

**Eigene Vorlage**

**Dossier zur Nutzenbewertung  
gemäß § 35a SGB V**

*Cannabidiol (Epidyolex®)*

**Separater Anhang 4-G  
zu Modul 4B**

Subgruppenanalysen

Stand: 30.11.2023

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Hinweis: In den nachstehenden Tabellen entspricht der Komparator, der mit „Placebo“ gekennzeichnet ist, der „patientenindividuellen anfallssuppressiven Therapie (PIAT) + Placebo“.

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Adhoc Table:

GWEP1414 Total Seizure Responder (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			Odds Ratio		Risk Difference				
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Total Seizures <=25pct	Age Group	10 mg/kg	0.7138	2-5 years	4	4	5	3	1.6667	0.8148	3.4093	0.4444	-	-	-	0.4000	-0.0294	0.8294
				6-11 years	14	10	13	6	1.5476	0.7886	3.0370	0.2519	2.9167	0.5938	14.3270	0.2527	-0.1070	0.6125
				12-17 years	7	5	12	7	1.2245	0.6269	2.3916	0.6562	1.7857	0.2413	13.2148	0.1310	-0.3047	0.5666
				18-55 years	12	8	7	4	1.1667	0.5478	2.4849	1.0000	1.5000	0.2202	10.2181	0.0952	-0.3581	0.5486
Sex	10 mg/kg	0.1175	F	21	16	16	6	2.0317	1.0332	3.9954	0.0233	5.3333	1.2817	22.1919	0.3869	0.0878	0.6860	
			M	16	11	21	14	1.0313	0.6590	1.6139	1.0000	1.1000	0.2731	4.4300	0.0208	-0.2829	0.3245	
Region	10 mg/kg	0.2012	REST OF THE WORLD	1	0	4	2	-	-	-	1.0000	-	-	-	-0.5000	-0.9900	-0.0100	
			USA	36	27	33	18	1.3750	0.9554	1.9789	0.0842	2.5000	0.9023	6.9269	0.2045	-0.0165	0.4256	
Valproate Use	10 mg/kg	0.7755	N	30	21	25	11	1.5909	0.9645	2.6241	0.0613	2.9697	0.9781	9.0163	0.2600	0.0055	0.5145	
			Y	7	6	12	9	1.1429	0.7323	1.7837	1.0000	2.0000	0.1662	24.0689	0.1071	-0.2495	0.4638	
Lamotrigine Use	10 mg/kg	0.5704	N	27	20	29	17	1.2636	0.8654	1.8451	0.2673	2.0168	0.6486	6.2711	0.1545	-0.0893	0.3984	
			Y	10	7	8	3	1.8667	0.6990	4.9852	0.3416	3.8889	0.5427	27.8658	0.3250	-0.1146	0.7646	
Levetiracetam Use	10 mg/kg	0.0182	N	28	18	23	14	1.0561	0.6881	1.6211	1.0000	1.1571	0.3702	3.6168	0.0342	-0.2328	0.3011	
			Y	9	9	14	6	2.3333	1.2744	4.2723	0.0072	-	-	-	0.5714	0.3122	0.8307	
Rufinamide Use	10 mg/kg	0.1615	N	25	19	29	14	1.5743	1.0175	2.4356	0.0516	3.3929	1.0512	10.9505	0.2772	0.0300	0.5244	
			Y	12	8	8	6	0.8889	0.5048	1.5652	1.0000	0.6667	0.0902	4.9279	-0.0833	-0.4848	0.3181	
Baseline Drop Seizure Frequency	10 mg/kg	-	<=55	12	7	12	7	-	-	-	-	-	-	-	-	-	-	
			>55 to <=125	11	9	18	10	-	-	-	-	-	-	-	-	-	-	
			>125	14	11	7	3	-	-	-	-	-	-	-	-	-	-	
Current AEDs	10 mg/kg	0.9469	<3	12	9	9	5	1.3500	0.6912	2.6368	0.3972	2.4000	0.3760	15.3192	0.1944	-0.2123	0.6012	
			>=3	25	18	28	15	1.3440	0.8807	2.0510	0.2565	2.2286	0.7083	7.0116	0.1843	-0.0709	0.4394	
Prior AEDs	10 mg/kg	0.3827	<6	16	13	21	15	1.1375	0.7947	1.6281	0.7023	1.7333	0.3598	8.3512	0.0982	-0.1736	0.3701	
			>=6	21	14	16	5	2.1333	0.9709	4.6874	0.0489	4.4000	1.0926	17.7199	0.3542	0.0505	0.6579	
Age Group	20 mg/kg	0.2873	2-5 years	5	5	5	3	1.6667	0.8148	3.4093	0.4444	-	-	-	0.4000	-0.0294	0.8294	
			6-11 years	11	9	13	6	1.7727	0.9256	3.3953	0.1049	5.2500	0.8006	34.4259	0.3566	0.0025	0.7107	
			12-17 years	7	7	12	7	1.7143	1.0627	2.7654	0.1060	-	-	-	0.4167	0.1377	0.6956	
			18-55 years	13	8	7	4	1.0769	0.4975	2.3310	1.0000	1.2000	0.1853	7.7702	0.0440	-0.4081	0.4960	
Sex	20 mg/kg	0.2953	F	15	12	16	6	2.1333	1.0794	4.2164	0.0290	6.6667	1.3191	33.6935	0.4250	0.1132	0.7368	
			M	21	17	21	14	1.2143	0.8415	1.7523	0.4841	2.1250	0.5149	8.7700	0.1429	-0.1195	0.4053	
Region	20 mg/kg	0.9298	REST OF THE WORLD	5	4	4	2	1.6000	0.5469	4.6810	0.5238	4.0000	0.2115	75.6593	0.3000	-0.3025	0.9025	
			USA	31	25	33	18	1.4785	1.0356	2.1107	0.0345	3.4722	1.1284	10.6847	0.2610	0.0414	0.4806	
Valproate Use	20 mg/kg	0.8028	N	26	20	25	11	1.7483	1.0713	2.8531	0.0227	4.2424	1.2694	14.1789	0.3292	0.0761	0.5824	
			Y	10	9	12	9	1.2000	0.8153	1.7662	0.5940	3.0000	0.2603	34.5745	0.1500	-0.1576	0.4576	
Lamotrigine Use	20 mg/kg	0.7698	N	24	20	29	17	1.4216	0.9975	2.0260	0.0729	3.5294	0.9587	12.9929	0.2471	0.0140	0.4803	
			Y	12	9	8	3	2.0000	0.7717	5.1837	0.1675	5.0000	0.7199	34.7265	0.3750	-0.0404	0.7904	
Levetiracetam Use	20 mg/kg	0.3807	N	24	19	23	14	1.3006	0.8835	1.9145	0.2124	2.4429	0.6705	8.9005	0.1830	-0.0743	0.4402	
			Y	12	10	14	6	1.9444	1.0094	3.7458	0.0511	6.6667	1.0475	42.4309	0.4048	0.0706	0.7389	
Rufinamide Use	20 mg/kg	0.2744	N	27	22	29	14	1.6878	1.1118	2.5623	0.0128	4.7143	1.4004	15.8700	0.3321	0.0985	0.5656	
			Y	9	7	8	6	1.0370	0.6098	1.7637	1.0000	1.1667	0.1238	10.9904	0.0278	-0.3770	0.4325	
Baseline Drop Seizure Frequency	20 mg/kg	-	<=55	15	13	12	7	-	-	-	-	-	-	-	-	-		
			>55 to <=125	11	9	18	10	-	-	-	-	-	-	-	-	-		

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		>125	10	7	7	3	-	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.1658 <3	8	8	9	5	1.8000	1.0034	3.2289	0.0824	-	-	-	0.4444	0.1198	0.7691	
		>=3	28	21	28	15	1.4000	0.9331	2.1006	0.1625	2.6000	0.8375	8.0715	0.2143	-0.0304	0.4589	
Prior AEDs	20 mg/kg	0.6656 <6	19	18	21	15	1.3263	0.9919	1.7735	0.0948	7.2000	0.7780	66.6339	0.2331	0.0153	0.4508	
		>=6	17	11	16	5	2.0706	0.9238	4.6411	0.0844	4.0333	0.9446	17.2211	0.3346	0.0133	0.6558	
Total Seizures <=50pct Age Group	10 mg/kg	0.1988 2-5 years	4	2	5	3	0.8333	0.2476	2.8043	1.0000	0.6667	0.0469	9.4720	-0.1000	-0.7515	0.5515	
		6-11 years	14	8	13	1	7.4286	1.0708	51.5359	0.0128	16.0000	1.6069	159.3097	0.4945	0.1976	0.7915	
		12-17 years	7	3	12	1	5.1429	0.6540	40.4432	0.1174	8.2500	0.6532	104.1946	0.3452	-0.0533	0.7438	
		18-55 years	12	5	7	0	-	-	-	0.1060	-	-	-	0.4167	-0.1377	0.6956	
Sex	10 mg/kg	0.1123 F	21	12	16	1	9.1429	1.3224	63.2130	0.0016	20.0000	2.2138	180.6852	0.5089	0.2663	0.7516	
		M	16	6	21	4	1.9688	0.6651	5.8274	0.2744	2.5500	0.5765	11.2790	0.1845	-0.1061	0.4752	
Region	10 mg/kg	- REST OF THE WORLD	1	0	4	0	-	-	-	-	-	-	-	-	-	-	
		USA	36	18	33	5	3.3000	1.3812	7.8845	0.0025	5.6000	1.7656	17.7614	0.3485	0.1444	0.5525	
Valproate Use	10 mg/kg	0.5497 N	30	13	25	3	3.6111	1.1576	11.2647	0.0164	5.6078	1.3747	22.8756	0.3133	0.0950	0.5317	
		Y	7	5	12	2	4.2857	1.1120	16.5173	0.0449	12.5000	1.3378	116.7963	0.5476	0.1521	0.9432	
Lamotrigine Use	10 mg/kg	0.8940 N	27	13	29	4	3.4907	1.2964	9.3992	0.0083	5.8036	1.5854	21.2452	0.3436	0.1171	0.5700	
		Y	10	5	8	1	4.0000	0.5775	27.7047	0.1516	7.0000	0.6135	79.8713	0.3750	-0.0104	0.7604	
Levetiracetam Use	10 mg/kg	0.2271 N	28	11	23	3	3.0119	0.9524	9.5246	0.0580	4.3137	1.0313	18.0437	0.2624	0.0351	0.4897	
		Y	9	7	14	2	5.4444	1.4403	20.5810	0.0066	21.0000	2.3969	183.9859	0.6349	0.3072	0.9626	
Rufinamide Use	10 mg/kg	0.3170 N	25	15	29	4	4.3500	1.6580	11.4126	0.0006	9.3750	2.4932	35.2524	0.4621	0.2327	0.6915	
		Y	12	3	8	1	2.0000	0.2501	15.9906	0.6186	2.3333	0.1975	27.5670	0.1250	-0.2105	0.4605	
Baseline Drop Seizure Frequency	10 mg/kg	- <=55	12	3	12	2	-	-	-	-	-	-	-	-	-	-	
		>55 to <=125	11	8	18	2	-	-	-	-	-	-	-	-	-	-	
		>125	14	7	7	1	-	-	-	-	-	-	-	-	-	-	
Current AEDs	10 mg/kg	0.8141 <3	12	7	9	2	2.6250	0.7065	9.7527	0.1842	4.9000	0.7000	34.3001	0.3611	-0.0282	0.7504	
		>=3	25	11	28	3	4.1067	1.2911	13.0619	0.0112	6.5476	1.5599	27.4836	0.3329	0.1071	0.5587	
Prior AEDs	10 mg/kg	0.2181 <6	16	7	21	4	2.2969	0.8101	6.5125	0.1514	3.3056	0.7598	14.3817	0.2470	-0.0484	0.5425	
		>=6	21	11	16	1	8.3810	1.2031	58.3821	0.0042	16.5000	1.8320	148.6058	0.4613	0.2170	0.7056	
Age Group	20 mg/kg	0.0204 2-5 years	5	2	5	3	0.6667	0.1835	2.4224	1.0000	0.4444	0.0354	5.5810	-0.2000	-0.8073	0.4073	
		6-11 years	11	7	13	1	8.2727	1.1944	57.2999	0.0078	21.0000	1.9410	227.2046	0.5594	0.2404	0.8785	
		12-17 years	7	6	12	1	10.2857	1.5373	68.8199	0.0017	66.0000	3.4721	1254.5672	0.7738	0.4711	1.0000	
		18-55 years	13	7	7	0	-	-	-	0.0445	-	-	-	0.5385	0.2675	0.8095	
Sex	20 mg/kg	0.1019 F	15	11	16	1	11.7333	1.7166	80.2014	0.0002	41.2500	4.0322	421.9884	0.6708	0.4176	0.9241	
		M	21	11	21	4	2.7500	1.0410	7.2649	0.0516	4.6750	1.1696	18.6858	0.3333	0.0616	0.6051	
Region	20 mg/kg	0.2434 REST OF THE WORLD	5	4	4	0	-	-	-	0.0476	-	-	-	0.8000	0.4494	1.0000	
		USA	31	18	33	5	3.8323	1.6200	9.0656	0.0006	7.7538	2.3606	25.4693	0.4291	0.2167	0.6416	
Valproate Use	20 mg/kg	0.5203 N	26	14	25	3	4.4872	1.4647	13.7468	0.0025	8.5556	2.0441	35.8100	0.4185	0.1884	0.6486	
		Y	10	8	12	2	4.8000	1.3048	17.6576	0.0083	20.0000	2.2852	175.0401	0.6333	0.3079	0.9588	
Lamotrigine Use	20 mg/kg	0.9651 N	24	15	29	4	4.5313	1.7329	11.8487	0.0004	10.4167	2.7262	39.8017	0.4871	0.2563	0.7179	
		Y	12	7	8	1	4.6667	0.7017	31.0363	0.0697	9.8000	0.8989	106.8451	0.4583	0.0973	0.8193	
Levetiracetam Use	20 mg/kg	0.8185 N	24	15	23	3	4.7917	1.5954	14.3917	0.0008	11.1111	2.5594	48.2359	0.4946	0.2570	0.7322	
		Y	12	7	14	2	4.0833	1.0383	16.0582	0.0375	8.4000	1.2738	55.3943	0.4405	0.1067	0.7743	
Rufinamide Use	20 mg/kg	0.8918 N	27	17	29	4	4.5648	1.7570	11.8598	0.0002	10.6250	2.8581	39.4989	0.4917	0.2705	0.7129	
		Y	9	5	8	1	4.4444	0.6488	30.4445	0.1312	8.7500	0.7374	103.8236	0.4306	0.0332	0.8279	

