.8	123	10.8	7	5.7	0.13	Algorithm converged.	0.02	1.08	-4,91	Algorithm converged.	-9.28	-0.54	0.14	Algorithm converged.	0.02	1.1	0.0331		7.28	Algorithm converged.	0.91	58.35		
	Other	38	3.2	1	2.6	36	3.1	5	13.9	0.17	Algorithm converged.	0.02	1.51	-11,257	Algorithm converged.	-23.65	1.13	0.19	Algorithm converged.	0.02	1.54	0.1027		5.28	Algorithm converged.	0.65	43.02		
	Unknown/Not Reported	18	1.5	1	5.6	22	1.9	4	18.2	0.26	Algorithm converged.	0.03	2.61	-12,626	Algorithm converged.	-31.91	6.65	0.31	Algorithm converged.	0.04	2.5	0.3555		3.27	Algorithm converged.	0.4	26.75		

Ethnicity	Hispanic or Latino	558 47,5	4 0,7	566 49,5	20 3,5	0,2	Algorithm converged.	0,07	0,58	-2,817	Algorithm converged.	-4,49	-1,14	0,2	Algorithm converged.	0,07	0,59	0,0014	0,8283	4,93	Algorithm converged.	1,7	14,33
	Not Hispanic or Latino	612 52,1	11 1,8	570 49,9	58 10,2	0,16	Algorithm converged.	0,08	0,31	-8,378	Algorithm converged.	-11,07	-5,68	0,18	Algorithm converged.	0,09	0,33	<0.0001		5,66	Algorithm converged.	3	10,68
	Unknown/not reported	4 0,3	0 0	7 0,6	0 0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103 8,8	1 1	117 10,2	6 5,1	0,18	Algorithm converged.	0,02	1,53	-4,157	Algorithm converged.	-8,58	0,27	0,19	Algorithm converged.	0,02	1,55	0,1243	0,9953	5,28	Algorithm converged.	0,65	43,15
	No	1062 90,5	14 1,3	1013 88,6	71 7	0,18	Algorithm converged.	0,1	0,32	-5,691	Algorithm converged.	-7,41	-3,98	0,19	Algorithm converged.	0,11	0,33	<0.0001		5,32	Algorithm converged.	3,02	9,37
	Unknown/not reported	9 0,8	0 0	13 1,1	1 7,7	0	Algorithm converged.	NE	NE	-7,692	Algorithm converged.	-22,18	6,79	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15 1,3	2 13,3	14 1,2	2 14,3	0,92	Algorithm converged.	0,11	7,62	-0,952	Algorithm converged.	-26,09	24,19	0,93	Algorithm converged.	0,15	5,76	1		1,07	Algorithm converged.	0,17	6,61
	Negative	1016 86,5	10 1	992 86,8	61 6,1	0,15	Algorithm converged.	0,08	0,3	-5,165	Algorithm converged.	-6,78	-3,55	0,16	Algorithm converged.	0,08	0,31	<0.0001		6,25	Algorithm converged.	3,22	12,12
	Unavailable	143 12,2	3 2,1	137 12	15 10,9	0,17	Algorithm converged.	0,05	0,62	-8,851	Algorithm converged.	-14,58	-3,12	0,19	Algorithm converged.	0,06	0,65	0,0028		5,22	Algorithm converged.	1,55	17,63
Serology status	Seropositive	276 23,5	2 0,7	251 22	6 2,4	0,3	Algorithm converged.	0,06	1,49	-1,666	Algorithm converged.	-3,8	0,47	0,3	Algorithm converged.	0,06	1,49	0,1594	0,5849	3,3	Algorithm converged.	0,67	16,2
	Seronegative	841 71,6	13 1,5	842 73,7	70 8,3	0,17	Algorithm converged.	0,1	0,32	-6,768	Algorithm converged.	-8,81	-4,73	0,19	Algorithm converged.	0,1	0,33	<0.0001		5,38	Algorithm converged.	3	9,65
	Unclear serology status	57 4,9	0 0	50 4,4	2 4	0	Algorithm converged.	NE	NE	-4	Algorithm converged.	-9,43	1,43	NE *	Algorithm not converged.	NE	NE	0,216		NE *	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.
 Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * Indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
 Output: t8-3a-eff-resp-asyprcb

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference			Standardized Mean Difference					
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	1174	100	15	1,278	23,857	0,02	0,007	-0,001	0,058	1143	100	78	6,824	336,286	0,294	0,053	0,272	0,058	-0,273	-0,378	-0,169	0	-0,213	-0,295	-0,132		

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-1-eff-smd-ANWSYMB

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	1174	100	15	1,278	23,857	0,02	0,007	0,02	0,037	1143	100	78	6,824	336,286	0,294	0,053	0,294	0,038	-0,274	-0,378	-0,17	0	-0,214	-0,295	-0,132	NE				
Sex	Male	539	45,911	7	1,299	10,286	0,019	0,01	0,019	0,053	555	48,556	30	5,405	130	0,234	0,072	0,234	0,052	-0,215	-0,36	-0,07	0,004	-0,176	-0,295	-0,058	0,2838				
	Female	635	54,089	8	1,26	13,571	0,021	0,009	0,021	0,053	588	51,444	48	8,163	206,286	0,351	0,079	0,351	0,055	-0,329	-0,479	-0,18	0	-0,247	-0,359	-0,135					
Age	12-17	52	4,429	0	0	0	0	0	0	0,097	47	4,112	4	8,511	12,857	0,274	0,148	0,274	0,102	-0,274	-0,553	0,006	0,055	-0,388	-0,784	0,008	0,1142				
	18-49	711	60,562	8	1,125	16,286	0,023	0,01	0,023	0,04	692	60,542	37	5,347	145,429	0,21	0,057	0,21	0,041	-0,187	-0,299	-0,075	0,001	-0,175	-0,28	-0,07					
	>=50	411	35,009	7	1,703	7,571	0,018	0,01	0,018	0,08	404	35,346	37	9,158	178	0,441	0,114	0,441	0,081	-0,422	-0,645	-0,199	0	-0,26	-0,398	-0,123					
Region	US	1087	92,589	14	1,288	22,429	0,021	0,007	0,021	0,04	1061	92,826	71	6,692	325,571	0,307	0,057	0,307	0,041	-0,286	-0,398	-0,174	0	-0,216	-0,301	-0,131	0,401				
	ex-US	87	7,411	1	1,149	1,429	0,016	0,016	0,016	0,044	82	7,174	7	8,537	10,714	0,131	0,063	0,131	0,046	-0,114	-0,24	0,011	0,074	-0,276	-0,578	0,027					
BMI	BMI < 30 kg/m2	752	64,055	6	0,798	10,857	0,014	0,007	0,014	0,055	736	64,392	52	7,065	252,714	0,343	0,079	0,343	0,056	-0,329	-0,483	-0,175	0	-0,217	-0,319	-0,116	0,1764				
	BMI >= 30 kg/m2	418	35,605	9	2,153	13	0,031	0,014	0,031	0,034	400	34,996	26	6,5	83,571	0,209	0,047	0,209	0,035	-0,178	-0,273	-0,083	0	-0,256	-0,393	-0,119					
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Number of study subjects in cohort B within a household	0	1123	95,656	15	1,336	23,857	0,021	0,007	0,021	0,039	1110	97,113	74	6,667	324,571	0,292	0,055	0,292	0,039	-0,271	-0,379	-0,163	0	-0,209	-0,292	-0,126	0,7736				
	>=1	51	4,344	0	0	0	0	0	0	0,093	33	2,887	4	12,121	11,714	0,355	0,185	0,355	0,116	-0,355	-0,65	-0,06	0,019	-0,53	-0,97	-0,09					
Total household size including the household member(s) not participating this study																															
	2	446	37,99	5	1,121	5,286	0,012	0,007	0,012	0,048	413	36,133	26	6,295	96	0,232	0,072	0,232	0,05	-0,221	-0,357	-0,084	0,002	-0,216	-0,35	-0,082	0,4489				
	>2	728	62,01	10	1,374	18,571	0,026	0,01	0,026	0,052	729	63,78	52	7,133	240,286	0,33	0,073	0,33	0,052	-0,304	-0,449	-0,159	0	-0,215	-0,318	-0,112					
Baseline high risk factor	Yes	315	26,831	6	1,905	6	0,019	0,012	0,019	0,067	307	26,859	27	8,795	101,286	0,33	0,096	0,33	0,068	-0,311	-0,498	-0,124	0,001	-0,262	-0,419	-0,105	0,6739				
	No	859	73,169	9	1,048	17,857	0,021	0,008	0,021	0,045	836	73,141	51	6,1	235	0,281	0,064	0,281	0,045	-0,26	-0,386	-0,135	0	-0,198	-0,293	-0,103					
Race	White	990	84,327	12	1,212	18,429	0,019	0,007	0,019	0,04	962	84,164	62	6,445	266,143	0,277	0,057	0,277	0,04	-0,258	-0,369	-0,147	0	-0,206	-0,294	-0,117	0,6764				
	Black or African American	128	10,903	1	0,781	1,286	0,01	0,01	0,01	0,043	123	10,761	7	5,691	20,286	0,165	0,062	0,165	0,044	-0,155	-0,276	-0,033	0,013	-0,316	-0,564	-0,068					
	Other	38	3,237	1	2,632	0,857	0,023	0,023	0,023	0,134	36	3,15	5	13,889	15,714	0,437	0,196	0,437	0,138	-0,414	-0,798	-0,03	0,035	-0,495	-0,954	-0,036					
	Unknown/Not Reported	18	1,533	1	5,556	3,286	0,183	0,183	0,183	0,921	22	1,925	4	18,182	34,143	1,552	1,111	1,552	0,833	-1,369	-3,885	1,146	0,277	-0,343	-0,974	0,287					

Ethnicity	Hispanic or Latino	558	47,53	4	0,717	7,571	0,014	0,008	0,014	0,038	566	49,519	20	3,534	91,857	0,162	0,053	0,162	0,038	-0,149	-0,255	-0,042	0,006	-0,164	-0,281	-0,047	0,0176
	Not Hispanic or Latino	612	52,129	11	1,797	16,286	0,027	0,01	0,027	0,063	570	49,869	58	10,175	244,429	0,429	0,093	0,429	0,065	-0,402	-0,58	-0,225	0	-0,259	-0,373	-0,145	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Healthcare worker	Yes	103	8,773	1	0,971	2,286	0,022	0,022	0,022	0,067	117	10,236	6	5,128	21,429	0,183	0,084	0,183	0,063	-0,161	-0,342	0,02	0,081	-0,236	-0,501	0,029	0,4875
	No	1062	90,46	14	1,318	21,571	0,02	0,007	0,02	0,041	1013	88,626	71	7,009	312,143	0,308	0,06	0,308	0,042	-0,288	-0,403	-0,173	0	-0,216	-0,302	-0,13	
	Unknown/not reported	9	0,767	0	0	0	0	0	0	0,194	13	1,137	1	7,692	2,714	0,209	0,209	0,209	0,162	-0,209	-0,736	0,319	0,419	-0,344	-1,215	0,526	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	2	13,333	3,571	0,238	0,219	0,238	0,262	14	1,225	2	14,286	6,429	0,459	0,312	0,459	0,271	-0,221	-0,994	0,552	0,562	-0,212	-0,953	0,529	0,9932
	Negative	1016	86,542	10	0,984	16,571	0,016	0,006	0,016	0,032	992	86,789	61	6,149	232,286	0,234	0,046	0,234	0,032	-0,218	-0,307	-0,129	0	-0,214	-0,301	-0,126	
	Unavailable	143	12,181	3	2,098	3,714	0,026	0,023	0,026	0,204	137	11,986	15	10,949	97,571	0,712	0,297	0,712	0,209	-0,686	-1,261	-0,111	0,02	-0,28	-0,515	-0,045	
Serology status	Seropositive	276	23,509	2	0,725	7,429	0,027	0,019	0,027	0,066	251	21,96	6	2,39	35,571	0,142	0,098	0,142	0,069	-0,115	-0,302	0,072	0,229	-0,105	-0,276	0,066	0,0982
	Seronegative	841	71,635	13	1,546	16,429	0,02	0,007	0,02	0,047	842	73,666	70	8,314	295	0,35	0,066	0,35	0,047	-0,331	-0,462	-0,2	0	-0,242	-0,337	-0,146	
	Unclear serology status	57	4,855	0	0	0	0	0	0	0,056	50	4,374	2	4	5,714	0,114	0,088	0,114	0,06	-0,114	-0,278	0,049	0,168	-0,267	-0,648	0,115	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-1-eff-smd-ANWSYMB

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo											Difference between treatments (Casirivimab/Imdevimab - Placebo)								
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA			Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA			Mean Difference			Standardized Mean Difference					
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL				
All	n/a	15	100	15	100	23,857	1,59	0,339	0,335	1,561	78	100	78	100	336,286	4,311	0,63	3,118	0,976	-2,782	-5,654	0,089	0,057	-0,538	-1,094	0,017				

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-1-eff-smd-ANWSYMB

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk							Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-4a-eff-resp-apcrcon

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab								
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio			Absolute Risk Difference			Relative Risk	Relative Risk				Interaction Test p-value (likelihood ratio)	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	Convergence Reason	95% Lower CL			95% upper CL	p-value	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	56	4.8	1143	100	145	12.7	0.34	Algorithm converged.	0.25	0.47	-7.916	Algorithm converged.	-10.2	-5.63	0.38	Algorithm converged.	0.28	0.51	<0.0001		2.66	Algorithm converged.		1.98	3.58
Sex	Male	539	45.9	27	5	555	48.6	66	11.9	0.39	Algorithm converged.	0.25	0.62	-6.883	Algorithm converged.	-10.15	-3.62	0.42	Algorithm converged.	0.27	0.65	<0.0001	0.4808	2.37	Algorithm converged.		1.54	3.66
	Female	635	54.1	29	4.6	588	51.4	79	13.4	0.31	Algorithm converged.	0.2	0.48	-8.868	Algorithm converged.	-12.07	-5.67	0.34	Algorithm converged.	0.23	0.51	<0.0001		2.94	Algorithm converged.		1.95	4.44
Age	12-17	52	4.4	2	3.8	47	4.1	10	21.3	0.15	Algorithm converged.	0.03	0.72	-17.43	Algorithm converged.	-30.25	-4.62	0.18	Algorithm converged.	0.04	0.78	0.0118	0.5374	5.53	Algorithm converged.		1.28	23.96
	18-49	711	60.6	31	4.4	692	60.5	79	11.4	0.35	Algorithm converged.	0.23	0.54	-7.056	Algorithm converged.	-9.86	-4.25	0.38	Algorithm converged.	0.26	0.57	<0.0001		2.62	Algorithm converged.		1.75	3.91
	>=50	411	35	23	5.6	404	35.3	56	13.9	0.37	Algorithm converged.	0.22	0.61	-8.265	Algorithm converged.	-12.3	-4.23	0.4	Algorithm converged.	0.25	0.64	<0.0001		2.48	Algorithm converged.		1.55	3.95
Region	US	1087	92.6	51	4.7	1061	92.8	134	12.6	0.34	Algorithm converged.	0.24	0.48	-7.938	Algorithm converged.	-10.3	-5.58	0.37	Algorithm converged.	0.27	0.51	<0.0001	0.7939	2.69	Algorithm converged.		1.97	3.67
	ex-US	87	7.4	5	5.7	82	7.2	11	13.4	0.39	Algorithm converged.	0.13	1.19	-7.668	Algorithm converged.	-16.52	1.18	0.43	Algorithm converged.	0.16	1.18	0.116		2.33	Algorithm converged.		0.85	6.43
BMI	BMI < 30 kg/m2	752	64.1	31	4.1	736	64.4	94	12.8	0.29	Algorithm converged.	0.19	0.45	-8.649	Algorithm converged.	-11.45	-5.85	0.32	Algorithm converged.	0.22	0.48	<0.0001	0.2039	3.1	Algorithm converged.		2.09	4.59
	BMI >= 30 kg/m2	418	35.6	25	6	400	35	50	12.5	0.45	Algorithm converged.	0.27	0.74	-6.519	Algorithm converged.	-10.48	-2.56	0.48	Algorithm converged.	0.3	0.76	0.0012		2.09	Algorithm converged.		1.32	3.31
	Unknown/not reported	4	0.3	0	0	7	0.6	1	14.3	0	Algorithm converged.	NE	NE	-14.286	Algorithm converged.	-40.21	11.64	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.		NE	NE
Number of study subjects in cohort B within a household	0	1123	95.7	53	4.7	1110	97.1	138	12.4	0.35	Algorithm converged.	0.25	0.48	-7.713	Algorithm converged.	-10.02	-5.41	0.38	Algorithm converged.	0.28	0.52	<0.0001	0.6326	2.63	Algorithm converged.		1.94	3.58
	>=1	51	4.3	3	5.9	33	2.9	7	21.2	0.23	Algorithm converged.	0.06	0.97	-15.33	Algorithm converged.	-30.7	0.04	0.28	Algorithm converged.	0.08	1	0.044		3.61	Algorithm converged.		1	12.97
Total household size including the household members not participating this study	2	446	38	21	4.7	413	36.1	47	11.4	0.38	Algorithm converged.	0.23	0.66	-6.672	Algorithm converged.	-10.31	-3.03	0.41	Algorithm converged.	0.25	0.68	0.0003	0.6463	2.42	Algorithm converged.		1.47	3.97
	>2	728	62	35	4.8	729	63.8	98	13.4	0.33	Algorithm converged.	0.22	0.49	-8.635	Algorithm converged.	-11.56	-5.71	0.36	Algorithm converged.	0.25	0.52	<0.0001		2.8	Algorithm converged.		1.93	4.06
Baseline high risk factor	Yes	315	26.8	14	4.4	307	26.9	44	14.3	0.28	Algorithm converged.	0.15	0.52	-9.888	Algorithm converged.	-14.42	-5.36	0.31	Algorithm converged.	0.17	0.55	<0.0001	0.4348	3.22	Algorithm converged.		1.8	5.76
	No	859	73.2	42	4.9	836	73.1	101	12.1	0.37	Algorithm converged.	0.26	0.54	-7.192	Algorithm converged.	-9.83	-4.55	0.4	Algorithm converged.	0.29	0.57	<0.0001		2.47	Algorithm converged.		1.75	3.5
Race	White	990	84.3	48	4.8	962	84.2	122	12.7	0.35	Algorithm converged.	0.25	0.5	-7.833	Algorithm converged.	-10.33	-5.34	0.38	Algorithm converged.	0.28	0.53	<0.0001	0.9884	2.62	Algorithm converged.		1.9	3.61
	Black or African American	128	10.9	4	3.1	123	10.8	11	8.9	0.33	Algorithm converged.	0.1	1.06	-5.818	Algorithm converged.	-11.69	0.06	0.35	Algorithm converged.	0.11	1.07	0.0638		2.86	Algorithm converged.		0.94	8.75
	Other	38	3.2	2	5.3	36	3.1	5	13.9	0.34	Algorithm converged.	0.06	1.9	-8.626	Algorithm converged.	-21.97	4.72	0.38	Algorithm converged.	0.08	1.83	0.2553		2.64	Algorithm converged.		0.55	12.75
	Unknown/Not Reported	18	1.5	2	11.1	22	1.9	7	31.8	0.27	Algorithm converged.	0.05	1.5	-20.707	Algorithm converged.	-44.99	3.57	0.35	Algorithm converged.	0.08	1.48	0.1489		2.86	Algorithm converged.		0.68	12.12

Ethnicity	Hispanic or Latino	558	47,5	21	3,8	566	49,5	53	9,4	0,38	Algorithm converged.	0,23	0,64	-5,601	Algorithm converged.	-8,47	-2,73	0,4	Algorithm converged.	0,25	0,66	0,0002	0,6896	2,49	Algorithm converged.	1,52	4,07
	Not Hispanic or Latino	612	52,1	35	5,7	570	49,9	92	16,1	0,32	Algorithm converged.	0,21	0,47	-10,421	Algorithm converged.	-13,96	-6,88	0,35	Algorithm converged.	0,24	0,51	<0.0001		2,82	Algorithm converged.	1,95	4,09
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	3	2,9	117	10,2	9	7,7	0,36	Algorithm converged.	0,09	1,37	-4,78	Algorithm converged.	-10,6	1,04	0,38	Algorithm converged.	0,11	1,36	0,1448	0,9731	2,64	Algorithm converged.	0,73	9,49
	No	1062	90,5	52	4,9	1013	88,6	134	13,2	0,34	Algorithm converged.	0,24	0,47	-8,332	Algorithm converged.	-10,79	-5,87	0,37	Algorithm converged.	0,27	0,5	<0.0001		2,7	Algorithm converged.	1,98	3,68
	Unknown/not reported	9	0,8	1	11,1	13	1,1	2	15,4	0,69	Algorithm converged.	0,05	8,96	-4,274	Algorithm converged.	-32,67	24,12	0,72	Algorithm converged.	0,08	6,82	1		1,38	Algorithm converged.	0,15	13,07
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	2	13,3	14	1,2	6	42,9	0,21	Algorithm converged.	0,03	1,27	-29,524	Algorithm converged.	-60,64	1,59	0,31	Algorithm converged.	0,07	1,29	0,1086	0,821	3,21	Algorithm converged.	0,77	13,36
	Negative	1016	86,5	44	4,3	992	86,8	117	11,8	0,34	Algorithm converged.	0,24	0,48	-7,464	Algorithm converged.	-9,83	-5,1	0,37	Algorithm converged.	0,26	0,51	<0.0001		2,72	Algorithm converged.	1,95	3,81
	Unavailable	143	12,2	10	7	137	12	22	16,1	0,39	Algorithm converged.	0,18	0,86	-9,065	Algorithm converged.	-16,5	-1,63	0,44	Algorithm converged.	0,21	0,89	0,0174		2,3	Algorithm converged.	1,13	4,67
Serology status	Seropositive	276	23,5	11	4	251	22	19	7,6	0,51	Algorithm converged.	0,24	1,09	-3,584	Algorithm converged.	-7,59	0,42	0,53	Algorithm converged.	0,26	1,08	0,0764	0,3051	1,9	Algorithm converged.	0,92	3,91
	Seronegative	841	71,6	42	5	842	73,7	122	14,5	0,31	Algorithm converged.	0,22	0,45	-9,495	Algorithm converged.	-12,29	-6,7	0,34	Algorithm converged.	0,25	0,48	<0.0001		2,9	Algorithm converged.	2,07	4,07
	Unclear serology status	57	4,9	3	5,3	50	4,4	4	8	0,64	Algorithm converged.	0,14	3	-2,737	Algorithm converged.	-12,23	6,76	0,66	Algorithm converged.	0,15	2,8	0,7031		1,52	Algorithm converged.	0,36	6,47

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-4a-eff-resp-apccon

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference			Standardized Mean Difference			
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	1174	100	56	4,77	64	0,055	0,008	0,047	0,027	1143	100	145	12,686	311	0,272	0,024	0,264	0,027	-0,217	-0,266	-0,169	0	-0,365	-0,446	-0,283

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-2-eff-smd-AIFNPDUR

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

			Casirivimab/Imdevimab								Placebo								Difference between treatments (Casirivimab/Imdevimab - Placebo)								
			Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference			Standardized Mean Difference			Interaction Test
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)
All	n/a	1174	100	56	4,77	64	0,055	0,008	0,055	0,017	1143	100	145	12,686	311	0,272	0,024	0,272	0,018	-0,218	-0,266	-0,169	0	-0,365	-0,446	-0,283	NE
Sex	Male	539	45,911	27	5,009	33	0,061	0,012	0,061	0,024	555	48,556	66	11,892	133	0,24	0,032	0,24	0,024	-0,178	-0,246	-0,111	0	-0,315	-0,433	-0,196	0,1284
	Female	635	54,089	29	4,567	31	0,049	0,009	0,049	0,025	588	51,444	79	13,435	178	0,303	0,036	0,303	0,026	-0,254	-0,324	-0,184	0	-0,408	-0,521	-0,296	
Age	12-17	52	4,429	2	3,846	2	0,038	0,027	0,038	0,097	47	4,112	10	21,277	21	0,447	0,145	0,447	0,102	-0,408	-0,688	-0,129	0,005	-0,579	-0,975	-0,182	0,0623
	18-49	711	60,562	31	4,36	38	0,053	0,01	0,053	0,021	692	60,542	79	11,416	159	0,23	0,028	0,23	0,021	-0,176	-0,234	-0,119	0	-0,321	-0,426	-0,216	
	>=50	411	35,009	23	5,596	24	0,058	0,012	0,058	0,032	404	35,346	56	13,861	131	0,324	0,045	0,324	0,033	-0,266	-0,356	-0,176	0	-0,405	-0,543	-0,268	
Region	US	1087	92,589	51	4,692	59	0,054	0,008	0,054	0,018	1061	92,826	134	12,63	294	0,277	0,025	0,277	0,019	-0,223	-0,274	-0,171	0	-0,367	-0,452	-0,282	0,444
	ex-US	87	7,411	5	5,747	5	0,057	0,025	0,057	0,047	82	7,174	11	13,415	17	0,207	0,064	0,207	0,048	-0,15	-0,283	-0,016	0,028	-0,34	-0,642	-0,037	
BMI	BMI < 30 kg/m2	752	64,055	31	4,122	34	0,045	0,008	0,045	0,021	736	64,392	94	12,772	198	0,269	0,029	0,269	0,022	-0,224	-0,283	-0,164	0	-0,382	-0,484	-0,28	0,7646
	BMI >= 30 kg/m2	418	35,605	25	5,981	30	0,072	0,015	0,072	0,03	400	34,996	50	12,5	112	0,28	0,041	0,28	0,031	-0,208	-0,293	-0,123	0	-0,336	-0,473	-0,199	
	Unknown/not reported	4	0,341	0	0	0	0	0		0,154	7	0,612	1	14,286	1	0,143	0,143	0,143	0,117	-0,143	-0,58	0,295	0,479	-0,423	-1,72	0,873	
Number of study subjects in cohort B within a household	0	1123	95,656	53	4,72	61	0,054	0,008	0,054	0,018	1110	97,113	138	12,432	296	0,267	0,024	0,267	0,018	-0,212	-0,262	-0,163	0	-0,358	-0,441	-0,275	0,1762
	>=1	51	4,344	3	5,882	3	0,059	0,033	0,059	0,094	33	2,887	7	21,212	15	0,455	0,18	0,455	0,117	-0,396	-0,694	-0,097	0,01	-0,584	-1,024	-0,143	
Total household size including the household member(s) not participating this study	2	446	37,99	21	4,709	22	0,049	0,011	0,049	0,027	413	36,133	47	11,38	105	0,254	0,039	0,254	0,028	-0,205	-0,282	-0,128	0	-0,356	-0,49	-0,222	0,6972
	>2	728	62,01	35	4,808	42	0,058	0,01	0,058	0,023	729	63,78	98	13,443	206	0,283	0,03	0,283	0,023	-0,225	-0,287	-0,162	0	-0,369	-0,472	-0,266	
Baseline high risk factor	Yes	315	26,831	14	4,444	18	0,057	0,017	0,057	0,036	307	26,859	44	14,332	98	0,319	0,049	0,319	0,037	-0,262	-0,363	-0,161	0	-0,408	-0,565	-0,25	0,2765
	No	859	73,169	42	4,889	46	0,054	0,008	0,054	0,02	836	73,141	101	12,081	213	0,255	0,027	0,255	0,02	-0,201	-0,256	-0,146	0	-0,348	-0,443	-0,253	
Race	White	990	84,327	48	4,848	53	0,054	0,008	0,054	0,019	962	84,164	122	12,682	270	0,281	0,027	0,281	0,02	-0,227	-0,281	-0,173	0	-0,374	-0,462	-0,285	0,3304
	Black or African American	128	10,903	4	3,125	6	0,047	0,027	0,047	0,044	123	10,761	11	8,943	20	0,163	0,057	0,163	0,044	-0,116	-0,238	0,007	0,064	-0,234	-0,482	0,014	
	Other	38	3,237	2	5,263	3	0,079	0,058	0,079	0,083	36	3,15	5	13,889	8	0,222	0,106	0,222	0,086	-0,143	-0,381	0,095	0,234	-0,276	-0,735	0,183	
	Unknown/Not Reported	18	1,533	2	11,111	2	0,111	0,076	0,111	0,167	22	1,925	7	31,818	13	0,591	0,194	0,591	0,151	-0,48	-0,936	-0,024	0,04	-0,663	-1,294	-0,033	

Ethnicity	Hispanic or Latino	558	47,53	21	3,763	23	0,041	0,009	0,041	0,021	566	49,519	53	9,364	104	0,184	0,027	0,184	0,021	-0,143	-0,2	-0,085	0	-0,292	-0,409	-0,175	0,0019
	Not Hispanic or Latino	612	52,129	35	5,719	41	0,067	0,012	0,067	0,027	570	49,869	92	16,14	207	0,363	0,039	0,363	0,028	-0,296	-0,374	-0,218	0	-0,435	-0,549	-0,321	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Healthcare worker	Yes	103	8,773	3	2,913	3	0,029	0,017	0,029	0,05	117	10,236	9	7,692	21	0,179	0,063	0,179	0,047	-0,15	-0,286	-0,015	0,029	-0,295	-0,561	-0,03	0,3674
	No	1062	90,46	52	4,896	60	0,056	0,008	0,056	0,019	1013	88,626	134	13,228	287	0,283	0,026	0,283	0,019	-0,227	-0,279	-0,175	0	-0,374	-0,46	-0,288	
	Unknown/not reported	9	0,767	1	11,111	1	0,111	0,111	0,111	0,17	13	1,137	2	15,385	3	0,231	0,166	0,231	0,141	-0,12	-0,581	0,341	0,594	-0,226	-1,096	0,644	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	2	13,333	3	0,2	0,145	0,2	0,25	14	1,225	6	42,857	13	0,929	0,339	0,929	0,259	-0,729	-1,467	0,01	0,053	-0,731	-1,472	0,01	0,0114
	Negative	1016	86,542	44	4,331	49	0,048	0,008	0,048	0,017	992	86,789	117	11,794	241	0,243	0,024	0,243	0,018	-0,195	-0,243	-0,146	0	-0,35	-0,438	-0,263	
	Unavailable	143	12,181	10	6,993	12	0,084	0,027	0,084	0,065	137	11,986	22	16,058	57	0,416	0,091	0,416	0,066	-0,332	-0,515	-0,149	0	-0,426	-0,66	-0,191	
Serology status	Seropositive	276	23,509	11	3,986	13	0,047	0,015	0,047	0,025	251	21,96	19	7,57	34	0,135	0,034	0,135	0,026	-0,088	-0,158	-0,018	0,014	-0,216	-0,387	-0,045	0,0036
	Seronegative	841	71,635	42	4,994	47	0,056	0,009	0,056	0,022	842	73,666	122	14,489	268	0,318	0,03	0,318	0,022	-0,262	-0,324	-0,201	0	-0,406	-0,502	-0,311	
	Unclear serology status	57	4,855	3	5,263	4	0,07	0,042	0,07	0,067	50	4,374	4	8	9	0,18	0,093	0,18	0,072	-0,11	-0,305	0,085	0,267	-0,215	-0,596	0,167	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-2-eff-smd-AIFNPDUR

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) that has an onset during the EAP

ENDPOINT: Number of weeks of RT-qPCR confirmed SARS-CoV-2 infection (regardless of symptoms) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo											Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA				Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference				
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL					
All	n/a	56	100	56	100	64	1,143	0,054	0,936	0,157	145	100	145	100	311	2,145	0,088	1,936	0,126	-1	-1,284	-0,716	0	-1,089	-1,398	-0,78					

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-2-eff-smd-AIFNPDIR

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-5a-eff-resp-asyprc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio			Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	Relative Risk	Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														

Ethnicity	Hispanic or Latino	558 47,5	2 0,4	566 49,5	16 2,8	0,12	Algorithm converged.	0,03	0,54	-2,468	Algorithm converged.	-3,92	-1,02	0,13	Algorithm converged.	0,03	0,55	0,0012	0,874	7,89	Algorithm converged.	1,82	34,14
	Not Hispanic or Latino	612 52,1	7 1,1	570 49,9	45 7,9	0,13	Algorithm converged.	0,06	0,3	-6,751	Algorithm converged.	-9,12	-4,38	0,14	Algorithm converged.	0,07	0,32	<0.0001		6,9	Algorithm converged.	3,14	15,18
	Unknown/not reported	4 0,3	0 0	7 0,6	0 0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103 8,8	1 1	117 10,2	5 4,3	0,22	Algorithm converged.	0,03	1,91	-3,303	Algorithm converged.	-7,43	0,82	0,23	Algorithm converged.	0,03	1,91	0,2181	0,6822	4,4	Algorithm converged.	0,52	37,06
	No	1062 90,5	8 0,8	1013 88,6	55 5,4	0,13	Algorithm converged.	0,06	0,28	-4,676	Algorithm converged.	-6,17	-3,19	0,14	Algorithm converged.	0,07	0,29	<0.0001		7,21	Algorithm converged.	3,45	15,06
	Unknown/not reported	9 0,8	0 0	13 1,1	1 7,7	0	Algorithm converged.	NE	NE	-7,692	Algorithm converged.	-22,18	6,79	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15 1,3	2 13,3	14 1,2	2 14,3	0,92	Algorithm converged.	0,11	7,62	-0,952	Algorithm converged.	-26,09	24,19	0,93	Algorithm converged.	0,15	5,76	1		1,07	Algorithm converged.	0,17	6,61
	Negative	1016 86,5	6 0,6	992 86,8	46 4,6	0,12	Algorithm converged.	0,05	0,29	-4,047	Algorithm converged.	-5,44	-2,66	0,13	Algorithm converged.	0,05	0,3	<0.0001		7,85	Algorithm converged.	3,37	18,3
	Unavailable	143 12,2	1 0,7	137 12	13 9,5	0,07	Algorithm converged.	0,01	0,52	-8,79	Algorithm converged.	-13,88	-3,7	0,07	Algorithm converged.	0,01	0,56	0,0006		13,57	Algorithm converged.	1,8	102,33
Serology status	Seropositive	276 23,5	2 0,7	251 22	6 2,4	0,3	Algorithm converged.	0,06	1,49	-1,666	Algorithm converged.	-3,8	0,47	0,3	Algorithm converged.	0,06	1,49	0,1594	0,3626	3,3	Algorithm converged.	0,67	16,2
	Seronegative	841 71,6	7 0,8	842 73,7	55 6,5	0,12	Algorithm converged.	0,05	0,27	-5,7	Algorithm converged.	-7,48	-3,92	0,13	Algorithm converged.	0,06	0,28	<0.0001		7,85	Algorithm converged.	3,59	17,13
	Unclear serology status	57 4,9	0 0	50 4,4	0 0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-5a-eff-resp-asyprc

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference			Standardized Mean Difference			
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	1174	100	9	0,767	18.286	0,016	0,006	-0,002	0,057	1143	100	61	5,337	299,571	0,262	0,053	0,244	0,057	-0,246	-0,349	-0,143	0	-0,195	-0,277	-0,114

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-3-eff-smd-ANWSYMC

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	SE	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)	
All	n/a	1174	100	9	0,767	18,286	0,016	0,006	0,016	0,037	1143	100	61	5,337	299,571	0,262	0,053	0,262	0,037	-0,247	-0,349	-0,144	0	-0,196	-0,277	-0,114	NE		
Sex	Male	539	45,911	3	0,557	8,429	0,016	0,01	0,016	0,052	555	48,556	23	4,144	117,143	0,211	0,071	0,211	0,051	-0,195	-0,339	-0,052	0,008	-0,162	-0,28	-0,043	0,3438		
	Female	635	54,089	6	0,945	9,857	0,016	0,007	0,016	0,052	588	51,444	38	6,463	182,429	0,31	0,077	0,31	0,054	-0,295	-0,441	-0,148	0	-0,226	-0,338	-0,114			
Age	12-17	52	4,429	0	0	0	0	0	0	0,032	47	4,112	2	4,255	2,714	0,058	0,049	0,058	0,034	-0,058	-0,151	0,035	0,22	-0,246	-0,643	0,15	0,0978		
	18-49	711	60,562	5	0,703	14	0,02	0,009	0,02	0,04	692	60,542	28	4,046	132,714	0,192	0,057	0,192	0,04	-0,172	-0,283	-0,061	0,002	-0,162	-0,267	-0,057			
	>=50	411	35,009	4	0,973	4,286	0,01	0,006	0,01	0,079	404	35,346	31	7,673	164,143	0,406	0,113	0,406	0,079	-0,396	-0,616	-0,176	0	-0,248	-0,385	-0,11			
Region	US	1087	92,589	8	0,736	16,857	0,016	0,006	0,016	0,04	1061	92,826	57	5,372	290	0,273	0,057	0,273	0,04	-0,258	-0,368	-0,148	0	-0,198	-0,282	-0,113	0,4341		
	ex-US	87	7,411	1	1,149	1,429	0,016	0,016	0,016	0,044	82	7,174	4	4,878	9,571	0,117	0,063	0,117	0,045	-0,1	-0,225	0,025	0,115	-0,243	-0,545	0,06			
BMI	BMI < 30 kg/m2	752	64,055	4	0,532	9,429	0,013	0,007	0,013	0,055	736	64,392	41	5,571	235,429	0,32	0,079	0,32	0,055	-0,307	-0,46	-0,154	0	-0,204	-0,306	-0,103	0,126		
	BMI >= 30 kg/m2	418	35,605	5	1,196	8,857	0,021	0,011	0,021	0,03	400	34,996	20	5	64,143	0,16	0,042	0,16	0,03	-0,139	-0,223	-0,055	0,001	-0,228	-0,365	-0,091			
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Number of study subjects in cohort B within a household	0	1123	95,656	9	0,801	18,286	0,016	0,006	0,016	0,038	1110	97,113	58	5,225	289,286	0,261	0,054	0,261	0,038	-0,244	-0,35	-0,138	0	-0,191	-0,274	-0,108	0,8141		
	>=1	51	4,344	0	0	0	0	0	0	0,092	33	2,887	3	9,091	10,286	0,312	0,182	0,312	0,114	-0,312	-0,602	-0,021	0,036	-0,472	-0,913	-0,032			
Total household size including the household member(s) not participating this study																													
	2	446	37,99	2	0,448	3,286	0,007	0,007	0,007	0,047	413	36,133	20	4,843	83,429	0,202	0,07	0,202	0,049	-0,195	-0,328	-0,061	0,004	-0,195	-0,329	-0,062	0,4538		
	>2	728	62,01	7	0,962	15	0,021	0,009	0,021	0,052	729	63,78	41	5,624	216,143	0,296	0,072	0,296	0,052	-0,276	-0,419	-0,133	0	-0,198	-0,301	-0,095			
Baseline high risk factor	Yes	315	26,831	3	0,952	2,571	0,008	0,005	0,008	0,064	307	26,859	21	6,84	86,571	0,282	0,092	0,282	0,065	-0,274	-0,453	-0,094	0,003	-0,24	-0,397	-0,083	0,752		
	No	859	73,169	6	0,698	15,714	0,018	0,008	0,018	0,044	836	73,141	40	4,785	213	0,255	0,064	0,255	0,045	-0,236	-0,361	-0,112	0	-0,182	-0,277	-0,086			
Race	White	990	84,327	7	0,707	16	0,016	0,007	0,016	0,039	962	84,164	49	5,094	241,571	0,251	0,056	0,251	0,04	-0,235	-0,345	-0,125	0	-0,19	-0,278	-0,101	0,651		
	Black or African American	128	10,903	1	0,781	1,286	0,01	0,01	0,01	0,035	123	10,761	5	4,065	13,857	0,113	0,05	0,113	0,036	-0,103	-0,202	-0,003	0,043	-0,256	-0,504	-0,008			
	Other	38	3,237	0	0	0	0	0	0	0,112	36	3,15	4	11,111	11,571	0,321	0,166	0,321	0,115	-0,321	-0,643	0	0,05	-0,459	-0,918	0			
	Unknown/Not Reported	18	1,533	1	5,556	1	0,056	0,056	0,056	0,916	22	1,925	3	13,636	32,571	1,481	1,114	1,481	0,828	-1,425	-3,925	1,075	0,256	-0,359	-0,99	0,271			

Ethnicity	Hispanic or Latino	558	47,53	2	0,358	4,286	0,008	0,006	0,008	0,038	566	49,519	16	2,827	84,143	0,149	0,053	0,149	0,038	-0,141	-0,246	-0,036	0,008	-0,158	-0,275	-0,041	0,0417
	Not Hispanic or Latino	612	52,129	7	1,144	14	0,023	0,01	0,023	0,062	570	49,869	45	7,895	215,429	0,378	0,092	0,378	0,064	-0,355	-0,53	-0,18	0	-0,232	-0,346	-0,118	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Healthcare worker	Yes	103	8,773	1	0,971	2,286	0,022	0,022	0,022	0,062	117	10,236	5	4,274	17,571	0,15	0,078	0,15	0,058	-0,128	-0,296	0,04	0,135	-0,202	-0,467	0,064	0,4604
	No	1062	90,46	8	0,753	16	0,015	0,006	0,015	0,04	1013	88,626	55	5,429	279,286	0,276	0,059	0,276	0,041	-0,261	-0,374	-0,148	0	-0,198	-0,284	-0,112	
	Unknown/not reported	9	0,767	0	0	0	0	0	0	0,194	13	1,137	1	7,692	2,714	0,209	0,209	0,209	0,162	-0,209	-0,736	0,319	0,419	-0,344	-1,215	0,526	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	2	13,333	3,571	0,238	0,219	0,238	0,262	14	1,225	2	14,286	6,429	0,459	0,312	0,459	0,271	-0,221	-0,994	0,552	0,562	-0,212	-0,953	0,529	0,9234
	Negative	1016	86,542	6	0,591	13,714	0,013	0,006	0,013	0,031	992	86,789	46	4,637	197,286	0,199	0,044	0,199	0,032	-0,185	-0,272	-0,099	0	-0,187	-0,274	-0,099	
	Unavailable	143	12,181	1	0,699	1	0,007	0,007	0,007	0,203	137	11,986	13	9,489	95,857	0,7	0,296	0,7	0,207	-0,693	-1,264	-0,122	0,018	-0,285	-0,519	-0,05	
Serology status	Seropositive	276	23,509	2	0,725	7,429	0,027	0,019	0,027	0,066	251	21,96	6	2,39	35,571	0,142	0,098	0,142	0,069	-0,115	-0,302	0,072	0,229	-0,105	-0,276	0,066	0,1491
	Seronegative	841	71,635	7	0,832	10,857	0,013	0,005	0,013	0,046	842	73,666	55	6,532	264	0,314	0,065	0,314	0,046	-0,301	-0,429	-0,172	0	-0,224	-0,319	-0,128	
	Unclear serology status	57	4,855	0	0	0	0	0	0	NE	50	4,374	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
 Output: t9-3-eff-smd-ANWSYMC

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC definition) during EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference						
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL					
All	n/a	9	100	9	100	18,286	2,032	0,413	0,999	2,204	61	100	61	100	299,571	4,911	0,781	3,697	1,427	-2,698	-6,834	1,439	0,197	-0,461	-1,169	0,246					

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-3-eff-smd-ANWSYMC

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	3	0,3	1143	100	33	2,9	0,09	Algorithm converged.	0,03	0,28	-2,632	Algorithm converged.	-3,64	-1,62	0,09	Algorithm converged.	0,03	0,29	<0.0001		11,3	Algorithm converged.	3,47	36,74

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-6a-eff-resp-asypcrs

POPULATION: Cohort A

ENDPOINT: Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
Name	Level	Patients		Event		Patients		Event		Odds Ratio	Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk										
		n	%	n	%	n	%	n	%		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1174	100	3	0,3	1143	100	33	2,9	0,09	Algorithm converged.	0,03	0,28	-2,632	Algorithm converged.	-3,64	-1,62	0,09	Algorithm converged.	0,03	0,29	<0.0001		11,3	Algorithm converged.	3,47	36,74								
Sex	Male	539	45,9	1	0,2	555	48,6	12	2,2	0,08	Algorithm converged.	0,01	0,65	-1,977	Algorithm converged.	-3,24	-0,71	0,09	Algorithm converged.	0,01	0,66	0,0033	0,9828	11,65	Algorithm converged.	1,52	89,32								
	Female	635	54,1	2	0,3	588	51,4	21	3,6	0,09	Algorithm converged.	0,02	0,37	-3,256	Algorithm converged.	-4,82	-1,69	0,09	Algorithm converged.	0,02	0,37	<0.0001		11,34	Algorithm converged.	2,67	48,15								
Age	12-17	52	4,4	0	0	47	4,1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE								
	18-49	711	60,6	2	0,3	692	60,5	17	2,5	0,11	Algorithm converged.	0,03	0,49	-2,175	Algorithm converged.	-3,39	-0,96	0,11	Algorithm converged.	0,03	0,49	0,0003		8,73	Algorithm converged.	2,03	37,66								
	>=50	411	35	1	0,2	404	35,3	16	4	0,06	Algorithm converged.	0,01	0,45	-3,717	Algorithm converged.	-5,68	-1,76	0,06	Algorithm converged.	0,01	0,46	0,0001		16,28	Algorithm converged.	2,17	122,17								
Region	US	1087	92,6	3	0,3	1061	92,8	32	3	0,09	Algorithm converged.	0,03	0,29	-2,74	Algorithm converged.	-3,82	-1,66	0,09	Algorithm converged.	0,03	0,3	<0.0001	0,6691	10,93	Algorithm converged.	3,36	35,58								
	ex-US	87	7,4	0	0	82	7,2	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE *	Algorithm not converged.	NE	NE	0,4852		NE *	Algorithm not converged.	NE	NE								
BMI	BMI < 30 kg/m2	752	64,1	2	0,3	736	64,4	20	2,7	0,1	Algorithm converged.	0,02	0,41	-2,451	Algorithm converged.	-3,68	-1,22	0,1	Algorithm converged.	0,02	0,42	<0.0001	0,8207	10,22	Algorithm converged.	2,4	43,56								
	BMI >= 30 kg/m2	418	35,6	1	0,2	400	35	13	3,3	0,07	Algorithm converged.	0,01	0,55	-3,011	Algorithm converged.	-4,81	-1,21	0,07	Algorithm converged.	0,01	0,56	0,0007		13,59	Algorithm converged.	1,79	103,37								
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE								
Number of study subjects in cohort B within a household	0	1123	95,7	3	0,3	1110	97,1	33	3	0,09	Algorithm converged.	0,03	0,29	-2,706	Algorithm converged.	-3,75	-1,66	0,09	Algorithm converged.	0,03	0,29	<0.0001	1	11,13	Algorithm converged.	3,42	36,18								
	>=1	51	4,3	0	0	33	2,9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE								
Total household size including the household members not participating this study	2	446	38	1	0,2	413	36,1	13	3,1	0,07	Algorithm converged.	0,01	0,53	-2,923	Algorithm converged.	-4,66	-1,18	0,07	Algorithm converged.	0,01	0,54	0,0006	0,786	14,04	Algorithm converged.	1,84	106,84								
	>2	728	62	2	0,3	729	63,8	20	2,7	0,1	Algorithm converged.	0,02	0,42	-2,469	Algorithm converged.	-3,71	-1,22	0,1	Algorithm converged.	0,02	0,43	0,0001		9,99	Algorithm converged.	2,34	42,57								
Baseline high risk factor	Yes	315	26,8	1	0,3	307	26,9	13	4,2	0,07	Algorithm converged.	0,01	0,55	-3,917	Algorithm converged.	-6,25	-1,58	0,07	Algorithm converged.	0,01	0,57	0,0008	0,8356	13,34	Algorithm converged.	1,76	101,35								
	No	859	73,2	2	0,2	836	73,1	20	2,4	0,1	Algorithm converged.	0,02	0,41	-2,16	Algorithm converged.	-3,24	-1,07	0,1	Algorithm converged.	0,02	0,42	<0.0001		10,28	Algorithm converged.	2,41	43,82								
Race	White	990	84,3	3	0,3	962	84,2	27	2,8	0,11	Algorithm converged.	0,03	0,35	-2,504	Algorithm converged.	-3,6	-1,41	0,11	Algorithm converged.	0,03	0,35	<0.0001	0,67	9,26	Algorithm converged.	2,82	30,43								
	Black or African American	128	10,9	0	0	123	10,8	3	2,4	0	Algorithm converged.	NE	NE	-2,439	Algorithm converged.	-5,17	0,29	NE *	Algorithm not converged.	NE	NE	0,1162		NE *	Algorithm not converged.	NE	NE								
	Other	38	3,2	0	0	36	3,1	1	2,8	0	Algorithm converged.	NE	NE	-2,778	Algorithm converged.	-8,15	2,59	NE *	Algorithm not converged.	NE	NE	0,4865		NE *	Algorithm not converged.	NE	NE								
	Unknown/Not Reported	18	1,5	0	0	22	1,9	2	9,1	0	Algorithm converged.	NE	NE	-9,091	Algorithm converged.	-21,1	2,92	NE *	Algorithm not converged.	NE	NE	0,4923		NE *	Algorithm not converged.	NE	NE								

Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	11	1,9	0		Algorithm converged.	NE	NE	-1,943		Algorithm converged.	-3,08	-0,81	NE	*	Algorithm not converged.	NE	NE	0,0009	0,1417	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	612	52,1	3	0,5	570	49,9	22	3,9	0,12		Algorithm converged.	0,04	0,41	-3,369		Algorithm converged.	-5,04	-1,69	0,13		Algorithm converged.	0,04	0,42	<0.0001		7,87		Algorithm converged.	2,37	26,16
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	1	1	117	10,2	2	1,7	0,56		Algorithm converged.	0,05	6,31	-0,739		Algorithm converged.	-3,76	2,28	0,57		Algorithm converged.	0,05	6,17	1	0,1548	1,76		Algorithm converged.	0,16	19,13
	No	1062	90,5	2	0,2	1013	88,6	31	3,1	0,06		Algorithm converged.	0,01	0,25	-2,872		Algorithm converged.	-3,96	-1,78	0,06		Algorithm converged.	0,01	0,26	<0.0001		16,25		Algorithm converged.	3,9	67,72
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	1	6,7	14	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	6,667		Algorithm converged.	-5,96	19,29	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Negative	1016	86,5	2	0,2	992	86,8	26	2,6	0,07		Algorithm converged.	0,02	0,31	-2,424		Algorithm converged.	-3,45	-1,39	0,08		Algorithm converged.	0,02	0,32	<0.0001		13,31		Algorithm converged.	3,17	55,95
	Unavailable	143	12,2	0	0	137	12	7	5,1	0		Algorithm converged.	NE	NE	-5,109		Algorithm converged.	-8,8	-1,42	NE	*	Algorithm not converged.	NE	NE	0,0062		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	276	23,5	1	0,4	251	22	5	2	0,18		Algorithm converged.	0,02	1,54	-1,63		Algorithm converged.	-3,5	0,24	0,18		Algorithm converged.	0,02	1,55	0,1075	0,498	5,5		Algorithm converged.	0,65	46,74
	Seronegative	841	71,6	2	0,2	842	73,7	28	3,3	0,07		Algorithm converged.	0,02	0,29	-3,088		Algorithm converged.	-4,34	-1,83	0,07		Algorithm converged.	0,02	0,3	<0.0001		13,98		Algorithm converged.	3,34	58,51
	Unclear serology status	57	4,9	0	0	50	4,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-6a-eff-resp-asyprcs

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	1174	100	3	0,256	6,714	0,006	0,004	-0,015	0,048	1143	100	33	2,887	186	0,163	0,044	0,141	0,048	-0,157	-0,243	-0,071	0	-0,148	-0,23	-0,067

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-4-eff-smd-ANWSYMS

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference			Standardized Mean Difference			Interaction Test	
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	1174	100	3	0,256	6,714	0,006	0,004	0,006	0,031	1143	100	33	2,887	186	0,163	0,044	0,163	0,031	-0,157	-0,243	-0,071	0	-0,149	-0,23	-0,067	NE		
Sex	Male	539	45,911	1	0,186	4,143	0,008	0,008	0,008	0,049	555	48,556	12	2,162	81,571	0,147	0,068	0,147	0,049	-0,139	-0,275	-0,003	0,044	-0,122	-0,24	-0,003	0,6966		
	Female	635	54,089	2	0,315	2,571	0,004	0,004	0,004	0,038	588	51,444	21	3,571	104,429	0,178	0,057	0,178	0,04	-0,174	-0,282	-0,065	0,002	-0,179	-0,291	-0,067			
Age	12-17	52	4,429	0	0	0	0	0	0	NE	47	4,112	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,2062		
	18-49	711	60,562	2	0,281	6,429	0,009	0,007	0,009	0,032	692	60,542	17	2,457	81,429	0,118	0,046	0,118	0,033	-0,109	-0,198	-0,019	0,018	-0,127	-0,232	-0,022			
	>=50	411	35,009	1	0,243	0,286	0,001	0,001	0,001	0,068	404	35,346	16	3,96	104,571	0,259	0,097	0,259	0,069	-0,258	-0,448	-0,069	0,008	-0,187	-0,325	-0,05			
Region	US	1087	92,589	3	0,276	6,714	0,006	0,004	0,006	0,033	1061	92,826	32	3,016	183,571	0,173	0,048	0,173	0,034	-0,167	-0,259	-0,074	0	-0,152	-0,237	-0,068	0,4159		
	ex-US	87	7,411	0	0	0	0	0	0	0,02	82	7,174	1	1,22	2,429	0,03	0,03	0,03	0,021	-0,03	-0,086	0,027	0,304	-0,158	-0,46	0,145			
BMI	BMI < 30 kg/m2	752	64,055	2	0,266	6,429	0,009	0,006	0,009	0,046	736	64,392	20	2,717	140	0,19	0,065	0,19	0,046	-0,182	-0,309	-0,054	0,005	-0,145	-0,246	-0,043	0,4645		
	BMI >= 30 kg/m2	418	35,605	1	0,239	0,286	0,001	0,001	0,001	0,026	400	34,996	13	3,25	46	0,115	0,038	0,115	0,027	-0,114	-0,187	-0,041	0,002	-0,214	-0,351	-0,077			
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Number of study subjects in cohort B within a household	0	1123	95,656	3	0,267	6,714	0,006	0,004	0,006	0,032	1110	97,113	33	2,973	186	0,168	0,046	0,168	0,032	-0,162	-0,251	-0,072	0	-0,15	-0,233	-0,067	0,5007		
	>=1	51	4,344	0	0	0	0	0	0	NE	33	2,887	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Total household size including the household member(s) not participating this study	2	446	37,99	1	0,224	0,286	0,001	0,001	0,001	0,046	413	36,133	13	3,148	64,714	0,157	0,068	0,157	0,047	-0,156	-0,285	-0,027	0,018	-0,162	-0,296	-0,028	0,9869		
	>2	728	62,01	2	0,275	6,429	0,009	0,006	0,009	0,041	729	63,78	20	2,743	121,286	0,166	0,058	0,166	0,041	-0,158	-0,271	-0,044	0,007	-0,142	-0,245	-0,04			
Baseline high risk factor	Yes	315	26,831	1	0,317	0,286	0,001	0,001	0,001	0,061	307	26,859	13	4,235	61,286	0,2	0,088	0,2	0,062	-0,199	-0,37	-0,027	0,023	-0,182	-0,34	-0,025	0,5644		
	No	859	73,169	2	0,233	6,429	0,007	0,006	0,007	0,036	836	73,141	20	2,392	124,714	0,149	0,051	0,149	0,036	-0,142	-0,241	-0,042	0,005	-0,136	-0,231	-0,041			
Race	White	990	84,327	3	0,303	6,714	0,007	0,005	0,007	0,032	962	84,164	27	2,807	145,143	0,151	0,046	0,151	0,032	-0,144	-0,233	-0,056	0,001	-0,144	-0,233	-0,056	0,7566		
	Black or African American	128	10,903	0	0	0	0	0	0	0,028	123	10,761	3	2,439	8,857	0,072	0,041	0,072	0,029	-0,072	-0,152	0,008	0,077	-0,224	-0,471	0,024			
	Other	38	3,237	0	0	0	0	0	0	0,022	36	3,15	1	2,778	1,143	0,032	0,032	0,032	0,022	-0,032	-0,093	0,03	0,307	-0,237	-0,695	0,222			
	Unknown/Not Reported	18	1,533	0	0	0	0	0	0	0,917	22	1,925	2	9,091	30,857	1,403	1,115	1,403	0,829	-1,403	-3,905	1,1	0,264	-0,353	-0,984	0,277			

Ethnicity	Hispanic or Latino	558	47,53	0	0	0	0	0	0	0,037	566	49,519	11	1,943	68,571	0,121	0,051	0,121	0,036	-0,121	-0,222	-0,02	0,019	-0,14	-0,257	-0,023	0,4019
	Not Hispanic or Latino	612	52,129	3	0,49	6,714	0,011	0,008	0,011	0,049	570	49,869	22	3,86	117,429	0,206	0,073	0,206	0,051	-0,195	-0,334	-0,057	0,006	-0,161	-0,275	-0,047	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Healthcare worker	Yes	103	8,773	1	0,971	2,286	0,022	0,022	0,022	0,058	117	10,236	2	1,709	11,571	0,099	0,072	0,099	0,054	-0,077	-0,233	0,08	0,336	-0,13	-0,395	0,135	0,5444
	No	1062	90,46	2	0,188	4,429	0,004	0,004	0,004	0,034	1013	88,626	31	3,06	174,429	0,172	0,049	0,172	0,034	-0,168	-0,263	-0,073	0,001	-0,153	-0,239	-0,067	
	Unknown/not reported	9	0,767	0	0	0	0	0	0	NE	13	1,137	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	1	6,667	0,286	0,019	0,019	0,019	0,014	14	1,225	0	0	0	0	0	0	0,014	0,019	-0,021	0,06	0,343	0,349	-0,393	1,09	0,6358
	Negative	1016	86,542	2	0,197	6,429	0,006	0,005	0,006	0,022	992	86,789	26	2,621	112,143	0,113	0,032	0,113	0,023	-0,107	-0,169	-0,044	0,001	-0,149	-0,237	-0,062	
	Unavailable	143	12,181	0	0	0	0	0	0	0,196	137	11,986	7	5,109	73,857	0,539	0,287	0,539	0,2	-0,539	-1,091	0,013	0,056	-0,229	-0,464	0,006	
Serology status	Seropositive	276	23,509	1	0,362	4,143	0,015	0,015	0,015	0,065	251	21,96	5	1,992	32,571	0,13	0,097	0,13	0,068	-0,115	-0,299	0,07	0,223	-0,106	-0,277	0,065	0,5508
	Seronegative	841	71,635	2	0,238	2,571	0,003	0,003	0,003	0,037	842	73,666	28	3,325	153,429	0,182	0,053	0,182	0,037	-0,179	-0,283	-0,076	0,001	-0,166	-0,261	-0,07	
	Unclear serology status	57	4,855	0	0	0	0	0	0	NE	50	4,374	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-4-eff-smd-ANWSYMS

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) that has an onset during the EAP

ENDPOINT: Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo												Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference							
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL					
All	n/a	3	100	3	100	6,714	2,238	1,114	0,422	5,285	33	100	33	100	186	5,636	1,206	3,699	3,53	-3,277	-11,747	5,194	0,437	-0,466	-1,67	0,738					

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-4-eff-smd-ANWSYMS

POPULATION: Cohort A

ENDPOINT: All-cause death at EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk						Relative Risk								
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100		0 0	1143	100		0 0																						

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-1a-eff-resp-dth29

POPULATION: Cohort A
ENDPOINT: All-cause death at EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
Name	Level	Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk				Interaction Test p-value (likelihood ratio)		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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1174	100	0	0	1143	100	0	0																				
Sex	Male	539	45,9	0	0	555	48,6	0	0																				
	Female	635	54,1	0	0	588	51,4	0	0																				
Age	12-17	52	4,4	0	0	47	4,1	0	0																				
	18-49	711	60,6	0	0	692	60,5	0	0																				
	>=50	411	35	0	0	404	35,3	0	0																				
Region	US	1087	92,6	0	0	1061	92,8	0	0																				
	ex-US	87	7,4	0	0	82	7,2	0	0																				
BMI	BMI < 30 kg/m2	752	64,1	0	0	736	64,4	0	0																				
	BMI >= 30 kg/m2	418	35,6	0	0	400	35	0	0																				
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0																				
Number of study subjects in cohort B within a household	0	1123	95,7	0	0	1110	97,1	0	0																				
	>=1	51	4,3	0	0	33	2,9	0	0																				
Total household size including the household members not participating this study	2	446	38	0	0	413	36,1	0	0																				
	>2	728	62	0	0	729	63,8	0	0																				
Baseline high risk factor	Yes	315	26,8	0	0	307	26,9	0	0																				
	No	859	73,2	0	0	836	73,1	0	0																				
Race	White	990	84,3	0	0	962	84,2	0	0																				
	Black or African American	128	10,9	0	0	123	10,8	0	0																				
	Other	38	3,2	0	0	36	3,1	0	0																				
	Unknown/Not Reported	18	1,5	0	0	22	1,9	0	0																				
Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	0	0																				
	Not Hispanic or Latino	612	52,1	0	0	570	49,9	0	0																				
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0																				
Healthcare worker	Yes	103	8,8	0	0	117	10,2	0	0																				
	No	1062	90,5	0	0	1013	88,6	0	0																				
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0																				
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	0	0	14	1,2	0	0																				
	Negative	1016	86,5	0	0	992	86,8	0	0																				
	Unavailable	143	12,2	0	0	137	12	0	0																				
Serology status	Seropositive	276	23,5	0	0	251	22	0	0																				
	Seronegative	841	71,6	0	0	842	73,7	0	0																				

[illegible]

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $np \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-1a-eff-resp-dth29

POPULATION: Cohort A

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	3	0,3	1143	100	1	0,1	2,93	Algorithm converged.	0,31	28,12	0,168	Algorithm converged.	-0,17	0,5	2,92	Algorithm converged.	0,3	28,04	0,6248		0,34	Algorithm converged.	0,04	3,29

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-2a-eff-resp-dthfu

POPULATION: Cohort A

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	3	0,3	1143	100	1	0,1	2,93	Algorithm converged.	0,3	28,17	0,168	Algorithm converged.	-0,17	0,5	2,92	Algorithm converged.	0,3	28,04	0,6248		0,34	Algorithm converged.	0,04	3,29
Sex	Male	539	45,9	2	0,4	555	48,6	1	0,2	2,06	Algorithm converged.	0,19	22,82	0,191	Algorithm converged.	-0,43	0,81	2,06	Algorithm converged.	0,19	22,64	0,6192	0,4279	0,49	Algorithm converged.	0,04	5,34
	Female	635	54,1	1	0,2	588	51,4	0	0	NE *	Algorithm not converged.	NE	NE	0,157	Algorithm converged.	-0,15	0,47	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Age	12-17	52	4,4	0	0	47	4,1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	18-49	711	60,6	1	0,1	692	60,5	1	0,1	0,97	Algorithm converged.	0,06	15,59	-0,004	Algorithm converged.	-0,4	0,39	0,97	Algorithm converged.	0,06	15,53	1		1,03	Algorithm converged.	0,06	16,39
	>=50	411	35	2	0,5	404	35,3	0	0	NE *	Algorithm not converged.	NE	NE	0,487	Algorithm converged.	-0,19	1,16	NE *	Algorithm not converged.	NE	NE	0,4994		NE *	Algorithm not converged.	NE	NE
Region	US	1087	92,6	3	0,3	1061	92,8	1	0,1	2,93	Algorithm converged.	0,3	28,25	0,182	Algorithm converged.	-0,18	0,54	2,93	Algorithm converged.	0,31	28,11	0,6248	1	0,34	Algorithm converged.	0,04	3,28
	ex-US	87	7,4	0	0	82	7,2	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	752	64,1	3	0,4	736	64,4	1	0,1	2,94	Algorithm converged.	0,31	28,37	0,263	Algorithm converged.	-0,26	0,79	2,94	Algorithm converged.	0,31	28,16	0,6246	1	0,34	Algorithm converged.	0,04	3,27
	BMI >= 30 kg/m2	418	35,6	0	0	400	35	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	1123	95,7	3	0,3	1110	97,1	1	0,1	2,97	Algorithm converged.	0,31	28,6	0,177	Algorithm converged.	-0,17	0,53	2,97	Algorithm converged.	0,31	28,46	0,6247	1	0,34	Algorithm converged.	0,04	3,24
	>=1	51	4,3	0	0	33	2,9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	446	38	0	0	413	36,1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	1	NE *	Algorithm not converged.	NE	NE
	>2	728	62	3	0,4	729	63,8	1	0,1	3,01	Algorithm converged.	0,31	29,03	0,275	Algorithm converged.	-0,26	0,81	3	Algorithm converged.	0,31	28,81	0,3741		0,33	Algorithm converged.	0,03	3,19
Baseline high risk factor	Yes	315	26,8	2	0,6	307	26,9	0	0	NE *	Algorithm not converged.	NE	NE	0,635	Algorithm converged.	-0,24	1,51	NE *	Algorithm not converged.	NE	NE	0,4993	0,1884	NE *	Algorithm not converged.	NE	NE
	No	859	73,2	1	0,1	836	73,1	1	0,1	0,97	Algorithm converged.	0,06	15,58	-0,003	Algorithm converged.	-0,33	0,32	0,97	Algorithm converged.	0,06	15,53	1		1,03	Algorithm converged.	0,06	16,4
Race	White	990	84,3	3	0,3	962	84,2	1	0,1	2,92	Algorithm converged.	0,3	28,13	0,199	Algorithm converged.	-0,2	0,6	2,92	Algorithm converged.	0,3	27,98	0,6248		0,34	Algorithm converged.	0,04	3,29
	Black or African American	128	10,9	0	0	123	10,8	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	Other	38	3,2	0	0	36	3,1	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	Unknown/Not Reported	18	1,5	0	0	22	1,9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

Ethnicity	Hispanic or Latino	558 47,5	0 0	566 49,5	1 0,2	0		Algorithm converged.	NE	NE	-0,177		Algorithm converged.	-0,52	0,17	NE	*	Algorithm not converged.	NE	NE	1	0,0365	NE	*	Algorithm not converged.	NE	NE	
	Not Hispanic or Latino	612 52,1	3 0,5	570 49,9	0 0	NE	*	Algorithm not converged.	NE	NE	0,49		Algorithm converged.	-0,06	1,04	NE	*	Algorithm not converged.	NE	NE	0,2503		NE	*	Algorithm not converged.	NE	NE	
	Unknown/not reported	4 0,3	0 0	7 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Healthcare worker	Yes	103 8,8	0 0	117 10,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	No	1062 90,5	3 0,3	1013 88,6	1 0,1	2,87		Algorithm converged.	0,3	27,61	0,184		Algorithm converged.	-0,19	0,56	2,86		Algorithm converged.	0,3	27,46	0,6251		0,35		Algorithm converged.	0,04	3,35	
	Unknown/not reported	9 0,8	0 0	13 1,1	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15 1,3	0 0	14 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Negative	1016 86,5	2 0,2	992 86,8	1 0,1	1,95		Algorithm converged.	0,18	21,59	0,096		Algorithm converged.	-0,24	0,43	1,95		Algorithm converged.	0,18	21,5	1		0,51		Algorithm converged.	0,05	5,64	
	Unavailable	143 12,2	1 0,7	137 12	0 0	NE	*	Algorithm not converged.	NE	NE	0,699		Algorithm converged.	-0,67	2,07	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Serology status	Seropositive	276 23,5	2 0,7	251 22	1 0,4	1,82		Algorithm converged.	0,16	20,25	0,326		Algorithm converged.	-0,94	1,59	1,82		Algorithm converged.	0,17	19,94	1	0,393	0,55		Algorithm converged.	0,05	6,03	
	Seronegative	841 71,6	1 0,1	842 73,7	0 0	NE	*	Algorithm not converged.	NE	NE	0,119		Algorithm converged.	-0,11	0,35	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	*	Algorithm not converged.	NE	NE	
	Unclear serology status	57 4,9	0 0	50 4,4	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-2a-eff-resp-dthfu

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7a-eff-resp-ahoer

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1174	100		0 0	1143	100	5	0,4	0	Algorithm converged.	NE	NE	-0,437	Algorithm converged.	-0,82	-0,05	NE	*	Algorithm not converged.	NE	NE	0,0291		NE	*	Algorithm not converged.	NE	NE
Sex	Male	539	45,9		0 0	555	48,6	2	0,4	0	Algorithm converged.	NE	NE	-0,36	Algorithm converged.	-0,86	0,14	NE	*	Algorithm not converged.	NE	NE	0,4996	1	NE	*	Algorithm not converged.	NE	NE
	Female	635	54,1		0 0	588	51,4	3	0,5	0	Algorithm converged.	NE	NE	-0,51	Algorithm converged.	-1,09	0,07	NE	*	Algorithm not converged.	NE	NE	0,1108		NE	*	Algorithm not converged.	NE	NE
Age	12-17	52	4,4		0 0	47	4,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE		
	18-49	711	60,6		0 0	692	60,5	2	0,3	0	Algorithm converged.	NE	NE	-0,289	Algorithm converged.	-0,69	0,11	NE	*	Algorithm not converged.	NE	NE	0,2431		NE	*	Algorithm not converged.	NE	NE
	>=50	411	35		0 0	404	35,3	3	0,7	0	Algorithm converged.	NE	NE	-0,743	Algorithm converged.	-1,58	0,09	NE	*	Algorithm not converged.	NE	NE	0,1214		NE	*	Algorithm not converged.	NE	NE
Region	US	1087	92,6		0 0	1061	92,8	4	0,4	0	Algorithm converged.	NE	NE	-0,377	Algorithm converged.	-0,75	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0594		NE	*	Algorithm not converged.	NE	NE
	ex-US	87	7,4		0 0	82	7,2	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE	*	Algorithm not converged.	NE	NE	0,4852		NE	*	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	752	64,1		0 0	736	64,4	2	0,3	0	Algorithm converged.	NE	NE	-0,272	Algorithm converged.	-0,65	0,1	NE	*	Algorithm not converged.	NE	NE	0,2445	1	NE	*	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	418	35,6		0 0	400	35	3	0,8	0	Algorithm converged.	NE	NE	-0,75	Algorithm converged.	-1,6	0,1	NE	*	Algorithm not converged.	NE	NE	0,1165		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	4	0,3		0 0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE		
Number of study subjects in cohort B within a household	0	1123	95,7		0 0	1110	97,1	5	0,5	0	Algorithm converged.	NE	NE	-0,45	Algorithm converged.	-0,84	-0,06	NE	*	Algorithm not converged.	NE	NE	0,0302		NE	*	Algorithm not converged.	NE	NE
	>=1	51	4,3		0 0	33	2,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE		
Total household size including the household members not participating this study	2	446	38		0 0	413	36,1	2	0,5	0	Algorithm converged.	NE	NE	-0,484	Algorithm converged.	-1,15	0,19	NE	*	Algorithm not converged.	NE	NE	0,2309	1	NE	*	Algorithm not converged.	NE	NE
	>2	728	62		0 0	729	63,8	3	0,4	0	Algorithm converged.	NE	NE	-0,412	Algorithm converged.	-0,88	0,05	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	*	Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	315	26,8		0 0	307	26,9	4	1,3	0	Algorithm converged.	NE	NE	-1,303	Algorithm converged.	-2,57	-0,03	NE	*	Algorithm not converged.	NE	NE	0,0588	1	NE	*	Algorithm not converged.	NE	NE
	No	859	73,2		0 0	836	73,1	1	0,1	0	Algorithm converged.	NE	NE	-0,12	Algorithm converged.	-0,35	0,11	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	*	Algorithm not converged.	NE	NE
Race	White	990	84,3		0 0	962	84,2	4	0,4	0	Algorithm converged.	NE	NE	-0,416	Algorithm converged.	-0,82	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0588		NE	*	Algorithm not converged.	NE	NE
	Black or African American	128	10,9		0 0	123	10,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE		
	Other	38	3,2		0 0	36	3,1	1	2,8	0	Algorithm converged.	NE	NE	-2,778	Algorithm converged.	-8,15	2,59	NE	*	Algorithm not converged.	NE	NE	0,4865		NE	*	Algorithm not converged.	NE	NE
	Unknown/Not Reported	18	1,5		0 0	22	1,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	*	Algorithm not converged.	NE	NE		

Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	1	0,2	0		Algorithm converged.	NE	NE	-0,177		Algorithm converged.	-0,52	0,17	NE	*	Algorithm not converged.	NE	NE	1	1	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	612	52,1	0	0	570	49,9	4	0,7	0		Algorithm converged.	NE	NE	-0,702		Algorithm converged.	-1,39	-0,02	NE	*	Algorithm not converged.	NE	NE	0,0538		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	0	0	117	10,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	No	1062	90,5	0	0	1013	88,6	5	0,5	0		Algorithm converged.	NE	NE	-0,494		Algorithm converged.	-0,93	-0,06	NE	*	Algorithm not converged.	NE	NE	0,0276		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	0	0	14	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Negative	1016	86,5	0	0	992	86,8	4	0,4	0		Algorithm converged.	NE	NE	-0,403		Algorithm converged.	-0,8	-0,01	NE	*	Algorithm not converged.	NE	NE	0,0594		NE	*	Algorithm not converged.	NE	NE
	Unavailable	143	12,2	0	0	137	12	1	0,7	0		Algorithm converged.	NE	NE	-0,73		Algorithm converged.	-2,16	0,7	NE	*	Algorithm not converged.	NE	NE	0,4893		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	276	23,5	0	0	251	22	1	0,4	0		Algorithm converged.	NE	NE	-0,398		Algorithm converged.	-1,18	0,38	NE	*	Algorithm not converged.	NE	NE	0,4763	1	NE	*	Algorithm not converged.	NE	NE
	Seronegative	841	71,6	0	0	842	73,7	4	0,5	0		Algorithm converged.	NE	NE	-0,475		Algorithm converged.	-0,94	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1246		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	57	4,9	0	0	50	4,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7a-eff-resp-ahoer

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	56	4,8	0	0	145	12,7	5	3,4	0	Algorithm converged.	NE	NE	-3,448	Algorithm converged.	-6,42	-0,48	NE	*	Algorithm not converged.	NE	NE	0,3248		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-7b-eff-resp-ahoer