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Baseline Drop Seizure Frequency	20 mg/kg	- <=55	15	10	12	7	-	-	-	-	-	-	-	-	-	-	
		>55 to <=125	11	7	18	10	-	-	-	-	-	-	-	-	-	-	-
		>125	10	5	7	3	-	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.9666 <3	8	6	9	2	3.3750	0.9327	12.2125	0.0567	10.5000	1.1146	98.9138	0.5278	0.1230	0.9325	
		>=3	28	16	28	3	5.3333	1.7466	16.2860	0.0005	11.1111	2.7067	45.6116	0.4643	0.2481	0.6804	
Prior AEDs	20 mg/kg	0.9334 <6	19	14	21	4	3.8684	1.5389	9.7241	0.0012	11.9000	2.6739	52.9595	0.5464	0.2867	0.8060	
		>=6	17	8	16	1	7.5294	1.0568	53.6446	0.0167	13.3333	1.4236	124.8804	0.4081	0.1428	0.6734	
Total Seizures <=75pct Age Group	10 mg/kg	0.1202 2-5 years	4	0	5	1	-	-	-	1.0000	-	-	-	-0.2000	-0.5506	0.1506	
		6-11 years	14	1	13	0	-	-	-	1.0000	-	-	-	0.0714	-0.0635	0.2063	
		12-17 years	7	2	12	0	-	-	-	0.1228	-	-	-	0.2857	-0.0489	0.6204	
		18-55 years	12	3	7	0	-	-	-	0.2632	-	-	-	0.2500	0.0050	0.4950	
Sex	10 mg/kg	0.2933 F	21	4	16	0	-	-	-	0.1182	-	-	-	0.1905	0.0225	0.3584	
		M	16	2	21	1	2.6250	0.2604	26.4629	0.5676	2.8571	0.2355	34.6587	0.0774	-0.1085	0.2633	
Region	10 mg/kg	- REST OF THE WORLD	1	0	4	0	-	-	-	-	-	-	-	-	-	-	
		USA	36	6	33	1	5.5000	0.6985	43.3100	0.1082	6.4000	0.7272	56.3233	0.1364	0.0013	0.2714	
Valproate Use	10 mg/kg	0.1718 N	30	5	25	0	-	-	-	0.0562	-	-	-	0.1667	0.0333	0.3000	
		Y	7	1	12	1	1.7143	0.1260	23.3212	1.0000	1.8333	0.0964	34.8491	0.0595	-0.2432	0.3623	
Lamotrigine Use	10 mg/kg	0.2143 N	27	2	29	1	2.1481	0.2064	22.3569	0.6045	2.2400	0.1913	26.2265	0.0396	-0.0794	0.1586	
		Y	10	4	8	0	-	-	-	0.0915	-	-	-	0.4000	0.0964	0.7036	
Levetiracetam Use	10 mg/kg	0.4983 N	28	3	23	0	-	-	-	0.2424	-	-	-	0.1071	-0.0074	0.2217	
		Y	9	3	14	1	4.6667	0.5700	38.2062	0.2601	6.5000	0.5546	76.1754	0.2619	-0.0743	0.5981	
Rufinamide Use	10 mg/kg	0.7449 N	25	5	29	1	5.8000	0.7251	46.3950	0.0849	7.0000	0.7584	64.6056	0.1655	-0.0048	0.3358	
		Y	12	1	8	0	-	-	-	1.0000	-	-	-	0.0833	-0.0730	0.2397	
Baseline Drop Seizure Frequency	10 mg/kg	- <=55	12	2	12	0	-	-	-	-	-	-	-	-	-	-	
		>55 to <=125	11	2	18	1	-	-	-	-	-	-	-	-	-	-	
		>125	14	2	7	0	-	-	-	-	-	-	-	-	-	-	
Current AEDs	10 mg/kg	0.7265 <3	12	1	9	0	-	-	-	1.0000	-	-	-	0.0833	-0.0730	0.2397	
		>=3	25	5	28	1	5.6000	0.7009	44.7442	0.0889	6.7500	0.7305	62.3695	0.1643	-0.0069	0.3355	
Prior AEDs	10 mg/kg	0.4533 <6	16	3	21	1	3.9375	0.4506	34.4065	0.2962	4.6154	0.4321	49.2957	0.1399	-0.0720	0.3517	
		>=6	21	3	16	0	-	-	-	0.2432	-	-	-	0.1429	-0.0068	0.2925	
Age Group	20 mg/kg	0.4992 2-5 years	5	2	5	1	2.0000	0.2560	15.6235	1.0000	2.6667	0.1575	45.1411	0.2000	-0.3544	0.7544	
		6-11 years	11	2	13	0	-	-	-	0.1993	-	-	-	0.1818	-0.0461	0.4097	
		12-17 years	7	2	12	0	-	-	-	0.1228	-	-	-	0.2857	-0.0489	0.6204	
		18-55 years	13	4	7	0	-	-	-	0.2487	-	-	-	0.3077	0.0568	0.5586	
Sex	20 mg/kg	0.5331 F	15	3	16	0	-	-	-	0.1012	-	-	-	0.2000	-0.0024	0.4024	
		M	21	7	21	1	7.0000	0.9416	52.0392	0.0448	10.0000	1.1038	90.5931	0.2857	0.0645	0.5070	
Region	20 mg/kg	0.4671 REST OF THE WORLD	5	3	4	0	-	-	-	0.1667	-	-	-	0.6000	0.1706	1.0000	
		USA	31	7	33	1	7.4516	0.9717	57.1434	0.0245	9.3333	1.0752	81.0195	0.1955	0.0371	0.3539	
Valproate Use	20 mg/kg	0.4406 N	26	5	25	0	-	-	-	0.0506	-	-	-	0.1923	0.0408	0.3438	
		Y	10	5	12	1	6.0000	0.8315	43.2929	0.0557	11.0000	1.0047	120.4297	0.4167	0.0695	0.7638	
Lamotrigine Use	20 mg/kg	0.5181 N	24	6	29	1	7.2500	0.9364	56.1344	0.0377	9.3333	1.0360	84.0863	0.2155	0.0300	0.4010	
		Y	12	4	8	0	-	-	-	0.1166	-	-	-	0.3333	0.0666	0.6001	
Levetiracetam Use	20 mg/kg	0.1008 N	24	8	23	0	-	-	-	0.0039	-	-	-	0.3333	0.1447	0.5219	
		Y	12	2	14	1	2.3333	0.2403	22.6588	0.5800	2.6000	0.2054	32.9038	0.0952	-0.1551	0.3456	

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Rufinamide Use	20 mg/kg	0.7873 N	27	9	29	1	9.6667	1.3104	71.3124	0.0046	14.0000	1.6321	120.0873	0.2989	0.1090	0.4887
		Y	9	1	8	0	-	-	-	1.0000	-	-	-	0.1111	-0.0942	0.3164
Baseline Drop Seizure Frequency	20 mg/kg	- <=55	15	3	12	7	-	-	-	-	-	-	-	-	-	-
		>55 to <=125	11	2	18	10	-	-	-	-	-	-	-	-	-	-
		>125	10	5	7	3	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.3358 <3	8	4	9	0	-	-	-	0.0294	-	-	-	0.5000	0.1535	0.8465
		>=3	28	6	28	1	6.0000	0.7715	46.6621	0.1012	7.3636	0.8236	65.8331	0.1786	0.0118	0.3454
Prior AEDs	20 mg/kg	0.4715 <6	19	6	21	1	6.6316	0.8762	50.1916	0.0395	9.2308	0.9934	85.7751	0.2682	0.0402	0.4962
		>=6	17	4	16	0	-	-	-	0.1026	-	-	-	0.2353	0.0337	0.4369

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table:

GWEP1414 Convulsive Seizure Responder (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference			
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Convulsive Seizures <=25pct	Age Group	10 mg/kg	0.6322	2-5 years	4	4	5	4	1.2500	0.8064	1.9375	1.0000	-	-	-	0.2000	-0.1506	0.5506
				6-11 years	14	10	13	5	1.8571	0.8657	3.9840	0.1283	4.0000	0.7993	20.0167	0.3297	-0.0252	0.6845
				12-17 years	7	6	12	7	1.4694	0.8345	2.5874	0.3331	4.2857	0.3857	47.6247	0.2738	-0.1070	0.6546
				18-55 years	12	7	7	4	1.0208	0.4586	2.2723	1.0000	1.0500	0.1592	6.9243	0.0119	-0.4487	0.4726
Sex	10 mg/kg	0.2666	F	21	16	16	7	1.7415	0.9511	3.1887	0.0857	4.1143	1.0059	16.8274	0.3244	0.0206	0.6282	
			M	16	11	21	13	1.1106	0.6935	1.7784	0.7386	1.3538	0.3420	5.3596	0.0685	-0.2393	0.3762	
Region	10 mg/kg	0.0560	REST OF THE WORLD	1	0	4	3	-	-	-	0.4000	-	-	-	-0.7500	-1.0000	-0.3257	
			USA	36	27	33	17	1.4559	0.9947	2.1310	0.0496	2.8235	1.0208	7.8101	0.2348	0.0133	0.4564	
Valproate Use	10 mg/kg	0.6081	N	30	21	25	13	1.3462	0.8639	2.0976	0.2649	2.1538	0.7120	6.5157	0.1800	-0.0754	0.4354	
			Y	7	6	12	7	1.4694	0.8345	2.5874	0.3331	4.2857	0.3857	47.6247	0.2738	-0.1070	0.6546	
Lamotrigine Use	10 mg/kg	0.9964	N	27	20	29	16	1.3426	0.9029	1.9964	0.1707	2.3214	0.7501	7.1849	0.1890	-0.0561	0.4341	
			Y	10	7	8	4	1.4000	0.6272	3.1251	0.6305	2.3333	0.3365	16.1802	0.2000	-0.2480	0.6480	
Levetiracetam Use	10 mg/kg	0.0420	N	28	18	23	13	1.1374	0.7235	1.7881	0.7737	1.3846	0.4472	4.2869	0.0776	-0.1917	0.3470	
			Y	9	9	14	7	2.0000	1.1845	3.3769	0.0189	-	-	-	0.5000	0.2381	0.7619	
Rufinamide Use	10 mg/kg	0.3751	N	25	18	29	17	1.2282	0.8304	1.8168	0.3952	1.8151	0.5783	5.6971	0.1338	-0.1174	0.3850	
			Y	12	9	8	3	2.0000	0.7717	5.1837	0.1675	5.0000	0.7199	34.7265	0.3750	-0.0404	0.7904	
Baseline Drop Seizure Frequency	10 mg/kg	-	<=55	12	8	12	8	-	-	-	-	-	-	-	-	-	-	
			>55 to <=125	11	9	18	8	-	-	-	-	-	-	-	-	-	-	
			>125	14	10	7	4	-	-	-	-	-	-	-	-	-	-	
Current AEDs	10 mg/kg	0.2928	<3	12	9	9	7	0.9643	0.5978	1.5555	1.0000	0.8571	0.1110	6.6166	-0.0278	-0.3936	0.3380	
			>=3	25	18	28	13	1.5508	0.9722	2.4737	0.0937	2.9670	0.9430	9.3350	0.2557	0.0006	0.5109	
Prior AEDs	10 mg/kg	0.5830	<6	16	12	21	13	1.2115	0.7812	1.8790	0.4912	1.8462	0.4401	7.7449	0.1310	-0.1660	0.4279	
			>=6	21	15	16	7	1.6327	0.8801	3.0288	0.1071	3.2143	0.8183	12.6265	0.2768	-0.0337	0.5873	
Age Group	20 mg/kg	0.5440	2-5 years	5	4	5	4	1.0000	0.5381	1.8585	1.0000	1.0000	0.0451	22.1752	0.0000	-0.4958	0.4958	
			6-11 years	11	7	13	5	1.6545	0.7287	3.7565	0.4136	2.8000	0.5321	14.7350	0.2517	-0.1365	0.6400	
			12-17 years	7	7	12	7	1.7143	1.0627	2.7654	0.1060	-	-	-	0.4167	0.1377	0.6956	
			18-55 years	13	10	7	4	1.3462	0.6636	2.7306	0.6126	2.5000	0.3465	18.0387	0.1978	-0.2345	0.6301	
Sex	20 mg/kg	0.3657	F	15	12	16	7	1.8286	0.9931	3.3671	0.0659	5.1429	1.0331	25.6019	0.3625	0.0462	0.6788	
			M	21	16	21	13	1.2308	0.8152	1.8582	0.5055	1.9692	0.5179	7.4882	0.1429	-0.1334	0.4191	
Region	20 mg/kg	0.5990	REST OF THE WORLD	5	4	4	3	1.0667	0.5215	2.1819	1.0000	1.3333	0.0571	31.1210	0.0500	-0.5004	0.6004	
			USA	31	24	33	17	1.5028	1.0260	2.2014	0.0393	3.2269	1.0915	9.5396	0.2590	0.0338	0.4843	
Valproate Use	20 mg/kg	0.4780	N	26	19	25	13	1.4053	0.9023	2.1887	0.1534	2.5055	0.7784	8.0647	0.2108	-0.0489	0.4704	
			Y	10	9	12	7	1.5429	0.9164	2.5975	0.1619	6.4286	0.6050	68.3122	0.3167	-0.0186	0.6519	
Lamotrigine Use	20 mg/kg	0.2024	N	24	17	29	16	1.2839	0.8464	1.9473	0.2702	1.9732	0.6281	6.1988	0.1566	-0.1000	0.4132	
			Y	12	11	8	4	1.8333	0.8981	3.7426	0.1089	11.0000	0.9285	130.3238	0.4167	0.0365	0.7968	
Levetiracetam Use	20 mg/kg	0.5391	N	24	20	23	13	1.4744	0.9877	2.2008	0.0599	3.8462	0.9936	14.8889	0.2681	0.0166	0.5197	
			Y	12	8	14	7	1.3333	0.6897	2.5775	0.4527	2.0000	0.4066	9.8384	0.1667	-0.2071	0.5405	
Rufinamide Use	20 mg/kg	0.5747	N	27	23	29	17	1.4532	1.0303	2.0495	0.0392	4.0588	1.1132	14.7984	0.2656	0.0418	0.4894	
			Y	9	5	8	3	1.4815	0.5089	4.3128	0.6372	2.0833	0.2983	14.5491	0.1806	-0.2863	0.6474	
Baseline Drop Seizure Frequency	20 mg/kg	-	<=55	15	12	12	8	-	-	-	-	-	-	-	-	-		



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			>55 to <=125	11	8	18	8	-	-	-	-	-	-	-	-	-
			>125	10	8	7	4	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.3914 <3	8	8	9	7	1.2857	0.9067	1.8231	0.4706	-	-	-	0.2222	-0.0494	0.4938
		>=3	28	20	28	13	1.5385	0.9695	2.4412	0.1022	2.8846	0.9542	8.7204	0.2500	0.0008	0.4992
Prior AEDs	20 mg/kg	0.4774 <6	19	17	21	13	1.4453	0.9991	2.0909	0.0692	5.2308	0.9465	28.9062	0.2757	0.0263	0.5251
		>=6	17	11	16	7	1.4790	0.7665	2.8536	0.3028	2.3571	0.5802	9.5760	0.2096	-0.1231	0.5423
Convulsive Seizures <=50pct																
Age Group	10 mg/kg	0.6474 2-5 years	4	2	5	2	1.2500	0.2922	5.3478	1.0000	1.5000	0.1056	21.3120	0.1000	-0.5515	0.7515
		6-11 years	14	8	13	3	2.4762	0.8315	7.3739	0.1201	4.4444	0.8376	23.5825	0.3407	-0.0052	0.6866
		12-17 years	7	4	12	1	6.8571	0.9438	49.8217	0.0379	14.6667	1.1613	185.2348	0.4881	0.0895	0.8867
		18-55 years	12	4	7	1	2.3333	0.3211	16.9532	0.6027	3.0000	0.2632	34.1984	0.1905	-0.1815	0.5624
Sex	10 mg/kg	0.7341 F	21	11	16	3	2.7937	0.9313	8.3800	0.0475	4.7667	1.0429	21.7868	0.3363	0.0496	0.6230
		M	16	7	21	4	2.2969	0.8101	6.5125	0.1514	3.3056	0.7598	14.3817	0.2470	-0.0484	0.5425
Region	10 mg/kg	0.3010 REST OF THE WORLD	1	0	4	1	-	-	-	1.0000	-	-	-	-0.2500	-0.6743	0.1743
		USA	36	18	33	6	2.7500	1.2430	6.0840	0.0106	4.5000	1.4984	13.5147	0.3182	0.1084	0.5279
Valproate Use	10 mg/kg	0.0863 N	30	12	25	5	2.0000	0.8146	4.9102	0.1472	2.6667	0.7855	9.0529	0.2000	-0.0352	0.4352
		Y	7	6	12	2	5.1429	1.4005	18.8857	0.0063	30.0000	2.2169	405.9798	0.6905	0.3563	1.0000
Lamotrigine Use	10 mg/kg	0.2833 N	27	13	29	4	3.4907	1.2964	9.3992	0.0083	5.8036	1.5854	21.2452	0.3436	0.1171	0.5700
		Y	10	5	8	3	1.3333	0.4490	3.9591	0.6641	1.6667	0.2509	11.0710	0.1250	-0.3317	0.5817
Levetiracetam Use	10 mg/kg	0.5366 N	28	12	23	4	2.4643	0.9174	6.6191	0.0713	3.5625	0.9588	13.2368	0.2547	0.0147	0.4946
		Y	9	6	14	3	3.1111	1.0311	9.3867	0.0771	7.3333	1.1142	48.2642	0.4524	0.0768	0.8279
Rufinamide Use	10 mg/kg	0.3338 N	25	14	29	7	2.3200	1.1149	4.8279	0.0252	4.0000	1.2532	12.7675	0.3186	0.0694	0.5679
		Y	12	4	8	0	-	-	-	0.1166	-	-	-	-	0.3333	0.0666
Baseline Drop Seizure Frequency	10 mg/kg	- <=55	12	4	12	4	-	-	-	-	-	-	-	-	-	-
		>55 to <=125	11	7	18	1	-	-	-	-	-	-	-	-	-	-
		>125	14	7	7	2	-	-	-	-	-	-	-	-	-	-
Current AEDs	10 mg/kg	0.2489 <3	12	7	9	4	1.3125	0.5482	3.1424	0.6699	1.7500	0.3056	10.0223	0.1389	-0.2891	0.5669
		>=3	25	11	28	3	4.1067	1.2911	13.0619	0.0112	6.5476	1.5599	27.4836	0.3329	0.1071	0.5587
Prior AEDs	10 mg/kg	0.1585 <6	16	6	21	5	1.5750	0.5836	4.2503	0.4753	1.9200	0.4614	7.9891	0.1369	-0.1622	0.4360
		>=6	21	12	16	2	4.5714	1.1871	17.6035	0.0073	9.3333	1.6792	51.8751	0.4464	0.1799	0.7130
Age Group	20 mg/kg	0.2496 2-5 years	5	2	5	2	1.0000	0.2191	4.5639	1.0000	1.0000	0.0796	12.5573	0.0000	-0.6073	0.6073
		6-11 years	11	5	13	3	1.9697	0.6023	6.4418	0.3905	2.7778	0.4812	16.0338	0.2238	-0.1491	0.5967
		12-17 years	7	5	12	1	8.5714	1.2390	59.2972	0.0095	27.5000	1.9962	378.8366	0.6310	0.2616	1.0000
		18-55 years	13	8	7	1	4.3077	0.6674	27.8038	0.0703	9.6000	0.8763	105.1662	0.4725	0.1022	0.8428
Sex	20 mg/kg	0.9013 F	15	8	16	3	2.8444	0.9239	8.7570	0.0659	4.9524	0.9860	24.8747	0.3458	0.0291	0.6626
		M	21	12	21	4	3.0000	1.1529	7.8067	0.0247	5.6667	1.4108	22.7605	0.3810	0.1108	0.6511
Region	20 mg/kg	0.5893 REST OF THE WORLD	5	4	4	1	3.2000	0.5544	18.4709	0.2063	12.0000	0.5141	280.0892	0.5500	-0.0004	1.0000
		USA	31	16	33	6	2.8387	1.2755	6.3177	0.0080	4.8000	1.5493	14.8710	0.3343	0.1146	0.5540
Valproate Use	20 mg/kg	0.3763 N	26	13	25	5	2.5000	1.0441	5.9861	0.0399	4.0000	1.1511	13.8992	0.3000	0.0520	0.5480
		Y	10	7	12	2	4.2000	1.1123	15.8585	0.0274	11.6667	1.5273	89.1210	0.5333	0.1796	0.8871
Lamotrigine Use	20 mg/kg	0.5899 N	24	12	29	4	3.6250	1.3416	9.7945	0.0066	6.2500	1.6621	23.5016	0.3621	0.1259	0.5982
		Y	12	8	8	3	1.7778	0.6672	4.7367	0.3618	3.3333	0.5148	21.5839	0.2917	-0.1369	0.7202
Levetiracetam Use	20 mg/kg	0.5910 N	24	14	23	4	3.3542	1.2937	8.6965	0.0065	6.6500	1.7249	25.6384	0.4094	0.1586	0.6602
		Y	12	6	14	3	2.3333	0.7376	7.3810	0.2177	3.6667	0.6659	20.1905	0.2857	-0.0696	0.6410

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Rufinamide Use	20 mg/kg	0.2698 N Y	27 9	16 4	29 8	7 0	2.4550 -	1.1985 -	5.0287 -	0.0137 0.0824	4.5714 -	1.4537 -	14.3760 -	0.3512 0.4444	0.1091 0.1198	0.5933 0.7691
Baseline Drop Seizure Frequency	20 mg/kg	- <=55 >55 to <=125 >125	15 11 10	10 5 5	12 18 7	4 1 2	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -
Current AEDs	20 mg/kg	0.2070 <3 >=3	8 28	5 15	9 28	4 3	1.4063 5.0000	0.5681 1.6257	3.4812 15.3776	0.6372 0.0013	2.0833 9.6154	0.2983 2.3495	14.5491 39.3512	0.1806 0.4286	-0.2863 0.2112	0.6474 0.6459
Prior AEDs	20 mg/kg	0.7622 <6 >=6	19 17	13 7	21 16	5 2	2.8737 3.2941	1.2608 0.7999	6.5497 13.5661	0.0100 0.1175	6.9333 4.9000	1.7195 0.8358	27.9568 28.7277	0.4461 0.2868	0.1689 0.0022	0.7234 0.5714
Convulsive Seizures <=75pct Age Group	10 mg/kg	0.1919 2-5 years 6-11 years 12-17 years 18-55 years	4 14 7 12	0 1 1 3	5 13 12 7	1 0 0 0	- - - -	- - - -	- - - -	1.0000 1.0000 0.3684 0.2632	- - - -	- - - -	- - - -	-0.2000 0.0714 0.1429 0.2500	-0.5506 -0.0635 -0.1164 0.0050	0.1506 0.2063 0.4021 0.4950
Sex	10 mg/kg	0.3645 F M	21 16	3 2	16 21	0 1	- 2.6250	- 0.2604	- 26.4629	0.2432 0.5676	- 2.8571	- 0.2355	- 34.6587	0.1429 0.0774	-0.0068 -0.1085	0.2925 0.2633
Region	10 mg/kg	. REST OF THE WORLD USA	1 36	0 5	4 33	0 1	- 4.5833	- 0.5644	- 37.2204	0.2005	5.1613	0.5701	46.7260	0.1086	-0.0186	0.2358
Valproate Use	10 mg/kg	0.2184 N Y	30 7	4 1	25 12	0 1	- 1.7143	- 0.1260	- 23.3212	0.1174 1.0000	- 1.8333	- 0.0964	- 34.8491	0.1333 0.0595	0.0117 -0.2432	0.2550 0.3623
Lamotrigine Use	10 mg/kg	0.1252 N Y	27 10	1 4	29 8	1 0	1.0741 -	0.0706 -	16.3341 -	1.0000 0.0915	1.0769 -	0.0640 -	18.1169 -	0.0026 0.4000	-0.0948 0.0964	0.0999 0.7036
Levetiracetam Use	10 mg/kg	0.5876 N Y	28 9	2 3	23 14	0 1	- 4.6667	- 0.5700	- 38.2062	0.4949 0.2601	- 6.5000	- 0.5546	- 76.1754	0.0714 0.2619	-0.0240 -0.0743	0.1668 0.5981
Rufinamide Use	10 mg/kg	. N Y	25 12	5 0	29 8	1 0	5.8000 -	0.7251 -	46.3950 -	0.0849 -	7.0000 -	0.7584 -	64.6056 -	0.1655 -	-0.0048 -	0.3358 -
Baseline Drop Seizure Frequency	10 mg/kg	- <=55 >55 to <=125 >125	12 11 14	1 2 2	12 18 7	0 1 0	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -
Current AEDs	10 mg/kg	. <3 >=3	12 25	0 5	9 28	0 1	- 5.6000	- 0.7009	- 44.7442	- 0.0889	- 6.7500	- 0.7305	- 62.3695	- 0.1643	- -0.0069	- 0.3355
Prior AEDs	10 mg/kg	0.5463 <6 >=6	16 21	3 2	21 16	1 0	3.9375 -	0.4506 -	34.4065 -	0.2962 0.4955	4.6154 -	0.4321 -	49.2957 -	0.1399 0.0952	-0.0720 -0.0303	0.3517 0.2208
Age Group	20 mg/kg	0.2365 2-5 years 6-11 years 12-17 years 18-55 years	5 11 7 13	1 2 2 5	5 13 12 7	1 0 0 0	1.0000 - - -	0.0838 - - -	11.9315 - - -	1.0000 0.1993 0.1228 0.1137	1.0000 - - -	0.0451 - - -	22.1752 - - -	0.0000 0.1818 0.2857 0.3846	-0.4958 -0.0461 -0.0489 0.1202	0.4958 0.4097 0.6204 0.6491
Sex	20 mg/kg	0.5331 F M	15 21	3 7	16 21	0 1	- 7.0000	- 0.9416	- 52.0392	0.1012 0.0448	- 10.0000	- 1.1038	- 90.5931	0.2000 0.2857	-0.0024 0.0645	0.4024 0.5070
Region	20 mg/kg	0.4671 REST OF THE WORLD USA	5 31	3 7	4 33	0 1	- 7.4516	- 0.9717	- 57.1434	0.1667 0.0245	- 9.3333	- 1.0752	- 81.0195	0.6000 0.1955	0.1706 0.0371	1.0000 0.3539
Valproate Use	20 mg/kg	0.3213 N Y	26 10	6 4	25 12	0 1	- 4.8000	- 0.6341	- 36.3378	0.0226 0.1353	- 7.3333	- 0.6609	- 81.3646	0.2308 0.3167	0.0688 -0.0249	0.3927 0.6582
Lamotrigine Use	20 mg/kg	0.4065 N Y	24 12	5 5	29 8	1 0	6.0417 -	0.7565 -	48.2537 -	0.0802 0.0547	7.3684 -	0.7966 -	68.1606 -	0.1739 0.4167	-0.0017 0.1377	0.3494 0.6956

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Levetiracetam Use	20 mg/kg	0.0315 N Y	24	9	23	0	-	-	-	0.0016	-	-	-	0.3750	0.1813	0.5687
			12	1	14	1	1.1667	0.0814	16.7192	1.0000	1.1818	0.0660	21.1749	0.0119	-0.1946	0.2184
Rufinamide Use	20 mg/kg	0.7873 N Y	27	9	29	1	9.6667	1.3104	71.3124	0.0046	14.0000	1.6321	120.0873	0.2989	0.1090	0.4887
			9	1	8	0	-	-	-	1.0000	-	-	-	0.1111	-0.0942	0.3164
Baseline Drop Seizure Frequency	20 mg/kg	- <=55 >55 to <=125 >125	15	4	12	0	-	-	-	-	-	-	-	-	-	-
			11	2	18	1	-	-	-	-	-	-	-	-	-	-
			10	4	7	0	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.3358 <3 >=3	8	4	9	0	-	-	-	0.0294	-	-	-	0.5000	0.1535	0.8465
			28	6	28	1	6.0000	0.7715	46.6621	0.1012	7.3636	0.8236	65.8331	0.1786	0.0118	0.3454
Prior AEDs	20 mg/kg	0.3621 <6 >=6	19	5	21	1	5.5263	0.7076	43.1600	0.0848	7.1429	0.7506	67.9762	0.2155	-0.0024	0.4335
			17	5	16	0	-	-	-	0.0445	-	-	-	0.2941	0.0775	0.5107

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1414 Non-Convulsive Seizure Responder (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference			
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Non-Convulsive Seizures <=25pct	Age Group	10 mg/kg	0.0379	2-5 years	2	2	3	1	3.0000	0.6055	14.8636	0.4000	-	-	-	0.6667	0.1332	1.0000
				6-11 years	4	4	12	5	2.4000	1.2288	4.6876	0.0885	-	-	-	0.5833	0.3044	0.8623
				12-17 years	6	3	10	8	0.6250	0.2650	1.4741	0.2995	0.2500	0.0269	2.3192	-0.3000	-0.7707	0.1707
				18-55 years	9	8	7	4	1.5556	0.7866	3.0762	0.2615	6.0000	0.4630	77.7498	0.3175	-0.1027	0.7376
	Sex	10 mg/kg	0.1705	F	12	11	15	8	1.7188	1.0392	2.8428	0.0433	9.6250	0.9799	94.5395	0.3833	0.0864	0.6803
				M	9	6	17	10	1.1333	0.6161	2.0850	1.0000	1.4000	0.2585	7.5818	0.0784	-0.3083	0.4652
	Region	10 mg/kg	-	REST OF THE WORLD	1	0	3	0	-	-	-	-	-	-	-	-	-	-
				USA	20	17	29	18	1.3694	0.9758	1.9219	0.1122	3.4630	0.8218	14.5932	0.2293	-0.0066	0.4653
	Valproate Use	10 mg/kg	0.6517	N	16	13	23	12	1.5573	0.9864	2.4586	0.0930	3.9722	0.8877	17.7745	0.2908	0.0110	0.5705
				Y	5	4	9	6	1.2000	0.6348	2.2685	1.0000	2.0000	0.1496	26.7340	0.1333	-0.3333	0.6000
	Lamotrigine Use	10 mg/kg	0.3108	N	14	11	24	15	1.2571	0.8315	1.9007	0.4722	2.2000	0.4808	10.0663	0.1607	-0.1286	0.4500
				Y	7	6	8	3	2.2857	0.8890	5.8768	0.1189	10.0000	0.7765	128.7748	0.4821	0.0582	0.9061
	Levetiracetam Use	10 mg/kg	0.1382	N	15	11	22	13	1.2410	0.7814	1.9710	0.4908	1.9038	0.4577	7.9195	0.1424	-0.1614	0.4462
				Y	6	6	10	5	2.0000	1.0761	3.7171	0.0934	-	-	-	0.5000	0.1901	0.8099
	Rufinamide Use	10 mg/kg	0.0044	N	15	13	25	11	1.9697	1.2131	3.1983	0.0095	8.2727	1.5339	44.6184	0.4267	0.1669	0.6864
				Y	6	4	7	7	0.6667	0.3786	1.1739	0.1923	-	-	-	-0.3333	-0.7105	0.0439
	Baseline Drop Seizure Frequency	10 mg/kg	-	<=55	12	4	12	0	-	-	-	-	-	-	-	-	-	-
				>55 to <=125	11	6	18	4	-	-	-	-	-	-	-	-	-	-
				>125	14	6	7	1	-	-	-	-	-	-	-	-	-	-
	Current AEDs	10 mg/kg	0.5492	<3	6	4	8	4	1.3333	0.5450	3.2618	0.6270	2.0000	0.2235	17.8938	0.1667	-0.3455	0.6788
>=3				15	13	24	14	1.4857	1.0038	2.1989	0.0832	4.6429	0.8520	25.3010	0.2833	0.0216	0.5451	
Prior AEDs	10 mg/kg	0.0191	<6	7	4	18	12	0.8571	0.4172	1.7608	0.6729	0.6667	0.1114	3.9898	-0.0952	-0.5216	0.3312	
			>=6	14	13	14	6	2.1667	1.1631	4.0360	0.0128	17.3333	1.7502	171.6623	0.5000	0.2078	0.7922	
Age Group	20 mg/kg	0.5157	2-5 years	4	4	3	1	3.0000	0.6055	14.8636	0.1429	-	-	-	0.6667	0.1332	1.0000	
			6-11 years	8	6	12	5	1.8000	0.8252	3.9262	0.1968	4.2000	0.5861	30.0950	0.3333	-0.0764	0.7430	
			12-17 years	7	6	10	8	1.0714	0.6949	1.6520	1.0000	1.5000	0.1088	20.6753	0.0571	-0.3016	0.4158	
			18-55 years	7	5	7	4	1.2500	0.5648	2.7664	1.0000	1.8750	0.2036	17.2695	0.1429	-0.3535	0.6392	
Sex	20 mg/kg	0.3787	F	9	6	15	8	1.2500	0.6451	2.4220	0.6785	1.7500	0.3142	9.7482	0.1333	-0.2649	0.5316	
			M	17	15	17	10	1.5000	0.9719	2.3150	0.1175	5.2500	0.9001	30.6207	0.2941	0.0145	0.5737	
Region	20 mg/kg	0.2524	REST OF THE WORLD	3	2	3	0	-	-	-	0.4000	-	-	-	0.6667	0.1332	1.0000	
			USA	23	19	29	18	1.3309	0.9466	1.8713	0.1318	2.9028	0.7805	10.7955	0.2054	-0.0295	0.4403	
Valproate Use	20 mg/kg	0.2994	N	19	16	23	12	1.6140	1.0426	2.4987	0.0478	4.8889	1.1131	21.4732	0.3204	0.0585	0.5822	
			Y	7	5	9	6	1.0714	0.5549	2.0688	1.0000	1.2500	0.1460	10.6993	0.0476	-0.4072	0.5024	
Lamotrigine Use	20 mg/kg	0.3941	N	20	18	24	15	1.4400	1.0223	2.0284	0.0445	5.4000	1.0080	28.9281	0.2750	0.0409	0.5091	
			Y	6	3	8	3	1.3333	0.4015	4.4278	1.0000	1.6667	0.1947	14.2657	0.1250	-0.3971	0.6471	
Levetiracetam Use	20 mg/kg	0.0689	N	17	12	22	13	1.1946	0.7513	1.8993	0.5178	1.6615	0.4326	6.3814	0.1150	-0.1836	0.4135	
			Y	9	9	10	5	2.0000	1.0761	3.7171	0.0325	-	-	-	0.5000	0.1901	0.8099	
Rufinamide Use	20 mg/kg	-	N	19	14	25	11	1.6746	0.9981	2.8097	0.0684	3.5636	0.9801	12.9569	0.2968	0.0192	0.5744	
			Y	7	7	7	7	-	-	-	-	-	-	-	-	-	-	
Baseline Drop Seizure Frequency	20 mg/kg	-	<=55	15	4	12	0	-	-	-	-	-	-	-	-	-	-	