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8a-eff-resp-hoeruc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
Name	Level	Patients		Event		Patients		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	1	0.1	1143	100	12	1	0.08	Algorithm converged.	0.01	0.62	-0.965	Algorithm converged.	-1.58	-0.35	0.08	Algorithm converged.	0.01	0.62	0.0016		12.33	Algorithm converged.	1.61	94.64
Sex	Male	539	45.9	1	0.2	555	48.6	7	1.3	0.15	Algorithm converged.	0.02	1.19	-1.076	Algorithm converged.	-2.07	-0.08	0.15	Algorithm converged.	0.02	1.19	0.0695	0.2925	6.8	Algorithm converged.	0.84	55.07
	Female	635	54.1	0	0	588	51.4	5	0.9	0	Algorithm converged.	NE	NE	-0.85	Algorithm converged.	-1.59	-0.11	NE	Algorithm not converged.	NE	NE	0.0255		NE	Algorithm not converged.	NE	NE
Age	12-17	52	4.4	0	0	47	4.1	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	18-49	711	60.6	1	0.1	692	60.5	6	0.9	0.16	Algorithm converged.	0.02	1.34	-0.726	Algorithm converged.	-1.47	0.02	0.16	Algorithm converged.	0.02	1.34	0.0662		6.16	Algorithm converged.	0.74	51.07
	>=50	411	35	0	0	404	35.3	6	1.5	0	Algorithm converged.	NE	NE	-1.485	Algorithm converged.	-2.66	-0.31	NE	Algorithm not converged.	NE	NE	0.0146		NE	Algorithm not converged.	NE	NE
Region	US	1087	92.6	1	0.1	1061	92.8	11	1	0.09	Algorithm converged.	0.01	0.68	-0.945	Algorithm converged.	-1.58	-0.31	0.09	Algorithm converged.	0.01	0.69	0.003	0.6779	11.27	Algorithm converged.	1.46	87.14
	ex-US	87	7.4	0	0	82	7.2	1	1.2	0	Algorithm converged.	NE	NE	-1.22	Algorithm converged.	-3.6	1.16	NE	Algorithm not converged.	NE	NE	0.4852		NE	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	752	64.1	0	0	736	64.4	6	0.8	0	Algorithm converged.	NE	NE	-0.815	Algorithm converged.	-1.46	-0.17	NE	Algorithm not converged.	NE	NE	0.0145	0.256	NE	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	418	35.6	1	0.2	400	35	6	1.5	0.16	Algorithm converged.	0.02	1.31	-1.261	Algorithm converged.	-2.54	0.02	0.16	Algorithm converged.	0.02	1.32	0.0637		6.27	Algorithm converged.	0.76	51.85
	Unknown/not reported	4	0.3	0	0	7	0.6	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	1123	95.7	1	0.1	1110	97.1	12	1.1	0.08	Algorithm converged.	0.01	0.63	-0.992	Algorithm converged.	-1.62	-0.36	0.08	Algorithm converged.	0.01	0.63	0.0017	1	12.14	Algorithm converged.	1.58	93.21
	>=1	51	4.3	0	0	33	2.9	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	446	38	1	0.2	413	36.1	5	1.2	0.18	Algorithm converged.	0.02	1.58	-0.986	Algorithm converged.	-2.13	0.16	0.19	Algorithm converged.	0.02	1.58	0.1109	0.2112	5.4	Algorithm converged.	0.63	46.02
	>2	728	62	0	0	729	63.8	7	1	0	Algorithm converged.	NE	NE	-0.96	Algorithm converged.	-1.67	-0.25	NE	Algorithm not converged.	NE	NE	0.0154		NE	Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	315	26.8	0	0	307	26.9	6	2	0	Algorithm converged.	NE	NE	-1.954	Algorithm converged.	-3.5	-0.41	NE	Algorithm not converged.	NE	NE	0.0141	0.2524	NE	Algorithm not converged.	NE	NE
	No	859	73.2	1	0.1	836	73.1	6	0.7	0.16	Algorithm converged.	0.02	1.34	-0.601	Algorithm converged.	-1.22	0.01	0.16	Algorithm converged.	0.02	1.34	0.0663		6.17	Algorithm converged.	0.74	51.1
Race	White	990	84.3	1	0.1	962	84.2	8	0.8	0.12	Algorithm converged.	0.02	0.97	-0.731	Algorithm converged.	-1.34	-0.12	0.12	Algorithm converged.	0.02	0.97	0.0196	0.6762	8.23	Algorithm converged.	1.03	65.7
	Black or African American	128	10.9	0	0	123	10.8	3	2.4	0	Algorithm converged.	NE	NE	-2.439	Algorithm converged.	-5.17	0.29	NE	Algorithm not converged.	NE	NE	0.1162		NE	Algorithm not converged.	NE	NE
	Other	38	3.2	0	0	36	3.1	1	2.8	0	Algorithm converged.	NE	NE	-2.778	Algorithm converged.	-8.15	2.59	NE	Algorithm not converged.	NE	NE	0.4865		NE	Algorithm not converged.	NE	NE
	Unknown/Not Reported	18	1.5	0	0	22	1.9	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	4	0,7	0		Algorithm converged.	NE	NE	-0,707		Algorithm converged.	-1,4	-0,02	NE	*	Algorithm not converged.	NE	NE	0,1244	0,3957	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	612	52,1	1	0,2	570	49,9	8	1,4	0,11		Algorithm converged.	0,01	0,92	-1,24		Algorithm converged.	-2,26	-0,22	0,12		Algorithm converged.	0,01	0,93	0,0173		8,59		Algorithm converged.	1,08	68,46
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	0	0	117	10,2	1	0,9	0		Algorithm converged.	NE	NE	-0,855		Algorithm converged.	-2,52	0,81	NE	*	Algorithm not converged.	NE	NE	1	0,7063	NE	*	Algorithm not converged.	NE	NE
	No	1062	90,5	1	0,1	1013	88,6	11	1,1	0,09		Algorithm converged.	0,01	0,67	-0,992		Algorithm converged.	-1,66	-0,33	0,09		Algorithm converged.	0,01	0,67	0,0027		11,53		Algorithm converged.	1,49	89,16
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	0	0	14	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	*	Algorithm not converged.	NE	NE
	Negative	1016	86,5	1	0,1	992	86,8	8	0,8	0,12		Algorithm converged.	0,02	0,97	-0,708		Algorithm converged.	-1,3	-0,12	0,12		Algorithm converged.	0,02	0,97	0,0198		8,19		Algorithm converged.	1,03	65,39
	Unavailable	143	12,2	0	0	137	12	4	2,9	0		Algorithm converged.	NE	NE	-2,92		Algorithm converged.	-5,74	-0,1	NE	*	Algorithm not converged.	NE	NE	0,056		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	276	23,5	0	0	251	22	3	1,2	0		Algorithm converged.	NE	NE	-1,195		Algorithm converged.	-2,54	0,15	NE	*	Algorithm not converged.	NE	NE	0,1074	0,4402	NE	*	Algorithm not converged.	NE	NE
	Seronegative	841	71,6	1	0,1	842	73,7	9	1,1	0,11		Algorithm converged.	0,01	0,87	-0,95		Algorithm converged.	-1,68	-0,22	0,11		Algorithm converged.	0,01	0,88	0,0211		8,99		Algorithm converged.	1,14	70,8
	Unclear serology status	57	4,9	0	0	50	4,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8a-eff-resp-hoeruc

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk							Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-8b-eff-resp-hoeruc

POPULATION: Cohort A

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-9a-eff-resp-amaveru

POPULATION: Cohort A

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
Name	Level	Patients		Event		Patients		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1174	100	1	0.1	1143	100	12	1	0.08	Algorithm converged.	0.01	0.62	-0.965	Algorithm converged.	-1.58	-0.35	0.08	Algorithm converged.	0.01	0.62	0.0016		12.33	Algorithm converged.	1.61	94.64
Sex	Male	539	45.9	1	0.2	555	48.6	7	1.3	0.15	Algorithm converged.	0.02	1.19	-1.076	Algorithm converged.	-2.07	-0.08	0.15	Algorithm converged.	0.02	1.19	0.0695	0.2925	6.8	Algorithm converged.	0.84	55.07
	Female	635	54.1	0	0	588	51.4	5	0.9	0	Algorithm converged.	NE	NE	-0.85	Algorithm converged.	-1.59	-0.11	NE	Algorithm not converged.	NE	NE	0.0255		NE	Algorithm not converged.	NE	NE
Age	12-17	52	4.4	0	0	47	4.1	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	18-49	711	60.6	1	0.1	692	60.5	7	1	0.14	Algorithm converged.	0.02	1.12	-0.871	Algorithm converged.	-1.67	-0.08	0.14	Algorithm converged.	0.02	1.13	0.0362		7.19	Algorithm converged.	0.89	58.3
	>=50	411	35	0	0	404	35.3	5	1.2	0	Algorithm converged.	NE	NE	-1.238	Algorithm converged.	-2.32	-0.16	NE	Algorithm not converged.	NE	NE	0.0296		NE	Algorithm not converged.	NE	NE
Region	US	1087	92.6	1	0.1	1061	92.8	12	1.1	0.08	Algorithm converged.	0.01	0.62	-1.039	Algorithm converged.	-1.7	-0.38	0.08	Algorithm converged.	0.01	0.62	0.0016	1	12.29	Algorithm converged.	1.6	94.38
	ex-US	87	7.4	0	0	82	7.2	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	752	64.1	0	0	736	64.4	6	0.8	0	Algorithm converged.	NE	NE	-0.815	Algorithm converged.	-1.46	-0.17	NE	Algorithm not converged.	NE	NE	0.0145	0.256	NE	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	418	35.6	1	0.2	400	35	6	1.5	0.16	Algorithm converged.	0.02	1.31	-1.261	Algorithm converged.	-2.54	0.02	0.16	Algorithm converged.	0.02	1.32	0.0637		6.27	Algorithm converged.	0.76	51.85
	Unknown/not reported	4	0.3	0	0	7	0.6	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	1123	95.7	1	0.1	1110	97.1	12	1.1	0.08	Algorithm converged.	0.01	0.63	-0.992	Algorithm converged.	-1.62	-0.36	0.08	Algorithm converged.	0.01	0.63	0.0017	1	12.14	Algorithm converged.	1.58	93.21
	>=1	51	4.3	0	0	33	2.9	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	446	38	1	0.2	413	36.1	5	1.2	0.18	Algorithm converged.	0.02	1.58	-0.986	Algorithm converged.	-2.13	0.16	0.19	Algorithm converged.	0.02	1.58	0.1109	0.2112	5.4	Algorithm converged.	0.63	46.02
	>2	728	62	0	0	729	63.8	7	1	0	Algorithm converged.	NE	NE	-0.96	Algorithm converged.	-1.67	-0.25	NE	Algorithm not converged.	NE	NE	0.0154		NE	Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	315	26.8	0	0	307	26.9	5	1.6	0	Algorithm converged.	NE	NE	-1.629	Algorithm converged.	-3.04	-0.21	NE	Algorithm not converged.	NE	NE	0.0288	0.3119	NE	Algorithm not converged.	NE	NE
	No	859	73.2	1	0.1	836	73.1	7	0.8	0.14	Algorithm converged.	0.02	1.12	-0.721	Algorithm converged.	-1.38	-0.06	0.14	Algorithm converged.	0.02	1.13	0.0363		7.19	Algorithm converged.	0.89	58.33
Race	White	990	84.3	1	0.1	962	84.2	8	0.8	0.12	Algorithm converged.	0.02	0.97	-0.731	Algorithm converged.	-1.34	-0.12	0.12	Algorithm converged.	0.02	0.97	0.0196	0.6762	8.23	Algorithm converged.	1.03	65.7
	Black or African American	128	10.9	0	0	123	10.8	3	2.4	0	Algorithm converged.	NE	NE	-2.439	Algorithm converged.	-5.17	0.29	NE	Algorithm not converged.	NE	NE	0.1162		NE	Algorithm not converged.	NE	NE
	Other	38	3.2	0	0	36	3.1	1	2.8	0	Algorithm converged.	NE	NE	-2.778	Algorithm converged.	-8.15	2.59	NE	Algorithm not converged.	NE	NE	0.4865		NE	Algorithm not converged.	NE	NE
	Unknown/Not Reported	18	1.5	0	0	22	1.9	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	5	0,9	0		Algorithm converged.	NE	NE	-0,883		Algorithm converged.	-1,65	-0,11	NE	*	Algorithm not converged.	NE	NE	0,062	0,3273	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	612	52,1	1	0,2	570	49,9	7	1,2	0,13		Algorithm converged.	0,02	1,07	-1,065		Algorithm converged.	-2,02	-0,11	0,13		Algorithm converged.	0,02	1,08	0,0327		7,52		Algorithm converged.	0,93	60,9
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	0	0	117	10,2	1	0,9	0		Algorithm converged.	NE	NE	-0,855		Algorithm converged.	-2,52	0,81	NE	*	Algorithm not converged.	NE	NE	1	0,7063	NE	*	Algorithm not converged.	NE	NE
	No	1062	90,5	1	0,1	1013	88,6	11	1,1	0,09		Algorithm converged.	0,01	0,67	-0,992		Algorithm converged.	-1,66	-0,33	0,09		Algorithm converged.	0,01	0,67	0,0027		11,53		Algorithm converged.	1,49	89,16
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	0	0	14	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	*	Algorithm not converged.	NE	NE
	Negative	1016	86,5	1	0,1	992	86,8	8	0,8	0,12		Algorithm converged.	0,02	0,97	-0,708		Algorithm converged.	-1,3	-0,12	0,12		Algorithm converged.	0,02	0,97	0,0198		8,19		Algorithm converged.	1,03	65,39
	Unavailable	143	12,2	0	0	137	12	4	2,9	0		Algorithm converged.	NE	NE	-2,92		Algorithm converged.	-5,74	-0,1	NE	*	Algorithm not converged.	NE	NE	0,056		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	276	23,5	0	0	251	22	3	1,2	0		Algorithm converged.	NE	NE	-1,195		Algorithm converged.	-2,54	0,15	NE	*	Algorithm not converged.	NE	NE	0,1074	0,4402	NE	*	Algorithm not converged.	NE	NE
	Seronegative	841	71,6	1	0,1	842	73,7	9	1,1	0,11		Algorithm converged.	0,01	0,87	-0,95		Algorithm converged.	-1,68	-0,22	0,11		Algorithm converged.	0,01	0,88	0,0211		8,99		Algorithm converged.	1,14	70,8
	Unclear serology status	57	4,9	0	0	50	4,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-9a-eff-resp-amaveru

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-9b-eff-resp-amaveru

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab											Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)								
Patients in analysis				Patients with Event		Total of visits	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	1174	100	1	0,085	1	0,001	0,001	-0,002	0,004	1143	100	12	1,05	13	0,011	0,003	0,009	0,004	-0,01	-0,017	-0,004	0,002	-0,127	-0,208	-0,045			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-5-eff-smd-ANMAVERU

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

				Casirivimab/Imdevimab							Placebo							Difference between treatments (Casirivimab/Imdevimab - Placebo)											
				Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test
Name	Level	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	1174	100	1	0,085	1	0,001	0,001	0,001	0,002	1143	100	12	1,05	13	0,011	0,003	0,011	0,002	-0,011	-0,017	-0,004	0,002	-0,127	-0,209	-0,046	NE		
Sex	Male	539	45,911	1	0,186	1	0,002	0,002	0,002	0,004	555	48,556	7	1,261	7	0,013	0,005	0,013	0,004	-0,011	-0,021	-0,001	0,037	-0,126	-0,245	-0,008	0,936		
	Female	635	54,089	0	0	0	0	0	0	0,003	588	51,444	5	0,85	6	0,01	0,005	0,01	0,003	-0,01	-0,019	-0,001	0,027	-0,126	-0,239	-0,014			
Age	12-17	52	4,429	0	0	0	0	0	0	NE	47	4,112	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,5701		
	18-49	711	60,562	1	0,141	1	0,001	0,001	0,001	0,003	692	60,542	7	1,012	7	0,01	0,004	0,01	0,003	-0,009	-0,017	-0,001	0,03	-0,116	-0,22	-0,011			
	>=50	411	35,009	0	0	0	0	0	0	0,005	404	35,346	5	1,238	6	0,015	0,007	0,015	0,005	-0,015	-0,028	-0,001	0,032	-0,15	-0,288	-0,013			
Region	US	1087	92,589	1	0,092	1	0,001	0,001	0,001	0,003	1061	92,826	12	1,131	13	0,012	0,004	0,012	0,003	-0,011	-0,019	-0,004	0,002	-0,132	-0,216	-0,047	0,3917		
	ex-US	87	7,411	0	0	0	0	0	0	NE	82	7,174	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
BMI	BMI < 30 kg/m2	752	64,055	0	0	0	0	0	0	0,002	736	64,392	6	0,815	6	0,008	0,003	0,008	0,002	-0,008	-0,015	-0,002	0,013	-0,129	-0,23	-0,027	0,3354		
	BMI >= 30 kg/m2	418	35,605	1	0,239	1	0,002	0,002	0,002	0,005	400	34,996	6	1,5	7	0,018	0,007	0,018	0,006	-0,015	-0,03	0	0,05	-0,137	-0,274	0			
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Number of study subjects in cohort B within a household	0	1123	95,656	1	0,089	1	0,001	0,001	0,001	0,003	1110	97,113	12	1,081	13	0,012	0,003	0,012	0,003	-0,011	-0,018	-0,004	0,002	-0,128	-0,211	-0,045	0,5654		
	>=1	51	4,344	0	0	0	0	0	0	NE	33	2,887	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Total household size including the household member(s) not participating this study	2	446	37,99	1	0,224	1	0,002	0,002	0,002	0,004	413	36,133	5	1,211	5	0,012	0,005	0,012	0,004	-0,01	-0,021	0,001	0,083	-0,118	-0,252	0,016	0,8763		
	>2	728	62,01	0	0	0	0	0	0	0,003	729	63,78	7	0,96	8	0,011	0,004	0,011	0,003	-0,011	-0,019	-0,002	0,011	-0,133	-0,236	-0,03			
Baseline high risk factor	Yes	315	26,831	0	0	0	0	0	0	0,006	307	26,859	5	1,629	6	0,02	0,009	0,02	0,006	-0,02	-0,037	-0,002	0,031	-0,173	-0,33	-0,016	0,1119		
	No	859	73,169	1	0,116	1	0,001	0,001	0,001	0,002	836	73,141	7	0,837	7	0,008	0,003	0,008	0,002	-0,007	-0,014	-0,001	0,03	-0,105	-0,2	-0,01			
Race	White	990	84,327	1	0,101	1	0,001	0,001	0,001	0,002	962	84,164	8	0,832	9	0,009	0,003	0,009	0,003	-0,008	-0,015	-0,001	0,018	-0,107	-0,195	-0,018	0,2406		
	Black or African American	128	10,903	0	0	0	0	0	0	0,01	123	10,761	3	2,439	3	0,024	0,014	0,024	0,01	-0,024	-0,051	0,003	0,076	-0,224	-0,472	0,024			
	Other	38	3,237	0	0	0	0	0	0	0,019	36	3,15	1	2,778	1	0,028	0,028	0,028	0,019	-0,028	-0,082	0,026	0,307	-0,237	-0,695	0,222			
	Unknown/Not Reported	18	1,533	0	0	0	0	0	0	NE	22	1,925	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Ethnicity	Hispanic or Latino	558	47,53	0	0	0	0	0	0	0,003	566	49,519	5	0,883	5	0,009	0,004	0,009	0,003	-0,009	-0,017	-0,001	0,026	-0,133	-0,25	-0,016	0,606		
	Not Hispanic or Latino	612	52,129	1	0,163	1	0,002	0,002	0,002	0,004	570	49,869	7	1,228	8	0,014	0,006	0,014	0,004	-0,012	-0,023	-0,001	0,027	-0,129	-0,243	-0,015			
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			

Healthcare worker	Yes	103	8,773	0	0	0	0	0	0	0,007	117	10,236	1	0,855	1	0,009	0,009	0,009	0,006	-0,009	-0,027	0,009	0,349	-0,126	-0,392	0,139	0,8419
	No	1062	90,46	1	0,094	1	0,001	0,001	0,001	0,003	1013	88,626	11	1,086	12	0,012	0,004	0,012	0,003	-0,011	-0,018	-0,004	0,003	-0,129	-0,215	-0,043	
	Unknown/not reported	9	0,767	0	0	0	0	0	0	NE	13	1,137	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	0	0	0	0	0	0	NE	14	1,225	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,7754
	Negative	1016	86,542	1	0,098	1	0,001	0,001	0,001	0,002	992	86,789	8	0,806	8	0,008	0,003	0,008	0,002	-0,007	-0,013	-0,001	0,018	-0,106	-0,194	-0,019	
	Unavailable	143	12,181	0	0	0	0	0	0	0,013	137	11,986	4	2,92	5	0,036	0,019	0,036	0,013	-0,036	-0,073	0	0,052	-0,232	-0,467	0,002	
Serology status	Seropositive	276	23,509	0	0	0	0	0	0	0,005	251	21,96	3	1,195	3	0,012	0,007	0,012	0,005	-0,012	-0,025	0,001	0,069	-0,159	-0,33	0,012	0,8813
	Seronegative	841	71,635	1	0,119	1	0,001	0,001	0,001	0,003	842	73,666	9	1,069	10	0,012	0,004	0,012	0,003	-0,011	-0,019	-0,002	0,012	-0,122	-0,218	-0,026	
	Unclear serology status	57	4,855	0	0	0	0	0	0	NE	50	4,374	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
 Output: t9-5-eff-smd-ANMAVERU

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference				
Name	Level	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	56	100	1	1,786	1	0,018	0,018	-0,01	0,045	145	100	11	7,586	12	0,083	0,025	0,054	0,037	-0,065	-0,147	0,018	0,124	-0,242	-0,551	0,067		

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-5-eff-smd-ANMAVERU

POPULATION: Cohort A

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab										Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
Patients						Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk													
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL												
All	n/a	1174	100		0/0	1143	100	1	0.1	0	Algorithm converged.	NE	NE	-0.087	Algorithm converged.	-0.26	0.08	NE	*	Algorithm not converged.	NE	NE	0.4933		NE	*	Algorithm not converged.	NE	NE										

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10a-eff-resp-ahosp

POPULATION: Cohort A

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1174	100		0 0	1143	100	1	0,1	0	Algorithm converged.	NE	NE	-0,087	Algorithm converged.	-0,26	0,08	NE	*	Algorithm not converged.	NE	NE	0,4933		NE	*	Algorithm not converged.	NE	NE	
Sex	Male	539	45,9		0 0	555	48,6	1	0,2	0	Algorithm converged.	NE	NE	-0,18	Algorithm converged.	-0,53	0,17	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
	Female	635	54,1		0 0	588	51,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Age	12-17	52	4,4		0 0	47	4,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	18-49	711	60,6		0 0	692	60,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=50	411	35		0 0	404	35,3	1	0,2	0	Algorithm converged.	NE	NE	-0,248	Algorithm converged.	-0,73	0,24	NE	*	Algorithm not converged.	NE	NE	0,4957		NE	*	Algorithm not converged.	NE	NE	
Region	US	1087	92,6		0 0	1061	92,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	ex-US	87	7,4		0 0	82	7,2	1	1,2	0	Algorithm converged.	NE	NE	-1,22	Algorithm converged.	-3,6	1,16	NE	*	Algorithm not converged.	NE	NE	0,4852		NE	*	Algorithm not converged.	NE	NE	
BMI	BMI < 30 kg/m2	752	64,1		0 0	736	64,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	418	35,6		0 0	400	35	1	0,3	0	Algorithm converged.	NE	NE	-0,25	Algorithm converged.	-0,74	0,24	NE	*	Algorithm not converged.	NE	NE	0,489		NE	*	Algorithm not converged.	NE	NE	
	Unknown/not reported	4	0,3		0 0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Number of study subjects in cohort B within a household	0	1123	95,7		0 0	1110	97,1	1	0,1	0	Algorithm converged.	NE	NE	-0,09	Algorithm converged.	-0,27	0,09	NE	*	Algorithm not converged.	NE	NE	0,4971		NE	*	Algorithm not converged.	NE	NE	
	>=1	51	4,3		0 0	33	2,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Total household size including the household members not participating this study	2	446	38		0 0	413	36,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>2	728	62		0 0	729	63,8	1	0,1	0	Algorithm converged.	NE	NE	-0,137	Algorithm converged.	-0,41	0,13	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Baseline high risk factor	Yes	315	26,8		0 0	307	26,9	1	0,3	0	Algorithm converged.	NE	NE	-0,326	Algorithm converged.	-0,96	0,31	NE	*	Algorithm not converged.	NE	NE	0,4936		NE	*	Algorithm not converged.	NE	NE	
	No	859	73,2		0 0	836	73,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Race	White	990	84,3		0 0	962	84,2	1	0,1	0	Algorithm converged.	NE	NE	-0,104	Algorithm converged.	-0,31	0,1	NE	*	Algorithm not converged.	NE	NE	0,4928		NE	*	Algorithm not converged.	NE	NE	
	Black or African American	128	10,9		0 0	123	10,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Other	38	3,2		0 0	36	3,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Unknown/Not Reported	18	1,5		0 0	22	1,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Ethnicity	Hispanic or Latino	558	47,5	0	0	566	49,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	612	52,1	0	0	570	49,9	1	0,2	0		Algorithm converged.	NE	NE	-0,175		Algorithm converged.	-0,52	0,17	NE	*	Algorithm not converged.	NE	NE	0,4822		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	4	0,3	0	0	7	0,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	103	8,8	0	0	117	10,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	No	1062	90,5	0	0	1013	88,6	1	0,1	0		Algorithm converged.	NE	NE	-0,099		Algorithm converged.	-0,29	0,09	NE	*	Algorithm not converged.	NE	NE	0,4882		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	9	0,8	0	0	13	1,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,3	0	0	14	1,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Negative	1016	86,5	0	0	992	86,8	1	0,1	0		Algorithm converged.	NE	NE	-0,101		Algorithm converged.	-0,3	0,1	NE	*	Algorithm not converged.	NE	NE	0,494		NE	*	Algorithm not converged.	NE	NE
	Unavailable	143	12,2	0	0	137	12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	276	23,5	0	0	251	22	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Seronegative	841	71,6	0	0	842	73,7	1	0,1	0		Algorithm converged.	NE	NE	-0,119		Algorithm converged.	-0,35	0,11	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	57	4,9	0	0	50	4,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

One placebo subject record was not reported in household member status CRF form but index case only to cause the household size is 1.

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* Indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10a-eff-resp-ahosp

POPULATION: Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
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Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas

Output: t8-10b-eff-resp-ahosp

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo												Difference between treatments (Casirivimab/Imdevimab - Placebo)									
Patients in analysis				Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference								
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL							
All	n/a	1174	100	0	0	0	0	0	0,03	0,01	1143	100	1	0,087	11	0,01	0,01	0,039	0,01	-0,01	-0,028	0,009	0,304	-0,043	-0,124	0,039							

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

				Casirivimab/Imdevimab								Placebo								Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)
All	n/a	1174	100	0	0	0	0	0	0	0,007	1143	100	1	0,087	11	0,01	0,01	0,01	0,007	-0,01	-0,028	0,009	0,311	-0,042	-0,124	0,039	NE
Sex	Male	539	45,911	0	0	0	0	0	0	0,014	555	48,556	1	0,18	11	0,02	0,02	0,02	0,014	-0,02	-0,059	0,02	0,325	-0,06	-0,178	0,059	0,2977
	Female	635	54,089	0	0	0	0	0	0	NE	588	51,444	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Age	12-17	52	4,429	0	0	0	0	0	0	NE	47	4,112	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,3919
	18-49	711	60,562	0	0	0	0	0	0	NE	692	60,542	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
	>=50	411	35,009	0	0	0	0	0	0	0,019	404	35,346	1	0,248	11	0,027	0,027	0,027	0,019	-0,027	-0,08	0,026	0,313	-0,071	-0,208	0,067	
Region	US	1087	92,589	0	0	0	0	0	0	NE	1061	92,826	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,0002
	ex-US	87	7,411	0	0	0	0	0	0	0,091	82	7,174	1	1,22	11	0,134	0,134	0,134	0,093	-0,134	-0,391	0,123	0,304	-0,158	-0,46	0,145	
BMI	BMI < 30 kg/m2	752	64,055	0	0	0	0	0	0	NE	736	64,392	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,1679
	BMI >= 30 kg/m2	418	35,605	0	0	0	0	0	0	0,019	400	34,996	1	0,25	11	0,028	0,028	0,028	0,019	-0,028	-0,08	0,025	0,307	-0,071	-0,209	0,066	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Number of study subjects in cohort B within a household	0	1123	95,656	0	0	0	0	0	0	0,007	1110	97,113	1	0,09	11	0,01	0,01	0,01	0,007	-0,01	-0,029	0,009	0,315	-0,043	-0,126	0,04	0,8488
	>=1	51	4,344	0	0	0	0	0	0	NE	33	2,887	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Total household size including the household member(s) not participating this study																											
	2	446	37,99	0	0	0	0	0	0	NE	413	36,133	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,4433
	>2	728	62,01	0	0	0	0	0	0	0,011	729	63,78	1	0,137	11	0,015	0,015	0,015	0,011	-0,015	-0,045	0,015	0,318	-0,052	-0,155	0,05	
Baseline high risk factor	Yes	315	26,831	0	0	0	0	0	0	0,025	307	26,859	1	0,326	11	0,036	0,036	0,036	0,025	-0,036	-0,105	0,034	0,311	-0,081	-0,238	0,076	0,0944
	No	859	73,169	0	0	0	0	0	0	NE	836	73,141	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Race	White	990	84,327	0	0	0	0	0	0	0,008	962	84,164	1	0,104	11	0,011	0,011	0,011	0,008	-0,011	-0,034	0,011	0,31	-0,046	-0,135	0,043	0,918
	Black or African American	128	10,903	0	0	0	0	0	0	NE	123	10,761	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
	Other	38	3,237	0	0	0	0	0	0	NE	36	3,15	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
	Unknown/Not Reported	18	1,533	0	0	0	0	0	0	NE	22	1,925	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Ethnicity	Hispanic or Latino	558	47,53	0	0	0	0	0	0	NE	566	49,519	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,3122
	Not Hispanic or Latino	612	52,129	0	0	0	0	0	0	0,013	570	49,869	1	0,175	11	0,019	0,019	0,019	0,013	-0,019	-0,056	0,017	0,3	-0,06	-0,174	0,054	
	Unknown/not reported	4	0,341	0	0	0	0	0	0	NE	7	0,612	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	

Healthcare worker	Yes	103	8,773	0	0	0	0	0	0	NE	117	10,236	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,7394
	No	1062	90,46	0	0	0	0	0	0	0,007	1013	88,626	1	0,099	11	0,011	0,011	0,011	0,008	-0,011	-0,032	0,01	0,306	-0,045	-0,131	0,041	
	Unknown/not reported	9	0,767	0	0	0	0	0	0	NE	13	1,137	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	15	1,278	0	0	0	0	0	0	NE	14	1,225	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,9033
	Negative	1016	86,542	0	0	0	0	0	0	0,008	992	86,789	1	0,101	11	0,011	0,011	0,011	0,008	-0,011	-0,033	0,01	0,312	-0,045	-0,133	0,042	
	Unavailable	143	12,181	0	0	0	0	0	0	NE	137	11,986	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Serology status	Seropositive	276	23,509	0	0	0	0	0	0	NE	251	21,96	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,5765
	Seronegative	841	71,635	0	0	0	0	0	0	0,009	842	73,666	1	0,119	11	0,013	0,013	0,013	0,009	-0,013	-0,039	0,013	0,318	-0,049	-0,144	0,047	
	Unclear serology status	57	4,855	0	0	0	0	0	0	NE	50	4,374	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of days of hospital and intensive care unit (ICU) stay in subjects hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	56	100	0	0	0	0	0	0,282	0,13	145	100	1	0,69	11	0,076	0,076	0,369	0,105	-0,087	-0,322	0,148	0,466	-0,115	-0,424	0,195

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-6-eff-smd-ANDHOSP

POPULATION: Modified Full Analysis Set - Cohort A

ENDPOINT: Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of days	Statistics		ANCOVA		Patients		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	1174	100	18	1,533	168	0,143	0,039	0,334	0,112	1143	100	52	4,549	592	0,518	0,097	0,71	0,113	-0,375	-0,578	-0,173	0,0003	-0,151	-0,233	-0,07			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-7-eff-smd-ANDABSEN

Template SMD

Output: t9-7-eff-smd-ANDABSEN

POPULATION: Modified Full Analysis Set - Cohort A only including patients with a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

ENDPOINT: Number of days missed for daily responsibilities due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	56	100	18	32,143	168	3	0,735	4,612	1,306	145	100	52	35,862	592	4,083	0,694	5,762	1,055	-1,15	-3,518	1,218	0,339	-0,15	-0,459	0,159			

Stratification factor = Age Region.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas

Output: t9-7-eff-smd-ANDABSEN

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Wirksamkeit

Ergänzende Dokumente

POPULATION: mFAS - Cohort A
ENDPOINT: --
MODEL: --
STUDY: R10933-10987-COV-2069
Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	106	100%	2317	100%	3	100%	2317	100%	2	100%	2317	100%
with <10 Patients per arm ¹	78	73.6%	494	21.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	28	26.4%	1823	78.7%	3	100%	2317	100%	2	100%	2317	100%

¹: ' <10 patients category' if at least one treatment arm has <10 patients.
²: ' >=10 patients ' category if all treatment arms have >=10 patients.
³: Geographical regions: US vs Ex-US (Romania; Republic of Moldova)
⁴: Number of centers, countries, or geographical regions
⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions
⁶: Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm)
⁷: % 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 cut-off: 01Jul2021

Program: t3_center.sas
Output: t3_center.xlsx

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A****Study: R10933-10987-COV-2069**

	Treatment	
	Placebo (N = 1143)	Casirivimab/Imdevimab (N = 1174)
Age (Years)		
n	1143	1174
Mean	42.11	41.87
SD	15.57	15.88
Median	43.0	42.0
Q1	29.0	28.0
Q3	54.0	54.0
Min	12.0	12.0
Max	92.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	47 (4.1)	52 (4.4)
>=18 to <45	558 (48.8)	580 (49.4)
>=45 to <65	454 (39.7)	441 (37.6)
>=65 to <80	77 (6.7)	98 (8.3)
>=80	7 (0.6)	3 (0.3)
Age Group (Years) [n (%)]		
>=12 to <50	739 (64.7)	763 (65.0)
>=50	404 (35.3)	411 (35.0)
Sex [n (%)]		
Male	555 (48.6)	539 (45.9)
Female	588 (51.4)	635 (54.1)
Race [n (%)]		
White	962 (84.2)	990 (84.3)
Black or African American	123 (10.8)	128 (10.9)
Asian	29 (2.5)	33 (2.8)
American Indian or Alaska Native	5 (0.4)	3 (0.3)
Native Hawaiian or Other Pacific Islander	2 (0.2)	2 (0.2)
Other	22 (1.9)	18 (1.5)
Ethnicity [n (%)]		
Hispanic or Latino	566 (49.5)	558 (47.5)
Not Hispanic or Latino	570 (49.9)	612 (52.1)
Other	7 (0.6)	4 (0.3)
Weight (kg)		
n	1137	1170
Missing	6	4
Mean	81.85	81.33
SD	19.90	19.45
Median	79.4	79.1
Q1	68.0	67.4
Q3	92.0	91.2
Min	35.5	32.7
Max	164.2	180.3
Height (cm)		
n	1136	1171
Missing	7	3
Mean	168.47	168.37
SD	10.19	10.58
Median	167.6	167.6
Q1	161.0	160.0
Q3	175.3	176.0
Min	125.0	71.5
Max	201.0	200.7
BMI (kg/m2)		
n	1136	1170
Missing	7	4
Mean	28.80	28.83
SD	6.39	10.49
Median	27.7	27.9
Q1	24.4	24.2
Q3	31.9	31.8
Min	14.1	15.1
Max	63.7	320.8

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A****Study: R10933-10987-COV-2069**

	Treatment	
	Placebo (N = 1143)	Casirivimab/Imdevimab (N = 1174)
BMI group (kg/m2) [n (%)]		
Missing	7 (0.6)	4 (0.3)
BMI < 30 kg/m2	736 (64.4)	752 (64.1)
BMI ≥ 30 kg/m2	400 (35.0)	418 (35.6)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	14 (1.2)	15 (1.3)
Negative	992 (86.8)	1016 (86.5)
Unavailable	137 (12.0)	143 (12.2)
Randomization strata: age [n (%)]		
12-17	47 (4.1)	52 (4.4)
18-49	692 (60.5)	711 (60.6)
≥50	404 (35.3)	411 (35.0)
Region [n (%)]		
US	1061 (92.8)	1087 (92.6)
ex-US	82 (7.2)	87 (7.4)
Country [n (%)]		
Moldova, Republic of	52 (4.5)	51 (4.3)
Romania	30 (2.6)	36 (3.1)
United States of America	1061 (92.8)	1087 (92.6)
Total household size including the house members not participating this study [n (%)]		
2	413 (36.1)	446 (38.0)
>2	729 (63.8)	728 (62.0)
Others	1 (0.1)	0 (0.0)
Number of study subjects in cohort B within a household [n (%)]		
0	1110 (97.1)	1123 (95.7)
≥1	33 (2.9)	51 (4.3)
No one wears a mask in home [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	567 (49.6)	638 (54.3)
No	566 (49.5)	528 (45.0)
N/A	9 (0.8)	8 (0.7)
Share a bedroom [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	355 (31.1)	353 (30.1)
No	777 (68.0)	816 (69.5)
N/A	10 (0.9)	5 (0.4)
Share a common room [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	1081 (94.6)	1104 (94.0)
No	52 (4.5)	65 (5.5)
N/A	9 (0.8)	5 (0.4)
Symptoms in suspected infected person [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	892 (78.0)	920 (78.4)
No	231 (20.2)	237 (20.2)
N/A	19 (1.7)	17 (1.4)
Aware of any treatment [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	389 (34.0)	408 (34.8)
No	734 (64.2)	748 (63.7)
N/A	19 (1.7)	18 (1.5)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	5 (0.4)	3 (0.3)
Yes	264 (23.1)	255 (21.7)
No	874 (76.5)	916 (78.0)

Clinical cut-off: 01Jul2021

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1143)	Casirivimab/Imdevimab (N = 1174)
Total household members, including index case, who participated at the R10933-10987-COV-2067 [n (%)]		
Missing	8 (0.7)	6 (0.5)
0	963 (84.3)	1006 (85.7)
1	167 (14.6)	154 (13.1)
2	4 (0.3)	6 (0.5)
3	1 (0.1)	1 (0.1)
4	0 (0.0)	1 (0.1)
Subject received influenza [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	243 (21.3)	264 (22.5)
No	899 (78.7)	910 (77.5)
Subject been quarantined [n (%)]		
Missing	1 (0.1)	0 (0.0)
Yes	219 (19.2)	219 (18.7)
No	923 (80.8)	955 (81.3)
First responder [n (%)]		
Missing	11 (1.0)	1 (0.1)
Yes	31 (2.7)	24 (2.0)
No	1101 (96.3)	1149 (97.9)
Healthcare worker [n (%)]		
Yes	117 (10.2)	103 (8.8)
No	1013 (88.6)	1062 (90.5)
Unknown/not reported	13 (1.1)	9 (0.8)
Contact with a stranger [n (%)]		
Missing	2 (0.2)	0 (0.0)
Yes	394 (34.5)	385 (32.8)
No	747 (65.4)	789 (67.2)
Serology status [n (%)]		
Seropositive	251 (22.0)	276 (23.5)
Seronegative	842 (73.7)	841 (71.6)
Unclear serology status	50 (4.4)	57 (4.9)
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	10 (0.9)	16 (1.4)
-4	0 (0.0)	1 (0.1)
-1	3 (0.3)	2 (0.2)
0	1130 (98.9)	1155 (98.4)
Baseline high risk factor [n (%)]		
Yes	307 (26.9)	315 (26.8)
No	836 (73.1)	859 (73.2)

Table 5.1. Summary of Overall Patient Disposition
Modified Full Analysis Set - Cohort A

	Placebo (N=1143)	Casirivimab/Imdevimab (N=1174)
Randomized patients	1143 (100%)	1174 (100%)
Randomized but not treated	1 (<0.1%)	2 (0.2%)
Randomized and treated	1142 (99.9%)	1172 (99.8%)
Complete the efficacy assessment period(EAP) (as derived)	1138 (99.6%)	1166 (99.3%)
Complete the end of study follow-up visit (as per CRF)	328 (28.7%)	343 (29.2%)
Did not complete the end of study follow-up visit	814 (71.2%)	829 (70.6%)
Subjects discontinued from the study during EAP	4 (0.3%)	6 (0.5%)
Reason for subjects discontinuing from the study during EAP		
Adverse Event	0	0
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	0	0
Lost To Follow-Up	1 (<0.1%)	2 (0.2%)
Subject Decision	3 (0.3%)	4 (0.3%)

Clinical cut-off: 01Jul2021

Table 5.3. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=3375)
Number of Subjects Screened	3375
Randomized Subject	3298 (97.7%)
Subjects treated but not randomized	0
Subjects randomized but not treated	28 (0.8%)
Screen Failure Patients	72 (2.1%)
Excl 01: Subject-reported history of prior positive SARS-CoV-2 RT-PCR test or positive SARS-CoV-2 serology test at any time before the screening	3 (<0.1%)
Excl 02: Subject has lived with individuals who have had previous SARS-CoV-2 infection	3 (<0.1%)
Excl 03: Active respiratory or non-respiratory symptoms consistent with COVID-19	3 (<0.1%)
Excl 06: Any PE, and/or MH, CM or recent live vaccines that, in the opinion of the study investigator, might confound the study results or pose an additional risk to the subject by their partic	3 (<0.1%)
Excl 08: Has a history of significant multiple and/or severe allergies or has had an anaphylactic reaction to prescription or non-prescription drugs or food	6 (0.2%)
Excl 09: Treatment with another investigational agent in the last 30 days or within 5 half-lives of the investigational drug, whichever is longer, prior to the screening visit	2 (<0.1%)
Excl 12: Use of hydroxychloroquine/chloroquine for prophylaxis/treatment of SARS-CoV-2 or anti-SARS-viral agents, eg, remdesivir, within 1 (<0.1%) 60 days of screening	
Excl 13: Member of the clinical site study team and/or immediate family	1 (<0.1%)
Excl 14: Sexually active men who are unwilling to use the following forms of medically acceptable birth control during the study drug follow-up period and for 8 months after single dose of stud	1 (<0.1%)

Clinical cut-off: 01Jul2021

Patients with two screen failure reasons will be counted twice in the frequency table.

Table 5.3. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=3375)
Excl 16: WOCBP and girls at or beyond menarche who are unwilling to use highly effective contraception prior to start of the first dose, during the study, and for at least 8 months after the la	11 (0.3%)
Incl 01: Adult subjects ≥ 18 years of age at the signing of informed consent or adolescent subjects ≥ 12 to < 18 years of age, or pediatric subjects < 12 years of age at the signing of the assent	1 ($< 0.1\%$)
Incl 02: Asymptomatic household contact with exposure to an individual with a diagnosis of SARS-CoV-2 infection (index case)	19 (0.6%)
Incl 03: Subject anticipates living in the same household with the index case until study day 29	9 (0.3%)
Incl 04: Is judged by the investigator to be in good health based on medical history and physical examination at screening/baseline, including subjects who have a chronic, stable medical condition	2 ($< 0.1\%$)
Incl 05: Willing and able to comply with study visits and study-related procedures/assessments	9 (0.3%)
Incl 06: Provide informed consent signed by study subject or legally acceptable representative	1 ($< 0.1\%$)
Missing	1 ($< 0.1\%$)

Clinical cut-off: 01Jul2021

Patients with two screen failure reasons will be counted twice in the frequency table.

Clinical cut-off: 01Jul2021

**Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set - Cohort A**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1143)	Casirivimab/Imdevimab (N = 1174)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Missing	1	2
Median	202.0	203.0

Table 14.4.3.5.1 Index Case Interaction at Baseline
Seronegative mFAS-A

	Placebo (N=842)	R10933+R10987 (N=841)	Total (N=1683)
Share a bedroom			
Yes	261 (31.0%)	253 (30.1%)	514 (30.5%)
No	572 (67.9%)	583 (69.3%)	1155 (68.6%)
N/A or Missing	9 (1.1%)	5 (0.6%)	14 (0.8%)
Share a common room			
Yes	795 (94.4%)	803 (95.5%)	1598 (94.9%)
No	39 (4.6%)	33 (3.9%)	72 (4.3%)
N/A or Missing	8 (1.0%)	5 (0.6%)	13 (0.8%)
No one wears a mask in home			
Yes	406 (48.2%)	446 (53.0%)	852 (50.6%)
No	427 (50.7%)	387 (46.0%)	814 (48.4%)
N/A or Missing	9 (1.1%)	8 (1.0%)	17 (1.0%)
Symptoms in suspected infected person or people in home[1]			
Yes	656 (77.9%)	663 (78.8%)	1319 (78.4%)
No	170 (20.2%)	164 (19.5%)	334 (19.8%)
N/A or Missing	16 (1.9%)	14 (1.7%)	30 (1.8%)

Note: All randomized subjects are included for CSR addendum. The cutoff date is 01Jul2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: Data collected from index interaction eCRF form. This information was not collected for subjects enrolled prior to protocol amendment 1. They are categorized to N/A.

[1] Any of symptoms including fever, and/or cough, shortness of breath, chills, GI upset, loss of smell and/or taste.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA2_allrand/Analysis_CSR/Programs/TFL/Generated/t_1050a_index.sas (izabella.peszek 23SEP2021 15:26 SAS Linux 9.4)

Table 14.4.3.5.1 Index Case Interaction at Baseline
Seronegative mFAS-A

	Placebo (N=842)	R10933+R10987 (N=841)	Total (N=1683)
Suspected infected person or people are receiving any treatment, investigational or approved			
Yes	296 (35.2%)	306 (36.4%)	602 (35.8%)
No	530 (62.9%)	522 (62.1%)	1052 (62.5%)
N/A or Missing	16 (1.9%)	13 (1.5%)	29 (1.7%)

Note: All randomized subjects are included for CSR addendum. The cutoff date is 01Jul2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: Data collected from index interaction eCRF form. This information was not collected for subjects enrolled prior to protocol amendment 1. They are categorized to N/A.

[1] Any of symptoms including fever, and/or cough, shortness of breath, chills, GI upset, loss of smell and/or taste.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA2_allrand/Analysis_CSR/Programs/TFL/Generated/t_1050a_index.sas (izabella.peszek 23SEP2021 15:26 SAS Linux 9.4)

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

Hauptdokumente

POPULATION: Safety - Cohort A
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1439	100	387	26,9	1428	100	494	34,6	0,7	Algorithm converged.	0,59	0,82	-7,7	Algorithm converged.	-11,07	-4,33	0,78	Algorithm converged.	0,7	0,87	<0.0001		1,29	Algorithm converged.	1,15	1,44				
Sex	Male	661	45,9	167	25,3	690	48,3	231	33,5	0,67	Algorithm converged.	0,53	0,85	-8,214	Algorithm converged.	-13,05	-3,38	0,75	Algorithm converged.	0,64	0,89	0,0009	0,6605	1,33	Algorithm converged.	1,12	1,57				
	Female	778	54,1	220	28,3	738	51,7	263	35,6	0,71	Algorithm converged.	0,57	0,88	-7,359	Algorithm converged.	-12,04	-2,67	0,79	Algorithm converged.	0,68	0,92	0,0021		1,26	Algorithm converged.	1,09	1,46				
Age	12-17	51	3,5	15	29,4	47	3,3	17	36,2	0,74	Algorithm converged.	0,32	1,71	-6,758	Algorithm converged.	-25,33	11,82	0,81	Algorithm converged.	0,46	1,44	0,4782	0,4811	1,23	Algorithm converged.	0,7	2,17				
	18-49	874	60,7	246	28,1	868	60,8	299	34,4	0,75	Algorithm converged.	0,61	0,91	-6,301	Algorithm converged.	-10,65	-1,96	0,82	Algorithm converged.	0,71	0,94	0,0046		1,22	Algorithm converged.	1,06	1,41				
	>=50	514	35,7	126	24,5	513	35,9	178	34,7	0,61	Algorithm converged.	0,47	0,8	-10,184	Algorithm converged.	-15,73	-4,63	0,71	Algorithm converged.	0,58	0,86	0,0004		1,42	Algorithm converged.	1,17	1,72				
Region	US	1348	93,7	372	27,6	1339	93,8	467	34,9	0,71	Algorithm converged.	0,6	0,84	-7,28	Algorithm converged.	-10,77	-3,79	0,79	Algorithm converged.	0,71	0,89	<0.0001	0,187	1,26	Algorithm converged.	1,13	1,42				
	ex-US	91	6,3	15	16,5	89	6,2	27	30,3	0,45	Algorithm converged.	0,22	0,93	-13,854	Algorithm converged.	-26,07	-1,63	0,54	Algorithm converged.	0,31	0,95	0,0285		1,84	Algorithm converged.	1,05	3,22				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-1-ae-raw-anyae-unstrat-saf1

POPULATION: Safety - Cohort A

ENDPOINT: Any AEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1439	100	329	22,9	1428	100	315	22,1	1,05	Algorithm converged.	0,88	1,25	0,804	Algorithm converged.	-2,25	3,86	1,04	Algorithm converged.	0,9	1,19	0,606		0,96	Algorithm converged.	0,84	1,11			
Sex	Male	661	45,9	135	20,4	690	48,3	145	21	0,96	Algorithm converged.	0,74	1,26	-0,591	Algorithm converged.	-4,91	3,73	0,97	Algorithm converged.	0,79	1,2	0,7889	0,4427	1,03	Algorithm converged.	0,84	1,27			
	Female	778	54,1	194	24,9	738	51,7	170	23	1,11	Algorithm converged.	0,88	1,41	1,901	Algorithm converged.	-2,4	6,2	1,08	Algorithm converged.	0,9	1,3	0,3867		0,92	Algorithm converged.	0,77	1,11			
Age	12-17	51	3,5	12	23,5	47	3,3	10	21,3	1,14	Algorithm converged.	0,44	2,95	2,253	Algorithm converged.	-14,25	18,76	1,11	Algorithm converged.	0,53	2,32	0,7905	0,3165	0,9	Algorithm converged.	0,43	1,89			
	18-49	874	60,7	215	24,6	868	60,8	191	22	1,16	Algorithm converged.	0,93	1,44	2,595	Algorithm converged.	-1,37	6,56	1,12	Algorithm converged.	0,94	1,33	0,2004		0,89	Algorithm converged.	0,75	1,06			
	>=50	514	35,7	102	19,8	513	35,9	114	22,2	0,87	Algorithm converged.	0,64	1,17	-2,378	Algorithm converged.	-7,36	2,61	0,89	Algorithm converged.	0,7	1,13	0,3501		1,12	Algorithm converged.	0,88	1,42			
Region	US	1348	93,7	317	23,5	1339	93,8	304	22,7	1,05	Algorithm converged.	0,87	1,25	0,813	Algorithm converged.	-2,37	4	1,04	Algorithm converged.	0,9	1,19	0,6173	0,9404	0,97	Algorithm converged.	0,84	1,11			
	ex-US	91	6,3	12	13,2	89	6,2	11	12,4	1,08	Algorithm converged.	0,45	2,59	0,827	Algorithm converged.	-8,92	10,58	1,07	Algorithm converged.	0,5	2,29	0,8683		0,94	Algorithm converged.	0,44	2,01			

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas

Output: t12-2-ae-raw-anyaenr-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade >= 3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1439	100	22	1,5	1428	100	28	2	0,78	Algorithm converged.	0,44	1,36	-0,432	Algorithm converged.	-1,39	0,53	0,78	Algorithm converged.	0,45	1,36	0,3771		1,28	Algorithm converged.	0,74	2,23				
Sex	Male	661	45,9	10	1,5	690	48,3	10	1,4	1,04	Algorithm converged.	0,43	2,53	0,064	Algorithm converged.	-1,23	1,35	1,04	Algorithm converged.	0,44	2,49	0,923	0,3847	0,96	Algorithm converged.	0,4	2,29				
	Female	778	54,1	12	1,5	738	51,7	18	2,4	0,63	Algorithm converged.	0,3	1,31	-0,897	Algorithm converged.	-2,31	0,51	0,63	Algorithm converged.	0,31	1,3	0,2104		1,58	Algorithm converged.	0,77	3,26				
Age	12-17	51	3,5	0	0	47	3,3	1	2,1	0	Algorithm converged.	NE	NE	-2,128	Algorithm converged.	-6,25	2	NE	*	Algorithm not converged.	NE	NE	0,4796	0,529	NE	*	Algorithm not converged.	NE	NE		
	18-49	874	60,7	11	1,3	868	60,8	14	1,6	0,78	Algorithm converged.	0,35	1,72	-0,354	Algorithm converged.	-1,47	0,76	0,78	Algorithm converged.	0,36	1,71	0,5343		1,28	Algorithm converged.	0,59	2,81				
	>=50	514	35,7	11	2,1	513	35,9	13	2,5	0,84	Algorithm converged.	0,37	1,9	-0,394	Algorithm converged.	-2,24	1,45	0,84	Algorithm converged.	0,38	1,87	0,6761		1,18	Algorithm converged.	0,54	2,62				
Region	US	1348	93,7	21	1,6	1339	93,8	24	1,8	0,87	Algorithm converged.	0,48	1,57	-0,235	Algorithm converged.	-1,21	0,74	0,87	Algorithm converged.	0,49	1,55	0,6358	0,2239	1,15	Algorithm converged.	0,64	2,06				
	ex-US	91	6,3	1	1,1	89	6,2	4	4,5	0,24	Algorithm converged.	0,03	2,16	-3,395	Algorithm converged.	-8,2	1,41	0,24	Algorithm converged.	0,03	2,15	0,2083		4,09	Algorithm converged.	0,47	35,88				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-3-ae-raw-toxgrgt3-unstrat-saf1

POPULATION: Safety - Cohort A

ENDPOINT: AEs Grade >=3 (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1439	100	22	1,5	1428	100	22	1,5	0,99	Algorithm converged.	0,55	1,8	-0,012	Algorithm converged.	-0,91	0,89	0,99	Algorithm converged.	0,55	1,78	0,9795		1,01	Algorithm converged.	0,56	1,81				
Sex	Male	661	45,9	10	1,5	690	48,3	7	1	1,5	Algorithm converged.	0,57	3,96	0,498	Algorithm converged.	-0,7	1,69	1,49	Algorithm converged.	0,57	3,89	0,4115	0,2744	0,67	Algorithm converged.	0,26	1,75				
	Female	778	54,1	12	1,5	738	51,7	15	2	0,76	Algorithm converged.	0,35	1,62	-0,49	Algorithm converged.	-1,83	0,85	0,76	Algorithm converged.	0,36	1,61	0,471		1,32	Algorithm converged.	0,62	2,8				
Age	12-17	51	3,5	0	0	47	3,3	1	2,1	0	Algorithm converged.	NE	NE	-2,128	Algorithm converged.	-6,25	2	NE	*	Algorithm not converged.	NE	NE	0,4796	0,4206	NE	*	Algorithm not converged.	NE	NE		
	18-49	874	60,7	11	1,3	868	60,8	12	1,4	0,91	Algorithm converged.	0,4	2,07	-0,124	Algorithm converged.	-1,2	0,95	0,91	Algorithm converged.	0,4	2,05	0,8208		1,1	Algorithm converged.	0,49	2,48				
	>=50	514	35,7	11	2,1	513	35,9	9	1,8	1,22	Algorithm converged.	0,5	2,98	0,386	Algorithm converged.	-1,3	2,08	1,22	Algorithm converged.	0,51	2,92	0,6549		0,82	Algorithm converged.	0,34	1,96				
Region	US	1348	93,7	21	1,6	1339	93,8	20	1,5	1,04	Algorithm converged.	0,56	1,93	0,064	Algorithm converged.	-0,86	0,99	1,04	Algorithm converged.	0,57	1,92	0,892	0,5343	0,96	Algorithm converged.	0,52	1,76				
	ex-US	91	6,3	1	1,1	89	6,2	2	2,2	0,48	Algorithm converged.	0,04	5,43	-1,148	Algorithm converged.	-4,9	2,6	0,49	Algorithm converged.	0,05	5,3	0,6187		2,04	Algorithm converged.	0,19	22,15				

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas

Output: t12-4-ae-raw-toxgtnr3-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	1439	100	17	1.2	1428	100	24	1.7	0.7	Algorithm converged.	0.37	1.31	-0.499	Algorithm converged.	-1.37	0.37	0.7	Algorithm converged.	0.38	1.3	0.2603		1.42	Algorithm converged.	0.77	2.64				
Sex	Male	661	45.9	7	1.1	690	48.3	8	1.2	0.91	Algorithm converged.	0.33	2.53	-0.1	Algorithm converged.	-1.22	1.02	0.91	Algorithm converged.	0.33	2.5	0.8603	0.5075	1.09	Algorithm converged.	0.4	3				
	Female	778	54.1	10	1.3	738	51.7	16	2.2	0.59	Algorithm converged.	0.26	1.3	-0.883	Algorithm converged.	-2.2	0.43	0.59	Algorithm converged.	0.27	1.3	0.186		1.69	Algorithm converged.	0.77	3.69				
Age	12-17	51	3.5	0	0	47	3.3	1	2.1	0	Algorithm converged.	NE	NE	-2.128	Algorithm converged.	-6.25	2	NE	*	Algorithm not converged.	NE	NE	0.4796	0.5589	NE	*	Algorithm not converged.	NE	NE		
	18-49	874	60.7	9	1	868	60.8	12	1.4	0.74	Algorithm converged.	0.31	1.77	-0.353	Algorithm converged.	-1.38	0.67	0.74	Algorithm converged.	0.32	1.76	0.5001		1.34	Algorithm converged.	0.57	3.17				
	>=50	514	35.7	8	1.6	513	35.9	11	2.1	0.72	Algorithm converged.	0.29	1.81	-0.588	Algorithm converged.	-2.24	1.06	0.73	Algorithm converged.	0.29	1.79	0.4848		1.38	Algorithm converged.	0.56	3.4				
Region	US	1348	93.7	17	1.3	1339	93.8	21	1.6	0.8	Algorithm converged.	0.42	1.53	-0.307	Algorithm converged.	-1.2	0.59	0.8	Algorithm converged.	0.43	1.52	0.5002	0.063	1.24	Algorithm converged.	0.66	2.35				
	ex-US	91	6.3	0	0	89	6.2	3	3.4	0	Algorithm converged.	NE	NE	-3.371	Algorithm converged.	-7.12	0.38	NE	*	Algorithm not converged.	NE	NE	0.1188		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-5-ae-raw-toxgr3-unstrat-saf1

POPULATION: Safety - Cohort A

ENDPOINT: AEs Grade 4

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo												Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk		Relative Risk		Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL												
All	n/a	1439	100	2	0.1	1428	100	2	0.1	0.99	Algorithm converged.	0.14	7.05	-0.001	Algorithm converged.	-0.27	0.27	0.99	Algorithm converged.	0.14	7.04	1		1.01	Algorithm converged.	0.14	7.14												
Sex	Male	661	45.9	1	0.2	690	48.3	1	0.1	1.04	Algorithm converged.	0.07	16.72	0.006	Algorithm converged.	-0.4	0.42	1.04	Algorithm converged.	0.07	16.65	1	0.9618	0.96	Algorithm converged.	0.06	15.28												
	Female	778	54.1	1	0.1	738	51.7	1	0.1	0.95	Algorithm converged.	0.06	15.19	-0.007	Algorithm converged.	-0.37	0.36	0.95	Algorithm converged.	0.06	15.14	1		1.05	Algorithm converged.	0.07	16.82												
Age	12-17	51	3.5	0	0	47	3.3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	*	Algorithm not converged.	NE	NE								
	18-49	874	60.7	1	0.1	868	60.8	1	0.1	0.99	Algorithm converged.	0.06	15.9	-0.001	Algorithm converged.	-0.32	0.32	0.99	Algorithm converged.	0.06	15.85	1	1.01	Algorithm converged.	0.06	16.07													
	>=50	514	35.7	1	0.2	513	35.9	1	0.2	1	Algorithm converged.	0.06	16	0	Algorithm converged.	0.06	15.91	1	Algorithm converged.	0.06	15.91	1		1.01	Algorithm converged.	0.06	15.98												
Region	US	1348	93.7	1	0.1	1339	93.8	1	0.1	0.99	Algorithm converged.	0.06	15.9	0	Algorithm converged.	-0.21	0.21	0.99	Algorithm converged.	0.06	15.86	1	0.9938	1.01	Algorithm converged.	0.06	16.08												
	ex-US	91	6.3	1	1.1	89	6.2	1	1.1	0.98	Algorithm converged.	0.06	15.88	-0.025	Algorithm converged.	-3.09	3.04	0.98	Algorithm converged.	0.06	15.4	1	1.02	Algorithm converged.	0.06	16.1													

POPULATION: Safety - Cohort A
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	1439	100	3	0,2	1428	100	2	0,1	1,49	Algorithm converged.	0,25	8,93	0,068	Algorithm converged.	-0,24	0,37	1,49	Algorithm converged.	0,25	8,89	1		0,67	Algorithm converged.	0,11	4,01								
Sex	Male	661	45,9	2	0,3	690	48,3	1	0,1	2,09	Algorithm converged.	0,19	23,12	0,158	Algorithm converged.	-0,35	0,66	2,09	Algorithm converged.	0,19	22,97	0,6168	0,6717	0,48	Algorithm converged.	0,04	5,27								
	Female	778	54,1	1	0,1	738	51,7	1	0,1	0,95	Algorithm converged.	0,06	15,19	-0,007	Algorithm converged.	-0,37	0,36	0,95	Algorithm converged.	0,06	15,14	1		1,05	Algorithm converged.	0,07	16,82								
Age	12-17	51	3,5	0	0	47	3,3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	0,9321	NE	*	Algorithm not converged.	NE	NE							
	18-49	874	60,7	1	0,1	868	60,8	1	0,1	0,99	Algorithm converged.	0,06	15,9	-0,001	Algorithm converged.	-0,32	0,32	0,99	Algorithm converged.	0,06	15,85	1		1,01	Algorithm converged.	0,06	16,07								
	>=50	514	35,7	2	0,4	513	35,9	1	0,2	2	Algorithm converged.	0,18	22,13	0,194	Algorithm converged.	-0,47	0,85	2	Algorithm converged.	0,18	21,94	1		0,5	Algorithm converged.	0,05	5,51								
Region	US	1348	93,7	3	0,2	1339	93,8	2	0,1	1,49	Algorithm converged.	0,25	8,94	0,073	Algorithm converged.	-0,25	0,4	1,49	Algorithm converged.	0,25	8,9	1	1	0,67	Algorithm converged.	0,11	4,01								
	ex-US	91	6,3	0	0	89	6,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE							

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t1-ae-raw.sas, binary1-excel12.sas
Output: t12-7-ae-raw-toxgr5-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo												Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk		Relative Risk		Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL												
All	n/a	1439	100			20	1.4																																

POPULATION: Safety - Cohort A
ENDPOINT: Any SAEs (excluding disease related events)
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	1439	100	20	1.4	1428	100	16	1.1	1.24	Algorithm converged.	0.64	2.41	0.269	Algorithm converged.	-0.55	1.08	1.24	Algorithm converged.	0.65	2.38	0.5172		0.81	Algorithm converged.	0.42	1.55						
Sex	Male	661	45.9	12	1.8	690	48.3	4	0.6	3.17	Algorithm converged.	1.02	9.88	1.236	Algorithm converged.	0.07	2.4	3.13	Algorithm converged.	1.02	9.66	0.0438	0.0223	0.32	Algorithm converged.	0.1	0.99						
	Female	778	54.1	8	1	738	51.7	12	1.6	0.63	Algorithm converged.	0.26	1.55	-0.598	Algorithm converged.	-1.75	0.56	0.63	Algorithm converged.	0.26	1.54	0.3081		1.58	Algorithm converged.	0.65	3.85						
Age	12-17	51	3.5	0	0	47	3.3	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	0.8571	NE *	Algorithm not converged.	NE	NE						
	18-49	874	60.7	12	1.4	868	60.8	11	1.3	1.08	Algorithm converged.	0.48	2.47	0.106	Algorithm converged.	-0.97	1.18	1.08	Algorithm converged.	0.48	2.44	0.8468		0.92	Algorithm converged.	0.41	2.08						
	>=50	514	35.7	8	1.6	513	35.9	5	1	1.61	Algorithm converged.	0.52	4.94	0.582	Algorithm converged.	-0.78	1.95	1.6	Algorithm converged.	0.53	4.85	0.5786		0.63	Algorithm converged.	0.21	1.9						
Region	US	1348	93.7	18	1.3	1339	93.8	16	1.2	1.12	Algorithm converged.	0.57	2.2	0.14	Algorithm converged.	-0.7	0.99	1.12	Algorithm converged.	0.57	2.18	0.7448	0.1186	0.89	Algorithm converged.	0.46	1.75						
	ex-US	91	6.3	2	2.2	89	6.2	0	0	NE *	Algorithm not converged.	NE	NE	2.198	Algorithm converged.	-0.81	5.21	NE *	Algorithm not converged.	NE	NE	0.4973		NE *	Algorithm not converged.	NE	NE						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t1-ae-raw.sas, binary1-excel12.sas
Output: t12-9-ae-raw-any-saenr-unstrat-saf1

POPULATION: Safety - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk							Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1439	100		0 0	1428	100		0 0																						
Sex	Male	661	45,9		0 0	690	48,3		0 0																						
	Female	778	54,1		0 0	738	51,7		0 0																						
Age	12-17	51	3,5		0 0	47	3,3		0 0																						
	18-49	874	60,7		0 0	868	60,8		0 0																						
	>=50	514	35,7		0 0	513	35,9		0 0																						
Region	US	1348	93,7		0 0	1339	93,8		0 0																						
	ex-US	91	6,3		0 0	89	6,2		0 0																						

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas

Output: t12-10-ae-raw-aeltdis-unstrat-saf1

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

AESI

POPULATION: Safety - Cohort A
ENDPOINT: Injection site reactions Grade >=3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1439	100		0 0	1428	100		0 0																						
Sex	Male	661	45,9		0 0	690	48,3		0 0																						
	Female	778	54,1		0 0	738	51,7		0 0																						
Age	12-17	51	3,5		0 0	47	3,3		0 0																						
	18-49	874	60,7		0 0	868	60,8		0 0																						
	>=50	514	35,7		0 0	513	35,9		0 0																						
Region	US	1348	93,7		0 0	1339	93,8		0 0																						
	ex-US	91	6,3		0 0	89	6,2		0 0																						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-11-ae-raw-isrge3-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: Serious injection site reactions
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk							Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1439	100		0 0	1428	100		0 0																						
Sex	Male	661	45,9		0 0	690	48,3		0 0																						
	Female	778	54,1		0 0	738	51,7		0 0																						
Age	12-17	51	3,5		0 0	47	3,3		0 0																						
	18-49	874	60,7		0 0	868	60,8		0 0																						
	>=50	514	35,7		0 0	513	35,9		0 0																						
Region	US	1348	93,7		0 0	1339	93,8		0 0																						
	ex-US	91	6,3		0 0	89	6,2		0 0																						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-12-ae-raw-sisr-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: Hypersensitivity reactions Grade >=3
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference					Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1439	100		0 0	1428	100		0 0																						
Sex	Male	661	45,9		0 0	690	48,3		0 0																						
	Female	778	54,1		0 0	738	51,7		0 0																						
Age	12-17	51	3,5		0 0	47	3,3		0 0																						
	18-49	874	60,7		0 0	868	60,8		0 0																						
	>=50	514	35,7		0 0	513	35,9		0 0																						
Region	US	1348	93,7		0 0	1339	93,8		0 0																						
	ex-US	91	6,3		0 0	89	6,2		0 0																						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-13-ae-raw-hyprgr3-unstrat-saf1

POPULATION: Safety - Cohort A
ENDPOINT: Serious hypersensitivity reactions
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk								
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1439	100		0 0	1428	100		0 0																									
Sex	Male	661	45,9		0 0	690	48,3		0 0																									
	Female	778	54,1		0 0	738	51,7		0 0																									
Age	12-17	51	3,5		0 0	47	3,3		0 0																									
	18-49	874	60,7		0 0	868	60,8		0 0																									
	>=50	514	35,7		0 0	513	35,9		0 0																									
Region	US	1348	93,7		0 0	1339	93,8		0 0																									
	ex-US	91	6,3		0 0	89	6,2		0 0																									

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-14-ae-raw-shypr-unstrat-saf1

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

SOC-PT

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirumab/Indinavir										Placebo										Casirumab/Indinavir vs. Placebo										Casirumab/Indinavir vs. Placebo										Placebo vs. Casirumab/Indinavir																			
		Patients										Patients										Odds Ratio										Absolute Risk Difference										Relative Risk										Relative Risk									
		Patients with Event										Patients with Event																																																	
		p-value										p-value																																																	
		Odds Ratio										Odds Ratio																																																	
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	Pyrrexia	--	1439	100	12	0.834	1428	100	12	0.84	0.992	Algorithm converged.	0.444	2.216	-0.006	Algorithm converged.	0.673	0.661	0.992	Algorithm converged.	0.447	2.201	0.9849	1.008	Algorithm converged.	0.454	2.236
	Saprapubic pain	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Swelling	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Vaccination site pain	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
Hepatobiliary disorders	--	1439	100	2	0.139	1428	100	2	0.14	0.992	Algorithm converged.	0.14	7.054	-0.001	Algorithm converged.	-0.274	0.272	0.992	Algorithm converged.	0.14	7.035	1	1.008	Algorithm converged.	0.142	7.144	
	Cholecystitis acute	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Cholelithiasis	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Gallbladder pty	--	1439	100	1	0.069	1428	100	1	0.069	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Hypertirubinaemia	--	1439	100	1	0.069	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Portal hypertension	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Immune system disorders	--	1439	100	1	0.069	1428	100	3	0.21	0.33	Algorithm converged.	0.034	3.179	-0.141	Algorithm converged.	-0.414	0.133	0.331	Algorithm converged.	0.034	3.176	0.3728	3.023	Algorithm converged.	0.315	29.028	
	Drug hypersensitivity	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Seasonal allergy	--	1439	100	0	0	1428	100	3	0.21	NE *	Algorithm not converged.	NE	NE	-0.21	Algorithm converged.	-0.448	0.027	NE *	Algorithm not converged.	NE	NE	1.1234	NE	Algorithm not converged.	NE	NE
Infections and infestations	--	1439	100	173	12.022	1428	100	308	21.569	0.497	Algorithm converged.	-0.406	0.609	-8.546	Algorithm converged.	-12.262	-6.831	0.567	Algorithm converged.	0.47	0.861	< .0001	1.794	Algorithm converged.	1.512	2.129	
	Axcess limb	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Acute sinusitis	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Appendicitis	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5.474	-0.071	Algorithm converged.	-0.308	0.166	0.496	Algorithm converged.	0.045	5.466	0.6234	2.015	Algorithm converged.	0.183	22.202
	Asymptomatic COVID-19	--	1439	100	67	4.656	1428	100	119	8.333	0.537	Algorithm converged.	0.647	1.877	-3.677	Algorithm converged.	-5.477	-1.877	0.559	Algorithm converged.	0.438	0.747	< .0001	1.79	Algorithm converged.	1.339	2.393
	Asymptomatic bacteremia	--	1439	100	2	0.139	1428	100	2	0.14	0.992	Algorithm converged.	0.14	7.054	-0.001	Algorithm converged.	-0.274	0.272	0.992	Algorithm converged.	0.14	7.035	1	1.008	Algorithm converged.	0.142	7.144
	Bacterial vaginosis	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095
	Bacteriuria	--	1439	100	2	0.139	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.331	NE *	Algorithm not converged.	NE	NE	0.4998	NE	Algorithm not converged.	NE	NE	
	Bone abscess	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Bronchitis	--	1439	100	3	0.208	1428	100	3	0.21	0.992	Algorithm converged.	0.134	6.412	-0.293	Algorithm converged.	-0.31	28.586	0.6247	Algorithm converged.	0.134	6.412	0.6247	2.015	Algorithm converged.	0.095	16.225
	COVID-19	--	1439	100	20	1.39	1428	100	137	9.594	0.133	Algorithm converged.	0.083	0.214	-8.204	Algorithm converged.	-9.847	-6.561	0.145	Algorithm converged.	0.091	0.23	< .0001	6.903	Algorithm converged.	4.343	10.972
	COVID-19 pneumonia	--	1439	100	1	0.069	1428	100	4	0.28	0.498	Algorithm converged.	0.028	2.218	-0.211	Algorithm converged.	-0.517	0.095	0.248	Algorithm converged.	0.028	2.217	0.2166	4.031	Algorithm converged.	0.451	36.019
	Cellulitis	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Cystitis	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.038	0.166	-0.496	Algorithm converged.	-0.045	0.466	0.6234	Algorithm converged.	0.045	0.466	0.6234	2.015	Algorithm converged.	0.183	22.202
	Diverticulitis	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Ear infection	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5.474	-0.071	Algorithm converged.	-0.308	0.166	0.496	Algorithm converged.	0.045	5.466	0.6234	2.015	Algorithm converged.	0.183	22.202
	Erythema induratum	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Fungal skin infection	--	1439	100	0	0	1428	100	1	0.069	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Gangrene	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Gastroenteritis	--	1439	100	2	0.139	1428	100	4	0.28	0.495	Algorithm converged.	0.091	2.709	-0.141	Algorithm converged.	-0.476	0.194	0.496	Algorithm converged.	0.091	2.705	0.4509	2.015	Algorithm converged.	0.37	10.986
	Gastroenteritis viral	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095
	Gastrointestinal viral infection	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Gonorrhea	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Helicobacter infection	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095
	Herpes zoster	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095
	Hidradenoma	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Infected dental cyst	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Infectious mononucleosis	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Influenza	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095
	Kidney infection	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Laryngitis	--	1439	100	1	0.069	1428	100	1	0.069	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Localised infection	--	1439	100	1	0.069	1428	100	1	0.069	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55
	Nasopharyngitis	--	1439	100	5	0.347	1428	100	10	0.7	0.494	Algorithm converged.	0.169	1.45	-0.353	Algorithm converged.	-0.881	0.176	0.496	Algorithm converged.	0.17	1.448	0.2073	2.015	Algorithm converged.	0.691	5.882
	Oral herpes	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Osteomyelitis	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Otitis externa	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Otitis media acute	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Paronychia	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Pelvic inflammatory disease	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Pharyngitis	--	1439	100	1	0.069	1428	100	0.28	0.495	Algorithm converged.	0.134	6.412	-0.709	Algorithm converged.	-0.31	28.586	0.6247	Algorithm converged.	0.091	2.705	0.4509	2.015	Algorithm converged.	0.37	10.986	
	Pharyngitis streptococcal	--	1439	100	1	0.069	1428	100	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Pneumonia	--	1439	100	3	0.208	1428	100	1	0.07	2.981	Algorithm converged.	0.31	28.694	0.138	Algorithm converged.	-0.134	0.411	2.977	Algorithm converged.	0.31	28.586	0.6247	2.036	Algorithm converged.	0.035	3.225
	Pyelonephritis	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not															

[illegible]

	Migraine	--	1439	100	4	0.278	1428	100	3	0.21	1,324	Algorithm converged.	0.296	5,926	0.068	Algorithm converged.	-0.293	0.429	1,323	*	Algorithm converged.	0.297	5,901	1		0.756	Algorithm converged.	0.169	3,371
	Nerve compression	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Parosmia	--	1439	100	1	0.069	1428	100	2	0.14	0.478	Algorithm converged.	0.045	5,474	-0.071	Algorithm converged.	-0.308	0.166	0.496	*	Algorithm not converged.	0.045	5,466	0.6234	NE	NE	Algorithm not converged.	0.183	22,202
	Radial nerve palsy	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Scoliosis	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Syncope	--	1439	100	2	0.139	1428	100	4	0.28	0.495	Algorithm converged.	0.091	2,709	-0.141	Algorithm converged.	-0.476	0.194	0.496	*	Algorithm converged.	0.091	2,705	0.4509	2.015	NE	Algorithm not converged.	0.37	10,986
	Tension headache	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4961	NE	NE	Algorithm not converged.	NE	NE
	Transient ischaemic attack	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
Pregnancy, puerperium and perinatal conditions	--	--	1439	100	2	0.139	1428	100	2	0.14	0.992	Algorithm converged.	0.14	7,054	-0.001	Algorithm converged.	-0.274	0.272	0.992	*	Algorithm converged.	0.14	7,035	1	1.008	NE	Algorithm not converged.	0.142	7,144
	Abortion spontaneous	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5,474	-0.071	Algorithm converged.	-0.308	0.166	0.496	*	Algorithm converged.	0.045	5,466	0.6234	2.015	NE	Algorithm not converged.	0.183	22,202
	Abortion threatened	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Complication of pregnancy	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
Psychiatric disorders	--	--	1439	100	9	0.625	1428	100	18	1.261	0.493	Algorithm converged.	0.221	1,101	-0.635	Algorithm converged.	-1.343	0.073	0.496	*	Algorithm converged.	0.224	1,101	0.0784	2.015	NE	Algorithm not converged.	0.908	4,471
	Adjustment disorder with depressed mood	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4961	NE	NE	Algorithm not converged.	NE	NE
	Anxiety	--	1439	100	2	0.139	1428	100	8	0.56	0.247	Algorithm converged.	0.052	1,165	-0.421	Algorithm converged.	-0.864	0.011	0.248	*	Algorithm converged.	0.053	1,166	0.064	4.031	NE	Algorithm not converged.	0.857	18,949
	Attention deficit hyperactivity disorder	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21,927	0.069	Algorithm converged.	-0.167	0.305	1.985	*	Algorithm converged.	0.18	21,863	1	0.504	NE	Algorithm not converged.	0.046	5.55
	Confusional state	--	1439	100	2	0.139	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.064	0.331	NE	*	Algorithm not converged.	NE	NE	0.4998	NE	NE	Algorithm not converged.	NE	NE
	Depression	--	1439	100	2	0.139	1428	100	3	0.21	0.661	Algorithm converged.	0.11	3,862	-0.071	Algorithm converged.	-0.207	0.235	0.662	*	Algorithm converged.	0.111	3,853	0.661	1.512	NE	Algorithm not converged.	0.253	9,033
	Initial insomnia	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Insomnia	--	1439	100	1	0.069	1428	100	3	0.21	0.33	Algorithm converged.	0.034	3,179	-0.141	Algorithm converged.	-0.414	0.133	0.331	*	Algorithm converged.	0.034	3,176	0.3728	3.023	NE	Algorithm not converged.	0.315	29,028
	Mania	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Panic attack	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Substance abuse	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Suicidal ideation	--	1439	100	0	0	1428	100	2	0.14	NE	* Algorithm not converged.	NE	NE	-0.14	Algorithm converged.	-0.334	0.054	NE	*	Algorithm not converged.	NE	NE	0.248	NE	NE	Algorithm not converged.	NE	NE
Renal and urinary disorders	--	--	1439	100	9	0.625	1428	100	10	0.7	0.892	Algorithm converged.	0.362	2,203	-0.075	Algorithm converged.	-0.669	0.519	0.893	*	Algorithm converged.	0.364	2,191	0.805	1.12	NE	Algorithm not converged.	0.456	2,747
	Acute kidney injury	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Chronic kidney disease	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Dysuria	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15,881	-0.001	Algorithm converged.	-0.194	0.193	0.992	*	Algorithm converged.	0.062	15,85	1	1.008	NE	Algorithm not converged.	0.063	16,095
	Glycosuria	--	1439	100	0	0	1428	100	4	0.28	NE	* Algorithm not converged.	NE	NE	-0.28	Algorithm converged.	-0.554	-0.006	NE	*	Algorithm not converged.	NE	NE	0.0614	NE	NE	Algorithm not converged.	NE	NE
	Haematuria	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Ketonuria	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Leukocyturia	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Nephrolithiasis	--	1439	100	2	0.139	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.064	0.331	NE	*	Algorithm not converged.	NE	NE	0.4998	NE	NE	Algorithm not converged.	NE	NE
	Podokuria	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Proteinuria	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Renal disorder	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Renal failure	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21,927	0.069	Algorithm converged.	-0.167	0.305	1.985	*	Algorithm converged.	0.18	21,863	1	0.504	NE	Algorithm not converged.	0.046	5.55
	Stenit pyuria	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Urinary retention	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
Reproductive system and breast disorders	--	--	1439	100	6	0.417	1428	100	4	0.28	1.491	Algorithm converged.	0.42	5,293	0.137	Algorithm converged.	-0.294	0.568	1.489	*	Algorithm converged.	0.421	5,264	0.7535	0.672	NE	Algorithm not converged.	0.19	2,376
	Benign prostatic hyperplasia	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Breast haematoma	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Breast mass	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Dysmenorrhea	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Endometriosis	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Erectile dysfunction	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15,881	-0.001	Algorithm converged.	-0.194	0.193	0.992	*	Algorithm converged.	0.062	15,85	1	1.008	NE	Algorithm not converged.	0.063	16,095
	Gastrotuboma	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Ovarian cyst	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
	Pelvic pain	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Prostatitis	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Rectocoele	--	1439	100	0	0	1428	100	1	0.07	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.607	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--	--	1439	100	84	5,837	1428	100	68	4,782	1.24	Algorithm converged.	0.893	1,722	1.075	Algorithm converged.	-0.564	2,715	1,226	*	Algorithm converged.	0.898	1,673	0.1989	0.816	NE	Algorithm not converged.	0.598	1,114
	Asthma	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15,881	-0.001	Algorithm converged.	-0.194	0.193	0.992	*	Algorithm converged.	0.062	15,85	1	1.008	NE	Algorithm not converged.	0.063	16,095
	Chronic obstructive pulmonary disease	--	1439	100	1	0.069	1428	100	0	0	NE	* Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.067												