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		>55 to <=125	11	3	18	4	-	-	-	-	-	-	-	-	-	-
		>125	10	3	7	1	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.7041 <3	6	5	8	4	1.6667	0.7641	3.6354	0.3007	5.0000	0.3883	64.3874	0.3333	-0.1238	0.7905
		>=3	20	16	24	14	1.3714	0.9166	2.0519	0.1948	2.8571	0.7308	11.1704	0.2167	-0.0472	0.4806
Prior AEDs	20 mg/kg	0.5910 <6	12	10	18	12	1.2500	0.8269	1.8896	0.4192	2.5000	0.4104	15.2303	0.1667	-0.1365	0.4698
		>=6	14	11	14	6	1.8333	0.9439	3.5608	0.1201	4.8889	0.9311	25.6699	0.3571	0.0204	0.6939
Non-Convulsive Seizures <=50pct																
Age Group	10 mg/kg	0.0881 2-5 years	2	1	3	1	1.5000	0.1806	12.4593	1.0000	2.0000	0.0511	78.2496	0.1667	-0.7078	1.0000
		6-11 years	4	4	12	2	6.0000	1.6932	21.2618	0.0082	-	-	-	0.8333	0.6225	1.0000
		12-17 years	6	3	10	6	0.8333	0.3233	2.1478	1.0000	0.6667	0.0867	5.1270	-0.1000	-0.6023	0.4023
		18-55 years	9	7	7	3	1.8148	0.7204	4.5719	0.3024	4.6667	0.5326	40.8857	0.3492	-0.1070	0.8055
Sex	10 mg/kg	0.2894 F	12	9	15	4	2.8125	1.1429	6.9214	0.0213	8.2500	1.4525	46.8587	0.4833	0.1515	0.8152
		M	9	6	17	8	1.4167	0.7150	2.8071	0.4291	2.2500	0.4187	12.0917	0.1961	-0.1927	0.5849
Region	10 mg/kg	- REST OF THE WORLD	1	0	3	0	-	-	-	-	-	-	-	-	-	-
		USA	20	15	29	12	1.8125	1.0975	2.9933	0.0396	4.2500	1.2138	14.8813	0.3362	0.0752	0.5973
Valproate Use	10 mg/kg	0.7597 N	16	11	23	7	2.2589	1.1210	4.5518	0.0253	5.0286	1.2642	20.0025	0.3832	0.0883	0.6780
		Y	5	4	9	5	1.4400	0.6936	2.9894	0.5804	3.2000	0.2485	41.2079	0.2444	-0.2334	0.7223
Lamotrigine Use	10 mg/kg	0.5782 N	14	10	24	10	1.7143	0.9619	3.0550	0.1008	3.5000	0.8500	14.4119	0.2976	-0.0104	0.6057
		Y	7	5	8	2	2.8571	0.7877	10.3631	0.1319	7.5000	0.7585	74.1574	0.4643	0.0148	0.9138
Levetiracetam Use	10 mg/kg	0.1254 N	15	9	22	8	1.6500	0.8275	3.2901	0.1931	2.6250	0.6807	10.1225	0.2364	-0.0828	0.5555
		Y	6	6	10	4	2.5000	1.1702	5.3408	0.0338	-	-	-	0.6000	0.2964	0.9036
Rufinamide Use	10 mg/kg	0.0090 N	15	13	25	8	2.7083	1.4791	4.9592	0.0011	13.8125	2.4995	76.3303	0.5467	0.2956	0.7977
		Y	6	2	7	4	0.5833	0.1589	2.1421	0.5921	0.3750	0.0390	3.6051	-0.2381	-0.7641	0.2879
Baseline Drop Seizure Frequency	10 mg/kg	- <=55	12	4	12	0	-	-	-	-	-	-	-	-	-	-
		>55 to <=125	11	6	18	4	-	-	-	-	-	-	-	-	-	-
		>125	14	6	7	1	-	-	-	-	-	-	-	-	-	-
Current AEDs	10 mg/kg	0.8124 <3	6	4	8	3	1.7778	0.6168	5.1236	0.5921	3.3333	0.3619	30.7013	0.2917	-0.2131	0.7965
		>=3	15	11	24	9	1.9556	1.0733	3.5629	0.0484	4.5833	1.1172	18.8025	0.3583	0.0624	0.6543
Prior AEDs	10 mg/kg	0.0308 <6	7	3	18	8	0.9643	0.3550	2.6192	1.0000	0.9375	0.1609	5.4609	-0.0159	-0.4484	0.4167
		>=6	14	12	14	4	3.0000	1.2753	7.0569	0.0063	15.0000	2.2581	99.6392	0.5714	0.2721	0.8708
Age Group	20 mg/kg	0.3314 2-5 years	4	4	3	1	3.0000	0.6055	14.8636	0.1429	-	-	-	0.6667	0.1332	1.0000
		6-11 years	8	6	12	2	4.5000	1.1938	16.9621	0.0194	15.0000	1.6523	136.1717	0.5833	0.2166	0.9501
		12-17 years	7	5	10	6	1.1905	0.5973	2.3726	1.0000	1.6667	0.2101	13.2231	0.1143	-0.3376	0.5662
		18-55 years	7	5	7	3	1.6667	0.6285	4.4200	0.5921	3.3333	0.3619	30.7013	0.2857	-0.2107	0.7821
Sex	20 mg/kg	0.9695 F	9	6	15	4	2.5000	0.9592	6.5159	0.0918	5.5000	0.9116	33.1836	0.4000	0.0193	0.7807
		M	17	14	17	8	1.7500	1.0095	3.0336	0.0707	5.2500	1.0933	25.2107	0.3529	0.0544	0.6515
Region	20 mg/kg	0.3505 REST OF THE WORLD	3	2	3	0	-	-	-	0.4000	-	-	-	0.6667	0.1332	1.0000
		USA	23	18	29	12	1.8913	1.1659	3.0681	0.0110	5.1000	1.4817	17.5540	0.3688	0.1228	0.6149
Valproate Use	20 mg/kg	0.2546 N	19	15	23	7	2.5940	1.3406	5.0191	0.0023	8.5714	2.0799	35.3229	0.4851	0.2225	0.7477
		Y	7	5	9	5	1.2857	0.6079	2.7191	0.6329	2.0000	0.2445	16.3622	0.1587	-0.3075	0.6250
Lamotrigine Use	20 mg/kg	0.4778 N	20	17	24	10	2.0400	1.2276	3.3901	0.0050	7.9333	1.8215	34.5519	0.4333	0.1816	0.6851
		Y	6	3	8	2	2.0000	0.4727	8.4625	0.5804	3.0000	0.3121	28.8406	0.2500	-0.2501	0.7501
Levetiracetam Use	20 mg/kg	0.4555 N	17	12	22	8	1.9412	1.0315	3.6529	0.0536	4.2000	1.0806	16.3242	0.3422	0.0467	0.6377
		Y	9	8	10	4	2.2222	1.0051	4.9134	0.0573	12.0000	1.0527	136.7937	0.4889	0.1223	0.8554

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Rufinamide Use	20 mg/kg	0.3203 N Y	19 7	13 7	25 7	8 4	2.1382 1.7500	1.1185 0.9213	4.0873 3.3240	0.0319 0.1923	4.6042 -	1.2784 -	16.5821 -	0.3642 0.4286	0.0865 0.0620	0.6419 0.7952
Baseline Drop Seizure Frequency	20 mg/kg	- <=55 >55 to <=125 >125	15 11 10	4 3 3	12 18 7	0 4 1	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -
Current AEDs	20 mg/kg	0.7286 <3 >=3	6 20	5 15	8 24	3 9	2.2222 2.0000	0.8479 1.1252	5.8242 3.5548	0.1375 0.0171	8.3333 5.0000	0.6312 1.3536	110.0215 18.4688	0.4583 0.3750	0.0095 0.1038	0.9072 0.6462
Prior AEDs	20 mg/kg	0.4557 <6 >=6	12 14	9 11	18 14	8 4	1.6875 2.7500	0.9159 1.1495	3.1092 6.5787	0.1414 0.0213	3.7500 9.1667	0.7544 1.6339	18.6415 51.4272	0.3056 0.5000	-0.0302 0.1803	0.6413 0.8197
Non-Convulsive Seizures <=75pct Age Group	10 mg/kg	0.3205 2-5 years 6-11 years 12-17 years 18-55 years	2 4 6 9	0 2 3 6	3 12 10 7	1 1 4 2	- 6.0000 1.2500 2.3333	- 0.7224 0.4149 0.6624	- 49.8372 3.7662 8.2187	1.0000 0.1357 1.0000 0.3147	- 11.0000 1.5000 5.0000	- 0.6465 0.1950 0.5842	- 187.1665 11.5359 42.7971	-0.3333 0.4167 0.1000 0.3810	-0.8668 -0.0977 -0.4023 -0.0739	0.2001 0.9310 0.6023 0.8358
Sex	10 mg/kg	0.3792 F M	12 9	7 4	15 17	3 5	2.9167 1.5111	0.9522 0.5356	8.9338 4.2635	0.0568 0.6673	5.6000 1.9200	1.0148 0.3584	30.9041 10.2855	0.3833 0.1503	0.0387 -0.2399	0.7280 0.5406
Region	10 mg/kg	- REST OF THE WORLD USA	1 20	0 11	3 29	0 8	- 1.9938	- 0.9797	- 4.0575	- 0.0755	- 3.2083	- 0.9667	- 10.6483	- 0.2741	- 0.0021	- 0.5462
Valproate Use	10 mg/kg	0.4908 N Y	16 5	8 3	23 9	4 4	2.8750 1.3500	1.0403 0.4855	7.9457 3.7536	0.0407 1.0000	4.7500 1.8750	1.1064 0.2036	20.3925 17.2695	0.3261 0.1556	0.0362 -0.3828	0.6159 0.6939
Lamotrigine Use	10 mg/kg	0.8282 N Y	14 7	7 4	24 8	6 2	2.0000 2.2857	0.8390 0.5861	4.7674 8.9139	0.1626 0.3147	3.0000 4.0000	0.7421 0.4471	12.1275 35.7876	0.2500 0.3214	-0.0640 -0.1523	0.5640 0.7952
Levetiracetam Use	10 mg/kg	0.1009 N Y	15 6	6 5	22 10	6 2	1.4667 4.1667	0.5834 1.1467	3.6870 15.1397	0.4879 0.0350	1.7778 20.0000	0.4404 1.4162	7.1768 282.4489	0.1273 0.6333	-0.1827 0.2455	0.4373 1.0000
Rufinamide Use	10 mg/kg	0.0997 N Y	15 6	9 2	25 7	5 3	3.0000 0.7778	1.2366 0.1883	7.2777 3.2130	0.0168 1.0000	6.0000 0.6667	1.4447 0.0693	24.9192 6.4090	0.4000 -0.0952	0.1067 -0.6212	0.6933 0.4308
Baseline Drop Seizure Frequency	10 mg/kg	- <=55 >55 to <=125 >125	12 11 14	4 6 6	12 18 7	0 4 1	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -
Current AEDs	10 mg/kg	0.5370 <3 >=3	6 15	3 8	8 24	1 7	4.0000 1.8286	0.5411 0.8359	29.5675 4.0002	0.2448 0.1817	7.0000 2.7755	0.5013 0.7246	97.7512 10.6319	0.3750 0.2417	-0.0861 -0.0695	0.8361 0.5528
Prior AEDs	10 mg/kg	0.1950 <6 >=6	7 14	3 8	18 14	6 2	1.2857 4.0000	0.4382 1.0257	3.7722 15.5993	0.6729 0.0461	1.5000 8.0000	0.2506 1.2790	8.9769 50.0399	0.0952 0.4286	-0.3312 0.1111	0.5216 0.7461
Age Group	20 mg/kg	0.7583 2-5 years 6-11 years 12-17 years 18-55 years	4 8 7 7	3 4 5 3	3 12 10 7	1 1 4 2	2.2500 6.0000 1.7857 1.5000	0.4121 0.8117 0.7318 0.3517	12.2841 44.3512 4.3573 6.3972	0.4857 0.1089 0.3348 1.0000	6.0000 11.0000 3.7500 1.8750	0.2215 0.9285 0.4727 0.2036	162.5313 130.3238 29.7520 17.2695	0.4167 0.4167 0.3143 0.1429	-0.2650 0.0365 -0.1376 -0.3535	1.0000 0.7968 0.7662 0.6392
Sex	20 mg/kg	0.3627 F M	9 17	6 9	15 17	3 5	3.3333 1.8000	1.0957 0.7601	10.1405 4.2626	0.0361 0.2960	8.0000 2.7000	1.2250 0.6575	52.2460 11.0878	0.4667 0.2353	0.0981 -0.0860	0.8352 0.5566
Region	20 mg/kg	0.2762 REST OF THE WORLD USA	3 23	2 13	3 29	0 8	- 2.0489	- 1.0276	- 4.0852	0.4000 0.0482	- 3.4125	- 1.0711	- 10.8723	0.6667 0.2894	0.1332 0.0295	1.0000 0.5492
Valproate Use	20 mg/kg	0.2696 N Y	19 7	11 4	23 9	4 4	3.3289 1.2857	1.2623 0.4863	8.7793 3.3990	0.0099 1.0000	6.5313 1.6667	1.5924 0.2273	26.7883 12.2214	0.4050 0.1270	0.1343 -0.3627	0.6757 0.6167
Lamotrigine Use	20 mg/kg	0.0875 N Y	20 6	14 1	24 8	6 2	2.8000 0.6667	1.3226 0.0773	5.9276 5.7489	0.0056 1.0000	7.0000 0.6000	1.8518 0.0412	26.4612 8.7320	0.4500 -0.0833	0.1848 -0.5064	0.7152 0.3397

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Levetiracetam Use	20 mg/kg	0.8269 N	17	10	22	6	2.1569	0.9791	4.7515	0.0586	3.8095	0.9910	14.6447	0.3155	0.0166	0.6145	
		Y	9	5	10	2	2.7778	0.7056	10.9361	0.1698	5.0000	0.6553	38.1518	0.3556	-0.0529	0.7640	
Rufinamide Use	20 mg/kg	0.8275 N	19	10	25	5	2.6316	1.0779	6.4244	0.0303	4.4444	1.1744	16.8200	0.3263	0.0525	0.6002	
		Y	7	5	7	3	1.6667	0.6285	4.4200	0.5921	3.3333	0.3619	30.7013	0.2857	-0.2107	0.7821	
Baseline Drop Seizure Frequency	20 mg/kg	- <=55	15	4	12	0	-	-	-	-	-	-	-	-	-	-	
		>55 to <=125	11	3	18	4	-	-	-	-	-	-	-	-	-	-	-
		>125	10	3	7	1	-	-	-	-	-	-	-	-	-	-	-
Current AEDs	20 mg/kg	0.2976 <3	6	4	8	1	5.3333	0.7829	36.3311	0.0909	14.0000	0.9441	207.5969	0.5417	0.1003	0.9830	
		>=3	20	11	24	7	1.8857	0.9008	3.9477	0.1250	2.9683	0.8544	10.3118	0.2583	-0.0256	0.5422	
Prior AEDs	20 mg/kg	0.0522 <6	12	5	18	6	1.2500	0.4905	3.1853	0.7116	1.4286	0.3159	6.4611	0.0833	-0.2705	0.4372	
		>=6	14	10	14	2	5.0000	1.3288	18.8143	0.0063	15.0000	2.2581	99.6392	0.5714	0.2721	0.8708	

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1414 CGIC Responder [VMI, MI, SI] (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference				
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI	
Last Visit (LOCF)	Age Group	10 mg/kg	0.6059	2-5 years	4	3	5	3	1.2500	0.5020	3.1126	1.0000	0.5000	0.0279	8.9517	0.1500	-0.4537	0.7537	
				6-11 years	14	13	13	6	2.0119	1.0988	3.6838	0.0128	0.0659	0.0066	0.6628	0.4670	0.1643	0.7697	
				12-17 years	7	5	12	6	1.4286	0.6853	2.9781	0.6332	0.4000	0.0545	2.9331	0.2143	-0.2239	0.6525	
				18-55 years	12	7	7	2	2.0417	0.5762	7.2349	0.3498	0.2857	0.0386	2.1144	0.2976	-0.1380	0.7333	
Last Visit (LOCF)	Sex	10 mg/kg	0.4245	F	21	17	16	7	1.8503	1.0226	3.3483	0.0357	0.1830	0.0421	0.7962	0.3720	0.0766	0.6675	
				M	16	11	21	10	1.4438	0.8271	2.5202	0.3161	0.4132	0.1060	1.6108	0.2113	-0.1005	0.5231	
Last Visit (LOCF)	Region	10 mg/kg	0.3351	REST OF THE WORLD	1	0	4	1	-	-	-	1.0000	-	-	-	-0.2500	-0.6743	0.1743	
				USA	36	28	33	16	1.6042	1.0832	2.3756	0.0138	0.2689	0.0950	0.7615	0.2929	0.0749	0.5109	
Last Visit (LOCF)	Valproate Use	10 mg/kg	0.3861	N	30	23	25	10	1.9167	1.1405	3.2210	0.0120	0.2029	0.0633	0.6501	0.3667	0.1222	0.6112	
				Y	7	5	12	7	1.2245	0.6269	2.3916	0.6562	0.5600	0.0757	4.1442	0.1310	-0.3047	0.5666	
Last Visit (LOCF)	Lamotrigine Use	10 mg/kg	0.2572	N	27	22	29	13	1.8177	1.1683	2.8280	0.0061	0.1847	0.0547	0.6229	0.3665	0.1337	0.5994	
				Y	10	6	8	4	1.2000	0.5088	2.8303	1.0000	0.6667	0.1021	4.3538	0.1000	-0.3607	0.5607	
Last Visit (LOCF)	Levetiracetam Use	10 mg/kg	0.3535	N	28	21	23	8	2.1563	1.1845	3.9253	0.0052	0.1778	0.0529	0.5971	0.4022	0.1500	0.6544	
				Y	9	7	14	9	1.2099	0.7166	2.0428	0.6570	0.5143	0.0758	3.4881	0.1349	-0.2349	0.5047	
Last Visit (LOCF)	Rufinamide Use	10 mg/kg	0.4214	N	25	20	29	13	1.7846	1.1393	2.7956	0.0119	0.2031	0.0598	0.6902	0.3517	0.1123	0.5912	
				Y	12	8	8	4	1.3333	0.5990	2.9678	0.6479	0.5000	0.0799	3.1275	0.1667	-0.2706	0.6039	
Last Visit (LOCF)	Baseline Drop Seizure Frequency	10 mg/kg	-	<=55	12	9	12	7	-	-	-	-	-	-	-	-	-	-	
				>55 to <=125	11	9	18	7	-	-	-	-	-	-	-	-	-	-	-
				>125	14	10	7	3	-	-	-	-	-	-	-	-	-	-	-
Last Visit (LOCF)	Current AEDs	10 mg/kg	0.1934	<3	12	11	9	4	2.0625	0.9742	4.3667	0.0464	0.0727	0.0064	0.8286	0.4722	0.1119	0.8326	
				>=3	25	17	28	13	1.4646	0.9061	2.3674	0.1661	0.4078	0.1329	1.2518	0.2157	-0.0442	0.4756	
Last Visit (LOCF)	Prior AEDs	10 mg/kg	0.8288	<6	16	12	21	10	1.5750	0.9267	2.6767	0.1757	0.3030	0.0733	1.2525	0.2738	-0.0273	0.5749	
				>=6	21	16	16	7	1.7415	0.9511	3.1887	0.0857	0.2431	0.0594	0.9941	0.3244	0.0206	0.6282	
Last Visit (LOCF)	Age Group	20 mg/kg	0.3466	2-5 years	4	4	5	3	-	-	-	0.4444	-	-	-	0.4000	-0.0294	0.8294	
				6-11 years	11	7	13	6	1.3788	0.6593	2.8834	0.4442	0.4898	0.0948	2.5316	0.1748	-0.2179	0.5676	
				12-17 years	7	7	12	6	-	-	-	0.0436	-	-	-	0.5000	0.2171	0.7829	
				18-55 years	13	10	7	2	2.6923	0.8040	9.0156	0.0623	0.1200	0.0149	0.9668	0.4835	0.0780	0.8890	
Last Visit (LOCF)	Sex	20 mg/kg	0.1821	F	14	9	16	7	1.4694	0.7451	2.8977	0.2989	0.4321	0.0990	1.8856	0.2054	-0.1440	0.5548	
				M	21	19	21	10	1.9000	1.1880	3.0386	0.0063	0.0957	0.0177	0.5186	0.4286	0.1808	0.6763	
Last Visit (LOCF)	Region	20 mg/kg	0.1312	REST OF THE WORLD	5	5	4	1	-	-	-	0.0476	-	-	-	0.7500	0.3257	1.0000	
				USA	30	23	33	16	1.5813	1.0564	2.3668	0.0368	0.2864	0.0966	0.8495	0.2818	0.0538	0.5098	
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.1655	N	25	21	25	10	2.1000	1.2615	3.4959	0.0031	0.1270	0.0334	0.4828	0.4400	0.2001	0.6799	



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		Y	10	7	12	7	1.2000	0.6409	2.2467	0.6749	0.6000	0.1018	3.5359	0.1167	-0.2814	0.5148
Last Visit (LOCF)																
Lamotrigine Use	20 mg/kg	0.9212 N	23	18	29	13	1.7458	1.1047	2.7590	0.0227	0.2257	0.0659	0.7735	0.3343	0.0870	0.5817
		Y	12	10	8	4	1.6667	0.7970	3.4852	0.1611	0.2000	0.0256	1.5623	0.3333	-0.0723	0.7389
Last Visit (LOCF)																
Levetiracetam Use	20 mg/kg	0.3663 N	24	19	23	8	2.2760	1.2541	4.1309	0.0032	0.1404	0.0380	0.5183	0.4438	0.1903	0.6974
		Y	11	9	14	9	1.2727	0.7878	2.0561	0.4065	0.4000	0.0609	2.6272	0.1753	-0.1637	0.5144
Last Visit (LOCF)																
Rufinamide Use	20 mg/kg	0.7523 N	26	21	29	13	1.8018	1.1544	2.8122	0.0115	0.1935	0.0572	0.6548	0.3594	0.1234	0.5954
		Y	9	7	8	4	1.5556	0.7160	3.3798	0.3348	0.2857	0.0352	2.3222	0.2778	-0.1625	0.7180
Last Visit (LOCF)																
Baseline Drop Seizure Frequency	20 mg/kg	- <=55	15	14	12	7	-	-	-	-	-	-	-	-	-	-
		>55 to <=125	11	7	18	7	-	-	-	-	-	-	-	-	-	-
		>125	9	7	7	3	-	-	-	-	-	-	-	-	-	-
Last Visit (LOCF)																
Current AEDs	20 mg/kg	0.6823 <3	7	6	9	4	1.9286	0.8748	4.2518	0.1451	0.1333	0.0110	1.6115	0.4127	-0.0027	0.8281
		>=3	28	22	28	13	1.6923	1.0873	2.6340	0.0261	0.2364	0.0734	0.7608	0.3214	0.0822	0.5606
Last Visit (LOCF)																
Prior AEDs	20 mg/kg	0.0788 <6	19	18	21	10	1.9895	1.2548	3.1544	0.0015	0.0505	0.0057	0.4505	0.4712	0.2352	0.7072
		>=6	16	10	16	7	1.4286	0.7289	2.7998	0.4795	0.4667	0.1135	1.9195	0.1875	-0.1521	0.5271

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1414 CGIC Responder [VMI, MI] (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference				
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI	
Last Visit (LOCF)	Age Group	10 mg/kg	0.9310	2-5 years	4	1	5	0	-	-	-	0.4444	-	-	-	0.2500	-0.1743	0.6743	
				6-11 years	14	6	13	1	5.5714	0.7709	40.2650	0.0768	0.1111	0.0112	1.1063	0.3516	0.0547	0.6486	
				12-17 years	7	4	12	2	3.4286	0.8300	14.1634	0.1287	0.1500	0.0178	1.2648	0.4048	-0.0182	0.8277	
				18-55 years	12	5	7	1	2.9167	0.4216	20.1775	0.3331	0.2333	0.0210	2.5929	0.2738	-0.1070	0.6546	
Last Visit (LOCF)	Sex	10 mg/kg	0.6412	F	21	11	16	3	2.7937	0.9313	8.3800	0.0475	0.2098	0.0459	0.9589	0.3363	0.0496	0.6230	
				M	16	5	21	1	6.5625	0.8481	50.7810	0.0662	0.1100	0.0114	1.0643	0.2649	0.0202	0.5096	
Last Visit (LOCF)	Region	10 mg/kg	-	REST OF THE WORLD	1	0	4	0	-	-	-	-	-	-	-	-	-	-	
				USA	36	16	33	4	3.6667	1.3643	9.8541	0.0037	0.1724	0.0501	0.5928	0.3232	0.1264	0.5201	
Last Visit (LOCF)	Valproate Use	10 mg/kg	0.3884	N	30	15	25	3	4.1667	1.3592	12.7729	0.0037	0.1364	0.0335	0.5544	0.3800	0.1604	0.5996	
				Y	7	1	12	1	1.7143	0.1260	23.3212	1.0000	0.5455	0.0287	10.3683	0.0595	-0.2432	0.3623	
Last Visit (LOCF)	Lamotrigine Use	10 mg/kg	0.7834	N	27	12	29	3	4.2963	1.3584	13.5884	0.0060	0.1442	0.0350	0.5942	0.3410	0.1232	0.5587	
				Y	10	4	8	1	3.2000	0.4399	23.2769	0.3137	0.2143	0.0185	2.4773	0.2750	-0.1054	0.6554	
Last Visit (LOCF)	Levetiracetam Use	10 mg/kg	0.1685	N	28	10	23	3	2.7381	0.8529	8.7901	0.1059	0.2700	0.0640	1.1382	0.2267	0.0021	0.4513	
				Y	9	6	14	1	9.3333	1.3354	65.2313	0.0049	0.0385	0.0033	0.4507	0.5952	0.2590	0.9315	
Last Visit (LOCF)	Rufinamide Use	10 mg/kg	0.0085	N	25	14	29	2	8.1200	2.0394	32.3300	<0.001	0.0582	0.0113	0.2998	0.4910	0.2757	0.7064	
				Y	12	2	8	2	0.6667	0.1166	3.8130	1.0000	1.6667	0.1836	15.1302	-0.0833	-0.4501	0.2834	
Last Visit (LOCF)	Baseline Drop Seizure Frequency	10 mg/kg	-	<=55	12	6	12	2	-	-	-	-	-	-	-	-	-	-	
				>55 to <=125	11	5	18	2	-	-	-	-	-	-	-	-	-	-	-
				>125	14	5	7	0	-	-	-	-	-	-	-	-	-	-	-
Last Visit (LOCF)	Current AEDs	10 mg/kg	0.1598	<3	12	9	9	1	6.7500	1.0336	44.0826	0.0075	0.0417	0.0036	0.4855	0.6389	0.3192	0.9585	
				>=3	25	7	28	3	2.6133	0.7560	9.0336	0.1622	0.3086	0.0701	1.3583	0.1729	-0.0371	0.3829	
Last Visit (LOCF)	Prior AEDs	10 mg/kg	0.5165	<6	16	7	21	3	3.0625	0.9355	10.0250	0.0667	0.2143	0.0445	1.0315	0.2946	0.0092	0.5801	
				>=6	21	9	16	1	6.8571	0.9650	48.7267	0.0230	0.0889	0.0098	0.8030	0.3661	0.1234	0.6087	
Last Visit (LOCF)	Age Group	20 mg/kg	0.6657	2-5 years	4	1	5	0	-	-	-	0.4444	-	-	-	0.2500	-0.1743	0.6743	
				6-11 years	11	3	13	1	3.5455	0.4273	29.4181	0.3002	0.2222	0.0195	2.5332	0.1958	-0.1046	0.4962	
				12-17 years	7	6	12	2	5.1429	1.4005	18.8857	0.0063	0.0333	0.0025	0.4511	0.6905	0.3563	1.0000	
				18-55 years	13	6	7	1	3.2308	0.4798	21.7567	0.3285	0.1944	0.0180	2.1037	0.3187	-0.0563	0.6937	
Last Visit (LOCF)	Sex	20 mg/kg	0.5830	F	14	8	16	3	3.0476	0.9980	9.3063	0.0567	0.1731	0.0335	0.8941	0.3839	0.0618	0.7061	
				M	21	8	21	1	8.0000	1.0947	58.4609	0.0205	0.0813	0.0091	0.7282	0.3333	0.1065	0.5601	
Last Visit (LOCF)	Region	20 mg/kg	0.1717	REST OF THE WORLD	5	4	4	0	-	-	-	0.0476	-	-	-	0.8000	0.4494	1.0000	
				USA	30	12	33	4	3.3000	1.1925	9.1319	0.0191	0.2069	0.0578	0.7406	0.2788	0.0711	0.4865	

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Last Visit (LOCF)																	
Valproate Use	20 mg/kg	0.9554 N	25	12	25	3	4.0000	1.2828	12.4725	0.0121	0.1477	0.0350	0.6229	0.3600	0.1264	0.5936	
		Y	10	4	12	1	4.8000	0.6341	36.3378	0.1353	0.1364	0.0123	1.5130	0.3167	-0.0249	0.6582	
Last Visit (LOCF)																	
Lamotrigine Use	20 mg/kg	0.6914 N	23	9	29	3	3.7826	1.1548	12.3906	0.0210	0.1795	0.0417	0.7723	0.2879	0.0597	0.5160	
		Y	12	7	8	1	4.6667	0.7017	31.0363	0.0697	0.1020	0.0094	1.1125	0.4583	0.0973	0.8193	
Last Visit (LOCF)																	
Levetiracetam Use	20 mg/kg	0.9393 N	24	12	23	3	3.8333	1.2401	11.8490	0.0114	0.1500	0.0351	0.6417	0.3696	0.1268	0.6124	
		Y	11	4	14	1	5.0909	0.6593	39.3118	0.1333	0.1346	0.0125	1.4489	0.2922	-0.0225	0.6069	
Last Visit (LOCF)																	
Rufinamide Use	20 mg/kg	0.0278 N	26	14	29	2	7.8077	1.9568	31.1530	0.0002	0.0635	0.0124	0.3241	0.4695	0.2568	0.6822	
		Y	9	2	8	2	0.8889	0.1603	4.9295	1.0000	1.1667	0.1238	10.9904	-0.0278	-0.4325	0.3770	
Last Visit (LOCF)																	
Baseline Drop Seizure Frequency	20 mg/kg	- <=55	15	7	12	2	-	-	-	-	-	-	-	-	-	-	
		>55 to <=125	11	6	18	2	-	-	-	-	-	-	-	-	-	-	
		>125	9	4	7	0	-	-	-	-	-	-	-	-	-	-	
Last Visit (LOCF)																	
Current AEDs	20 mg/kg	0.7195 <3	7	4	9	1	5.1429	0.7273	36.3677	0.1058	0.0938	0.0072	1.2148	0.4603	0.0401	0.8805	
		>=3	28	12	28	3	4.0000	1.2645	12.6532	0.0141	0.1600	0.0390	0.6568	0.3214	0.1053	0.5376	
Last Visit (LOCF)																	
Prior AEDs	20 mg/kg	0.8284 <6	19	10	21	3	3.6842	1.1887	11.4183	0.0171	0.1500	0.0329	0.6846	0.3835	0.1136	0.6533	
		>=6	16	6	16	1	6.0000	0.8117	44.3512	0.0829	0.1111	0.0116	1.0682	0.3125	0.0473	0.5777	

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

**Adhoc Table: GWEP1414 Any AE (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]		
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI
Age Group	10 mg/kg	0.8116	2-5 years	4	4	5	5	0.9818	0.6722	1.4341	1.0000
			6-11 years	13	10	13	9	1.1053	0.6904	1.7694	
			12-17 years	7	7	12	9	1.2829	0.8814	1.8672	
			18-55 years	11	10	7	5	1.2727	0.7614	2.1275	
Sex	10 mg/kg	0.5148	F	19	17	16	11	1.3014	0.9038	1.8739	0.2075
			M	16	14	21	17	1.0809	0.8185	1.4274	0.6796
Region	10 mg/kg	0.4533	REST OF THE WORLD	1	1	4	1	2.5000	0.5255	11.8945	0.4000
			USA	34	30	33	27	1.0774	0.8758	1.3253	0.5118
Valproate Use	10 mg/kg	0.5103	N	28	25	25	18	1.2401	0.9409	1.6344	0.1622
			Y	7	6	12	10	1.0286	0.6934	1.5258	1.0000
Lamotrigine Use	10 mg/kg	0.9549	N	27	24	29	22	1.1717	0.9173	1.4967	0.2992
			Y	8	7	8	6	1.1667	0.7232	1.8820	1.0000
Levetiracetam Use	10 mg/kg	0.7900	N	27	24	23	17	1.2026	0.9116	1.5865	0.2697
			Y	8	7	14	11	1.1136	0.7625	1.6264	1.0000
Rufinamide Use	10 mg/kg	0.7189	N	23	20	29	22	1.1462	0.8845	1.4855	0.4815
			Y	12	11	8	6	1.2222	0.7912	1.8882	0.5368
Baseline Drop Seizure Frequency	10 mg/kg	0.0863	<=55	10	9	12	10	1.0693	0.7503	1.5238	1.0000
			>55 to <=125	11	11	18	11	1.5833	1.0808	2.3195	0.0259
			>125	14	11	7	7	0.8178	0.5870	1.1393	0.5211
Current AEDs	10 mg/kg	0.6248	<3	11	10	9	8	1.0227	0.7598	1.3766	1.0000
			>=3	24	21	28	20	1.2250	0.9269	1.6189	0.1903
Prior AEDs	10 mg/kg	0.8438	<6	16	14	21	16	1.1484	0.8487	1.5540	0.6745
			>=6	19	17	16	12	1.1930	0.8644	1.6465	0.3791
Age Group	20 mg/kg	0.3115	2-5 years	5	4	5	5	0.8182	0.4859	1.3778	1.0000
			6-11 years	12	12	13	9	1.4170	0.9724	2.0649	0.0957
			12-17 years	7	6	12	9	1.1118	0.6958	1.7766	1.0000
			18-55 years	14	13	7	5	1.3091	0.7966	2.1512	0.2474

Sex	20 mg/kg	0.8281 F	17	15	16	11	1.2834	0.8837	1.8640	0.2245
		M	21	20	21	17	1.1765	0.9362	1.4784	0.3433
Region	20 mg/kg	0.8023 REST OF THE WORLD	5	3	4	1	2.4000	0.3804	15.1433	0.5238
		USA	33	32	33	27	1.1852	0.9981	1.4073	0.1048
Valproate Use	20 mg/kg	0.0819 N	28	27	25	18	1.3393	1.0382	1.7277	0.0199
		Y	10	8	12	10	0.9600	0.6435	1.4323	1.0000
Lamotrigine Use	20 mg/kg	0.8918 N	24	22	29	22	1.2083	0.9523	1.5332	0.1595
		Y	14	13	8	6	1.2381	0.8089	1.8950	0.5273
Levetiracetam Use	20 mg/kg	0.8865 N	25	23	23	17	1.2447	0.9512	1.6287	0.1300
		Y	13	12	14	11	1.1748	0.8571	1.6104	0.5956
Rufinamide Use	20 mg/kg	0.5412 N	29	26	29	22	1.1778	0.9227	1.5034	0.2973
		Y	9	9	8	6	1.3154	0.8562	2.0209	0.2059
Baseline Drop Seizure Frequency	20 mg/kg	0.0955 <=55	17	16	12	10	1.1349	0.8411	1.5314	0.5534
		>55 to <=125	11	11	18	11	1.5833	1.0808	2.3195	0.0259
		>125	10	8	7	7	0.8242	0.5710	1.1898	0.4853
Current AEDs	20 mg/kg	0.3062 <3	9	8	9	8	1.0000	0.7213	1.3863	1.0000
		>=3	29	27	28	20	1.3034	1.0107	1.6809	0.0411
Prior AEDs	20 mg/kg	0.1676 <6	19	16	21	16	1.1000	0.8031	1.5066	0.6984
		>=6	19	19	16	12	1.3260	0.9885	1.7787	0.0348