		Hypertensive urgency	–	1439	100	0	0	1428	100	1	0.07	NE	*	Algorithn not converged.	NE	NE	-0.07		Algorithm converged.	-0.207	0.067	NE	*	Algorithm not converged.	NE	NE	0.4981		NE		Algorithm not converged.	NE	NE
		Peripheral arterial occlusive disease	–	1439	100	1	0.069	1428	100	0	0	NE	*	Algorithn not converged.	NE	NE	0.069		Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Peripheral vascular disorder	–	1439	100	1	0.069	1428	100	0	0	NE	*	Algorithn not converged.	NE	NE	0.069		Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Thrombosis	–	1439	100	1	0.069	1428	100	0	0	NE	*	Algorithn not converged.	NE	NE	0.069		Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Venous thrombosis limb	–	1439	100	1	0.069	1428	100	0	0	NE	*	Algorithn not converged.	NE	NE	0.069		Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-Binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.1342021

Program: f-ae-raw-soc.sas
Output: 113-f-ae-raw-soc-anyae-8s

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Odds Ratio				Casirivimab/Imdevimab vs. Placebo				Absolute Risk Difference				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event												Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL	
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Sex	Blood and lymphatic system disorders	--	Male	661	45.935	6	0.908	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.908	Algorithm converged.	0.185	1.631	NE	*	Algorithm not converged.	NE	NE	0.0136	1.556	NE	NE	NE	NE			
			Female	778	54.065	14	1.799	738	51.681	9	1.22	1.484	Algorithm converged.	0.639	3.45	0.58	Algorithm converged.	-0.645	1.805	1.476		Algorithm converged.	0.643	3.388	0.356	0.678	Algorithm converged.	0.295	1.556	NE	NE		
	Anaemia		Male	661	45.935	4	0.605	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.605	Algorithm converged.	0.014	1.196	NE	*	Algorithm not converged.	NE	NE	0.057	0.0715	NE	Algorithm not converged.	NE	NE			
			Female	778	54.065	9	1.157	738	51.681	5	0.678	1.716	Algorithm converged.	0.572	5.143	0.479	Algorithm converged.	-0.477	1.436	1.707		Algorithm converged.	0.575	5.071	0.4241	0.586	Algorithm converged.	0.197	1.739	NE	NE		
	Hilar lymphadenopathy		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Hypochronic anaemia		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Leukocytosis		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	2	0.257	738	51.681	2	0.271	0.948	Algorithm converged.	0.133	6.751	-0.014	Algorithm converged.	-0.531	0.503	0.949		Algorithm converged.	0.134	6.717	1	1.054	Algorithm not converged.	NE	NE	0.145	7.464		
	Leukopenia		Male	661	45.935	1	0.151	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	0.0902	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	NE	NE	
	Polycythemia		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	NE	NE	
	Retropertoneal lymphadenopathy		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Thrombocytopenia		Male	661	45.935	1	0.151	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE	NE	NE		
			Female	778	54.065	0	0	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
	Thrombocytosis		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	2	0.257	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.257	Algorithm converged.	-0.099	0.613	NE	*	Algorithm not converged.	NE	NE	0.5	NE	Algorithm not converged.	NE	NE	NE	NE		
	Cardiac disorders	--	Male	661	45.935	3	0.454	690	48.319	2	0.29	1.568	Algorithm converged.	0.261	9.416	0.164	Algorithm converged.	-0.487	0.815	1.566		Algorithm converged.	0.262	9.341	0.6806	0.639	Algorithm converged.	0.107	3.81	NE	NE		
			Female	778	54.065	3	0.386	738	51.681	3	0.407	0.948	Algorithm converged.	0.191	4.714	-0.021	Algorithm converged.	-0.654	0.612	0.949		Algorithm converged.	0.192	4.685	1	1.054	Algorithm converged.	0.213	5.207	NE	NE		
	Acute myocardial infarction		Male	661	45.935	1	0.151	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	1	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Angina pectoris		Male	661	45.935	0	0	690	48.319	2	0.29	NE	* Algorithm not converged.	NE	NE	-0.29	Algorithm converged.	-0.691	0.111	NE	*	Algorithm not converged.	NE	NE	0.4999	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
	Arteriosclerosis coronary artery		Male	661	45.935	1	0.151	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE	NE	NE		
			Female	778	54.065	0	0	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
	Cardiac arrest		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	* Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	NE	NE		
	Cardiac failure congestive		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Cardio-respiratory arrest		Male	661	45.935	1	0.151	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE	NE	NE		
			Female	778	54.065	0	0	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
	Cardiomegaly		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	* Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	NE	NE		
	Coronary artery disease		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Hypertensive cardiomyopathy		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Mitral valve stenosis		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
	Palpitations		Male	661	45.935	0	0	690	48.319	1	0.145	NE	* Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE		
			Female	778	54.065	0	0	738	51.681	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
	Pericardial effusion		Male	661	45.935	0	0	690	48.319	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	* Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	NE	NE		
	Tachycardia		Male	661	45.935	0	0	690	48.319	0	0	NE																					

			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE		
			Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Thyroid mass	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			--	Male	661	45.935	5	0.756	690	48.319	2	0.29	2.622	*	Algorithm converged.	0.507	13.561	0.467	Algorithm converged.	-0.306	1.239	2.61	NE	*	Algorithm converged.	0.508	13.404	0.2781	0.1656	0.283	Algorithm converged.	0.075	1.968
			Female	778	54.065	4	0.514	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	0.514	Algorithm converged.	0.001	1.017	NE	*	Algorithm not converged.	NE	NE	0.125	NE		Algorithm not converged.	NE	NE		
			Blépharospasm	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Conjunctival haemorrhage	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.48	NE	*	Algorithm not converged.	NE	NE	0.4893	NE		Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			Dry eye	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Eye irritation	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Lacrimation increased	Male	661	45.935	2	0.303	690	48.319	1	0.145	2.091	*	Algorithm converged.	0.189	23.115	0.158	Algorithm converged.	-0.348	0.663	2.088	NE	*	Algorithm converged.	0.19	22.97	0.6168	1	0.479	Algorithm converged.	0.044	5.27
			Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			Ocular hyperaemia	Male	661	45.935	1	0.151	690	48.319	1	0.145	1.044	*	Algorithm converged.	0.065	16.724	0.006	Algorithm converged.	-0.404	0.417	1.044	NE	*	Algorithm converged.	0.065	16.655	1	0.3211	0.958	Algorithm converged.	0.06	15.284
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Vision blurred	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.48	NE	*	Algorithm not converged.	NE	NE	0.4893	NE		Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			--	Male	661	45.935	12	1.815	690	48.319	19	2.754	0.653	Algorithm converged.	0.314	1.356	-0.938	Algorithm converged.	-2.528	0.651	0.659		Algorithm converged.	0.323	1.347	0.2498	0.6223	1.517	Algorithm converged.	0.742	3.1		
			Female	778	54.065	21	2.699	738	51.681	24	3.252	0.825	Algorithm converged.	0.455	1.496	-0.553	Algorithm converged.	-2.266	1.16	0.83		Algorithm converged.	0.466	1.478	0.5263	1.205		Algorithm converged.	0.677	2.145			
			Abdominal discomfort	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.48	NE	*	Algorithm not converged.	NE	NE	0.4893	0.9092	NE	Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Abdominal pain	Male	661	45.935	0	0	690	48.319	7	1.014	NE	*	Algorithm not converged.	NE	NE	-1.014	Algorithm converged.	-1.762	-0.267	NE	*	Algorithm not converged.	NE	NE	0.0155	1.831	NE	Algorithm not converged.	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	4	0.542	0.236	Algorithm converged.	0.026	2.118	-0.413	Algorithm converged.	-1	0.173	0.237		Algorithm converged.	0.027	2.117	0.2054		4.217	Algorithm converged.	0.472	37.64			
			Abdominal pain lower	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Abdominal pain upper	Male	661	45.935	1	0.151	690	48.319	1	0.145	1.044	Algorithm converged.	0.065	16.724	0.006	Algorithm converged.	-0.404	0.417	1.044	Algorithm converged.	0.065	16.655	1	0.5799	0.958	Algorithm converged.	0.06	15.284			
			Female	778	54.065	0	0.386	738	51.681	1	0.136	2.853	Algorithm converged.	0.296	27.488	0.25	Algorithm converged.	-0.26	0.76	2.846	Algorithm converged.	0.297	27.297	0.625		0.391	Algorithm converged.	0.037	3.371				
			Abdominal tenderness	Male	661	45.935	0	0	690	48.319	0	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			Bowel movement irregularity	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Constipation	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.48	NE	*	Algorithm not converged.	NE	NE	0.4893	0.9092	NE	Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Dental caries	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.1017	NE	Algorithm not converged.	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Diarrhoea	Male	661	45.935	5	0.756	690	48.319	5	0.725	1.044	Algorithm converged.	0.301	3.624	0.032	Algorithm converged.	-0.883	0.947	1.044		Algorithm converged.	0.304	3.589	1	0.7658	0.958	Algorithm converged.	0.279	3.294		
			Female	778	54.065	6	0.771	738	51.681	7	0.949	0.812	Algorithm converged.	0.271	2.426	-0.177	Algorithm converged.	-1.106	0.754	0.813		Algorithm converged.	0.275	2.408	0.7083		1.23	Algorithm converged.	0.415	3.643			
			Dyspepsia	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.48	NE	*	Algorithm not converged.	NE	NE	0.4893	1	NE	Algorithm not converged.	NE	NE	
			Female	778	54.065	2	0.257	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	0.257	Algorithm converged.	-0.099	0.613	NE	*	Algorithm not converged.	NE	NE	0.5	NE		Algorithm not converged.	NE	NE		
			Food poisoning	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Gastritis	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Gastrointestinal tract irritation	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			Gastroesophageal reflux disease	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	778	54.065	0	0	738	51.681	3	0.407	NE	*	Algorithm not converged.	NE	NE	-0.407	Algorithm converged.	-0.866	0.053	NE	*	Algorithm not converged.	NE	NE	0.1151	NE		Algorithm not converged.	NE	NE		
			Haematemesis	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			Haematochezia	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE																	

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						Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.	0.059	15.192	-0.007		Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054		Algorithm converged.	0.066	16.823				
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	2	0.303	690	48,319	1	0.145	2.091	Algorithm converged.	0.189	23.115	0.158		Algorithm converged.	-0.348	0.663	2.088		Algorithm converged.	0.19	22.97	0.6168	0.7185	0.479		Algorithm converged.	0.044	5.27			
						Female	778	54,065	4	0.514	738	51,681	1	0.136	3.809	Algorithm converged.	0.425	34.156	0.378		Algorithm converged.	-0.19	0.947	3.794		Algorithm converged.	0.425	33.869	0.375	0.284	0.294		Algorithm converged.	0.03	2.353			
						Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	NE	-0.145	*	Algorithm not converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	NE	-0.145	*	Algorithm not converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.1017	NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	3	0.454	690	48,319	3	0.435	1.044	Algorithm converged.	0.21	5.191	0.019		Algorithm converged.	-0.691	0.729	1.044		Algorithm converged.	0.211	5.154	1	0.9338	0.958		Algorithm converged.	0.194	4.729			
						Female	778	54,065	3	0.386	738	51,681	3	0.407	0.948	Algorithm converged.	0.191	4.714	-0.021		Algorithm converged.	-0.654	0.612	0.949		Algorithm converged.	0.192	4.685	1		1.054		Algorithm converged.	0.213	5.207			
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	1	0.145	1.044	Algorithm converged.	0.065	16.724	0.006		Algorithm converged.	-0.404	0.417	1.044		Algorithm converged.	0.065	16.655	1	1	0.958		Algorithm converged.	0.06	15.284			
						Female	778	54,065	0	0.151	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	0.06	15.284
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	-0.136	*	Algorithm not converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	6	0.508	690	48,319	8	1.159	0.781	Algorithm converged.	0.269	2.263	-0.252		Algorithm converged.	-1.229	0.826	0.783		Algorithm converged.	0.273	2.244	0.648	0.5028	1.527		Algorithm converged.	0.448	3.661			
						Female	778	54,065	7	0.9	738	51,681	5	0.678	1.331	Algorithm converged.	0.421	4.212	0.222		Algorithm converged.	-0.667	1.111	1.328		Algorithm converged.	0.423	4.166	0.7745		0.753		Algorithm converged.	0.24	2.362			
						Male	661	45,935	3	0.454	690	48,319	6	0.87	0.52	Algorithm converged.	0.129	2.087	-0.416		Algorithm converged.	-1.277	0.446	0.522		Algorithm converged.	0.131	2.078	0.5073	0.4718	1.916		Algorithm converged.	0.483	7.629			
						Female	778	54,065	19	2.442	738	51,681	20	2.71	0.899	Algorithm converged.	0.478	1.698	-0.288		Algorithm converged.	-0.485	1.329	0.901		Algorithm converged.	0.485	1.675	0.742		1.911		Algorithm converged.	0.597	2.062			
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	2	0.303	690	48,319	2	0.29	1.044	Algorithm converged.	0.147	7.433	0.013		Algorithm converged.	-0.567	0.583	1.044		Algorithm converged.	0.147	7.389	1	0.375	0.958		Algorithm converged.	0.135	6.781			
						Female	778	54,065	4	0.514	738	51,681	1	0.136	3.809	Algorithm converged.	0.425	34.156	0.378		Algorithm converged.	-0.19	0.947	3.794		Algorithm converged.	0.425	33.869	0.375	0.284	0.294		Algorithm converged.	0.03	2.353			
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	17	2.572	690	48,319	15	2.174	1.188	Algorithm converged.	0.588	2.398	0.398		Algorithm converged.	-1.227	0.203	1.183		Algorithm converged.	0.596	2.349	0.6308	0.0406	0.845		Algorithm converged.	0.428	1.679			
						Female	778	54,065	12	1.542	738	51,681	26	3.523	0.429	Algorithm converged.	0.215	0.857	-1.981		Algorithm converged.	-0.568	-0.393	0.438		Algorithm converged.	0.223	0.861	0.0137		2.284		Algorithm converged.	1.161	4.493			
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	0	0	738	51,681	1	-0.136	NE	*	Algorithm not converged.	NE	NE	NE	-0.136	*	Algorithm not converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	0.2916	NE		Algorithm not converged.	0.066	16.823	
						Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.	0.059	15.192	-0.007		Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1		1.054		Algorithm converged.	0.066	16.823			
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.151	*	Algorithm not converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	NE	-0.145	*	Algorithm not converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
						Female	778	54,065	0	0	738	51,681	3	0.407	NE	*	Algorithm not converged.	NE	NE	NE	-0.407	*	Algorithm not converged.	-0.866	0.053	NE	*	Algorithm not converged.	NE	NE	0.1151		NE		Algorithm not converged.	NE	NE	
						Male	661	45,935	1	0.151	690	48,319	1	0.145	1.044	Algorithm converged.	0.065	16.724	0.006		Algorithm converged.	-0.404	0.417	1.044		Algorithm converged.	0.065	16.655	1	1	0.958		Algorithm converged.	0.06	15.284			
						Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	-0.813	*	Algorithm not converged.	-1.461														

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Musculoskeletal and connective tissue disorders	--	Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
		Male	661	45,935	8	1.21	690	48,319	16	2.319	0.516	Algorithm converged.		0.219	1.214	-1.109	Algorithm converged.	-2.507	0.29	0.522		Algorithm converged.	0.225	1.211	0.1232	0.4315	1.916	Algorithm converged.	0.826	4.447	
		Female	778	54,065	16	2.057	738	51,681	19	2.575	0.795	Algorithm converged.		0.405	1.551	-0.518	Algorithm converged.	-2.035	0.999	0.799		Algorithm converged.	0.414	1.541	0.5022		1.252	Algorithm converged.	0.649	2.416	
Anthralgia	--	Male	661	45,935	0	0	690	48,319	5	0.725	NE	*	Algorithm not converged.	NE	NE	-0.725	Algorithm converged.	-1.357	-0.092	NE	*	Algorithm not converged.	NE	NE	0.0623	0.0375	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	3	0.386	738	51,681	3	0.407	0.948	Algorithm converged.		0.191	4.714	-0.021	Algorithm converged.	-0.654	0.612	0.949		Algorithm converged.	0.192	4.685	1	1.054	NE	Algorithm not converged.	0.213	5.207	
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Arthritis	--	Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
		Male	661	45,935	2	0.303	690	48,319	1	0.145	2.091	Algorithm converged.		0.189	23.115	0.158	Algorithm converged.	-0.348	0.663	2.088		Algorithm converged.	0.19	22.97	0.6168	0.1812	0.479	Algorithm converged.	0.044	5.27	
		Female	778	54,065	2	0.257	738	51,681	6	0.813	0.314	Algorithm converged.		0.063	1.563	-0.956	Algorithm converged.	-1.295	0.183	0.316		Algorithm converged.	0.064	1.562	0.1682		3.163	Algorithm converged.	0.64	15.62	
Bursitis	--	Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	NE	Algorithm not converged.	NE	NE	
Costochondritis	--	Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	0	0	690	48,319	0	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.4937	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	1	0.129	738	51,681	3	0.407	0.315	Algorithm converged.		0.033	3.038	-0.278	Algorithm converged.	-0.802	0.246	0.316		Algorithm converged.	0.033	3.033	0.3618		3.163	Algorithm converged.	0.33	30.36	
Foot deformity	--	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Goin pain	--	Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Joint stiffness	--	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Muscle discomfort	--	Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.		0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054	NE	Algorithm not converged.	0.066	16.823	
Muscle spasms	--	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.		0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054	NE	Algorithm not converged.	0.066	16.823	
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
Muscular weakness	--	Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.		0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054	NE	Algorithm not converged.	0.066	16.823	
		Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.3211	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.		0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054	NE	Algorithm not converged.	0.066	16.823	
Musculoskeletal chest pain	--	Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.3211	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.		0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15.138	1	1.054	NE	Algorithm not converged.	0.066	16.823	
		Male	661	45,935	2	0.303	690	48,319	3	0.435	0.695	Algorithm converged.		0.116	4.173	-0.132	Algorithm converged.	-0.777	0.513	0.696		Algorithm converged.	0.117	4.152	1	0.8185	1.437	Algorithm converged.	0.241	8.572	
Myalgia	--	Female	778	54,065	2	0.257	738	51,681	2	0.271	0.948	Algorithm converged.		0.133	6.751	-0.014	Algorithm converged.	-0.531	0.503	0.949		Algorithm converged.	0.134	6.717	1	1.054	NE	Algorithm not converged.	0.149	7.464	
		Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
Osteoarthritis	--	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
		Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Osteoporosis	--	Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	0	0	690	48,319	2	0.29	NE	*	Algorithm not converged.	NE	NE	-0.29	Algorithm converged.	-0.691	0.111	NE	*	Algorithm not converged.	NE	NE	0.4999	0.0706	NE	Algorithm not converged.	NE	NE	
		Female	778	54,065	4	0.514	738	51,681	2	0.271	1.902	Algorithm converged.		0.347	10.414	0.243	Algorithm converged.	-0.384	0.87	1.897		Algorithm converged.	0.349	10.327	0.6875	0.527	NE	Algorithm not converged.	0.097	2.869	
Pain in extremity	--	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE		
		Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Patellofemoral pain syndrome	--	Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE		
		Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Plantar fasciitis	--	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE		
		Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged.	NE	NE		
Rotator cuff syndrome	--	Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	NE	Algorithm not converged				

	Anosmia	Male	661	45.935	2	0.303	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.303	Algorithm converged.	-0.176	0.721	NE	*	Algorithm not converged.	NE	NE	1	0.1767	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	1	0.136	NE	*	Algorithm converged.	0.059	NE	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949	*	Algorithm converged.	0.059	NE	15.138	1	1.054	Algorithm converged.	0.066	16.823
	Carpal tunnel syndrome	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Cerebral infarction	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Dizziness	Male	661	45.935	2	0.303	690	48.319	2	0.29	1.044	Algorithm converged.	0.147	7.433	0.013	Algorithm converged.	-0.567	0.593	1.044	Algorithm converged.	0.147	7.389	1	0.9156	0.958	Algorithm converged.	0.135	6.781			
		Female	778	54.065	5	0.643	738	51.681	4	0.542	1.187	Algorithm converged.	0.317	4.437	0.101	Algorithm converged.	-0.671	0.873	1.186	Algorithm converged.	0.32	4.399	1	0.843	Algorithm converged.	0.227	3.129				
	Headache	Male	661	45.935	9	1.362	690	48.319	29	4.203	0.315	Algorithm converged.	0.148	0.67	-2.841	Algorithm converged.	-4.58	-1.103	0.324	Algorithm converged.	0.155	0.679	0.0016	0.0171	3.087	Algorithm converged.	1.472	6.471			
		Female	778	54.065	30	3.856	738	51.681	31	4.201	0.915	Algorithm converged.	0.540	1.527	-0.345	Algorithm converged.	-2.326	1.637	0.918	Algorithm converged.	0.561	1.501	0.7331	1.089	Algorithm converged.	0.566	1.781				
	Hypoesthesia	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	1	0.4868	NE	Algorithm not converged.	NE	NE	
	Migraine	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.1777	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	4	0.514	738	51.681	2	0.271	1.902	Algorithm converged.	0.347	10.414	0.343	Algorithm converged.	-0.384	0.87	1.897	Algorithm converged.	0.349	10.327	0.6875	0.527	Algorithm converged.	0.097	2.865				
	Nerve compression	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Presyncope	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	0.0469	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	2	0.271	NE	*	Algorithm not converged.	NE	NE	-0.271	Algorithm converged.	-0.646	0.104	NE	*	Algorithm not converged.	NE	NE	0.2368	NE	NE	Algorithm not converged.	NE	NE	
	Radial nerve palsy	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	NE	Algorithm not converged.	NE	NE	
	Sciatica	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Syncope	Male	661	45.935	2	0.303	690	48.319	1	0.145	2.051	NE	*	Algorithm converged.	0.189	23.115	0.158	Algorithm converged.	-0.348	0.663	2.088	Algorithm converged.	0.119	22.97	0.6168	0.045	0.479	Algorithm converged.	0.044	5.27	
		Female	778	54.065	0	0	738	51.681	3	0.407	NE	*	Algorithm not converged.	NE	NE	-0.407	Algorithm converged.	-0.866	0.063	NE	*	Algorithm not converged.	NE	NE	0.1153	NE	NE	Algorithm not converged.	NE	NE	
	Tension headache	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	NE	Algorithm not converged.	NE	NE	
	Transient ischaemic attack	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Pregnancy, puerperium and perinatal conditions	--	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Female	778	54.065	2	0.257	738	51.681	2	0.271	0.948	Algorithm converged.	0.133	6.751	-0.014	Algorithm converged.	-0.531	0.503	0.949	Algorithm converged.	0.134	6.717	1	1.054	Algorithm converged.	0.149	7.464				
	Abortion spontaneous	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Female	778	54.065	1	0.129	738	51.681	2	0.271	0.474	Algorithm converged.	0.043	5.234	-0.142	Algorithm converged.	-0.594	0.309	0.474	Algorithm converged.	0.043	5.22	0.6151	2.108	Algorithm converged.	0.192	23.203				
	Abortion threatened	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Complication of pregnancy	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Psychiatric disorders	--	Male	661	45.935	2	0.303	690	48.319	10	1.449	0.206	Algorithm converged.	0.045	0.945	-1.147	Algorithm converged.	-2.132	-0.162	0.209	Algorithm converged.	0.046	0.949	0.0083	0.1152	4.79	Algorithm converged.	1.053	21.779			
		Female	778	54.065	7	0.9	738	51.681	8	1.084	0.828	Algorithm converged.	0.299	2.296	-0.184	Algorithm converged.	-1.183	0.815	0.83	Algorithm converged.	0.302	2.277	0.712	1.205	Algorithm converged.	0.439	3.906				
	Adjustment disorder with depressed mood	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Anxiety	Male	661	45.935	0	0	690	48.319	5	0.725	NE	*	Algorithm not converged.	NE	NE	-0.725	Algorithm converged.	-1.357	-0.092	NE	*	Algorithm not converged.	NE	NE	0.0623	0.0785	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	2	0.257	738	51.681	3	0.407	0.631	Algorithm converged.	0.105	3.79	-0.149	Algorithm converged.	-0.73	0.431	0.632	Algorithm converged.	0.106	3.774	0.6793	1.581	Algorithm converged.	0.265	9.437				
	Attention deficit hyperactivity disorder	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.0546	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	2	0.257	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.257	Algorithm converged.	-0.099	0.613	NE	*	Algorithm not converged.	NE	NE	0.5	NE	Algorithm not converged.	NE	NE	
	Confusional state	Male	661	45.935	1	0.151	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893	1	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	0.129	*	Algorithm not converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Depression	Male	661	45.935	1	0.151	690	48.319	2	0.29	0.521	Algorithm converged.	0.047	5.762	-0.139	Algorithm converged.	-0.637	0.36	0.522	Algorithm converged.	0.047	5.742	1	0.7483	1.916	Algorithm converged.	0.174	21.079			
		Female	778	54.065	1	0.129	738	51.681	1	0.136	0.949	Algorithm converged.	0.059	15.192	-0.007	Algorithm converged.	-0.373	0.359	0.949	Algorithm converged.	0.059	15.138	1	1.054	Algorithm converged.	0.066	16.823				
	Initial insomnia	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
		Female	778	54.065	0	0	738	51.681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Insomnia	Male	661	45.935	0	0	690	48.319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1	0.4261	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	1	0.129	738	51.681	2	0.271	0.474	Algorithm converged.	0.043	5.234	-0.142	Algorithm converged.	-0.594	0.309	0.474	Algorithm converged.	0.043	5.22	0.6151	2.108	Algorithm converged.	0.192	23.203				
	Mania	Male	661	45.935	0	0	690	48.319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Female	778	54.065	0	0	738	51.681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868	NE	NE	Algorithm not converged.	NE	NE	
	Panic attack	Male	661	45.935	0	0	690	48.319	1</																						

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[illegible]

		Peripheral vascular disorder	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE		Algorithm converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombosis	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151		Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Venous thrombosis limb	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129		Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: 112-21ae-raw-soc-anyae-5s

Name	Age	SOC	PT	Casir/mab/Indin/mab										Placebo										Casir/mab/Indin/mab vs. Placebo										Placebo vs. Casir/mab/Indin/mab									
				Patients										Patients										Absolute Risk Difference										Relative Risk									
				Level	n	%	n	%	n	%	n	%	n	%	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Blood and lymphatic system disorders			--	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.937	NE	Algorithm not converged.	NE	NE	NE	NE			
				18-49	874	60,737	11	1,259	868	60,784	6	0.691	1,831	Algorithm converged.	0.674	4,974	4,567	Algorithm converged.	-0.355	1,489	1,821	Algorithm converged.	0.676	4,901	0.286	Algorithm converged.	-0.146	2,478	2,994	Algorithm converged.	0.676	4,901	0.286	0.549	Algorithm converged.	0.034	1,479	1,277	NE				
				>=50	514	35,719	9	1,751	513	35,924	3	0.585	3,03	Algorithm converged.	0.815	11,256	1,166	Algorithm converged.	-0.166	2,11	3,493	Algorithm converged.	0.676	4,901	0.286	Algorithm converged.	-0.146	2,478	2,994	Algorithm converged.	0.676	4,901	0.286	0.334	Algorithm converged.	0.091	1,427	1,427	NE				
				12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.872	NE	Algorithm not converged.	NE	NE	NE	NE			
				18-49	874	60,737	6	0.686	868	60,784	3	0.346	1,993	Algorithm converged.	0.497	7,995	0.341	Algorithm converged.	-0.332	1,013	1,986	Algorithm converged.	0.498	7,917	0.5067	Algorithm converged.	-0.166	2,11	3,493	Algorithm converged.	0.498	7,917	0.5067	0.503	Algorithm converged.	0.126	2,007	2,007	NE				
				>=50	514	35,719	7	1,362	513	35,924	2	0.39	3,528	Algorithm converged.	0.729	17,063	0.972	Algorithm converged.	-0.166	2,11	3,493	Algorithm converged.	0.498	7,917	0.5067	Algorithm converged.	-0.166	2,11	3,493	Algorithm converged.	0.498	7,917	0.5067	0.286	Algorithm converged.	0.06	1,371	1,371	NE				
				12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE			
				18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE			
				>=50	514	35,719	1	0.195	513	35,924	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE			
				12-17	51	3,544	0</																																				

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[illegible]

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[illegible]

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t-ae-row-soc.sas
Output: t13-1f-ae-row-soc-anyae-ts

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

[illegible]

								ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Goutte		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thyroid mass		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		--		US	1348	93,676	9	0	0.668	1339	93,768	2	0.149	4,493	NE	*	Algorithm converged.	0.969	20,835	0.518	*	Algorithm converged	0.037	1	4.47	*	Algorithm converged.	0.968	20,649	0.0649	1	0.224		Algorithm converged.	0.048	1,033				
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Blepharospasm		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged.	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Conjunctival haemorrhage		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dry eye		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Eye irritation		US	1348	93,676	1	0	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Lacrimation increased		US	1348	93,676	2	0.148	1339	93,768	1	0.075	1,988	NE	*	Algorithm converged.	0.18	21,951	0.074	*	Algorithm converged	-0.179	0.326	1,987	*	Algorithm converged.	0.18	21,883	1	1	0.503		Algorithm converged.	0.046	5,545					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ocular hyperaemia		US	1348	93,676	2	0.148	1339	93,768	1	0.075	1,988	NE	*	Algorithm converged.	0.18	21,951	0.074	*	Algorithm converged	-0.179	0.326	1,987	*	Algorithm converged.	0.18	21,883	1	1	0.503		Algorithm converged.	0.046	5,545					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Vision blurred		US	1348	93,676	1	0.074	1339	93,768	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastrointestinal disorders		--	US	1348	93,676	33	2.448	1339	93,768	43	3.211	0.756	NE	*	Algorithm converged.	0.477	1,198	-0.763	*	Algorithm converged	-2.017	0.491	0.762	*	Algorithm converged.	0.487	1,192	0.2328	1	1.312		Algorithm converged.	0.839	2,052				
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal discomfort		US	1348	93,676	1	0.074	1339	93,768	1	0.075	0.993	NE	*	Algorithm converged.	0.062	15,897	0	*	Algorithm converged	-0.207	0.206	0.993	*	Algorithm converged.	0.062	15,864	1	1	1.007		Algorithm converged.	0.063	16,078					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal pain		US	1348	93,676	1	0.074	1339	93,768	11	0.822	0.09	NE	*	Algorithm converged.	0.012	0.695	-0.747	*	Algorithm converged	-1.252	0.242	0.09	*	Algorithm converged.	0.012	0.698	0.0033	1	11.074		Algorithm converged.	1.432	85,654					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal pain lower		US	1348	93,676	0	0		1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper		US	1348	93,676	4	0.297	1339	93,768	2	0.149	1.99	NE	*	Algorithm converged.	0.364	10,881	0.147	*	Algorithm converged	-0.209	0.504	1,987	*	Algorithm converged.	0.364	10,828	0.6872	1	0.503		Algorithm converged.	0.092	2,744					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal tenderness		US	1348	93,676	0	0		1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bowel movement irregularity		US	1348	93,676	0	0		1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Constipation		US	1348	93,676	1	0.074	1339	93,768	1	0.075	0.993	NE	*	Algorithm converged.	0.062	15,897	0	*	Algorithm converged	-0.207	0.206	0.993	*	Algorithm converged.	0.062	15,864	1	1	1.007		Algorithm converged.	0.063	16,078					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dental caries		US	1348	93,676	1	0.074	1339	93,768	1	0.075	0.993	NE	*	Algorithm converged.	0.062	15,897	0	*	Algorithm converged	-0.207	0.206	0.993	*	Algorithm converged.	0.062	15,864	1	1	1.007		Algorithm converged.	0.063	16,078					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea		US	1348	93,676	11	0.816	1339	93,768	12	0.896	0.91	NE	*	Algorithm converged.	0.4	2,069	-0.08	*	Algorithm converged	-0.777	0.617	0.911	*	Algorithm converged.	0.403	2,056	0.8216	1	1.089		Algorithm converged.	0.486	248					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspepsia		US	1348	93,676	3	0.223	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.223	*	Algorithm converged.	-0.029	0.474	NE	*	Algorithm not converged.	NE	NE	0.2497		NE		Algorithm not converged.	NE	NE						
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Food poisoning		US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	*	Algorithm converged	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastritis		US	1348	93,676	0	0		1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE					
				ex-US	91	6,324	0	0		89	6,232	0	0				0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastrointestinal tract irritation		US	1348	93,676	0	0		1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE					
				ex-US	91	6,324	0	0																																

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				Bone abscess	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
				Bronchitis	US ex-US	1348 91	93,676 6,324	3 0	0.223 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm converged. Algorithm not converged.	0.31 NE	28.727 -0.148	0.148 NE	*	Algorithm converged. Algorithm not converged.	-0.143 NE	0.439 NE	2.98 NE	*	Algorithm converged. Algorithm not converged.	0.31 NE	28.612 NE	0.6247 NE	1 NE	0.336 NE	Algorithm converged. Algorithm not converged.	0.035 NE	3.222 NE	
				COVID-19	US ex-US	1348 91	93,676 6,324	19 1	1.409 1.099	1339 89	93,768 6,232	126 11	9.41 12.36	0.138 0.079	Algorithm converged. Algorithm converged.	0.084 0.01	0.224 -11.261	-8.001 -11.261	Algorithm converged. Algorithm converged.	-9.686 -18.426	-6.315 -4.095	0.15 0.089		Algorithm converged. Algorithm converged.	0.093 0.012	0.241 0.074	<0.001 0.0023	0.5993 NE	6.676 11.247	Algorithm converged. Algorithm converged.	4.146 1.483	10.75 85.308		
				COVID-19 pneumonia	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	3 1	0.224 -1.124	0.331 NE	*	Algorithm converged. Algorithm not converged.	0.034 NE	3.182 -1.124	Algorithm converged. Algorithm not converged.	-0.442 -0.313	0.142 1.066	0.331 NE	*	Algorithm converged. Algorithm not converged.	0.034 NE	3.179 NE	0.3731 0.4944	0.474 NE	3.02 NE	Algorithm converged. Algorithm not converged.	0.315 NE	28.988 NE		
				Cellulitis	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	1 0	0.075 NE	1.988 NE	*	Algorithm converged. Algorithm not converged.	0.18 NE	21.951 NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.179 NE	0.326 NE	1.967 NE	*	Algorithm converged. Algorithm not converged.	0.18 NE	21.883 NE	1 NE	0.503 NE	Algorithm converged. Algorithm not converged.	0.046 NE	5.545 NE	
				Cystitis	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	2 0	0.149 0	0.496 NE	*	Algorithm converged. Algorithm not converged.	0.045 NE	5.48 NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.328 NE	0.178 NE	0.497 NE	*	Algorithm converged. Algorithm not converged.	0.045 NE	5.471 NE	0.6236 NE	1 NE	2.013 NE	Algorithm converged. Algorithm not converged.	0.183 NE	22.178 NE
				Diverticulitis	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Ear infection	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	2 0	0.149 NE	0.496 NE	*	Algorithm converged. Algorithm not converged.	0.045 NE	5.48 NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.328 NE	0.178 NE	0.497 NE	*	Algorithm converged. Algorithm not converged.	0.045 NE	5.471 NE	0.6236 NE	1 NE	2.013 NE	Algorithm converged. Algorithm not converged.	0.183 NE	22.178 NE
				Erythema induratum	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		
				Fungal skin infection	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Gangrene	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Gastroenteritis	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	4 0	0.299 NE	0.496 NE	*	Algorithm converged. Algorithm not converged.	0.091 NE	2.712 -0.15	-0.15 NE	*	Algorithm converged. Algorithm not converged.	-0.508 NE	0.207 NE	0.497 NE	*	Algorithm converged. Algorithm not converged.	0.091 NE	2.707 NE	0.4511 NE	1 NE	2.013 NE	Algorithm converged. Algorithm not converged.	0.369 NE	10.974 NE
				Gastroenteritis viral	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.897 NE	0 NE	*	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE	
				Gastrointestinal viral infection	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Gonorrhea	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Helicobacter infection	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.897 NE	0 NE	*	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE	
				Herpes zoster	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.897 NE	0 NE	*	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE	
				Hordeolum	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Infected dermal cyst	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Infectious mononucleosis	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Influenza	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.897 NE	0 NE	*	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1 NE	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE
				Kidney infection	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Laryngitis	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Localised infection	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Nasopharyngitis	US ex-US	1348 91	93,676 6,324	5 0	0.371 0	1339 89	93,768 6,232	10 0	0.747 NE	0.495 NE	*	Algorithm converged. Algorithm not converged.	0.169 NE	1.451 NE	-0.376 NE	*	Algorithm converged. Algorithm not converged.	-0.94 NE	0.188 NE	0.497 NE	*	Algorithm converged. Algorithm not converged.	0.17 NE	1.449 NE	0.2074 NE	1 NE	2.013 NE	Algorithm converged. Algorithm not converged.	0.69 NE	5.875 NE
				Oral herpes	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Osteomyelitis	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Otitis externa	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Otitis media acute	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Paronychia	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Pelvic inflammatory disease	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Pharyngitis	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	4 0	0.299 NE	0.496 NE	*	Algorithm converged. Algorithm not converged.	0.091 NE	2.712 -0.15	-0.15 NE	*	Algorithm converged. Algorithm not converged.	-0.508 NE	0.207 NE	0.497 NE	*	Algorithm converged. Algorithm not converged.	0.091 NE	2.707 NE	0.4511 NE	1 NE	2.013 NE	Algorithm converged. Algorithm not converged.	0.369 NE	10.974 NE
				Pharyngitis streptococcal	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	0 0	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	*	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
				Pneumonia	US ex-US	1348 91	93,676 6,324	1 2	0.074 2.198	1339 89	93,768 6,232	1 0	0.075 NE	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.897 2.198	0 NE		Algorithm converged. Algorithm converged.	-0.207 -0.814	0.206 5.21	0.993 NE	*	Algorithm converged. Algorithm not converged.	0.062 NE	15.864 NE	0.1901 0.4873	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE	
				Pylephlebitis	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	*	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	*	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE NE	Algorithm not converged. Algorithm not converged.</			

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	Limb injury	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	1 0	0.075 0	1.988 NE *	Algorithm converged. Algorithm not converged.	0.18 NE	21,951 NE	0.074 NE *	Algorithm converged. Algorithm not converged.	-0.179 NE	0.326 NE	1.987 NE *	Algorithm converged. Algorithm not converged.	0.18 NE	21,883 NE	1 1	0.503 NE	Algorithm converged. Algorithm not converged.	0.046 NE	5.545 NE
	Meniscus injury	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	0.074 NE	* NE *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE 1		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Muscle injury	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE *	* Algorithm converged.	-0.221 NE	0.072 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Neck injury	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE *	* Algorithm converged.	-0.221 NE	0.072 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Post procedural haemorrhage	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE *	* Algorithm converged.	-0.071 NE	0.22 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE 1		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Procedural pain	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE *	* Algorithm converged.	-0.071 NE	0.22 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE 1		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Road traffic accident	US ex-US	1348 91	93,676 6,324	0 0	0.223 0	1339 89	93,768 6,232	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.223 NE *	* Algorithm converged.	-0.029 NE	0.474 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Seroma	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE *	* Algorithm converged.	-0.221 NE	0.072 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Skin abrasion	US ex-US	1348 91	93,676 6,324	0 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 0	0.993 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15,897 NE	0 NE *	* Algorithm converged.	-0.207 NE	0.206 NE	0.993 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15,864 NE	1 1	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16,078 NE
	Skin laceration	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	1 0	0.075 0	0.993 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15,897 NE	0 NE *	* Algorithm converged.	-0.207 NE	0.206 NE	0.993 NE *	Algorithm converged. Algorithm not converged.	0.062 NE	15,864 NE	1 1	1.007 NE	Algorithm converged. Algorithm not converged.	0.063 NE	16,078 NE
	Soft tissue injury	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE *	* Algorithm converged.	-0.221 NE	0.072 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Stress fracture	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE *	* Algorithm converged.	-0.221 NE	0.072 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE
	Thermal burn	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE *	* Algorithm converged.	-0.071 NE	0.22 NE	NE NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE 1		NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE

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Musculoskeletal and connective tissue disorders	--	ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
		US	1348	93,676	24	0	1,78	1339	93,768	35	0	2,614	0.675	NE	*	Algorithm converged.	0.399	1,142	-0.833	NE	NE	NE	*	Algorithm converged.	-1.942	0.275	0.681	*	Algorithm converged.	0.407	1,139	0.1405	1	1,468	Algorithm converged.
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Arthralgia	US	1348	93,676	3	0.223	1339	93,768	8	0.597	0.371	NE	*	Algorithm converged.	0.098	1,402	-0.375	NE	NE	NE	*	Algorithm converged.	-0.858	0.108	0.372	*	Algorithm converged.	0.099	1,401	0.1439	1	2,685	Algorithm converged.	0.714	10,097
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Arthritis	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Back pain	US	1348	93,676	4	0.297	1339	93,768	7	0.523	0.566	NE	*	Algorithm converged.	0.165	1,939	-0.226	NE	NE	NE	*	Algorithm converged.	-0.709	0.257	0.568	*	Algorithm converged.	0.167	1,934	0.3852	1	1,762	Algorithm converged.	0.517	6,004
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Bursitis	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Costochondritis	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Flank pain	US	1348	93,676	1	0.074	1339	93,768	4	0.299	0.248	NE	*	Algorithm converged.	0.028	2,22	-0.225	NE	NE	NE	*	Algorithm converged.	-0.551	0.102	0.248	*	Algorithm converged.	0.028	2,219	0.2168	1	4,027	Algorithm converged.	0.451	35,981
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Foot deformity	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Groin pain	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Joint stiffness	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Muscle discomfort	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Muscle spasms	US	1348	93,676	1	0.074	1339	93,768	1	0.075	0.993	NE	*	Algorithm converged.	0.062	15,897	0	NE	NE	NE	*	Algorithm converged.	-0.207	0.206	0.993	*	Algorithm converged.	0.062	15,864	1	1	1,007	Algorithm converged.	0.063	16,078
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Muscular weakness	US	1348	93,676	1	0.074	1339	93,768	1	0.075	0.993	NE	*	Algorithm converged.	0.062	15,897	0	NE	NE	NE	*	Algorithm converged.	-0.207	0.206	0.993	*	Algorithm converged.	0.062	15,864	1	1	1,007	Algorithm converged.	0.063	16,078
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Musculoskeletal chest pain	US	1348	93,676	1	0.074	1339	93,768	2	0.149	0.496	NE	*	Algorithm converged.	0.045	5,48	-0.075	NE	NE	NE	*	Algorithm converged.	-0.328	0.178	0.497	*	Algorithm converged.	0.045	5,471	0.6236	1	2,013	Algorithm converged.	0.183	22,178
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Myalgia	US	1348	93,676	4	0.297	1339	93,768	5	0.373	0.794	NE	*	Algorithm converged.	0.213	2,963	-0.077	NE	NE	NE	*	Algorithm converged.	-0.514	0.36	0.795	*	Algorithm converged.	0.214	2,963	0.7527	1	1,258	Algorithm converged.	0.339	4,676
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Neck pain	US	1348	93,676	0	0	1339	93,768	2	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	NE	NE	NE	*	Algorithm converged.	-0.356	0.057	NE	*	Algorithm not converged.	NE	NE	0.2482		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Osteoarthritis	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Osteoporosis	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Pain in extremity	US	1348	93,676	4	0.297	1339	93,768	4	0.299	0.993	NE	*	Algorithm converged.	0.248	3,98	-0.002	NE	NE	NE	*	Algorithm converged.	-0.414	0.41	0.993	*	Algorithm converged.	0.249	3,964	1	1	1,007	Algorithm converged.	0.252	4,017
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Pain in jaw	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Patellofemoral pain syndrome	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Plantar fasciitis	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Rotator cuff syndrome	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Systemic lupus erythematosus	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Tendonitis	US	1348	93,676	0	0	1339	93,768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	NE	NE	NE	*	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
	Trigger finger	US	1348	93,676	1	0.074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	NE	NE	NE	*	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE</																

		Anosmia	US ex-US	1348 91	93,676 6,324	3 0	0.223 0	1339 89	93,768 6,232	1 0	0.075 0	2,984 NE	* *	Algorithm converged. Algorithm not converged.	0.31 NE	28,727 NE	0.148 NE	* *	Algorithm converged. Algorithm not converged.	-0.143 NE	0.439 NE	2.98 NE	* *	Algorithm converged. Algorithm not converged.	0.31 NE	28,612 NE	0.6247 NE	1 NE	0.336 NE		Algorithm converged. Algorithm not converged.	0.035 NE	3,222 NE
		Carpal tunnel syndrome	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 1	0 1.124	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	0.074 NE	0.074 NE	* *	Algorithm not converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Cerebral infarction	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Dizziness	US ex-US	1348 91	93,676 6,324	7 2	0.519 2.198	1339 89	93,768 6,232	5 3	0.373 3.371	1.393 0.635	* *	Algorithm converged. Algorithm converged.	0.441 0.105	4.399 3.95	0.146 -1.124		Algorithm converged. Algorithm converged.	-0.358 -3.313	0.65 1.066	1.391 NE	* *	Algorithm converged. Algorithm not converged.	0.442 NE	4.371 NE	0.7739 0.4944	0.1965 NE	0.719 NE		Algorithm converged. Algorithm not converged.	0.229 NE	2.26 NE
		Headache	US ex-US	1348 91	93,676 6,324	37 2	2.745 2.198	1339 89	93,768 6,232	57 3	4.257 3.371	0.635 0.644	* *	Algorithm converged. Algorithm converged.	0.417 0.105	0.967 3.95	-1.512 -1.173		Algorithm converged. Algorithm converged.	-2.901 -5.983	-0.123 3.637	0.645 0.652		Algorithm converged. Algorithm not converged.	0.429 0.112	0.968 3.809	0.033 0.6805	0.9904 1.551	1.551 1.534		Algorithm converged. Algorithm converged.	1.033 0.263	2,329 8,961
		Hypoesthesia	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	2 0	0.149 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.149 NE	* *	Algorithm converged. Algorithm not converged.	-0.356 NE	0.057 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2482 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Migraine	US ex-US	1348 91	93,676 6,324	4 0	0.297 0	1339 89	93,768 6,232	3 0	0.224 0	1.325 NE	* *	Algorithm converged. Algorithm not converged.	0.296 NE	5.933 NE	0.073 NE	* *	Algorithm converged. Algorithm not converged.	-0.313 NE	0.458 NE	1.324 NE	* *	Algorithm converged. Algorithm not converged.	0.297 NE	5.906 NE	1 NE	1 NE	0.755 NE		Algorithm converged. Algorithm not converged.	0.169 NE	3,367 NE
		Nerve compression	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Presyncope	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	2 0	0.149 0	0.496 NE	* *	Algorithm converged. Algorithm not converged.	0.045 NE	5.48 NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.328 NE	0.178 NE	0.497 NE	* *	Algorithm converged. Algorithm not converged.	0.045 NE	5.471 NE	0.6236 NE	1 NE	2.013 NE		Algorithm converged. Algorithm not converged.	0.183 NE	22,178 NE
		Radial nerve palsy	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Sciatica	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Syncope	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	4 0	0.299 0	0.496 NE	* *	Algorithm converged. Algorithm not converged.	0.091 NE	2.712 NE	-0.15 NE	* *	Algorithm converged. Algorithm not converged.	-0.508 NE	0.207 NE	0.497 NE	* *	Algorithm converged. Algorithm not converged.	0.091 NE	2.707 NE	0.4511 NE	1 NE	2.013 NE		Algorithm converged. Algorithm not converged.	0.369 NE	10,974 NE
		Tension headache	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Transient ischaemic attack	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
	Pregnancy, puerperium and perinatal conditions	--	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	2 0	0.149 0	0.993 NE	* *	Algorithm converged. Algorithm not converged.	0.14 NE	7.062 NE	-0.001 NE	* *	Algorithm converged. Algorithm not converged.	-0.293 NE	0.291 NE	0.993 NE	* *	Algorithm converged. Algorithm not converged.	0.14 NE	7.041 NE	1 NE	1 NE	1.007 NE		Algorithm converged. Algorithm not converged.	0.142 NE	7,136 NE
		Abortion spontaneous	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	2 0	0.149 0	0.496 NE	* *	Algorithm converged. Algorithm not converged.	0.045 NE	5.48 NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.328 NE	0.178 NE	0.497 NE	* *	Algorithm converged. Algorithm not converged.	0.045 NE	5.471 NE	0.6236 NE	1 NE	2.013 NE		Algorithm converged. Algorithm not converged.	0.183 NE	22,178 NE
		Abortion threatened	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Complication of pregnancy	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
	Psychiatric disorders	--	US ex-US	1348 91	93,676 6,324	9 0	0.668 0	1339 89	93,768 6,232	18 0	1.344 0	0.493 NE	* *	Algorithm converged. Algorithm not converged.	0.221 NE	1.102 NE	-0.677 NE	* *	Algorithm converged. Algorithm not converged.	-1.431 NE	0.078 NE	0.497 NE	* *	Algorithm converged. Algorithm not converged.	0.224 NE	1.102 NE	0.0787 NE	1 NE	2.013 NE		Algorithm converged. Algorithm not converged.	0.908 NE	4,466 NE
		Adjustment disorder with depressed mood	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Anxiety	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	8 0	0.597 0	0.247 NE	* *	Algorithm converged. Algorithm not converged.	0.052 NE	1.166 NE	-0.449 NE	* *	Algorithm converged. Algorithm not converged.	-0.91 NE	0.012 NE	0.248 NE	* *	Algorithm converged. Algorithm not converged.	0.053 NE	1.167 NE	0.0641 NE	1 NE	4.027 NE		Algorithm converged. Algorithm not converged.	0.857 NE	18,928 NE
		Attention deficit hyperactivity disorder	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	1 0	0.075 0	1.988 NE	* *	Algorithm converged. Algorithm not converged.	0.18 NE	21.951 NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.179 NE	0.326 NE	1.987 NE	* *	Algorithm converged. Algorithm not converged.	0.18 NE	21.883 NE	1 NE	0.503 NE		Algorithm converged. Algorithm not converged.	0.046 NE	5,545 NE	
		Confusional state	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.148 NE	* *	Algorithm converged. Algorithm not converged.	-0.057 NE	0.354 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4986 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Depression	US ex-US	1348 91	93,676 6,324	2 0	0.148 0	1339 89	93,768 6,232	3 0	0.224 0	0.662 NE	* *	Algorithm converged. Algorithm not converged.	0.11 NE	3.966 NE	-0.076 NE	* *	Algorithm converged. Algorithm not converged.	-0.402 NE	0.25 NE	0.662 NE	* *	Algorithm converged. Algorithm not converged.	0.111 NE	3.957 NE	0.6862 NE	1 NE	1.51 NE		Algorithm converged. Algorithm not converged.	0.253 NE	9,023 NE
		Initial insomnia	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Insomnia	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	3 0	0.224 0	0.331 NE	* *	Algorithm converged. Algorithm not converged.	0.034 NE	3.182 NE	-0.15 NE	* *	Algorithm converged. Algorithm not converged.	-0.442 NE	0.142 NE	0.331 NE	* *	Algorithm converged. Algorithm not converged.	0.034 NE	3.179 NE	0.3731 NE	1 NE	3.02 NE		Algorithm converged. Algorithm not converged.	0.315 NE	28,998 NE
		Mania	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Panic attack	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	1 0	0.075 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	* *	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Substance abuse	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Suicidal ideation	US ex-US	1348 91	93,676 6,324	0 0	0 0	1339 89	93,768 6,232	2 0	0.149 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.149 NE	* *	Algorithm converged. Algorithm not converged.	-0.356 NE	0.057 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2482 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
	Renal and urinary disorders	--	US ex-US	1348 91	93,676 6,324	9 0	0.668 0	1339 89	93,768 6,232	10 0	0.747 0	0.893 NE	* *	Algorithm converged. Algorithm not converged.	0.362 NE	2.205 NE	-0.079 NE	* *	Algorithm converged. Algorithm not converged.	-0.713 NE	0.555 NE	0.894 NE	* *	Algorithm converged. Algorithm not converged.	0.364 NE	2.193 NE	0.8066 NE	1 NE	1.119 NE		Algorithm converged. Algorithm not converged.	0.456 NE	2,744 NE
		Acute kidney injury	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Chronic kidney disease	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89	93,768 6,232	0 0	0 0	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	* *	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	* *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE	NE NE		Algorithm not converged. Algorithm not converged.	NE NE	NE NE	
		Dysuria	US ex-US	1348 91	93,676 6,324	1 0	0.074 0	1339 89</																									

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		Peripheral vascular disorder	US	1348	93,676	1		0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0		0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombosis	US	1348	93,676	1		0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0		0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Venous thrombosis limb	US	1348	93,676	1		0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0		0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: 112-21ae-raw-soc-anyae-5s

[illegible]

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: 1-ae-raw-soc.sas
Output: 113-21ae-raw-soc-foxggr3.txt

Name Sex	SOC	PT	Level	Casim/mab/mdeumab				Placebo				Odds Ratio				Casim/mab/mdeumab vs. Placebo				Absolute Risk Difference				Casim/mab/mdeumab vs. Placebo				Relative Risk				Interaction				Placebo vs. Casim/mab/mdeumab				
				Patients		Patients with Event		Patients		Patients with Event		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	Test p-value (likelihood ratio)	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL	p-value	Test p-value (likelihood ratio)	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL
				n	%	n	%	n	%	n	%																													
Cardiac disorders	--	Male	Female	661	45.935	2	0.302	690	48.319	1	0.145	2.021	Algorithm converged.	Algorithm converged.	0.189	0.159	0.208	Algorithm converged.	Algorithm converged.	0.159	0.139	0.189	Algorithm converged.	Algorithm converged.	0.119	0.093	0.148	0.9559	0.527	Algorithm converged.	Algorithm converged.	0.048	0.048	0.527	Algorithm converged.	Algorithm converged.	0.048	0.581		
			Female	778	54.065	2	0.257	738	51.681	1	0.136	1.899	Algorithm converged.	Algorithm converged.	0.172	0.20	0.122	Algorithm converged.	Algorithm converged.	-0.322	0.565	1.897	Algorithm converged.	Algorithm converged.	0.172	0.20	0.122	0.9559	0.527	Algorithm converged.	Algorithm converged.	0.048	0.581	0.527	Algorithm converged.	Algorithm converged.	0.048	5.801		
			Male	661	45.935	1	0.151	690	48.319	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	Algorithm converged.	-0.145	0.448	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	0.4893	1	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	
			Female	778	54.065	1	0.129	738	51.681	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	
			Male	661	45.935	0	0	690	48.319	1	0.145	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	Algorithm converged.	-0.429	0.139	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE		
			Female	778	54.065	0	0	738	51.681	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm converged.	Algorithm converged.	NE	NE	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE		
			Male	661	45.935	0	0	690	48.319	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm converged.	Algorithm converged.	NE	NE	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE		
			Female	778	54.065	1	0.129	738	51.681	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	Algorithm converged.	-0.401	0.13	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	0.4868	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	Algorithm not converged.	NE	NE		
			Male	661	45.935	0	0	690	48.319	0	0	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	NE	Algorithm converged.	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	Algorithm not converged.	NE								

		Diabetic foot	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151		Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	~	Male	661	45,935	1	0.151	690	48,319	1	0.145	1,044		Algorithm converged.	0.065	16,724	0.006		Algorithm converged.	-0.404	0.417	1,044		Algorithm converged.	0.065	16,655	1	0.9618	0.958		Algorithm converged.	0.06	15,284
			Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949		Algorithm converged.	0.059	15,192	-0.007		Algorithm converged.	-0.373	0.359	0.949		Algorithm converged.	0.059	15,138	1		1.054		Algorithm converged.	0.066	16,823
		Essential hypertension	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136		Algorithm converged.	-0.401	0.13	NE	*	Algorithm not converged.	NE	NE	0.4868		NE		Algorithm not converged.	NE	NE
		Hypertensive urgency	Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	Algorithm not converged.	NE	NE	-0.145		Algorithm converged.	-0.429	0.139	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peripheral arterial occlusive disease	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	0.151		Algorithm converged.	-0.145	0.448	NE	*	Algorithm not converged.	NE	NE	0.4893		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peripheral vascular disorder	Male	661	45,935	0	0	690	48,319	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	Algorithm not converged.	NE	NE	0.129		Algorithm converged.	-0.123	0.38	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-Binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.s3e
Output: t13-2f-ae-raw-soc-toxggr3-6

					Casimir/mab/Indinavir/mab	Patients		Placebo		Casimir/mab/Indinavir/mab vs. Placebo		Casimir/mab/Indinavir/mab vs. Placebo				Placebo vs. Casimir/mab/Indinavir/mab							
		SOC				Patients			Odds Ratio	Absolute Risk Difference													
Name	Age		PT	Level	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Cardiac disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	*		NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	1	0.114	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	0.339	NE	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	3	0.584	513	35,924	2	0.39	1.5	Algorithm converged.	0.25	9.015	0.194	-0.657	1.045	1.497	Algorithm converged.	0.251	8.922
			Acute myocardial infarction	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	1	0.114	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	0.339	NE	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	-0.186	0.575	NE	Algorithm not converged.	NE	NE
			Angina pectoris	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	0	0	513	35,924	1	0.195	NE *	Algorithm not converged.	NE	NE	-0.195	-0.577	0.187	NE	Algorithm not converged.	NE	NE
			Cardiac arrest	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	0	0	513	35,924	1	0.195	NE *	Algorithm not converged.	NE	NE	-0.195	-0.577	0.187	NE	Algorithm not converged.	NE	NE
			Cardiac failure congestive	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	-0.186	0.575	NE	Algorithm not converged.	NE	NE
			Cardio-respiratory arrest	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	-0.186	0.575	NE	Algorithm not converged.	NE	NE
			Coronary artery disease	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	-0.186	0.575	NE	Algorithm not converged.	NE	NE
			Hypertensive cardiomyopathy	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	NE	Algorithm not converged.	NE	NE	
				18-49	874	60,737	0	0	868	60,784	0	0	NE										

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Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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Program: t-ae-raw-soc.sas
Output: t13-2f-ae-raw-soc-toxgrpt3-ts

Name Region	SOC	PT	Casirivimab/Indinavir												Placebo												Casirivimab/Indinavir vs. Placebo														Placebo vs. Casirivimab/Indinavir																																																																																																																																																																																																																																																																																																													
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk				Convergence				Relative Risk			

		Diabetic foot	US	1348	93,676	1	0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	US	1348	93,676	2	0,148	1339	93,768	2	0,149	0,993		Algorithm converged.	0,14	7,062	-0,001		Algorithm converged.	-0,293	0,291	0,993		Algorithm converged.	0,14	7,041	1	1	1,007		Algorithm converged.	0,142	7,136
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Essential hypertension	US	1348	93,676	0	0	1339	93,768	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075		Algorithm converged.	-0,221	0,072	NE	*	Algorithm not converged.	NE	NE	0,4983		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypertensive urgency	US	1348	93,676	0	0	1339	93,768	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075		Algorithm converged.	-0,221	0,072	NE	*	Algorithm not converged.	NE	NE	0,4983		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peripheral arterial occlusive disease	US	1348	93,676	1	0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peripheral vascular disorder	US	1348	93,676	1	0,074	1339	93,768	0	0	NE	*	Algorithm not converged.	NE	NE	0,074		Algorithm converged.	-0,071	0,22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			ex-US	91	6,324	0	0	89	6,232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

 Program: t-ae-raw-soc.sas
 Output: t13-2f-ae-raw-soc-toxggr3-4s

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab														
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk				
Name	SOC	PT	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 p-risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL																	
All	Cardiac disorders	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1		0.504	Algorithm converged.		0.046	5.55																	
		--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																		
		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																		
Gastrointestinal disorders	--	1439	100	2	0.139	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.321	NE *	Algorithm not converged.	NE	NE	0.4998	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
Hepatobiliary disorders	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1		1.008	Algorithm converged.		0.063	16.095																		
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
Infections and infestations	--	1439	100	5	0.347	1428	100	11	0.77	0.449	Algorithm converged.	0.156	1.296	-0.423	Algorithm converged.	-0.969	0.123	0.451	Algorithm converged.	0.157	1.295	0.1409	2.217	Algorithm converged.		0.772	6.364																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	2	0.14	NE *	Algorithm not converged.	NE	NE	-0.14	Algorithm converged.	-0.334	0.054	NE *	Algorithm not converged.	NE	NE	0.248	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	5	0.35	NE *	Algorithm not converged.	NE	NE	-0.35	Algorithm converged.	-0.657	-0.044	NE *	Algorithm not converged.	NE	NE	0.0305	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1		1.008	Algorithm converged.		0.063	16.095																		
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
Injury, poisoning and procedural complications	--	1439	100	4	0.278	1428	100	5	0.35	0.793	Algorithm converged.	0.213	2.96	-0.072	Algorithm converged.	-0.482	0.338	0.794	Algorithm converged.	0.214	2.95	0.7526	1.26	Algorithm converged.		0.339	4.681																			
	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1		0.504	Algorithm converged.		0.046	5.55																		
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
	Investigations	--	1439	100	0	0	1428	100	2	0.14	NE *	Algorithm not converged.	NE	NE	-0.14	Algorithm converged.	-0.334	0.054	NE *	Algorithm not converged.	NE	NE	0.248	NE	NE	Algorithm not converged.	NE	NE																		
--		1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
--		1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
Musculoskeletal and connective tissue disorders	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1		1.008	Algorithm converged.		0.063	16.095																		
	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE																			
	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	NE	Algorithm not converged.	NE	NE																			
Nervous system disorders	--	1439	100	2	0.139	1428	100	1	0.07	1.986																																				

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																															
				Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Convergence Reason					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk					Convergence Reason					95% Lower CL					95% upper CL																																																																																																																																																																																																																																																																																																																																																																																											
Name				Level	n	%	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk

Test for interaction based on RR (Log-Binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t13-3f-ae-row-soc.sas
Output: t13-3f-ae-row-soc-toxgr3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Inmunevab				Placebo				Odds Ratio			Casirivimab/Inmunevab vs. Placebo				Casirivimab/Inmunevab vs. Placebo				Placebo vs. Casirivimab/Inmunevab								
			Patients		Patients with Event		Patients		Patients with Event					95% Lower CL		95% upper CL		Absolute Risk		95% Lower CL		95% upper CL		Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk		95% Lower CL
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Age	Cardiac disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	2	0.389	513	35,924	1	0.195	2	Algorithm converged.	0.181	22.125	0.194	Algorithm converged.	-0.466	0.854	1.996	Algorithm converged.	0.182	21.945	1	0.501	Algorithm converged.	0.046	5.508		
	Angina pectoris		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	0	0	513	35,924	1	0.195	NE *	Algorithm not converged.	NE	NE	-0.195	Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE	Algorithm not converged.	NE	NE	
	Coronary artery disease		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Hypertensive cardiomyopathy		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Mitral valve stenosis		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Abdominal pain upper		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	1	0.114	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	0	0	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Dental caries		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	1	0.114	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	0	0	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	1	0.115	NE *	Algorithm not converged.	NE	NE	-0.115	Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Cholecystitis acute		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Cholelithiasis		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	1	0.115	NE *	Algorithm not converged.	NE	NE	-0.115	Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	0	0	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.7999	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	4	0.458	868	60,784	7	0.806	0.566	Algorithm converged.	0.165	1.939	-0.349	Algorithm converged.	-1.093	0.396	0.568	Algorithm converged.	0.167	1.932	0.3847	1.762	Algorithm not converged.	0.518	5.998		
			>=50	514	35,719	1	0.195	513	35,924	4	0.78	0.248	Algorithm converged.	0.028	2.227	-0.585	Algorithm converged.	-1.436	0.266	0.25	Algorithm converged.	0.028	2.225	0.2174	4.008	Algorithm converged.	0.449	35.735		
	Abscess limb		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Appendicitis		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	2	0.23	NE *	Algorithm not converged.	NE	NE	-0.23	Algorithm converged.	-0.549	0.089	NE	*	Algorithm not converged.	NE	NE	0.2481	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	0	0	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	COVID-19		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	3	0.346	NE *	Algorithm not converged.	NE	NE	-0.346	Algorithm converged.	-0.736	0.045	NE	*	Algorithm not converged.	NE	NE	0.1235	NE	Algorithm not converged.	NE	NE	
			>=50	514	35,719	0	0	513	35,924	2	0.39	NE *	Algorithm not converged.	NE	NE	-0.39	Algorithm converged.	-0.929	0.149	NE	*	Algorithm not converged.	NE	NE	0.2493	NE	Algorithm not converged.	NE	NE	
	COVID-19 pneumonia		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	0	0	513	35,924	1	0.195	NE *	Algorithm not converged.	NE	NE	-0.195	Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE	Algorithm not converged.	NE	NE	
	Gangrene		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Gastroenteritis		12-17	51	3,544	0	0	47	3,291	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0																								

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t-ae-row-soc.sas
Output: t13-3f-ae-row-soc-toxpr3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirumab/Indinavir								Placebo								Casirumab/Indinavir vs. Placebo								Placebo vs. Casirumab/Indinavir											
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk			
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
Cardiac disorders		--	US	1348	93.676	2	0.148	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.148	Algorithm converged.	-0.057	0.354	NE	*	Algorithm not converged.	NE	NE	0.4998		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	1.066	NE	*	Algorithm not converged.	NE	NE	0.4944		NE		Algorithm not converged.	NE	NE						
Angina pectoris			US	1348	93.676	0	0	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			ex-US	91	6.324	0	0	89	6.232	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	1.066	NE	*	Algorithm not converged.	NE	NE	0.4944		NE		Algorithm not converged.	NE	NE						
Coronary artery disease			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Hypertensive cardiomyopathy			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Mitral valve stenosis			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Gastrointestinal disorders	--		US	1348	93.676	2	0.148	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.148	Algorithm converged.	-0.057	0.354	NE	*	Algorithm not converged.	NE	NE	0.4998		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Abdominal pain upper			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Dental caries			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Hepatobiliary disorders	--		US	1348	93.676	1	0.074	1339	93.768	1	0.075	0.993	Algorithm converged.	0.062	15.897	0	0	Algorithm converged.	-0.207	0.206	0.993	Algorithm converged.	0.062	15.864	1	1	1.007	Algorithm converged.	0.063	16.078								
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Cholecystitis acute			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Cholelithiasis			US	1348	93.676	0	0	1339	93.768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Infections and infestations	--		US	1348	93.676	4	0.297	1339	93.768	10	0.747	0.396	Algorithm converged.	0.124	1.264	-0.45	Algorithm converged.	-0.995	0.095	0.397	Algorithm converged.	0.125	1.264	0.1164	0.5585	2.517	Algorithm converged.	0.791	8.005									
			ex-US	91	6.324	1	1.099	89	6.232	1	1.124	0.978	Algorithm converged.	0.06	15.877	-0.025	Algorithm converged.	-3.088	3.038	0.978	Algorithm converged.	0.062	15.397	1	1.022	0.065	16.096											
Abscess limb			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Appendicitis			US	1348	93.676	0	0	1339	93.768	2	0.149	NE	*	Algorithm not converged.	NE	NE	-0.149	Algorithm converged.	-0.356	0.057	NE	*	Algorithm not converged.	NE	NE	0.2482		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
COVID-19			US	1348	93.676	0	0	1339	93.768	4	0.299	NE	*	Algorithm not converged.	NE	NE	-0.299	Algorithm converged.	-0.591	-0.006	NE	*	Algorithm not converged.	NE	NE	0.6615		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	1	1.124	NE	*	Algorithm not converged.	NE	NE	-1.124	Algorithm converged.	-3.313	1.066	NE	*	Algorithm not converged.	NE	NE	0.4944		NE		Algorithm not converged.	NE	NE						
COVID-19 pneumonia			US	1348	93.676	0	0	1339	93.768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Gangrene			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Gastroenteritis			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Osteomyelitis			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Pneumonia			US	1348	93.676	0	0	1339	93.768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	1	1.099	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	1.099	Algorithm converged.	-1.043	3.241	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
Scrotal abscess			US	1348	93.676	0	0	1339	93.768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Sepsis			US	1348	93.676	1	0.074	1339	93.768	1	0.075	0.993	Algorithm converged.	0.062	15.897	0	0	Algorithm converged.	-0.207	0.206	0.993	Algorithm converged.	0.062	15.864	1	1	1.007	Algorithm converged.	0.063	16.078								
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Subcutaneous abscess			US	1348	93.676	0	0	1339	93.768	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE	*	Algorithm not converged.	NE	NE	0.4983		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Tooth abscess			US	1348	93.676	1	0.074	1339	93.768	0	0	NE	*	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			ex-US	91	6.324	0	0	89	6.232	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
Injury, poisoning and procedural complications	--		US	1348	93.676	4	0.297	1339	93.768	5	0.373	0.794	Algorithm converged.	0.213	2.963	-0.077	Algorithm converged.	-0.514	0.36	0.795	Algorithm converged.	0.214	2.963	0.7527	1	1.258	Algorithm converged.	0.339	4.676									
			ex-US	91	6.324	0	0	89																														

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p -value is based on Fisher Exact Test.