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table: GWEP1414 Maximal AE Mild (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]		
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI
Age Group	10 mg/kg	0.2234	2-5 years	4	2	5	1	2.5000	0.3355	18.6278	0.5238
			6-11 years	13	5	13	9	0.5556	0.2554	1.2086	0.2377
			12-17 years	7	3	12	5	1.0286	0.3471	3.0477	1.0000
			18-55 years	11	1	7	3	0.2121	0.0272	1.6564	0.2451
Sex	10 mg/kg	0.6422	F	19	7	16	8	0.7368	0.3425	1.5850	0.5060
			M	16	4	21	10	0.5250	0.2010	1.3711	0.1908
Region	10 mg/kg	0.7894	REST OF THE WORLD	1	0	4	1	0.8333	0.0533	13.0174	1.0000
			USA	34	11	33	17	0.6384	0.3592	1.1346	0.1407
Valproate Use	10 mg/kg	0.5562	N	28	10	25	13	0.6868	0.3682	1.2813	0.2756
			Y	7	1	12	5	0.3429	0.0496	2.3719	0.3331
Lamotrigine Use	10 mg/kg	0.0354	N	27	11	29	13	0.9127	0.5037	1.6538	0.7928
			Y	8	0	8	5	0.0909	0.0058	1.4131	0.0256
Levetiracetam Use	10 mg/kg	0.6707	N	27	10	23	13	0.6553	0.3566	1.2042	0.2552
			Y	8	1	14	5	0.3500	0.0491	2.4934	0.3512
Rufinamide Use	10 mg/kg	0.5619	N	23	6	29	14	0.5404	0.2466	1.1839	0.1523
			Y	12	5	8	4	0.8333	0.3180	2.1841	1.0000
Baseline Drop Seizure Frequency	10 mg/kg	0.4931	<=55	10	3	12	8	0.4500	0.1610	1.2577	0.1984
			>55 to <=125	11	4	18	7	0.9351	0.3534	2.4738	1.0000
			>125	14	4	7	3	0.6667	0.2027	2.1928	0.6384
Current AEDs	10 mg/kg	0.1070	<3	11	7	9	5	1.1455	0.5490	2.3901	1.0000
			>=3	24	4	28	13	0.3590	0.1349	0.9556	0.0371
Prior AEDs	10 mg/kg	0.6422	<6	16	4	21	10	0.5250	0.2010	1.3711	0.1908
			>=6	19	7	16	8	0.7368	0.3425	1.5850	0.5060
Age Group	20 mg/kg	0.8390	2-5 years	5	2	5	1	2.0000	0.2560	15.6235	1.0000
			6-11 years	12	8	13	9	0.9630	0.5613	1.6521	1.0000
			12-17 years	7	2	12	5	0.6857	0.1779	2.6428	0.6562

			18-55 years	14	5	7	3	0.8333	0.2754	2.5212	1.0000
Sex	20 mg/kg	0.7028	F	17	7	16	8	0.8235	0.3889	1.7439	0.7319
			M	21	10	21	10	1.0000	0.5303	1.8859	1.0000
Region	20 mg/kg	0.9211	REST OF THE WORLD	5	1	4	1	0.8000	0.0697	9.1797	1.0000
			USA	33	16	33	17	0.9412	0.5807	1.5255	1.0000
Valproate Use	20 mg/kg	0.3193	N	28	15	25	13	1.0302	0.6183	1.7167	1.0000
			Y	10	2	12	5	0.4800	0.1173	1.9637	0.3808
Lamotrigine Use	20 mg/kg	0.4287	N	24	11	29	13	1.0224	0.5648	1.8509	1.0000
			Y	14	6	8	5	0.6857	0.3054	1.5394	0.6594
Levetiracetam Use	20 mg/kg	0.0535	N	25	9	23	13	0.6369	0.3379	1.2004	0.2461
			Y	13	8	14	5	1.7231	0.7560	3.9270	0.2568
Rufinamide Use	20 mg/kg	0.3212	N	29	11	29	14	0.7857	0.4317	1.4301	0.5964
			Y	9	6	8	4	1.3333	0.5798	3.0664	0.6372
Baseline Drop Seizure Frequency	20 mg/kg	0.9062	<=55	17	11	12	8	0.9706	0.5700	1.6527	1.0000
			>55 to <=125	11	3	18	7	0.7013	0.2276	2.1611	0.6942
			>125	10	3	7	3	0.7000	0.1954	2.5075	0.6437
Current AEDs	20 mg/kg	0.8505	<3	9	5	9	5	1.0000	0.4376	2.2851	1.0000
			>=3	29	12	28	13	0.8912	0.4949	1.6049	0.7921
Prior AEDs	20 mg/kg	0.2091	<6	19	11	21	10	1.2158	0.6739	2.1936	0.5450
			>=6	19	6	16	8	0.6316	0.2772	1.4390	0.3167

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table: GWEP1414 Maximal AE Moderate (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]		
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI
Age Group	10 mg/kg	0.2004	2-5 years	4	2	5	3	0.8571	0.2833	2.5933	1.0000
			6-11 years	13	5	13	0	11.0000	0.6698	180.6517	0.0391
			12-17 years	7	3	12	4	1.2639	0.4274	3.7375	1.0000
			18-55 years	11	5	7	0	7.3333	0.4672	115.1002	0.1013
Sex	10 mg/kg	0.6341	F	19	7	16	3	1.9649	0.6052	6.3799	0.2853
			M	16	8	21	4	2.6250	0.9573	7.1980	0.0768
Region	10 mg/kg	0.2685	REST OF THE WORLD	1	1	4	0	7.5000	0.4801	117.1570	0.2000
			USA	34	14	33	7	1.8781	0.8920	3.9544	0.1142
Valproate Use	10 mg/kg	0.6355	N	28	11	25	3	3.2738	1.0293	10.4129	0.0317
			Y	7	4	12	4	1.7143	0.6147	4.7807	0.3765
Lamotrigine Use	10 mg/kg	0.2394	N	27	10	29	6	1.7901	0.7531	4.2551	0.2397
			Y	8	5	8	1	5.0000	0.7402	33.7768	0.1189
Levetiracetam Use	10 mg/kg	0.2527	N	27	11	23	2	4.6852	1.1551	19.0038	0.0119
			Y	8	4	14	5	1.4000	0.5218	3.7563	0.6619
Rufinamide Use	10 mg/kg	0.6980	N	23	10	29	6	2.1014	0.8969	4.9236	0.1295
			Y	12	5	8	1	3.3333	0.4734	23.4707	0.3246
Baseline Drop Seizure Frequency	10 mg/kg	0.1723	<=55	10	4	12	1	4.8000	0.6341	36.3378	0.1353
			>55 to <=125	11	6	18	3	3.2727	1.0205	10.4960	0.0478
			>125	14	5	7	3	0.8333	0.2754	2.5212	1.0000
Current AEDs	10 mg/kg	0.5349	<3	11	2	9	1	1.6364	0.1754	15.2632	1.0000
			>=3	24	13	28	6	2.5278	1.1369	5.6203	0.0213
Prior AEDs	10 mg/kg	0.9651	<6	16	7	21	4	2.2969	0.8101	6.5125	0.1514
			>=6	19	8	16	3	2.2456	0.7123	7.0794	0.1667
Age Group	20 mg/kg	0.1213	2-5 years	5	1	5	3	0.4286	0.0917	2.0033	0.5238
			6-11 years	12	2	13	0	5.3846	0.2844	101.9588	0.2200
			12-17 years	7	2	12	4	0.9028	0.2534	3.2168	1.0000
			18-55 years	14	6	7	0	6.9333	0.4452	107.9659	0.0609



Sex	20 mg/kg	0.6040 F	17	6	16	3	1.8824	0.5635	6.2879	0.4384
		M	21	5	21	4	1.2500	0.3890	4.0170	1.0000
Region	20 mg/kg	0.3707 REST OF THE WORLD	5	2	4	0	4.1667	0.2547	68.1647	0.4444
		USA	33	9	33	7	1.2667	0.5518	2.9078	0.7746
Valproate Use	20 mg/kg	0.2956 N	28	8	25	3	2.3810	0.7083	8.0033	0.1834
		Y	10	3	12	4	0.9000	0.2606	3.1088	1.0000
Lamotrigine Use	20 mg/kg	0.6762 N	24	7	29	6	1.4097	0.5469	3.6336	0.5335
		Y	14	4	8	1	2.2857	0.3057	17.0894	0.6130
Levetiracetam Use	20 mg/kg	0.0614 N	25	8	23	2	3.6800	0.8699	15.5679	0.0753
		Y	13	3	14	5	0.6462	0.1915	2.1801	0.6776
Rufinamide Use	20 mg/kg	0.5352 N	29	8	29	6	1.3333	0.5287	3.3623	0.7598
		Y	9	3	8	1	2.6667	0.3423	20.7773	0.5765
Baseline Drop Seizure Frequency	20 mg/kg	0.3214 <=55	17	3	12	1	2.1176	0.2494	17.9831	0.6221
		>55 to <=125	11	5	18	3	2.7273	0.8059	9.2292	0.1975
		>125	10	3	7	3	0.7000	0.1954	2.5075	0.6437
Current AEDs	20 mg/kg	0.8235 <3	9	2	9	1	2.0000	0.2182	18.3324	1.0000
		>=3	29	9	28	6	1.4483	0.5930	3.5373	0.5497
Prior AEDs	20 mg/kg	0.0207 <6	19	1	21	4	0.2763	0.0338	2.2601	0.3451
		>=6	19	10	16	3	2.8070	0.9292	8.4801	0.0776

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Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

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Adhoc Table: GWEP1423 Total Seizure Responder (subgroups)

Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			Odds Ratio		Risk Difference				
				N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Total Seizures <=25pct Age Group	20 mg/kg	0.8347	2-5 years	5	5	7	4	1.7500	0.9213	3.3240	0.2045	-	-	-	0.4286	0.0620	0.7952
			6-11 years	16	14	17	8	1.8594	1.0867	3.1816	0.0255	7.8750	1.3531	45.8319	0.4044	0.1171	0.6917
			12-17 years	9	7	11	5	1.7111	0.8200	3.5704	0.1968	4.2000	0.5861	30.0950	0.3232	-0.0772	0.7237
			18-55 years	12	8	7	2	2.3333	0.6768	8.0449	0.1698	5.0000	0.6553	38.1518	0.3810	-0.0470	0.8089
Sex	20 mg/kg	0.1869	F	20	18	21	9	2.1000	1.2547	3.5147	0.0025	12.0000	2.1980	65.5154	0.4714	0.2223	0.7206
			M	22	16	21	10	1.5273	0.9112	2.5598	0.1243	2.9333	0.8235	10.4485	0.2511	-0.0322	0.5344
Region	20 mg/kg	0.5291	REST OF THE WORLD	3	2	4	2	1.3333	0.3763	4.7248	1.0000	2.0000	0.0902	44.3504	0.1667	-0.5577	0.8910
			USA	39	32	38	17	1.8341	1.2509	2.6891	0.0009	5.6471	1.9997	15.9470	0.3731	0.1744	0.5719
Valproate Use	20 mg/kg	0.7750	N	30	25	30	14	1.7857	1.1796	2.7033	0.0061	5.7143	1.7237	18.9439	0.3667	0.1438	0.5895
			Y	12	9	12	5	1.8000	0.8546	3.7912	0.2138	4.2000	0.7379	23.9068	0.3333	-0.0379	0.7046
Lamotrigine Use	20 mg/kg	0.1754	N	25	22	28	12	2.0533	1.3073	3.2252	0.0013	9.7778	2.3643	40.4363	0.4514	0.2282	0.6746
			Y	17	12	14	7	1.4118	0.7693	2.5907	0.2883	2.4000	0.5471	10.5273	0.2059	-0.1340	0.5458
Levetiracetam Use	20 mg/kg	0.3508	N	28	23	24	9	2.1905	1.2706	3.7762	0.0015	7.6667	2.1485	27.3573	0.4464	0.2063	0.6865
			Y	14	11	18	10	1.4143	0.8616	2.3214	0.2656	2.9333	0.6046	14.2306	0.2302	-0.0843	0.5446
Rufinamide Use	20 mg/kg	0.0119	N	29	21	31	16	1.4030	0.9328	2.1103	0.1175	2.4609	0.8385	7.2228	0.2080	-0.0316	0.4476
			Y	13	13	11	3	3.6667	1.3969	9.6244	0.0002	-	-	-	0.7273	0.4641	0.9905
Baseline Drop Seizure Frequency	20 mg/kg	0.2830	<=45	19	14	6	4	1.1053	0.5908	2.0677	1.0000	1.4000	0.1931	10.1485	0.0702	-0.3558	0.4962
			>45 to <=110	15	13	20	8	2.1667	1.2225	3.8400	0.0069	9.7500	1.7168	55.3725	0.4667	0.1915	0.7418
			>110	8	7	16	7	2.0000	1.0821	3.6965	0.0791	9.0000	0.8876	91.2547	0.4375	0.1034	0.7716
Current AEDs	20 mg/kg	0.1843	<3	9	9	6	3	2.0000	0.8985	4.4518	0.0440	-	-	-	0.5000	0.0999	0.9001
			>=3	33	25	36	16	1.7045	1.1277	2.5764	0.0136	3.9063	1.3911	10.9688	0.3131	0.0947	0.5316
Prior AEDs	20 mg/kg	0.5835	<6	25	20	22	11	1.6000	1.0085	2.5384	0.0373	4.0000	1.1033	14.5014	0.3000	0.0388	0.5612
			>=6	17	14	20	8	2.0588	1.1526	3.6776	0.0176	7.0000	1.5087	32.4782	0.4235	0.1426	0.7045
Total Seizures <=50pct Age Group	20 mg/kg	0.6247	2-5 years	5	4	7	2	2.8000	0.8017	9.7789	0.2424	10.0000	0.6477	154.3968	0.5143	0.0296	0.9990
			6-11 years	16	9	17	5	1.9125	0.8143	4.4918	0.1663	3.0857	0.7335	12.9806	0.2684	-0.0572	0.5940
			12-17 years	9	7	11	2	4.2778	1.1643	15.7173	0.0216	15.7500	1.7543	141.4042	0.5960	0.2414	0.9505
			18-55 years	12	5	7	1	2.9167	0.4216	20.1775	0.3331	4.2857	0.3857	47.6247	0.2738	-0.1070	0.6546
Sex	20 mg/kg	0.8595	F	20	11	21	4	2.8875	1.0982	7.5923	0.0247	5.1944	1.2798	21.0825	0.3595	0.0843	0.6347
			M	22	14	21	6	2.2273	1.0559	4.6981	0.0329	4.3750	1.2105	15.8123	0.3506	0.0718	0.6295
Region	20 mg/kg	0.8828	REST OF THE WORLD	3	2	4	1	2.6667	0.4083	17.4153	0.4857	6.0000	0.2215	162.5313	0.4167	-0.2650	1.0000
			USA	39	23	38	9	2.4900	1.3290	4.6655	0.0025	4.6319	1.7331	12.3794	0.3529	0.1477	0.5581
Valproate Use	20 mg/kg	0.1211	N	30	17	30	9	1.8889	1.0062	3.5460	0.0673	3.0513	1.0533	8.8388	0.2667	0.0251	0.5082
			Y	12	8	12	1	8.0000	1.1744	54.4966	0.0094	22.0000	2.0504	236.0547	0.5833	0.2742	0.8925
Lamotrigine Use	20 mg/kg	0.6984	N	25	16	28	8	2.2400	1.1632	4.3136	0.0136	4.4444	1.3971	14.1382	0.3543	0.1025	0.6061
			Y	17	9	14	2	3.7059	0.9520	14.4261	0.0570	6.7500	1.1449	39.7959	0.3866	0.0867	0.6864
Levetiracetam Use	20 mg/kg	0.2456	N	28	16	24	3	4.5714	1.5125	13.8165	0.0013	9.3333	2.2503	38.7114	0.4464	0.2204	0.6725
			Y	14	9	18	7	1.6531	0.8222	3.3236	0.2852	2.8286	0.6656	12.0196	0.2540	-0.0833	0.5912

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Rufinamide Use	20 mg/kg	0.6091 N Y	29	17	31	8	2.2716	1.1616	4.4420	0.0177	4.0729	1.3661	12.1428	0.3281	0.0918	0.5645
			13	8	11	2	3.3846	0.8994	12.7363	0.0472	7.2000	1.0809	47.9617	0.4336	0.0844	0.7827
Baseline Drop Seizure Frequency	20 mg/kg	0.5736 <=45 >45 to <=110 >110	19	10	6	2	1.5789	0.4712	5.2914	0.6447	2.2222	0.3253	15.1801	0.1930	-0.2460	0.6319
			15	9	20	4	3.0000	1.1384	7.9062	0.0322	6.0000	1.3310	27.0474	0.4000	0.0964	0.7036
			8	6	16	4	3.0000	1.1739	7.6666	0.0324	9.0000	1.2678	63.8916	0.5000	0.1325	0.8675
Current AEDs	20 mg/kg	0.5185 <3 >=3	9	6	6	1	4.0000	0.6303	25.3852	0.1189	10.0000	0.7765	128.7748	0.5000	0.0713	0.9287
			33	19	36	9	2.3030	1.2179	4.3550	0.0075	4.0714	1.4643	11.3201	0.3258	0.1057	0.5459
Prior AEDs	20 mg/kg	0.3566 <6 >=6	25	15	22	7	1.8857	0.9455	3.7610	0.0799	3.2143	0.9661	10.6946	0.2818	0.0084	0.5552
			17	10	20	3	3.9216	1.2840	11.9771	0.0075	8.0952	1.6980	38.5952	0.4382	0.1568	0.7197
Total Seizures <=75pct																
Age Group	20 mg/kg	0.5703 2-5 years 6-11 years 12-17 years 18-55 years	5	2	7	0	-	-	-	0.1515	-	-	-	0.4000	-0.0294	0.8294
			16	7	17	2	3.7188	0.9030	15.3148	0.0570	5.8333	0.9881	34.4359	0.3199	0.0326	0.6072
			9	6	11	1	7.3333	1.0697	50.2714	0.0166	20.0000	1.6762	238.6296	0.5758	0.2240	0.9275
			12	0	7	0										
Sex	20 mg/kg	0.9044 F M	20	5	21	1	5.2500	0.6706	41.1029	0.0931	6.6667	0.7034	63.1872	0.2024	-0.0081	0.4129
			22	10	21	2	4.7727	1.1823	19.2669	0.0157	7.9167	1.4734	42.5378	0.3593	0.1163	0.6023
Region	20 mg/kg	0.3236 REST OF THE WORLD USA	3	2	4	0	-	-	-	0.1429	-	-	-	0.6667	0.1332	1.0000
			39	13	38	3	4.2222	1.3063	13.6475	0.0101	5.8333	1.5061	22.5933	0.2544	0.0834	0.4254
Valproate Use	20 mg/kg	0.2131 N Y	30	10	30	3	3.3333	1.0173	10.9221	0.0575	4.5000	1.0944	18.5030	0.2333	0.0334	0.4333
			12	5	12	0	-	-	-	0.0373	-	-	-	0.4167	0.1377	0.6956
Lamotrigine Use	20 mg/kg	0.5139 N Y	25	11	28	2	6.1600	1.5087	25.1506	0.0031	10.2143	1.9799	52.6964	0.3686	0.1519	0.5853
			17	4	14	1	3.2941	0.4140	26.2099	0.3445	4.0000	0.3922	40.7941	0.1639	-0.0787	0.4065
Levetiracetam Use	20 mg/kg	0.1187 N Y	28	9	24	0	-	-	-	0.0022	-	-	-	0.3214	0.1484	0.4944
			14	6	18	3	2.5714	0.7768	8.5123	0.1317	3.7500	0.7347	19.1402	0.2619	-0.0493	0.5731
Rufinamide Use	20 mg/kg	0.1826 N Y	29	9	31	3	3.2069	0.9615	10.6958	0.0544	4.2000	1.0080	17.4995	0.2136	0.0156	0.4115
			13	6	11	0	-	-	-	0.0162	-	-	-	0.4615	0.1905	0.7325
Baseline Drop Seizure Frequency	20 mg/kg	0.5465 <=45 >45 to <=110 >110	19	6	6	1	1.8947	0.2812	12.7658	0.6372	2.3077	0.2190	24.3160	0.1491	-0.2150	0.5133
			15	6	20	1	8.0000	1.0737	59.6090	0.0274	12.6667	1.3209	121.4694	0.3500	0.0843	0.6157
			8	3	16	1	6.0000	0.7362	48.8999	0.0909	9.0000	0.7543	107.3833	0.3125	-0.0433	0.6683
Current AEDs	20 mg/kg	0.2592 <3 >=3	9	5	6	0	-	-	-	0.0440	-	-	-	0.5556	0.2309	0.8802
			33	10	36	3	3.6364	1.0946	12.0808	0.0299	4.7826	1.1844	19.3118	0.2197	0.0388	0.4006
Prior AEDs	20 mg/kg	0.1294 <6 >=6	25	9	22	3	2.6400	0.8158	8.5429	0.1026	3.5625	0.8223	15.4346	0.2236	-0.0129	0.4602
			17	6	20	0	-	-	-	0.0053	-	-	-	0.3529	0.1258	0.5801

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1423 Convulsive Seizure Responder (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			Odds Ratio		Risk Difference				
		p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Convulsive Seizures <=25pct																	
Age Group	20 mg/kg	0.8100	2-5 years	5	4	7	5	1.1200	0.5897	2.1274	1.0000	1.6000	0.1036	24.7035	0.0857	-0.3990	0.5704
			6-11 years	16	12	17	9	1.4167	0.8339	2.4068	0.2818	2.6667	0.6076	11.7030	0.2206	-0.0977	0.5389
			12-17 years	9	7	11	6	1.4259	0.7499	2.7114	0.3742	2.9167	0.4070	20.8993	0.2323	-0.1681	0.6328
			18-55 years	12	9	7	2	2.6250	0.7781	8.8559	0.0739	7.5000	0.9214	61.0472	0.4643	0.0495	0.8790
Sex	20 mg/kg	0.3245	F	20	17	21	11	1.6227	1.0374	2.5384	0.0431	5.1515	1.1534	23.0092	0.3262	0.0614	0.5910
			M	22	15	21	11	1.3017	0.7912	2.1413	0.3580	1.9481	0.5636	6.7335	0.1580	-0.1310	0.4470
Region	20 mg/kg	0.8065	REST OF THE WORLD	3	2	4	2	1.3333	0.3763	4.7248	1.0000	2.0000	0.0902	44.3504	0.1667	-0.5577	0.8910
			USA	39	30	38	20	1.4615	1.0328	2.0682	0.0327	3.0000	1.1260	7.9932	0.2429	0.0363	0.4495
Valproate Use	20 mg/kg	0.9676	N	30	23	30	16	1.4375	0.9746	2.1202	0.1033	2.8750	0.9483	8.7166	0.2333	-0.0007	0.4674
			Y	12	9	12	6	1.5000	0.7805	2.8829	0.4003	3.0000	0.5326	16.8970	0.2500	-0.1242	0.6242
Lamotrigine Use	20 mg/kg	0.6319	N	25	21	28	16	1.4700	1.0220	2.1145	0.0410	3.9375	1.0675	14.5229	0.2686	0.0357	0.5015
			Y	17	11	14	6	1.5098	0.7502	3.0384	0.2895	2.4444	0.5719	10.4475	0.2185	-0.1262	0.5632
Levetiracetam Use	20 mg/kg	0.4134	N	28	21	24	10	1.8000	1.0707	3.0260	0.0231	4.2000	1.2918	13.6559	0.3333	0.0791	0.5876
			Y	14	11	18	12	1.1786	0.7697	1.8047	0.6942	1.8333	0.3667	9.1661	0.1190	-0.1869	0.4250
Rufinamide Use	20 mg/kg	0.0397	N	29	20	31	18	1.1877	0.8073	1.7475	0.4307	1.6049	0.5549	4.6417	0.1090	-0.1329	0.3509
			Y	13	12	11	4	2.5385	1.1436	5.6345	0.0078	21.0000	1.9410	227.2046	0.5594	0.2404	0.8785
Baseline Drop Seizure Frequency	20 mg/kg	0.0574	<=45	19	11	6	4	0.8684	0.4384	1.7202	1.0000	0.6875	0.1002	4.7189	-0.0877	-0.5254	0.3500
			>45 to <=110	15	13	20	9	1.9259	1.1409	3.2511	0.0158	7.9444	1.4087	44.8038	0.4167	0.1389	0.6944
			>110	8	8	16	9	1.7778	1.1540	2.7387	0.0538	-	-	-	0.4375	0.1944	0.6806
Current AEDs	20 mg/kg	0.3910	<3	9	8	6	3	1.7778	0.7730	4.0885	0.2352	8.0000	0.5804	110.2682	0.3889	-0.0608	0.8386
			>=3	33	24	36	19	1.3780	0.9490	2.0010	0.1352	2.3860	0.8712	6.5345	0.1995	-0.0234	0.4224
Prior AEDs	20 mg/kg	0.8289	<6	25	19	22	12	1.3933	0.8969	2.1645	0.1388	2.6389	0.7609	9.1524	0.2145	-0.0525	0.4816
			>=6	17	13	20	10	1.5294	0.9171	2.5507	0.1734	3.2500	0.7834	13.4824	0.2647	-0.0331	0.5625
Convulsive Seizures <=50pct																	
Age Group	20 mg/kg	0.7070	2-5 years	5	4	7	4	1.4000	0.6437	3.0448	0.5758	3.0000	0.2111	42.6239	0.2286	-0.2787	0.7358
			6-11 years	16	8	17	4	2.1250	0.7918	5.7027	0.1571	3.2500	0.7334	14.4018	0.2647	-0.0526	0.5820
			12-17 years	9	6	11	3	2.4444	0.8386	7.1257	0.1748	5.3333	0.7829	36.3311	0.3939	-0.0112	0.7991
			18-55 years	12	5	7	0	-	-	-	0.1060	-	-	-	0.4167	0.1377	0.6956
Sex	20 mg/kg	0.5128	F	20	10	21	6	1.7500	0.7817	3.9175	0.2082	2.5000	0.6880	9.0838	0.2143	-0.0779	0.5064
			M	22	13	21	5	2.4818	1.0710	5.7510	0.0305	4.6222	1.2402	17.2263	0.3528	0.0782	0.6274
Region	20 mg/kg	0.7279	REST OF THE WORLD	3	2	4	1	2.6667	0.4083	17.4153	0.4857	6.0000	0.2215	162.5313	0.4167	-0.2650	1.0000
			USA	39	21	38	10	2.0462	1.1160	3.7515	0.0200	3.2667	1.2533	8.5141	0.2753	0.0653	0.4853
Valproate Use	20 mg/kg	0.0552	N	30	15	30	10	1.5000	0.8071	2.7878	0.2949	2.0000	0.7046	5.6770	0.1667	-0.0792	0.4126
			Y	12	8	12	1	8.0000	1.1744	54.4966	0.0094	22.0000	2.0504	236.0547	0.5833	0.2742	0.8925
Lamotrigine Use	20 mg/kg	0.5852	N	25	16	28	8	2.2400	1.1632	4.3136	0.0136	4.4444	1.3971	14.1382	0.3543	0.1025	0.6061
			Y	17	7	14	3	1.9216	0.6067	6.0856	0.2802	2.5667	0.5178	12.7233	0.1975	-0.1202	0.5152
Levetiracetam Use	20 mg/kg	0.1179	N	28	15	24	3	4.2857	1.4078	13.0467	0.0030	8.0769	1.9533	33.3988	0.4107	0.1835	0.6379
			Y	14	8	18	8	1.2857	0.6465	2.5568	0.7224	1.6667	0.4074	6.8185	0.1270	-0.2193	0.4732

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Rufinamide Use	20 mg/kg	0.3587 N Y	29	15	31	9	1.7816	0.9272	3.4234	0.1133	2.6190	0.9038	7.5892	0.2269	-0.0152	0.4690
			13	8	11	2	3.3846	0.8994	12.7363	0.0472	7.2000	1.0809	47.9617	0.4336	0.0844	0.7827
Baseline Drop Seizure Frequency	20 mg/kg	0.6212 <=45 >45 to <=110 >110	19	9	6	2	1.4211	0.4167	4.8464	0.6609	1.8000	0.2635	12.2959	0.1404	-0.2986	0.5793
			15	9	20	4	3.0000	1.1384	7.9062	0.0322	6.0000	1.3310	27.0474	0.4000	0.0964	0.7036
			8	5	16	5	2.0000	0.8103	4.9364	0.2038	3.6667	0.6187	21.7299	0.3125	-0.0926	0.7176
Current AEDs	20 mg/kg	0.6055 <3 >=3	9	6	6	3	1.3333	0.5293	3.3589	0.6224	2.0000	0.2408	16.6124	0.1667	-0.3382	0.6716
			33	17	36	8	2.3182	1.1569	4.6450	0.0138	3.7188	1.3132	10.5304	0.2929	0.0749	0.5109
Prior AEDs	20 mg/kg	0.3476 <6 >=6	25	13	22	7	1.6343	0.7968	3.3519	0.2384	2.3214	0.7049	7.6448	0.2018	-0.0743	0.4779
			17	10	20	4	2.9412	1.1233	7.7009	0.0210	5.7143	1.3263	24.6205	0.3882	0.0959	0.6806
Convulsive Seizures <=75pct Age Group	20 mg/kg	0.2672 2-5 years 6-11 years 12-17 years 18-55 years	5	3	7	1	4.2000	0.5972	29.5385	0.2222	9.0000	0.5629	143.8876	0.4571	-0.0444	0.9587
			16	3	17	1	3.1875	0.3684	27.5771	0.3353	3.6923	0.3422	39.8375	0.1287	-0.0929	0.3502
			9	6	11	0	-	-	-	0.0022	-	-	-	0.6667	0.3587	0.9746
			12	0	7	0	-	-	-	-	-	-	-	-	-	-
Sex	20 mg/kg	0.9336 F M	20	6	21	1	6.3000	0.8303	47.8011	0.0448	8.5714	0.9268	79.2717	0.2524	0.0319	0.4729
			22	6	21	1	5.7273	0.7516	43.6430	0.0946	7.5000	0.8172	68.8291	0.2251	0.0179	0.4323
Region	20 mg/kg	0.6077 REST OF THE WORLD USA	3	1	4	0	-	-	-	0.4286	-	-	-	0.3333	-0.2001	0.8668
			39	11	38	2	5.3590	1.2711	22.5932	0.0127	7.0714	1.4485	34.5213	0.2294	0.0713	0.3875
Valproate Use	20 mg/kg	0.3140 N Y	30	8	30	2	4.0000	0.9248	17.3018	0.0797	5.0909	0.9806	26.4297	0.2000	0.0183	0.3817
			12	4	12	0	-	-	-	0.0932	-	-	-	0.3333	0.0666	0.6001
Lamotrigine Use	20 mg/kg	0.5201 N Y	25	9	28	2	5.0400	1.2012	21.1476	0.0160	7.3125	1.3989	38.2250	0.2886	0.0776	0.4995
			17	3	14	0	-	-	-	0.2323	-	-	-	0.1765	-0.0047	0.3577
Levetiracetam Use	20 mg/kg	0.6587 N Y	28	6	24	1	5.1429	0.6650	39.7735	0.1072	6.2727	0.6977	56.3972	0.1726	0.0009	0.3443
			14	6	18	1	7.7143	1.0456	56.9144	0.0265	12.7500	1.3071	124.3645	0.3730	0.0930	0.6530
Rufinamide Use	20 mg/kg	0.3692 N Y	29	8	31	2	4.2759	0.9886	18.4933	0.0392	5.5238	1.0628	28.7084	0.2113	0.0271	0.3956
			13	4	11	0	-	-	-	0.0983	-	-	-	0.3077	0.0568	0.5586
Baseline Drop Seizure Frequency	20 mg/kg	0.8515 <=45 >45 to <=110 >110	19	5	6	0	-	-	-	0.2887	-	-	-	0.2632	0.0652	0.4612
			15	4	20	1	5.3333	0.6620	42.9707	0.1411	6.9091	0.6833	69.8635	0.2167	-0.0267	0.4600
			8	3	16	1	6.0000	0.7362	48.8999	0.0909	9.0000	0.7543	107.3833	0.3125	-0.0433	0.6683
Current AEDs	20 mg/kg	0.5025 <3 >=3	9	3	6	0	-	-	-	0.2286	-	-	-	0.3333	0.0254	0.6413
			33	9	36	2	4.9091	1.1429	21.0866	0.0202	6.3750	1.2631	32.1757	0.2172	0.0478	0.3865
Prior AEDs	20 mg/kg	0.9845 <6 >=6	25	7	22	1	6.1600	0.8209	46.2245	0.0516	8.1667	0.9160	72.8124	0.2345	0.0382	0.4309
			17	5	20	1	5.8824	0.7593	45.5734	0.0752	7.9167	0.8217	76.2772	0.2441	0.0074	0.4808