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POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk									
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Cardiac disorders	Acute myocardial infarction	--	1439	100	2	0.139	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.331	NE	*	Algorithm not converged.	NE	NE	0.4998	NE	Algorithm not converged.	NE	NE
			--	1439	100	2	0.139	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.331	NE	*	Algorithm not converged.	NE	NE	0.4998	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	Portal hypertension	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Infections and infestations	COVID-19 pneumonia	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
			--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
	Investigations	Blood creatine phosphokinase increased	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE
			--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE	*	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.1362021

Program: 1-ae-raw-soc_sas
Output: T13-4f-ae-raw-soc-toxg4-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk						Relative Risk									
		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Name	SOC	PT																											
Sex	Cardiac disorders	--	Male	661	45,935	1	0.151	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	0.151	Algorithm not converged.	-0.145	0.448	NE *	Algorithm not converged.	NE	NE	0.4893	1	NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	Male	661	45,935	1	0.151	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE *	Algorithm not converged.	NE	NE	0.4893	1	NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Portal hypertension		Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	661	45,935	0	0	690	48,319	1	0.145	NE *	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia		Male	661	45,935	0	0	690	48,319	1	0.145	NE *	Algorithm not converged.	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Blood creatine phosphokinase increased		Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	1	0.129	738	51,681	0	0	NE *	Algorithm not converged.	NE	NE	0.129	Algorithm converged.	-0.123	0.38	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	1	0.136	NE *	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE *	Algorithm not converged.	NE	NE	0.4868		NE	Algorithm not converged.	NE	NE
	Abortion spontaneous		Male	661	45,935	0	0	690	48,319	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	778	54,065	0	0	738	51,681	1	0.136	NE *	Algorithm not converged.	NE	NE	-0.136	Algorithm converged.	-0.401	0.13	NE *	Algorithm not converged.	NE	NE	0.4868		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 113-48-ae-raw-soc-toxgr4-6

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

												Casiirivmab/Imdevimab				Placebo				Odds Ratio				Absolute Risk Difference				Casiirivmab/Imdevimab vs. Placebo				Placebo vs. Casiirivmab/Imdevimab							
												Patients		Patients with Event		Patients		Patients with Event										Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL	
Name	SOC											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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	PT																																						
Cardiac disorders	--											12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	1	0.114	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Acute myocardial infarction												12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	1	0.114	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Hepatobiliary disorders	--											12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Portal hypertension												12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Infections and infestations	--											12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	0	0	513	35,924	1	0.195	NE	* Algorithm not converged.	NE	NE	-0.195	Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE	Algorithm not converged.	NE	NE	
COVID-19 pneumonia												12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	0	0	513	35,924	1	0.195	NE	* Algorithm not converged.	NE	NE	-0.195	Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE	Algorithm not converged.	NE	NE	
Investigations	--											12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Blood creatine phosphokinase increased												12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												>=50	514	35,719	1	0.195	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Pregnancy, puerperium and perinatal conditions	--											12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	1	0.115	NE	* Algorithm not converged.	NE	NE	-0.115	Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE	
												>=50	514	35,719	0	0	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Abortion spontaneous												12-17	51	3,544	0	0	47	3,291	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
												18-49	874	60,737	0	0	868	60,784	1	0.115	NE	* Algorithm not converged.	NE	NE	-0.115	Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE	
												>=50	514	35,719	0	0	513	35,924	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.13/0.021

Program: 1-ae-raw-soc.sas
Output: 133-4f-ae-raw-soc-toxgr4-4s

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

Casirivimab/Imdevimab vs. Placebo																														Placebo vs. Casirivimab/Imdevimab									
Casirivimab/Imdevimab															Placebo																								
Patients															Patients with Event																								
Patients															Patients with Event																								
Odds Ratio															Absolute Risk Difference																								
Relative Risk															Relative Risk																								
Interaction Test p-value (likelihood ratio)															Relative Risk																								
Convergence Reason															Convergence Reason																								
95% Lower CL															95% Lower CL																								
95% upper CL															95% upper CL																								
Absolute Risk															Absolute Risk																								
Convergence Reason															Convergence Reason																								
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95% upper CL															95% upper CL																								
Relative Risk															Relative Risk																								
Convergence Reason															Convergence Reason																								
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95% upper CL															95% upper CL																								
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Convergence Reason															Convergence Reason																								
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Relative Risk															Relative Risk																								
Convergence Reason															Convergence Reason																								
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95% upper CL															95% upper CL																								
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Convergence Reason															Convergence Reason																								
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95% upper CL															95% upper CL																								
p-value															p-value																								
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Test for interaction based on RR (Log-binomial regression).
* Indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 113-5t-ae-raw-soc-toxg5-b

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casin/mab/mde/mab										Placebo										Casin/mab/mde/mab vs. Placebo										Casin/mab/mde/mab vs. Placebo										Placebo vs. Casin/mab/mde/mab																			
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk					Convergence Reason					95% Lower CL					95% upper CL				
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL																												
All	Cardiac disorders	--	--	1439	100	3	0.208	1428	100	1	0.07	2.981	Algorithm converged.	0.138	28.694	0.21	Algorithm converged.	-0.134	0.411	2.977	Algorithm converged.	0.31	28.595	0.6247	0.336	Algorithm converged.	0.035	3.225																																	
		Acute myocardial infarction	--	1439	100	2	0.139	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.331	NE *	Algorithm not converged.	NE	NE	0.4998	NE	Algorithm not converged.	NE	NE																																	
		Cardiac arrest	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																	
		Cardiac failure congestive	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
		Cardio-respiratory arrest	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
Gastrointestinal disorders	--	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Abdominal pain upper	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Hepatobiliary disorders	--	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095																																		
	Cholecystitis acute	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Cholelithiasis	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Infections and infestations	--	--	1439	100	7	0.486	1428	100	11	0.77	0.63	Algorithm converged.	0.243	1.629	-0.284	Algorithm converged.	-0.863	0.295	0.631	Algorithm converged.	0.246	1.624	0.3361	1.584	Algorithm converged.	0.616	4.073																																		
	Abscess limb	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Appendicitis	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5.474	-0.071	Algorithm converged.	-0.308	0.166	0.496	Algorithm converged.	0.045	5.466	0.6234	2.015	Algorithm converged.	0.183	22.202																																		
	COVID-19	--	1439	100	0	0	1428	100	4	0.28	NE *	Algorithm not converged.	NE	NE	-0.28	Algorithm converged.	-0.554	-0.006	NE *	Algorithm not converged.	NE	NE	0.0614	NE	Algorithm not converged.	NE	NE																																		
	COVID-19 pneumonia	--	1439	100	0	0	1428	100	3	0.21	NE *	Algorithm not converged.	NE	NE	-0.21	Algorithm converged.	-0.448	0.027	NE *	Algorithm not converged.	NE	NE	0.1234	NE	Algorithm not converged.	NE	NE																																		
	Gangrene	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Gastroenteritis	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Osteomyelitis	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Pneumonia	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55																																		
	Pyelonephritis	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
	Scrota abscess	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
	Sepsis	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095																																		
	Soft tissue infection	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Injury, poisoning and procedural complications	--	--	1439	100	5	0.347	1428	100	3	0.21	1.656	Algorithm converged.	0.395	6.943	0.137	Algorithm converged.	-0.248	0.523	1.654	Algorithm converged.	0.396	6.908	0.7262	0.605	Algorithm converged.	0.145	2.525																																	
		Ankle fracture	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
		Burns second degree	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
		Foot fracture	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
Gun shot wound		--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Humerus fracture		--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Post procedural haemorrhage		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Road traffic accident		--	1439	100	2	0.139	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.139	Algorithm converged.	-0.054	0.331	NE *	Algorithm not converged.	NE	NE	0.4998	NE	Algorithm not converged.	NE	NE																																		
Soft tissue injury		--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Tibia fracture		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Traumatic lung injury		--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		--	--	1439	100	1	0.069	1428	100	1	0.07	0.992	Algorithm converged.	0.062	15.881	-0.001	Algorithm converged.	-0.194	0.193	0.992	Algorithm converged.	0.062	15.85	1	1.008	Algorithm converged.	0.063	16.095																																	
		Cervix carcinoma recurrent	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																	
	Invasive ductal breast carcinoma	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Nervous system disorders	--	--	1439	100	2	0.139	1428	100	1	0.07	1.986	Algorithm converged.	0.18	21.927	0.069	Algorithm converged.	-0.167	0.305	1.985	Algorithm converged.	0.18	21.863	1	0.504	Algorithm converged.	0.046	5.55																																		
	Cerebral infection	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
	Syncope	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Transient ischaemic attack	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Pregnancy, puerperium and perinatal conditions	--	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5.474	-0.071	Algorithm converged.	-0.308	0.166	0.496	Algorithm converged.	0.045	5.466	0.6234	2.015	Algorithm converged.	0.183	22.202																																		
	Abortion spontaneous	--	1439	100	1	0.069	1428	100	2	0.14	0.496	Algorithm converged.	0.045	5.474	-0.071	Algorithm converged.	-0.308	0.166	0.496	Algorithm converged.	0.045	5.466	0.6234	2.015	Algorithm converged.	0.183	22.202																																		
Psychiatric disorders	--	--	1439	100	0	0	1428	100	2	0.14	NE *	Algorithm not converged.	NE	NE	-0.14	Algorithm converged.	-0.334	0.054	NE *	Algorithm not converged.	NE	NE	0.248	NE	Algorithm not converged.	NE	NE																																		
	Mania	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
	Suicidal ideation	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Renal and urinary disorders	--	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Acute kidney injury	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Reproductive system and breast disorders	--	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
	Breast haematoma	--	1439	100	0	0	1428	100	1	0.07	NE *	Algorithm not converged.	NE	NE	-0.07	Algorithm converged.	-0.207	0.067	NE *	Algorithm not converged.	NE	NE	0.4981	NE	Algorithm not converged.	NE	NE																																		
Skin and subcutaneous tissue disorders	--	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
	Diabetic foot	--	1439	100	1	0.069	1428	100	0	0	NE *	Algorithm not converged.	NE	NE	0.069	Algorithm converged.	-0.067	0.206	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE																																		
Vascular disorders	--	--	1439	100	0	0	1428	100	2	0.14	NE *	Algorithm not converged.	NE	NE	-0.14	Algorithm converged.	-0.334	0.054	NE *	Algorithm not converged.	NE	NE	0.248	NE	Algorithm not converged.	NE	NE																																		
	Essential hypertension	--	1439	100	0	0	1428																																																						

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirumab/Imdevimab				Placebo				Casirumab/Imdevimab vs. Placebo												Placebo vs. Casirumab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test				Relative Risk						
				Level	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	p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% upper CI				
Name	Sex	SOC	PT	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	NE	NE	0.4893	0.2916	NE	Algorithm not converged.	NE	NE	NE	NE		
				Female	778	54,065	1	0.129	738	51,681	1	0.136	0.949	Algorithm converged.	0.059	15,192	-0.007	Algorithm converged.	-0.373	0.359	0.949	Algorithm converged.	0.059	15,138	1		1.054	Algorithm converged.	0.066	16,823				
				Cardiac arrest	Male	661	45,935	0	0	690	48,319	0	0	NE	*	NE	NE	-0.136	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE			
				Female	778	54,065	0	0	738	51,681	1	0.136	NE	*	NE	NE	0.129	Algorithm not converged.	NE	NE	NE	*	NE	NE	0.4868		NE	Algorithm not converged.	NE	NE				
				Cardiac failure congestive	Male	661	45,935	0	0	690	48,319	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE			
				Female	778	54,065	1	0.129	738	51,681	0	0	NE	*	NE	NE	0.129	Algorithm not converged.	NE	NE	NE	*	NE	NE	1		NE	Algorithm not converged.	NE	NE				
				Cardio-respiratory arrest	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	NE	NE	0.151	Algorithm not converged.	NE	NE	NE	*	NE	NE	0.4893		NE	Algorithm not converged.	NE	NE			
				Female	778	54,065	0	0	738	51,681	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
				Injury, poisoning and procedural complications	Male	661	45,935	1	0.151	690	48,319	1	0.145	1.044	Algorithm converged.	0.065	16,724	0.006	Algorithm converged.	-0.404	0.417	1.044	Algorithm converged.	0.065	16,655	1	1	0.958	Algorithm converged.	0.06	15,284			
				Female	778	54,065	0	0	738	51,681	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
				Gun shot wound	Male	661	45,935	0	0	690	48,319	1	0.145	NE	*	NE	NE	-0.145	Algorithm converged.	-0.429	0.139	NE	*	NE	NE	1		NE	Algorithm not converged.	NE	NE			
				Female	778	54,065	0	0	738	51,681	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
				Road traffic accident	Male	661	45,935	1	0.151	690	48,319	0	0	NE	*	NE	NE	0.151	Algorithm converged.	-0.145	0.448	NE	*	NE	NE	0.4893		NE	Algorithm not converged.	NE	NE			
				Female	778	54,065	0	0	738	51,681	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE	Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 1135f-ae-raw-soc-toxgr5-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casir/mab/mde/mab						Patients		Placebo		Patients with Event				Odds Ratio		Casir/mab/mde/mab vs. Placebo						Absolute Risk Difference						Casir/mab/mde/mab vs. Placebo						Relative Risk						Placebo vs. Casir/mab/mde/mab																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
		Patients		Patients with Event				Patients		Patients with Event								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		Interaction Test p-value (likelihood ratio)		Relative Risk				Convergence Reason		95% Lower CL		95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																					
Name	SOC	Level	n	%	n	%	n	%	n	%	n	%	n	%	Odds Ratio	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95%

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.1Jul2021

Program: 1-ae-raw-soc.sas
Output: 113-5f4e-raw-soc-tougr5-ft

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab								Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab															
			Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk			
Name	SOC	PT	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
Cardiac disorders		--	US	1348	93.676	2	0.148	1339	93.768	1	0.075	1.988	Algorithm converged.	0.18	21.951	0.074	Algorithm converged.	-0.179	0.326	1.987	Algorithm converged.	0.18	21.883	1	0.503	Algorithm converged.	0.046	5.545										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
		Cardiac arrest	US	1348	93.676	0	0	1339	93.768	1	0.075	NE *	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE *	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
		Cardiac failure congestive	US	1348	93.676	1	0.074	1339	93.768	0	0	NE *	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
		Cardio-respiratory arrest	US	1348	93.676	1	0.074	1339	93.768	0	0	NE *	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
Injury, poisoning and procedural complications		--	US	1348	93.676	1	0.074	1339	93.768	1	0.075	0.993	Algorithm converged.	0.062	15.897	0	Algorithm converged.	-0.207	0.206	0.993	Algorithm converged.	0.062	15.864	1	1.007	Algorithm converged.	0.063	16.078										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
		Gun shot wound	US	1348	93.676	0	0	1339	93.768	1	0.075	NE *	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE *	Algorithm not converged.	NE	NE	0.4983	NE	Algorithm not converged.	NE	NE										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										
		Road traffic accident	US	1348	93.676	1	0.074	1339	93.768	0	0	NE *	Algorithm not converged.	NE	NE	0.074	Algorithm converged.	-0.071	0.22	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE										
			ex-US	91	6.324	0	0	89	6.232	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE										

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 1135f-ae-raw-soc-toxgr5-b

[illegible]

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t-ae-row-soc.sas
Output: t13-6f-ae-row-soc-anysae-fs

										Casimilmb/Indemlmb	Patients	Casimilmb/Indemlmb vs. Placebo	Odds Ratio	Absolute Risk Difference	Casimilmb/Indemlmb vs. Placebo	Relative Risk	Placebo vs. Casimilmb/Indemlmb											
Name	SOC	PT	Level	n	%	n	%	n	%	Ratio	Reason	95% Lower CL	95% upper CL	Absolute Risk	Reason	95% Lower CL	95% upper CL	Relative Risk	Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Age	Cardiac disorders	--	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	1	0.114	868	60,784	0	NE *	Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	2	0.389	513	35,924	1	0.195	2	0.195	0.194	Algorithm converged.	-0.46	0.854	1.996	* Algorithm not converged.	Algorithm converged.	0.182	21,945	1	0.501	NE	Algorithm converged.	0.046	5,508
		Acute myocardial infarction	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	1	0.114	868	60,784	0	NE *	Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Cardiac arrest	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	0	0	513	35,924	1	0.195	NE	NE	-0.195	Algorithm converged.	-0.577	0.187	NE *	Algorithm not converged.	NE	NE	0.4995	NE	NE	Algorithm not converged.	NE	NE	
		Cardiac failure congestive	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Cardio-respiratory arrest	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	0	0	868	60,784	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	1	0.195	513	35,924	0	NE *	Algorithm not converged.	NE	NE	0.195	Algorithm converged.	-0.186	0.575	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	12-17	51	3,544	0	0	47	3,291	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	874	60,737	1	0.114	868	60,784	0	NE *	Algorithm not converged.	NE	NE	0.114	Algorithm converged.	-0.11	0.339	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	514	35,719	0	0	513	35,924	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Abdominal pain upper	12																									

[illegible]

Reproductive system and breast disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		18-49	874	60,737	0	0	868	60,784	1	0.115	NE	*	Algorithm not converged.	NE	NE	NE	-0.115		Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE		Algorithm not converged.	NE	NE
		>=50	514	35,719	0	0	513	35,924	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
Breast haematoma	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	18-49	874	60,737	0	0	868	60,784	1	0.115	NE	*	Algorithm not converged.	NE	NE	NE	-0.115		Algorithm converged.	-0.341	0.11	NE	*	Algorithm not converged.	NE	NE	0.4983	NE		Algorithm not converged.	NE	NE	
	>=50	514	35,719	0	0	513	35,924	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
Skin and subcutaneous tissue disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		>=50	514	35,719	1	0.195	513	35,924	0	0	NE	*	Algorithm not converged.	NE	NE	0.195		Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
Diabetic foot	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
	>=50	514	35,719	1	0.195	513	35,924	0	0	NE	*	Algorithm not converged.	NE	NE	0.195		Algorithm converged.	-0.186	0.575	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE		
Vascular disorders	--	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		>=50	514	35,719	0	0	513	35,924	2	0.39	NE	*	Algorithm not converged.	NE	NE	-0.39		Algorithm converged.	-0.929	0.149	NE	*	Algorithm not converged.	NE	NE	0.2493	NE		Algorithm not converged.	NE	NE	
Essential hypertension	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
	>=50	514	35,719	0	0	513	35,924	1	0.195	NE	*	Algorithm not converged.	NE	NE	-0.195		Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE		Algorithm not converged.	NE	NE		
Hypertensive urgency	12-17	51	3,544	0	0	47	3,291	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	18-49	874	60,737	0	0	868	60,784	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
	>=50	514	35,719	0	0	513	35,924	1	0.195	NE	*	Algorithm not converged.	NE	NE	-0.195		Algorithm converged.	-0.577	0.187	NE	*	Algorithm not converged.	NE	NE	0.4995	NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If rp < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas

Output: 113-6f-ae-raw-soc-any.sae-8s

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casi/mab/inde/mab										Placebo										Casi/mab/inde/mab v. Placebo										Casi/mab/inde/mab v. Placebo										Placebo v. Casi/mab/inde/mab									
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk									
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL																						
Region	Cardiac disorders	--	US ex-US	1348 91	93.676 6.324	2 1	0.148 1.099	1339 89	93.768 6.232	0 0	0.075 NE	NE *	Algorithm converged. Algorithm not converged.	0.074 NE	21.951 1.099	0.074 1.099	Algorithm converged. Algorithm converged.	-0.173 -1.043	0.287 3.241	0.987 NE	Algorithm converged. Algorithm not converged.	NE NE	NE NE	1 1	0.4119	0.503 NE	Algorithm converged. Algorithm not converged.	NE NE	NE NE																						
		Acute myocardial infarction	US ex-US	1348 91	93.676 6.324	1 0	0.074 1.099	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 1.099	Algorithm converged. Algorithm not converged.	-0.071 -1.043	0.22 3.241	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 1		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Cardiac arrest	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	0 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Cardiac failure congestive	US ex-US	1348 91	93.676 6.324	0 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Cardio-respiratory arrest	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
	Gastrointestinal disorders	--	US ex-US	1348 91	93.676 6.324	0 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Abdominal pain upper	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
	Hepatobiliary disorders	--	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	1 0	0.075 NE	Algorithm converged. Algorithm not converged.	0.993 NE	0.062 NE	15.897 NE	0 NE	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	Algorithm not converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1.007	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE																							
		Cholecystitis acute	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Cholelithiasis	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	0 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
	Infections and infestations	--	US ex-US	1348 91	93.676 6.324	5 2	0.371 2.198	1339 89	93.768 6.232	8 3	0.597 3.371	0.619 Algorithm converged.	0.202 1.05	1.898 3.95	-0.227 -1.173	Algorithm converged. Algorithm converged.	-0.752 -5.983	0.299 3.637	0.621 0.652	Algorithm not converged. Algorithm converged.	0.204 1.112	1.893 3.809	0.4213 0.6805	0.9633 1.531		1.611	Algorithm converged. Algorithm not converged.	0.528 0.263	4.911 8.961																						
		Abscess limb	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Appendicitis	US ex-US	1348 91	93.676 6.324	0 0	0.074 NE	1339 89	93.768 6.232	2 0	0.149 NE	0.496 Algorithm not converged.	0.045 NE	5.48 NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.328 NE	0.178 NE	0.497 NE	Algorithm not converged. Algorithm not converged.	0.045 NE	5.471 NE	0.6236 NE	1 NE	2.013	Algorithm converged. Algorithm not converged.	0.183 NE	22.178 NE																							
		COVID-19	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	2 2	0.149 2.247	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.149 -2.247	Algorithm converged. Algorithm converged.	-0.356 -5.326	0.057 0.832	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2482 0.2431		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		COVID-19 pneumonia	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	2 1	0.149 1.124	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.149 -1.124	Algorithm converged. Algorithm converged.	-0.356 -3.313	0.057 1.066	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2482 0.4944		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Gangrene	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Gastroenteritis	US ex-US	1348 91	93.676 6.324	0 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Osteomyelitis	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Pneumonia	US ex-US	1348 91	93.676 6.324	2 2	2.198	0 1339	93.768 6.232	1 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 2.198	Algorithm converged. Algorithm converged.	-0.221 -0.814	0.072 5.21	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 0.4793		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Pyelonephritis	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	1 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Scrotal abscess	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	1 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Sepsis	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	1 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.075 NE	Algorithm converged. Algorithm not converged.	-0.207 NE	0.206 NE	0.993 NE	Algorithm not converged. Algorithm not converged.	0.062 NE	15.864 NE	1 NE	1.007	Algorithm converged. Algorithm not converged.	0.063 NE	16.078 NE																							
		Soft tissue infection	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
	Injury, poisoning and procedural complications	--	US ex-US	1348 91	93.676 6.324	5 0	0.371 NE	1339 89	93.768 6.232	3 0	0.224 NE	1.658 Algorithm not converged.	0.395 NE	6.951 NE	0.147 NE	Algorithm converged. Algorithm not converged.	-0.265 NE	0.559 NE	1.656 NE	Algorithm not converged. Algorithm not converged.	0.396 NE	6.914 NE	0.7262 NE	1 NE	0.604	Algorithm converged. Algorithm not converged.	0.145 NE	2.522 NE																							
		Ankle fracture	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Burns second degree	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Foot fracture	US ex-US	1348 91	93.676 6.324	1 0	0.074 NE	1339 89	93.768 6.232	0 0	0 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.074 NE	Algorithm converged. Algorithm not converged.	-0.071 NE	0.22 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Gun shot wound	US ex-US	1348 91	93.676 6.324	0 0	0 NE	1339 89	93.768 6.232	1 0	0.075 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.075 NE	Algorithm converged. Algorithm not converged.	-0.221 NE	0.072 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4983 NE		NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE																						
		Humerus fracture	US	1348	93.676	0	0	1339	93.768	1	0.075	NE *	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.221	0.072	NE *	Algorithm not converged.	NE	NE	0.4983		NE	Algorithm not converged.	NE	NE																						

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t-ae-raw-soc.sas
Output: t13-6f-ae-raw-soc-anysae-ts

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	--	--	--	1439	100	0	0	1428	100	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	--	--	Male	661	45,935	0	0	690	48,319	0	0
			Female	778	54,065	0	0	738	51,681	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Age	--	--	12-17	51	3,544	0	0	47	3,291	0	0
			18-49	874	60,737	0	0	868	60,784	0	0
			>=50	514	35,719	0	0	513	35,924	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort A

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Region	--	--	US	1348	93,676	0	0	1339	93,768	0	0
			ex-US	91	6,324	0	0	89	6,232	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

KohorteA

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

Ergänzende Dokumente

POPULATION: SAFETY - Cohort A
ENDPOINT: Adverse Events
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Outcome of Adverse Events

Category of Adverse Events	Casi/mab/mde/mab (N=1439)																Placebo (N=1428)																			
	Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE			NOT RECOVERED/NOT RESOLVED			FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE			NOT RECOVERED/NOT RESOLVED			FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%		n	%		n	%		n	%	n	%	n	%	n	%	n	n	%		n	%		n	%		n	%	n	%	n	%		
Any AEs	932	805	86.373	5	0.536		72	7.725	3	0.322	29	3.112	6	0.644	12	1.288	1006	892	88.668	3	0.298		62	6.163	2	0.199	31	3.082	6	0.596	10	0.994				
All	729	650	89.163	3	0.412		44	6.036	0	0	17	2.332	4	0.549	11	1.509	805	721	89.565	3	0.373		48	5.963	0	0	20	2.484	5	0.621	8	0.994				
Grade 1	163	127	77.914	0	0		25	15.337	0	0	9	5.521	1	0.613	1	0.613	169	142	84.024	0	0		13	7.692	0	0	11	6.509	1	0.592	2	1.183				
Grade 2	33	26	78.788	1	3.03		3	9.091	0	0	3	9.091	0	0	0	0	28	27	96.429	0	0		1	3.571	0	0	0	0	0	0	0	0				
Grade 3	4	2	50	1	25		0	0	0	0	0	0	1	25	0	0	2	2	100	0	0		0	0	0	0	0	0	0	0	0					
Grade 4	3	0	0	0	0		0	0	3	100	0	0	0	0	0	0	2	0	0	0	0		0	0	2	100	0	0	0	0	0	0				
Grade 5	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0				
Missing	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0				
Any SAEs	31	25	80.645	1	3.226		1	3.226	3	9.677	1	3.226	0	0	0	0	27	24	88.889	0	0		1	3.704	2	7.407	0	0	0	0	0	0	0			
All	1	1	100	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0				
Grade 1	4	4	100	0	0		0	0	0	0	0	0	0	0	0	0	7	7	100	0	0		0	0	0	0	0	0	0	0	0	0				
Grade 2	21	19	90.476	0	0		1	4.762	0	0	1	4.762	0	0	0	0	16	15	93.75	0	0		1	6.25	0	0	0	0	0	0	0	0	0			
Grade 3	2	1	50	1	50		0	0	0	0	0	0	0	0	0	0	2	2	100	0	0		0	0	0	0	0	0	0	0	0	0				
Grade 4	3	0	0	0	0		0	0	3	100	0	0	0	0	0	0	2	0	0	0	0		0	0	2	100	0	0	0	0	0	0				
Grade 5	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0				
Missing	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0				
Any AESIs	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
All	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Grade 1	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Grade 2	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Grade 5	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			
Missing	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0			

Clinical cut-off: 01Jul2021

Program: 1-ae-resolved-general.sas
Output: 110-ae-resolved-general

Clinical cut-off: 01Jul2021

Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set - Cohort A

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 1428)	Casirivimab/Imdevimab (N = 1439)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Median	211.0	210.0

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Übersicht:

Studie COV-2069

Kohorte B

Datenschnitt: 11.03.2021 (DCO1)

Wirksamkeit	
Hauptdokumente	
t8-3-eff-resp-bsymbr14-strat	Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR
t8-3-eff-resp-bsymbr14-unstrat	Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR (subgroup)
t9-1a-eff-smd-strat-BNWSYMBR	Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
t9-1a-eff-smd-unstrat-BNWSYMBR	Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP (subgroup)
t8-4-eff-resp-bsymcd14-strat	Proportion of participants who subsequently develop signs and symptoms (CDC-definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
t8-4-eff-resp-bsymcd14-unstrat	Proportion of participants who subsequently develop signs and symptoms (CDC-definition) within 14 days of a positive RT-qPCR at baseline or during the EAP (subgroup)
t9-2a-eff-smd-strat-BNWSYMCD	Number of weeks of symptomatic SARS-CoV-2 infection (CDC-definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
t9-2a-eff-smd-unstrat-BNWSYMCD	Number of weeks of symptomatic SARS-CoV-2 infection (CDC-definition) within 14 days of a positive RT-qPCR at baseline or during the EAP (subgroup)
t8-5-eff-resp-bsymst14-strat	Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
t8-5-eff-resp-bsymst14-unstrat	Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP (subgroup)
t9-3a-eff-smd-strat-BNWSYMST	Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
t9-3a-eff-smd-unstrat-BNWSYMST	Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP (subgroup)
t8-1-eff-resp-dth29-strat	All-cause death at EAP
t8-1-eff-resp-dth29-unstrat	All-cause death at EAP (subgroup)
t8-2-eff-resp-dthfu-strat	All-cause death at End of Follow-Up
t8-2-eff-resp-dthfu-unstrat	All-cause death at End of Follow-Up (subgroup)
t8-6-eff-resp-bhoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
t8-6-eff-resp-bhoer-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death (subgroup)
t8-7-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
t8-7-eff-resp-hoeruc-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death (subgroup)
t8-8-eff-resp-bmaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t8-8-eff-resp-bmaveru-unstrat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
t9-4a-eff-smd-strat-BNMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t9-4a-eff-smd-unstrat-BNMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
t8-9-eff-resp-bhosp-strat	Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t8-9-eff-resp-bhosp-unstrat	Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
t9-5a-eff-smd-strat-BNDHOSP	Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t9-5a-eff-smd-unstrat-BNDHOSP	Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)

t9-6a-eff-smd-strat-BNDABSEN	Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t9-6a-eff-smd-unstrat-BNDABSEN	Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
Ergänzende Dokumente	
t3-center-mFAS	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm
t4-dstat-demo	Demographic and Baseline Characteristics per arm
t5_1-mFAS	Table 5.1. Summary of Overall Patient Disposition
t5_3	Number of screened patients and reason for screening failure
t2-dstat-dur-mFAS	Duration of Follow-up by domain and arm
Verträglichkeit	
Hauptdokumente	
t12-1-ae-raw-anyae-unstrat-saf1	Any AEs (subgroup)
t12-2-ae-raw-anyae-unstrat-saf1	Any AEs (excluding disease related events) (subgroup)
t12-3-ae-raw-toxgrgt3-unstrat-saf1	AEs Grade >= 3 (subgroup)
t12-4-ae-raw-toxgr3-unstrat-saf1	AEs Grade >=3 (excluding disease related events) (subgroup)
t12-5-ae-raw-toxgr3-unstrat-saf1	AEs Grade 3 (subgroup)
t12-6-ae-raw-toxgr4-unstrat-saf1	AEs Grade 4(subgroup)
t12-7-ae-raw-toxgr5-unstrat-saf1	AEs Grade 5 (AEs leading to death) (subgroup)
t12-8-ae-raw-anysae-unstrat-saf1	Any SAEs (subgroup)
t12-9-ae-raw-anysaenr-unstrat-saf1	Any SAEs (excluding disease related events) (subgroup)
t12-10-ae-raw-aeltdis-unstrat-saf1	AEs leading to treatment discontinuation(subgroup)
AESI	
t12-11-ae-raw-isrge3-unstrat-saf1	Injection site reactions Grade >=3 (subgroup)
t12-12-ae-raw-sisr-unstrat-saf1	Serious injection site reactions(subgroup)
t12-13-ae-raw-hyprgr3-unstrat-saf1	Hypersensitivity reactions Grade >=3 (subgroup)
t12-14-ae-raw-shypr-unstrat-saf1	Serious hypersensitivity reactions (subgroup)
SOC/PT	
t13-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t13-2f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade >= 3
t13-3f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t13-4f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t13-5f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t13-6f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t14-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Ergänzende Dokumente	
t10-ae-resolved-general	AE resolved general
t2-dstat-dur-SAF	Duration of Follow-up by domain and arm Safety Analysis Set

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Wirksamkeit

Hauptdokumente

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	34	21,9	156	100	53	34	0,54	Algorithm converged.	0,33	0,9	-12,039	Algorithm converged.	-21,9	-2,16	0,65	Algorithm converged.	0,45	0,93	0,017		1,55	Algorithm converged.	1,07	2,24		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk			
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	34	21,9	156	100	53	34	0,55	Algorithm converged.	0,33	0,9	-12,039	Algorithm converged.	-21,9	-2,16	0,65	Algorithm converged.	0,45	0,93	0,018		1,55	Algorithm converged.	1,07	2,24
Sex	Male	80	51,6	19	23,8	71	45,5	17	23,9	0,99	Algorithm converged.	0,47	2,09	-0,194	Algorithm converged.	-13,8	13,43	0,99	Algorithm converged.	0,56	1,76	0,978	0,055	1,01	Algorithm converged.	0,57	1,78
	Female	75	48,4	15	20	85	54,5	36	42,4	0,34	Algorithm converged.	0,17	0,69	-22,353	Algorithm converged.	-36,2	-8,49	0,47	Algorithm converged.	0,28	0,79	0,003		2,12	Algorithm converged.	1,26	3,55
Age	12-17	21	13,5	2	9,5	17	10,9	8	47,1	0,12	Algorithm converged.	0,02	0,68	-37,535	Algorithm converged.	-64,4	-10,7	0,2	Algorithm converged.	0,05	0,83	0,023	0,0418	4,94	Algorithm converged.	1,2	20,3
	18-49	83	53,5	24	28,9	82	52,6	26	31,7	0,88	Algorithm converged.	0,45	1,7	-2,792	Algorithm converged.	-16,8	11,23	0,91	Algorithm converged.	0,57	1,45	0,697		1,1	Algorithm converged.	0,69	1,74
	>=50	51	32,9	8	15,7	57	36,5	19	33,3	0,37	Algorithm converged.	0,15	0,95	-17,647	Algorithm converged.	-33,4	-1,86	0,47	Algorithm converged.	0,23	0,98	0,035		2,13	Algorithm converged.	1,02	4,43
Region	US	137	88,4	30	21,9	136	87,2	48	35,3	0,51	Algorithm converged.	0,3	0,88	-13,396	Algorithm converged.	-24	-2,79	0,62	Algorithm converged.	0,42	0,92	0,015	0,5667	1,61	Algorithm converged.	1,09	2,38
	ex-US	18	11,6	4	22,2	20	12,8	5	25	0,86	Algorithm converged.	0,19	3,85	-2,778	Algorithm converged.	-29,8	24,22	0,89	Algorithm converged.	0,28	2,81	1		1,13	Algorithm converged.	0,36	3,55

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	34	21,9	156	100	53	34	0,55	Algorithm converged.	0,33	0,9	-12,039	Algorithm converged.	-21,9	-2,16	0,65	Algorithm converged.	0,45	0,93	0,018		1,55	Algorithm converged.	1,07	2,24		
BMI	BMI < 30 kg/m2	96	61,9	23	24	112	71,8	38	33,9	0,61	Algorithm converged.	0,33	1,13	-9,97	Algorithm converged.	-22,2	2,27	0,71	Algorithm converged.	0,45	1,1	0,116	0,5205	1,42	Algorithm converged.	0,91	2,2		
	BMI >= 30 kg/m2	58	37,4	11	19	40	25,6	14	35	0,43	Algorithm converged.	0,17	1,09	-16,034	Algorithm converged.	-33,9	1,86	0,54	Algorithm converged.	0,27	1,07	0,075		1,85	Algorithm converged.	0,94	3,64		
	Unknown/not reported	1	0,6	0	0	4	2,6	1	25	0	Algorithm converged.	NE	NE	-25	Algorithm converged.	-67,4	17,43	NE	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE	
Total household size including the household members not participating this study	2	60	38,7	10	16,7	66	42,3	25	37,9	0,33	Algorithm converged.	0,14	0,76	-21,212	Algorithm converged.	-36,2	-6,18	0,44	Algorithm converged.	0,23	0,84	0,008	0,1209	2,27	Algorithm converged.	1,19	4,33		
	>2	95	61,3	24	25,3	90	57,7	28	31,1	0,75	Algorithm converged.	0,39	1,42	-5,848	Algorithm converged.	-18,8	7,11	0,81	Algorithm converged.	0,51	1,29	0,378		1,23	Algorithm converged.	0,78	1,96		
Baseline high risk factor	Yes	45	29	10	22,2	54	34,6	18	33,3	0,57	Algorithm converged.	0,23	1,41	-11,111	Algorithm converged.	-28,6	6,37	0,67	Algorithm converged.	0,34	1,3	0,224	0,9077	1,5	Algorithm converged.	0,77	2,91		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	34	21,9	156	100	53	34	0,55		Algorithm converged.	0,33	0,9	-12,039		Algorithm converged.	-21,9	-2,16	0,65		Algorithm converged.	0,45	0,93	0,018		1,55		Algorithm converged.	1,07	2,24
	No	110	71	24	21,8	102	65,4	35	34,3	0,53		Algorithm converged.	0,29	0,98	-12,496		Algorithm converged.	-24,5	-0,48	0,64		Algorithm converged.	0,41	0,99	0,043		1,57		Algorithm converged.	1,01	2,45
Race	White	129	83,2	26	20,2	134	85,9	44	32,8	0,52		Algorithm converged.	0,29	0,91	-12,681		Algorithm converged.	-23,2	-2,14	0,61		Algorithm converged.	0,4	0,93	0,02	0,7401	1,63		Algorithm converged.	1,07	2,48
	Black or African American	8	5,2	2	25	10	6,4	2	20	1,33		Algorithm converged.	0,14	12,4	5		Algorithm converged.	-33,9	43,92	1,25		Algorithm converged.	0,22	7,02	1		0,8		Algorithm converged.	0,14	4,49
	Other	12	7,7	4	33,3	8	5,1	4	50	0,5		Algorithm converged.	0,08	3,13	-16,667		Algorithm converged.	-60,4	27,06	0,67		Algorithm converged.	0,23	1,92	0,648		1,5		Algorithm converged.	0,52	4,32
	Unknown/Not Reported	6	3,9	2	33,3	4	2,6	3	75	0,17		Algorithm converged.	0,01	2,82	-41,667		Algorithm converged.	-98,4	15,11	0,44		Algorithm converged.	0,13	1,57	0,524		2,25		Algorithm converged.	0,63	7,97
Ethnicity	Hispanic or Latino	65	41,9	12	18,5	58	37,2	13	22,4	0,78		Algorithm converged.	0,33	1,89	-3,952		Algorithm converged.	-18,2	10,34	0,82		Algorithm converged.	0,41	1,66	0,588	0,4353	1,21		Algorithm converged.	0,6	2,45
	Not Hispanic or Latino	89	57,4	22	24,7	96	61,5	40	41,7	0,46		Algorithm converged.	0,24	0,86	-16,948		Algorithm converged.	-30,3	-3,62	0,59		Algorithm converged.	0,38	0,91	0,015		1,69		Algorithm converged.	1,09	2,6
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE *		Algorithm not	NE	NE	NE *		Algorithm not	NE	NE	NE *		Algorithm not	NE	NE	NE		NE *		Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	34	21,9	156	100	53	34	0,55		Algorithm converged.	0,33	0,9	-12,039		Algorithm converged.	-21,9	-2,16	0,65		Algorithm converged.	0,45	0,93	0,018		1,55		Algorithm converged.	1,07	2,24		
Healthcare worker	Yes	9	5,8	3	33,3	10	6,4	5	50	0,5		Algorithm converged.	0,08	3,21	-16,667		Algorithm converged.	-60,4	27,02	0,67		Algorithm converged.	0,22	2,03	0,65	0,9762	1,5		Algorithm converged.	0,49	4,56		
	No	144	92,9	31	21,5	146	93,6	48	32,9	0,56		Algorithm converged.	0,33	0,95	-11,349		Algorithm converged.	-21,5	-1,19	0,65		Algorithm converged.	0,44	0,97	0,03		1,53		Algorithm converged.	1,04	2,25		
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE		
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	29	27,6	103	66	36	35	0,71		Algorithm converged.	0,39	1,28	-7,332		Algorithm converged.	-19,9	5,23	0,79		Algorithm converged.	0,53	1,19	0,255	0,0522	1,27		Algorithm converged.	0,84	1,9		
	No	50	32,3	5	10	53	34	17	32,1	0,24		Algorithm converged.	0,08	0,7	-22,075		Algorithm converged.	-37,1	-7,01	0,31		Algorithm converged.	0,12	0,78	0,008		3,21		Algorithm converged.	1,28	8,04		
Local test result of diagnostic assay for SARS-CoV-2	Positive	90	58,1	23	25,6	82	52,6	28	34,1	0,66		Algorithm converged.	0,34	1,28	-8,591		Algorithm converged.	-22,3	5,07	0,75		Algorithm converged.	0,47	1,19	0,219	0,9358	1,34		Algorithm converged.	0,84	2,12		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk								
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	155	100	34	21,9	156	100	53	34	0,55		Algorithm converged.	0,33	0,9	-12,039		Algorithm converged.	-21,9	-2,16	0,65		Algorithm converged.	0,45	0,93	0,018			1,55		Algorithm converged.	1,07	2,24
	Negative	44	28,4	7	15,9	49	31,4	10	20,4	0,74		Algorithm converged.	0,25	2,14	-4,499		Algorithm converged.	-20,1	11,13	0,78		Algorithm converged.	0,32	1,87	0,577			1,28		Algorithm converged.	0,53	3,08
	Unavailable	21	13,5	4	19	25	16	15	60	0,16		Algorithm converged.	0,04	0,61	-40,952		Algorithm converged.	-66,5	-15,4	0,32		Algorithm converged.	0,12	0,81	0,007			3,15		Algorithm converged.	1,23	8,05
Serology status	Seropositive	46	29,7	4	8,7	38	24,4	5	13,2	0,63		Algorithm converged.	0,16	2,53	-4,462		Algorithm converged.	-18	9,02	0,66		Algorithm converged.	0,19	2,29	0,725	0,956		1,51		Algorithm converged.	0,44	5,24
	Seronegative	100	64,5	29	29	104	66,7	44	42,3	0,56		Algorithm converged.	0,31	1	-13,308		Algorithm converged.	-26,3	-0,3	0,69		Algorithm converged.	0,47	1	0,048			1,46		Algorithm converged.	1	2,13
	Unclear serology status	9	5,8	1	11,1	14	9	4	28,6	0,31		Algorithm converged.	0,03	3,38	-17,46		Algorithm converged.	-48,8	13,87	0,39		Algorithm converged.	0,05	2,95	0,611			2,57		Algorithm converged.	0,34	19,5

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	155	100	34	21,94	101,714	0,656	0,18	0,351	0,3	156	100	53	33,97	206,286	1,322	0,27	1,036	0,3	-0,685	-1,325	-0,045	0,036	-0,238	-0,46	-0,02

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	34	21,94	101,714	0,656	0,176	0,656	0,231	156	100	53	33,97	206,286	1,322	0,273	1,322	0,23	-0,666	-1,307	-0,026	0,042	-0,232	-0,45	-0,01	NE				
Sex	Male	80	51,61	19	23,75	57,571	0,72	0,294	0,72	0,223	71	45,51	17	23,94	25,286	0,356	0,095	0,356	0,237	0,364	-0,279	1,006	0,265	0,181	-0,14	0,502	0,0031				
	Female	75	48,39	15	20	44,143	0,589	0,186	0,589	0,393	85	54,49	36	42,35	181	2,129	0,479	2,129	0,369	-1,541	-2,606	-0,476	0,005	-0,451	-0,76	-0,14					
Age	12-17	21	13,55	2	9,524	11	0,524	0,446	0,524	0,443	17	10,9	8	47,06	22,857	1,345	0,489	1,345	0,492	-0,821	-2,164	0,523	0,223	-0,396	-1,04	0,252	0,8527				
	18-49	83	53,55	24	28,92	75,143	0,905	0,294	0,905	0,372	82	52,56	26	31,71	115,429	1,408	0,44	1,408	0,375	-0,502	-1,545	0,54	0,343	-0,147	-0,45	0,159					
	>=50	51	32,9	8	15,69	15,571	0,305	0,149	0,305	0,307	57	36,54	19	33,33	68	1,193	0,376	1,193	0,29	-0,888	-1,724	-0,051	0,038	-0,403	-0,78	-0,02					
Region	US	137	88,39	30	21,9	95,714	0,699	0,198	0,699	0,26	136	87,18	48	35,29	198,143	1,457	0,311	1,457	0,261	-0,758	-1,482	-0,034	0,04	-0,249	-0,49	-0,01	0,4916				
	ex-US	18	11,61	4	22,22	6	0,333	0,19	0,333	0,184	20	12,82	5	25	8,143	0,407	0,17	0,407	0,175	-0,074	-0,589	0,441	0,773	-0,092	-0,74	0,553					
BMI	BMI < 30 kg/m2	96	61,94	23	23,96	83,714	0,872	0,273	0,872	0,287	112	71,8	38	33,93	131,429	1,173	0,276	1,173	0,266	-0,301	-1,072	0,47	0,442	-0,107	-0,38	0,166	0,2373				
	BMI >= 30 kg/m2	58	37,42	11	18,97	18	0,31	0,121	0,31	0,329	40	25,64	14	35	56,429	1,411	0,597	1,411	0,397	-1,1	-2,124	-0,077	0,035	-0,435	-0,84	-0,03					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	9,214	4	2,564	1	25	18,429	4,607	4,607	4,607	4,607	-4,607	-37,392	28,178	0,685	-0,364	-2,95	2,224					
Total household size including the household member(s) not participating this study																															
	2	60	38,71	10	16,67	42,286	0,705	0,321	0,705	0,436	66	42,31	25	37,88	111	1,682	0,495	1,682	0,416	-0,977	-2,169	0,215	0,107	-0,288	-0,64	0,063	0,4132				
	>2	95	61,29	24	25,26	59,429	0,626	0,205	0,626	0,253	90	57,69	28	31,11	95,286	1,059	0,304	1,059	0,26	-0,433	-1,15	0,284	0,235	-0,175	-0,46	0,114					
Baseline high risk factor	Yes	45	29,03	10	22,22	11,857	0,263	0,11	0,263	0,463	54	34,62	18	33,33	91,143	1,688	0,564	1,688	0,422	-1,424	-2,668	-0,181	0,025	-0,455	-0,85	-0,06	0,1132				
	No	110	70,97	24	21,82	89,857	0,817	0,243	0,817	0,262	102	65,39	35	34,31	115,143	1,129	0,293	1,129	0,272	-0,312	-1,058	0,434	0,41	-0,113	-0,38	0,157					
Race	White	129	83,23	26	20,16	71,143	0,551	0,163	0,551	0,225	134	85,9	44	32,84	159,857	1,193	0,266	1,193	0,221	-0,641	-1,262	-0,021	0,043	-0,25	-0,49	-0,01	0,3573				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	34	21,94	101,714	0,656	0,176	0,656	0,231	156	100	53	33,97	206,286	1,322	0,273	1,322	0,23	-0,666	-1,307	-0,026	0,042	-0,232	-0,45	-0,01	NE				
	Black or African American	8	5,161	2	25	1	0,125	0,091	0,125	0,563	10	6,41	2	20	7,143	0,714	0,668	0,714	0,504	-0,589	-2,192	1,013	0,447	-0,352	-1,31	0,605					
	Other	12	7,742	4	33,33	21,571	1,798	1,328	1,798	1,051	8	5,128	4	50	5,429	0,679	0,32	0,679	1,287	1,119	-2,372	4,611	0,509	0,294	-0,62	1,213					
	Unknown/Not Reported	6	3,871	2	33,33	8	1,333	1,25	1,333	2,61	4	2,564	3	75	33,857	8,464	4,832	8,464	3,197	-7,131	-16,649	2,387	0,122	-1,007	-2,35	0,337					
Ethnicity	Hispanic or Latino	65	41,94	12	18,46	22	0,338	0,138	0,338	0,193	58	37,18	13	22,41	45,143	0,778	0,254	0,778	0,204	-0,44	-0,996	0,116	0,12	-0,281	-0,64	0,074	0,608				
	Not Hispanic or Latino	89	57,42	22	24,72	79,714	0,896	0,288	0,896	0,368	96	61,54	40	41,67	161,143	1,679	0,413	1,679	0,354	-0,783	-1,791	0,225	0,127	-0,224	-0,51	0,065					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	2	1,282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,806	3	33,33	7,429	0,825	0,458	0,825	1,088	10	6,41	5	50	26,286	2,629	1,358	2,629	1,032	-1,803	-4,967	1,361	0,246	-0,528	-1,45	0,398	0,3701				
	No	144	92,9	31	21,53	94,286	0,655	0,187	0,655	0,238	146	93,59	48	32,88	180	1,233	0,277	1,233	0,236	-0,578	-1,238	0,081	0,086	-0,202	-0,43	0,028					
	Unknown/not reported	2	1,29	0	0	0	0	0	NE	NE	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,74	29	27,62	85,571	0,815	0,245	0,815	0,243	103	66,03	36	34,95	112,857	1,096	0,243	1,096	0,245	-0,281	-0,962	0,4	0,417	-0,112	-0,39	0,16	0,0943				
	No	50	32,26	5	10	16,143	0,323	0,176	0,323	0,496	53	33,97	17	32,08	93,429	1,763	0,651	1,763	0,482	-1,44	-2,812	-0,068	0,04	-0,407	-0,8	-0,02					
Test result of a local diagnostic assay for SARS-CoV-2	Positive	90	58,07	23	25,56	74,571	0,829	0,282	0,829	0,236	82	52,56	28	34,15	64,857	0,791	0,18	0,791	0,247	0,038	-0,637	0,713	0,912	0,017	-0,28	0,317	0,1867				
	Negative	44	28,39	7	15,91	12,429	0,282	0,122	0,282	0,423	49	31,41	10	20,41	53	1,082	0,541	1,082	0,401	-0,799	-1,957	0,359	0,174	-0,282	-0,69	0,127					
	Unavailable	21	13,55	4	19,05	14,714	0,701	0,395	0,701	0,941	25	16,03	15	60	88,429	3,537	1,12	3,537	0,862	-2,836	-5,408	-0,265	0,031	-0,647	-1,23	-0,06					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	155	100	34	21,94	101,714	0,656	0,176	0,656	0,231	156	100	53	33,97	206,286	1,322	0,273	1,322	0,23	-0,666	-1,307	-0,026	0,042	-0,232	-0,45	-0,01	NE		
Serology status	Seropositive	46	29,68	4	8,696	9,857	0,214	0,166	0,214	0,386	38	24,36	5	13,16	30,429	0,801	0,6	0,801	0,425	-0,586	-1,729	0,556	0,31	-0,222	-0,65	0,21	0,8402		
	Seronegative	100	64,52	29	29	89,571	0,896	0,259	0,896	0,308	104	66,67	44	42,31	170,286	1,637	0,343	1,637	0,302	-0,742	-1,593	0,109	0,087	-0,24	-0,52	0,035			
	Unclear serology status	9	5,806	1	11,11	2,286	0,254	0,254	0,254	0,275	14	8,974	4	28,57	5,571	0,398	0,23	0,398	0,22	-0,144	-0,877	0,589	0,687	-0,168	-1,03	0,688			

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

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Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference			Interaction Test			
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' q	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	34	21.94	101,714	0.656	0.18	0.656	0.23	156	100	53	33.97	206,286	1.322	0.27	1.322	0.23	-0.666	-1.307		-0.026	0.042	-0.232	-0.45	NE				
	Unavailable	21	13.55	4	19.05	14,714	0.701	0.4	0.701	0.94	25	16.03	15	60	88,429	3.537	1.12	3.537	0.86	-2.836	-5.408		-0.265	0.031	-0.647	-1.23	-0.06				
Serology status	Seropositive	46	29.68	4	8.696	9,857	0.214	0.17	0.214	0.39	38	24.36	5	13.16	30,429	0.801	0.6	0.801	0.43	-0.586	-1.729		0.556	0.31	-0.222	-0.65	0.21	0.8402			
	Seronegative	100	64.52	29	29	89,571	0.896	0.26	0.896	0.31	104	66.67	44	42.31	170,286	1.637	0.34	1.637	0.3	-0.742	-1.593		0.109	0.087	-0.24	-0.52	0.035				
	Unclear serology status	9	5.806	1	11.11	2,286	0.254	0.25	0.254	0.28	14	8.974	4	28.57	5,571	0.398	0.23	0.398	0.22	-0.144	-0.877		0.589	0.687	-0.168	-1.03	0.688				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	31	20	156	100	49	31,4	0,53	Algorithm converged.	0,32	0,9	-11,41	Algorithm converged.	-21	-1,78	0,64	Algorithm converged.	0,43	0,94	0,017		1,57	Algorithm converged.	1,06	2,32				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk			
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	31	20	156	100	49	31,4	0,55	Algorithm converged.	0,32	0,92	-11,41	Algorithm converged.	-21	-1,78	0,64	Algorithm converged.	0,43	0,94	0,022		1,57	Algorithm converged.	1,06	2,32
Sex	Male	80	51,6	17	21,3	71	45,5	15	21,1	1,01	Algorithm converged.	0,46	2,2	0,123	Algorithm converged.	-12,9	13,18	1,01	Algorithm converged.	0,54	1,86	0,985	0,0623	0,99	Algorithm converged.	0,54	1,84
	Female	75	48,4	14	18,7	85	54,5	34	40	0,34	Algorithm converged.	0,17	0,71	-21,333	Algorithm converged.	-35	-7,69	0,47	Algorithm converged.	0,27	0,8	0,003		2,14	Algorithm converged.	1,25	3,67
Age	12-17	21	13,5	2	9,5	17	10,9	8	47,1	0,12	Algorithm converged.	0,02	0,68	-37,535	Algorithm converged.	-64,4	-10,7	0,2	Algorithm converged.	0,05	0,83	0,023	0,0389	4,94	Algorithm converged.	1,2	20,3
	18-49	83	53,5	23	27,7	82	52,6	25	30,5	0,87	Algorithm converged.	0,45	1,71	-2,777	Algorithm converged.	-16,6	11,08	0,91	Algorithm converged.	0,56	1,46	0,695		1,1	Algorithm converged.	0,68	1,77
	>=50	51	32,9	6	11,8	57	36,5	16	28,1	0,34	Algorithm converged.	0,12	0,96	-16,305	Algorithm converged.	-30,9	-1,67	0,42	Algorithm converged.	0,18	0,99	0,037		2,39	Algorithm converged.	1,01	5,63
Region	US	137	88,4	28	20,4	136	87,2	45	33,1	0,52	Algorithm converged.	0,3	0,9	-12,65	Algorithm converged.	-23,1	-2,25	0,62	Algorithm converged.	0,41	0,93	0,018	0,6816	1,62	Algorithm converged.	1,08	2,43
	ex-US	18	11,6	3	16,7	20	12,8	4	20	0,8	Algorithm converged.	0,15	4,18	-3,333	Algorithm converged.	-27,9	21,24	0,83	Algorithm converged.	0,22	3,23	1		1,2	Algorithm converged.	0,31	4,65

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	31	20	156	100	49	31,4	0,55		Algorithm converged.	0,32	0,92	-11,41		Algorithm converged.	-21	-1,78	0,64		Algorithm converged.	0,43	0,94	0,022		1,57		Algorithm converged.	1,06	2,32		
BMI	BMI < 30 kg/m2	96	61,9	21	21,9	112	71,8	36	32,1	0,59		Algorithm converged.	0,32	1,11	-10,268		Algorithm converged.	-22,2	1,7	0,68		Algorithm converged.	0,43	1,08	0,099	0,7032	1,47		Algorithm converged.	0,92	2,34		
	BMI >= 30 kg/m2	58	37,4	10	17,2	40	25,6	12	30	0,49		Algorithm converged.	0,19	1,27	-12,759		Algorithm converged.	-30	4,45	0,57		Algorithm converged.	0,28	1,2	0,139		1,74		Algorithm converged.	0,83	3,63		
	Unknown/not reported	1	0,6	0	0	4	2,6	1	25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,4	17,43	NE	*	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE		
Total household size including the household members not participating this study	2	60	38,7	8	13,3	66	42,3	23	34,8	0,29		Algorithm converged.	0,12	0,71	-21,515		Algorithm converged.	-35,9	-7,16	0,38		Algorithm converged.	0,19	0,79	0,005	0,0669	2,61		Algorithm converged.	1,27	5,39		
	>2	95	61,3	23	24,2	90	57,7	26	28,9	0,79		Algorithm converged.	0,41	1,51	-4,678		Algorithm converged.	-17,4	8,04	0,84		Algorithm converged.	0,52	1,36	0,472		1,19		Algorithm converged.	0,74	1,93		
Baseline high risk factor	Yes	45	29	8	17,8	54	34,6	16	29,6	0,51		Algorithm converged.	0,2	1,34	-11,852		Algorithm converged.	-28,4	4,67	0,6		Algorithm converged.	0,28	1,27	0,173	0,8682	1,67		Algorithm converged.	0,79	3,53		

Test for interaction based on RR (Log-binomial regression).
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95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	31	20	156	100	49	31,4	0,55	Algorithm converged.	0,32	0,92	-11,41	Algorithm converged.	-21	-1,78	0,64	Algorithm converged.	0,43	0,94	0,022		1,57	Algorithm converged.	1,06	2,32		
	No	110	71	23	20,9	102	65,4	33	32,4	0,55	Algorithm converged.	0,3	1,03	-11,444	Algorithm converged.	-23,3	0,4	0,65	Algorithm converged.	0,41	1,02	0,06		1,55	Algorithm converged.	0,98	2,45		
Race	White	129	83,2	23	17,8	134	85,9	40	29,9	0,51	Algorithm converged.	0,28	0,91	-12,021	Algorithm converged.	-22,2	-1,84	0,6	Algorithm converged.	0,38	0,94	0,023	0,7231	1,67	Algorithm converged.	1,07	2,63		
	Black or African American	8	5,2	2	25	10	6,4	2	20	1,33	Algorithm converged.	0,14	12,4	5	Algorithm converged.	-33,9	43,92	1,25	Algorithm converged.	0,22	7,02	1		0,8	Algorithm converged.	0,14	4,49		
	Other	12	7,7	4	33,3	8	5,1	4	50	0,5	Algorithm converged.	0,08	3,13	-16,667	Algorithm converged.	-60,4	27,06	0,67	Algorithm converged.	0,23	1,92	0,648		1,5	Algorithm converged.	0,52	4,32		
	Unknown/Not Reported	6	3,9	2	33,3	4	2,6	3	75	0,17	Algorithm converged.	0,01	2,82	-41,667	Algorithm converged.	-98,4	15,11	0,44	Algorithm converged.	0,13	1,57	0,524		2,25	Algorithm converged.	0,63	7,97		
Ethnicity	Hispanic or Latino	65	41,9	11	16,9	58	37,2	13	22,4	0,71	Algorithm converged.	0,29	1,73	-5,491	Algorithm converged.	-19,6	8,59	0,76	Algorithm converged.	0,37	1,55	0,445	0,5979	1,32	Algorithm converged.	0,64	2,72		
	Not Hispanic or Latino	89	57,4	20	22,5	96	61,5	36	37,5	0,48	Algorithm converged.	0,25	0,92	-15,028	Algorithm converged.	-28	-2,03	0,6	Algorithm converged.	0,38	0,95	0,027		1,67	Algorithm converged.	1,05	2,65		
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE		NE *	Algorithm not	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	31	20	156	100	49	31,4	0,55	Algorithm converged.	0,32	0,92	-11,41	Algorithm converged.	-21	-1,78	0,64	Algorithm converged.	0,43	0,94	0,022		1,57	Algorithm converged.	1,06	2,32		
Healthcare worker	Yes	9	5,8	3	33,3	10	6,4	5	50	0,5	Algorithm converged.	0,08	3,21	-16,667	Algorithm converged.	-60,4	27,02	0,67	Algorithm converged.	0,22	2,03	0,65	0,957	1,5	Algorithm converged.	0,49	4,56		
	No	144	92,9	28	19,4	146	93,6	44	30,1	0,56	Algorithm converged.	0,32	0,96	-10,693	Algorithm converged.	-20,6	-0,83	0,65	Algorithm converged.	0,43	0,98	0,035		1,55	Algorithm converged.	1,02	2,35		
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE *	Algorithm not	NE	NE	NE	Algorithm not	NE	NE	NE	Algorithm not	NE	NE	NE		NE *	Algorithm not	NE	NE		
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	26	24,8	103	66	34	33	0,67	Algorithm converged.	0,37	1,22	-8,248	Algorithm converged.	-20,5	4,03	0,75	Algorithm converged.	0,49	1,16	0,19	0,1327	1,33	Algorithm converged.	0,87	2,05		
	No	50	32,3	5	10	53	34	15	28,3	0,28	Algorithm converged.	0,09	0,85	-18,302	Algorithm converged.	-33	-3,6	0,35	Algorithm converged.	0,14	0,9	0,025		2,83	Algorithm converged.	1,11	7,21		
Local test result of diagnostic assay for SARS-CoV-2	Positive	90	58,1	21	23,3	82	52,6	25	30,5	0,69	Algorithm converged.	0,35	1,37	-7,154	Algorithm converged.	-20,4	6,1	0,77	Algorithm converged.	0,47	1,26	0,291	0,7994	1,31	Algorithm converged.	0,79	2,15		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	31	20	156	100	49	31,4	0,55		Algorithm converged.	0,32	0,92	-11,41		Algorithm converged.	-21	-1,78	0,64		Algorithm converged.	0,43	0,94	0,022		1,57		Algorithm converged.	1,06	2,32
	Negative	44	28,4	6	13,6	49	31,4	10	20,4	0,62		Algorithm converged.	0,2	1,86	-6,772		Algorithm converged.	-21,9	8,4	0,67		Algorithm converged.	0,26	1,69	0,39		1,5		Algorithm converged.	0,59	3,78
	Unavailable	21	13,5	4	19	25	16	14	56	0,18		Algorithm converged.	0,05	0,71	-36,952		Algorithm converged.	-62,7	-11,3	0,34		Algorithm converged.	0,13	0,88	0,016		2,94		Algorithm converged.	1,14	7,58
Serology status	Seropositive	46	29,7	3	6,5	38	24,4	5	13,2	0,46		Algorithm converged.	0,1	2,07	-6,636		Algorithm converged.	-19,5	6,26	0,5		Algorithm converged.	0,13	1,94	0,458	0,6523	2,02		Algorithm converged.	0,52	7,9
	Seronegative	100	64,5	27	27	104	66,7	41	39,4	0,57		Algorithm converged.	0,31	1,03	-12,423		Algorithm converged.	-25,2	0,38	0,68		Algorithm converged.	0,46	1,02	0,061		1,46		Algorithm converged.	0,98	2,18
	Unclear serology status	9	5,8	1	11,1	14	9	3	21,4	0,46		Algorithm converged.	0,04	5,26	-10,317		Algorithm converged.	-40	19,41	0,52		Algorithm converged.	0,06	4,25	1		1,93		Algorithm converged.	0,24	15,8

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	155	100	31	20	99,571	0,642	0,18	0,309	0,3	156	100	49	31,4	212,571	1,363	0,28	1,052	0,3	-0,743	-1,39	-0,096	0,025	-0,256	-0,48	-0,03

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	31	20	99,571	0,642	0,176	0,642	0,233	156	100	49	31,41	212,571	1,363	0,278	1,363	0,232	-0,72	-1,368	-0,072	0,029	-0,247	-0,47	-0,03	NE				
Sex	Male	80	51,61	17	21,25	56,857	0,711	0,295	0,711	0,237	71	45,51	15	21,13	34,429	0,485	0,157	0,485	0,252	0,226	-0,458	0,909	0,515	0,106	-0,22	0,426	0,0073				
	Female	75	48,39	14	18,67	42,714	0,57	0,185	0,57	0,393	85	54,49	34	40	178,143	2,096	0,48	2,096	0,369	-1,526	-2,592	-0,46	0,005	-0,446	-0,76	-0,14					
Age	12-17	21	13,55	2	9,524	11	0,524	0,446	0,524	0,443	17	10,9	8	47,06	22,857	1,345	0,489	1,345	0,492	-0,821	-2,164	0,523	0,223	-0,396	-1,04	0,252	0,9679				
	18-49	83	53,55	23	27,71	73,714	0,888	0,294	0,888	0,378	82	52,56	25	30,49	126,286	1,54	0,45	1,54	0,38	-0,652	-1,71	0,406	0,225	-0,189	-0,5	0,117					
	>=50	51	32,9	6	11,77	14,857	0,291	0,15	0,291	0,307	57	36,54	16	28,07	63,429	1,113	0,377	1,113	0,291	-0,821	-1,66	0,017	0,055	-0,372	-0,75	0,008					
Region	US	137	88,39	28	20,44	93,857	0,685	0,197	0,685	0,262	136	87,18	45	33,09	205,286	1,509	0,316	1,509	0,263	-0,824	-1,557	-0,092	0,027	-0,268	-0,51	-0,03	0,4398				
	ex-US	18	11,61	3	16,67	5,714	0,317	0,191	0,317	0,184	20	12,82	4	20	7,286	0,364	0,169	0,364	0,175	-0,047	-0,562	0,468	0,855	-0,059	-0,7	0,586					
BMI	BMI < 30 kg/m2	96	61,94	21	21,88	82,857	0,863	0,273	0,863	0,291	112	71,8	36	32,14	135	1,205	0,283	1,205	0,27	-0,342	-1,125	0,44	0,389	-0,12	-0,39	0,154	0,2158				
	BMI >= 30 kg/m2	58	37,42	10	17,24	16,714	0,288	0,117	0,288	0,333	40	25,64	12	30	59,143	1,479	0,605	1,479	0,401	-1,19	-2,224	-0,157	0,024	-0,466	-0,87	-0,06					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	9,214	4	2,564	1	25	18,429	4,607	4,607	4,607	4,607	-4,607	-37,392	28,178	0,685	-0,364	-2,95	2,224					
Total household size including the household member(s) not participating this study																															
	2	60	38,71	8	13,33	41,429	0,69	0,321	0,69	0,444	66	42,31	23	34,85	118,429	1,794	0,507	1,794	0,424	-1,104	-2,319	0,111	0,075	-0,319	-0,67	0,032	0,3187				
	>2	95	61,29	23	24,21	58,143	0,612	0,204	0,612	0,253	90	57,69	26	28,89	94,143	1,046	0,304	1,046	0,26	-0,434	-1,15	0,282	0,234	-0,175	-0,46	0,114					
Baseline high risk factor	Yes	45	29,03	8	17,78	10,286	0,229	0,102	0,229	0,463	54	34,62	16	29,63	88,714	1,643	0,565	1,643	0,422	-1,414	-2,658	-0,171	0,026	-0,452	-0,85	-0,06	0,1546				
	No	110	70,97	23	20,91	89,286	0,812	0,243	0,812	0,268	102	65,39	33	32,35	123,857	1,214	0,303	1,214	0,278	-0,403	-1,163	0,358	0,298	-0,143	-0,41	0,127					
Race	White	129	83,23	23	17,83	69,857	0,542	0,163	0,542	0,229	134	85,9	40	29,85	166,143	1,24	0,273	1,24	0,225	-0,698	-1,33	-0,066	0,03	-0,268	-0,51	-0,03	0,3754				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		Interaction Test	
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)
All	n/a	155	100	31	20	99,571	0,642	0,176	0,642	0,233	156	100	49	31,41	212,571	1,363	0,278	1,363	0,232	-0,72	-1,368	-0,072	0,029	-0,247	-0,47	-0,03	NE
	Black or African American	8	5,161	2	25	1	0,125	0,091	0,125	0,563	10	6,41	2	20	7,143	0,714	0,668	0,714	0,504	-0,589	-2,192	1,013	0,447	-0,352	-1,31	0,605	
	Other	12	7,742	4	33,33	20,714	1,726	1,326	1,726	1,05	8	5,128	4	50	5,429	0,679	0,32	0,679	1,286	1,048	-2,439	4,534	0,536	0,276	-0,64	1,194	
	Unknown/Not Reported	6	3,871	2	33,33	8	1,333	1,25	1,333	2,61	4	2,564	3	75	33,857	8,464	4,832	8,464	3,197	-7,131	-16,649	2,387	0,122	-1,007	-2,35	0,337	
Ethnicity	Hispanic or Latino	65	41,94	11	16,92	21,429	0,33	0,138	0,33	0,199	58	37,18	13	22,41	49,714	0,857	0,266	0,857	0,211	-0,527	-1,102	0,047	0,072	-0,326	-0,68	0,029	0,6675
	Not Hispanic or Latino	89	57,42	20	22,47	78,143	0,878	0,288	0,878	0,372	96	61,54	36	37,5	162,857	1,696	0,419	1,696	0,358	-0,818	-1,837	0,2	0,115	-0,232	-0,52	0,057	
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	2	1,282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	
Healthcare worker	Yes	9	5,806	3	33,33	7,429	0,825	0,458	0,825	1,161	10	6,41	5	50	31,857	3,186	1,457	3,186	1,101	-2,36	-5,736	1,015	0,158	-0,648	-1,57	0,278	0,2013
	No	144	92,9	28	19,44	92,143	0,64	0,187	0,64	0,239	146	93,59	44	30,14	180,714	1,238	0,278	1,238	0,237	-0,598	-1,26	0,064	0,077	-0,208	-0,44	0,022	
	Unknown/not reported	2	1,29	0	0	0	0	0	NE	NE	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																											
	Yes	105	67,74	26	24,76	84,286	0,803	0,245	0,803	0,245	103	66,03	34	33,01	114,429	1,111	0,247	1,111	0,247	-0,308	-0,994	0,378	0,377	-0,122	-0,4	0,15	0,0773
	No	50	32,26	5	10	15,286	0,306	0,172	0,306	0,504	53	33,97	15	28,3	98,143	1,852	0,662	1,852	0,489	-1,546	-2,939	-0,153	0,03	-0,431	-0,82	-0,04	
Test result of a local diagnostic assay for SARS-CoV-2																											
	Positive	90	58,07	21	23,33	73,857	0,821	0,282	0,821	0,239	82	52,56	25	30,49	64,857	0,791	0,188	0,791	0,25	0,03	-0,653	0,712	0,932	0,013	-0,29	0,313	0,1665
	Negative	44	28,39	6	13,64	11	0,25	0,115	0,25	0,422	49	31,41	10	20,41	54	1,102	0,541	1,102	0,4	-0,852	-2,008	0,304	0,147	-0,302	-0,71	0,108	
	Unavailable	21	13,55	4	19,05	14,714	0,701	0,395	0,701	0,952	25	16,03	14	56	93,714	3,749	1,134	3,749	0,872	-3,048	-5,649	-0,447	0,023	-0,687	-1,27	-0,1	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		Interaction Test			
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	155	100	31	20	99,571	0,642	0,176	0,642	0,233	156	100	49	31,41	212,571	1,363	0,278	1,363	0,232	-0,72	-1,368	-0,072	0,029	-0,247	-0,47	-0,03	NE		
Serology status	Seropositive	46	29,68	3	6,522	9,571	0,208	0,166	0,208	0,386	38	24,36	5	13,16	30,429	0,801	0,6	0,801	0,425	-0,593	-1,736	0,55	0,305	-0,224	-0,66	0,208	0,7615		
	Seronegative	100	64,52	27	27	87,714	0,877	0,258	0,877	0,313	104	66,67	41	39,42	177,429	1,706	0,35	1,706	0,306	-0,829	-1,692	0,034	0,06	-0,264	-0,54	0,011			
	Unclear serology status	9	5,806	1	11,11	2,286	0,254	0,254	0,254	0,274	14	8,974	3	21,43	4,714	0,337	0,229	0,337	0,22	-0,083	-0,813	0,647	0,816	-0,097	-0,95	0,759			

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference		Interaction Test				
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' q	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	31	20	99,571	0,642	0,18	0,642	0,23	156	100	49	31,41	212,571	1,363	0,28	1,363	0,23	-0,72	-1,368	-0,072	0,029	-0,247	-0,47	-0,03	NE				
	Unavailable	21	13,55	4	19,05	14,714	0,701	0,4	0,701	0,95	25	16,03	14	56	93,714	3,749	1,13	3,749	0,87	-3,048	-5,649	-0,447	0,023	-0,687	-1,27	-0,1					
Serology status	Seropositive	46	29,68	3	6,522	9,571	0,208	0,17	0,208	0,39	38	24,36	5	13,16	30,429	0,801	0,6	0,801	0,43	-0,593	-1,736	0,55	0,305	-0,224	-0,66	0,208	0,7615				
	Seronegative	100	64,52	27	27	87,714	0,877	0,26	0,877	0,31	104	66,67	41	39,42	177,429	1,706	0,35	1,706	0,31	-0,829	-1,692	0,034	0,06	-0,264	-0,54	0,011					
	Unclear serology status	9	5,806	1	11,11	2,286	0,254	0,25	0,254	0,27	14	8,974	3	21,43	4,714	0,337	0,23	0,337	0,22	-0,083	-0,813	0,647	0,816	-0,097	-0,95	0,759					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4	Algorithm converged.	0,18	0,87	-8,292	Algorithm converged.	-15,1	-1,52	0,44	Algorithm converged.	0,22	0,89	0,019		2,29	Algorithm converged.	1,13	4,64		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4	Algorithm converged.	0,18	0,87	-8,292	Algorithm converged.	-15,1	-1,52	0,44	Algorithm converged.	0,22	0,89	0,018		2,29	Algorithm converged.	1,13	4,64		
Sex	Male	80	51,6	6	7,5	71	45,5	7	9,9	0,74	Algorithm converged.	0,24	2,32	-2,359	Algorithm converged.	-11,4	6,66	0,76	Algorithm converged.	0,27	2,16	0,607	0,1833	1,31	Algorithm converged.	0,46	3,73		
	Female	75	48,4	4	5,3	85	54,5	16	18,8	0,24	Algorithm converged.	0,08	0,76	-13,49	Algorithm converged.	-23,2	-3,75	0,28	Algorithm converged.	0,1	0,81	0,015		3,53	Algorithm converged.	1,23	10,1		
Age	12-17	21	13,5	0	0	17	10,9	3	17,6	0	Algorithm converged.	NE	NE	-17,647	Algorithm converged.	-35,8	0,47	NE	Algorithm not	NE	NE	0,081	0,2074	NE	Algorithm not	NE	NE		
	18-49	83	53,5	5	6	82	52,6	11	13,4	0,41	Algorithm converged.	0,14	1,25	-7,391	Algorithm converged.	-16,4	1,59	0,45	Algorithm converged.	0,16	1,24	0,123		2,23	Algorithm converged.	0,81	6,13		
	>=50	51	32,9	5	9,8	57	36,5	9	15,8	0,58	Algorithm converged.	0,18	1,86	-5,986	Algorithm converged.	-18,5	6,51	0,62	Algorithm converged.	0,22	1,73	0,403		1,61	Algorithm converged.	0,58	4,49		
Region	US	137	88,4	10	7,3	136	87,2	21	15,4	0,43	Algorithm converged.	0,19	0,95	-8,142	Algorithm converged.	-15,6	-0,67	0,47	Algorithm converged.	0,23	0,97	0,034	0,2354	2,12	Algorithm converged.	1,04	4,32		
	ex-US	18	11,6	0	0	20	12,8	2	10	0	Algorithm converged.	NE	NE	-10	Algorithm converged.	-23,2	3,15	NE	Algorithm not	NE	NE	0,488		NE	Algorithm not	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4	Algorithm converged.	0,18	0,87	-8,292	Algorithm converged.	-15,1	-1,52	0,44	Algorithm converged.	0,22	0,89	0,018		2,29	Algorithm converged.	1,13	4,64		
BMI	BMI < 30 kg/m2	96	61,9	7	7,3	112	71,8	18	16,1	0,41	Algorithm converged.	0,16	1,03	-8,78	Algorithm converged.	-17,3	-0,22	0,45	Algorithm converged.	0,2	1,04	0,053	0,9103	2,2	Algorithm converged.	0,96	5,05		
	BMI >= 30 kg/m2	58	37,4	3	5,2	40	25,6	5	12,5	0,38	Algorithm converged.	0,09	1,7	-7,328	Algorithm converged.	-19,1	4,4	0,41	Algorithm converged.	0,1	1,63	0,265		2,42	Algorithm converged.	0,61	9,54		
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE		NE *	Algorithm not	NE	NE		
Total household size including the household members not participating this study	2	60	38,7	5	8,3	66	42,3	14	21,2	0,34	Algorithm converged.	0,11	1	-12,879	Algorithm converged.	-25	-0,79	0,39	Algorithm converged.	0,15	1,03	0,05	0,6875	2,55	Algorithm converged.	0,98	6,64		
	>2	95	61,3	5	5,3	90	57,7	9	10	0,5	Algorithm converged.	0,16	1,55	-4,737	Algorithm converged.	-12,4	2,92	0,53	Algorithm converged.	0,18	1,51	0,272		1,9	Algorithm converged.	0,66	5,45		
Baseline high risk factor	Yes	45	29	3	6,7	54	34,6	7	13	0,48	Algorithm converged.	0,12	1,97	-6,296	Algorithm converged.	-17,9	5,25	0,51	Algorithm converged.	0,14	1,87	0,34	0,7654	1,94	Algorithm converged.	0,53	7,09		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4	Algorithm converged.	0,18	0,87	-8,292	Algorithm converged.	-15,1	-1,52	0,44	Algorithm converged.	0,22	0,89	0,018		2,29	Algorithm converged.	1,13	4,64		
	No	110	71	7	6,4	102	65,4	16	15,7	0,37	Algorithm converged.	0,14	0,93	-9,323	Algorithm converged.	-17,7	-0,92	0,41	Algorithm converged.	0,17	0,95	0,03		2,46	Algorithm converged.	1,06	5,75		
Race	White	129	83,2	6	4,7	134	85,9	20	14,9	0,28	Algorithm converged.	0,11	0,72	-10,274	Algorithm converged.	-17,3	-3,23	0,31	Algorithm converged.	0,13	0,75	0,005	0,0732	3,21	Algorithm converged.	1,33	7,73		
	Black or African American	8	5,2	1	12,5	10	6,4	1	10	1,29	Algorithm converged.	0,07	24,4	2,5	Algorithm converged.	-27	32	1,25	Algorithm converged.	0,09	17	1		0,8	Algorithm converged.	0,06	10,9		
	Other	12	7,7	2	16,7	8	5,1	0	0	NE *	Algorithm not	NE	NE	16,667	Algorithm converged.	-4,42	37,8	NE *	Algorithm not	NE	NE	0,495		NE *	Algorithm not	NE	NE		
	Unknown/Not Reported	6	3,9	1	16,7	4	2,6	2	50	0,2	Algorithm converged.	0,01	3,66	-33,333	Algorithm converged.	-90,7	24	0,33	Algorithm converged.	0,04	2,56	0,5		3	Algorithm converged.	0,39	23,1		
Ethnicity	Hispanic or Latino	65	41,9	3	4,6	58	37,2	6	10,3	0,42	Algorithm converged.	0,1	1,76	-5,729	Algorithm converged.	-15,1	3,62	0,45	Algorithm converged.	0,12	1,7	0,304	0,9955	2,24	Algorithm converged.	0,59	8,56		
	Not Hispanic or Latino	89	57,4	7	7,9	96	61,5	17	17,7	0,4	Algorithm converged.	0,16	1,01	-9,843	Algorithm converged.	-19,3	-0,38	0,44	Algorithm converged.	0,19	1,02	0,047		2,25	Algorithm converged.	0,98	5,17		
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE *	Algorithm not	NE	NE	NE		NE *	Algorithm not	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4	Algorithm converged.	0,18	0,87	-8,292	Algorithm converged.	-15,1	-1,52	0,44	Algorithm converged.	0,22	0,89	0,018		2,29	Algorithm converged.	1,13	4,64		
Healthcare worker	Yes	9	5,8	2	22,2	10	6,4	4	40	0,43	Algorithm converged.	0,06	3,22	-17,778	Algorithm converged.	-58,5	23	0,56	Algorithm converged.	0,13	2,34	0,629	0,7573	1,8	Algorithm converged.	0,43	7,59		
	No	144	92,9	8	5,6	146	93,6	19	13	0,39	Algorithm converged.	0,17	0,93	-7,458	Algorithm converged.	-14,1	-0,84	0,43	Algorithm converged.	0,19	0,94	0,029		2,34	Algorithm converged.	1,06	5,18		
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE *	Algorithm not	NE	NE	NE	Algorithm not	NE	NE	NE	Algorithm not	NE	NE	NE		NE *	Algorithm not	NE	NE		
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	8	7,6	103	66	17	16,5	0,42	Algorithm converged.	0,17	1,02	-8,886	Algorithm converged.	-17,7	-0,1	0,46	Algorithm converged.	0,21	1,02	0,049	0,7607	2,17	Algorithm converged.	0,98	4,8		
	No	50	32,3	2	4	53	34	6	11,3	0,33	Algorithm converged.	0,06	1,7	-7,321	Algorithm converged.	-17,4	2,79	0,35	Algorithm converged.	0,07	1,67	0,271		2,83	Algorithm converged.	0,6	13,4		
Local test result of diagnostic assay for SARS-CoV-2	Positive	90	58,1	5	5,6	82	52,6	12	14,6	0,34	Algorithm converged.	0,12	1,02	-9,079	Algorithm converged.	-18,1	-0,08	0,38	Algorithm converged.	0,14	1,03	0,071	0,8681	2,63	Algorithm converged.	0,97	7,16		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolut e Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL	
All	n/a	155	100	10	6,5	156	100	23	14,7	0,4		Algorithm converged.	0,18	0,87	-8,292		Algorithm converged.	-15,1	-1,52	0,44		Algorithm converged.	0,22	0,89	0,018			2,29		Algorithm converged.	1,13	4,64
	Negative	44	28,4	2	4,5	49	31,4	5	10,2	0,42		Algorithm converged.	0,08	2,28	-5,659		Algorithm converged.	-16,1	4,82	0,45		Algorithm converged.	0,09	2,18	0,44			2,24		Algorithm converged.	0,46	11
	Unavailable	21	13,5	3	14,3	25	16	6	24	0,53		Algorithm converged.	0,11	2,43	-9,714		Algorithm converged.	-32,2	12,7	0,6		Algorithm converged.	0,17	2,1	0,478			1,68		Algorithm converged.	0,48	5,91
Serology status	Seropositive	46	29,7	0	0	38	24,4	1	2,6	0		Algorithm converged.	NE	NE	-2,632		Algorithm converged.	-7,72	2,46	NE	*	Algorithm not	NE	NE	0,452	0,3261	NE	*	Algorithm not	NE	NE	
	Seronegative	100	64,5	10	10	104	66,7	20	19,2	0,47		Algorithm converged.	0,21	1,05	-9,231		Algorithm converged.	-18,8	0,36	0,52		Algorithm converged.	0,26	1,06	0,063			1,92		Algorithm converged.	0,95	3,9
	Unclear serology status	9	5,8	0	0	14	9	2	14,3	0		Algorithm converged.	NE	NE	-14,286		Algorithm converged.	-32,6	4,04	NE	*	Algorithm not	NE	NE	0,502			NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	n	%	n	%	w	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	155	100	10	6,45	40	0,258	0,12	0,137	0,16	156	100	23	14,74	75,143	0,482	0,13	0,364	0,16	-0,227	-0,574	0,12	0,199	-0,146	-0,37	0,08

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	155	100	10	6,452	40	0,258	0,122	0,258	0,125	156	100	23	14,74	75,143	0,482	0,127	0,482	0,124	-0,224	-0,57	0,123	0,205	-0,144	-0,37	0,079	NE		
Sex	Male	80	51,61	6	7,5	22,286	0,279	0,206	0,279	0,16	71	45,51	7	9,859	15,429	0,217	0,085	0,217	0,17	0,061	-0,399	0,521	0,793	0,043	-0,28	0,363	0,1346		
	Female	75	48,39	4	5,333	17,714	0,236	0,125	0,236	0,191	85	54,49	16	18,82	59,714	0,703	0,22	0,703	0,179	-0,466	-0,983	0,05	0,077	-0,281	-0,59	0,03			
Age	12-17	21	13,55	0	0	0	0	0	0	0,174	17	10,9	3	17,65	9	0,529	0,289	0,529	0,193	-0,529	-1,056	-0,003	0,049	-0,652	-1,3	-0	0,8113		
	18-49	83	53,55	5	6,024	26,143	0,315	0,208	0,315	0,208	82	52,56	11	13,42	40,143	0,49	0,208	0,49	0,209	-0,175	-0,756	0,407	0,554	-0,092	-0,4	0,214			
	>=50	51	32,9	5	9,804	13,857	0,272	0,149	0,272	0,158	57	36,54	9	15,79	26	0,456	0,157	0,456	0,15	-0,184	-0,617	0,248	0,4	-0,162	-0,54	0,218			
Region	US	137	88,39	10	7,299	40	0,292	0,138	0,292	0,141	136	87,18	21	15,44	71,571	0,526	0,144	0,526	0,141	-0,234	-0,627	0,158	0,241	-0,142	-0,38	0,096	0,9177		
	ex-US	18	11,61	0	0	0	0	0	0	0,095	20	12,82	2	10	3,571	0,179	0,124	0,179	0,09	-0,179	-0,444	0,087	0,181	-0,434	-1,08	0,211			
BMI	BMI < 30 kg/m2	96	61,94	7	7,292	32,429	0,338	0,186	0,338	0,181	112	71,8	18	16,07	59,286	0,529	0,164	0,529	0,168	-0,192	-0,679	0,296	0,44	-0,107	-0,38	0,166	0,8484		
	BMI >= 30 kg/m2	58	37,42	3	5,172	7,571	0,131	0,103	0,131	0,127	40	25,64	5	12,5	15,857	0,396	0,187	0,396	0,153	-0,266	-0,66	0,129	0,184	-0,273	-0,68	0,132			
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	4	2,564	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Total household size including the household member(s) not participating this study																													
	2	60	38,71	5	8,333	29,571	0,493	0,294	0,493	0,292	66	42,31	14	21,21	53,714	0,814	0,277	0,814	0,278	-0,321	-1,12	0,478	0,428	-0,141	-0,49	0,21	0,5883		
	>2	95	61,29	5	5,263	10,429	0,11	0,069	0,11	0,073	90	57,69	9	10	21,429	0,238	0,078	0,238	0,075	-0,128	-0,334	0,077	0,219	-0,181	-0,47	0,108			
Baseline high risk factor	Yes	45	29,03	3	6,667	4,714	0,105	0,086	0,105	0,179	54	34,62	7	12,96	27	0,5	0,21	0,5	0,164	-0,395	-0,877	0,087	0,107	-0,326	-0,72	0,072	0,521		
	No	110	70,97	7	6,364	35,286	0,321	0,168	0,321	0,161	102	65,39	16	15,69	48,143	0,472	0,16	0,472	0,168	-0,151	-0,61	0,308	0,517	-0,089	-0,36	0,181			
Race	White	129	83,23	6	4,651	20,857	0,162	0,076	0,162	0,11	134	85,9	20	14,93	62,857	0,469	0,133	0,469	0,108	-0,307	-0,612	-0,003	0,048	-0,245	-0,49	-0	0,0354		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	10	6,452	40	0,258	0,122	0,258	0,125	156	100	23	14,74	75,143	0,482	0,127	0,482	0,124	-0,224	-0,57	0,123	0,205	-0,144	-0,37	0,079	NE				
	Black or African American	8	5,161	1	12,5	0,714	0,089	0,089	0,089	0,069	10	6,41	1	10	0,429	0,043	0,043	0,062	0,046	-0,15	0,243	0,623	0,226	-0,73	1,184						
	Other	12	7,742	2	16,67	18	1,5	1,34	1,5	1,048	8	5,128	0	0	0	0	0	0	1,283	1,5	-1,98	4,98	0,377	0,396	-0,52	1,314					
	Unknown/Not Reported	6	3,871	1	16,67	0,429	0,071	0,071	0,071	0,998	4	2,564	2	50	11,857	2,964	1,993	2,964	1,222	-2,893	-6,531	0,746	0,104	-1,069	-2,41	0,276					
Ethnicity	Hispanic or Latino	65	41,94	3	4,615	5	0,077	0,054	0,077	0,116	58	37,18	6	10,35	18,571	0,32	0,168	0,32	0,123	-0,243	-0,577	0,091	0,152	-0,259	-0,61	0,097	0,8965				
	Not Hispanic or Latino	89	57,42	7	7,865	35	0,393	0,208	0,393	0,197	96	61,54	17	17,71	56,571	0,589	0,179	0,589	0,19	-0,196	-0,735	0,343	0,474	-0,105	-0,39	0,184					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	2	1,282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,806	2	22,22	5,714	0,635	0,452	0,635	1,095	10	6,41	4	40	23,143	2,314	1,369	2,314	1,039	-1,679	-4,863	1,505	0,281	-0,488	-1,41	0,438	0,0313				
	No	144	92,9	8	5,556	34,286	0,238	0,128	0,238	0,112	146	93,59	19	13,01	52	0,356	0,094	0,356	0,112	-0,118	-0,43	0,194	0,456	-0,087	-0,32	0,143					
	Unknown/not reported	2	1,29	0	0	0	0	0	NE	NE	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,74	8	7,619	34,857	0,332	0,175	0,332	0,156	103	66,03	17	16,51	53,571	0,52	0,135	0,52	0,158	-0,188	-0,626	0,249	0,398	-0,117	-0,39	0,155	0,7571				
	No	50	32,26	2	4	5,143	0,103	0,081	0,103	0,206	53	33,97	6	11,32	21,571	0,407	0,268	0,407	0,2	-0,304	-0,874	0,265	0,292	-0,207	-0,6	0,181					
Test result of a local diagnostic assay for SARS-CoV-2	Positive	90	58,07	5	5,556	22,429	0,249	0,184	0,249	0,165	82	52,56	12	14,63	36,143	0,441	0,148	0,441	0,173	-0,192	-0,662	0,279	0,423	-0,122	-0,42	0,178	0,8911				
	Negative	44	28,39	2	4,545	4,286	0,097	0,088	0,097	0,108	49	31,41	5	10,2	11,857	0,242	0,116	0,242	0,102	-0,145	-0,439	0,15	0,332	-0,201	-0,61	0,208					
	Unavailable	21	13,55	3	14,29	13,286	0,633	0,394	0,633	0,537	25	16,03	6	24	27,143	1,086	0,579	1,086	0,492	-0,453	-1,921	1,015	0,537	-0,181	-0,77	0,405					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	155	100	10	6,452	40	0,258	0,122	0,258	0,125	156	100	23	14,74	75,143	0,482	0,127	0,482	0,124	-0,224	-0,57	0,123	0,205	-0,144	-0,37	0,079	NE		
Serology status	Seropositive	46	29,68	0	0	0	0	0	0	0,007	38	24,36	1	2,632	0,429	0,011	0,011	0,011	0,008	-0,011	-0,032	0,009	0,274	-0,239	-0,67	0,193	0,5159		
	Seronegative	100	64,52	10	10	40	0,4	0,188	0,4	0,188	104	66,67	20	19,23	70,714	0,68	0,185	0,68	0,185	-0,28	-0,8	0,24	0,29	-0,148	-0,42	0,127			
	Unclear serology status	9	5,806	0	0	0	0	0	0	0,224	14	8,974	2	14,29	4	0,286	0,228	0,286	0,179	-0,286	-0,882	0,311	0,331	-0,41	-1,27	0,446			

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference		Interaction Test				
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	10	6,452	40	0,258	0,12	0,258	0,13	156	100	23	14,74	75,143	0,482	0,13	0,482	0,12	-0,224	-0,57	0,123	0,205	-0,144	-0,37	0,079	NE				
	Unavailable	21	13,55	3	14,29	13,286	0,633	0,39	0,633	0,54	25	16,03	6	24	27,143	1,086	0,58	1,086	0,49	-0,453	-1,921	1,015	0,537	-0,181	-0,77	0,405					
Serology status	Seropositive	46	29,68	0	0	0	0	0	0	0,01	38	24,36	1	2,632	0,429	0,011	0,01	0,011	0,01	-0,011	-0,032	0,009	0,274	-0,239	-0,67	0,193	0,5159				
	Seronegative	100	64,52	10	10	40	0,4	0,19	0,4	0,19	104	66,67	20	19,23	70,714	0,68	0,19	0,68	0,19	-0,28	-0,8	0,24	0,29	-0,148	-0,42	0,127					
	Unclear serology status	9	5,806	0	0	0	0	0	0	0,22	14	8,974	2	14,29	4	0,286	0,23	0,286	0,18	-0,286	-0,882	0,311	0,331	-0,41	-1,27	0,446					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-1-eff-resp-dth29

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-1-eff-resp-dth29

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				
Sex	Male	80	51,6	0	0	71	45,5	0	0																				
	Female	75	48,4	0	0	85	54,5	0	0																				
Age	12-17	21	13,5	0	0	17	10,9	0	0																				
	18-49	83	53,5	0	0	82	52,6	0	0																				
	>=50	51	32,9	0	0	57	36,5	0	0																				
Region	US	137	88,4	0	0	136	87,2	0	0																				
	ex-US	18	11,6	0	0	20	12,8	0	0																				
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	0	0																				
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	0	0																				
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				
Total household size including the household members not participating this study																													
	2	60	38,7	0	0	66	42,3	0	0																				
	>2	95	61,3	0	0	90	57,7	0	0																				
Baseline high risk factor	Yes	45	29	0	0	54	34,6	0	0																				
	No	110	71	0	0	102	65,4	0	0																				
Race	White	129	83,2	0	0	134	85,9	0	0																				
	Black or African American	8	5,2	0	0	10	6,4	0	0																				
	Other	12	7,7	0	0	8	5,1	0	0																				
	Unknown/Not Reported	6	3,9	0	0	4	2,6	0	0																				
Ethnicity	Hispanic or	65	41,9	0	0	58	37,2	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk			
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	0	0																				
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0																				
Healthcare worker		9	5,8	0	0	10	6,4	0	0																				
	No	144	92,9	0	0	146	93,6	0	0																				
	Unknown/not reported	2	1,3	0	0	0	0	0	0																				
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																													
	Yes	105	67,7	0	0	103	66	0	0																				
	No	50	32,3	0	0	53	34	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio																							
											Convergen e Reason	95% Lower CL	95% upper CL	Absolut e Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL	p- value	Interaction Test p-value (likelihood ratio)	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	0	0																								
Local test result of diagnostic assay for SARS-CoV-2																																	
	Positive	90	58,1	0	0	82	52,6	0	0																								
	Negative	44	28,4	0	0	49	31,4	0	0																								
	Unavailable	21	13,5	0	0	25	16	0	0																								
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0																								
	Seronegative	100	64,5	0	0	104	66,7	0	0																								
	Unclear serology status	9	5,8	0	0	14	9	0	0																								

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				
Sex	Male	80	51,6	0	0	71	45,5	0	0																				
	Female	75	48,4	0	0	85	54,5	0	0																				
Age	12-17	21	13,5	0	0	17	10,9	0	0																				
	18-49	83	53,5	0	0	82	52,6	0	0																				
	>=50	51	32,9	0	0	57	36,5	0	0																				
Region	US	137	88,4	0	0	136	87,2	0	0																				
	ex-US	18	11,6	0	0	20	12,8	0	0																				
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	0	0																				
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	0	0																				
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
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Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk			
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	0	0																				
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	0	0																				
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0																				
Healthcare worker		9	5,8	0	0	10	6,4	0	0																				
	No	144	92,9	0	0	146	93,6	0	0																				
	Unknown/not reported	2	1,3	0	0	0	0	0	0																				
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																													
	Yes	105	67,7	0	0	103	66	0	0																				
	No	50	32,3	0	0	53	34	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: All-cause death at end of Follow-Up

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio																							
										Convergen e Reason	95% Lower CL	95% upper CL	Absolut e Risk	Convergen e Reason	95% Lower CL	95% upper CL	Relativ e Risk	Convergen e Reason	95% Lower CL	95% upper CL	p- value	Interaction Test p-value (likelihood ratio)	Relativ e Risk	Convergen e Reason	95% Lower CL	95% upper CL							
All	n/a	155	100	0	0	156	100	0	0																								
Local test result of diagnostic assay for SARS-CoV-2																																	
	Positive	90	58,1	0	0	82	52,6	0	0																								
	Negative	44	28,4	0	0	49	31,4	0	0																								
	Unavailable	21	13,5	0	0	25	16	0	0																								
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0																								
	Seronegative	100	64,5	0	0	104	66,7	0	0																								
	Unclear serology status	9	5,8	0	0	14	9	0	0																								

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk							Relative Risk				
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	6	3,8	0	Algorithm converged.	NE	NE	-3,846	Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not converged.	NE	NE	0,03		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03			NE	*	Algorithm not	NE	NE		
Sex	Male	80	51,6	0	0	71	45,5	2	2,8	0		Algorithm converged.	NE	NE	-2,817		Algorithm converged.	-6,67	1,03	NE	*	Algorithm not	NE	NE	0,219	1		NE	*	Algorithm not	NE	NE		
	Female	75	48,4	0	0	85	54,5	4	4,7	0		Algorithm converged.	NE	NE	-4,706		Algorithm converged.	-9,21	-0,2	NE	*	Algorithm not	NE	NE	0,123			NE	*	Algorithm not	NE	NE		
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE		
	18-49	83	53,5	0	0	82	52,6	4	4,9	0		Algorithm converged.	NE	NE	-4,878		Algorithm converged.	-9,54	-0,22	NE	*	Algorithm not	NE	NE	0,059			NE	*	Algorithm not	NE	NE		
	>=50	51	32,9	0	0	57	36,5	2	3,5	0		Algorithm converged.	NE	NE	-3,509		Algorithm converged.	-8,29	1,27	NE	*	Algorithm not	NE	NE	0,497			NE	*	Algorithm not	NE	NE		
Region	US	137	88,4	0	0	136	87,2	6	4,4	0		Algorithm converged.	NE	NE	-4,412		Algorithm converged.	-7,86	-0,96	NE	*	Algorithm not	NE	NE	0,014			NE	*	Algorithm not	NE	NE		
	ex-US	18	11,6	0	0	20	12,8	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk										
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE				
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	3	2,7	0		Algorithm converged.	NE	NE	-2,679		Algorithm converged.	-5,67	0,31	NE	*	Algorithm not	NE	NE	0,251	1	NE	*	Algorithm not	NE	NE				
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	3	7,5	0		Algorithm converged.	NE	NE	-7,5		Algorithm converged.	-15,7	0,66	NE	*	Algorithm not	NE	NE	0,065		NE	*	Algorithm not	NE	NE				
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE				
Total household size including the household members not participating this study	2	60	38,7	0	0	66	42,3	6	9,1	0		Algorithm converged.	NE	NE	-9,091		Algorithm converged.	-16	-2,16	NE	*	Algorithm not converged.	NE	NE	0,029		NE	*	Algorithm not converged.	NE	NE				
	>2	95	61,3	0	0	90	57,7	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE				
Baseline high risk factor	Yes	45	29	0	0	54	34,6	4	7,4	0		Algorithm converged.	NE	NE	-7,407		Algorithm converged.	-14,4	-0,42	NE	*	Algorithm not	NE	NE	0,124		NE	*	Algorithm not	NE	NE				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE			
	No	110	71	0	0	102	65,4	2	2	0		Algorithm converged.	NE	NE	-1,961		Algorithm converged.	-4,65	0,73	NE	*	Algorithm not	NE	NE	0,23		NE	*	Algorithm not	NE	NE			
Race	White	129	83,2	0	0	134	85,9	5	3,7	0		Algorithm converged.	NE	NE	-3,731		Algorithm converged.	-6,94	-0,52	NE	*	Algorithm not	NE	NE	0,06		NE	*	Algorithm not	NE	NE			
	Black or African American	8	5,2	0	0	10	6,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			
	Other	12	7,7	0	0	8	5,1	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			
	Unknown/Not Reported	6	3,9	0	0	4	2,6	1	25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,4	17,4	NE	*	Algorithm not	NE	NE	0,4		NE	*	Algorithm not	NE	NE			
Ethnicity	Hispanic or Latino	65	41,9	0	0	58	37,2	2	3,4	0		Algorithm converged.	NE	NE	-3,448		Algorithm converged.	-8,14	1,25	NE	*	Algorithm not	NE	NE	0,22	1	NE	*	Algorithm not	NE	NE			
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	4	4,2	0		Algorithm converged.	NE	NE	-4,167		Algorithm converged.	-8,16	-0,17	NE	*	Algorithm not	NE	NE	0,122		NE	*	Algorithm not	NE	NE			
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	6	3,8	0	Algorithm converged.	NE	NE	-3,846	Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not converged.	NE	NE	0,03		NE	*	Algorithm not converged.	NE	NE	
Healthcare worker	Yes	9	5,8	0	0	10	6,4	2	20	0	Algorithm converged.	NE	NE	-20	Algorithm converged.	-44,8	4,79	NE	*	Algorithm not converged.	NE	NE	0,474		NE	*	Algorithm not converged.	NE	NE	
	No	144	92,9	0	0	146	93,6	4	2,7	0	Algorithm converged.	NE	NE	-2,74	Algorithm converged.	-5,39	-0,09	NE	*	Algorithm not converged.	NE	NE	0,122		NE	*	Algorithm not converged.	NE	NE	
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	0	0	103	66	4	3,9	0	Algorithm converged.	NE	NE	-3,883	Algorithm converged.	-7,61	-0,15	NE	*	Algorithm not converged.	NE	NE	0,058	1	NE	*	Algorithm not converged.	NE	NE	
	No	50	32,3	0	0	53	34	2	3,8	0	Algorithm converged.	NE	NE	-3,774	Algorithm converged.	-8,9	1,36	NE	*	Algorithm not converged.	NE	NE	0,496		NE	*	Algorithm not converged.	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	90	58,1	0	0	82	52,6	3	3,7	0	Algorithm converged.	NE	NE	-3,659	Algorithm converged.	-7,72	0,4	NE	*	Algorithm not converged.	NE	NE	0,106	1	NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk										
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03			NE	*	Algorithm not	NE	NE			
	Negative	44	28,4	0	0	49	31,4	2	4,1	0		Algorithm converged.	NE	NE	-4,082		Algorithm converged.	-9,62	1,46	NE	*	Algorithm not	NE	NE	0,496			NE	*	Algorithm not	NE	NE			
	Unavailable	21	13,5	0	0	25	16	1	4	0		Algorithm converged.	NE	NE	-4		Algorithm converged.	-11,7	3,68	NE	*	Algorithm not	NE	NE	1			NE	*	Algorithm not	NE	NE			
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE			
	Seronegative	100	64,5	0	0	104	66,7	6	5,8	0		Algorithm converged.	NE	NE	-5,769		Algorithm converged.	-10,3	-1,29	NE	*	Algorithm not	NE	NE	0,029			NE	*	Algorithm not	NE	NE			
	Unclear serology status	9	5,8	0	0	14	9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE			

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	7	4,5	0	Algorithm converged.	NE	NE	-4,487	Algorithm converged.	-7,74	-1,24	NE	*	Algorithm not converged.	NE	NE	0,0146		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	7	4,5	0	Algorithm converged.	NE	NE	-4,487	Algorithm converged.	-7,74	-1,24	NE	*	Algorithm not	NE	NE	0,015		NE	*	Algorithm not	NE	NE
Sex	Male	80	51,6	0	0	71	45,5	3	4,2	0	Algorithm converged.	NE	NE	-4,225	Algorithm converged.	-8,9	0,45	NE	*	Algorithm not	NE	NE	0,102	1	NE	*	Algorithm not	NE	NE
	Female	75	48,4	0	0	85	54,5	4	4,7	0	Algorithm converged.	NE	NE	-4,706	Algorithm converged.	-9,21	-0,2	NE	*	Algorithm not	NE	NE	0,123		NE	*	Algorithm not	NE	NE
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	NE	NE			NE	*	Algorithm not	NE	NE
	18-49	83	53,5	0	0	82	52,6	5	6,1	0	Algorithm converged.	NE	NE	-6,098	Algorithm converged.	-11,3	-0,92	NE	*	Algorithm not	NE	NE	0,029		NE	*	Algorithm not	NE	NE
	>=50	51	32,9	0	0	57	36,5	2	3,5	0	Algorithm converged.	NE	NE	-3,509	Algorithm converged.	-8,29	1,27	NE	*	Algorithm not	NE	NE	0,497		NE	*	Algorithm not	NE	NE
Region	US	137	88,4	0	0	136	87,2	7	5,1	0	Algorithm converged.	NE	NE	-5,147	Algorithm converged.	-8,86	-1,43	NE	*	Algorithm not	NE	NE	0,007		NE	*	Algorithm not	NE	NE
	ex-US	18	11,6	0	0	20	12,8	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	NE	NE			NE	*	Algorithm not	NE	NE
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	4	3,6	0	Algorithm converged.	NE	NE	-3,571	Algorithm converged.	-7,01	-0,13	NE	*	Algorithm not	NE	NE	0,126		NE	*	Algorithm not	NE	NE
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	3	7,5	0	Algorithm converged.	NE	NE	-7,5	Algorithm converged.	-15,7	0,66	NE	*	Algorithm not	NE	NE	0,065		NE	*	Algorithm not	NE	NE
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	NE	NE			NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	0	0	156	100	7	4,5	0		Algorithm converged.	NE	NE	-4,487		Algorithm converged.	-7,74	-1,24	NE	*	Algorithm not	NE	NE	0,015		NE	*	Algorithm not	NE	NE
Total household size including the household members not participating this study	2	60	38,7	0	0	66	42,3	6	9,1	0		Algorithm converged.	NE	NE	-9,091		Algorithm converged.	-16	-2,16	NE	*	Algorithm not converged.	NE	NE	0,029		NE	*	Algorithm not converged.	NE	NE
	>2	95	61,3	0	0	90	57,7	1	1,1	0		Algorithm converged.	NE	NE	-1,111		Algorithm converged.	-3,28	1,05	NE	*	Algorithm not	NE	NE	0,487		NE	*	Algorithm not	NE	NE
Baseline high risk factor	Yes	45	29	0	0	54	34,6	4	7,4	0		Algorithm converged.	NE	NE	-7,407		Algorithm converged.	-14,4	-0,42	NE	*	Algorithm not	NE	NE	0,124		NE	*	Algorithm not	NE	NE
	No	110	71	0	0	102	65,4	3	2,9	0		Algorithm converged.	NE	NE	-2,941		Algorithm converged.	-6,22	0,34	NE	*	Algorithm not	NE	NE	0,11		NE	*	Algorithm not	NE	NE
Race	White	129	83,2	0	0	134	85,9	6	4,5	0		Algorithm converged.	NE	NE	-4,478		Algorithm converged.	-7,98	-0,98	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE
	Black or African American	8	5,2	0	0	10	6,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	Other	12	7,7	0	0	8	5,1	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	Unknown/Not Reported	6	3,9	0	0	4	2,6	1	25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,4	17,4	NE	*	Algorithm not	NE	NE	0,4		NE	*	Algorithm not	NE	NE
Ethnicity	Hispanic or Latino	65	41,9	0	0	58	37,2	2	3,4	0		Algorithm converged.	NE	NE	-3,448		Algorithm converged.	-8,14	1,25	NE	*	Algorithm not	NE	NE	0,22		NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	155	100	0	0	156	100	7	4,5	0		Algorithm converged.	NE	NE	-4,487		Algorithm converged.	-7,74	-1,24	NE	*	Algorithm not	NE	NE	0,015		NE	*	Algorithm not	NE	NE	
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	5	5,2	0		Algorithm converged.	NE	NE	-5,208		Algorithm converged.	-9,65	-0,76	NE	*	Algorithm not	NE	NE	0,06		NE	*	Algorithm not	NE	NE	
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	
Healthcare worker	Yes	9	5,8	0	0	10	6,4	2	20	0		Algorithm converged.	NE	NE	-20		Algorithm converged.	-44,8	4,79	NE	*	Algorithm not	NE	NE	0,474		NE	*	Algorithm not	NE	NE	
	No	144	92,9	0	0	146	93,6	5	3,4	0		Algorithm converged.	NE	NE	-3,425		Algorithm converged.	-6,37	-0,47	NE	*	Algorithm not	NE	NE	0,06		NE	*	Algorithm not	NE	NE	
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	0	0	103	66	5	4,9	0		Algorithm converged.	NE	NE	-4,854		Algorithm converged.	-9	-0,7	NE	*	Algorithm not converged.	NE	NE	0,028		NE	*	Algorithm not converged.	NE	NE	
	No	50	32,3	0	0	53	34	2	3,8	0		Algorithm converged.	NE	NE	-3,774		Algorithm converged.	-8,9	1,36	NE	*	Algorithm not	NE	NE	0,496		NE	*	Algorithm not	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2												Algorithm converged.	NE	NE			Algorithm converged.						Algorithm not converged.							Algorithm not converged.		
	Positive	90	58,1	0	0	82	52,6	3	3,7	0		Algorithm converged.	NE	NE	-3,659		Algorithm converged.	-7,72	0,4	NE	*	Algorithm not converged.	NE	NE	0,106		NE	*	Algorithm not converged.	NE	NE	
	Negative	44	28,4	0	0	49	31,4	3	6,1	0		Algorithm converged.	NE	NE	-6,122		Algorithm converged.	-12,8	0,59	NE	*	Algorithm not	NE	NE	0,244		NE	*	Algorithm not	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL	p- value	Interaction Test p-value (likelihood ratio)	Relativ e Risk		Convergen e Reason	95% Lower CL	95% upper CL	
All	n/a	155	100	0	0	156	100	7	4,5	0		Algorithm converged.	NE	NE	-4,487		Algorithm converged.	-7,74	-1,24	NE	*	Algorithm not	NE	NE	0,015		NE	*	Algorithm not	NE	NE	
	Unavailable	21	13,5	0	0	25	16	1	4	0		Algorithm converged.	NE	NE	-4		Algorithm converged.	-11,7	3,68	NE	*	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE	
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	
	Seronegative	100	64,5	0	0	104	66,7	7	6,7	0		Algorithm converged.	NE	NE	-6,731		Algorithm converged.	-11,6	-1,92	NE	*	Algorithm not	NE	NE	0,014		NE	*	Algorithm not	NE	NE	
	Unclear serology status	9	5,8	0	0	14	9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	6	3,8	0	Algorithm converged.	NE	NE	-3,846	Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not converged.	NE	NE	0,0298		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE
Sex	Male	80	51,6	0	0	71	45,5	3	4,2	0		Algorithm converged.	NE	NE	-4,225		Algorithm converged.	-8,9	0,45	NE	*	Algorithm not	NE	NE	0,102	1	NE	*	Algorithm not	NE	NE
	Female	75	48,4	0	0	85	54,5	3	3,5	0		Algorithm converged.	NE	NE	-3,529		Algorithm converged.	-7,45	0,39	NE	*	Algorithm not	NE	NE	0,248		NE	*	Algorithm not	NE	NE
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	18-49	83	53,5	0	0	82	52,6	4	4,9	0		Algorithm converged.	NE	NE	-4,878		Algorithm converged.	-9,54	-0,22	NE	*	Algorithm not	NE	NE	0,059		NE	*	Algorithm not	NE	NE
	>=50	51	32,9	0	0	57	36,5	2	3,5	0		Algorithm converged.	NE	NE	-3,509		Algorithm converged.	-8,29	1,27	NE	*	Algorithm not	NE	NE	0,497		NE	*	Algorithm not	NE	NE
Region	US	137	88,4	0	0	136	87,2	6	4,4	0		Algorithm converged.	NE	NE	-4,412		Algorithm converged.	-7,86	-0,96	NE	*	Algorithm not	NE	NE	0,014		NE	*	Algorithm not	NE	NE
	ex-US	18	11,6	0	0	20	12,8	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	4	3,6	0		Algorithm converged.	NE	NE	-3,571		Algorithm converged.	-7,01	-0,13	NE	*	Algorithm not	NE	NE	0,126	1	NE	*	Algorithm not	NE	NE
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	2	5	0		Algorithm converged.	NE	NE	-5		Algorithm converged.	-11,8	1,75	NE	*	Algorithm not	NE	NE	0,164		NE	*	Algorithm not	NE	NE
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	155	100		0	156	100		6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE
Total household size including the household members not participating this study																																
	2	60	38,7		0	66	42,3		5	7,6	0		Algorithm converged.	NE	NE	-7,576		Algorithm converged.	-14	-1,19	NE	*	Algorithm not converged.	NE	NE	0,059	1	NE	*	Algorithm not converged.	NE	NE
	>2	95	61,3		0	90	57,7		1	1,1	0		Algorithm converged.	NE	NE	-1,111		Algorithm converged.	-3,28	1,05	NE	*	Algorithm not	NE	NE	0,487		NE	*	Algorithm not	NE	NE
Baseline high risk factor																																
	Yes	45	29		0	54	34,6		3	5,6	0		Algorithm converged.	NE	NE	-5,556		Algorithm converged.	-11,7	0,55	NE	*	Algorithm not	NE	NE	0,249		NE	*	Algorithm not	NE	NE
	No	110	71		0	102	65,4		3	2,9	0		Algorithm converged.	NE	NE	-2,941		Algorithm converged.	-6,22	0,34	NE	*	Algorithm not	NE	NE	0,11		NE	*	Algorithm not	NE	NE
Race	White	129	83,2		0	134	85,9		5	3,7	0		Algorithm converged.	NE	NE	-3,731		Algorithm converged.	-6,94	-0,52	NE	*	Algorithm not	NE	NE	0,06		NE	*	Algorithm not	NE	NE
	Black or African American	8	5,2		0	10	6,4		0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	Other	12	7,7		0	8	5,1		0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	Unknown/Not Reported	6	3,9		0	4	2,6		1	25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,4	17,4	NE	*	Algorithm not	NE	NE	0,4		NE	*	Algorithm not	NE	NE
Ethnicity	Hispanic or Latino	65	41,9		0	58	37,2		2	3,4	0		Algorithm converged.	NE	NE	-3,448		Algorithm converged.	-8,14	1,25	NE	*	Algorithm not	NE	NE	0,22	1	NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE	
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	4	4,2	0		Algorithm converged.	NE	NE	-4,167		Algorithm converged.	-8,16	-0,17	NE	*	Algorithm not	NE	NE	0,122		NE	*	Algorithm not	NE	NE	
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	
Healthcare worker	Yes	9	5,8	0	0	10	6,4	2	20	0		Algorithm converged.	NE	NE	-20		Algorithm converged.	-44,8	4,79	NE	*	Algorithm not	NE	NE	0,474		NE	*	Algorithm not	NE	NE	
	No	144	92,9	0	0	146	93,6	4	2,7	0		Algorithm converged.	NE	NE	-2,74		Algorithm converged.	-5,39	-0,09	NE	*	Algorithm not	NE	NE	0,122		NE	*	Algorithm not	NE	NE	
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	0	0	103	66	5	4,9	0		Algorithm converged.	NE	NE	-4,854		Algorithm converged.	-9	-0,7	NE	*	Algorithm not converged.	NE	NE	0,028	1	NE	*	Algorithm not converged.	NE	NE	
	No	50	32,3	0	0	53	34	1	1,9	0		Algorithm converged.	NE	NE	-1,887		Algorithm converged.	-5,55	1,78	NE	*	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2												Algorithm converged.	NE	NE			Algorithm converged.						Algorithm not converged.							Algorithm not converged.		
	Positive	90	58,1	0	0	82	52,6	3	3,7	0		Algorithm converged.	NE	NE	-3,659		Algorithm converged.	-7,72	0,4	NE	*	Algorithm not converged.	NE	NE	0,106	1	NE	*	Algorithm not converged.	NE	NE	
	Negative	44	28,4	0	0	49	31,4	2	4,1	0		Algorithm converged.	NE	NE	-4,082		Algorithm converged.	-9,62	1,46	NE	*	Algorithm not	NE	NE	0,496		NE	*	Algorithm not	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	0	0	156	100	6	3,8	0		Algorithm converged.	NE	NE	-3,846		Algorithm converged.	-6,86	-0,83	NE	*	Algorithm not	NE	NE	0,03		NE	*	Algorithm not	NE	NE
	Unavailable	21	13,5	0	0	25	16	1	4	0		Algorithm converged.	NE	NE	-4		Algorithm converged.	-11,7	3,68	NE	*	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE
	Seronegative	100	64,5	0	0	104	66,7	6	5,8	0		Algorithm converged.	NE	NE	-5,769		Algorithm converged.	-10,3	-1,29	NE	*	Algorithm not	NE	NE	0,029		NE	*	Algorithm not	NE	NE
	Unclear serology status	9	5,8	0	0	14	9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

Casirivimab/Imdevimab												Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
Patients in analysis				Patients with Event		Total of Visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference					
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	155	100	0	0	0	0	0	-0,009	0,01	156	100	6	3,85	6	0,038	0,02	0,03	0,01	-0,039	-0,069	-0,008	0,013	-0,282	-0,51	-0,06			

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Visits	Statistics		ANCOVA		Mean Difference					Standardized Mean Difference			Interaction Test			
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	0	0	0	0	0	0	0.011	156	100	6	3,846	6	0.038	0.015	0.038	0.011	-0.038	-0.069	-0.008	0.014	-0.281	-0.5	-0.06	NE				
Sex	Male	80	51.61	0	0	0	0	0	0	0.016	71	45.51	3	4,225	3	0.042	0.024	0.042	0.016	-0.042	-0.087	0.002	0.064	-0.303	-0.62	0.018	0.8234				
	Female	75	48.39	0	0	0	0	0	0	0.016	85	54.49	3	3,529	3	0.035	0.02	0.035	0.015	-0.035	-0.078	0.007	0.102	-0.26	-0.57	0.052					
Age	12-17	21	13.55	0	0	0	0	0	0	NE	17	10.9	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0.6105				
	18-49	83	53.55	0	0	0	0	0	0	0.017	82	52.56	4	4,878	4	0.049	0.024	0.049	0.017	-0.049	-0.096	-0.002	0.042	-0.318	-0.62	-0.01					
	>=50	51	32.9	0	0	0	0	0	0	0.019	57	36.54	2	3,509	2	0.035	0.025	0.035	0.018	-0.035	-0.087	0.016	0.18	-0.258	-0.64	0.121					
Region	US	137	88.39	0	0	0	0	0	0	0.012	136	87.18	6	4,412	6	0.044	0.018	0.044	0.012	-0.044	-0.079	-0.009	0.013	-0.302	-0.54	-0.07	0.3526				
	ex-US	18	11.61	0	0	0	0	0	0	NE	20	12.82	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
BMI	BMI < 30 kg/m2	96	61.94	0	0	0	0	0	0	0.014	112	71.8	4	3,571	4	0.036	0.018	0.036	0.013	-0.036	-0.073	0.002	0.062	-0.26	-0.53	0.013	0.677				
	BMI >= 30 kg/m2	58	37.42	0	0	0	0	0	0	0.018	40	25.64	2	5	2	0.05	0.035	0.05	0.022	-0.05	-0.107	0.007	0.087	-0.353	-0.76	0.052					
	Unknown/not reported	1	0.645	0	0	0	0	NE	0	NE	4	2.564	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Total household size including the household member(s) not participating this study																															
	2	60	38.71	0	0	0	0	0	0	0.025	66	42.31	5	7,576	5	0.076	0.033	0.076	0.024	-0.076	-0.144	-0.008	0.03	-0.39	-0.74	-0.04	0.0394				
	>2	95	61.29	0	0	0	0	0	0	0.008	90	57.69	1	1,111	1	0.011	0.011	0.011	0.008	-0.011	-0.032	0.01	0.306	-0.151	-0.44	0.139					
Baseline high risk factor	Yes	45	29.03	0	0	0	0	0	0	0.025	54	34.62	3	5,556	3	0.056	0.031	0.056	0.023	-0.056	-0.124	0.013	0.111	-0.323	-0.72	0.075	0.4345				
	No	110	70.97	0	0	0	0	0	0	0.011	102	65.39	3	2,941	3	0.029	0.017	0.029	0.012	-0.029	-0.061	0.002	0.071	-0.249	-0.52	0.021					
Race	White	129	83.23	0	0	0	0	0	0	0.012	134	85.9	5	3,731	5	0.037	0.016	0.037	0.012	-0.037	-0.07	-0.004	0.027	-0.274	-0.52	-0.03	0.708				
	Black or African American	8	5.161	0	0	0	0	0	0	NE	10	6.41	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Other	12	7.742	0	0	0	0	0	0	NE	8	5.128	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Unknown/Not Reported	6	3.871	0	0	0	0	0	0	0.125	4	2.564	1	25	1	0.25	0.25	0.25	0.153	-0.25	-0.706	0.206	0.242	-0.737	-2.08	0.607					
Ethnicity	Hispanic or Latino	65	41.94	0	0	0	0	0	0	0.016	58	37.18	2	3,448	2	0.034	0.024	0.034	0.017	-0.034	-0.08	0.011	0.133	-0.271	-0.63	0.084	0.823				
	Not Hispanic or Latino	89	57.42	0	0	0	0	0	0	0.015	96	61.54	4	4,167	4	0.042	0.021	0.042	0.015	-0.042	-0.084	0	0.052	-0.287	-0.58	0.002					
	Unknown/not reported	1	0.645	0	0	0	0	NE	0	NE	2	1.282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5.806	0	0	0	0	0	0	0.102	10	6.41	2	20	2	0.2	0.133	0.2	0.097	-0.2	-0.497	0.097	0.174	-0.623	-1.55	0.303	0.0071				
	No	144	92.9	0	0	0	0	0	0	0.01	146	93.59	4	2,74	4	0.027	0.014	0.027	0.01	-0.027	-0.054	-0.001	0.046	-0.235	-0.47	-0.01					
	Unknown/not reported	2	1.29	0	0	0	0	0	NE	NE	0	0	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																															
	Yes	105	67.74	0	0	0	0	0	0	0.015	103	66.03	5	4,854	5	0.049	0.021	0.049	0.015	-0.049	-0.09	-0.007	0.022	-0.318	-0.59	-0.05	0.3686				
	No	50	32.26	0	0	0	0	0	0	0.014	53	33.97	1	1,887	1	0.019	0.019	0.019	0.014	-0.019	-0.057	0.02	0.334	-0.19	-0.58	0.198					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Visits	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of Visits	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All Test result of a local diagnostic assay for SARS-CoV-2	n/a	155	100	0	0	0	0	0	0	0,011	156	100	6	3,846	6	0,038	0,015	0,038	0,011	0,038	-0,069	-0,008	0,014	-0,281	-0,5	-0,06	NE				
	Positive	90	58,07	0	0	0	0	0	0	0,014	82	52,56	3	3,659	3	0,037	0,021	0,037	0,014	-0,037	-0,076	0,003	0,068	-0,279	-0,58	0,021	0,9038				
	Negative	44	28,39	0	0	0	0	0	0	0,022	49	31,41	2	4,082	2	0,041	0,029	0,041	0,021	-0,041	-0,101	0,019	0,179	-0,279	-0,69	0,13					
	Unavailable	21	13,55	0	0	0	0	0	0	0,032	25	16,03	1	4	1	0,04	0,04	0,04	0,03	-0,04	-0,128	0,048	0,365	-0,266	-0,85	0,32					
Serology status	Seropositive	46	29,68	0	0	0	0	0	0	NE	38	24,36	0	0	0	0	0	0	0,016	0	NE	NE	NE	NE	NE	NE	0,1171				
	Seronegative	100	64,52	0	0	0	0	0	0	0,017	104	66,67	6	5,769	6	0,058	0,023	0,058	0,016	-0,058	-0,104	-0,011	0,015	-0,344	-0,62	-0,07					
	Unclear serology status	9	5,806	0	0	0	0	0	0	NE	14	8,974	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk							Relative Risk				
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	3	1,9	0	Algorithm converged.	NE	NE	-1,923	Algorithm converged.	-4,08	0,23	NE	*	Algorithm not converged.	NE	NE	0,248		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
All	n/a	155	100	0	0	156	100	3	1,9	0	Algorithm converged.	NE	NE	-1,923	Algorithm converged.	-4,08	0,23	NE	*	Algorithm not	NE	NE	0,248		NE	*	Algorithm not	NE	NE					
Sex	Male	80	51,6	0	0	71	45,5	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE		NE	*	Algorithm not	NE	NE				
	Female	75	48,4	0	0	85	54,5	3	3,5	0	Algorithm converged.	NE	NE	-3,529	Algorithm converged.	-7,45	0,39	NE	*	Algorithm not	NE	NE	0,248		NE	*	Algorithm not	NE	NE					
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE		NE	*	Algorithm not	NE	NE				
	18-49	83	53,5	0	0	82	52,6	2	2,4	0	Algorithm converged.	NE	NE	-2,439	Algorithm converged.	-5,78	0,9	NE	*	Algorithm not	NE	NE	0,246		NE	*	Algorithm not	NE	NE					
	>=50	51	32,9	0	0	57	36,5	1	1,8	0	Algorithm converged.	NE	NE	-1,754	Algorithm converged.	-5,16	1,65	NE	*	Algorithm not	NE	NE	1		NE	*	Algorithm not	NE	NE					
Region	US	137	88,4	0	0	136	87,2	3	2,2	0	Algorithm converged.	NE	NE	-2,206	Algorithm converged.	-4,67	0,26	NE	*	Algorithm not	NE	NE	0,122		NE	*	Algorithm not	NE	NE					
	ex-US	18	11,6	0	0	20	12,8	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE		NE	*	Algorithm not	NE	NE				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	*	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	0	0	156	100	3	1,9	0		Algorithm converged.	NE	NE	-1,923		Algorithm converged.	-4,08	0,23	NE	*		Algorithm not	NE	NE	0,248		NE	*		Algorithm not	NE	NE
BMI	BMI < 30 kg/m2	96	61,9	0	0	112	71,8	2	1,8	0		Algorithm converged.	NE	NE	-1,786		Algorithm converged.	-4,24	0,67	NE	*		Algorithm not	NE	NE	0,501	1	NE	*		Algorithm not	NE	NE
	BMI >= 30 kg/m2	58	37,4	0	0	40	25,6	1	2,5	0		Algorithm converged.	NE	NE	-2,5		Algorithm converged.	-7,34	2,34	NE	*		Algorithm not	NE	NE	0,408		NE	*		Algorithm not	NE	NE
	Unknown/not reported	1	0,6	0	0	4	2,6	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*		Algorithm not	NE	NE	NE		NE	*		Algorithm not	NE	NE
Total household size including the household members not participating this study	2	60	38,7	0	0	66	42,3	3	4,5	0		Algorithm converged.	NE	NE	-4,545		Algorithm converged.	-9,57	0,48	NE	*		Algorithm not converged.	NE	NE	0,246		NE	*		Algorithm not converged.	NE	NE
	>2	95	61,3	0	0	90	57,7	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*		Algorithm not	NE	NE	NE		NE	*		Algorithm not	NE	NE
Baseline high risk factor	Yes	45	29	0	0	54	34,6	3	5,6	0		Algorithm converged.	NE	NE	-5,556		Algorithm converged.	-11,7	0,55	NE	*		Algorithm not	NE	NE	0,249		NE	*		Algorithm not	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
All	n/a	155	100	0	0	156	100	3	1,9	0	Algorithm converged.	NE	NE	-1,923	Algorithm converged.	-4,08	0,23	NE	*	Algorithm not	NE	NE	0,248		NE	*	Algorithm not	NE	NE					
	No	110	71	0	0	102	65,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			
Race	White	129	83,2	0	0	134	85,9	2	1,5	0	Algorithm converged.	NE	NE	-1,493	Algorithm converged.	-3,55	0,56	NE	*	Algorithm not	NE	NE	0,498		NE	*	Algorithm not	NE	NE					
	Black or African American	8	5,2	0	0	10	6,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			
	Other	12	7,7	0	0	8	5,1	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			
	Unknown/Not Reported	6	3,9	0	0	4	2,6	1	25	0	Algorithm converged.	NE	NE	-25	Algorithm converged.	-67,4	17,4	NE	*	Algorithm not	NE	NE	0,4		NE	*	Algorithm not	NE	NE					
Ethnicity	Hispanic or Latino	65	41,9	0	0	58	37,2	1	1,7	0	Algorithm converged.	NE	NE	-1,724	Algorithm converged.	-5,07	1,63	NE	*	Algorithm not	NE	NE	0,472	1	NE	*	Algorithm not	NE	NE					
	Not Hispanic or Latino	89	57,4	0	0	96	61,5	2	2,1	0	Algorithm converged.	NE	NE	-2,083	Algorithm converged.	-4,94	0,77	NE	*	Algorithm not	NE	NE	0,498		NE	*	Algorithm not	NE	NE					
	Unknown/not reported	1	0,6	0	0	2	1,3	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE		NE	*	Algorithm not	NE	NE			

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk										
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	3	1,9	0		Algorithm converged.	NE	NE	-1,923		Algorithm converged.	-4,08	0,23	NE	*	Algorithm not converged.	NE	NE	0,248		NE	*	Algorithm not converged.	NE	NE				
Healthcare worker	Yes	9	5,8	0	0	10	6,4	1	10	0		Algorithm converged.	NE	NE	-10		Algorithm converged.	-28,6	8,59	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE				
	No	144	92,9	0	0	146	93,6	2	1,4	0		Algorithm converged.	NE	NE	-1,37		Algorithm converged.	-3,26	0,52	NE	*	Algorithm not converged.	NE	NE	0,498		NE	*	Algorithm not converged.	NE	NE				
	Unknown/not reported	2	1,3	0	0	0	0	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE				
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,7	0	0	103	66	2	1,9	0		Algorithm converged.	NE	NE	-1,942		Algorithm converged.	-4,61	0,72	NE	*	Algorithm not converged.	NE	NE	0,244	1	NE	*	Algorithm not converged.	NE	NE				
	No	50	32,3	0	0	53	34	1	1,9	0		Algorithm converged.	NE	NE	-1,887		Algorithm converged.	-5,55	1,78	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE				
Local test result of diagnostic assay for SARS-CoV-2	Positive	90	58,1	0	0	82	52,6	1	1,2	0		Algorithm converged.	NE	NE	-1,22		Algorithm converged.	-3,6	1,16	NE	*	Algorithm not converged.	NE	NE	0,477	1	NE	*	Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Cohort B

ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	0	0	156	100	3	1,9	0		Algorithm converged.	NE	NE	-1,923		Algorithm converged.	-4,08	0,23	NE	*	Algorithm not	NE	NE	0,248			NE	*	Algorithm not	NE	NE			
	Negative	44	28,4	0	0	49	31,4	2	4,1	0		Algorithm converged.	NE	NE	-4,082		Algorithm converged.	-9,62	1,46	NE	*	Algorithm not	NE	NE	0,496			NE	*	Algorithm not	NE	NE			
	Unavailable	21	13,5	0	0	25	16	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE			
Serology status	Seropositive	46	29,7	0	0	38	24,4	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE			
	Seronegative	100	64,5	0	0	104	66,7	3	2,9	0		Algorithm converged.	NE	NE	-2,885		Algorithm converged.	-6,1	0,33	NE	*	Algorithm not	NE	NE	0,247			NE	*	Algorithm not	NE	NE			
	Unclear serology status	9	5,8	0	0	14	9	0	0	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE	*	Algorithm not	NE	NE	NE			NE	*	Algorithm not	NE	NE			

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference					Standardized Mean Difference		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	155	100	0	0	0	0	0	-0,064	0,16	156	100	3	1,92	40	0,256	0,18	0,196	0,16	-0,26	-0,606	0,086	0,141	-0,167	-0,39	0,06			

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	0	0	0	0	0	0	0,124	156	100	3	1,923	40	0,256	0,175	0,256	0,124	-0,256	-0,602	0,089	0,145	-0,165	-0,39	0,057	NE				
Sex	Male	80	51,61	0	0	0	0	0	0	NE	71	45,51	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,1808				
	Female	75	48,39	0	0	0	0	0	0	0,248	85	54,49	3	3,529	40	0,471	0,32	0,471	0,233	-0,471	-1,144	0,203	0,169	-0,218	-0,53	0,094					
Age	12-17	21	13,55	0	0	0	0	0	0	NE	17	10,9	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,7663				
	18-49	83	53,55	0	0	0	0	0	0	0,217	82	52,56	2	2,439	30	0,366	0,31	0,366	0,219	-0,366	-0,975	0,243	0,237	-0,184	-0,49	0,122					
	>=50	51	32,9	0	0	0	0	0	0	0,135	57	36,54	1	1,754	10	0,175	0,175	0,175	0,128	-0,175	-0,543	0,192	0,347	-0,181	-0,56	0,198					
Region	US	137	88,39	0	0	0	0	0	0	0,141	136	87,18	3	2,206	40	0,294	0,201	0,294	0,142	-0,294	-0,687	0,099	0,142	-0,178	-0,42	0,06	0,5847				
	ex-US	18	11,61	0	0	0	0	0	0	NE	20	12,82	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
BMI	BMI < 30 kg/m2	96	61,94	0	0	0	0	0	0	0,19	112	71,8	2	1,786	35	0,313	0,24	0,313	0,176	-0,313	-0,823	0,198	0,229	-0,167	-0,44	0,106	0,6293				
	BMI >= 30 kg/m2	58	37,42	0	0	0	0	0	0	0,066	40	25,64	1	2,5	5	0,125	0,125	0,125	0,08	-0,125	-0,331	0,081	0,23	-0,246	-0,65	0,159					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	4	2,564	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Total household size including the household member(s) not participating this study																															
	2	60	38,71	0	0	0	0	0	0	0,312	66	42,31	3	4,545	40	0,606	0,411	0,606	0,298	-0,606	-1,46	0,248	0,163	-0,249	-0,6	0,102	0,0892				
	>2	95	61,29	0	0	0	0	0	0	NE	90	57,69	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Baseline high risk factor	Yes	45	29,03	0	0	0	0	0	0	0,406	54	34,62	3	5,556	40	0,741	0,502	0,741	0,371	-0,741	-1,832	0,351	0,181	-0,27	-0,67	0,128	0,0486				
	No	110	70,97	0	0	0	0	0	0	NE	102	65,39	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Race	White	129	83,23	0	0	0	0	0	0	0,061	134	85,9	2	1,493	15	0,112	0,083	0,112	0,059	-0,112	-0,279	0,055	0,188	-0,162	-0,41	0,08	0,8857				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	0	0	0	0	0	0	0,124	156	100	3	1,923	40	0,256	0,175	0,256	0,124	-0,256	-0,602	0,089	0,145	-0,165	-0,39	0,057	NE				
	Black or African American	8	5,161	0	0	0	0	0	0	NE	10	6,41	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Other	12	7,742	0	0	0	0	0	0	NE	8	5,128	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Unknown/Not Reported	6	3,871	0	0	0	0	0	0	3,125	4	2,564	1	25	25	6,25	6,25	6,25	3,827	-6,25	-17,644	5,144	0,242	-0,737	-2,08	0,607					
Ethnicity	Hispanic or Latino	65	41,94	0	0	0	0	0	0	0,279	58	37,18	1	1,724	25	0,431	0,431	0,431	0,296	-0,431	-1,237	0,375	0,292	-0,19	-0,55	0,165	0,4493				
	Not Hispanic or Latino	89	57,42	0	0	0	0	0	0	0,087	96	61,54	2	2,083	15	0,156	0,116	0,156	0,084	-0,156	-0,394	0,081	0,196	-0,19	-0,48	0,099					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	2	1,282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,806	0	0	0	0	0	0	0,767	10	6,41	1	10	10	1	1	1	0,728	-1	-3,23	1,23	0,357	-0,415	-1,34	0,511	0,281				
	No	144	92,9	0	0	0	0	0	0	0,125	146	93,59	2	1,37	30	0,205	0,174	0,205	0,124	-0,205	-0,551	0,14	0,243	-0,137	-0,37	0,093					
	Unknown/not reported	2	1,29	0	0	0	0	0	NE	NE	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,74	0	0	0	0	0	0	0,182	103	66,03	2	1,942	35	0,34	0,261	0,34	0,183	-0,34	-0,849	0,169	0,189	-0,182	-0,45	0,09	0,5117				
	No	50	32,26	0	0	0	0	0	0	0,07	53	33,97	1	1,887	5	0,094	0,094	0,094	0,068	-0,094	-0,287	0,098	0,334	-0,19	-0,58	0,198					
Test result of a local diagnostic assay for SARS-CoV-2	Positive	90	58,07	0	0	0	0	0	0	0,201	82	52,56	1	1,22	25	0,305	0,305	0,305	0,21	-0,305	-0,879	0,269	0,296	-0,159	-0,46	0,141	0,9977				
	Negative	44	28,39	0	0	0	0	0	0	0,173	49	31,41	2	4,082	15	0,306	0,226	0,306	0,164	-0,306	-0,781	0,168	0,203	-0,264	-0,67	0,145					
	Unavailable	21	13,55	0	0	0	0	0	0	NE	25	16,03	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	0	0	0	0	0	0	0,124	156	100	3	1,923	40	0,256	0,175	0,256	0,124	-0,256	-0,602	0,089	0,145	-0,165	-0,39	0,057	NE				
Serology status	Seropositive	46	29,68	0	0	0	0	0	0	NE	38	24,36	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,3587				
	Seronegative	100	64,52	0	0	0	0	0	0	0,191	104	66,67	3	2,885	40	0,385	0,262	0,385	0,187	-0,385	-0,911	0,142	0,151	-0,201	-0,48	0,074					
	Unclear serology status	9	5,806	0	0	0	0	0	0	NE	14	8,974	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Stratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab									Placebo									Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL
All	n/a	155	100	57	36,77	646	4,168	0,63	4,897	0,96	156	100	69	44,23	990	6,346	0,83	7,124	0,94	-2,227	-4,267	-0,188	0,032	-0,243	-0,47	-0,02

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	155	100	57	36,77	646	4,168	0,631	4,168	0,739	156	100	69	44,23	990	6,346	0,831	6,346	0,737	-2,178	-4,232	-0,125	0,038	-0,236	-0,46	-0,01	NE		
Sex	Male	80	51,61	27	33,75	355	4,438	1,058	4,438	1,066	71	45,51	32	45,07	454	6,394	1,14	6,394	1,131	-1,957	-5,028	1,114	0,21	-0,204	-0,53	0,116	0,8233		
	Female	75	48,39	30	40	291	3,88	0,658	3,88	1,032	85	54,49	37	43,53	536	6,306	1,196	6,306	0,969	-2,426	-5,223	0,371	0,089	-0,27	-0,58	0,041			
Age	12-17	21	13,55	6	28,57	44	2,095	0,864	2,095	1,075	17	10,9	7	41,18	75	4,412	1,435	4,412	1,195	-2,317	-5,577	0,944	0,158	-0,46	-1,11	0,187	0,9819		
	18-49	83	53,55	36	43,37	450	5,422	1,052	5,422	1,201	82	52,56	40	48,78	636	7,756	1,344	7,756	1,209	-2,334	-5,699	1,03	0,173	-0,212	-0,52	0,094			
	>=50	51	32,9	15	29,41	152	2,98	0,729	2,98	0,975	57	36,54	22	38,6	279	4,895	1,089	4,895	0,922	-1,914	-4,575	0,746	0,157	-0,273	-0,65	0,106			
Region	US	137	88,39	47	34,31	543	3,964	0,689	3,964	0,808	136	87,18	55	40,44	809	5,949	0,916	5,949	0,811	-1,985	-4,24	0,27	0,084	-0,209	-0,45	0,028	0,6739		
	ex-US	18	11,61	10	55,56	103	5,722	1,395	5,722	1,619	20	12,82	14	70	181	9,05	1,704	9,05	1,536	-3,328	-7,854	1,198	0,145	-0,474	-1,12	0,171			
BMI	BMI < 30 kg/m2	96	61,94	40	41,67	474	4,938	0,893	4,938	0,847	112	71,8	49	43,75	606	5,411	0,745	5,411	0,784	-0,473	-2,748	1,802	0,682	-0,057	-0,33	0,216	0,0141		
	BMI >= 30 kg/m2	58	37,42	17	29,31	172	2,966	0,79	2,966	1,416	40	25,64	18	45	362	9,05	2,415	9,05	1,705	-6,084	-10,484	-1,685	0,007	-0,56	-0,97	-0,16			
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	9,713	4	2,564	2	50	22	5,5	4,856	5,5	4,856	-5,5	-40,058	29,058	0,647	-0,412	-3	2,176			
Total household size including the household member(s) not participating this study																													
	2	60	38,71	21	35	235	3,917	0,791	3,917	0,959	66	42,31	28	42,42	343	5,197	1,039	5,197	0,915	-1,28	-3,904	1,343	0,336	-0,171	-0,52	0,18	0,4578		
	>2	95	61,29	36	37,9	411	4,326	0,902	4,326	1,05	90	57,69	41	45,56	647	7,189	1,219	7,189	1,079	-2,863	-5,833	0,108	0,059	-0,279	-0,57	0,01			
Baseline high risk factor	Yes	45	29,03	18	40	204	4,533	1,018	4,533	1,594	54	34,62	28	51,85	450	8,333	1,777	8,333	1,455	-3,8	-8,084	0,484	0,082	-0,353	-0,75	0,045	0,2608		
	No	110	70,97	39	35,46	442	4,018	0,787	4,018	0,799	102	65,39	41	40,2	540	5,294	0,843	5,294	0,83	-1,276	-3,547	0,995	0,269	-0,152	-0,42	0,118			
Race	White	129	83,23	46	35,66	530	4,109	0,712	4,109	0,813	134	85,9	58	43,28	796	5,94	0,883	5,94	0,798	-1,832	-4,074	0,41	0,109	-0,198	-0,44	0,044	0,6089		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	57	36,77	646	4,168	0,631	4,168	0,739	156	100	69	44,23	990	6,346	0,831	6,346	0,737	-2,178	-4,232	-0,125	0,038	-0,236	-0,46	-0,01	NE				
	Black or African American	8	5,161	2	25	31	3,875	2,741	3,875	2,869	10	6,41	7	70	96	9,6	2,651	9,6	2,566	-5,725	-13,884	2,434	0,156	-0,672	-1,63	0,286					
	Other	12	7,742	7	58,33	52	4,333	1,559	4,333	2,109	8	5,128	2	25	35	4,375	3,38	4,375	2,583	-0,042	-7,047	6,963	0,99	-0,005	-0,92	0,913					
	Unknown/Not Reported	6	3,871	2	33,33	33	5,5	3,538	5,5	5,386	4	2,564	2	50	63	15,75	9,205	15,75	6,596	-10,25	-29,887	9,387	0,263	-0,702	-2,05	0,643					
Ethnicity	Hispanic or Latino	65	41,94	18	27,69	293	4,508	1,297	4,508	1,411	58	37,18	17	29,31	334	5,759	1,618	5,759	1,493	-1,251	-5,318	2,816	0,544	-0,109	-0,47	0,246	0,454				
	Not Hispanic or Latino	89	57,42	39	43,82	353	3,966	0,561	3,966	0,798	96	61,54	52	54,17	656	6,833	0,931	6,833	0,768	-2,867	-5,053	-0,681	0,01	-0,379	-0,67	-0,09					
	Unknown/not reported	1	0,645	0	0	0	0	NE	0	NE	2	1,282	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,806	5	55,56	48	5,333	1,818	5,333	1,556	10	6,41	9	90	75	7,5	1,213	7,5	1,476	-2,167	-6,692	2,359	0,327	-0,443	-1,37	0,483	0,9905				
	No	144	92,9	52	36,11	598	4,153	0,669	4,153	0,788	146	93,59	60	41,1	915	6,267	0,884	6,267	0,782	-2,114	-4,3	0,071	0,058	-0,223	-0,45	0,008					
	Unknown/not reported	2	1,29	0	0	0	0	0	NE	NE	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	105	67,74	47	44,76	557	5,305	0,862	5,305	0,884	103	66,03	45	43,69	627	6,087	0,915	6,087	0,892	-0,783	-3,259	1,694	0,534	-0,086	-0,36	0,186	0,053				
	No	50	32,26	10	20	89	1,78	0,627	1,78	1,323	53	33,97	24	45,28	363	6,849	1,69	6,849	1,285	-5,069	-8,727	-1,411	0,007	-0,538	-0,93	-0,15					
Test result of a local diagnostic assay for SARS-CoV-2	Positive	90	58,07	36	40	424	4,711	0,933	4,711	0,969	82	52,56	35	42,68	497	6,061	1,055	6,061	1,015	-1,35	-4,119	1,42	0,337	-0,146	-0,45	0,154	0,3422				
	Negative	44	28,39	12	27,27	93	2,114	0,608	2,114	1,45	49	31,41	16	32,65	282	5,755	1,812	5,755	1,374	-3,641	-7,61	0,327	0,072	-0,375	-0,79	0,034					
	Unavailable	21	13,55	9	42,86	129	6,143	1,91	6,143	1,792	25	16,03	18	72	211	8,44	1,547	8,44	1,643	-2,297	-7,197	2,603	0,35	-0,275	-0,86	0,311					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

POPULATION: Modified Full Analysis Set - Cohort B

ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	155	100	57	36,77	646	4,168	0,631	4,168	0,739	156	100	69	44,23	990	6,346	0,831	6,346	0,737	-2,178	-4,232	-0,125	0,038	-0,236	-0,46	-0,01	NE				
Serology status	Seropositive	46	29,68	10	21,74	111	2,413	0,752	2,413	1,541	38	24,36	18	47,37	320	8,421	2,353	8,421	1,696	-6,008	-10,566	-1,45	0,01	-0,57	-1	-0,14	0,0247				
	Seronegative	100	64,52	45	45	518	5,18	0,894	5,18	0,887	104	66,67	45	43,27	592	5,692	0,863	5,692	0,87	-0,512	-2,962	1,937	0,68	-0,058	-0,33	0,218					
	Unclear serology status	9	5,806	2	22,22	17	1,889	1,274	1,889	2,078	14	8,974	6	42,86	78	5,571	1,96	5,571	1,666	-3,683	-9,222	1,857	0,181	-0,569	-1,43	0,287					

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 11Mar2021.

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Wirksamkeit

Ergänzende Dokumente

POPULATION: mFAS - Cohort B
ENDPOINT: --
MODEL: --
STUDY: R10933-10987-COV-2069
Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	76	100%	311	100%	3	100%	311	100%	2	100%	311	100%
with <10 Patients per arm ¹	74	97.4%	269	86.5%	1	33.3%	16	5.1%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	2	2.6%	42	13.5%	2	66.7%	295	94.9%	2	100%	311	100%

¹: ' <10 patients category' if at least one treatment arm has <10 patients.
²: ' >=10 patients ' category if all treatment arms have >=10 patients.
³: Geographical regions: US vs Ex-US (Romania; Republic of Moldova)
⁴: Number of centers, countries, or geographical regions
⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions
⁶: Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm)
⁷: % 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 cut-off: 11MAR21

Program: 0:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2069_CohortB\Analysis_MA\Programs\t3_center.sas
Output: 0:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2069_CohortB\Analysis_MA\Outputs\t3_center.xlsx

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 156)	Casirivimab/Imdevimab (N = 155)
Age (Years)		
n	156	155
Mean	42.44	39.28
SD	18.11	17.67
Median	42.0	39.0
Q1	24.5	24.0
Q3	58.0	51.0
Min	12.0	12.0
Max	87.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	17 (10.9)	21 (13.5)
>=18 to <45	67 (42.9)	71 (45.8)
>=45 to <65	51 (32.7)	49 (31.6)
>=65 to <80	19 (12.2)	13 (8.4)
>=80	2 (1.3)	1 (0.6)
Age Group (Years) [n (%)]		
>=12 to <50	99 (63.5)	104 (67.1)
>=50	57 (36.5)	51 (32.9)
Sex [n (%)]		
Male	71 (45.5)	80 (51.6)
Female	85 (54.5)	75 (48.4)
Race [n (%)]		
White	134 (85.9)	129 (83.2)
Black or African American	10 (6.4)	8 (5.2)
Asian	8 (5.1)	11 (7.1)
American Indian or Alaska Native	0 (0.0)	1 (0.6)
Other	4 (2.6)	6 (3.9)
Ethnicity [n (%)]		
Hispanic or Latino	58 (37.2)	65 (41.9)
Not Hispanic or Latino	96 (61.5)	89 (57.4)
Other	2 (1.3)	1 (0.6)
Weight (kg)		
n	152	154
Missing	4	1
Mean	78.47	82.21
SD	19.33	21.59
Median	75.7	81.3
Q1	63.8	65.6
Q3	90.8	95.0
Min	33.1	41.3
Max	144.2	145.1
Height (cm)		
n	153	155
Missing	3	0
Mean	168.34	169.27
SD	10.26	11.45
Median	168.0	170.0
Q1	162.5	162.6
Q3	175.0	176.5
Min	121.9	123.0
Max	195.6	201.2
BMI (kg/m2)		
n	152	154
Missing	4	1
Mean	27.61	28.53
SD	6.30	6.33
Median	26.8	28.1
Q1	23.1	23.5
Q3	30.1	31.9
Min	17.9	16.9
Max	47.5	51.2

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 156)	Casirivimab/Imdevimab (N = 155)
BMI group (kg/m2) [n (%)]		
Missing	4 (2.6)	1 (0.6)
BMI < 30 kg/m2	112 (71.8)	96 (61.9)
BMI ≥ 30 kg/m2	40 (25.6)	58 (37.4)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	82 (52.6)	90 (58.1)
Negative	49 (31.4)	44 (28.4)
Unavailable	25 (16.0)	21 (13.5)
Randomization strata: age [n (%)]		
12-17	17 (10.9)	21 (13.5)
18-49	82 (52.6)	83 (53.5)
≥50	57 (36.5)	51 (32.9)
Region [n (%)]		
US	136 (87.2)	137 (88.4)
ex-US	20 (12.8)	18 (11.6)
Country [n (%)]		
Moldova, Republic of	10 (6.4)	12 (7.7)
Romania	10 (6.4)	6 (3.9)
United States of America	136 (87.2)	137 (88.4)
Total household size including the house members not participating this study [n (%)]		
2	66 (42.3)	60 (38.7)
>2	90 (57.7)	95 (61.3)
No one wears a mask in home [n (%)]		
Missing	2 (1.3)	2 (1.3)
Yes	80 (51.3)	80 (51.6)
No	73 (46.8)	72 (46.5)
N/A	1 (0.6)	1 (0.6)
Share a bedroom [n (%)]		
Missing	2 (1.3)	2 (1.3)
Yes	70 (44.9)	63 (40.6)
No	82 (52.6)	90 (58.1)
N/A	2 (1.3)	0 (0.0)
Share a common room [n (%)]		
Missing	2 (1.3)	2 (1.3)
Yes	152 (97.4)	150 (96.8)
No	1 (0.6)	3 (1.9)
N/A	1 (0.6)	0 (0.0)
Symptoms in suspected infected person [n (%)]		
Missing	2 (1.3)	2 (1.3)
Yes	128 (82.1)	126 (81.3)
No	24 (15.4)	26 (16.8)
N/A	2 (1.3)	1 (0.6)
Aware of any treatment [n (%)]		
Missing	2 (1.3)	2 (1.3)
Yes	66 (42.3)	73 (47.1)
No	85 (54.5)	79 (51.0)
N/A	3 (1.9)	1 (0.6)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	2 (1.3)	0 (0.0)
Yes	49 (31.4)	57 (36.8)
No	105 (67.3)	98 (63.2)
Total household members, including index case, who participate the R10933-10987-COV-2067 [n (%)]		
Missing	2 (1.3)	6 (3.9)
0	128 (82.1)	112 (72.3)
1	24 (15.4)	31 (20.0)
2	2 (1.3)	4 (2.6)
3	0 (0.0)	2 (1.3)

Clinical cut-off: 11MAR21

**Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 156)	Casirivimab/Imdevimab (N = 155)
Subject received influenza [n (%)]		
Yes	32 (20.5)	29 (18.7)
No	124 (79.5)	126 (81.3)
Subject been quarantined [n (%)]		
Yes	31 (19.9)	36 (23.2)
No	125 (80.1)	119 (76.8)
First responder [n (%)]		
Missing	0 (0.0)	2 (1.3)
Yes	3 (1.9)	3 (1.9)
No	153 (98.1)	150 (96.8)
Healthcare worker [n (%)]		
Yes	10 (6.4)	9 (5.8)
No	146 (93.6)	144 (92.9)
Unknown/not reported	0 (0.0)	2 (1.3)
Contact with a stranger [n (%)]		
Yes	42 (26.9)	51 (32.9)
No	114 (73.1)	104 (67.1)
Serology status [n (%)]		
Seropositive	38 (24.4)	46 (29.7)
Seronegative	104 (66.7)	100 (64.5)
Unclear serology status	14 (9.0)	9 (5.8)
Viral load (log10 copies/mL) at baseline		
n	151	150
Missing	5	5
Mean	5.60	5.62
SD	2.27	2.12
Median	5.2	5.6
Q1	3.6	3.6
Q3	7.8	7.3
Min	2.6	2.6
Max	10.1	9.7
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	7 (4.5)	6 (3.9)
-1	1 (0.6)	1 (0.6)
0	148 (94.9)	148 (95.5)
Baseline high risk factor [n (%)]		
Yes	54 (34.6)	45 (29.0)
No	102 (65.4)	110 (71.0)

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 104)	Casirivimab/Imdevimab (N = 100)
Age (Years)		
n	104	100
Mean	42.41	38.93
SD	18.23	17.55
Median	42.5	39.0
Q1	24.5	24.0
Q3	58.0	50.5
Min	12.0	12.0
Max	87.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	11 (10.6)	15 (15.0)
>=18 to <45	45 (43.3)	44 (44.0)
>=45 to <65	35 (33.7)	33 (33.0)
>=65 to <80	11 (10.6)	7 (7.0)
>=80	2 (1.9)	1 (1.0)
Age Group (Years) [n (%)]		
>=12 to <50	66 (63.5)	70 (70.0)
>=50	38 (36.5)	30 (30.0)
Sex [n (%)]		
Male	43 (41.3)	50 (50.0)
Female	61 (58.7)	50 (50.0)
Race [n (%)]		
White	94 (90.4)	78 (78.0)
Black or African American	4 (3.8)	7 (7.0)
Asian	3 (2.9)	9 (9.0)
American Indian or Alaska Native	0 (0.0)	1 (1.0)
Other	3 (2.9)	5 (5.0)
Ethnicity [n (%)]		
Hispanic or Latino	38 (36.5)	34 (34.0)
Not Hispanic or Latino	65 (62.5)	65 (65.0)
Other	1 (1.0)	1 (1.0)
Weight (kg)		
n	102	99
Missing	2	1
Mean	78.39	81.90
SD	19.01	22.91
Median	75.7	79.4
Q1	64.6	64.6
Q3	90.9	95.3
Min	33.1	41.3
Max	133.7	145.1
Height (cm)		
n	102	100
Missing	2	0
Mean	168.05	169.13
SD	10.70	12.38
Median	168.0	170.0
Q1	162.5	162.6
Q3	174.0	177.8
Min	121.9	123.0
Max	195.6	201.2
BMI (kg/m2)		
n	102	99
Missing	2	1
Mean	27.72	28.43
SD	6.37	6.66
Median	26.9	27.8
Q1	23.2	23.2
Q3	30.1	32.0
Min	18.8	16.9
Max	47.5	51.2

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 104)	Casirivimab/Imdevimab (N = 100)
BMI group (kg/m2) [n (%)]		
Missing	2 (1.9)	1 (1.0)
BMI < 30 kg/m2	73 (70.2)	62 (62.0)
BMI >= 30 kg/m2	29 (27.9)	37 (37.0)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	56 (53.8)	59 (59.0)
Negative	28 (26.9)	27 (27.0)
Unavailable	20 (19.2)	14 (14.0)
Randomization strata: age [n (%)]		
12-17	11 (10.6)	15 (15.0)
18-49	55 (52.9)	55 (55.0)
>=50	38 (36.5)	30 (30.0)
Region [n (%)]		
US	90 (86.5)	89 (89.0)
ex-US	14 (13.5)	11 (11.0)
Country [n (%)]		
Moldova, Republic of	9 (8.7)	8 (8.0)
Romania	5 (4.8)	3 (3.0)
United States of America	90 (86.5)	89 (89.0)
Total household size including the house members not participating this study [n (%)]		
2	44 (42.3)	33 (33.0)
>2	60 (57.7)	67 (67.0)
No one wears a mask in home [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	54 (51.9)	51 (51.0)
No	50 (48.1)	47 (47.0)
N/A	0 (0.0)	1 (1.0)
Share a bedroom [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	50 (48.1)	41 (41.0)
No	53 (51.0)	58 (58.0)
N/A	1 (1.0)	0 (0.0)
Share a common room [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	103 (99.0)	97 (97.0)
No	1 (1.0)	2 (2.0)
Symptoms in suspected infected person [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	89 (85.6)	83 (83.0)
No	14 (13.5)	15 (15.0)
N/A	1 (1.0)	1 (1.0)
Aware of any treatment [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	46 (44.2)	53 (53.0)
No	57 (54.8)	45 (45.0)
N/A	1 (1.0)	1 (1.0)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	1 (1.0)	0 (0.0)
Yes	30 (28.8)	39 (39.0)
No	73 (70.2)	61 (61.0)

Clinical cut-off: 11MAR21

Table 4.2: Demographic and Baseline Characteristics per arm seronegative mFAS-B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 104)	Casirivimab/Imdevimab (N = 100)
Total household members, including index case, who participated at the R10933-10987-COV-2067 [n (%)]		
Missing	2 (1.9)	3 (3.0)
0	90 (86.5)	73 (73.0)
1	11 (10.6)	21 (21.0)
2	1 (1.0)	2 (2.0)
3	0 (0.0)	1 (1.0)
Subject received influenza [n (%)]		
Yes	26 (25.0)	21 (21.0)
No	78 (75.0)	79 (79.0)
Subject been quarantined [n (%)]		
Yes	18 (17.3)	26 (26.0)
No	86 (82.7)	74 (74.0)
First responder [n (%)]		
Missing	0 (0.0)	1 (1.0)
Yes	2 (1.9)	3 (3.0)
No	102 (98.1)	96 (96.0)
Healthcare worker [n (%)]		
Yes	8 (7.7)	8 (8.0)
No	96 (92.3)	90 (90.0)
Unknown/not reported	0 (0.0)	2 (2.0)
Contact with a stranger [n (%)]		
Yes	25 (24.0)	33 (33.0)
No	79 (76.0)	67 (67.0)
Serology status [n (%)]		
Seronegative	104 (100.0)	100 (100.0)
Viral load (log10 copies/mL) at baseline		
n	100	96
Missing	4	4
Mean	6.16	6.33
SD	2.23	1.94
Median	6.2	6.5
Q1	4.2	5.1
Q3	8.1	7.8
Min	2.6	2.6
Max	10.1	9.7
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	5 (4.8)	4 (4.0)
-1	0 (0.0)	1 (1.0)
0	99 (95.2)	95 (95.0)
Baseline high risk factor [n (%)]		
Yes	34 (32.7)	31 (31.0)
No	70 (67.3)	69 (69.0)

Table 5.1. Summary of Overall Patient Disposition
Modified Full Analysis Set - Cohort B

	Placebo (N=156)	Casirivimab/Imdevimab (N=155)
Randomized patients	156 (100%)	155 (100%)
Randomized but not treated	2 (1.3%)	1 (0.6%)
Randomized and treated	154 (98.7%)	154 (99.4%)
Complete the efficacy assessment period (EAP) (as derived)	153 (98.1%)	154 (99.4%)
Complete the end of study follow-up visit (as per CRF)	1 (0.6%)	2 (1.3%)
Did not complete the end of study follow-up visit	153 (98.1%)	152 (98.1%)
Subjects discontinued from the study during EAP	1 (0.6%)	0
Reason for subjects discontinuing from the study during EAP		
Adverse Event	0	0
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	0	0
Lost To Follow-Up	0	0
Subject Decision	1 (0.6%)	0
Screen Patients	156 (100%)	155 (100%)
Reasons for screen phase discontinuation		
Adverse Event	0	0
Screen Failure	0	0
Subject Decision	0	0

Clinical cut-off: 11MAR21

Table 5.1. Summary of Overall Patient Disposition
Modified Full Analysis Set - Cohort B

	Placebo (N=156)	Casirivimab/Imdevimab (N=155)
Lost To Follow-Up	0	0
Death	0	0
Sponsor Request	0	0
Other	0	0

Clinical cut-off: 11MAR21

Table 14.1.1 Disposition of Screened Subjects
All Screened Subjects

	Total (N=3096)
Number of Subjects Screened	3096
Randomized Subject	3029 (97.8%)
Subjects treated but not randomized	0
Subjects randomized but not treated	27 (0.9%)
Screen phase discontinuation	83 (2.7%)
Adverse Event	1 (<0.1%)
Screen Failure	65 (2.1%)
Subject Decision	9 (0.3%)
Lost To Follow-Up	0
Death	0
Sponsor Request	0
Other	8 (0.3%)
Screen phase discontinuation and randomized	16 (0.5%)
Adverse Event	0
Screen Failure	5 (0.2%)
Subject Decision	5 (0.2%)
Lost To Follow-Up	0
Death	0
Sponsor Request	0

Note: For the first step analysis, all subjects randomized by 28Jan2021 are included. The cutoff date is 11Mar2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: % calculated using the number of subjects screened as denominator.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA_rand28Jan/Analysis_CSR/Programs/TFL/Generated/t_1011_scr.sas (bryan.zhu 04JUN2021 14:41 SAS Linux 9.4)

Table 14.1.1 Disposition of Screened Subjects
All Screened Subjects

	Total (N=3096)
Screen phase discontinuation and randomized	
Other	6 (0.2%)

Note: For the first step analysis, all subjects randomized by 28Jan2021 are included. The cutoff date is 11Mar2021. For efficacy analysis, 554 subjects in cohort A who were in the administrative assessment are excluded.

Note: % calculated using the number of subjects screened as denominator.

/sasdata/Data/Production/BDM/R10933-10987/R10933-10987-COV/R10933-10987-COV-2069/BLA_IA_rand28Jan/Analysis_CSR/Programs/TFL/Generated/t_1011_scr.sas (bryan.zhu 04JUN2021 14:41 SAS Linux 9.4)

Clinical cut-off: 11MAR2021

**Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set - Cohort B**

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 156)	Casirivimab/Imdevimab (N = 155)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Missing	2	1
Median	100.0	98.0

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

Hauptdokumente

POPULATION: Safety - Cohort B

ENDPOINT: Any AEs

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event				Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	52	33,5	156	100	75	48,1	0,55		Algorithm converged.	0,34	0,86	-14,529		Algorithm converged.	-25,3	-3,72	0,7		Algorithm converged.	0,53	0,92	0,009		1,43		Algorithm converged.	1,09	1,89		
Sex	Male	80	51,6	26	32,5	69	44,2	31	44,9	0,59		Algorithm converged.	0,3	1,15	-12,428		Algorithm converged.	-28	3,16	0,72		Algorithm converged.	0,48	1,09	0,121	0,849	1,38		Algorithm converged.	0,92	2,08		
	Female	75	48,4	26	34,7	87	55,8	44	50,6	0,52		Algorithm converged.	0,27	0,98	-15,908		Algorithm converged.	-31	-0,86	0,69		Algorithm converged.	0,47	1	0,042		1,46		Algorithm converged.	1	2,12		
Age	12-17	21	13,5	2	9,5	17	10,9	8	47,1	0,12		Algorithm converged.	0,02	0,68	-37,535		Algorithm converged.	-64,4	-10,7	0,2		Algorithm converged.	0,05	0,83	0,023	0,0965	4,94		Algorithm converged.	1,2	20,3		
	18-49	83	53,5	33	39,8	81	51,9	40	49,4	0,68		Algorithm converged.	0,36	1,26	-9,624		Algorithm converged.	-24,8	5,52	0,81		Algorithm converged.	0,57	1,14	0,216		1,24		Algorithm converged.	0,88	1,75		
	>=50	51	32,9	17	33,3	58	37,2	27	46,6	0,57		Algorithm converged.	0,26	1,25	-13,218		Algorithm converged.	-31,4	5,01	0,72		Algorithm converged.	0,44	1,15	0,162		1,4		Algorithm converged.	0,87	2,25		
Region	US	138	89	44	31,9	138	88,5	68	49,3	0,48		Algorithm converged.	0,3	0,79	-17,391		Algorithm converged.	-28,8	-5,99	0,65		Algorithm converged.	0,48	0,87	0,003	0,1391	1,55		Algorithm converged.	1,15	2,08		
	ex-US	17	11	8	47,1	18	11,5	7	38,9	1,4		Algorithm converged.	0,36	5,35	8,17		Algorithm converged.	-24,5	40,88	1,21		Algorithm converged.	0,56	2,61	0,63		0,83		Algorithm converged.	0,38	1,78		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Any AEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	155	100	17	11	156	100	25	16	0,65	Algorithm converged.	0,33	1,25	-5,058	Algorithm converged.	-12,6	2,51	0,68	Algorithm converged.	0,39	1,22	0,193		1,46	Algorithm converged.	0,82	2,6						
Sex	Male	80	51,6	9	11,3	69	44,2	12	17,4	0,6	Algorithm converged.	0,24	1,53	-6,141	Algorithm converged.	-17,5	5,17	0,65	Algorithm converged.	0,29	1,44	0,284	0,8668	1,55	Algorithm converged.	0,69	3,45						
	Female	75	48,4	8	10,7	87	55,8	13	14,9	0,68	Algorithm converged.	0,27	1,74	-4,276	Algorithm converged.	-14,5	5,97	0,71	Algorithm converged.	0,31	1,63	0,421		1,4	Algorithm converged.	0,61	3,2						
Age	12-17	21	13,5	1	4,8	17	10,9	1	5,9	0,8	Algorithm converged.	0,05	13,8	-1,12	Algorithm converged.	-15,5	13,3	0,81	Algorithm converged.	0,05	12	1	0,765	1,24	Algorithm converged.	0,08	18,3						
	18-49	83	53,5	9	10,8	81	51,9	10	12,3	0,86	Algorithm converged.	0,33	2,25	-1,502	Algorithm converged.	-11,3	8,3	0,88	Algorithm converged.	0,38	2,05	0,765		1,14	Algorithm converged.	0,49	2,66						
	>=50	51	32,9	7	13,7	58	37,2	14	24,1	0,5	Algorithm converged.	0,18	1,36	-10,412	Algorithm converged.	-24,9	4,1	0,57	Algorithm converged.	0,25	1,3	0,171		1,76	Algorithm converged.	0,77	4,02						
Region	US	138	89	14	10,1	138	88,5	23	16,7	0,56	Algorithm converged.	0,28	1,15	-6,522	Algorithm converged.	-14,5	1,48	0,61	Algorithm converged.	0,33	1,13	0,113	0,2825	1,64	Algorithm converged.	0,88	3,06						
	ex-US	17	11	3	17,6	18	11,5	2	11,1	1,71	Algorithm converged.	0,25	11,8	6,536	Algorithm converged.	-16,7	29,8	1,59	Algorithm converged.	0,3	8,37	0,658		0,63	Algorithm converged.	0,12	3,32						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade >= 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	155	100	1	0,6	156	100	4	2,6	0,25	Algorithm converged.	0,03	2,23	-1,919	Algorithm converged.	-4,7	0,86	0,25	Algorithm converged.	0,03	2,23	0,371		3,97	Algorithm converged.	0,45	35,2				
Sex	Male	80	51,6	1	1,3	69	44,2	1	1,4	0,86	Algorithm converged.	0,05	14	-0,199	Algorithm converged.	-3,92	3,53	0,86	Algorithm converged.	0,05	13,5	1	0,1672	1,16	Algorithm converged.	0,07	18,2				
	Female	75	48,4	0	0	87	55,8	3	3,4	0	Algorithm converged.	NE	NE	-3,448	Algorithm converged.	-7,28	0,39	NE	*	Algorithm not converged.	NE	NE	0,25		NE	*	Algorithm not converged.	NE	NE		
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	18-49	83	53,5	0	0	81	51,9	2	2,5	0	Algorithm converged.	NE	NE	-2,469	Algorithm converged.	-5,85	0,91	NE	*	Algorithm not converged.	NE	NE	0,242		NE	*	Algorithm not converged.	NE	NE		
	>=50	51	32,9	1	2	58	37,2	2	3,4	0,56	Algorithm converged.	0,05	6,36	-1,487	Algorithm converged.	-7,53	4,56	0,57	Algorithm converged.	0,05	6,09	1		1,76	Algorithm converged.	0,16	18,8				
Region	US	138	89	1	0,7	138	88,5	3	2,2	0,33	Algorithm converged.	0,03	3,2	-1,449	Algorithm converged.	-4,26	1,37	0,33	Algorithm converged.	0,04	3,17	0,622	0,4849	3	Algorithm converged.	0,32	28,5				
	ex-US	17	11	0	0	18	11,5	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade >=3 (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	155	100	1	0,6	156	100	1	0,6	1,01	Algorithm converged.	0,06	16,2	0,004	Algorithm converged.	-1,77	1,78	1,01	Algorithm converged.	0,06	16	1			0,99	Algorithm converged.	0,06	15,7	
Sex	Male	80	51,6	1	1,3	69	44,2	1	1,4	0,86	Algorithm converged.	0,05	14	-0,199	Algorithm converged.	-3,92	3,53	0,86	Algorithm converged.	0,05	13,5	1	1		1,16	Algorithm converged.	0,07	18,2	
	Female	75	48,4	0	0	87	55,8	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			NE *	Algorithm not converged.	NE	NE	
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			NE *	Algorithm not converged.	NE	NE	
	18-49	83	53,5	0	0	81	51,9	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			NE *	Algorithm not converged.	NE	NE	
	>=50	51	32,9	1	2	58	37,2	1	1,7	1,14	Algorithm converged.	0,07	18,7	0,237	Algorithm converged.	-4,83	5,31	1,14	Algorithm converged.	0,07	17,7	1			0,88	Algorithm converged.	0,06	13,7	
Region	US	138	89	1	0,7	138	88,5	0	0	NE *	Algorithm not converged.	NE	NE	0,725	Algorithm converged.	-0,69	2,14	NE *	Algorithm not converged.	NE	NE	1			NE *	Algorithm not converged.	NE	NE	
	ex-US	17	11	0	0	18	11,5	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE *	Algorithm not converged.	NE	NE	1			NE *	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	155	100	1	0,6	156	100	4	2,6	0,25	Algorithm converged.	0,03	2,23	-1,919	Algorithm converged.	-4,7	0,86	0,25	Algorithm converged.	0,03	2,23	0,371		3,97	Algorithm converged.	0,45	35,2
Sex	Male	80	51,6	1	1,3	69	44,2	1	1,4	0,86	Algorithm converged.	0,05	14	-0,199	Algorithm converged.	-3,92	3,53	0,86	Algorithm converged.	0,05	13,5	1	0,1672	1,16	Algorithm converged.	0,07	18,2
	Female	75	48,4	0	0	87	55,8	3	3,4	0	Algorithm converged.	NE	NE	-3,448	Algorithm converged.	-7,28	0,39	NE	Algorithm not converged.	NE	NE	0,25		NE	Algorithm not converged.	NE	NE
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	18-49	83	53,5	0	0	81	51,9	2	2,5	0	Algorithm converged.	NE	NE	-2,469	Algorithm converged.	-5,85	0,91	NE	Algorithm not converged.	NE	NE	0,242		NE	Algorithm not converged.	NE	NE
	>=50	51	32,9	1	2	58	37,2	2	3,4	0,56	Algorithm converged.	0,05	6,36	-1,487	Algorithm converged.	-7,53	4,56	0,57	Algorithm converged.	0,05	6,09	1		1,76	Algorithm converged.	0,16	18,8
Region	US	138	89	1	0,7	138	88,5	3	2,2	0,33	Algorithm converged.	0,03	3,2	-1,449	Algorithm converged.	-4,26	1,37	0,33	Algorithm converged.	0,04	3,17	0,622	0,4849	3	Algorithm converged.	0,32	28,5
	ex-US	17	11	0	0	18	11,5	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade 4

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab													
		Patients				Event				Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Any SAEs

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	155	100	0	0	156	100	4	2,6	0	Algorithm converged.	NE	NE	-2,564	Algorithm converged.	-5,04	-0,08	NE	*	Algorithm not converged.	NE	NE	0,123		NE	*	Algorithm not converged.	NE	NE				
Sex	Male	80	51,6	0	0	69	44,2	1	1,4	0	Algorithm converged.	NE	NE	-1,449	Algorithm converged.	-4,27	1,37	NE	*	Algorithm not converged.	NE	NE	0,463	1	NE	*	Algorithm not converged.	NE	NE				
	Female	75	48,4	0	0	87	55,8	3	3,4	0	Algorithm converged.	NE	NE	-3,448	Algorithm converged.	-7,28	0,39	NE	*	Algorithm not converged.	NE	NE	0,25		NE	*	Algorithm not converged.	NE	NE				
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE		
	18-49	83	53,5	0	0	81	51,9	2	2,5	0	Algorithm converged.	NE	NE	-2,469	Algorithm converged.	-5,85	0,91	NE	*	Algorithm not converged.	NE	NE	0,242		NE	*	Algorithm not converged.	NE	NE				
	>=50	51	32,9	0	0	58	37,2	2	3,4	0	Algorithm converged.	NE	NE	-3,448	Algorithm converged.	-8,14	1,25	NE	*	Algorithm not converged.	NE	NE	0,498		NE	*	Algorithm not converged.	NE	NE				
Region	US	138	89	0	0	138	88,5	3	2,2	0	Algorithm converged.	NE	NE	-2,174	Algorithm converged.	-4,61	0,26	NE	*	Algorithm not converged.	NE	NE	0,247		NE	*	Algorithm not converged.	NE	NE				
	ex-US	17	11	0	0	18	11,5	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Any SAEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	1	0,6	0	Algorithm converged.	NE	NE	-0,641	Algorithm converged.	-1,89	0,61	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Sex	Male	80	51,6	0	0	69	44,2	1	1,4	0	Algorithm converged.	NE	NE	-1,449	Algorithm converged.	-4,27	1,37	NE	*	Algorithm not converged.	NE	NE	0,463		NE	*	Algorithm not converged.	NE	NE	
	Female	75	48,4	0	0	87	55,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Age	12-17	21	13,5	0	0	17	10,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	18-49	83	53,5	0	0	81	51,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=50	51	32,9	0	0	58	37,2	1	1,7	0	Algorithm converged.	NE	NE	-1,724	Algorithm converged.	-5,07	1,63	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Region	US	138	89	0	0	138	88,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	ex-US	17	11	0	0	18	11,5	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

AESI

POPULATION: Safety - Cohort B

ENDPOINT: Injection site reactions Grade ≥ 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Serious injection site reactions

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	155	100	0	0	156	100	0	0																					
Sex	Male	80	51,6	0	0	69	44,2	0	0																					
	Female	75	48,4	0	0	87	55,8	0	0																					
Age	12-17	21	13,5	0	0	17	10,9	0	0																					
	18-49	83	53,5	0	0	81	51,9	0	0																					
	>=50	51	32,9	0	0	58	37,2	0	0																					
Region	US	138	89	0	0	138	88,5	0	0																					
	ex-US	17	11	0	0	18	11,5	0	0																					

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Hypersensitivity reactions Grade ≥ 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 11MAR2021

POPULATION: Safety - Cohort B

ENDPOINT: Serious hypersensitivity reactions

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk							

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

SOC-PT

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab														
			Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test (likelihood ratio)					Relative Risk				
Name	SOC	PT	Level	n	%	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk																
All	Cardiac disorders	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
		Supraventricular tachycardia	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE														
	Ear and labyrinth disorders	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
		Ear pain	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE														
Gastrointestinal disorders	--	--	155	100	3	1.935	156	100	2	1.282	1.52	Algorithm not converged.	0.25	9.223	0.653	Algorithm not converged.	-2.143	NE	1.51	*	Algorithm not converged.	0.256	8.91	0.6845	0.662	Algorithm not converged.	0.112	3.91																			
	Abdominal pain upper	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Diarrhoea	--	--	155	100	1	0.645	156	100	1	0.641	1.006	Algorithm not converged.	0.062	16.236	0.004	Algorithm not converged.	-1.773	NE	1.006	*	Algorithm not converged.	0.064	15.948	1	0.994	Algorithm not converged.	0.063	15.744																		
	Gingival pain	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Pancreatitis acute	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Vomiting	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	General disorders and administration site conditions	--	--	155	100	8	5.161	156	100	2	1.282	4.19	Algorithm not converged.	0.875	20.059	3.879	Algorithm not converged.	-0.026	NE	4.026	*	Algorithm not converged.	0.869	18.656	0.0608	0.248	Algorithm not converged.	0.054	1.151																		
General disorders and administration site conditions	Fatigue	--	--	155	100	1	0.645	156	100	1	0.641	1.006	Algorithm not converged.	0.062	16.236	0.004	Algorithm not converged.	-1.773	NE	1.006	*	Algorithm not converged.	0.064	15.948	1	0.994	Algorithm not converged.	0.063	15.744																		
	Injection site reaction	--	--	155	100	6	3.871	156	100	1	0.641	6.242	Algorithm not converged.	0.743	52.465	3.23	Algorithm not converged.	-0.055	NE	6.039	*	Algorithm not converged.	0.736	49.575	0.0668	0.166	Algorithm not converged.	0.02	1.359																		
	Pyrexia	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Hepatobiliary disorders	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Hepatic steatosis	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Infections and infestations	--	--	155	100	41	26.452	156	100	64	41.026	0.517	Algorithm not converged.	0.32	0.834	-14.574	Algorithm not converged.	-24.956	NE	0.645	*	Algorithm not converged.	0.467	0.891	0.0067	1.551	Algorithm not converged.	1.123	2.142																		
	COVID-19	--	--	155	100	34	21.935	156	100	49	31.41	0.614	Algorithm not converged.	0.369	1.021	-9.475	Algorithm not converged.	-19.247	NE	0.698	*	Algorithm not converged.	0.479	1.018	0.0593	1.432	Algorithm not converged.	0.982	2.087																		
Infections and infestations	COVID-19 pneumonia	--	--	155	100	0	0	156	100	3	1.923	NE *	Algorithm not converged.	NE	NE	-1.923	Algorithm not converged.	-4.078	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2476	NE	Algorithm not converged.	NE	NE	NE	NE															
	Ear infection	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Gastroenteritis	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Herpes ophthalmic	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Pharyngitis streptococcal	--	--	155	100	1	0.645	156	100	1	0.641	1.006	Algorithm not converged.	0.062	16.236	0.004	Algorithm not converged.	-1.773	NE	1.006	*	Algorithm not converged.	0.064	15.948	1	0.994	Algorithm not converged.	0.063	15.744																		
	Pyuria	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Urinary tract infection	--	--	155	100	0	0	156	100	3	1.923	NE *	Algorithm not converged.	NE	NE	-1.923	Algorithm not converged.	-4.078	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2476	NE	Algorithm not converged.	NE	NE	NE	NE															
Injury, poisoning and procedural complications	--	--	155	100	1	0.645	156	100	3	1.923	0.331	Algorithm not converged.	0.034	3.219	-1.278	Algorithm not converged.	-3.775	NE	0.335	*	Algorithm not converged.	0.035	3.19	0.6226	2.981	Algorithm not converged.	0.313	28.344																			
	Alcohol poisoning	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Limb injury	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Meniscus injury	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Skin abrasion	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
Investigations	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE																
	Hepatic enzyme increased	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
Metabolism and nutrition disorders	--	--	155	100	0	0	156	100	2	1.282	NE *	Algorithm not converged.	NE	NE	-1.282	Algorithm not converged.	-3.047	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE																
	Diabetes mellitus	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Steroid diabetes	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
Musculoskeletal and connective tissue disorders	--	--	155	100	2	1.29	156	100	3	1.923	0.667	Algorithm not converged.	0.11	4.040	-0.633	Algorithm not converged.	-3.426	NE	0.671	*	Algorithm not converged.	0.114	3.96	1	1.49	Algorithm not converged.	0.253	8.797																			
	Back pain	--	--	155	100	1	0.645	156	100	1	0.641	1.006	Algorithm not converged.	0.062	16.236	0.004	Algorithm not converged.	-1.773	NE	1.006	*	Algorithm not converged.	0.064	15.948	1	0.994	Algorithm not converged.	0.063	15.744																		
	Pain in jaw	--	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm not converged.	-0.615	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Rhabdomyolysis	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Tendinitis	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
Nervous system disorders	--	--	155	100	0	0	156	100	4	2.564	NE *	Algorithm not converged.	NE	NE	-2.564	Algorithm not converged.	-5.044	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.1226	NE	Algorithm not converged.	NE	NE	NE	NE																
	Dizziness	--	--	155	100	0	0	156	100	2	1.282	NE *	Algorithm not converged.	NE	NE	-1.282	Algorithm not converged.	-3.047	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	NE	NE															
	Dysgeusia	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Headache	--	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm not converged.	-1.893	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE															
	Transient ischaemic attack	--	--	155	100	0	0	156	100	1	0.641	NE *																																			

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casir/mab/rndev/mab										Placebo										Casir/mab/rndev/mab vs. Placebo										Casir/mab/rndev/mab vs. Placebo										Placebo vs. Casir/mab/rndev/mab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
		Patients										Patients with Event										Patients										Patients with Event										Odds Ratio										Absolute Risk Difference										Relative Risk										Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: 1-ae-raw-soc.sas
Output: 113-14-ae-raw-soc-anyae-ts

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

[illegible]

		18-49	83	32,948	1	1,205	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	1,205	Algorithm converged.	-1,142	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Herpes ophthalmic	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Pharyngitis streptococcal	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	1	1,205	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	1,205	Algorithm converged.	-1,142	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Pyuria	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Urinary tract infection	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	2	2,469	NE	*	Algorithm not converged.	NE	NE	-2,469	Algorithm converged.	-5,849	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.2424	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Injury, poisoning and procedural complications	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	2	2,469	NE	*	Algorithm not converged.	NE	NE	-2,469	Algorithm converged.	-5,849	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.2424	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	1	1,961	58	37,179	1	1,724	1.14	Algorithm converged.	0.069	18,704	0.237	Algorithm converged.	-4,833	NE	1.137	Algorithm converged.	0.073	17,721	1	0.879	NE	0.056	13,702	Algorithm converged.	0.056	13,702	
	Alcohol poisoning	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	1	1,235	NE	*	Algorithm not converged.	NE	NE	-1,235	Algorithm converged.	-3,639	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4939	NE	Algorithm not converged.	NE	NE	
	>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Limb injury	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	1	1,235	NE	*	Algorithm not converged.	NE	NE	-1,235	Algorithm converged.	-3,639	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4939	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Meniscus injury	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	1	1,961	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Skin abrasion	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Investigations	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	1	1,961	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Hepatic enzyme increased	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	1	1,961	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
Metabolism and nutrition disorders	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	2	3,448	NE	*	Algorithm not converged.	NE	NE	-3,448	Algorithm converged.	-8,144	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Diabetes mellitus	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Steroid diabetes	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	0	0	58	37,179	1	1,724	NE	*	Algorithm not converged.	NE	NE	-1,724	Algorithm converged.	-5,074	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Musculoskeletal and connective tissue disorders	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	1	1,235	NE	*	Algorithm not converged.	NE	NE	-1,235	Algorithm converged.	-3,639	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4939	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	2	3,922	58	37,179	2	3,448	1.143	Algorithm converged.	0.155	8,42	0.473	Algorithm converged.	-6,628	NE	1.137	Algorithm converged.	0.166	7,784	1	0.879	NE	0.128	6,019	Algorithm converged.	0.128	6,019	
	Back pain	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	1	1,961	58	37,179	1	1,724	1.14	Algorithm converged.	0.069	18,704	0.237	Algorithm converged.	-4,833	NE	1.137	Algorithm converged.	0.073	17,721	1	0.879	NE	0.056	13,702	Algorithm converged.	0.056	13,702	
	Pain in jaw	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		>=50	51	32,903	1	1,961	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Rhabdomyolysis	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		18-49	83	32,948	0	0	81	51,923	1	1,235	NE	*	Algorithm not converged.	NE	NE	-1,235	Algorithm converged.	-3,639	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.4939	NE	Algorithm not converged.	NE	NE	
		>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Tendinitis	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Program: t-ae-row-soc.sas
Output: t13-1f-ae-row-soc-anyae-fs

							Casimir/mab/Indinavir	Patients	Patients with Event		Patients	Patients with Event		Odds Ratio		Casimir/mab/Indinavir vs. Placebo	Absolute Risk Difference		Casimir/mab/Indinavir vs. Placebo	Relative Risk	Placebo vs. Casimir/mab/Indinavir	Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Region	Cardiac disorders	--	US ex-US	138 17	89.032 10.968	0 0	0 0	138 18	88.462 11.538	0 1	5.556 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	-5.556	Algorithm not converged.	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
		Supraventricular tachycardia	US ex-US	138 17	89.032 10.968	0 0	0 0	138 18	88.462 11.538	0 1	5.556 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	-5.556	Algorithm not converged.	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
	Ear and labyrinth disorders	--	US ex-US	138 17	89.032 10.968	0 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.725	Algorithm not converged.	-0.69	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
		Ear pain	US ex-US	138 17	89.032 10.968	0 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.725	Algorithm not converged.	-0.69	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
	Gastrointestinal disorders	--	US ex-US	138 17	89.032 10.968	2 1	1,449 5,882	88.462 11.538	2 2	0 1,111	0.5 * Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	1,449 6,082	Algorithm not converged.	-0.545 -23.556	NE NE	0.4982 0.529	*	Algorithm not converged.	NE NE	0.4982 0.538	1	NE	1,889	Algorithm not converged.	NE NE	0.188 38.975
		Abdominal pain upper	US ex-US	138 17	89.032 10.968	0 0	0 0	138 18	88.462 11.538	0 1	5.556 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	-5.556	Algorithm not converged.	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
		Diarhoea	US ex-US	138 17	89.032 10.968	0 0	5.882 138	88.462 11.538	1 1	5.556 1.063	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.327	Algorithm not converged.	-15.071	NE NE	1.059	*	Algorithm not converged.	NE NE	NE NE	1	NE	0.944	Algorithm not converged.	NE NE	0.064 13.932
		Gingival pain	US ex-US	138 17	89.032 10.968	1 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.725	Algorithm not converged.	-0.69	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
		Pancreatitis acute	US ex-US	138 17	89.032 10.968	0 0	0 0	138 18	88.462 11.538	0 1	5.556 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	-5.556	Algorithm not converged.	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
		Vomiting	US ex-US	138 17	89.032 10.968	1 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.725	Algorithm not converged.	-0.69	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE	Algorithm not converged.	NE NE	NE NE
	General disorders and administration site conditions	--	US ex-US	138 17	89.032 10.968	6 2	4,348 11,765	88.462 11.538	2 1	4,449 3,091	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	2,899 11,765	Algorithm not converged.	-1,045 -3,551	NE NE	3 0.2818	*	Algorithm not converged.	NE NE	0.2818 0.2286	1	NE	0.333	Algorithm not converged.	NE NE	0.068 1.623
		Fatigue	US ex-US	138 17	89.032 10.968	1 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.165	0.062	16.15	0	1	*	Algorithm not converged.	NE NE	15.827	1	1	1	Algorithm not converged.	NE NE	0.063 15.827
		Injection site reaction	US ex-US	138 17	89.032 10.968	4 2	2,899 11,765	88.462 11.538	1 0	0.725 4.09	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	3,074 11,765	Algorithm not converged.	-0.963 -3,551	NE NE	4 0.2296	*	Algorithm not converged.	NE NE	3,353 0.2296	1	0.3764	0.25	Algorithm not converged.	NE NE	0.028 2.208
		Pyrexia	US ex-US	138 17	89.032 10.968	1 0	0.725 138	88.462 11.538	0 0	0 NE	* Algorithm not converged.	Algorithm not converged.	NE NE	NE NE	0.725	Algorithm not converged.	-0.69	NE NE	NE NE	*	Algorithm not converged.	NE NE	NE NE	1	NE	NE			

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: f-ae-raw-soc.sas
Output: 113-31-ae-raw-soc-any-ae-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casir/mab/mdeu/mab								Placebo				Casir/mab/mdeu/mab vs. Placebo										Placebo vs. Casir/mab/mdeu/mab											
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio		Absolute Risk Difference				Relative Risk						Interaction Test				Relative Risk	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program: t-ae-raw-soc.sas
Output: t13-2f-ae-raw-soc-toxngt3.b

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Sex	Cardiac disorders	--		Male	80	51,613	0	0	69	44,231	1	1,449	NE	*	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-4,269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Supraventricular tachycardia		Male	80	51,613	0	0	69	44,231	1	1,449	NE	*	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-4,269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--		Male	80	51,613	0	0	69	44,231	1	1,449	NE	*	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-4,269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pancreatitis acute		Male	80	51,613	0	0	69	44,231	1	1,449	NE	*	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-4,269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--		Male	80	51,613	0	0	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	75	48,387	0	0	87	55,769	3	3,448	NE	*	Algorithm not converged.	NE	NE	-3,448	Algorithm converged.	-7,282	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2495	NE	Algorithm not converged.	NE	NE
		COVID-19		Male	80	51,613	0	0	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	75	48,387	0	0	87	55,769	2	2,299	NE	*	Algorithm not converged.	NE	NE	-2,299	Algorithm converged.	-5,448	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4997	NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia		Male	80	51,613	0	0	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	75	48,387	0	0	87	55,769	1	1,149	NE	*	Algorithm not converged.	NE	NE	-1,149	Algorithm converged.	-3,389	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--		Male	80	51,613	1	1.25	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	1.25	Algorithm converged.	-1,185	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Back pain		Male	80	51,613	1	1.25	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	1.25	Algorithm converged.	-1,185	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
				Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: 113-2t-ae-raw-soc-toxggr3.fs

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
		Level		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		(likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
Name	SOC	PT																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: f-ae-raw-soc.sas
Output: 113-2f-ae-raw-soc-foxmgr3.xls

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk			
				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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Name	SOC			PT																											
Region	Cardiac disorders		--	US	138	89,032	0	0	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	1	5,556	NE *	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				US	138	89,032	0	0	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	1	5,556	NE *	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders		--	US	138	89,032	0	0	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	1	5,556	NE *	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				US	138	89,032	0	0	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	1	5,556	NE *	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Pancreatitis acute		--	US	138	89,032	0	0	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	1	5,556	NE *	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Infections and infestations		--	US	138	89,032	0	0	138	88,462	3	2,174	NE *	Algorithm not converged.	NE	NE	-2,174	Algorithm converged.	-4,607	NE	NE	* Algorithm not converged.	NE	NE	0,2473		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				US	138	89,032	0	0	138	88,462	2	1,449	NE *	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-3,443	NE	NE	* Algorithm not converged.	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				US	138	89,032	0	0	138	88,462	1	0,725	NE *	Algorithm not converged.	NE	NE	-0,725	Algorithm converged.	-2,14	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders		--	US	138	89,032	1	0,725	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	0,725	Algorithm converged.	-0,69	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
				US	138	89,032	1	0,725	138	88,462	0	0	NE *	Algorithm not converged.	NE	NE	0,725	Algorithm converged.	-0,69	NE	NE	* Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
				ex-US	17	10,968	0	0	18	11,538	0	0	NE *	Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: 113-2t-ae-raw-soc-toxgr3.fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirumab/mdeumab								Placebo				Casirumab/mdeumab vs. Placebo										Placebo vs. Casirumab/mdeumab							
		Patients				Patients with Event				Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk						Interaction Test				Relative Risk	
Name	SOC	PT	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	p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Cardiac disorders	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm converged.	-1.893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Supraventricular tachycardia	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm converged.	-1.893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm converged.	-1.893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Pancreatitis acute	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm converged.	-1.893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Infections and infestations	--	155	100	0	0	156	100	3	1.923	NE *	Algorithm not converged.	NE	NE	-1.923	Algorithm converged.	-4.078	NE	NE	*	Algorithm not converged.	NE	NE	0.2476		NE	Algorithm not converged.	NE	NE		
		COVID-19	--	155	100	0	0	156	100	2	1.282	NE *	Algorithm not converged.	NE	NE	-1.282	Algorithm converged.	-3.047	NE	NE	*	Algorithm not converged.	NE	NE	0.4984		NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	--	155	100	0	0	156	100	1	0.641	NE *	Algorithm not converged.	NE	NE	-0.641	Algorithm converged.	-1.893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Musculoskeletal and connective tissue disorders	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm converged.	-0.615	NE	NE	*	Algorithm not converged.	NE	NE	0.4984		NE	Algorithm not converged.	NE	NE		
		Back pain	--	155	100	1	0.645	156	100	0	0	NE *	Algorithm not converged.	NE	NE	0.645	Algorithm converged.	-0.615	NE	NE	*	Algorithm not converged.	NE	NE	0.4984		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021
Program: t-ae-raw-soc.sas
Output: t13-3f-ae-raw-soc-toxg3-b

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casi/mab/Inde/mab								Placebo						Casi/mab/Inde/mab vs. Placebo								Casi/mab/Inde/mab vs. Placebo								Placebo vs. Casi/mab/Inde/mab			
		Patients				Patients with Event				Patients				Patients with Event				Relative Risk				Relative Risk				Relative Risk				Relative Risk					
		PT		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	Interaction Test p-value (Boschod ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
Name	SOC																																		
Sex	Cardiac disorders	--		Male	80	51.613	0	0	69	44.231	0	1.449	0	NE *	Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE				
				Female	75	48.387	0	0	87	55.769	0	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
		Supraventricular tachycardia		Male	80	51.613	0	0	69	44.231	1	1.449	0	NE *	Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE				
				Female	75	48.387	0	0	87	55.769	0	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
	Gastrointestinal disorders	--		Male	80	51.613	0	0	69	44.231	1	1.449	0	NE *	Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE				
				Female	75	48.387	0	0	87	55.769	0	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
		Pancreatitis acute		Male	80	51.613	0	0	69	44.231	1	1.449	0	NE *	Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	*	Algorithm not converged.	NE	NE	0.4631	NE	Algorithm not converged.	NE	NE				
				Female	75	48.387	0	0	87	55.769	0	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
	Infections and infestations	--		Male	80	51.613	0	0	69	44.231	0	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE				
				Female	75	48.387	0	0	87	55.769	3	3.448	NE	*	Algorithm not converged.	NE	NE	-3.448	Algorithm converged.	-7.282	NE	NE	*	Algorithm not converged.	NE	NE	0.2495	NE	Algorithm not converged.	NE	NE				
		COVID-19		Male	80	51.613	0	0	69	44.231	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE					
				Female	75	48.387	0	0	87	55.769	2	2.299	NE	*	Algorithm not converged.	NE	NE	-2.299	Algorithm converged.	-5.448	NE	NE	*	Algorithm not converged.	NE	NE	0.4997	NE	Algorithm not converged.	NE	NE				
		COVID-19 pneumonia		Male	80	51.613	0	0	69	44.231	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE					
				Female	75	48.387	0	0	87	55.769	1	1.149	NE	*	Algorithm not converged.	NE	NE	-1.149	Algorithm converged.	-3.389	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE				
	Musculoskeletal and connective tissue disorders	--		Male	80	51.613	1	1.25	69	44.231	0	0	NE *	Algorithm not converged.	NE	NE	1.25	Algorithm converged.	-1.185	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE					
				Female	75	48.387	0	0	87	55.769	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE					
		Back pain		Male	80	51.613	1	1.25	69	44.231	0	0	NE *	Algorithm not converged.	NE	NE	1.25	Algorithm converged.	-1.185	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE					
				Female	75	48.387	0	0	87	55.769	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE					

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $p < .05$ in any treatment group, p -value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas

Output: t13-3f-ae-raw-soc-toxqr3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casir/mab/Inde/mab										Placebo				Casir/mab/Inde/mab vs. Placebo										Casir/mab/Inde/mab vs. Placebo										Placebo vs. Casir/mab/Inde/mab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
		Level		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		(likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
Name	SOC	PT																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
Age	Cardiac disorders	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
			18-49	83	53,548	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: f-ae-raw-soc.sas
Output: 113-3f-ae-raw-soc-foxg3-8s

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL						
Name	SOC			PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Region	Cardiac disorders			--	US	138	89,032	0	0	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	* Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
				Supraventricular tachycardia	US	138	89,032	0	0	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	* Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	Gastrointestinal disorders			--	US	138	89,032	0	0	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	* Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
				Pancreatitis acute	US	138	89,032	0	0	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	* Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	Infections and infestations			--	US	138	89,032	0	0	138	88,462	3	2,174	NE	* Algorithm not converged.	NE	NE	-2,174	Algorithm converged.	-4,607	NE	NE	NE	* Algorithm not converged.	NE	NE	0,2473	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
				COVID-19	US	138	89,032	0	0	138	88,462	2	1,449	NE	* Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-3,443	NE	NE	NE	* Algorithm not converged.	NE	NE	0,4982	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
				COVID-19 pneumonia	US	138	89,032	0	0	138	88,462	1	0,725	NE	* Algorithm not converged.	NE	NE	-0,725	* Algorithm converged.	-2,14	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Musculoskeletal and connective tissue disorders			--	US	138	89,032	1	0,725	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	0,725	* Algorithm converged.	-0,69	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
				Back pain	US	138	89,032	1	0,725	138	88,462	0	0	NE	* Algorithm not converged.	NE	NE	0,725	* Algorithm converged.	-0,69	NE	NE	NE	* Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
					ex-US	17	10,968	0	0	18	11,538	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t333f-ae-raw-soc-toxg3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk			
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Reason	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	Interaction Test p-value (likelihood ratio)	Relative Reason	Convergence Reason	95% Lower CL	95% upper CL		
All	--	--	--	155	100	0	0	156	100	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	.	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk					
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	--	--	Male	80	51,613	0	0	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Age	--	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
			18-49	83	53,548	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
			>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Region	--	US	138	89,032	0		138	88,462	0		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Reason	Convergence Reason	95% Lower CL	95% upper CL	Absolute Reason	Convergence Reason	95% Lower CL	95% upper CL	Relative Reason	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Reason	Convergence Reason	95% Lower CL	95% upper CL				
All	--	--	--	155	100	0	0	156	100	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		.	NE	Algorithm not converged.	NE	NE			

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference								Relative Risk				Relative Risk											
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
Sex	--	--	Male	80	51,613	0	0	69	44,231	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		.	NE		Algorithm not converged.	NE	NE			
			Female	75	48,387	0	0	87	55,769	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		.	NE		Algorithm not converged.	NE	NE			

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk								
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Age	--	--	12-17	21	13,548	0	0	17	10,897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE			
			18-49	83	53,548	0	0	81	51,923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE			
			>=50	51	32,903	0	0	58	37,179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE			

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Region	--	US	138	89,032	0		138	88,462	0		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-ts

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% upper CI		
All	Gastrointestinal disorders	--	--	155	100	0	0	156	100	1	0,641	NE *	Algorithm not converged.	NE	NE	-0,641	Algorithm converged.	-1,893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Pancreatitis acute	--	--	155	100	0	0	156	100	1	0,641	NE *	Algorithm not converged.	NE	NE	-0,641	Algorithm converged.	-1,893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	--	155	100	0	0	156	100	3	1,923	NE *	Algorithm not converged.	NE	NE	-1,923	Algorithm converged.	-4,078	NE	NE	*	Algorithm not converged.	NE	NE	0,2476		NE		Algorithm not converged.	NE	NE
	COVID-19	--	--	155	100	0	0	156	100	2	1,282	NE *	Algorithm not converged.	NE	NE	-1,282	Algorithm converged.	-3,047	NE	NE	*	Algorithm not converged.	NE	NE	0,4984		NE		Algorithm not converged.	NE	NE
	COVID-19 pneumonia	--	--	155	100	0	0	156	100	1	0,641	NE *	Algorithm not converged.	NE	NE	-0,641	Algorithm converged.	-1,893	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* Indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-6f-ae-raw-soc-anyxae-fs

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Interaction Test p-value (likelihood ratio)				Relative Risk		Relative Risk			
Name	SOC	PT	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
Sex	Gastrointestinal disorders	--	Male	80	51.613	0	0	69	44.231	1	1.449	NE	* Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4631		NE		Algorithm not converged.	NE	NE			
			Female	75	48.387	0	0	87	55.769	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
		Pancreatitis acute	Male	80	51.613	0	0	69	44.231	1	1.449	NE	* Algorithm not converged.	NE	NE	-1.449	Algorithm converged.	-4.269	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4631		NE		Algorithm not converged.	NE	NE			
			Female	75	48.387	0	0	87	55.769	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
		Infections and infestations	Male	80	51.613	0	0	69	44.231	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
			Female	75	48.387	0	0	87	55.769	3	3.448	NE	* Algorithm not converged.	NE	NE	-3.448	Algorithm converged.	-7.282	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2495		NE		Algorithm not converged.	NE	NE			
		COVID-19	Male	80	51.613	0	0	69	44.231	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
			Female	75	48.387	0	0	87	55.769	2	2.299	NE	* Algorithm not converged.	NE	NE	-2.299	Algorithm converged.	-5.448	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4997		NE		Algorithm not converged.	NE	NE			
		COVID-19 pneumonia	Male	80	51.613	0	0	69	44.231	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
			Female	75	48.387	0	0	87	55.769	1	1.149	NE	* Algorithm not converged.	NE	NE	-1.149	Algorithm converged.	-3.389	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-6f-ae-raw-soc-anyxae-fs

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk						
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			
Age	Gastrointestinal disorders	--	12-17	21	13.548	0	0	17	10.897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	83	53.548	0	0	81	51.923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	51	32.903	0	0	58	37.179	1	1.724	NE	*	Algorithm not converged.	NE	NE	-1.724	Algorithm converged.	-5.074	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Pancreatitis acute		12-17	21	13.548	0	0	17	10.897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	83	53.548	0	0	81	51.923	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=50	51	32.903	0	0	58	37.179	1	1.724	NE	*	Algorithm not converged.	NE	NE	-1.724	Algorithm converged.	-5.074	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	12-17	21	13.548	0	0	17	10.897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	83	53.548	0	0	81	51.923	2	2.469	NE	*	Algorithm not converged.	NE	NE	-2.469	Algorithm converged.	-5.849	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.2424	NE	NE	Algorithm not converged.	NE	NE
			>=50	51	32.903	0	0	58	37.179	1	1.724	NE	*	Algorithm not converged.	NE	NE	-1.724	Algorithm converged.	-5.074	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	COVID-19		12-17	21	13.548	0	0	17	10.897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	83	53.548	0	0	81	51.923	1	1.235	NE	*	Algorithm not converged.	NE	NE	-1.235	Algorithm converged.	-3.639	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4939	NE	NE	Algorithm not converged.	NE	NE
			>=50	51	32.903	0	0	58	37.179	1	1.724	NE	*	Algorithm not converged.	NE	NE	-1.724	Algorithm converged.	-5.074	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia		12-17	21	13.548	0	0	17	10.897	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			18-49	83	53.548	0	0	81	51.923	1	1.235	NE	*	Algorithm not converged.	NE	NE	-1.235	Algorithm converged.	-3.639	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4939	NE	NE	Algorithm not converged.	NE	NE
			>=50	51	32.903	0	0	58	37.179	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* Indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-law-soc.sas
Output: t13-6f-ae-law-soc-anyxae-fs

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk						
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Region	Gastrointestinal disorders	--	US	138	89,032	0	0	138	88,462	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-16,137	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	*	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE
	Pancreatitis acute		US	138	89,032	0	0	138	88,462	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	-16,137	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	1	5,556	NE	*	Algorithm not converged.	NE	NE	-5,556	Algorithm converged.	-16,137	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	US	138	89,032	0	0	138	88,462	3	2,174	NE	*	Algorithm not converged.	NE	NE	-2,174	Algorithm converged.	-4,607	NE	NE	*	Algorithm not converged.	NE	NE	0.2473	NE	NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
	COVID-19		US	138	89,032	0	0	138	88,462	2	1,449	NE	*	Algorithm not converged.	NE	NE	-1,449	Algorithm converged.	-3,443	NE	NE	*	Algorithm not converged.	NE	NE	0.4982	NE	NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
	COVID-19 pneumonia		US	138	89,032	0	0	138	88,462	1	0.725	NE	*	Algorithm not converged.	NE	NE	-0.725	Algorithm converged.	-2,14	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE
			ex-US	17	10,968	0	0	18	11,538	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 11Mar2021

Program: t-ae-raw-soc.sas
Output: t13-8f-ae-raw-soc-any-sae-ts

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	--	--	--	155	100	0	0	156	100	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas
Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	--	--	Male	80	51,613	0	0	69	44,231	0	0
			Female	75	48,387	0	0	87	55,769	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas
Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	P T	Level	n	%	n	%	n	%	n	%
Age	--	--	12-17	21	13,548	0	0	17	10,897	0	0
			18-49	83	53,548	0	0	81	51,923	0	0
			>=50	51	32,903	0	0	58	37,179	0	0

Clinical cut-off: 11Mar2021

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Region	--	--	US	138	89,032	0	0	138	88,462	0	0
			ex-US	17	10,968	0	0	18	11,538	0	0

Clinical cut-off: 11Mar2021

Program: t-ae-soc-descriptive.sas
Output: t14-1-ae-soc-descriptive-trtdc

KohorteB

Datenschnitt 11.03.2021 (DCO1)

Verträglichkeit

Ergänzende Dokumente

POPULATION: SAFETY - Cohort B

ENDPOINT: All patients

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Outcome of Adverse Events

	Casirivimab/Imdevimab (N=155)																Placebo (N=156)															
Category of Adverse Events	Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs	67	82.09	0	0	4	5.97	0	0	7	10.45	1	1.493	0	0	109	86	78.9	0	0	8	7.339	0	0	13	11.93	2	1.835	0	0			
All	67	82.54	0	0	4	6.349	0	0	7	11.11	0	0	0	0	82	63	76.83	0	0	5	6.098	0	0	12	14.63	2	2.439	0	0			
Grade 1	3	66.67	0	0	0	0	0	0	0	0	1	33.33	0	0	22	19	86.36	0	0	2	9.091	0	0	1	4.545	0	0	0	0			
Grade 2	1	100	0	0	0	0	0	0	0	0	0	0	0	0	5	4	80	0	0	1	20	0	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Any SAEs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	3	75	0	0	1	25	0	0	0	0	0	0	0	0	0		
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	3	75	0	0	1	25	0	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Any AESIs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			

Clinical cut-off: 11Mar2021

POPULATION: SAFETY - Cohort B

ENDPOINT: All patients

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Outcome of Adverse Events

	Casirivimab/Imdevimab (N=155)														Placebo (N=156)															
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														

Clinical cut-off: 11Mar2021

Clinical cut-off: 11MAR2021

Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 156)	Casirivimab/Imdevimab (N = 155)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Median	99.5	98.0

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Übersicht:

Studie COV-2069

Kohorte B

Datenschnitt: 01.07.2021 (DCO2)

Wirksamkeit	
Hauptdokumente	
t8-3-eff-resp-bsymbr14-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t8-3-eff-resp-bsymbr14-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t9-1a-eff-smd-strat-BNWSYMBR	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP
t9-1a-eff-smd-unstrat-BNWSYMBR	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (broad-term) during the EAP (subgroup)
t8-4-eff-resp-bsymcd14-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP
t8-4-eff-resp-bsymcd14-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during the EAP (subgroup)
t9-2a-eff-smd-strat-BNWSYMCD	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP
t9-2a-eff-smd-unstrat-BNWSYMCD	Number of weeks of symptomatic RT-qPCR confirmed SARS-CoV-2 infection (CDC-definition) during EAP (subgroup)
t8-5-eff-resp-bsymst14-strat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP
t8-5-eff-resp-bsymst14-unstrat	Proportion of subjects who have a symptomatic RT-qPCR confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t9-3a-eff-smd-strat-BNWSYMST	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP
t9-3a-eff-smd-unstrat-BNWSYMST	Number of weeks of symptomatic RT-qPCR-confirmed SARS-CoV-2 infection (strict-term) during the EAP (subgroup)
t8-1-eff-resp-dth29-strat	All-cause death at EAP
t8-1-eff-resp-dth29-unstrat	All-cause death at EAP (subgroup)
t8-2-eff-resp-dthfu-strat	All-cause death at End of Follow-Up
t8-2-eff-resp-dthfu-unstrat	All-cause death at End of Follow-Up (subgroup)
t8-6-eff-resp-bhoer-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-6-eff-resp-bhoer-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-7-eff-resp-hoeruc-strat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP
t8-7-eff-resp-hoeruc-unstrat	Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR, or all-cause death, during the EAP (subgroup)
t8-8-eff-resp-bmaveru-strat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-8-eff-resp-bmaveru-unstrat	Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP(subgroup)
t9-4a-eff-smd-strat-BNMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t9-4a-eff-smd-unstrat-BNMAVERU	Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
t8-9-eff-resp-bhosp-strat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t8-9-eff-resp-bhosp-unstrat	Proportion of subjects hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset during the EAP(subgroup)
t9-5a-eff-smd-strat-BNDHOSP	Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
t9-5a-eff-smd-unstrat-BNDHOSP	Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP (subgroup)
t9-6a-eff-smd-strat-BNDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family

	obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP
t9-6a-eff-smd-unstrat-BNDABSEN	Number of days missed for daily responsibilities (where applicable), including work (employed adults) or school (students), daycare or family obligations/responsibilities (childcare or eldercare) due to a RTqPCR confirmed SARS-CoV-2 infection that has an onset during the EAP (subgroup)
Ergänzende Dokumente	
t3-center-mFAS	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm
t4-dstat-demo-mFAS	Demographic and Baseline Characteristics per arm
t5_1	Table 5.1. Summary of Overall Patient Disposition
t5_3	Table 5.2. Number of screened patients and reason for screening failure
t2-dstat-dur-mFAS	Duration of Follow-up by domain and arm
Verträglichkeit	
Hauptdokumente	
t12-1-ae-raw-anyae-unstrat-saf1	Any AEs (subgroup)
t12-2-ae-raw-anyae-nr-unstrat-saf1	Any AEs (excluding disease related events) (subgroup)
t12-3-ae-raw-toxgrgt3-unstrat-saf1	AEs Grade >= 3(subgroup)
t12-4-ae-raw-toxgtnr3-unstrat-saf1	AEs Grade >=3 (excluding disease related events) (subgroup)
t12-5-ae-raw-toxgr3-unstrat-saf1	AEs Grade 3(subgroup)
t12-6-ae-raw-toxgr4-unstrat-saf1	AEs Grade 4(subgroup)
t12-7-ae-raw-toxgr5-unstrat-saf1	AEs Grade 5 (AEs leading to death) (subgroup)
t12-8-ae-raw-anysae-unstrat-saf1	Any SAEs (subgroup)
t12-9-ae-raw-anysaenr-unstrat-saf1	Any SAEs (excluding disease related events) (subgroup)
t12-10-ae-raw-aeltdis-unstrat-saf1	AEs leading to treatment discontinuation (subgroup)
AESI	
t12-11-ae-raw-isrge3-unstrat-saf1	Injection site reactions Grade >=3 (subgroup)
t12-12-ae-raw-sisr-unstrat-saf1	Serious injection site reactions(subgroup)
t12-13-ae-raw-hyprgr3-unstrat-saf1	Hypersensitivity reactions Grade >=3(subgroup)
t12-14-ae-raw-shypr-unstrat-saf1	Serious hypersensitivity reactions(subgroup)
SOC/PT	
t13-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t13-2f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade >= 3
t13-3f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t13-4f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t13-5f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t13-6f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t14-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Ergänzende Dokumente	
t10-ae-resolved-general	AE resolved general
t2-dstat-dur-SAF	Duration of Follow-up by domain and arm Safety Analysis Set

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Wirksamkeit

Hauptdokumente

POPULATION: Cohort B
ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergen ce Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergen ce Reason	95% Lower CL	95% upper CL	Relative Risk	Convergen ce Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergen ce Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	35	21,2	171	100	59	34,5	0,51	Algorithm converged.	0,31	0,83	-13,291	Algorithm converged.	-22,76	-3,82	0,61	Algorithm converged.	0,43	0,88	0,0063		1,63	Algorithm converged.	1,14	2,33		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-3-eff-resp-bsymbr14

POPULATION: Cohort B
ENDPOINT: Proportion of subjects who subsequently develop signs and symptoms (broad-term) within 14 days of a positive RT-qPCR
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab											
		Patients		Event		Patients		Event				Odds Ratio				Absolute Risk Difference						Relative Risk				Interaction Test p-value (likelihood ratio)				Relative Risk				Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL	p-value		Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL						
All	n/a	165	100	35	21,2	171	100	59	34,5	0,51		Algorithm converged.	0,31	0,83	-13,291		Algorithm converged.	-22,76	-3,82	0,61		Algorithm converged.	0,43	0,88	0,0067		1,63		Algorithm converged.	1,14	2,33						
Sex	Male	85	51,5	19	22,4	76	44,4	21	27,6	0,75		Algorithm converged.	0,37	1,54	-5,279		Algorithm converged.	-18,68	8,12	0,81		Algorithm converged.	0,47	1,39	0,4405	0,197	1,24		Algorithm converged.	0,72	2,12						
	Female	80	48,5	16	20	95	55,6	38	40	0,38		Algorithm converged.	0,19	0,74	-20		Algorithm converged.	-33,19	-6,81	0,5		Algorithm converged.	0,3	0,83	0,0044		2		Algorithm converged.	1,21	3,31						
Age	12-17	23	13,9	3	13	20	11,7	10	50	0,15		Algorithm converged.	0,03	0,67	-36,957		Algorithm converged.	-62,83	-11,08	0,26		Algorithm converged.	0,08	0,82	0,018	0,0573	3,83		Algorithm converged.	1,22	12,02						
	18-49	87	52,7	24	27,6	91	53,2	29	31,9	0,81		Algorithm converged.	0,43	1,55	-4,282		Algorithm converged.	-17,69	9,13	0,87		Algorithm converged.	0,55	1,36	0,5334		1,16		Algorithm converged.	0,73	1,82						
	>=50	55	33,3	8	14,5	60	35,1	20	33,3	0,34		Algorithm converged.	0,14	0,86	-18,788		Algorithm converged.	-33,92	-3,65	0,44		Algorithm converged.	0,21	0,91	0,0196		2,29		Algorithm converged.	1,1	4,77						
Region	US	147	89,1	31	21,1	151	88,3	54	35,8	0,48		Algorithm converged.	0,29	0,81	-14,673		Algorithm converged.	-24,77	-4,58	0,59		Algorithm converged.	0,4	0,86	0,0051	0,513	1,7		Algorithm converged.	1,16	2,48						
	ex-US	18	10,9	4	22,2	20	11,7	5	25	0,86		Algorithm converged.	0,19	3,85	-2,778		Algorithm converged.	-29,78	24,22	0,89		Algorithm converged.	0,28	2,81	1		1,13		Algorithm converged.	0,36	3,55						
BMI	BMI < 30 kg/m2	98	59,4	23	23,5	118	69	41	34,7	0,58		Algorithm converged.	0,32	1,05	-11,276		Algorithm converged.	-23,29	0,73	0,68		Algorithm converged.	0,44	1,04	0,0714	0,4849	1,48		Algorithm converged.	0,96	2,29						
	BMI >= 30 kg/m2	66	40	12	18,2	48	28,1	17	35,4	0,41		Algorithm converged.	0,17	0,96	-17,235		Algorithm converged.	-33,66	-0,81	0,51		Algorithm converged.	0,27	0,97	0,0378		1,95		Algorithm converged.	1,03	3,69						
	Unknown/not reported	1	0,6	0	0	5	2,9	1	20	0		Algorithm converged.	NE	NE	-20		Algorithm converged.	-55,06	15,06	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE						
Total household size including the household members not participating this study																																					
	2	66	40	10	15,2	75	43,9	26	34,7	0,34		Algorithm converged.	0,15	0,77	-19,515		Algorithm converged.	-33,33	-5,7	0,44		Algorithm converged.	0,23	0,84	0,0082	0,184	2,29		Algorithm converged.	1,19	4,38						
	>2	99	60	25	25,3	96	56,1	33	34,4	0,64		Algorithm converged.	0,35	1,2	-9,122		Algorithm converged.	-21,91	3,66	0,73		Algorithm converged.	0,47	1,14	0,1646		1,36		Algorithm converged.	0,88	2,11						
Baseline high risk factor	Yes	45	27,3	10	22,2	54	31,6	17	31,5	0,62		Algorithm converged.	0,25	1,54	-9,259		Algorithm converged.	-26,61	8,09	0,71		Algorithm converged.	0,36	1,38	0,3055	0,6322	1,42		Algorithm converged.	0,72	2,78						
	No	120	72,7	25	20,8	117	68,4	42	35,9	0,47		Algorithm converged.	0,26	0,84	-15,064		Algorithm converged.	-26,39	-3,73	0,58		Algorithm converged.	0,38	0,89	0,0102		1,72		Algorithm converged.	1,13	2,63						
Race	White	139	84,2	28	20,1	147	86	50	34	0,49		Algorithm converged.	0,29	0,84	-13,87		Algorithm converged.	-24,02	-3,72	0,59		Algorithm converged.	0,4	0,88	0,0086	0,6967	1,69		Algorithm converged.	1,13	2,52						
	Black or African American	9	5,5	2	22,2	11	6,4	2	18,2	1,29		Algorithm converged.	0,14	11,54	4,04		Algorithm converged.	-31,42	39,5	1,22		Algorithm converged.	0,21	7,04	1		0,82		Algorithm converged.	0,14	4,71						
	Other	12	7,3	4	33,3	9	5,3	4	44,4	0,63		Algorithm converged.	0,11	3,71	-11,111		Algorithm converged.	-53,13	30,9	0,75		Algorithm converged.	0,25	2,22	0,6731		1,33		Algorithm converged.	0,45	3,94						
	Unknown/Not Reported	5	3	1	20	4	2,3	3	75	0,08		Algorithm converged.	0	1,95	-55		Algorithm converged.	-100	0,04	0,27		Algorithm converged.	0,04	1,68	0,2063		3,75		Algorithm converged.	0,59	23,66						
Ethnicity	Hispanic or Latino	69	41,8	12	17,4	66	38,6	14	21,2	0,78		Algorithm converged.	0,33	1,84	-3,821		Algorithm converged.	-17,13	9,49	0,82		Algorithm converged.	0,41	1,64	0,575	0,3447	1,22		Algorithm converged.	0,61	2,44						
	Not Hispanic or Latino	95	57,6	23	24,2	103	60,2	45	43,7	0,41		Algorithm converged.	0,22	0,76	-19,479		Algorithm converged.	-32,36	-6,6	0,55		Algorithm converged.	0,36	0,84	0,004		1,8		Algorithm converged.	1,19	2,74						

	Unknown/n ot reported	1 0,6	0 0	2 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	9 5,5	3 33,3	10 5,8	5 50	0,5		Algorithm converged.	0,08	3,21	-16,667		Algorithm converged.	-60,36	27,02	0,67		Algorithm converged.	0,22	2,03	0,6499	0,8952	1,5		Algorithm converged.	0,49	4,56
	No	154 93,3	32 20,8	160 93,6	54 33,8	0,51		Algorithm converged.	0,31	0,86	-12,971		Algorithm converged.	-22,7	-3,24	0,62		Algorithm converged.	0,42	0,9	0,0101		1,62		Algorithm converged.	1,11	2,37
	Unknown/n ot reported	2 1,2	0 0	1 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113 68,5	31 27,4	113 66,1	41 36,3	0,66		Algorithm converged.	0,38	1,17	-8,85		Algorithm converged.	-20,94	3,24	0,76		Algorithm converged.	0,51	1,11	0,1543	0,0263	1,32		Algorithm converged.	0,9	1,95
	No	52 31,5	4 7,7	58 33,9	18 31	0,19		Algorithm converged.	0,06	0,59	-23,342		Algorithm converged.	-37,28	-9,41	0,25		Algorithm converged.	0,09	0,69	0,0035		4,03		Algorithm converged.	1,46	11,15
Local test result of diagnostic assay for SARS-CoV-2	Positive	95 57,6	24 25,3	90 52,6	31 34,4	0,64		Algorithm converged.	0,34	1,21	-9,181		Algorithm converged.	-22,32	3,96	0,73		Algorithm converged.	0,47	1,15	0,1732	0,8531	1,36		Algorithm converged.	0,87	2,13
	Negative	47 28,5	7 14,9	54 31,6	12 22,2	0,61		Algorithm converged.	0,22	1,71	-7,329		Algorithm converged.	-22,38	7,72	0,67		Algorithm converged.	0,29	1,56	0,3496		1,49		Algorithm converged.	0,64	3,48
	Unavailable	23 13,9	4 17,4	27 15,8	16 59,3	0,14		Algorithm converged.	0,04	0,54	-41,868		Algorithm converged.	-66,02	-17,71	0,29		Algorithm converged.	0,11	0,75	0,0037		3,41		Algorithm converged.	1,33	8,76
Serology status	Seropositive	49 29,7	3 6,1	43 25,1	6 14	0,4		Algorithm converged.	0,09	1,72	-7,831		Algorithm converged.	-20,17	4,51	0,44		Algorithm converged.	0,12	1,65	0,2957	0,5094	2,28		Algorithm converged.	0,61	8,57
	Seronegative	108 65,5	32 29,6	114 66,7	49 43	0,56		Algorithm converged.	0,32	0,97	-13,353		Algorithm converged.	-25,87	-0,83	0,69		Algorithm converged.	0,48	0,99	0,0393		1,45		Algorithm converged.	1,01	2,08
	Unclear serology status	8 4,8	0 0	14 8,2	4 28,6	0		Algorithm converged.	NE	NE	-28,571		Algorithm converged.	-52,24	-4,91	NE	*	Algorithm not converged.	NE	NE	0,2536		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: l8-3-eff-resp-bsymbr14

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

				Casirivimab/Imdevimab										Placebo					Difference between treatments (Casirivimab/Imdevimab - Placebo)										
Patients in analysis				Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL			
All	n/a	165	100	35	21,212	144,429	0,875	0,316	0,419	0,493	171	100	59	34,503	287,714	1,683	0,411	1,243	0,483	-0,824	-1,848	0,199	0,114	-0,172	-0,387	0,042			

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01.Jul2021.

Program: t-eff-smd.sas
Output: t9-1-eff-smd-BNWSYMBR

POPULATION: Modified Full Analysis Set - Cohort B
 ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (broad-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2069
 Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)							
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference			Standardized Mean Difference			Interaction Test	
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	165	100	35	21,212	144,429	0,875	0,316	0,875	0,372	171	100	59	34,503	287,714	1,683	0,411	1,683	0,365	-0,807	-1,832	0,217	0,122	-0,169	-0,383	0,045	NE		
Sex	Male	85	51,515	19	22,353	82,429	0,97	0,526	0,97	0,473	76	44,444	21	27,632	62,857	0,827	0,428	0,827	0,5	0,143	-1,216	1,502	0,836	0,033	-0,278	0,343	0,0966		
	Female	80	48,485	16	20	62	0,775	0,339	0,775	0,569	95	55,556	38	40	224,857	2,367	0,649	2,367	0,522	-1,592	-3,117	-0,067	0,041	-0,311	-0,61	-0,013			
Age	12-17	23	13,939	3	13,043	28,857	1,255	1,098	1,255	0,847	20	11,696	10	50	26,429	1,321	0,421	1,321	0,909	-0,067	-2,576	2,442	0,957	-0,016	-0,622	0,59	0,8213		
	18-49	87	52,727	24	27,586	100	1,149	0,518	1,149	0,603	91	53,216	29	31,868	176	1,934	0,66	1,934	0,59	-0,785	-2,45	0,881	0,354	-0,139	-0,433	0,156			
	>=50	55	33,333	8	14,545	15,571	0,283	0,139	0,283	0,46	60	35,088	20	33,333	85,286	1,421	0,596	1,421	0,44	-1,138	-2,4	0,123	0,076	-0,332	-0,699	0,036			
Region	US	147	89,091	31	21,088	138,429	0,942	0,354	0,942	0,416	151	88,304	54	35,762	279,571	1,851	0,463	1,851	0,411	-0,91	-2,061	0,241	0,121	-0,18	-0,407	0,048	0,612		
	ex-US	18	10,909	4	22,222	6	0,333	0,19	0,333	0,184	20	11,696	5	25	8,143	0,407	0,17	0,407	0,175	-0,074	-0,589	0,441	0,773	-0,092	-0,738	0,553			
BMI	BMI < 30 kg/m2	98	59,394	23	23,469	126	1,286	0,524	1,286	0,529	118	69,006	41	34,746	192,571	1,632	0,485	1,632	0,482	-0,346	-1,756	1,064	0,629	-0,066	-0,334	0,203	0,5398		
	BMI >= 30 kg/m2	66	40	12	18,182	18,429	0,279	0,107	0,279	0,288	48	28,07	17	35,417	60,714	1,265	0,5	1,265	0,338	-0,986	-1,865	-0,107	0,028	-0,419	-0,792	-0,045			
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	15,397	5	2,924	1	20	34,429	6,886	6,886	6,886	6,886	-6,886	-53,715	39,943	0,704	-0,358	-2,791	2,075			
Total household size including the household member(s) not participating this study	2	66	40	10	15,152	51,143	0,775	0,5	0,775	0,699	75	43,86	26	34,667	177,429	2,366	0,784	2,366	0,655	-1,591	-3,485	0,303	0,099	-0,279	-0,611	0,053	0,1905		
	>2	99	60	25	25,253	93,286	0,942	0,41	0,942	0,4	96	56,14	33	34,375	110,286	1,149	0,396	1,149	0,407	-0,207	-1,332	0,919	0,718	-0,052	-0,333	0,23			
Baseline high risk factor	Yes	45	27,273	10	22,222	11,857	0,263	0,11	0,263	0,63	54	31,579	17	31,481	104,571	1,937	0,772	1,937	0,575	-1,673	-3,366	0,02	0,053	-0,393	-0,79	0,005	0,2912		
	No	120	72,727	25	20,833	132,571	1,105	0,431	1,105	0,455	117	68,421	42	35,897	183,143	1,565	0,485	1,565	0,461	-0,461	-1,737	0,816	0,478	-0,092	-0,347	0,163			
Race	White	139	84,242	28	20,144	105,429	0,758	0,298	0,758	0,392	147	85,965	50	34,014	240,714	1,638	0,451	1,638	0,381	-0,879	-1,955	0,197	0,109	-0,19	-0,422	0,043	0,282		
	Black or African American	9	5,455	2	22,222	1	0,111	0,082	0,111	0,504	11	6,433	2	18,182	7,143	0,649	0,608	0,649	0,456	-0,538	-1,965	0,889	0,438	-0,341	-1,246	0,563			
	Other	12	7,273	4	33,333	37,571	3,131	2,649	3,131	2,023	9	5,263	4	44,444	5,429	0,603	0,292	0,603	2,336	2,528	-3,939	8,994	0,423	0,346	-0,54	1,232			
	Unknown/not Reported	5	3,03	1	20	0,429	0,086	0,086	0,086	2,831	4	2,339	3	75	34,429	8,607	4,834	8,607	3,165	-8,521	-18,564	1,521	0,085	-1,196	-2,606	0,214			
Ethnicity	Hispanic or Latino	69	41,818	12	17,391	14,857	0,215	0,074	0,215	0,165	66	38,596	14	21,212	45,571	0,69	0,228	0,69	0,168	-0,475	-0,941	-0,009	0,046	-0,345	-0,684	-0,007	0,6301		
	Not Hispanic or Latino	95	57,576	23	24,211	129,571	1,364	0,542	1,364	0,621	103	60,234	45	43,689	242,143	2,351	0,659	2,351	0,597	-0,987	-2,686	0,712	0,253	-0,162	-0,442	0,117			
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	2	1,17	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Healthcare worker	Yes	9	5,455	3	33,333	7,429	0,825	0,458	0,825	3,086	10	5,848	5	50	72,143	7,214	4,003	7,214	2,928	-6,389	-15,364	2,586	0,151	-0,659	-1,585	0,267	0,0081		
	No	154	93,333	32	20,779	137	0,89	0,338	0,89	0,348	160	93,567	54	33,75	215,571	1,347	0,351	1,347	0,341	-0,458	-1,417	0,502	0,349	-0,106	-0,327	0,116			

	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0	NE	0	NE	0	NE	NE	NE	NE	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																											
	Yes	113	68,485	31	27,434	135,857	1,202	0,457	1,202	0,404	113	66,082	41	36,283	138,571	1,226	0,343	1,226	0,404	-0,024	-1,15	1,102	0,966	-0,006	-0,267	0,256	0,032
	No	52	31,515	4	7,692	8,571	0,165	0,092	0,165	0,775	58	33,918	18	31,034	149,143	2,571	1,006	2,571	0,734	-2,407	-4,521	-0,292	0,026	-0,428	-0,804	-0,052	
Test result of a local diagnostic assay for SARS-CoV-2																											
	Positive	95	57,576	24	25,263	117,286	1,235	0,537	1,235	0,402	90	52,632	31	34,444	69,429	0,771	0,169	0,771	0,413	0,463	-0,673	1,599	0,422	0,118	-0,171	0,407	0,1924
	Negative	47	28,485	7	14,894	12,429	0,264	0,115	0,264	0,348	54	31,579	12	22,222	49,714	0,921	0,433	0,921	0,325	-0,656	-1,601	0,289	0,171	-0,273	-0,666	0,12	
	Unavailable	23	13,939	4	17,391	14,714	0,64	0,362	0,64	1,791	27	15,789	16	59,259	168,571	6,243	2,224	6,243	1,653	-5,604	-10,503	-0,704	0,026	-0,642	-1,204	-0,081	
Serology status																											
	Seropositive	49	29,697	3	6,122	2,286	0,047	0,029	0,047	0,341	43	25,146	6	13,953	32,571	0,757	0,532	0,757	0,364	-0,711	-1,701	0,28	0,157	-0,295	-0,707	0,116	0,8941
	Seronegative	108	65,455	32	29,63	142,143	1,316	0,478	1,316	0,54	114	66,667	49	42,982	249,571	2,189	0,577	2,189	0,526	-0,873	-2,359	0,613	0,248	-0,155	-0,419	0,109	
	Unclear serology status	8	4,848	0	0	0	0	0	0	0,245	14	8,187	4	28,571	5,571	0,398	0,23	0,398	0,186	-0,398	-1,04	0,244	0,211	-0,551	-1,441	0,338	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-1-eff-smd-BNWSYMBR

POPULATION: Cohort B
ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference								Relative Risk				Interaction Test p-value (likelihood ratio)		Relative Risk			
Name	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		Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	32	19,4	171	100	55	32,2	0,5		Algorithm converged.	0,3	0,83	-12,77		Algorithm converged.	-22,01	-3,53	0,6		Algorithm converged.	0,41	0,88	0,0065		1,66		Algorithm converged.	1,13	2,42

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: 18-4-eff-resp-bsymcd14

POPULATION: Cohort B
ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference								Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergency Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergency Reason	95% Lower CL	95% upper CL	Relative Risk		Convergency Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergency Reason	95% Lower CL	95% upper CL			
All	n/a	165	100	32	19,4	171	100	55	32,2	0,51		Algorithm converged.	0,31	0,84	-12,77		Algorithm converged.	-22,01	-3,53	0,6		Algorithm converged.	0,41	0,88	0,0076		1,66		Algorithm converged.	1,13	2,42			
Sex	Male	85	51,5	17	20	76	44,4	19	25	0,75		Algorithm converged.	0,36	1,58	-5		Algorithm converged.	-17,93	7,93	0,8		Algorithm converged.	0,45	1,42	0,4486	0,2238	1,25		Algorithm converged.	0,7	2,22			
	Female	80	48,5	15	18,8	95	55,6	36	37,9	0,38		Algorithm converged.	0,19	0,76	-19,145		Algorithm converged.	-32,12	-6,17	0,49		Algorithm converged.	0,29	0,84	0,0056		2,02		Algorithm converged.	1,2	3,41			
Age	12-17	23	13,9	3	13	20	11,7	9	45	0,18		Algorithm converged.	0,04	0,82	-31,957		Algorithm converged.	-57,74	-6,17	0,29		Algorithm converged.	0,09	0,93	0,0387	0,0646	3,45		Algorithm converged.	1,08	11,02			
	18-49	87	52,7	23	26,4	91	53,2	28	30,8	0,81		Algorithm converged.	0,42	1,55	-4,332		Algorithm converged.	-17,59	8,93	0,86		Algorithm converged.	0,54	1,37	0,524		1,16		Algorithm converged.	0,73	1,86			
	>=50	55	33,3	6	10,9	60	35,1	18	30	0,29		Algorithm converged.	0,1	0,79	-19,091		Algorithm converged.	-33,32	-4,87	0,36		Algorithm converged.	0,16	0,85	0,0122		2,75		Algorithm converged.	1,18	6,42			
Region	US	147	89,1	29	19,7	151	88,3	51	33,8	0,48		Algorithm converged.	0,28	0,82	-14,047		Algorithm converged.	-23,96	-4,13	0,58		Algorithm converged.	0,39	0,87	0,0063	0,6264	1,71		Algorithm converged.	1,15	2,54			
	ex-US	18	10,9	3	16,7	20	11,7	4	20	0,8		Algorithm converged.	0,15	4,18	-3,333		Algorithm converged.	-27,9	21,24	0,83		Algorithm converged.	0,22	3,23	1		1,2		Algorithm converged.	0,31	4,65			
BMI	BMI < 30 kg/m2	98	59,4	21	21,4	118	69	38	32,2	0,57		Algorithm converged.	0,31	1,07	-10,775		Algorithm converged.	-22,48	0,93	0,67		Algorithm converged.	0,42	1,05	0,0775	0,4901	1,5		Algorithm converged.	0,95	2,38			
	BMI >= 30 kg/m2	66	40	11	16,7	48	28,1	16	33,3	0,4		Algorithm converged.	0,17	0,97	-16,667		Algorithm converged.	-32,75	-0,58	0,5		Algorithm converged.	0,26	0,98	0,0396		2		Algorithm converged.	1,02	3,91			
	Unknown/not reported	1	0,6	0	0	5	2,9	1	20	0		Algorithm converged.	NE	NE	-20		Algorithm converged.	-55,06	15,06	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE			
Total household size including the household members not participating this study																																		
	2	66	40	8	12,1	75	43,9	25	33,3	0,28		Algorithm converged.	0,11	0,67	-21,212		Algorithm converged.	-34,47	-7,95	0,36		Algorithm converged.	0,18	0,75	0,0031	0,0716	2,75		Algorithm converged.	1,33	5,67			
	>2	99	60	24	24,2	96	56,1	30	31,3	0,7		Algorithm converged.	0,37	1,32	-7,008		Algorithm converged.	-19,55	5,53	0,78		Algorithm converged.	0,49	1,23	0,2755		1,29		Algorithm converged.	0,82	2,04			
Baseline high risk factor	Yes	45	27,3	8	17,8	54	31,6	15	27,8	0,56		Algorithm converged.	0,21	1,48	-10		Algorithm converged.	-26,36	6,36	0,64		Algorithm converged.	0,3	1,37	0,2431	0,8416	1,56		Algorithm converged.	0,73	3,35			
	No	120	72,7	24	20	117	68,4	40	34,2	0,48		Algorithm converged.	0,27	0,87	-14,188		Algorithm converged.	-25,37	-3	0,59		Algorithm converged.	0,38	0,91	0,0141		1,71		Algorithm converged.	1,1	2,65			
Race	White	139	84,2	25	18	147	86	46	31,3	0,48		Algorithm converged.	0,28	0,84	-13,307		Algorithm converged.	-23,15	-3,46	0,57		Algorithm converged.	0,37	0,88	0,0093	0,6719	1,74		Algorithm converged.	1,13	2,67			
	Black or African American	9	5,5	2	22,2	11	6,4	2	18,2	1,29		Algorithm converged.	0,14	11,54	4,04		Algorithm converged.	-31,42	39,5	1,22		Algorithm converged.	0,21	7,04	1		0,82		Algorithm converged.	0,14	4,71			
	Other	12	7,3	4	33,3	9	5,3	4	44,4	0,63		Algorithm converged.	0,11	3,71	-11,111		Algorithm converged.	-53,13	30,9	0,75		Algorithm converged.	0,25	2,22	0,6731		1,33		Algorithm converged.	0,45	3,94			
	Unknown/Not Reported	5	3	1	20	4	2,3	3	75	0,08		Algorithm converged.	0	1,95	-55		Algorithm converged.	-100	0,04	0,27		Algorithm converged.	0,04	1,68	0,2063		3,75		Algorithm converged.	0,59	23,66			
Ethnicity	Hispanic or Latino	69	41,8	11	15,9	66	38,6	14	21,2	0,7		Algorithm converged.	0,29	1,69	-5,27		Algorithm converged.	-18,38	7,84	0,75		Algorithm converged.	0,37	1,53	0,4324	0,4828	1,33		Algorithm converged.	0,65	2,72			
	Not Hispanic or Latino	95	57,6	21	22,1	103	60,2	41	39,8	0,43		Algorithm converged.	0,23	0,8	-17,701		Algorithm converged.	-30,31	-5,09	0,56		Algorithm converged.	0,36	0,87	0,0074		1,8		Algorithm converged.	1,15	2,81			

	Unknown/n ot reported	1 0,6	0 0	2 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	9 5,5	3 33,3	10 5,8	5 50	0,5		Algorithm converged.	0,08	3,21	-16,667		Algorithm converged.	-60,36	27,02	0,67		Algorithm converged.	0,22	2,03	0,6499	0,8682	1,5		Algorithm converged.	0,49	4,56
	No	154 93,3	29 18,8	160 93,6	50 31,3	0,51		Algorithm converged.	0,3	0,86	-12,419		Algorithm converged.	-21,89	-2,95	0,6		Algorithm converged.	0,4	0,9	0,0114		1,66		Algorithm converged.	1,11	2,48
	Unknown/n ot reported	2 1,2	0 0	1 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113 68,5	28 24,8	113 66,1	38 33,6	0,65		Algorithm converged.	0,36	1,16	-8,85		Algorithm converged.	-20,65	2,95	0,74		Algorithm converged.	0,49	1,11	0,1444	0,0453	1,36		Algorithm converged.	0,9	2,05
	No	52 31,5	4 7,7	58 33,9	17 29,3	0,2		Algorithm converged.	0,06	0,65	-21,618		Algorithm converged.	-35,39	-7,85	0,26		Algorithm converged.	0,09	0,73	0,0065		3,81		Algorithm converged.	1,37	10,6
Local test result of diagnostic assay for SARS-CoV-2	Positive	95 57,6	22 23,2	90 52,6	27 30	0,7		Algorithm converged.	0,36	1,36	-6,842		Algorithm converged.	-19,55	5,87	0,77		Algorithm converged.	0,48	1,25	0,2931	0,5657	1,3		Algorithm converged.	0,8	2,1
	Negative	47 28,5	6 12,8	54 31,6	12 22,2	0,51		Algorithm converged.	0,18	1,49	-9,456		Algorithm converged.	-24,08	5,17	0,57		Algorithm converged.	0,23	1,41	0,2178		1,74		Algorithm converged.	0,71	4,28
	Unavailable	23 13,9	4 17,4	27 15,8	16 59,3	0,14		Algorithm converged.	0,04	0,54	-41,868		Algorithm converged.	-66,02	-17,71	0,29		Algorithm converged.	0,11	0,75	0,0037		3,41		Algorithm converged.	1,33	8,76
Serology status	Seropositive	49 29,7	2 4,1	43 25,1	6 14	0,26		Algorithm converged.	0,05	1,38	-9,872		Algorithm converged.	-21,62	1,87	0,29		Algorithm converged.	0,06	1,37	0,1401	0,2627	3,42		Algorithm converged.	0,73	16,06
	Seronegativ e	108 65,5	30 27,8	114 66,7	46 40,4	0,57		Algorithm converged.	0,32	1	-12,573		Algorithm converged.	-24,92	-0,23	0,69		Algorithm converged.	0,47	1	0,049		1,45		Algorithm converged.	1	2,12
	Unclear serology status	8 4,8	0 0	14 8,2	3 21,4	0		Algorithm converged.	NE	NE	-21,429		Algorithm converged.	-42,92	0,07	NE	*	Algorithm not converged.	NE	NE	0,2727		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-4-eff-resp-bsymcd14

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo					Difference between treatments (Casirivimab/Imdevimab - Placebo)											
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	165	100	32	19,394	142,286	0,862	0,316	0,434	0,464	171	100	55	32,164	263,286	1,54	0,372	1,127	0,455	-0,693	-1,656	0,27	0,158	-0,154	-0,368	0,06		

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01.Jul2021.

Program: t-eff-smd.sas
Output: t9-2-eff-smd-BNWSYMCD

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (CDC definition) within 14 days of a positive RT-qPCR at baseline or during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)				
All	n/a	165	100	32	19,394	142,286	0,862	0,316	0,862	0,35	171	100	55	32,164	263,286	1,54	0,372	1,54	0,343	-0,677	-1,641	0,286	0,168	-0,151	-0,365	0,064	NE				
Sex	Male	85	51,515	17	20	81,714	0,961	0,526	0,961	0,395	76	44,444	19	25	41,571	0,547	0,152	0,547	0,418	0,414	-0,721	1,549	0,472	0,113	-0,197	0,424	0,0421				
	Female	80	48,485	15	18,75	60,571	0,757	0,338	0,757	0,57	95	55,556	36	37,895	221,714	2,334	0,649	2,334	0,523	-1,577	-3,102	-0,051	0,043	-0,308	-0,606	-0,01					
Age	12-17	23	13,939	3	13,043	28,857	1,255	1,098	1,255	0,848	20	11,696	9	45	24,429	1,221	0,424	1,221	0,909	0,033	-2,478	2,544	0,979	0,008	-0,598	0,614	0,7683				
	18-49	87	52,727	23	26,437	98,571	1,133	0,518	1,133	0,554	91	53,216	28	30,769	157	1,725	0,574	1,725	0,542	-0,592	-2,122	0,937	0,446	-0,114	-0,409	0,181					
	>=50	55	33,333	6	10,909	14,857	0,27	0,139	0,27	0,46	60	35,088	18	30	81,857	1,364	0,596	1,364	0,441	-1,094	-2,357	0,168	0,089	-0,318	-0,686	0,049					
Region	US	147	89,091	29	19,728	136,571	0,929	0,354	0,929	0,392	151	88,304	51	33,775	256	1,695	0,42	1,695	0,386	-0,766	-1,849	0,316	0,165	-0,161	-0,388	0,066	0,6426				
	ex-US	18	10,909	3	16,667	5,714	0,317	0,191	0,317	0,184	20	11,696	4	20	7,286	0,364	0,169	0,364	0,175	-0,047	-0,562	0,468	0,855	-0,059	-0,704	0,586					
BMI	BMI < 30 kg/m2	98	59,394	21	21,429	125,143	1,277	0,524	1,277	0,487	118	69,006	38	32,203	164,857	1,397	0,413	1,397	0,444	-0,12	-1,419	1,178	0,855	-0,025	-0,293	0,244	0,3257				
	BMI >= 30 kg/m2	66	40	11	16,667	17,143	0,26	0,103	0,26	0,29	48	28,07	16	33,333	64	1,333	0,506	1,333	0,341	-1,074	-1,96	-0,187	0,018	-0,452	-0,825	-0,079					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	15,397	5	2,924	1	20	34,429	6,886	6,886	6,886	6,886	-6,886	-53,715	39,943	0,704	-0,358	-2,791	2,075					
Total household size including the household member(s) not participating this study																															
	2	66	40	8	12,121	50,286	0,762	0,5	0,762	0,629	75	43,86	25	33,333	156,143	2,082	0,679	2,082	0,59	-1,32	-3,025	0,385	0,128	-0,257	-0,589	0,075	0,255				
	>2	99	60	24	24,242	92	0,929	0,41	0,929	0,4	96	56,14	30	31,25	107,143	1,116	0,397	1,116	0,407	-0,187	-1,313	0,939	0,744	-0,047	-0,328	0,235					
Baseline high risk factor																															
	Yes	45	27,273	8	17,778	10,286	0,229	0,102	0,229	0,63	54	31,579	15	27,778	102,143	1,892	0,773	1,892	0,575	-1,663	-3,356	0,03	0,054	-0,39	-0,788	0,007	0,1996				
	No	120	72,727	24	20	132	1,1	0,431	1,1	0,42	117	68,421	40	34,188	161,143	1,377	0,412	1,377	0,425	-0,277	-1,454	0,899	0,643	-0,06	-0,315	0,195					
Race	White	139	84,242	25	17,986	104,143	0,749	0,298	0,749	0,363	147	85,965	46	31,293	216,286	1,471	0,403	1,471	0,353	-0,722	-1,718	0,274	0,155	-0,168	-0,401	0,064	0,2846				
	Black or African American	9	5,455	2	22,222	1	0,111	0,082	0,111	0,504	11	6,433	2	18,182	7,143	0,649	0,608	0,649	0,456	-0,538	-1,965	0,889	0,438	-0,341	-1,246	0,563					
	Other	12	7,273	4	33,333	36,714	3,06	2,652	3,06	2,024	9	5,263	4	44,444	5,429	0,603	0,292	0,603	2,338	2,456	-4,016	8,929	0,437	0,336	-0,55	1,222					
	Unknown/Not Reported	5	3,03	1	20	0,429	0,086	0,086	0,086	2,831	4	2,339	3	75	34,429	8,607	4,834	8,607	3,165	-8,521	-18,564	1,521	0,085	-1,196	-2,606	0,214					
Ethnicity	Hispanic or Latino	69	41,818	11	15,942	14,286	0,207	0,074	0,207	0,171	66	38,596	14	21,212	49,571	0,751	0,238	0,751	0,175	-0,544	-1,028	-0,06	0,028	-0,381	-0,719	-0,042	0,8546				
	Not Hispanic or Latino	95	57,576	21	22,105	128	1,347	0,542	1,347	0,583	103	60,234	41	39,806	213,714	2,075	0,595	2,075	0,56	-0,728	-2,323	0,868	0,369	-0,127	-0,407	0,152					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	2	1,17	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,455	3	33,333	7,429	0,825	0,458	0,825	2,255	10	5,848	5	50	47,857	4,786	2,911	4,786	2,139	-3,96	-10,518	2,598	0,22	-0,559	-1,485	0,367	0,101				
	No	154	93,333	29	18,831	134,857	0,876	0,338	0,876	0,349	160	93,567	50	31,25	215,429	1,346	0,352	1,346	0,342	-0,471	-1,432	0,49	0,336	-0,109	-0,33	0,113					

	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0	NE	0	NE	0	NE	NE	NE	NE	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																											
	Yes	113	68,485	28	24,779	134,571	1,191	0,457	1,191	0,405	113	66,082	38	33,628	138,714	1,228	0,345	1,228	0,405	-0,037	-1,165	1,092	0,949	-0,008	-0,27	0,253	0,0606
	No	52	31,515	4	7,692	7,714	0,148	0,085	0,148	0,669	58	33,918	17	29,31	124,571	2,148	0,869	2,148	0,633	-1,999	-3,826	-0,173	0,032	-0,412	-0,787	-0,036	
Test result of a local diagnostic assay for SARS-CoV-2																											
	Positive	95	57,576	22	23,158	116,571	1,227	0,537	1,227	0,403	90	52,632	27	30	67,429	0,749	0,175	0,749	0,414	0,478	-0,662	1,618	0,409	0,121	-0,168	0,41	0,1694
	Negative	47	28,485	6	12,766	11	0,234	0,108	0,234	0,347	54	31,579	12	22,222	50,714	0,939	0,433	0,939	0,324	-0,705	-1,648	0,238	0,141	-0,294	-0,687	0,099	
	Unavailable	23	13,939	4	17,391	14,714	0,64	0,362	0,64	1,605	27	15,789	16	59,259	145,143	5,376	1,989	5,376	1,481	-4,736	-9,126	-0,346	0,035	-0,606	-1,167	-0,044	
Serology status																											
	Seropositive	49	29,697	2	4,082	2	0,041	0,029	0,041	0,34	43	25,146	6	13,953	32	0,744	0,531	0,744	0,363	-0,703	-1,692	0,286	0,161	-0,293	-0,704	0,119	0,9897
	Seronegative	108	65,455	30	27,778	140,286	1,299	0,478	1,299	0,506	114	66,667	46	40,351	226,571	1,987	0,517	1,987	0,492	-0,689	-2,08	0,703	0,331	-0,131	-0,394	0,133	
	Unclear serology status	8	4,848	0	0	0	0	0	0	0,244	14	8,187	3	21,429	4,714	0,337	0,229	0,337	0,185	-0,337	-0,975	0,302	0,284	-0,469	-1,359	0,42	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-2-eff-smd-BNWSYMCD

POPULATION: Cohort B
ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk									
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	n/a	165	100	10	6,1	171	100	26	15,2	0,36	Algorithm converged.	0,16	0,77	-9,144	Algorithm converged.	-15,64	-2,65	0,4	Algorithm converged.	0,2	0,8	0,0068		2,51	Algorithm converged.	1,25	5,04								

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: 18-5-eff-resp-bsymst14

POPULATION: Cohort B
ENDPOINT: Proportion of participants who subsequently develop signs and symptoms (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference								Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL			
All	n/a	165	100	10	6,1	171	100	26	15,2	0,36		Algorithm converged.	0,17	0,77	-9,144		Algorithm converged.	-15,64	-2,65	0,4		Algorithm converged.	0,2	0,8	0,0068		2,51		Algorithm converged.	1,25	5,04			
Sex	Male	85	51,5	6	7,1	76	44,4	9	11,8	0,57		Algorithm converged.	0,19	1,67	-4,783		Algorithm converged.	-13,86	4,3	0,6		Algorithm converged.	0,22	1,6	0,2987	0,2955	1,68		Algorithm converged.	0,63	4,49			
	Female	80	48,5	4	5	95	55,6	17	17,9	0,24		Algorithm converged.	0,08	0,75	-12,895		Algorithm converged.	-21,96	-3,83	0,28		Algorithm converged.	0,1	0,8	0,0099		3,58		Algorithm converged.	1,26	10,2			
Age	12-17	23	13,9	0	0	20	11,7	3	15	0		Algorithm converged.	NE	NE	-15		Algorithm converged.	-30,65	0,65	NE	*	Algorithm not converged.	NE	NE	0,0924	0,278	NE	*	Algorithm not converged.	NE	NE			
	18-49	87	52,7	5	5,7	91	53,2	12	13,2	0,4		Algorithm converged.	0,14	1,19	-7,44		Algorithm converged.	-15,94	1,06	0,44		Algorithm converged.	0,16	1,19	0,1258		2,29		Algorithm converged.	0,84	6,24			
	>=50	55	33,3	5	9,1	60	35,1	11	18,3	0,45		Algorithm converged.	0,14	1,38	-9,242		Algorithm converged.	-21,64	3,15	0,5		Algorithm converged.	0,18	1,34	0,1842		2,02		Algorithm converged.	0,75	5,44			
Region	US	147	89,1	10	6,8	151	88,3	24	15,9	0,39		Algorithm converged.	0,18	0,84	-9,091		Algorithm converged.	-16,2	-1,98	0,43		Algorithm converged.	0,21	0,86	0,0137	0,255	2,34		Algorithm converged.	1,16	4,71			
	ex-US	18	10,9	0	0	20	11,7	2	10	0		Algorithm converged.	NE	NE	-10		Algorithm converged.	-23,15	3,15	NE	*	Algorithm not converged.	NE	NE	0,4879		NE	*	Algorithm not converged.	NE	NE			
BMI	BMI < 30 kg/m2	98	59,4	7	7,1	118	69	19	16,1	0,4		Algorithm converged.	0,16	1	-8,959		Algorithm converged.	-17,32	-0,59	0,44		Algorithm converged.	0,19	1,01	0,0444	0,65	2,25		Algorithm converged.	0,99	5,14			
	BMI >= 30 kg/m2	66	40	3	4,5	48	28,1	7	14,6	0,28		Algorithm converged.	0,07	1,14	-10,038		Algorithm converged.	-21,22	1,14	0,31		Algorithm converged.	0,08	1,14	0,0923		3,21		Algorithm converged.	0,87	11,78			
	Unknown/not reported	1	0,6	0	0	5	2,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE			
Total household size including the household members not participating this study																																		
	2	66	40	5	7,6	75	43,9	15	20	0,33		Algorithm converged.	0,11	0,96	-12,424		Algorithm converged.	-23,5	-1,35	0,38		Algorithm converged.	0,15	0,99	0,0514	0,8317	2,64		Algorithm converged.	1,01	6,87			
	>2	99	60	5	5,1	96	56,1	11	11,5	0,41		Algorithm converged.	0,14	1,23	-6,408		Algorithm converged.	-14,1	1,29	0,44		Algorithm converged.	0,16	1,22	0,1223		2,27		Algorithm converged.	0,82	6,29			
Baseline high risk factor	Yes	45	27,3	3	6,7	54	31,6	7	13	0,48		Algorithm converged.	0,12	1,97	-6,296		Algorithm converged.	-17,85	5,25	0,51		Algorithm converged.	0,14	1,87	0,3396	0,6513	1,94		Algorithm converged.	0,53	7,09			
	No	120	72,7	7	5,8	117	68,4	19	16,2	0,32		Algorithm converged.	0,13	0,79	-10,406		Algorithm converged.	-18,3	-2,52	0,36		Algorithm converged.	0,16	0,82	0,0105		2,78		Algorithm converged.	1,22	6,37			
Race	White	139	84,2	6	4,3	147	86	23	15,6	0,24		Algorithm converged.	0,1	0,62	-11,33		Algorithm converged.	-18,1	-4,55	0,28		Algorithm converged.	0,12	0,66	0,0015	0,05	3,62		Algorithm converged.	1,52	8,63			
	Black or African American	9	5,5	1	11,1	11	6,4	1	9,1	1,25		Algorithm converged.	0,07	23,26	2,02		Algorithm converged.	-24,63	28,67	1,22		Algorithm converged.	0,09	16,92	1		0,82		Algorithm converged.	0,06	11,33			
	Other	12	7,3	2	16,7	9	5,3	0	0	NE	*	Algorithm not converged.	NE	NE	16,667		Algorithm converged.	-4,42	37,75	NE	*	Algorithm not converged.	NE	NE	0,4857		NE	*	Algorithm not converged.	NE	NE			
	Unknown/N ot Reported	5	3	1	20	4	2,3	2	50	0,25		Algorithm converged.	0,01	4,73	-30		Algorithm converged.	-90,25	30,25	0,4		Algorithm converged.	0,05	2,98	0,5238		2,5		Algorithm converged.	0,34	18,63			
Ethnicity	Hispanic or Latino	69	41,8	3	4,3	66	38,6	6	9,1	0,45		Algorithm converged.	0,11	1,9	-4,743		Algorithm converged.	-13,18	3,7	0,48		Algorithm converged.	0,12	1,83	0,3181	0,7744	2,09		Algorithm converged.	0,55	8,02			

Not Hispanic or Latino	Unknown/not reported	95 57,6	7 7,4	103 60,2	20 19,4	0,33		Algorithm converged.	0,13	0,82	-12,049		Algorithm converged.	-21,32	-2,78	0,38		Algorithm converged.	0,17	0,86	0,0138		2,64		Algorithm converged.	1,17	5,95
		1 0,6	0 0	2 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	9 5,5	2 22,2	10 5,8	4 40	0,43		Algorithm converged.	0,06	3,22	-17,778		Algorithm converged.	-58,52	22,96	0,56		Algorithm converged.	0,13	2,34	0,6285	0,6525	1,8		Algorithm converged.	0,43	7,59
	No	154 93,3	8 5,2	160 93,6	22 13,8	0,34		Algorithm converged.	0,15	0,8	-8,555		Algorithm converged.	-14,94	-2,17	0,38		Algorithm converged.	0,17	0,82	0,0101		2,65		Algorithm converged.	1,22	5,76
	Unknown/not reported	2 1,2	0 0	1 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113 68,5	8 7,1	113 66,1	20 17,7	0,35		Algorithm converged.	0,15	0,84	-10,619		Algorithm converged.	-19,1	-2,14	0,4		Algorithm converged.	0,18	0,87	0,0156	0,9341	2,5		Algorithm converged.	1,15	5,44
	No	52 31,5	2 3,8	58 33,9	6 10,3	0,35		Algorithm converged.	0,07	1,8	-6,499		Algorithm converged.	-15,92	2,92	0,37		Algorithm converged.	0,08	1,76	0,2768		2,69		Algorithm converged.	0,57	12,75
Local test result of diagnostic assay for SARS-CoV-2	Positive	95 57,6	5 5,3	90 52,6	13 14,4	0,33		Algorithm converged.	0,11	0,96	-9,181		Algorithm converged.	-17,72	-0,64	0,36		Algorithm converged.	0,14	0,98	0,0465	0,9578	2,74		Algorithm converged.	1,02	7,39
	Negative	47 28,5	2 4,3	54 31,6	6 11,1	0,36		Algorithm converged.	0,07	1,85	-6,856		Algorithm converged.	-17,03	3,32	0,38		Algorithm converged.	0,08	1,81	0,2789		2,61		Algorithm converged.	0,55	12,32
	Unavailable	23 13,9	3 13	27 15,8	7 25,9	0,43		Algorithm converged.	0,1	1,9	-12,882		Algorithm converged.	-34,39	8,63	0,5		Algorithm converged.	0,15	1,73	0,3079		1,99		Algorithm converged.	0,58	6,82
Serology status	Seropositive	49 29,7	0 0	43 25,1	1 2,3	0		Algorithm converged.	NE	NE	-2,326		Algorithm converged.	-6,83	2,18	NE	*	Algorithm not converged.	NE	NE	0,4674	0,3618	NE	*	Algorithm not converged.	NE	NE
	Seronegative	108 65,5	10 9,3	114 66,7	23 20,2	0,4		Algorithm converged.	0,18	0,89	-10,916		Algorithm converged.	-20,09	-1,74	0,46		Algorithm converged.	0,23	0,92	0,0226		2,18		Algorithm converged.	1,09	4,36
	Unclear serology status	8 4,8	0 0	14 8,2	2 14,3	0		Algorithm converged.	NE	NE	-14,286		Algorithm converged.	-32,62	4,04	NE	*	Algorithm not converged.	NE	NE	0,5152		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: l8-5-eff-resp-bsymst14

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

				Casirivimab/Imdevimab										Placebo				Difference between treatments (Casirivimab/Imdevimab - Placebo)										
Patients in analysis				Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference		
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL		
All	n/a	165	100	10	6,061	56	0,339	0,203	0,169	0,267	171	100	26	15,205	98,857	0,578	0,194	0,412	0,261	-0,243	-0,797	0,31	0,388	-0,094	-0,308	0,12		

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01.Jul2021.

Program: t-eff-smd.sas
Output: t9-3-eff-smd-BNWSYMT

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of weeks of symptomatic SARS-CoV-2 infection (strict-term) within 14 days of a positive RT-qPCR at baseline or during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab -										Interaction	
		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of Weeks	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test				
Name	Level	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	n	%	n	%	w	mean (w/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)						
All	n/a	165	100	10	6,061	56	0,339	0,203	0,339	0,2	171	100	26	15,205	98,857	0,578	0,194	0,578	0,197	-0,239	-0,791	0,314	0,396	-0,093	-0,307	0,122	NE						
Sex	Male	85	51,515	6	7,059	38,286	0,45	0,38	0,45	0,282	76	44,444	9	11,842	20,286	0,267	0,09	0,267	0,298	0,184	-0,627	0,994	0,656	0,07	-0,24	0,381	0,1623						
	Female	80	48,485	4	5	17,714	0,221	0,117	0,221	0,285	95	55,556	17	17,895	78,571	0,827	0,341	0,827	0,261	-0,606	-1,369	0,157	0,119	-0,237	-0,535	0,061							
Age	12-17	23	13,939	0	0	0	0	0	0	0,158	20	11,696	3	15	9	0,45	0,249	0,45	0,169	-0,45	-0,917	0,017	0,059	-0,584	-1,19	0,022	0,9489						
	18-49	87	52,727	5	5,747	42,143	0,484	0,376	0,484	0,365	91	53,216	12	13,187	59,429	0,653	0,347	0,653	0,357	-0,169	-1,177	0,839	0,742	-0,049	-0,344	0,245							
	>=50	55	33,333	5	9,091	13,857	0,252	0,138	0,252	0,151	60	35,088	11	18,333	30,429	0,507	0,155	0,507	0,145	-0,255	-0,67	0,16	0,226	-0,226	-0,593	0,141							
Region	US	147	89,091	10	6,803	56	0,381	0,228	0,381	0,225	151	88,304	24	15,894	95,286	0,631	0,219	0,631	0,222	-0,25	-0,872	0,372	0,429	-0,091	-0,319	0,136	0,936						
	ex-US	18	10,909	0	0	0	0	0	0	0,095	20	11,696	2	10	3,571	0,179	0,124	0,179	0,09	-0,179	-0,444	0,087	0,181	-0,434	-1,079	0,211							
BMI	BMI < 30 kg/m2	98	59,394	7	7,143	48,429	0,494	0,337	0,494	0,317	118	69,006	19	16,102	78,571	0,666	0,273	0,666	0,289	-0,172	-1,017	0,674	0,689	-0,055	-0,323	0,214	0,8229						
	BMI >= 30 kg/m2	66	40	3	4,545	7,571	0,115	0,091	0,115	0,115	48	28,07	7	14,583	20,286	0,423	0,166	0,423	0,135	-0,308	-0,658	0,043	0,085	-0,328	-0,701	0,045							
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	5	2,924	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Total household size including the household member(s) not participating this study																																	
	2	66	40	5	7,576	45,571	0,69	0,498	0,69	0,476	75	43,86	15	20	74,286	0,99	0,428	0,99	0,447	-0,3	-1,591	0,991	0,647	-0,077	-0,409	0,255	0,7923						
	>2	99	60	5	5,051	10,429	0,105	0,066	0,105	0,072	96	56,14	11	11,458	24,571	0,256	0,078	0,256	0,073	-0,151	-0,352	0,051	0,142	-0,211	-0,492	0,071							
Baseline high risk factor																																	
	Yes	45	27,273	3	6,667	4,714	0,105	0,086	0,105	0,185	54	31,579	7	12,963	27,571	0,511	0,217	0,511	0,169	-0,406	-0,904	0,092	0,109	-0,324	-0,721	0,074	0,7179						
	No	120	72,727	7	5,833	51,286	0,427	0,278	0,427	0,27	117	68,421	19	16,239	71,286	0,609	0,266	0,609	0,274	-0,182	-0,94	0,576	0,637	-0,061	-0,316	0,194							
Race	White	139	84,242	6	4,317	20,857	0,15	0,071	0,15	0,167	147	85,965	23	15,646	86	0,585	0,217	0,585	0,163	-0,435	-0,895	0,025	0,063	-0,22	-0,452	0,012	0,0185						
	Black or African American	9	5,455	1	11,111	0,714	0,079	0,079	0,079	0,062	11	6,433	1	9,091	0,429	0,039	0,039	0,039	0,056	0,04	-0,135	0,216	0,634	0,208	-0,696	1,113							
	Other	12	7,273	2	16,667	34	2,833	2,669	2,833	2,031	9	5,263	0	0	0	0	0	0	2,345	2,833	-3,659	9,326	0,372	0,387	-0,499	1,273							
	Unknown/Not Reported	5	3,03	1	20	0,429	0,086	0,086	0,086	1,245	4	2,339	2	50	12,429	3,107	2,124	3,107	1,392	-3,021	-7,439	1,396	0,15	-0,964	-2,374	0,446							
Ethnicity	Hispanic or Latino	69	41,818	3	4,348	5	0,072	0,051	0,072	0,112	66	38,596	6	9,091	19,143	0,29	0,155	0,29	0,115	-0,218	-0,536	0,1	0,178	-0,232	-0,57	0,107	0,973						
	Not Hispanic or Latino	95	57,576	7	7,368	51	0,537	0,35	0,537	0,334	103	60,234	20	19,417	79,714	0,774	0,306	0,774	0,321	-0,237	-1,151	0,677	0,609	-0,073	-0,352	0,207							
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	2	1,17	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE							
Healthcare worker	Yes	9	5,455	2	22,222	5,714	0,635	0,452	0,635	2,262	10	5,848	4	40	39,143	3,914	2,922	3,914	2,146	-3,279	-9,859	3,3	0,308	-0,462	-1,388	0,464	0,0071						
	No	154	93,333	8	5,195	50,286	0,327	0,216	0,327	0,165	160	93,567	22	13,75	59,714	0,373	0,091	0,373	0,162	-0,047	-0,502	0,409	0,84	-0,023	-0,244	0,199							

	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0	NE	0	NE	0	NE	NE	NE	NE	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																											
	Yes	113	68,485	8	7,08	50,857	0,45	0,294	0,45	0,228	113	66,082	20	17,699	61,286	0,542	0,13	0,542	0,228	-0,092	-0,726	0,542	0,775	-0,038	-0,299	0,223	0,4475
	No	52	31,515	2	3,846	5,143	0,099	0,078	0,099	0,4	58	33,918	6	10,345	37,571	0,648	0,516	0,648	0,379	-0,549	-1,64	0,543	0,321	-0,189	-0,565	0,187	
Test result of a local diagnostic assay for SARS-CoV-2																											
	Positive	95	57,576	5	5,263	38,429	0,405	0,34	0,405	0,262	90	52,632	13	14,444	39,429	0,438	0,142	0,438	0,269	-0,034	-0,775	0,708	0,929	-0,013	-0,302	0,276	0,7963
	Negative	47	28,485	2	4,255	4,286	0,091	0,082	0,091	0,104	54	31,579	6	11,111	14	0,259	0,111	0,259	0,097	-0,168	-0,45	0,114	0,24	-0,234	-0,627	0,159	
	Unavailable	23	13,939	3	13,043	13,286	0,578	0,361	0,578	0,915	27	15,789	7	25,926	45,429	1,683	1,106	1,683	0,845	-1,105	-3,609	1,399	0,379	-0,248	-0,809	0,314	
Serology status																											
	Seropositive	49	29,697	0	0	0	0	0	0	0,006	43	25,146	1	2,326	0,429	0,01	0,01	0,01	0,007	-0,01	-0,029	0,009	0,288	-0,221	-0,633	0,19	0,6487
	Seronegative	108	65,455	10	9,259	56	0,519	0,31	0,519	0,302	114	66,667	23	20,175	94,429	0,828	0,287	0,828	0,294	-0,31	-1,141	0,522	0,464	-0,098	-0,362	0,165	
	Unclear serology status	8	4,848	0	0	0	0	0	0	0,243	14	8,187	2	14,286	4	0,286	0,228	0,286	0,184	-0,286	-0,922	0,35	0,36	-0,399	-1,289	0,49	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-3-eff-smd-BNWSYMST

POPULATION: Cohort B
ENDPOINT: All-cause death at EAP
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Odds Ratio				Casirivimab/Imdevimab vs. Placebo				Absolute Risk Difference				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event										Relative Risk		Interaction Test		Relative Risk		Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergen e Reason	95% Lower CL	95% upper CL	Relative Risk	Convergen e Reason	95% Lower CL	95% upper CL	p-value	(likelihood ratio)	Relative Risk	Convergen e Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	0	0	171	100	0	0																				

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-1-eff-resp-dth29

POPULATION: Cohort B
ENDPOINT: All-cause death at EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL	
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio																							
All	n/a	165	100	0	0	171	100	0	0																								
Sex	Male	85	51.5	0	0	76	44.4	0	0																								
	Female	80	48.5	0	0	95	55.6	0	0																								
Age	12-17	23	13.9	0	0	20	11.7	0	0																								
	18-49	87	52.7	0	0	91	53.2	0	0																								
	>=50	55	33.3	0	0	60	35.1	0	0																								
Region	US	147	89.1	0	0	151	88.3	0	0																								
	ex-US	18	10.9	0	0	20	11.7	0	0																								
BMI	BMI < 30 kg/m2	98	59.4	0	0	118	69	0	0																								
	BMI >= 30 kg/m2	66	40	0	0	48	28.1	0	0																								
	Unknown/not reported	1	0.6	0	0	5	2.9	0	0																								
Total household size including the household members not participating this study																																	
	2	66	40	0	0	75	43.9	0	0																								
	>2	99	60	0	0	96	56.1	0	0																								
Baseline high risk factor																																	
	Yes	45	27.3	0	0	54	31.6	0	0																								
	No	120	72.7	0	0	117	68.4	0	0																								
Race	White	139	84.2	0	0	147	86	0	0																								
	Black or African American	9	5.5	0	0	11	6.4	0	0																								
	Other	12	7.3	0	0	9	5.3	0	0																								
	Unknown/N or Reported	5	3	0	0	4	2.3	0	0																								
Ethnicity	Hispanic or Latino	69	41.8	0	0	66	38.6	0	0																								
	Not Hispanic or Latino	95	57.6	0	0	103	60.2	0	0																								
	Unknown/not reported	1	0.6	0	0	2	1.2	0	0																								
Healthcare worker	Yes	9	5.5	0	0	10	5.8	0	0																								
	No	154	93.3	0	0	160	93.6	0	0																								
	Unknown/not reported	2	1.2	0	0	1	0.6	0	0																								
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																																	
	Yes	113	68.5	0	0	113	66.1	0	0																								
	No	52	31.5	0	0	58	33.9	0	0																								

POPULATION: Cohort B
ENDPOINT: All-cause death at end of Follow-Up
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
Patients					Event					Patients					Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test (likelihood ratio)					Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
Name	Level	n	%		n	%				n	%		n	%																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			</

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-2-eff-resp-dthfu

POPULATION: Cohort B
ENDPOINT: All-cause death at end of Follow-Up
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Interaction Test		Relative Risk		Relative Risk					
Name	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	p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	165	100	0	0	171	100	0	0																								
Sex	Male	85	51.5	0	0	76	44.4	0	0																								
	Female	80	48.5	0	0	95	55.6	0	0																								
Age	12-17	23	13.9	0	0	20	11.7	0	0																								
	18-49	87	52.7	0	0	91	53.2	0	0																								
	>=50	55	33.3	0	0	60	35.1	0	0																								
Region	US	147	89.1	0	0	151	88.3	0	0																								
	ex-US	18	10.9	0	0	20	11.7	0	0																								
BMI	BMI < 30 kg/m2	98	59.4	0	0	118	69	0	0																								
	BMI >= 30 kg/m2	66	40	0	0	48	28.1	0	0																								
	Unknown/not reported	1	0.6	0	0	5	2.9	0	0																								
Total household size including the household members not participating this study	2	66	40	0	0	75	43.9	0	0																								
	>2	99	60	0	0	96	56.1	0	0																								
Baseline high risk factor	Yes	45	27.3	0	0	54	31.6	0	0																								
	No	120	72.7	0	0	117	68.4	0	0																								
Race	White	139	84.2	0	0	147	86	0	0																								
	Black or African American	9	5.5	0	0	11	6.4	0	0																								
	Other	12	7.3	0	0	9	5.3	0	0																								
	Unknown/N or Reported	5	3	0	0	4	2.3	0	0																								
Ethnicity	Hispanic or Latino	69	41.8	0	0	66	38.6	0	0																								
	Not Hispanic or Latino	95	57.6	0	0	103	60.2	0	0																								
	Unknown/not reported	1	0.6	0	0	2	1.2	0	0																								
Healthcare worker	Yes	9	5.5	0	0	10	5.8	0	0																								
	No	154	93.3	0	0	160	93.6	0	0																								
	Unknown/not reported	2	1.2	0	0	1	0.6	0	0																								
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113	68.5	0	0	113	66.1	0	0																								
	No	52	31.5	0	0	58	33.9	0	0																								

[illegible]

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-2-eff-resp-dthfu

POPULATION: Cohort B
ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Interaction Test		Relative Risk		Relative Risk		Relative Risk									
Name	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		Relative Risk		Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	165	100	0	0	171	100	7	4.1	0	Algorithm converged.	NE	NE	-4.094	Algorithm converged.	-7.06	-1.12	NE	*	Algorithm not converged.	NE	NE	0.0148		NE	*	Algorithm not converged.	NE	NE						

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: i8-6-eff-resp-bhoer

POPULATION: Cohort B
ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab																
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference								Relative Risk						Relative Risk																
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL											
All	n/a	165	100		0	0		171	100		7	4,1	0				Algorithm converged.	NE	NE	-4,094			Algorithm converged.	-7,06	-1,12	NE	*		Algorithm not converged.	NE	NE	0,0148		NE	*		Algorithm not converged.	NE	NE			
Sex	Male	85	51,5		0	0		76	44,4		2	2,6	0				Algorithm converged.	NE	NE	-2,632			Algorithm converged.	-6,23	0,97	NE	*		Algorithm not converged.	NE	NE	0,2213	1	NE	*		Algorithm not converged.	NE	NE			
	Female	80	48,5		0	0		95	55,6		5	5,3	0				Algorithm converged.	NE	NE	-5,263			Algorithm converged.	-9,75	-0,77	NE	*		Algorithm not converged.	NE	NE	0,0635		NE	*		Algorithm not converged.	NE	NE			
Age	12-17	23	13,9		0	0		20	11,7		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE		NE	*		Algorithm not converged.	NE	NE
	18-49	87	52,7		0	0		91	53,2		4	4,4	0				Algorithm converged.	NE	NE	-4,396			Algorithm converged.	-8,61	-0,18	NE	*		Algorithm not converged.	NE	NE	0,1212		NE	*		Algorithm not converged.	NE	NE			
	>=50	55	33,3		0	0		60	35,1		3	5	0				Algorithm converged.	NE	NE	-5			Algorithm converged.	-10,51	0,51	NE	*		Algorithm not converged.	NE	NE	0,2449		NE	*		Algorithm not converged.	NE	NE			
Region	US	147	89,1		0	0		151	88,3		7	4,6	0				Algorithm converged.	NE	NE	-4,636			Algorithm converged.	-7,99	-1,28	NE	*		Algorithm not converged.	NE	NE	0,0146		NE	*		Algorithm not converged.	NE	NE			
	ex-US	18	10,9		0	0		20	11,7		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE		NE	*		Algorithm not converged.	NE	NE
BMI	BMI < 30 kg/m2	98	59,4		0	0		118	69		3	2,5	0				Algorithm converged.	NE	NE	-2,542			Algorithm converged.	-5,38	0,3	NE	*		Algorithm not converged.	NE	NE	0,253	1	NE	*		Algorithm not converged.	NE	NE			
	BMI >= 30 kg/m2	66	40		0	0		48	28,1		4	8,3	0				Algorithm converged.	NE	NE	-8,333			Algorithm converged.	-16,15	-0,51	NE	*		Algorithm not converged.	NE	NE	0,0292		NE	*		Algorithm not converged.	NE	NE			
	Unknown/not reported	1	0,6		0	0		5	2,9		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE		NE	*		Algorithm not converged.	NE	NE
Total household size including the household members not participating this study																																										
	2	66	40		0	0		75	43,9		7	9,3	0				Algorithm converged.	NE	NE	-9,333			Algorithm converged.	-15,92	-2,75	NE	*		Algorithm not converged.	NE	NE	0,0146		NE	*		Algorithm not converged.	NE	NE			
	>2	99	60		0	0		96	56,1		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE		NE	*		Algorithm not converged.	NE	NE
Baseline high risk factor	Yes	45	27,3		0	0		54	31,6		4	7,4	0				Algorithm converged.	NE	NE	-7,407			Algorithm converged.	-14,39	-0,42	NE	*		Algorithm not converged.	NE	NE	0,1236		NE	*		Algorithm not converged.	NE	NE			
	No	120	72,7		0	0		117	68,4		3	2,6	0				Algorithm converged.	NE	NE	-2,564			Algorithm converged.	-5,43	0,3	NE	*		Algorithm not converged.	NE	NE	0,1187		NE	*		Algorithm not converged.	NE	NE			
Race	White	139	84,2		0	0		147	86		6	4,1	0				Algorithm converged.	NE	NE	-4,082			Algorithm converged.	-7,28	-0,88	NE	*		Algorithm not converged.	NE	NE	0,03		NE	*		Algorithm not converged.	NE	NE			

	Black or African American	9 5,5	0 0	11 6,4	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Other	12 7,3	0 0	9 5,3	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not Reported	5 3	0 0	4 2,3	1 25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,43	17,43	NE	*	Algorithm not converged.	NE	NE	0,4444		NE	*	Algorithm not converged.	NE	NE	
Ethnicity	Hispanic or Latino	69 41,8	0 0	66 38,6	2 3	0		Algorithm converged.	NE	NE	-3,03		Algorithm converged.	-7,17	1,11	NE	*	Algorithm not converged.	NE	NE	0,2371	1	NE	*	Algorithm not converged.	NE	NE	
	Not Hispanic or Latino	95 57,6	0 0	103 60,2	5 4,9	0		Algorithm converged.	NE	NE	-4,854		Algorithm converged.	-9	-0,7	NE	*	Algorithm not converged.	NE	NE	0,0604		NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not reported	1 0,6	0 0	2 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Healthcare worker	Yes	9 5,5	0 0	10 5,8	2 20	0		Algorithm converged.	NE	NE	-20		Algorithm converged.	-44,79	4,79	NE	*	Algorithm not converged.	NE	NE	0,4737		NE	*	Algorithm not converged.	NE	NE	
	No	154 93,3	0 0	160 93,6	5 3,1	0		Algorithm converged.	NE	NE	-3,125		Algorithm converged.	-5,82	-0,43	NE	*	Algorithm not converged.	NE	NE	0,0607		NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not reported	2 1,2	0 0	1 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113 68,5	0 0	113 66,1	4 3,5	0		Algorithm converged.	NE	NE	-3,54		Algorithm converged.	-6,95	-0,13	NE	*	Algorithm not converged.	NE	NE	0,1217		NE	*	Algorithm not converged.	NE	NE	
	No	52 31,5	0 0	58 33,9	3 5,2	0		Algorithm converged.	NE	NE	-5,172		Algorithm converged.	-10,87	0,53	NE	*	Algorithm not converged.	NE	NE	0,2454		NE	*	Algorithm not converged.	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	95 57,6	0 0	90 52,6	3 3,3	0		Algorithm converged.	NE	NE	-3,333		Algorithm converged.	-7,04	0,38	NE	*	Algorithm not converged.	NE	NE	0,1132	1	NE	*	Algorithm not converged.	NE	NE	
	Negative	47 28,5	0 0	54 31,6	2 3,7	0		Algorithm converged.	NE	NE	-3,704		Algorithm converged.	-8,74	1,33	NE	*	Algorithm not converged.	NE	NE	0,4974		NE	*	Algorithm not converged.	NE	NE	
	Unavailable	23 13,9	0 0	27 15,8	2 7,4	0		Algorithm converged.	NE	NE	-7,407		Algorithm converged.	-17,29	2,47	NE	*	Algorithm not converged.	NE	NE	0,4931		NE	*	Algorithm not converged.	NE	NE	
Serology status	Seropositive	49 29,7	0 0	43 25,1	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Seronegative	108 65,5	0 0	114 66,7	7 6,1	0		Algorithm converged.	NE	NE	-6,14		Algorithm converged.	-10,55	-1,73	NE	*	Algorithm not converged.	NE	NE	0,0144		NE	*	Algorithm not converged.	NE	NE	
	Unclear serology status	8 4,8	0 0	14 8,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-6-eff-resp-bhoer

POPULATION: Cohort B
ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Interaction Test (likelihood ratio)		Relative Risk		Relative Risk					
Name	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	165	100	0	0	171	100	9	5,3	0	Algorithm converged.	NE	NE	-5,263	Algorithm converged.	-8,61	-1,92	NE	*	Algorithm not converged.	NE	NE	0,0035	NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-7-eff-resp-hoeruc

POPULATION: Cohort B
ENDPOINT: Proportion of subjects with at least 1 COVID-19 related hospitalization or emergency room visit or urgent care center visit associated with a positive RT-qPCR at baseline or during the EAP, or all-cause death
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Interaction Test p-value (likelihood ratio)		Relative Risk		Relative Risk					
Name	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		Relative Risk		Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	165	100		0/0	171	100		9/5,3	0	Algorithm converged.	NE	NE	-5,263	Algorithm converged.	-8,61	-1,92	NE	*	Algorithm not converged.	NE	NE	0,0035		NE	*	Algorithm not converged.	NE	NE				
Sex	Male	85	51,5		0/0	76	44,4		3/3,9	0	Algorithm converged.	NE	NE	-3,947	Algorithm converged.	-8,33	0,43	NE	*	Algorithm not converged.	NE	NE	0,103		NE	*	Algorithm not converged.	NE	NE				
	Female	80	48,5		0/0	95	55,6		6/6,3	0	Algorithm converged.	NE	NE	-6,316	Algorithm converged.	-11,21	-1,42	NE	*	Algorithm not converged.	NE	NE	0,032		NE	*	Algorithm not converged.	NE	NE				
Age	12-17	23	13,9		0/0	20	11,7		0/0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE			
	18-49	87	52,7		0/0	91	53,2		5/5,5	0	Algorithm converged.	NE	NE	-5,495	Algorithm converged.	-10,18	-0,81	NE	*	Algorithm not converged.	NE	NE	0,0593		NE	*	Algorithm not converged.	NE	NE				
	>=50	55	33,3		0/0	60	35,1		4/6,7	0	Algorithm converged.	NE	NE	-6,667	Algorithm converged.	-12,98	-0,35	NE	*	Algorithm not converged.	NE	NE	0,1199		NE	*	Algorithm not converged.	NE	NE				
Region	US	147	89,1		0/0	151	88,3		9/6	0	Algorithm converged.	NE	NE	-5,96	Algorithm converged.	-9,74	-2,18	NE	*	Algorithm not converged.	NE	NE	0,0035		NE	*	Algorithm not converged.	NE	NE				
	ex-US	18	10,9		0/0	20	11,7		0/0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE			
BMI	BMI < 30 kg/m2	98	59,4		0/0	118	69		4/3,4	0	Algorithm converged.	NE	NE	-3,39	Algorithm converged.	-6,66	-0,12	NE	*	Algorithm not converged.	NE	NE	0,128		NE	*	Algorithm not converged.	NE	NE				
	BMI >= 30 kg/m2	66	40		0/0	48	28,1		5/10,4	0	Algorithm converged.	NE	NE	-10,417	Algorithm converged.	-19,06	-1,77	NE	*	Algorithm not converged.	NE	NE	0,0117		NE	*	Algorithm not converged.	NE	NE				
	Unknown/not reported	1	0,6		0/0	5	2,9		0/0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE			
Total household size including the household members not participating this study																																	
	2	66	40		0/0	75	43,9		8/10,7	0	Algorithm converged.	NE	NE	-10,667	Algorithm converged.	-17,65	-3,68	NE	*	Algorithm not converged.	NE	NE	0,0071		NE	*	Algorithm not converged.	NE	NE				
	>2	99	60		0/0	96	56,1		1/1	0	Algorithm converged.	NE	NE	-1,042	Algorithm converged.	-3,07	0,99	NE	*	Algorithm not converged.	NE	NE	0,4923		NE	*	Algorithm not converged.	NE	NE				
Baseline high risk factor	Yes	45	27,3		0/0	54	31,6		4/7,4	0	Algorithm converged.	NE	NE	-7,407	Algorithm converged.	-14,39	-0,42	NE	*	Algorithm not converged.	NE	NE	0,1236		NE	*	Algorithm not converged.	NE	NE				
	No	120	72,7		0/0	117	68,4		5/4,3	0	Algorithm converged.	NE	NE	-4,274	Algorithm converged.	-7,94	-0,61	NE	*	Algorithm not converged.	NE	NE	0,0281		NE	*	Algorithm not converged.	NE	NE				
Race	White	139	84,2		0/0	147	86		8/5,4	0	Algorithm converged.	NE	NE	-5,442	Algorithm converged.	-9,11	-1,78	NE	*	Algorithm not converged.	NE	NE	0,0072		NE	*	Algorithm not converged.	NE	NE				
	Black or African American	9	5,5		0/0	11	6,4		0/0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE			
	Other	12	7,3		0/0	9	5,3		0/0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE			
	Unknown/Not Reported	5	3		0/0	4	2,3		1/25	0	Algorithm converged.	NE	NE	-25	Algorithm converged.	-67,43	17,43	NE	*	Algorithm not converged.	NE	NE	0,4444		NE	*	Algorithm not converged.	NE	NE				

Ethnicity	Hispanic or Latino	69	41,8		0	0		66	38,6		2	3	0		Algorithm converged.	NE	NE		-3,03		Algorithm converged.	-7,17	1,11	NE	*	Algorithm not converged.	NE	NE		0,2371		NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	95	57,6		0	0		103	60,2		7	6,8	0		Algorithm converged.	NE	NE		-6,796		Algorithm converged.	-11,66	-1,94	NE	*	Algorithm not converged.	NE	NE		0,0145		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	1	0,6		0	0		2	1,2		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	9	5,5		0	0		10	5,8		2	20	0		Algorithm converged.	NE	NE		-20		Algorithm converged.	-44,79	4,79	NE	*	Algorithm not converged.	NE	NE		0,4737		NE	*	Algorithm not converged.	NE	NE
	No	154	93,3		0	0		160	93,6		7	4,4	0		Algorithm converged.	NE	NE		-4,375		Algorithm converged.	-7,54	-1,21	NE	*	Algorithm not converged.	NE	NE		0,0147		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	2	1,2		0	0		1	0,6		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113	68,5		0	0		113	66,1		6	5,3	0		Algorithm converged.	NE	NE		-5,31		Algorithm converged.	-9,44	-1,18	NE	*	Algorithm not converged.	NE	NE		0,0292		NE	*	Algorithm not converged.	NE	NE
	No	52	31,5		0	0		58	33,9		3	5,2	0		Algorithm converged.	NE	NE		-5,172		Algorithm converged.	-10,87	0,53	NE	*	Algorithm not converged.	NE	NE		0,2454		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	95	57,6		0	0		90	52,6		3	3,3	0		Algorithm converged.	NE	NE		-3,333		Algorithm converged.	-7,04	0,38	NE	*	Algorithm not converged.	NE	NE		0,1132		NE	*	Algorithm not converged.	NE	NE
	Negative	47	28,5		0	0		54	31,6		3	5,6	0		Algorithm converged.	NE	NE		-5,556		Algorithm converged.	-11,67	0,55	NE	*	Algorithm not converged.	NE	NE		0,2461		NE	*	Algorithm not converged.	NE	NE
	Unavailable	23	13,9		0	0		27	15,8		3	11,1	0		Algorithm converged.	NE	NE		-11,111		Algorithm converged.	-22,97	0,74	NE	*	Algorithm not converged.	NE	NE		0,2396		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	49	29,7		0	0		43	25,1		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
	Seronegative	108	65,5		0	0		114	66,7		9	7,9	0		Algorithm converged.	NE	NE		-7,895		Algorithm converged.	-12,84	-2,94	NE	*	Algorithm not converged.	NE	NE		0,0034		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	8	4,8		0	0		14	8,2		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excelB.sas
Output: t8-7-eff-resp-hoeruc

POPULATION: Cohort B
ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Interaction Test p-value (likelihood ratio)		Relative Risk		Relative Risk					
Name	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		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	0	0	171	100	7	4,1	0	Algorithm converged.	NE	NE	-4,094	Algorithm converged.	-7,06	-1,12	NE	*	Algorithm not converged.	NE	NE	0,0148		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-8-eff-resp-bmaveru

POPULATION: Cohort B
ENDPOINT: Proportion of subjects requiring medically attended visits in emergency rooms or urgent care centers related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Placebo vs. Casirivimab/Imdevimab																	
		Patients		Event		Patients		Event		Odds Ratio		95% Lower CL		95% upper CL		Absolute Risk Difference		95% Lower CL		95% upper CL		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL	
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL	Convergence Reason	95% Lower CL	95% upper CL						
All	n/a	165	100		0 0	171	100		7 4,1	0	Algorithm converged.	NE	NE	-4,094	Algorithm converged.	-7,06	-1,12	NE	*	Algorithm not converged.	NE	NE	0,0148		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE				
Sex	Male	85	51,5		0 0	76	44,4		3 3,9	0	Algorithm converged.	NE	NE	-3,947	Algorithm converged.	-8,33	0,43	NE	*	Algorithm not converged.	Algorithm not converged.	NE	NE	0,103	1	NE	*	Algorithm not converged.	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE					
	Female	80	48,5		0 0	95	55,6		4 4,2	0	Algorithm converged.	NE	NE	-4,211	Algorithm converged.	-8,25	-0,17	NE	*	Algorithm not converged.	NE	NE	0,1262		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
Age	12-17	23	13,9		0 0	20	11,7		0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE					
	18-49	87	52,7		0 0	91	53,2		4 4,4	0	Algorithm converged.	NE	NE	-4,396	Algorithm converged.	-8,61	-0,18	NE	*	Algorithm not converged.	NE	NE	0,1212		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	>=50	55	33,3		0 0	60	35,1		3 5	0	Algorithm converged.	NE	NE	-5	Algorithm converged.	-10,51	0,51	NE	*	Algorithm not converged.	NE	NE	0,2449		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
Region	US	147	89,1		0 0	151	88,3		7 4,6	0	Algorithm converged.	NE	NE	-4,636	Algorithm converged.	-7,99	-1,28	NE	*	Algorithm not converged.	NE	NE	0,0146		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	ex-US	18	10,9		0 0	20	11,7		0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE						
BMI	BMI < 30 kg/m2	98	59,4		0 0	118	69		4 3,4	0	Algorithm converged.	NE	NE	-3,39	Algorithm converged.	-6,66	-0,12	NE	*	Algorithm not converged.	NE	NE	0,128	1	NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	BMI >= 30 kg/m2	66	40		0 0	48	28,1		3 6,3	0	Algorithm converged.	NE	NE	-6,25	Algorithm converged.	-13,1	0,6	NE	*	Algorithm not converged.	NE	NE	0,0719		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	Unknown/n ot reported	1	0,6		0 0	5	2,9		0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE						
Total household size including the household members not participating this study																																							
	2	66	40		0 0	75	43,9		6 8	0	Algorithm converged.	NE	NE	-8	Algorithm converged.	-14,14	-1,86	NE	*	Algorithm not converged.	Algorithm not converged.	NE	NE	0,0298	1	NE	*	Algorithm not converged.	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE					
	>2	99	60		0 0	96	56,1		1 1	0	Algorithm converged.	NE	NE	-1,042	Algorithm converged.	-3,07	0,99	NE	*	Algorithm not converged.	NE	NE	0,4923		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
Baseline high risk factor	Yes	45	27,3		0 0	54	31,6		3 5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-11,67	0,55	NE	*	Algorithm not converged.	NE	NE	0,2486		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	No	120	72,7		0 0	117	68,4		4 3,4	0	Algorithm converged.	NE	NE	-3,419	Algorithm converged.	-6,71	-0,13	NE	*	Algorithm not converged.	NE	NE	0,0578		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
Race	White	139	84,2		0 0	147	86		6 4,1	0	Algorithm converged.	NE	NE	-4,082	Algorithm converged.	-7,28	-0,88	NE	*	Algorithm not converged.	NE	NE	0,03		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							
	Black or African American	9	5,5		0 0	11	6,4		0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE						
	Other	12	7,3		0 0	9	5,3		0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE						
	Unknown/N ot Reported	5	3		0 0	4	2,3		1 25	0	Algorithm converged.	NE	NE	-25	Algorithm converged.	-67,43	17,43	NE	*	Algorithm not converged.	NE	NE	0,4444		NE	*	Algorithm not converged.	NE	NE	Algorithm not converged.	NE	NE							

Ethnicity	Hispanic or Latino	69	41,8		0	0		66	38,6		2	3	0		Algorithm converged.	NE	NE		-3,03		Algorithm converged.	-7,17	1,11	NE	*	Algorithm not converged.	NE	NE		0,2371	1	NE	*	Algorithm not converged.	NE	NE
	Not Hispanic or Latino	95	57,6		0	0		103	60,2		5	4,9	0		Algorithm converged.	NE	NE		-4,854		Algorithm converged.	-9	-0,7	NE	*	Algorithm not converged.	NE	NE		0,0604		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	1	0,6		0	0		2	1,2		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
Healthcare worker	Yes	9	5,5		0	0		10	5,8		2	20	0		Algorithm converged.	NE	NE		-20		Algorithm converged.	-44,79	4,79	NE	*	Algorithm not converged.	NE	NE		0,4737		NE	*	Algorithm not converged.	NE	NE
	No	154	93,3		0	0		160	93,6		5	3,1	0		Algorithm converged.	NE	NE		-3,125		Algorithm converged.	-5,82	-0,43	NE	*	Algorithm not converged.	NE	NE		0,0607		NE	*	Algorithm not converged.	NE	NE
	Unknown/not reported	2	1,2		0	0		1	0,6		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113	68,5		0	0		113	66,1		6	5,3	0		Algorithm converged.	NE	NE		-5,31		Algorithm converged.	-9,44	-1,18	NE	*	Algorithm not converged.	NE	NE		0,0292		NE	*	Algorithm not converged.	NE	NE
	No	52	31,5		0	0		58	33,9		1	1,7	0		Algorithm converged.	NE	NE		-1,724		Algorithm converged.	-5,07	1,63	NE	*	Algorithm not converged.	NE	NE		1		NE	*	Algorithm not converged.	NE	NE
Local test result of diagnostic assay for SARS-CoV-2	Positive	95	57,6		0	0		90	52,6		3	3,3	0		Algorithm converged.	NE	NE		-3,333		Algorithm converged.	-7,04	0,38	NE	*	Algorithm not converged.	NE	NE		0,1132	1	NE	*	Algorithm not converged.	NE	NE
	Negative	47	28,5		0	0		54	31,6		2	3,7	0		Algorithm converged.	NE	NE		-3,704		Algorithm converged.	-8,74	1,33	NE	*	Algorithm not converged.	NE	NE		0,4974		NE	*	Algorithm not converged.	NE	NE
	Unavailable	23	13,9		0	0		27	15,8		2	7,4	0		Algorithm converged.	NE	NE		-7,407		Algorithm converged.	-17,29	2,47	NE	*	Algorithm not converged.	NE	NE		0,4931		NE	*	Algorithm not converged.	NE	NE
Serology status	Seropositive	49	29,7		0	0		43	25,1		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE
	Seronegative	108	65,5		0	0		114	66,7		7	6,1	0		Algorithm converged.	NE	NE		-6,14		Algorithm converged.	-10,55	-1,73	NE	*	Algorithm not converged.	NE	NE		0,0144		NE	*	Algorithm not converged.	NE	NE
	Unclear serology status	8	4,8		0	0		14	8,2		0	0	NE	*	Algorithm not converged.	NE	NE		NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE		NE		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excelB.sas
Output: t8-8-eff-resp-bmaveru

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments						
		Patients in analysis		Patients with Event		Total of visits	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics			ANCOVA		Mean Difference			Standardized Mean Difference			
Name	Level	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	LSMean	SE	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	
All	n/a	165	100	0	0	0	0	0	-0.009	0.015	171	100	7	4.094	7	0.041	0.015	0.032	0.014	-0.041	-0.071	-0.011	0.009	-0.288	-0.502	-0.074		

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-4-eff-smd-BNMAVERU

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of medically attended visits in emergency rooms or urgent care centers related to RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of visits	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of visits	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction		
Name	Level	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	n	%	n	%	v	mean (v/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	Test p-value (likelihood ratio)				
All	n/a	165	100	0	0	0	0	0	0	0,011	171	100	7	4,094	7	0,041	0,015	0,041	0,011	-0,041	-0,071	-0,011	0,009	-0,288	-0,502	-0,074	NE				
Sex	Male	85	51,515	0	0	0	0	0	0	0,015	76	44,444	3	3,947	3	0,039	0,022	0,039	0,015	-0,039	-0,081	0,003	0,065	-0,292	-0,602	0,018	0,9327				
	Female	80	48,485	0	0	0	0	0	0	0,017	95	55,556	4	4,211	4	0,042	0,021	0,042	0,015	-0,042	-0,087	0,002	0,064	-0,282	-0,58	0,017					
Age	12-17	23	13,939	0	0	0	0	0	0	NE	20	11,696	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,6004				
	18-49	87	52,727	0	0	0	0	0	0	0,016	91	53,216	4	4,396	4	0,044	0,022	0,044	0,015	-0,044	-0,088	0	0,048	-0,297	-0,592	-0,002					
	>=50	55	33,333	0	0	0	0	0	0	0,021	60	35,088	3	5	3	0,05	0,028	0,05	0,021	-0,05	-0,109	0,009	0,094	-0,313	-0,68	0,055					
Region	US	147	89,091	0	0	0	0	0	0	0,012	151	88,304	7	4,636	7	0,046	0,017	0,046	0,012	-0,046	-0,081	-0,012	0,008	-0,308	-0,535	-0,08	0,3439				
	ex-US	18	10,909	0	0	0	0	0	0	NE	20	11,696	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
BMI	BMI < 30 kg/m2	98	59,394	0	0	0	0	0	0	0,014	118	69,006	4	3,39	4	0,034	0,017	0,034	0,012	-0,034	-0,07	0,002	0,066	-0,251	-0,52	0,017	0,3933				
	BMI ≥ 30 kg/m2	66	40	0	0	0	0	0	0	0,02	48	28,07	3	6,25	3	0,063	0,035	0,063	0,023	-0,063	-0,122	-0,003	0,04	-0,392	-0,765	-0,018					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	5	2,924	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Total household size including the household member(s) not participating this study																															
	2	66	40	0	0	0	0	0	0	0,025	75	43,86	6	8	6	0,08	0,032	0,08	0,023	-0,08	-0,146	-0,014	0,019	-0,399	-0,731	-0,067	0,0254				
	>2	99	60	0	0	0	0	0	0	0,007	96	56,14	1	1,042	1	0,01	0,01	0,01	0,007	-0,01	-0,031	0,01	0,311	-0,145	-0,426	0,137					
Baseline high risk factor																															
	Yes	45	27,273	0	0	0	0	0	0	0,025	54	31,579	3	5,556	3	0,056	0,031	0,056	0,023	-0,056	-0,124	0,013	0,111	-0,323	-0,72	0,075	0,5312				
	No	120	72,727	0	0	0	0	0	0	0,012	117	68,421	4	3,419	4	0,034	0,017	0,034	0,012	-0,034	-0,067	-0,001	0,041	-0,266	-0,521	-0,011					
Race	White	139	84,242	0	0	0	0	0	0	0,012	147	85,965	6	4,082	6	0,041	0,016	0,041	0,012	-0,041	-0,074	-0,008	0,016	-0,286	-0,518	-0,054	0,6634				
	Black or African American	9	5,455	0	0	0	0	0	0	NE	11	6,433	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Other	12	7,273	0	0	0	0	0	0	NE	9	5,263	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
	Unknown/Not Reported	5	3,03	0	0	0	0	0	0	0,146	4	2,339	1	25	1	0,25	0,25	0,25	0,164	-0,25	-0,769	0,269	0,292	-0,679	-2,089	0,731					
Ethnicity	Hispanic or Latino	69	41,818	0	0	0	0	0	0	0,015	66	38,596	2	3,03	2	0,03	0,021	0,03	0,015	-0,03	-0,071	0,011	0,147	-0,25	-0,588	0,089	0,5674				
	Not Hispanic or Latino	95	57,576	0	0	0	0	0	0	0,016	103	60,234	5	4,854	5	0,049	0,021	0,049	0,015	-0,049	-0,092	-0,005	0,03	-0,31	-0,59	-0,031					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	2	1,17	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,455	0	0	0	0	0	0	0,102	10	5,848	2	20	2	0,2	0,133	0,2	0,097	-0,2	-0,497	0,097	0,174	-0,623	-1,549	0,303	0,0113				
	No	154	93,333	0	0	0	0	0	0	0,01	160	93,567	5	3,125	5	0,031	0,014	0,031	0,01	-0,031	-0,059	-0,004	0,027	-0,25	-0,472	-0,029					
	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0	NE	0	NE	0	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																															
	Yes	113	68,485	0	0	0	0	0	0	0,015	113	66,082	6	5,31	6	0,053	0,021	0,053	0,015	-0,053	-0,095	-0,011	0,013	-0,332	-0,594	-0,071	0,2777				
	No	52	31,515	0	0	0	0	0	0	0,013	58	33,918	1	1,724	1	0,017	0,017	0,017	0,013	-0,017	-0,053	0,019	0,346	-0,179	-0,555	0,196					

POPULATION: Cohort B
ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
MODEL: Stratified analysis for overall; stratification factor = Region (US vs ex- US), Age group (age in years:>=12 to<50 and >=50)
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event				Odds Ratio				Absolute Risk Difference						Relative Risk				Interaction Test				Relative Risk	
Name	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	p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	0	0	171	100	4	2,3	0		Algorithm converged.	NE	NE	-2,339		Algorithm converged.	-4,6	-0,07	NE	*	Algorithm not converged.	NE	NE	0,123		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: 18-9-eff-resp-bhosp

POPULATION: Cohort B
ENDPOINT: Proportion of participants hospitalized related to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference								Relative Risk						Relative Risk													
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergen e Reason	95% Lower CL	95% upper CL	Absolute Risk		Convergen e Reason	95% Lower CL	95% upper CL	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergen e Reason	95% Lower CL	95% upper CL								
All	n/a	165	100		0	0		171	100		4	2,3	0				Algorithm converged.	NE	NE	-2,339			Algorithm converged.	-4,6	-0,07	NE	*		Algorithm not converged.	NE	NE	0,123		NE	*		Algorithm not converged.	NE	NE
Sex	Male	85	51,5		0	0		76	44,4		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE				
	Female	80	48,5		0	0		95	55,6		4	4,2	0				Algorithm converged.	NE	NE	-4,211			Algorithm converged.	-8,25	-0,17	NE	*		Algorithm not converged.	NE	NE	0,1262		NE	*		Algorithm not converged.	NE	NE
Age	12-17	23	13,9		0	0		20	11,7		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE				
	18-49	87	52,7		0	0		91	53,2		2	2,2	0				Algorithm converged.	NE	NE	-2,198			Algorithm converged.	-5,21	0,81	NE	*		Algorithm not converged.	NE	NE	0,4974		NE	*		Algorithm not converged.	NE	NE
	>=50	55	33,3		0	0		60	35,1		2	3,3	0				Algorithm converged.	NE	NE	-3,333			Algorithm converged.	-7,88	1,21	NE	*		Algorithm not converged.	NE	NE	0,4966		NE	*		Algorithm not converged.	NE	NE
Region	US	147	89,1		0	0		151	88,3		4	2,6	0				Algorithm converged.	NE	NE	-2,649			Algorithm converged.	-5,21	-0,09	NE	*		Algorithm not converged.	NE	NE	0,1226		NE	*		Algorithm not converged.	NE	NE
	ex-US	18	10,9		0	0		20	11,7		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE				
BMI	BMI < 30 kg/m2	98	59,4		0	0		118	69		2	1,7	0				Algorithm converged.	NE	NE	-1,695			Algorithm converged.	-4,02	0,63	NE	*		Algorithm not converged.	NE	NE	0,502	1	NE	*		Algorithm not converged.	NE	NE
	BMI >= 30 kg/m2	66	40		0	0		48	28,1		2	4,2	0				Algorithm converged.	NE	NE	-4,167			Algorithm converged.	-9,82	1,49	NE	*		Algorithm not converged.	NE	NE	0,1751		NE	*		Algorithm not converged.	NE	NE
	Unknown/n ot reported	1	0,6		0	0		5	2,9		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE				
Total household size including the household members not participating this study																																							
	2	66	40		0	0		75	43,9		4	5,3	0				Algorithm converged.	NE	NE	-5,333			Algorithm converged.	-10,42	-0,25	NE	*		Algorithm not converged.	NE	NE	0,1227		NE	*		Algorithm not converged.	NE	NE
	>2	99	60		0	0		96	56,1		0	0	NE	*			Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE			NE	*		Algorithm not converged.	NE	NE	NE				
Baseline high risk factor	Yes	45	27,3		0	0		54	31,6		3	5,6	0				Algorithm converged.	NE	NE	-5,556			Algorithm converged.	-11,67	0,55	NE	*		Algorithm not converged.	NE	NE	0,2486	1	NE	*		Algorithm not converged.	NE	NE
	No	120	72,7		0	0		117	68,4		1	0,9	0				Algorithm converged.	NE	NE	-0,855			Algorithm converged.	-2,52	0,81	NE	*		Algorithm not converged.	NE	NE	0,4937		NE	*		Algorithm not converged.	NE	NE
Race	White	139	84,2		0	0		147	86		3	2	0				Algorithm converged.	NE	NE	-2,041			Algorithm converged.	-4,33	0,24	NE	*		Algorithm not converged.	NE	NE	0,248		NE	*		Algorithm not converged.	NE	NE

	Black or African American	9 5,5	0 0	11 6,4	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Other	12 7,3	0 0	9 5,3	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Unknown/Not Reported	5 3	0 0	4 2,3	1 25	0		Algorithm converged.	NE	NE	-25		Algorithm converged.	-67,43	17,43	NE	*	Algorithm not converged.	NE	NE	0,4444		NE	*	Algorithm not converged.	NE	NE	
Ethnicity	Hispanic or Latino	69 41,8	0 0	66 38,6	1 1,5	0		Algorithm converged.	NE	NE	-1,515		Algorithm converged.	-4,46	1,43	NE	*	Algorithm not converged.	NE	NE	0,4889	1	NE	*	Algorithm not converged.	NE	NE	
	Not Hispanic or Latino	95 57,6	0 0	103 60,2	3 2,9	0		Algorithm converged.	NE	NE	-2,913		Algorithm converged.	-6,16	0,33	NE	*	Algorithm not converged.	NE	NE	0,2474		NE	*	Algorithm not converged.	NE	NE	
	Unknown/n ot reported	1 0,6	0 0	2 1,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Healthcare worker	Yes	9 5,5	0 0	10 5,8	1 10	0		Algorithm converged.	NE	NE	-10		Algorithm converged.	-28,59	8,59	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
	No	154 93,3	0 0	160 93,6	3 1,9	0		Algorithm converged.	NE	NE	-1,875		Algorithm converged.	-3,98	0,23	NE	*	Algorithm not converged.	NE	NE	0,2479		NE	*	Algorithm not converged.	NE	NE	
	Unknown/n ot reported	2 1,2	0 0	1 0,6	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)	Yes	113 68,5	0 0	113 66,1	2 1,8	0		Algorithm converged.	NE	NE	-1,77		Algorithm converged.	-4,2	0,66	NE	*	Algorithm not converged.	NE	NE	0,4978	1	NE	*	Algorithm not converged.	NE	NE	
	No	52 31,5	0 0	58 33,9	2 3,4	0		Algorithm converged.	NE	NE	-3,448		Algorithm converged.	-8,14	1,25	NE	*	Algorithm not converged.	NE	NE	0,4969		NE	*	Algorithm not converged.	NE	NE	
Local test result of diagnostic assay for SARS-CoV-2	Positive	95 57,6	0 0	90 52,6	1 1,1	0		Algorithm converged.	NE	NE	-1,111		Algorithm converged.	-3,28	1,05	NE	*	Algorithm not converged.	NE	NE	0,4865	1	NE	*	Algorithm not converged.	NE	NE	
	Negative	47 28,5	0 0	54 31,6	2 3,7	0		Algorithm converged.	NE	NE	-3,704		Algorithm converged.	-8,74	1,33	NE	*	Algorithm not converged.	NE	NE	0,4974		NE	*	Algorithm not converged.	NE	NE	
	Unavailable	23 13,9	0 0	27 15,8	1 3,7	0		Algorithm converged.	NE	NE	-3,704		Algorithm converged.	-10,83	3,42	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Serology status	Seropositive	49 29,7	0 0	43 25,1	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	Seronegative	108 65,5	0 0	114 66,7	4 3,5	0		Algorithm converged.	NE	NE	-3,509		Algorithm converged.	-6,89	-0,13	NE	*	Algorithm not converged.	NE	NE	0,1222		NE	*	Algorithm not converged.	NE	NE	
	Unclear serology status	8 4,8	0 0	14 8,2	0 0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-eff-resp.sas, binary1-excel8.sas
Output: t8-9-eff-resp-bhosp

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo				Difference between treatments											
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA				Mean Difference		95% Difference		Standardized Mean	
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	
All	n/a	165	100	0	0	0	0	0	-0,063	0,163	171	100	4	2,339	47	0,275	0,168	0,213	0,16	-0,276	-0,614	0,062	0,109	-0,175	-0,389	0,039	

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-5-eff-smd-BNDHOSP

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of days of hospital and ICU stay in participants hospitalized for a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

Casirivimab/Imdevimab														Placebo						Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	165	100	0		0	0	0		0.122	171	100	4	2,339	47	0.275	0.168	0.275	0.12	-0.275	-0.612	0.062	0.11	-0.175	-0.389	0.04	NE		
Sex	Male	85	51.515	0	0	0	0	0	0	NE	76	44.444	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0.1499		
	Female	80	48.485	0	0	0	0	0	0	0.242	95	55.556	4	4,211	47	0.495	0.302	0.495	0.223	-0.495	-1.144	0.155	0.135	-0.227	-0.525	0.071			
Age	12-17	23	13.939	0	0	0	0	0	0	NE	20	11.696	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0.8179		
	18-49	87	52.727	0	0	0	0	0	0	0.212	91	53.216	2	2,198	31	0.341	0.29	0.341	0.208	-0.341	-0.927	0.245	0.253	-0.171	-0.466	0.123			
	>=50	55	33.333	0	0	0	0	0	0	0.146	60	35.088	2	3,333	16	0.267	0.193	0.267	0.139	-0.267	-0.666	0.133	0.188	-0.245	-0.613	0.122			
Region	US	147	89.091	0	0	0	0	0	0	0.137	151	88.304	4	2,649	47	0.311	0.191	0.311	0.136	-0.311	-0.691	0.069	0.108	-0.186	-0.414	0.041	0.5668		
	ex-US	18	10.909	0	0	0	0	0	0	NE	20	11.696	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
BMI	BMI < 30 kg/m2	98	59,394	0	0	0	0	0	0	0.191	118	69,006	2	1,695	36	0.305	0.235	0.305	0.174	-0.305	-0.814	0.204	0.239	-0.161	-0.429	0.108	0.8382		
	BMI >= 30 kg/m2	66	40	0	0	0	0	0	0	0.089	48	28.07	2	4,167	11	0.229	0.161	0.229	0.104	-0.229	-0.501	0.042	0.097	-0.315	-0.688	0.058			
	Unknown/not reported	1	0.606	0	0	0		NE	0	NE	5	2.924	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Total household size including the household member(s) not participating this study																													
	2 >2	66	40	0	0	0	0	0	0	0.297	75	43.86	4	5,333	47	0.627	0.381	0.627	0.278	-0.627	-1.431	0.178	0.126	-0.259	-0.59	0.073	0.0704		
		99	60	0	0	0	0	0	0	NE	96	56.14	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Baseline high risk factor																													
	Yes	45	27.273	0	0	0	0	0	0	0.42	54	31.579	3	5,556	41	0.759	0.519	0.759	0.383	-0.759	-1.888	0.369	0.185	-0.267	-0.665	0.13	0.0592		
	No	120	72.727	0	0	0	0	0	0	0.036	117	68.421	1	0.855	6	0.051	0.051	0.051	0.036	-0.051	-0.151	0.048	0.312	-0.131	-0.386	0.124			
Race	White	139	84,242	0	0	0	0	0	0	0.063	147	85,965	3	2,041	21	0.143	0.086	0.143	0.062	-0.143	-0.317	0.031	0.107	-0.191	-0.423	0.041	0.8326		
	Black or African American	9	5,455	0	0	0	0	0	0	NE	11	6,433	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
	Other	12	7,273	0	0	0	0	0	0	NE	9	5,263	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
	Unknown/Not Reported	5	3.03	0	0	0	0	0	0	3.806	4	2,339	1	25	26	6.5	6.5	6.5	4.255	-6.5	-20	7	0.292	-0.679	-2.089	0.731			
Ethnicity	Hispanic or Latino	69	41,818	0	0	0	0	0	0	0.269	66	38,596	1	1,515	26	0.394	0.394	0.394	0.275	-0.394	-1.156	0.368	0.308	-0.175	-0.514	0.164	0.5908		
	Not Hispanic or Latino	95	57,576	0	0	0	0	0	0	0.092	103	60,234	3	2,913	21	0.204	0.122	0.204	0.088	-0.204	-0.455	0.047	0.111	-0.227	-0.507	0.052			
	Unknown/not reported	1	0.606	0	0	0	0		NE	0	NE	2	1.17	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE			
Healthcare worker	Yes	9	5,455	0	0	0	0	0	0	0.767	10	5,848	1	10	10	1	1	1	0.728	-1	-3.23	1.23	0.357	-0.415	-1.341	0.511	0.3037		
	No	154	93,333	0	0	0	0	0	0	0.123	160	93,567	3	1,875	37	0.231	0.169	0.231	0.121	-0.231	-0.571	0.108	0.181	-0.151	-0.373	0.071			
	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0		NE	0	NE	NE	NE	NE	NE	NE	NE			
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																													
	Yes	113	68,485	0	0	0	0	0	0	0.174	113	66,082	2	1,77	36	0.319	0.246	0.319	0.174	-0.319	-0.803	0.166	0.196	-0.172	-0.433	0.089	0.7253		
	No	52	31.515	0	0	0	0	0	0	0.102	58	33,918	2	3,448	11	0.19	0.133	0.19	0.097	-0.19	-0.469	0.09	0.182	-0.255	-0.631	0.121			

Test result of a local diagnostic assay for SARS-CoV-2																												
	Positive	95	57,576	0	0	0	0	0	0	0,196	90	52,632	1	1,111	26	0,289	0,289	0,289	0,201	-0,289	-0,844	0,266	0,306	-0,151	-0,44	0,139	0,9786	
	Negative	47	28,485	0	0	0	0	0	0	0,161	54	31,579	2	3,704	15	0,278	0,205	0,278	0,15	-0,278	-0,715	0,16	0,21	-0,25	-0,642	0,143		
	Unavailable	23	13,939	0	0	0	0	0	0	0,177	27	15,789	1	3,704	6	0,222	0,222	0,222	0,164	-0,222	-0,707	0,263	0,361	-0,257	-0,819	0,304		
Serology status																												
	Seropositive	49	29,697	0	0	0	0	0	0	NE	43	25,146	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE	0,3076	
	Seronegative	108	65,455	0	0	0	0	0	0	0,186	114	66,667	4	3,509	47	0,412	0,252	0,412	0,181	-0,412	-0,922	0,098	0,113	-0,213	-0,477	0,051		
	Unclear serology status	8	4,848	0	0	0	0	0	0	NE	14	8,187	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-5-eff-smd-BNDHOSP

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Stratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

Casirivimab/Imdevimab											Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)						
		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics		ANCOVA		Mean Difference				Standardized Mean Difference			
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	
All	n/a	165	100	60	36,364	656	3,976	0,595	4,887	0,912	171	100	77	45,029	1053	6,158	0,757	7,072	0,894	-2,184	-4,078	-0,291	0,024	-0,247	-0,461	-0,033	

Stratification factor = Age Region.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-6-eff-smd-BNDABSEN

POPULATION: Modified Full Analysis Set - Cohort B
ENDPOINT: Number of days missed for daily responsibilities due to a RT-qPCR confirmed SARS-CoV-2 infection that has an onset at baseline or during the EAP
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template SMD

		Casirivimab/Imdevimab										Placebo										Difference between treatments (Casirivimab/Imdevimab - Placebo)									
		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Patients in analysis		Patients with Event		Total of days	Statistics			ANCOVA		Mean Difference				Standardized Mean Difference			Interaction Test		
Name	Level	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	n	%	n	%	d	mean (d/N)	SE	LSMean	SE	LSMean	95% Lower CL	95% Upper CL	p-value	Hedges' g	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)			
All	n/a	165	100	60	36,364	656	3,976	0,595	3,976	0,69	171	100	77	45,029	1053	6,158	0,757	6,158	0,678	-2,182	-4,084	-0,28	0,025	-0,246	-0,46	-0,032	NE				
Sex	Male	85	51,515	29	34,118	360	4,235	0,993	4,235	0,977	76	44,444	36	47,368	473	6,224	1,014	6,224	1,034	-1,988	-4,798	0,821	0,164	-0,22	-0,53	0,091	0,8305				
	Female	80	48,485	31	38,75	296	3,7	0,632	3,7	0,98	95	55,556	41	43,158	580	6,105	1,098	6,105	0,9	-2,405	-5,031	0,221	0,072	-0,273	-0,571	0,025					
Age	12-17	23	13,939	7	30,435	46	2	0,793	2	0,98	20	11,696	9	45	79	3,95	1,243	3,95	1,051	-1,95	-4,851	0,951	0,182	-0,407	-1,014	0,199	0,9969				
	18-49	87	52,727	36	41,379	433	4,977	0,998	4,977	1,113	91	53,216	44	48,352	652	7,165	1,185	7,165	1,088	-2,188	-5,259	0,884	0,162	-0,21	-0,505	0,085					
	>=50	55	33,333	17	30,909	177	3,218	0,734	3,218	0,976	60	35,088	24	40	322	5,367	1,105	5,367	0,935	-2,148	-4,826	0,529	0,115	-0,295	-0,662	0,073					
Region	US	147	89,091	50	34,014	553	3,762	0,645	3,762	0,747	151	88,304	63	41,722	872	5,775	0,823	5,775	0,737	-2,013	-4,078	0,052	0,056	-0,222	-0,449	0,006	0,6668				
	ex-US	18	10,909	10	55,556	103	5,722	1,395	5,722	1,619	20	11,696	14	70	181	9,05	1,704	9,05	1,536	-3,328	-7,854	1,198	0,145	-0,474	-1,119	0,171					
BMI	BMI < 30 kg/m2	98	59,394	40	40,816	460	4,694	0,869	4,694	0,802	118	69,006	52	44,068	610	5,169	0,675	5,169	0,731	-0,476	-2,614	1,663	0,662	-0,06	-0,328	0,209	0,0102				
	BMI >= 30 kg/m2	66	40	20	30,303	196	2,97	0,727	2,97	1,266	48	28,07	23	47,917	421	8,771	2,06	8,771	1,484	-5,801	-9,666	-1,936	0,004	-0,56	-0,934	-0,187					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	8,764	5	2,924	2	40	22	4,4	3,919	4,4	3,919	-4,4	-31,054	22,254	0,671	-0,402	-2,835	2,031					
Total household size including the household member(s) not participating this study																															
	2	66	40	23	34,848	240	3,636	0,713	3,636	0,906	75	43,86	31	41,333	398	5,307	0,982	5,307	0,85	-1,67	-4,127	0,786	0,181	-0,226	-0,558	0,106	0,6286				
	>2	99	60	37	37,374	416	4,202	0,873	4,202	0,986	96	56,14	46	47,917	655	6,823	1,108	6,823	1,001	-2,621	-5,393	0,151	0,064	-0,266	-0,547	0,015					
Baseline high risk factor																															
	Yes	45	27,273	18	40	207	4,6	1,033	4,6	1,61	54	31,579	28	51,852	462	8,556	1,793	8,556	1,47	-3,956	-8,282	0,371	0,073	-0,363	-0,761	0,034	0,2115				
	No	120	72,727	42	35	449	3,742	0,722	3,742	0,715	117	68,421	49	41,88	591	5,051	0,717	5,051	0,725	-1,31	-3,316	0,696	0,2	-0,167	-0,422	0,089					
Race	White	139	84,242	50	35,971	559	4,022	0,672	4,022	0,754	147	85,965	65	44,218	848	5,769	0,801	5,769	0,733	-1,747	-3,816	0,322	0,098	-0,196	-0,428	0,036	0,6552				
	Black or African American	9	5,455	2	22,222	31	3,444	2,456	3,444	2,665	11	6,433	7	63,636	96	8,727	2,552	8,727	2,41	-5,283	-12,832	2,266	0,159	-0,633	-1,537	0,272					
	Other	12	7,273	7	58,333	52	4,333	1,559	4,333	2,094	9	5,263	3	33,333	46	5,111	3,071	5,111	2,418	-0,778	-7,472	5,916	0,81	-0,103	-0,989	0,783					
	Unknown/Not Reported	5	3,03	1	20	14	2,8	2,8	2,8	5,791	4	2,339	2	50	63	15,75	9,205	15,75	6,474	-12,95	-33,489	7,589	0,18	-0,889	-2,299	0,521					
Ethnicity	Hispanic or Latino	69	41,818	19	27,536	286	4,145	1,213	4,145	1,304	66	38,596	21	31,818	361	5,47	1,424	5,47	1,334	-1,325	-5,015	2,365	0,479	-0,122	-0,46	0,217	0,4514				
	Not Hispanic	95	57,576	41	43,158	370	3,895	0,545	3,895	0,749	103	60,234	56	54,369	692	6,718	0,861	6,718	0,72	-2,824	-4,872	-0,775	0,007	-0,385	-0,665	-0,106					
	Unknown/not reported	1	0,606	0	0	0	0	NE	0	NE	2	1,17	0	0	0	0	0	0	NE	0	NE	NE	NE	NE	NE	NE					
Healthcare worker	Yes	9	5,455	5	55,556	48	5,333	1,818	5,333	1,872	10	5,848	9	90	87	8,7	1,82	8,7	1,776	-3,367	-8,81	2,077	0,209	-0,573	-1,499	0,353	0,7619				
	No	154	93,333	55	35,714	608	3,948	0,628	3,948	0,729	160	93,567	68	42,5	966	6,038	0,799	6,038	0,715	-2,089	-4,099	-0,08	0,042	-0,23	-0,452	-0,009					
	Unknown/not reported	2	1,212	0	0	0	0	0	0	NE	1	0,585	0	0	0	0	NE	0	NE	0	NE	NE	NE	NE	NE	NE					
High viral load (> 4 log 10 copies/ml) at baseline (Yes/No)																															
	Yes	113	68,485	51	45,133	583	5,159	0,812	5,159	0,817	113	66,082	50	44,248	668	5,912	0,822	5,912	0,817	-0,752	-3,029	1,525	0,516	-0,086	-0,348	0,175	0,0293				
	No	52	31,515	9	17,308	73	1,404	0,53	1,404	1,252	58	33,918	27	46,552	385	6,638	1,561	6,638	1,185	-5,234	-8,652	-1,817	0,003	-0,576	-0,952	-0,2					

Test result of a local diagnostic assay for SARS-CoV-2																												
	Positive	95	57,576	38	40	419	4,411	0,879	4,411	0,912	90	52,632	39	43,333	513	5,7	0,972	5,7	0,937	-1,289	-3,869	1,29	0,325	-0,144	-0,433	0,145	0,2183	
	Negative	47	28,485	12	25,532	93	1,979	0,573	1,979	1,34	54	31,579	19	35,185	325	6,019	1,634	6,019	1,25	-4,04	-7,675	-0,404	0,03	-0,436	-0,829	-0,044		
	Unavailable	23	13,939	10	43,478	144	6,261	1,805	6,261	1,642	27	15,789	19	70,37	215	7,963	1,376	7,963	1,516	-1,702	-6,195	2,791	0,45	-0,213	-0,774	0,349		
Serology status																												
	Seropositive	49	29,697	10	20,408	107	2,184	0,674	2,184	1,432	43	25,146	21	48,837	338	7,86	2,101	7,86	1,529	-5,677	-9,838	-1,515	0,008	-0,562	-0,973	-0,15	0,0233	
	Seronegative	108	65,455	49	45,37	539	4,991	0,837	4,991	0,818	114	66,667	50	43,86	637	5,588	0,778	5,588	0,796	-0,597	-2,847	1,653	0,601	-0,07	-0,334	0,194		
	Unclear serology status	8	4,848	1	12,5	10	1,25	1,25	1,25	2,218	14	8,187	6	42,857	78	5,571	1,96	5,571	1,676	-4,321	-10,121	1,478	0,136	-0,663	-1,552	0,227		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

Clinical cut-off: 01Jul2021.

Program: t-eff-smd.sas
Output: t9-6-eff-smd-BNDABSEN

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Wirksamkeit

Ergänzende Dokumente

POPULATION: mFAS - Cohort B
ENDPOINT: --
MODEL: --
STUDY: R10933-10987-COV-2069
Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	77	100%	336	100%	3	100%	336	100%	2	100%	336	100%
with <10 Patients per arm ¹	75	97.4%	294	87.5%	1	33.3%	16	4.8%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	2	2.6%	42	12.5%	2	66.7%	320	95.2%	2	100%	336	100%

¹: ' <10 patients category' if at least one treatment arm has <10 patients.
²: ' >=10 patients ' category if all treatment arms have >=10 patients.
³: Geographical regions: US vs Ex-US (Romania; Republic of Moldova)
⁴: Number of centers, countries, or geographical regions
⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions
⁶: Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm)
⁷: % 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 cut-off: 01Jul21

Program: t3_center.sas
Output: t3_center.xlsx

Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 171)	Casirivimab/Imdevimab (N = 165)
Age (Years)		
n	171	165
Mean	41.77	39.33
SD	18.08	17.75
Median	41.0	39.0
Q1	24.0	24.0
Q3	57.0	52.0
Min	12.0	12.0
Max	87.0	87.0
Age Group (Years) [n (%)]		
>=12 to <18	20 (11.7)	23 (13.9)
>=18 to <45	74 (43.3)	73 (44.2)
>=45 to <65	55 (32.2)	54 (32.7)
>=65 to <80	20 (11.7)	14 (8.5)
>=80	2 (1.2)	1 (0.6)
Age Group (Years) [n (%)]		
>=12 to <50	111 (64.9)	110 (66.7)
>=50	60 (35.1)	55 (33.3)
Sex [n (%)]		
Male	76 (44.4)	85 (51.5)
Female	95 (55.6)	80 (48.5)
Race [n (%)]		
White	147 (86.0)	139 (84.2)
Black or African American	11 (6.4)	9 (5.5)
Asian	8 (4.7)	11 (6.7)
American Indian or Alaska Native	1 (0.6)	1 (0.6)
Other	4 (2.3)	5 (3.0)
Ethnicity [n (%)]		
Hispanic or Latino	66 (38.6)	69 (41.8)
Not Hispanic or Latino	103 (60.2)	95 (57.6)
Other	2 (1.2)	1 (0.6)
Weight (kg)		
n	166	164
Missing	5	1
Mean	78.76	82.81
SD	19.50	21.74
Median	75.7	82.0
Q1	64.0	65.7
Q3	91.0	95.3
Min	33.1	41.3
Max	144.2	145.1
Height (cm)		
n	167	165
Missing	4	0
Mean	167.97	169.25
SD	10.26	11.18
Median	167.6	170.0
Q1	161.0	162.6
Q3	175.0	176.0
Min	121.9	123.0
Max	195.6	201.2
BMI (kg/m2)		
n	166	164
Missing	5	1
Mean	27.84	28.74
SD	6.38	6.39
Median	27.1	28.2
Q1	23.2	23.5
Q3	30.3	32.1
Min	17.9	16.9
Max	47.5	51.2

Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 171)	Casirivimab/Imdevimab (N = 165)
BMI group (kg/m ²) [n (%)]		
Missing	5 (2.9)	1 (0.6)
BMI < 30 kg/m ²	118 (69.0)	98 (59.4)
BMI ≥ 30 kg/m ²	48 (28.1)	66 (40.0)
Randomization strata: local RT-qPCR status [n (%)]		
Positive	90 (52.6)	95 (57.6)
Negative	54 (31.6)	47 (28.5)
Unavailable	27 (15.8)	23 (13.9)
Randomization strata: age [n (%)]		
12-17	20 (11.7)	23 (13.9)
18-49	91 (53.2)	87 (52.7)
≥ 50	60 (35.1)	55 (33.3)
Region [n (%)]		
US	151 (88.3)	147 (89.1)
ex-US	20 (11.7)	18 (10.9)
Country [n (%)]		
Moldova, Republic of	10 (5.8)	12 (7.3)
Romania	10 (5.8)	6 (3.6)
United States of America	151 (88.3)	147 (89.1)
Total household size including the house members not participating this study [n (%)]		
2	75 (43.9)	66 (40.0)
>2	96 (56.1)	99 (60.0)
No one wears a mask in home [n (%)]		
Missing	3 (1.8)	2 (1.2)
Yes	88 (51.5)	86 (52.1)
No	79 (46.2)	76 (46.1)
N/A	1 (0.6)	1 (0.6)
Share a bedroom [n (%)]		
Missing	3 (1.8)	2 (1.2)
Yes	78 (45.6)	69 (41.8)
No	88 (51.5)	94 (57.0)
N/A	2 (1.2)	0 (0.0)
Share a common room [n (%)]		
Missing	3 (1.8)	2 (1.2)
Yes	165 (96.5)	160 (97.0)
No	2 (1.2)	3 (1.8)
N/A	1 (0.6)	0 (0.0)
Symptoms in suspected infected person [n (%)]		
Missing	3 (1.8)	2 (1.2)
Yes	145 (84.8)	136 (82.4)
No	21 (12.3)	26 (15.8)
N/A	2 (1.2)	1 (0.6)
Aware of any treatment [n (%)]		
Missing	3 (1.8)	2 (1.2)
Yes	74 (43.3)	77 (46.7)
No	91 (53.2)	85 (51.5)
N/A	3 (1.8)	1 (0.6)
Status of index case participating R10933-10987-COV-2067 [n (%)]		
Missing	2 (1.2)	0 (0.0)
Yes	55 (32.2)	58 (35.2)
No	114 (66.7)	107 (64.8)
Total household members, including index case, who participate the R10933-10987-COV-2067 [n (%)]		
Missing	1 (0.6)	1 (0.6)
0	140 (81.9)	124 (75.2)
1	27 (15.8)	34 (20.6)
2	3 (1.8)	4 (2.4)
3	0 (0.0)	2 (1.2)

Table 4.1: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 171)	Casirivimab/Imdevimab (N = 165)
Subject received influenza [n (%)]		
Missing	1 (0.6)	0 (0.0)
Yes	35 (20.5)	36 (21.8)
No	135 (78.9)	129 (78.2)
Subject been quarantined [n (%)]		
Missing	1 (0.6)	0 (0.0)
Yes	33 (19.3)	36 (21.8)
No	137 (80.1)	129 (78.2)
First responder [n (%)]		
Missing	1 (0.6)	3 (1.8)
Yes	3 (1.8)	3 (1.8)
No	167 (97.7)	159 (96.4)
Healthcare worker [n (%)]		
Yes	10 (5.8)	9 (5.5)
No	160 (93.6)	154 (93.3)
Unknown/not reported	1 (0.6)	2 (1.2)
Contact with a stranger [n (%)]		
Missing	1 (0.6)	0 (0.0)
Yes	46 (26.9)	56 (33.9)
No	124 (72.5)	109 (66.1)
Serology status [n (%)]		
Seropositive	43 (25.1)	49 (29.7)
Seronegative	114 (66.7)	108 (65.5)
Unclear serology status	14 (8.2)	8 (4.8)
Viral load (log10 copies/mL) at baseline		
n	166	160
Missing	5	5
Mean	5.59	5.64
SD	2.25	2.10
Median	5.3	5.6
Q1	3.6	3.6
Q3	7.7	7.3
Min	2.6	2.6
Max	10.1	9.7
Days between baseline central RT-qPCR test and study drug administration [n (%)]		
Missing	8 (4.7)	6 (3.6)
-1	1 (0.6)	1 (0.6)
0	162 (94.7)	158 (95.8)
Baseline high risk factor [n (%)]		
Yes	54 (31.6)	45 (27.3)
No	117 (68.4)	120 (72.7)

Table 5.1. Summary of Overall Patient Disposition
Modified Full Analysis Set - Cohort B

	Placebo (N=171)	Casirivimab/Imdevimab (N=165)
Randomized patients	171 (100%)	165 (100%)
Randomized but not treated	3 (1.8%)	1 (0.6%)
Randomized and treated	168 (98.2%)	164 (99.4%)
Complete the efficacy assessment period (EAP) (as derived)	166 (97.1%)	164 (99.4%)
Complete the end of study follow-up visit (as per CRF)	59 (34.5%)	58 (35.2%)
Did not complete the end of study follow-up visit	109 (63.7%)	106 (64.2%)
Subjects discontinued from the study during EAP	2 (1.2%)	0
Reason for subjects discontinuing from the study during EAP		
Adverse Event	0	0
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	0	0
Lost To Follow-Up	0	0
Subject Decision	2 (1.2%)	0

Clinical cut-off: 01Jul2021

Table 5.3. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=3375)
Number of Subjects Screened	3375
Randomized Subject	3298 (97.7%)
Subjects treated but not randomized	0
Subjects randomized but not treated	28 (0.8%)
Screen Failure Patients	72 (2.1%)
Excl 01: Subject-reported history of prior positive SARS-CoV-2 RT-PCR test or positive SARS-CoV-2 serology test at any time before the screening	3 (<0.1%)
Excl 02: Subject has lived with individuals who have had previous SARS-CoV-2 infection	3 (<0.1%)
Excl 03: Active respiratory or non-respiratory symptoms consistent with COVID-19	3 (<0.1%)
Excl 06: Any PE, and/or MH, CM or recent live vaccines that, in the opinion of the study investigator, might confound the study results or pose an additional risk to the subject by their partic	3 (<0.1%)
Excl 08: Has a history of significant multiple and/or severe allergies or has had an anaphylactic reaction to prescription or non-prescription drugs or food	6 (0.2%)
Excl 09: Treatment with another investigational agent in the last 30 days or within 5 half-lives of the investigational drug, whichever is longer, prior to the screening visit	2 (<0.1%)
Excl 12: Use of hydroxychloroquine/chloroquine for prophylaxis/treatment of SARS-CoV-2 or anti-SARS-viral agents, eg, remdesivir, within 1 (<0.1%) 60 days of screening	
Excl 13: Member of the clinical site study team and/or immediate family	1 (<0.1%)
Excl 14: Sexually active men who are unwilling to use the following forms of medically acceptable birth control during the study drug follow-up period and for 8 months after single dose of stud	1 (<0.1%)

Clinical cut-off: 01Jul2021

Patients with two screen failure reasons will be counted twice in the frequency table.

Table 5.3. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=3375)
Excl 16: WOCBP and girls at or beyond menarche who are unwilling to use highly effective contraception prior to start of the first dose, during the study, and for at least 8 months after the last dose	11 (0.3%)
Incl 01: Adult subjects ≥ 18 years of age at the signing of informed consent or adolescent subjects ≥ 12 to < 18 years of age, or pediatric subjects < 12 years of age at the signing of the assent	1 ($< 0.1\%$)
Incl 02: Asymptomatic household contact with exposure to an individual with a diagnosis of SARS-CoV-2 infection (index case)	19 (0.6%)
Incl 03: Subject anticipates living in the same household with the index case until study day 29	9 (0.3%)
Incl 04: Is judged by the investigator to be in good health based on medical history and physical examination at screening/baseline, including subjects who have a chronic, stable medical condition	2 ($< 0.1\%$)
Incl 05: Willing and able to comply with study visits and study-related procedures/assessments	9 (0.3%)
Incl 06: Provide informed consent signed by study subject or legally acceptable representative	1 ($< 0.1\%$)
Missing	1 ($< 0.1\%$)

Clinical cut-off: 01Jul2021

Patients with two screen failure reasons will be counted twice in the frequency table.

Clinical cut-off: 01Jul2021

Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 171)	Casirivimab/Imdevimab (N = 165)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Missing	3	1
Median	208.0	205.5

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

Hauptdokumente

POPULATION: Safety - Cohort B

ENDPOINT: Any AEs

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	58	35,2	170	100	88	51,8	0,51		Algorithm converged.	0,33	0,78	-16,613		Algorithm converged.	-27,1	-6,15	0,68		Algorithm converged.	0,53	0,87	0,002		1,47		Algorithm converged.	1,14	1,9		
Sex	Male	85	51,5	29	34,1	74	43,5	37	50	0,52		Algorithm converged.	0,27	0,98	-15,882		Algorithm converged.	-31,1	-0,67	0,68		Algorithm converged.	0,47	0,99	0,043	1	1,47		Algorithm converged.	1,01	2,13		
	Female	80	48,5	29	36,3	96	56,5	51	53,1	0,5		Algorithm converged.	0,27	0,92	-16,875		Algorithm converged.	-31,4	-2,36	0,68		Algorithm converged.	0,48	0,96	0,026		1,47		Algorithm converged.	1,04	2,07		
Age	12-17	23	13,9	3	13	20	11,8	11	55	0,12		Algorithm converged.	0,03	0,55	-41,957		Algorithm converged.	-67,7	-16,2	0,24		Algorithm converged.	0,08	0,73	0,008	0,061	4,22		Algorithm converged.	1,37	13		
	18-49	87	52,7	35	40,2	89	52,4	44	49,4	0,69		Algorithm converged.	0,38	1,25	-9,208		Algorithm converged.	-23,8	5,42	0,81		Algorithm converged.	0,58	1,13	0,221		1,23		Algorithm converged.	0,88	1,71		
	>=50	55	33,3	20	36,4	61	35,9	33	54,1	0,48		Algorithm converged.	0,23	1,02	-17,735		Algorithm converged.	-35,6	0,1	0,67		Algorithm converged.	0,44	1,02	0,057		1,49		Algorithm converged.	0,98	2,26		
Region	US	148	89,7	50	33,8	152	89,4	80	52,6	0,46		Algorithm converged.	0,29	0,73	-18,848		Algorithm converged.	-29,9	-7,84	0,64		Algorithm converged.	0,49	0,84	0,001	0,211	1,56		Algorithm converged.	1,19	2,04		
	ex-US	17	10,3	8	47,1	18	10,6	8	44,4	1,11		Algorithm converged.	0,29	4,21	2,614		Algorithm converged.	-30,4	35,63	1,06		Algorithm converged.	0,51	2,18	0,878		0,94		Algorithm converged.	0,46	1,94		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: Any AEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event				Patients				Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	26	15,8	170	100	42	24,7	0,57		Algorithm converged.	0,33	0,98	-8,948		Algorithm converged.	-17,5	-0,41	0,64		Algorithm converged.	0,41	0,99	0,042		1,57		Algorithm converged.	1,01	2,43		
Sex	Male	85	51,5	15	17,6	74	43,5	19	25,7	0,62		Algorithm converged.	0,29	1,33	-8,029		Algorithm converged.	-20,9	4,81	0,69		Algorithm converged.	0,38	1,25	0,22	0,69	1,45		Algorithm converged.	0,8	2,65		
	Female	80	48,5	11	13,8	96	56,5	23	24	0,51		Algorithm converged.	0,23	1,12	-10,208		Algorithm converged.	-21,6	1,19	0,57		Algorithm converged.	0,3	1,1	0,089		1,74		Algorithm converged.	0,91	3,35		
Age	12-17	23	13,9	1	4,3	20	11,8	3	15	0,26		Algorithm converged.	0,02	2,7	-10,652		Algorithm converged.	-28,4	7,08	0,29		Algorithm converged.	0,03	2,57	0,324	0,6528	3,45		Algorithm converged.	0,39	30,6		
	18-49	87	52,7	14	16,1	89	52,4	19	21,3	0,71		Algorithm converged.	0,33	1,52	-5,256		Algorithm converged.	-16,8	6,24	0,75		Algorithm converged.	0,4	1,41	0,373		1,33		Algorithm converged.	0,71	2,48		
	>=50	55	33,3	11	20	61	35,9	20	32,8	0,51		Algorithm converged.	0,22	1,2	-12,787		Algorithm converged.	-28,6	3,04	0,61		Algorithm converged.	0,32	1,16	0,122		1,64		Algorithm converged.	0,87	3,11		
Region	US	148	89,7	23	15,5	152	89,4	39	25,7	0,53		Algorithm converged.	0,3	0,95	-10,117		Algorithm converged.	-19,2	-1,05	0,61		Algorithm converged.	0,38	0,96	0,031	0,4773	1,65		Algorithm converged.	1,04	2,62		
	ex-US	17	10,3	3	17,6	18	10,6	3	16,7	1,07		Algorithm converged.	0,18	6,22	0,98		Algorithm converged.	-24	26	1,06		Algorithm converged.	0,25	4,54	1		0,94		Algorithm converged.	0,22	4,05		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade >= 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	1	0,6	170	100	5	2,9	0,2	Algorithm converged.	0,02	1,74	-2,335	Algorithm converged.	-5,14	0,47	0,21	Algorithm converged.	0,02	1,74	0,215		4,85	Algorithm converged.	0,57	41,1
Sex	Male	85	51,5	1	1,2	74	43,5	1	1,4	0,87	Algorithm converged.	0,05	14,1	-0,175	Algorithm converged.	-3,66	3,31	0,87	Algorithm converged.	0,06	13,7	1	0,1342	1,15	Algorithm converged.	0,07	18
	Female	80	48,5	0	0	96	56,5	4	4,2	0	Algorithm converged.	NE	NE	-4,167	Algorithm converged.	-8,16	-0,17	NE *	Algorithm not converged.	NE	NE	0,127		NE *	Algorithm not converged.	NE	NE
Age	12-17	23	13,9	0	0	20	11,8	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	18-49	87	52,7	1	1,1	89	52,4	2	2,2	0,51	Algorithm converged.	0,05	5,68	-1,098	Algorithm converged.	-4,91	2,71	0,51	Algorithm converged.	0,05	5,54	1		1,96	Algorithm converged.	0,18	21,2
	>=50	55	33,3	0	0	61	35,9	3	4,9	0	Algorithm converged.	NE	NE	-4,918	Algorithm converged.	-10,3	0,51	NE *	Algorithm not converged.	NE	NE	0,246		NE *	Algorithm not converged.	NE	NE
Region	US	148	89,7	1	0,7	152	89,4	4	2,6	0,25	Algorithm converged.	0,03	2,28	-1,956	Algorithm converged.	-4,82	0,91	0,26	Algorithm converged.	0,03	2,27	0,371	0,5291	3,89	Algorithm converged.	0,44	34,4
	ex-US	17	10,3	0	0	18	10,6	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade >=3 (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	1	0,6	170	100	1	0,6	1,03	Algorithm converged.	0,06	16,6	0,018	Algorithm converged.	-1,63	1,67	1,03	Algorithm converged.	0,06	16,3	1		0,97		Algorithm converged.	0,06	15,4	
Sex	Male	85	51,5	1	1,2	74	43,5	1	1,4	0,87	Algorithm converged.	0,05	14,1	-0,175	Algorithm converged.	-3,66	3,31	0,87	Algorithm converged.	0,06	13,7	1	1	1,15		Algorithm converged.	0,07	18	
	Female	80	48,5	0	0	96	56,5	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Age	12-17	23	13,9	0	0	20	11,8	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	18-49	87	52,7	1	1,1	89	52,4	0	0	NE *	Algorithm not converged.	NE	NE	1,149	Algorithm converged.	-1,09	3,39	NE	Algorithm not converged.	NE	NE	0,494		NE	*	Algorithm not converged.	NE	NE	
	>=50	55	33,3	0	0	61	35,9	1	1,6	0	Algorithm converged.	NE	NE	-1,639	Algorithm converged.	-4,83	1,55	NE	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Region	US	148	89,7	1	0,7	152	89,4	0	0	NE *	Algorithm not converged.	NE	NE	0,676	Algorithm converged.	-0,64	2	NE	Algorithm not converged.	NE	NE	0,493		NE	*	Algorithm not converged.	NE	NE	
	ex-US	17	10,3	0	0	18	10,6	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	1	0,6	170	100	5	2,9	0,2	Algorithm converged.	0,02	1,74	-2,335	Algorithm converged.	-5,14	0,47	0,21	Algorithm converged.	0,02	1,74	0,215		4,85	Algorithm converged.	0,57	41,1
Sex	Male	85	51,5	1	1,2	74	43,5	1	1,4	0,87	Algorithm converged.	0,05	14,1	-0,175	Algorithm converged.	-3,66	3,31	0,87	Algorithm converged.	0,06	13,7	1	0,1342	1,15	Algorithm converged.	0,07	18
	Female	80	48,5	0	0	96	56,5	4	4,2	0	Algorithm converged.	NE	NE	-4,167	Algorithm converged.	-8,16	-0,17	NE	Algorithm not converged.	NE	NE	0,127		NE	Algorithm not converged.	NE	NE
Age	12-17	23	13,9	0	0	20	11,8	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	18-49	87	52,7	1	1,1	89	52,4	2	2,2	0,51	Algorithm converged.	0,05	5,68	-1,098	Algorithm converged.	-4,91	2,71	0,51	Algorithm converged.	0,05	5,54	1		1,96	Algorithm converged.	0,18	21,2
	>=50	55	33,3	0	0	61	35,9	3	4,9	0	Algorithm converged.	NE	NE	-4,918	Algorithm converged.	-10,3	0,51	NE	Algorithm not converged.	NE	NE	0,246		NE	Algorithm not converged.	NE	NE
Region	US	148	89,7	1	0,7	152	89,4	4	2,6	0,25	Algorithm converged.	0,03	2,28	-1,956	Algorithm converged.	-4,82	0,91	0,26	Algorithm converged.	0,03	2,27	0,371	0,5291	3,89	Algorithm converged.	0,44	34,4
	ex-US	17	10,3	0	0	18	10,6	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs Grade 4

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Odds Ratio				Casirivimab/Imdevimab vs. Placebo				Absolute Risk Difference				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event												Relative Risk				Relative Risk						
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100		0 0	170	100		0 0																					
Sex	Male	85	51.5		0 0	74	43.5		0 0																					
	Female	80	48.5		0 0	96	56.5		0 0																					
Age	12-17	23	13.9		0 0	20	11.8		0 0																					
	18-49	87	52.7		0 0	89	52.4		0 0																					
	>=50	55	33.3		0 0	61	35.9		0 0																					
Region	US	148	89.7		0 0	152	89.4		0 0																					
	ex-US	17	10.3		0 0	18	10.6		0 0																					

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-7-ae-raw-toxgr5-unstrat-saf1

POPULATION: Safety - Cohort B

ENDPOINT: Any SAEs

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	1	0,6	170	100	5	2,9	0,2	Algorithm converged.	0,02	1,74	-2,335	Algorithm converged.	-5,14	0,47	0,21	Algorithm converged.	0,02	1,74	0,215		4,85	Algorithm converged.	0,57	41,1
Sex	Male	85	51,5	1	1,2	74	43,5	1	1,4	0,87	Algorithm converged.	0,05	14,1	-0,175	Algorithm converged.	-3,66	3,31	0,87	Algorithm converged.	0,06	13,7	1	0,1342	1,15	Algorithm converged.	0,07	18
	Female	80	48,5	0	0	96	56,5	4	4,2	0	Algorithm converged.	NE	NE	-4,167	Algorithm converged.	-8,16	-0,17	NE *	Algorithm not converged.	NE	NE	0,127		NE *	Algorithm not converged.	NE	NE
Age	12-17	23	13,9	0	0	20	11,8	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	18-49	87	52,7	1	1,1	89	52,4	2	2,2	0,51	Algorithm converged.	0,05	5,68	-1,098	Algorithm converged.	-4,91	2,71	0,51	Algorithm converged.	0,05	5,54	1		1,96	Algorithm converged.	0,18	21,2
	>=50	55	33,3	0	0	61	35,9	3	4,9	0	Algorithm converged.	NE	NE	-4,918	Algorithm converged.	-10,3	0,51	NE *	Algorithm not converged.	NE	NE	0,246		NE *	Algorithm not converged.	NE	NE
Region	US	148	89,7	1	0,7	152	89,4	4	2,6	0,25	Algorithm converged.	0,03	2,28	-1,956	Algorithm converged.	-4,82	0,91	0,26	Algorithm converged.	0,03	2,27	0,371	0,5291	3,89	Algorithm converged.	0,44	34,4
	ex-US	17	10,3	0	0	18	10,6	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: Any SAEs (excluding disease related events)

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
Patients				Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	165	100	1	0,6	170	100	1	0,6	1,03	Algorithm converged.	0,06	16,6	0,018	Algorithm converged.	-1,63	1,67	1,03	Algorithm converged.	0,06	16,3	1		0,97		Algorithm converged.	0,06	15,4	
Sex	Male	85	51,5	1	1,2	74	43,5	1	1,4	0,87	Algorithm converged.	0,05	14,1	-0,175	Algorithm converged.	-3,66	3,31	0,87	Algorithm converged.	0,06	13,7	1	1	1,15		Algorithm converged.	0,07	18	
	Female	80	48,5	0	0	96	56,5	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
Age	12-17	23	13,9	0	0	20	11,8	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE	
	18-49	87	52,7	1	1,1	89	52,4	0	0	NE *	Algorithm not converged.	NE	NE	1,149	Algorithm converged.	-1,09	3,39	NE	Algorithm not converged.	NE	NE	0,494		NE	*	Algorithm not converged.	NE	NE	
	>=50	55	33,3	0	0	61	35,9	1	1,6	0	Algorithm converged.	NE	NE	-1,639	Algorithm converged.	-4,83	1,55	NE	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
Region	US	148	89,7	1	0,7	152	89,4	0	0	NE *	Algorithm not converged.	NE	NE	0,676	Algorithm converged.	-0,64	2	NE	Algorithm not converged.	NE	NE	0,493		NE	*	Algorithm not converged.	NE	NE	
	ex-US	17	10,3	0	0	18	10,6	1	5,6	0	Algorithm converged.	NE	NE	-5,556	Algorithm converged.	-16,1	5,03	NE	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
																								</						

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

AESI

POPULATION: Safety - Cohort B

ENDPOINT: Injection site reactions Grade ≥ 3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01Jul2021

POPULATION: Safety - Cohort B

ENDPOINT: Serious injection site reactions

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 01 Jul 2021

POPULATION: Safety - Cohort B

ENDPOINT: Hypersensitivity reactions Grade >=3

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk								

POPULATION: Safety - Cohort B
ENDPOINT: Serious hypersensitivity reactions
MODEL: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk			Interaction Test		Relative Risk							
Name	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	(likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	165	100	0	0	170	100	0	0																		
Sex	Male	85	51.5	0	0	74	43.5	0	0																		
	Female	80	48.5	0	0	96	56.5	0	0																		
Age	12-17	23	13.9	0	0	20	11.8	0	0																		
	18-49	87	52.7	0	0	89	52.4	0	0																		
	>=50	55	33.3	0	0	61	35.9	0	0																		
Region	US	148	89.7	0	0	152	89.4	0	0																		
	ex-US	17	10.3	0	0	18	10.6	0	0																		

Test for interaction based on RR (Log-binomial regression).
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 01Jul2021

Program: t-ae-raw.sas, binary1-excel12.sas
Output: t12-14-ae-raw-shypr-unstrat-saf1

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

SOC-PT

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Casirivimab/Imdevimab vs. Placebo					Absolute Risk Difference					Casirivimab/Imdevimab vs. Placebo					Relative Risk					Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															

Psychiatric disorders	--	--	165	100	1	0.606	170	100	5	2.941	0.201	Algorithm converged.	0.023	1.741	-2.335	Algorithm converged.	-5.137	0.467	0.206	Algorithm converged.	0.024	1.745	0.2148	4.853	Algorithm converged.	0.573	41,096
Anxiety	--	--	165	100	0	0	170	100	3	1.765	NE	* Algorithm not converged.	NE	NE	-1.765	Algorithm converged.	-3.744	0.215	NE	* Algorithm not converged.	NE	NE	0.2479	NE	Algorithm not converged.	NE	NE
Behaviour disorder	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Depression	--	--	165	100	1	0.606	170	100	1	0.588	1.03	Algorithm converged.	0.064	16.612	0.018	Algorithm converged.	-1.633	1.668	1.03	Algorithm converged.	0.065	16.336	1	0.971	Algorithm converged.	0.063	15,389
Generalised anxiety disorder	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Renal and urinary disorders	--	--	165	100	0	0	170	100	2	1.176	NE	* Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	* Algorithm not converged.	NE	NE	0.4986	NE	Algorithm not converged.	NE	NE
Dysuria	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Potlakturia	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Reproductive system and breast disorders	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Prostatomegaly	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--	--	165	100	5	3.03	170	100	7	4.118	0.728	Algorithm converged.	0.226	2.34	-1.087	Algorithm converged.	-5.058	2.883	0.736	Algorithm converged.	0.238	2.272	0.7706	1.359	Algorithm converged.	0.44	4,196
Cough	--	--	165	100	1	0.606	170	100	1	0.588	1.03	Algorithm converged.	0.064	16.612	0.018	Algorithm converged.	-1.633	1.668	1.03	Algorithm converged.	0.065	16.336	1	0.971	Algorithm converged.	0.061	15,389
Dysphoria	--	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	* Algorithm not converged.	NE	NE	0.4925	NE	Algorithm not converged.	NE	NE
Dyspnoea	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Nasal congestion	--	--	165	100	1	0.606	170	100	1	0.588	1.03	Algorithm converged.	0.064	16.612	0.018	Algorithm converged.	-1.633	1.668	1.03	Algorithm converged.	0.065	16.336	1	0.971	Algorithm converged.	0.061	15,389
Oropharyngeal pain	--	--	165	100	2	1.212	170	100	3	1.765	0.683	Algorithm converged.	0.113	4.141	-0.553	Algorithm converged.	-3.142	2.037	0.687	Algorithm converged.	0.116	4.058	1	1.456	Algorithm converged.	0.246	8,602
Pneumothorax	--	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	* Algorithm not converged.	NE	NE	0.4925	NE	Algorithm not converged.	NE	NE
Respiratory symptom	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Rhinorrhoea	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Upper-airway cough syndrome	--	--	165	100	1	0.606	170	100	1	0.588	1.03	Algorithm converged.	0.064	16.612	0.018	Algorithm converged.	-1.633	1.668	1.03	Algorithm converged.	0.065	16.336	1	0.971	Algorithm converged.	0.061	15,389
Skin and subcutaneous tissue disorders	--	--	165	100	1	0.606	170	100	6	3.529	0.167	Algorithm converged.	0.02	1.4	-2.923	Algorithm converged.	-5.939	0.093	0.172	Algorithm converged.	0.021	1.411	0.1214	5.824	Algorithm converged.	0.709	47,849
Acne	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Dermatitis	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Dry skin	--	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	* Algorithm not converged.	NE	NE	0.4925	NE	Algorithm not converged.	NE	NE
Rash	--	--	165	100	0	0	170	100	2	1.176	NE	* Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	* Algorithm not converged.	NE	NE	0.4986	NE	Algorithm not converged.	NE	NE
Rash erythematous	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Skin lesion	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	* Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Vascular disorders	--	--	165	100	2	1.212	170	100	1	0.588	2.074	Algorithm converged.	0.186	23.089	0.624	Algorithm converged.	-1.403	2.651	2.061	Algorithm converged.	0.189	22.908	0.6183	0.485	Algorithm converged.	0.044	5,301
Hypertension	--	--	165	100	1	0.606	170	100	1	0.588	1.03	Algorithm converged.	0.064	16.612	0.018	Algorithm converged.	-1.633	1.668	1.03	Algorithm converged.	0.065	16.336	1	0.971	Algorithm converged.	0.063	15,389
Hypertensive crisis	--	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	* Algorithm not converged.	NE	NE	0.4925	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-Binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $p < .05$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.1342021

Program: f-ae-raw-soc.sas
Output: 113-1f-ae-raw-soc-anyae-ts

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo				Odds Ratio		Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																					
		Patients					Patients with Event					Patients		Patients with Event				Absolute Risk Difference					Relative Risk																										
		Level		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		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% upper CL	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	n	%	n	%	Odds Ratio	Algorithm not converged.	Algorithm converged.	95% Lower CL	95% upper CL	Absolute Risk	Algorithm not converged.	Algorithm converged.	95% Lower CL	95% upper CL	Absolute Risk	Algorithm not converged.	Algorithm converged.	95% Lower CL	95% upper CL	Relative Risk	Algorithm not converged.	Algorithm converged.	95% Lower CL	95% upper CL	Interaction Test p-value (likelihood ratio)	Relative Risk	Algorithm not converged.	Algorithm converged.	95% Lower CL	95% upper CL								
Sex	Blood and lymphatic system disorders	--	Male 85	51,515	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	NE	NE	1,176	NE	NE	1,176	NE	NE	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE							
			Female 80	48,485	1	1,25	96	56,471	1	1,042	1,203	Algorithm converged.	NE	NE	0,074	19,536	0,208	Algorithm converged.	NE	NE	0,208	Algorithm converged.	NE	NE	-2,962	3,379	1,2		Algorithm converged.	NE	NE	1,2		Algorithm converged.	NE	NE	1,2		0,833	Algorithm converged.	NE	NE							
	Lymphadenopathy		Male 85	51,515	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	NE	NE	1,176	NE	NE	1,176	NE	NE	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE							
			Female 80	48,485	1	1,25	96	56,471	1	1,042	1,203	Algorithm converged.	NE	NE	0,074	19,536	0,208	Algorithm converged.	NE	NE	0,208	Algorithm converged.	NE	NE	-2,962	3,379	1,2		Algorithm converged.	NE	NE	1,2		Algorithm converged.	NE	NE	1,2		0,833	Algorithm converged.	NE	NE							
	Cardiac disorders	--	Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654	1	NE	NE	0,4654	1	NE	NE	0,4654	1	NE	NE							
			Female 80	48,485	0	0	96	56,471	1	1,042	NE *	Algorithm not converged.	NE	NE	-1,042	NE	NE	-1,042	NE	NE	-1,042	NE	NE	-3,073	0,989	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	1	NE	NE	1	NE	NE									
	Palpitations		Male 85	51,515	0	0	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
			Female 80	48,485	0	0	96	56,471	1	1,042	NE *	Algorithm not converged.	NE	NE	-1,042	NE	NE	-1,042	NE	NE	-1,042	NE	NE	-3,073	0,989	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	1	NE	NE	1	NE	NE									
	Supraventricular tachycardia		Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654		NE	NE	0,4654		NE	NE	0,4654		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Ear and labyrinth disorders	--	Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654	0,0773	NE	NE	0,4654	0,0773	NE	NE	0,4654	0,0773	NE	NE							
			Female 80	48,485	1	1,25	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	1,25	NE	NE	1,25	NE	NE	1,25	NE	NE	-1,185	3,685	NE	*	Algorithm not converged.	NE	NE	0,4545		NE	NE	0,4545		NE	NE	0,4545		NE	NE							
	Ear pain		Male 85	51,515	0	0	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
			Female 80	48,485	1	1,25	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	1,25	NE	NE	1,25	NE	NE	1,25	NE	NE	-1,185	3,685	NE	*	Algorithm not converged.	NE	NE	0,4545		NE	NE	0,4545		NE	NE	0,4545		NE	NE							
	Vertigo		Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654		NE	NE	0,4654		NE	NE	0,4654		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Gastrointestinal disorders	--	Male 85	51,515	3	3,529	74	43,529	2	2,703	1,317	Algorithm converged.	0,214	8,104	0,827	Algorithm converged.	NE	NE	0,827	NE	NE	0,827	NE	NE	-4,562	6,215	1,306		Algorithm converged.	0,224	7,604	1	1	0,766	Algorithm converged.	0,132	4,459		NE	NE	0,132	4,459							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Abdominal pain upper		Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654		NE	NE	0,4654		NE	NE	0,4654		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Diarrhoea		Male 85	51,515	1	1,176	74	43,529	1	1,351	0,869	Algorithm converged.	0,053	14,142	-0,175	Algorithm converged.	NE	NE	-0,175	NE	NE	-0,175	NE	NE	-3,664	3,314	0,871		Algorithm converged.	0,055	13,676	1	1	1,149	Algorithm converged.	0,073	18,044		NE	NE	0,073	18,044							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Gingival pain		Male 85	51,515	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	NE	NE	1,176	NE	NE	1,176	NE	NE	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	1		NE	NE	1		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Pancreatitis acute		Male 85	51,515	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-1,351	NE	NE	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0,4654		NE	NE	0,4654		NE	NE	0,4654		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	Vomiting		Male 85	51,515	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	NE	NE	1,176	NE	NE	1,176	NE	NE	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	1		NE	NE	1		NE	NE							
			Female 80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE									
	General disorders and administration site conditions	--	Male 85	51,515	4	4,706	74	43,529	3	4,054	1,169	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652	Algorithm converged.	0,253	5,4	0,652						
			Female 80	48,485	6	7,5	96	56,471	3	3,125	2,514	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375	Algorithm converged.	0,608	10,39	4,375						
	Fatigue		Male 85	51,515	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	NE	NE	1,176	NE	NE	1,176	NE	NE	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE	1	0,3561	NE	NE							
			Female 80	48,485	1	1,25	96	56,471	1	1,042	1,203	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208	Algorithm converged.	0,074	19,536	0,208</						

[illegible]

587

Vascular disorders	--	Male	85	51,515	1	1,176	74	43,529	0	0	NE	*	Algorithm not converged.	NE	NE	1,176	Algorithm converged.	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	0.3561	NE	Algorithm not converged.	NE	NE	
		Female	80	48,485	1	1,25	96	56,471	1	1,042	1,203	Algorithm converged.	0.074	19,536	0.208	Algorithm converged.	-2,962	3,379	1.2	Algorithm converged.	0.076	18,882	1	0.833	Algorithm converged.	0.053	13,112				
	Hypertension	Male	85	51,515	1	1,176	74	43,529	0	0	NE	*	Algorithm not converged.	NE	NE	1,176	Algorithm converged.	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	0.1157	NE	Algorithm not converged.	NE	NE	
		Female	80	48,485	0	0	96	56,471	1	1,042	NE	*	Algorithm not converged.	NE	NE	-1,042	Algorithm converged.	-3,073	0,989	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Hypertensive crisis	Male	85	51,515	0	0	74	43,529	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Female	80	48,485	1	1,25	96	56,471	0	0	NE	*	Algorithm not converged.	NE	NE	1,25	Algorithm converged.	-1,185	3,685	NE	*	Algorithm not converged.	NE	NE	0.4545	NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-3f-ae-raw-soc-anyae-3s

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[illegible]

591

[illegible]

POPULATION: SAFETY
ENDPOINT: Any AEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
		Patients					Patients with Event					Patients					Patients with Event					Odds Ratio					Absolute Risk Difference					Relative Risk					Interaction Test p-value (likelihood ratio)					Relative Risk					Convergence Reason					95% Lower CL					95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n

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			Rhabdomyolysis	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE				
			Tendinitis	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE				
		Nervous system disorders	--	US ex-US	148 17	89,697 10,303	3 0	2,027 0	152 18	89,412 10,588	6 0	3,947 0	0.503 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.124 NE	0.261 NE	-1.92 -	Algorithm converged. Algorithm not converged.	-5.759 -5.759	1,919 NE	0.514 NE *	Algorithm converged. Algorithm not converged.	0.131 NE	2,015 NE	0.5015 NE	1 -	1,947 NE	Algorithm converged. Algorithm not converged.	NE NE	7,643 NE	
			Ageusia	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.676 -	Algorithm converged. Algorithm not converged.	-0.644 -0.644	1,995 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4933 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dizziness	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	3 0	1,974 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-1.974 -	Algorithm converged. Algorithm not converged.	-4.185 -4.185	0.238 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2476 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dysgeusia	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Headache	US ex-US	148 17	89,697 10,303	2 0	1,351 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm converged. Algorithm not converged.	NE NE	0.186 NE	23,058 NE	0.693 -	Algorithm converged. Algorithm not converged.	-1.567 -1.567	2,954 NE	2,054 NE *	Algorithm converged. Algorithm not converged.	0.188 NE	22,412 NE	0.6188 NE	1 -	0,487 NE	Algorithm converged. Algorithm not converged.	NE NE	0.045 NE	5,31 NE
			Sciatica	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Transient ischaemic attack	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
		Psychiatric disorders	--	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	5 0	3,289 0	0.2 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.023 NE	1,733 NE	-2.614 -	Algorithm converged. Algorithm not converged.	-5.741 -5.741	0.514 NE	0.205 NE *	Algorithm converged. Algorithm not converged.	0.004 NE	1,737 NE	0.2143 NE	1 -	4,868 NE	Algorithm converged. Algorithm not converged.	NE NE	0.576 NE	41,175 NE
			Anxiety	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	3 0	1,974 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-1.974 -	Algorithm converged. Algorithm not converged.	-4.185 -4.185	0.238 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.2476 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Behaviour disorder	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Depression	US ex-US	148 17	89,697 10,303	0 0	0.676 0	152 18	89,412 10,588	1 0	0.658 0	1,027 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.064 NE	16,576 NE	0.018 NE *	Algorithm converged. Algorithm not converged.	-1.824 -1.824	1,86 NE	1,027 NE *	Algorithm converged. Algorithm not converged.	0.065 NE	16,268 NE	1 -	0.974 NE	Algorithm converged. Algorithm not converged.	NE NE	0.061 NE	15,423 NE	
			Generalised anxiety disorder	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
		Renal and urinary disorders	--	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	2 0	1,316 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-1.316 -	Algorithm converged. Algorithm not converged.	-3.127 -3.127	0.496 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4984 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dysuria	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Potakuria	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
		Reproductive system and breast disorders	--	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Prostatomegaly	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
		Respiratory, thoracic and mediastinal disorders	--	US ex-US	148 17	89,697 10,303	5 0	3,378 0	152 18	89,412 10,588	7 0	4,605 0	0.724 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.225 NE	2,335 NE	-1.227 NE *	Algorithm converged. Algorithm not converged.	-5.651 -5.651	3,198 NE	0.734 NE *	Algorithm converged. Algorithm not converged.	0.238 NE	2,26 NE	0.77 NE	1.363 NE	Algorithm converged. Algorithm not converged.	NE NE	0.443 NE	4,199 NE	
			Cough	US ex-US	148 17	89,697 10,303	0 0	0.676 0	152 18	89,412 10,588	1 0	0.658 0	1,027 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.064 NE	16,576 NE	0.018 NE *	Algorithm converged. Algorithm not converged.	-1.824 -1.824	1,86 NE	1,027 NE *	Algorithm converged. Algorithm not converged.	0.065 NE	16,268 NE	1 -	0.974 NE	Algorithm converged. Algorithm not converged.	NE NE	0.061 NE	15,423 NE	
			Dysphonia	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.676 -	Algorithm converged. Algorithm not converged.	-0.644 -0.644	1,995 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4933 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dyspnoea	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Nasal congestion	US ex-US	148 17	89,697 10,303	0 0	0.676 0	152 18	89,412 10,588	1 0	0.658 0	1,027 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.064 NE	16,576 NE	0.018 NE *	Algorithm converged. Algorithm not converged.	-1.824 -1.824	1,86 NE	1,027 NE *	Algorithm converged. Algorithm not converged.	0.065 NE	16,268 NE	1 -	0.974 NE	Algorithm converged. Algorithm not converged.	NE NE	0.061 NE	15,423 NE	
			Oropharyngeal pain	US ex-US	148 17	89,697 10,303	2 0	1,351 0	152 18	89,412 10,588	3 0	1,974 0	0.68 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.112 NE	4,131 NE	-0.622 NE *	Algorithm converged. Algorithm not converged.	-3.512 -3.512	2,267 NE	0.685 NE *	Algorithm converged. Algorithm not converged.	0.116 NE	4,039 NE	1 -	1,461 NE	Algorithm converged. Algorithm not converged.	NE NE	0.248 NE	8,61 NE	
			Pneumothorax	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.676 -	Algorithm converged. Algorithm not converged.	-0.644 -0.644	1,995 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4933 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Respiratory symptom	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Rhinorrhoea	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Upper-airway cough syndrome	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	1 0	0.658 0	1,027 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.064 NE	16,576 NE	0.018 NE *	Algorithm converged. Algorithm not converged.	-1.824 -1.824	1,86 NE	1,027 NE *	Algorithm converged. Algorithm not converged.	0.065 NE	16,268 NE	1 -	0.974 NE	Algorithm converged. Algorithm not converged.	NE NE	0.061 NE	15,423 NE	
		Skin and subcutaneous tissue disorders	--	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	6 0	3,947 0	0.166 NE *	Algorithm converged. Algorithm not converged.	NE NE	0.02 NE	1,392 NE	-3.272 NE *	Algorithm converged. Algorithm not converged.	-6.637 -6.637	0.093 NE	0.171 NE *	Algorithm converged. Algorithm not converged.	0.021 NE	1,405 NE	1.1208 NE	1 -	5,842 NE	Algorithm converged. Algorithm not converged.	NE NE	0.712 NE	47,94 NE
			Acne	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dermatitis	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Dry skin	US ex-US	148 17	89,697 10,303	1 0	0.676 0	152 18	89,412 10,588	0 0	0 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.676 -	Algorithm converged. Algorithm not converged.	-0.644 -0.644	1,995 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4933 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Rash	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	2 0	1,316 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-1.316 -	Algorithm converged. Algorithm not converged.	-3.127 -3.127	0.496 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	0.4984 NE	NE NE	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Rash erythematous	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			
			Skin lesion	US ex-US	148 17	89,697 10,303	0 0	0 0	152 18	89,412 10,588	1 0	0.658 0	NE * NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	-0.658 -	Algorithm converged. Algorithm not converged.	-1.943 -1.943	0.627 NE	NE *	Algorithm not converged. Algorithm not converged.	NE NE	NE NE	1 -	NE -	Algorithm not converged. Algorithm not converged.	NE NE	NE NE			

Vascular disorders	--	US	148	89,697	1	0.676	152	89,412	1	0.658	1,027	Algorithm converged.	0.064	16,576	0.018	Algorithm converged.	-1,824	1.86	1,027	Algorithm converged.	0.065	16,268	1	0.2963	0.974	Algorithm converged.	0.061	15,423	
		ex-US	17	10,303	1	5.882	18	10,588	0	0	NE *	Algorithm not converged.	NE	NE	5.882	Algorithm converged.	-5,303	17,067	NE *	Algorithm not converged.	NE	NE	0.4857		NE	Algorithm not converged.	NE	NE	
	Hypertension	US	148	89,697	1	0.676	152	89,412	1	0.658	1,027	Algorithm converged.	0.064	16,576	0.018	Algorithm converged.	-1,824	1.86	1,027	Algorithm converged.	0.065	16,268	1	1	0.974	Algorithm converged.	0.061	15,423	
		ex-US	17	10,303	0	0	18	10,588	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hypertensive crisis	US	148	89,697	0	0	152	89,412	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		ex-US	17	10,303	1	5.882	18	10,588	0	0	NE *	Algorithm not converged.	NE	NE	5.882	Algorithm converged.	-5,303	17,067	NE *	Algorithm not converged.	NE	NE	0.4857		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-3f-ae-raw-soc-anyae-5

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Interaction Test p-value (likelihood ratio)		Relative Risk		Convergence Reason		95% Lower CL		95% Upper CL			
Name	SOC	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	Cardiac disorders	--	165	100	0	0	170	100	1	0,588	NE *	Algorithm not converged.	NE	NE	-0,588	Algorithm converged.	-1,738	0,561	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		--	165	100	0	0	170	100	1	0,588	NE *	Algorithm not converged.	NE	NE	-0,588	Algorithm converged.	-1,738	0,561	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	165	100	0	0	170	100	1	0,588	NE *	Algorithm not converged.	NE	NE	-0,588	Algorithm converged.	-1,738	0,561	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		--	165	100	0	0	170	100	1	0,588	NE *	Algorithm not converged.	NE	NE	-0,588	Algorithm converged.	-1,738	0,561	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Infections and infestations	--	165	100	0	0	170	100	4	2,353	NE *	Algorithm not converged.	NE	NE	-2,353	Algorithm converged.	-4,631	-0,074	NE *	Algorithm not converged.	NE	NE	0,1229		NE	Algorithm not converged.	NE	NE	
		COVID-19	--	165	100	0	0	170	100	2	1,176	NE *	Algorithm not converged.	NE	NE	-1,176	Algorithm converged.	-2,797	0,444	NE *	Algorithm not converged.	NE	NE	0,4986		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	--	165	100	0	0	170	100	2	1,176	NE *	Algorithm not converged.	NE	NE	-1,176	Algorithm converged.	-2,797	0,444	NE *	Algorithm not converged.	NE	NE	0,4986		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	165	100	1	0,606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0,606	Algorithm converged.	-0,578	1,79	NE *	Algorithm not converged.	NE	NE	0,4925		NE	Algorithm not converged.	NE	NE	
		Rib fracture	--	165	100	1	0,606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0,606	Algorithm converged.	-0,578	1,79	NE *	Algorithm not converged.	NE	NE	0,4925		NE	Algorithm not converged.	NE	NE
		Road traffic accident	--	165	100	1	0,606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0,606	Algorithm converged.	-0,578	1,79	NE *	Algorithm not converged.	NE	NE	0,4925		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	165	100	1	0,606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0,606	Algorithm converged.	-0,578	1,79	NE *	Algorithm not converged.	NE	NE	0,4925		NE	Algorithm not converged.	NE	NE	
		Lactic acidosis	--	165	100	1	0,606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0,606	Algorithm converged.	-0,578	1,79	NE *	Algorithm not converged.	NE	NE	0,4925		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 113-2f-ae-raw-soc-toxgrg3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab								Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
		Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
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		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
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		Level		n		n		n		n		n		n		n		n		n		n		n		n		n		n			
		Level		n		n		n		n		n		n		n		n															

POPULATION: SAFETY
ENDPOINT: AEs Grade ≥ 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $np \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas

Output: t13-2f-ae-raw-soc-toxgrgt3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade >= 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Odds Ratio				Absolute Risk Difference				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Name	SOC	PT	Level	n	%	n	%	n	%	n	%																	
Cardiac disorders		-	US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
			ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	
	Supraventricular tachycardia		US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
			ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	
Gastrointestinal disorders	-		US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
			ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	
	Pancreatitis acute		US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
			ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	
Infections and infestations	-		US	148	89.697	0	0	152	89.412	4	2.632	NE	*	Algorithm not converged.	NE	NE	-2.632	Algorithm converged.	-5.176	-0.087	NE	*	Algorithm not converged.	NE	NE	0.1226	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
	COVID-19		US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316	Algorithm converged.	-3.127	0.496	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
	COVID-19 pneumonia		US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316	Algorithm converged.	-3.127	0.496	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
Injury, poisoning and procedural complications	-		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
	Rib fracture		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
	Road traffic accident		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
Metabolism and nutrition disorders	-		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE
	Lactic acidosis		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	
			ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is unreliable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.13/2021

Program: f-ae-raw-soc.sas
Output: 113-2f-ae-raw-soc-toxggg3.xls

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab								Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				Relative Risk			
				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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
All	Cardiac disorders	SOC	PT	--	165	100	0	0	170	100	1	0.588	NE *	Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE					
				Supraventricular tachycardia	--	165	100	0	0	170	100	1	0.588	NE *	Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE				
	Gastrointestinal disorders		PT	--	165	100	0	0	170	100	1	0.588	NE *	Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE					
				Pancreatitis acute	--	165	100	0	0	170	100	1	0.588	NE *	Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE				
	Infections and infestations		PT	--	165	100	0	0	170	100	4	2.353	NE *	Algorithm not converged.	NE	NE	-2.353	Algorithm converged.	-4.631	-0.074	NE	*	Algorithm not converged.	NE	NE	0.1229		NE		Algorithm not converged.	NE	NE	NE	NE					
				COVID-19	--	165	100	0	0	170	100	2	1.176	NE *	Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	*	Algorithm not converged.	NE	NE	0.4986		NE		Algorithm not converged.	NE	NE	NE	NE				
				COVID-19 pneumonia	--	165	100	0	0	170	100	2	1.176	NE *	Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	*	Algorithm not converged.	NE	NE	0.4986		NE		Algorithm not converged.	NE	NE	NE	NE				
	Injury, poisoning and procedural complications		PT	--	165	100	1	0.606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE		Algorithm not converged.	NE	NE	NE	NE					
				Rib fracture	--	165	100	1	0.606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE		Algorithm not converged.	NE	NE	NE	NE				
				Road traffic accident	--	165	100	1	0.606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE		Algorithm not converged.	NE	NE	NE	NE				
	Metabolism and nutrition disorders		PT	--	165	100	1	0.606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE		Algorithm not converged.	NE	NE	NE	NE					
				Lactic acidosis	--	165	100	1	0.606	170	100	0	0	NE *	Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE		Algorithm not converged.	NE	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01.3u2021
Program: t-ae-raw-soc.sas
Output: 113-3f-ae-raw-soc-toxgr3-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
				Patients				Patients with Event				Patients				Patients with Event				Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
				Level				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				Interaction Test p-value (likelihood ratio)				Relative Risk				Convergence Reason				95% Lower CL				95% upper CL																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
Name	SOC	PT		Male	85	51,515	0	0	0	74	43,529	1	1,351	NE	*	Algorithm not converged.	NE	NE	-1,351	Algorithm converged.	-3,982	1,279	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01.3.2021

Program: f-w-raw-soc.sas
Output: 113-3f-w-raw-soc-10xg3-6

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																																																																															
		Patients										Patients with Event										Odds Ratio										Absolute Risk Difference										Relative Risk										Relative Risk																																																																					

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.13/0.021

Program: 1-ae-raw-soc.sas

Output: 113-3f-ae-raw-soc-toxgr3-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 3
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Odds Ratio				Absolute Risk Difference				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Convergence Reason		Absolute Risk		Convergence Reason		Relative Risk		Convergence Reason		Relative Risk		Convergence Reason								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio				95% Lower CL	95% upper CL	Absolute Risk			Relative Risk			95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk			95% Lower CL	95% upper CL		
Region	Cardiac disorders	--	US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	5.026	NE	NE	NE	NE	NE	NE	NE
	Supraventricular tachycardia		US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	5.026	NE	NE	NE	NE	NE	NE	NE
	Gastrointestinal disorders	--	US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	5.026	NE	NE	NE	NE	NE	NE	NE
	Pancreatitis acute		US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	5.026	NE	NE	NE	NE	NE	NE	NE
	Infections and infestations	--	US	148	89.697	0	0	152	89.412	4	2.632	NE	*	Algorithm not converged.	NE	NE	-2.632		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	0.1226	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	COVID-19		US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	0.496	NE	NE	0.4984	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	COVID-19 pneumonia		US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	0.496	NE	NE	0.4984	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Injury, poisoning and procedural complications	--	US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	1.995	NE	NE	0.4933	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Rib fracture		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	1.995	NE	NE	0.4933	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Road traffic accident		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	1.995	NE	NE	0.4933	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Metabolism and nutrition disorders	--	US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	1.995	NE	NE	0.4933	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Lactic acidosis		US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676		Algorithm converged.	NE	NE	*	Algorithm not converged.	NE	NE	1.995	NE	NE	0.4933	NE	NE	NE	NE	NE
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.13/2021

Program: f-w-raw-soc.sas
Output: 113-3f-w-raw-soc-toxg3-b

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference								Relative Risk								Relative Risk			
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
All	--	--	--	165	100	0	0	170	100	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	.	NE	Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk											
Name	SOC	PT	Level	n	p-value	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
Sex	--	--	Male	85	51,515	0	0	74	43,529	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE						
			Female	80	48,485	0	0	96	56,471	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE						

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
Age	--	--	12-17	23	13,939	0	0	20	11,765	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE					
			18-49	87	52,727	0	0	89	52,353	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE					
			>=50	55	33,333	0	0	61	35,882	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE					

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-ts

POPULATION: SAFETY
ENDPOINT: AEs Grade 4
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Region	--	--	US	148	89,697	0	0	152	89,412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			ex-US	17	10,303	0	0	18	10,588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-4f-ae-raw-soc-toxgr4-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	--	--	--	165	100	0	0	170	100	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	.	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk					
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	--	--	Male	85	51,515	0	0	74	43,529	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			Female	80	48,485	0	0	96	56,471	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo												Casirivimab/Imdevimab vs. Placebo												Placebo vs. Casirivimab/Imdevimab			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk				Relative Risk											
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
Age	--	--	12-17	23	13,939	0	0	20	11,765	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE									
			18-49	87	52,727	0	0	89	52,353	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE									
			>=50	55	33,333	0	0	61	35,882	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE									

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-fs

POPULATION: SAFETY
ENDPOINT: AEs Grade 5
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Region	--	--	US	148	89,697	0	0	152	89,412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			ex-US	17	10,303	0	0	18	10,588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-raw-soc.sas
Output: t13-5f-ae-raw-soc-toxgr5-ts

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk										
Name	SOC	PT	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	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Gastrointestinal disorders	--	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pancreatitis acute	--	165	100	0	0	170	100	1	0.588	NE	* Algorithm not converged.	NE	NE	-0.588	Algorithm converged.	-1.738	0.561	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	165	100	0	0	170	100	4	2.353	NE	* Algorithm not converged.	NE	NE	-2.353	Algorithm converged.	-4.631	-0.074	NE	*	Algorithm not converged.	NE	NE	0.1229		NE	Algorithm not converged.	NE	NE
		COVID-19	--	165	100	0	0	170	100	2	1.176	NE	* Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	*	Algorithm not converged.	NE	NE	0.4986		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	--	165	100	0	0	170	100	2	1.176	NE	* Algorithm not converged.	NE	NE	-1.176	Algorithm converged.	-2.797	0.444	NE	*	Algorithm not converged.	NE	NE	0.4986		NE	Algorithm not converged.	NE	NE
			--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE	Algorithm not converged.	NE	NE
		Road traffic accident	--	165	100	1	0.606	170	100	0	0	NE	* Algorithm not converged.	NE	NE	0.606	Algorithm converged.	-0.578	1.79	NE	*	Algorithm not converged.	NE	NE	0.4925		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 0.13/0.021

Program: 1-ae-raw-soc.sas
Output: 113-6f-ae-raw-soc-any-sae-6

Template Dichotomous analysis (safety)

Name	SOC		PT	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	Interaction Test p-value (baseline ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Sex	Gastrointestinal disorders	--		Male	85	51,535	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	Algorithm converged.	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0.4654	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Pancreatitis acute			Male	85	51,535	0	0	74	43,529	1	1,351	NE *	Algorithm not converged.	NE	NE	-1,351	Algorithm converged.	-3,982	1,279	NE	*	Algorithm not converged.	NE	NE	0.4654	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--		Male	85	51,535	0	0	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	4	4,167	NE *	Algorithm not converged.	NE	NE	-4,167	Algorithm converged.	-8,164	-0,169	NE	*	Algorithm not converged.	NE	NE	0.1269	NE	Algorithm not converged.	NE	NE
	COVID-19			Male	85	51,535	0	0	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	2	2,083	NE *	Algorithm not converged.	NE	NE	-2,083	Algorithm converged.	-4,94	0,774	NE	*	Algorithm not converged.	NE	NE	0.5013	NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia			Male	85	51,535	0	0	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	2	2,083	NE *	Algorithm not converged.	NE	NE	-2,083	Algorithm converged.	-4,94	0,774	NE	*	Algorithm not converged.	NE	NE	0.5013	NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--		Male	85	51,535	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	Algorithm converged.	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
				Female	80	48,485	0	0	96	56,471	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Road traffic accident			Male	85	51,535	1	1,176	74	43,529	0	0	NE *	Algorithm not converged.	NE	NE	1,176	Algorithm converged.	-1,116	3,469	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method 95% CI for the relative risk use Farrington-Manning method.

Program: t-ae-raw-soc.sas
Output: t13-6f-ae-raw-soc-arysae-ts

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

[illegible]

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021

Program: t-ae-row-soc.sas
Output: t13-6f-ae-row-soc-anysae-ts

POPULATION: SAFETY
ENDPOINT: Any SAEs
Model: Unstratified analysis
STUDY: R10933-10987-COV-2069
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Interaction Test p-value (likelihood ratio)		Relative Risk		Relative Risk	
Name Region	SOC	PT	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	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
				ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US	ex-US	US		
Gastrointestinal disorders		--	US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Pancreatitis acute			US	148	89.697	0	0	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	1	5.556	NE	*	Algorithm not converged.	NE	NE	-5.556	Algorithm converged.	-16.137	5.026	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Infections and infestations		--	US	148	89.697	0	0	152	89.412	4	2.632	NE	*	Algorithm not converged.	NE	NE	-2.632	Algorithm converged.	-5.176	-0.087	NE	*	Algorithm not converged.	NE	NE	0.1226	NE	Algorithm not converged.	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE
COVID-19			US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316	Algorithm converged.	-3.127	0.496	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE
COVID-19 pneumonia			US	148	89.697	0	0	152	89.412	2	1.316	NE	*	Algorithm not converged.	NE	NE	-1.316	Algorithm converged.	-3.127	0.496	NE	*	Algorithm not converged.	NE	NE	0.4984	NE	Algorithm not converged.	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE
Injury, poisoning and procedural complications		--	US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	Algorithm not converged.	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE
Road traffic accident			US	148	89.697	1	0.676	152	89.412	0	0	NE	*	Algorithm not converged.	NE	NE	0.676	Algorithm converged.	-0.644	1.995	NE	*	Algorithm not converged.	NE	NE	0.4933	NE	Algorithm not converged.	NE	NE	
				ex-US	17	10.303	0	0	18	10.588	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 01Jul2021
Program: t-ae-raw-soc.sas
Output: 113-6f-ae-raw-soc-any-sae-ts

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	--	--	--	165	100	0	0	170	100	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas
Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	--	--	Male	85	51,515	0	0	74	43,529	0	0
			Female	80	48,485	0	0	96	56,471	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas

Output: t14-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	P T	Level	n	%	n	%	n	%	n	%
Age	--	--	12-17	23	13,939	0	0	20	11,765	0	0
			18-49	87	52,727	0	0	89	52,353	0	0
			>=50	55	33,333	0	0	61	35,882	0	0

POPULATION: SAFETY - Cohort B

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Region	--	--	US	148	89,697	0	0	152	89,412	0	0
			ex-US	17	10,303	0	0	18	10,588	0	0

Clinical cut-off: 01Jul2021

Program: t-ae-soc-descriptive.sas
Output: t14-1-ae-soc-descriptive-trtdc

KohorteB

Datenschnitt 01.07.2021 (DCO2)

Verträglichkeit

Ergänzende Dokumente

POPULATION: SAFETY - Cohort B

ENDPOINT: Adverse Events

Model: Unstratified analysis

STUDY: R10933-10987-COV-2069

Template Outcome of Adverse Events

	Casirivimab/Imdevimab (N=165)															Placebo (N=170)														
Category of Adverse Events	Total	RECOVERE D/RESOLVE D		RECOVERE D/RESOLVE D WITH SEQUELAE		NOT RECOVERE D/NOT RESOLVED		FATAL		RECOVERIN G/RESOLVI NG		UNKNOWN		MISSING		Total	RECOVERE D/RESOLVE D		RECOVERE D/RESOLVE D WITH SEQUELAE		NOT RECOVERE D/NOT RESOLVED		FATAL		RECOVERIN G/RESOLVI NG		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs	101	88	87.13	1	0.99	5	4.95	0	0	1	0.99	0	0	6	5.94	151	124	82.12	2	1.325	14	9.272	0	0	8	5.3	3	1.99	0	0
Grade 1	90	82	91.11	0	0	3	3.333	0	0	1	1.11	0	0	4	4.44	117	98	83.76	0	0	10	8.547	0	0	6	5.13	3	2.56	0	0
Grade 2	7	5	71.43	0	0	2	28.57	0	0	0	0	0	0	0	0	28	21	75	1	3.571	4	14.29	0	0	2	7.14	0	0	0	0
Grade 3	4	1	25	1	25	0	0	0	0	0	0	0	0	2	50	6	5	83.33	1	16.67	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Any SAEs	1	0	0	1	100	0	0	0	0	0	0	0	0	0	0	5	4	80	1	20	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	1	0	0	1	100	0	0	0	0	0	0	0	0	0	0	5	4	80	1	20	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Any AESIs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Clinical cut-off: 01Jul2021

Clinical cut-off: 01Jul2021

Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set - Cohort B

Study: R10933-10987-COV-2069

	Treatment	
	Placebo (N = 170)	Casirivimab/Imdevimab (N = 165)
Efficacy Follow-up (Days)		
Median	28.0	28.0
Safety Follow-up (Days)		
Median	207.0	205.0