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1423 Non-Convulsive Seizure Responder (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]				Odds Ratio		Risk Difference			
				N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Non-Convulsive Seizures <=25pct																	
Age Group	20 mg/kg	0.0776	2-5 years	4	4	6	1	6.0000	1.0026	35.9078	0.0476	-	-	-	0.8333	0.5351	1.0000
			6-11 years	14	11	10	5	1.5714	0.7981	3.0940	0.2038	3.6667	0.6187	21.7299	0.2857	-0.0914	0.6629
			12-17 years	9	9	10	5	2.0000	1.0761	3.7171	0.0325	-	-	-	0.5000	0.1901	0.8099
			18-55 years	8	5	6	4	0.9375	0.4298	2.0449	1.0000	0.8333	0.0905	7.6753	-0.0417	-0.5465	0.4631
Sex	20 mg/kg	0.7261	F	17	14	19	8	1.9559	1.1046	3.4631	0.0189	6.4167	1.3700	30.0545	0.4025	0.1159	0.6891
			M	18	15	13	7	1.5476	0.8982	2.6664	0.1143	4.2857	0.8223	22.3366	0.2949	-0.0262	0.6159
Region	20 mg/kg	0.6748	REST OF THE WORLD	2	2	3	2	1.5000	0.6739	3.3388	1.0000	-	-	-	0.3333	-0.2001	0.8668
			USA	33	27	29	13	1.8252	1.1818	2.8188	0.0034	5.5385	1.7570	17.4581	0.3699	0.1461	0.5937
Valproate Use	20 mg/kg	0.9366	N	24	20	25	12	1.7361	1.1120	2.7106	0.0157	5.4167	1.4330	20.4742	0.3533	0.1072	0.5995
			Y	11	9	7	3	1.9091	0.7765	4.6938	0.1414	6.0000	0.7045	51.1016	0.3896	-0.0421	0.8213
Lamotrigine Use	20 mg/kg	0.7408	N	21	17	20	8	2.0238	1.1383	3.5982	0.0109	6.3750	1.5572	26.0982	0.4095	0.1369	0.6821
			Y	14	12	12	7	1.4694	0.8702	2.4810	0.1904	4.2857	0.6499	28.2624	0.2738	-0.0600	0.6076
Levetiracetam Use	20 mg/kg	0.0886	N	24	21	19	7	2.3750	1.2933	4.3616	0.0010	12.0000	2.6057	55.2627	0.5066	0.2525	0.7606
			Y	11	8	13	8	1.1818	0.6738	2.0728	0.6792	1.6667	0.2941	9.4453	0.1119	-0.2612	0.4850
Rufinamide Use	20 mg/kg	0.4961	N	27	22	24	12	1.6296	1.0510	2.5269	0.0357	4.4000	1.2503	15.4844	0.3148	0.0669	0.5628
			Y	8	7	8	3	2.3333	0.9186	5.9266	0.1189	11.6667	0.9224	147.5633	0.5000	0.0937	0.9063
Baseline Drop Seizure Frequency	20 mg/kg	0.6208	<=45	16	13	6	4	1.2188	0.6604	2.2493	0.5853	2.1667	0.2624	17.8923	0.1458	-0.2771	0.5687
			>45 to <=110	11	9	14	5	2.2909	1.0757	4.8789	0.0419	8.1000	1.2333	53.2003	0.4610	0.1220	0.8001
			>110	8	7	12	6	1.7500	0.9381	3.2644	0.1577	7.0000	0.6470	75.7349	0.3750	0.0109	0.7391
Current AEDs	20 mg/kg	0.1481	<3	8	8	5	2	2.5000	0.8545	7.3141	0.0350	-	-	-	0.6000	0.1706	1.0000
			>=3	27	21	27	13	1.6154	1.0400	2.5090	0.0473	3.7692	1.1579	12.2699	0.2963	0.0511	0.5415
Prior AEDs	20 mg/kg	0.3527	<6	19	15	13	7	1.4662	0.8423	2.5521	0.2439	3.2143	0.6816	15.1586	0.2510	-0.0762	0.5782
			>=6	16	14	19	8	2.0781	1.1884	3.6339	0.0125	9.6250	1.6909	54.7885	0.4539	0.1791	0.7288
Non-Convulsive Seizures <=50pct																	
Age Group	20 mg/kg	0.0948	2-5 years	4	4	6	1	6.0000	1.0026	35.9078	0.0476	-	-	-	0.8333	0.5351	1.0000
			6-11 years	14	9	10	5	1.2857	0.6180	2.6747	0.6785	1.8000	0.3447	9.3987	0.1429	-0.2559	0.5416
			12-17 years	9	7	10	3	2.5926	0.9451	7.1119	0.0698	8.1667	1.0271	64.9365	0.4778	0.0848	0.8708
			18-55 years	8	2	6	2	0.7500	0.1441	3.9035	1.0000	0.6667	0.0647	6.8713	-0.0833	-0.5653	0.3987
Sex	20 mg/kg	0.1407	F	17	12	19	5	2.6824	1.1902	6.0452	0.0180	6.7200	1.5609	28.9310	0.4427	0.1493	0.7362
			M	18	10	13	6	1.2037	0.5871	2.4679	0.7224	1.4583	0.3480	6.1120	0.0940	-0.2611	0.4492
Region	20 mg/kg	0.2711	REST OF THE WORLD	2	1	3	2	0.7500	0.1514	3.7159	1.0000	0.5000	0.0128	19.5624	-0.1667	-1.0000	0.7078
			USA	33	21	29	9	2.0505	1.1245	3.7390	0.0126	3.8889	1.3484	11.2160	0.3260	0.0909	0.5612
Valproate Use	20 mg/kg	0.5424	N	24	17	25	9	1.9676	1.0991	3.5223	0.0222	4.3175	1.2995	14.3444	0.3483	0.0867	0.6100
			Y	11	5	7	2	1.5909	0.4173	6.0654	0.6371	2.0833	0.2752	15.7716	0.1688	-0.2768	0.6145
Lamotrigine Use	20 mg/kg	0.7520	N	21	14	20	7	1.9048	0.9752	3.7203	0.0629	3.7143	1.0211	13.5107	0.3167	0.0262	0.6071
			Y	14	8	12	4	1.7143	0.6833	4.3008	0.2671	2.6667	0.5382	13.2121	0.2381	-0.1338	0.6100
Levetiracetam Use	20 mg/kg	0.1888	N	24	15	19	4	2.9688	1.1781	7.4811	0.0125	6.2500	1.5752	24.7980	0.4145	0.1478	0.6812
			Y	11	7	13	7	1.1818	0.6030	2.3163	0.6968	1.5000	0.2902	7.7530	0.0979	-0.2948	0.4906

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Rufinamide Use	20 mg/kg	0.3048 N Y	27	16	24	9	1.5802	0.8640	2.8904	0.1637	2.4242	0.7847	7.4892	0.2176	-0.0505	0.4857
			8	6	8	2	3.0000	0.8466	10.6309	0.1319	9.0000	0.9362	86.5218	0.5000	0.0757	0.9243
Baseline Drop Seizure Frequency	20 mg/kg	0.2211 <=45 >45 to <=110 >110	16	8	6	3	1.0000	0.3913	2.5555	1.0000	1.0000	0.1531	6.5308	0.0000	-0.4691	0.4691
			11	7	14	3	2.9697	0.9905	8.9038	0.0486	6.4167	1.0911	37.7347	0.4221	0.0657	0.7785
			8	7	12	5	2.1000	1.0233	4.3094	0.0697	9.8000	0.8989	106.8451	0.4583	0.0973	0.8193
Current AEDs	20 mg/kg	0.0198 <3 >=3	8	8	5	1	5.0000	0.8662	28.8608	0.0070	-	-	-	0.8000	0.4494	1.0000
			27	14	27	10	1.4000	0.7595	2.5806	0.4117	1.8308	0.6178	5.4250	0.1481	-0.1140	0.4103
Prior AEDs	20 mg/kg	0.4126 <6 >=6	19	12	13	6	1.3684	0.6931	2.7017	0.4727	2.0000	0.4764	8.3955	0.1700	-0.1771	0.5171
			16	10	19	5	2.3750	1.0225	5.5163	0.0442	4.6667	1.1082	19.6519	0.3618	0.0529	0.6708
Non-Convulsive Seizures <=75pct Age Group	20 mg/kg	0.3794 2-5 years 6-11 years 12-17 years 18-55 years	4	0	6	1	-	-	-	1.0000	-	-	-	-0.1667	-0.4649	0.1315
Sex	20 mg/kg	0.2253 F M	14	8	10	4	1.4286	0.5900	3.4590	0.6802	2.0000	0.3843	10.4093	0.1714	-0.2278	0.5707
			9	6	10	2	3.3333	0.8879	12.5140	0.0698	8.0000	1.0006	63.9625	0.4667	0.0713	0.8620
			8	2	6	1	1.5000	0.1739	12.9350	1.0000	1.6667	0.1145	24.2556	0.0833	-0.3397	0.5064
			17	8	19	3	2.9804	0.9396	9.4537	0.0704	4.7407	0.9981	22.5169	0.3127	0.0243	0.6011
Region	20 mg/kg	0.8901 REST OF THE WORLD USA	2	1	3	1	1.5000	0.1806	12.4593	1.0000	2.0000	0.0511	78.2496	0.1667	-0.7078	1.0000
			33	15	29	7	1.8831	0.8934	3.9693	0.1118	2.6190	0.8786	7.8069	0.2132	-0.0173	0.4436
Valproate Use	20 mg/kg	0.5107 N Y	24	12	25	6	2.0833	0.9322	4.6558	0.0792	3.1667	0.9371	10.7009	0.2600	-0.0008	0.5208
			11	4	7	2	1.2727	0.3113	5.2038	1.0000	1.4286	0.1841	11.0853	0.0779	-0.3612	0.5170
Lamotrigine Use	20 mg/kg	0.3573 N Y	21	9	20	6	1.4286	0.6217	3.2824	0.5204	1.7500	0.4822	6.3512	0.1286	-0.1632	0.4203
			14	7	12	2	3.0000	0.7629	11.7979	0.1100	5.0000	0.7905	31.6269	0.3333	-0.0029	0.6696
Levetiracetam Use	20 mg/kg	0.2736 N Y	24	11	19	3	2.9028	0.9416	8.9485	0.0521	4.5128	1.0361	19.6567	0.3004	0.0423	0.5585
			11	5	13	5	1.1818	0.4596	3.0387	1.0000	1.3333	0.2612	6.8054	0.0699	-0.3257	0.4656
Rufinamide Use	20 mg/kg	0.1591 N Y	27	11	24	7	1.3968	0.6456	3.0222	0.5580	1.6696	0.5193	5.3685	0.1157	-0.1439	0.3754
			8	5	8	1	5.0000	0.7402	33.7768	0.1189	11.6667	0.9224	147.5633	0.5000	0.0937	0.9063
Baseline Drop Seizure Frequency	20 mg/kg	0.6132 <=45 >45 to <=110 >110	16	6	6	2	1.1250	0.3077	4.1131	1.0000	1.2000	0.1663	8.6586	0.0417	-0.4039	0.4873
			11	6	14	3	2.5455	0.8150	7.9504	0.1153	4.4000	0.7699	25.1450	0.3312	-0.0332	0.6956
			8	4	12	3	2.0000	0.6023	6.6417	0.3563	3.0000	0.4466	20.1530	0.2500	-0.1743	0.6743
Current AEDs	20 mg/kg	0.0298 <3 >=3	8	6	5	0	-	-	-	0.0210	-	-	-	0.7500	0.4499	1.0000
			27	10	27	8	1.2500	0.5837	2.6767	0.7734	1.3971	0.4482	4.3546	0.0741	-0.1766	0.3248
Prior AEDs	20 mg/kg	0.3291 <6 >=6	19	9	13	5	1.2316	0.5343	2.8389	0.7249	1.4400	0.3429	6.0480	0.0891	-0.2578	0.4360
			16	7	19	3	2.7708	0.8534	8.9967	0.1316	4.1481	0.8545	20.1377	0.2796	-0.0136	0.5728

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table: GWEP1423 CGIC Responder [VMI, MI, SI] (subgroups) (ITT Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1] Factor Level	Active		Placebo		Relative Risk [2]			Odds Ratio			Risk Difference				
				N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI	
Last Visit (LOCF)	Age Group	20 mg/kg	0.6104	2-5 years	5	5	7	2	-	-	-	0.0278	-	-	-	0.7143	0.3796	1.0000
				6-11 years	15	11	17	4	3.1167	1.2549	7.7403	0.0118	0.1119	0.0226	0.5551	0.4980	0.1968	0.7993
				12-17 years	9	7	11	5	1.7111	0.8200	3.5704	0.1968	0.2381	0.0332	1.7061	0.3232	-0.0772	0.7237
				18-55 years	11	9	7	2	2.8636	0.8591	9.5455	0.0491	0.0889	0.0094	0.8385	0.5325	0.1276	0.9374
Last Visit (LOCF)	Sex	20 mg/kg	0.8294	F	20	16	21	6	2.8000	1.3754	5.7001	0.0016	0.1000	0.0235	0.4255	0.5143	0.2534	0.7752
				M	20	16	21	7	2.4000	1.2613	4.5667	0.0044	0.1250	0.0301	0.5185	0.4667	0.1995	0.7338
Last Visit (LOCF)	Region	20 mg/kg	0.3493	REST OF THE WORLD	3	3	4	1	-	-	-	0.1429	-	-	-	0.7500	0.3257	1.0000
				USA	37	29	38	12	2.4820	1.5089	4.0826	<.0001	0.1273	0.0450	0.3600	0.4680	0.2694	0.6666
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.5032	N	29	24	30	9	2.7586	1.5581	4.8843	<.0001	0.0893	0.0258	0.3086	0.5276	0.3136	0.7416
				Y	11	8	12	4	2.1818	0.9066	5.2506	0.0995	0.1875	0.0313	1.1221	0.3939	0.0192	0.7686
Last Visit (LOCF)	Lamotrigine Use	20 mg/kg	0.6922	N	23	18	28	9	2.4348	1.3637	4.3472	0.0017	0.1316	0.0370	0.4681	0.4612	0.2196	0.7027
				Y	17	14	14	4	2.8824	1.2234	6.7909	0.0040	0.0857	0.0156	0.4705	0.5378	0.2398	0.8359
Last Visit (LOCF)	Levetiracetam Use	20 mg/kg	0.3467	N	26	22	24	7	2.9011	1.5226	5.5276	0.0001	0.0749	0.0188	0.2982	0.5545	0.3258	0.7832
				Y	14	10	18	6	2.1429	1.0301	4.4578	0.0732	0.2000	0.0438	0.9128	0.3810	0.0594	0.7025
Last Visit (LOCF)	Rufinamide Use	20 mg/kg	0.5803	N	27	22	31	9	2.8066	1.5730	5.0077	<.0001	0.0930	0.0268	0.3222	0.5245	0.3077	0.7413
				Y	13	10	11	4	2.1154	0.9164	4.8831	0.0953	0.1714	0.0289	1.0181	0.4056	0.0405	0.7707
Last Visit (LOCF)	Baseline Drop Seizure Frequency	20 mg/kg	0.7193	<=45	17	13	6	2	2.2941	0.7178	7.3320	0.1310	0.1538	0.0201	1.1760	0.4314	0.0037	0.8591
				>45 to <=110	15	12	20	7	2.2857	1.1949	4.3724	0.0155	0.1346	0.0282	0.6429	0.4500	0.1590	0.7410
				>110	8	7	16	4	3.5000	1.4399	8.5075	0.0078	0.0476	0.0044	0.5152	0.6250	0.3127	0.9373
Last Visit (LOCF)	Current AEDs	20 mg/kg	0.7129	<3	8	7	6	2	2.6250	0.8217	8.3862	0.0909	0.0714	0.0048	1.0592	0.5417	0.1003	0.9830
				>=3	32	25	36	11	2.5568	1.5118	4.3243	0.0001	0.1232	0.0411	0.3693	0.4757	0.2679	0.6834
Last Visit (LOCF)	Prior AEDs	20 mg/kg	0.4746	<6	23	19	22	6	3.0290	1.4927	6.1466	0.0003	0.0789	0.0189	0.3297	0.5534	0.3112	0.7955
				>=6	17	13	20	7	2.1849	1.1373	4.1972	0.0202	0.1657	0.0389	0.7057	0.4147	0.1243	0.7051

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.



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**Adhoc Table: GWEP1423 CGIC Responder [VMI, MI] (subgroups) (ITT Analysis Set, Patients Taking Clobazam)**

Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			Odds Ratio		Risk Difference				
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	p-value (vs. Placebo)	Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Last Visit (LOCF)																		
	Age Group	20 mg/kg	0.2729	2-5 years	5	4	7	0	-	-	-	0.0101	-	-	-	0.8000	0.4494	1.0000
				6-11 years	15	6	17	2	3.4000	0.8041	14.3768	0.1058	0.2000	0.0330	1.2112	0.2824	-0.0091	0.5738
				12-17 years	9	4	11	3	1.6296	0.4858	5.4665	0.6424	0.4688	0.0724	3.0352	0.1717	-0.2462	0.5896
				18-55 years	11	6	7	1	3.8182	0.5751	25.3516	0.1507	0.1389	0.0123	1.5729	0.4026	0.0104	0.7947
Last Visit (LOCF)																		
	Sex	20 mg/kg	0.7118	F	20	11	21	3	3.8500	1.2560	11.8013	0.0088	0.1364	0.0302	0.6152	0.4071	0.1427	0.6716
				M	20	9	21	3	3.1500	0.9932	9.9908	0.0431	0.2037	0.0452	0.9190	0.3071	0.0427	0.5716
Last Visit (LOCF)																		
	Region	20 mg/kg	0.9815	REST OF THE WORLD	3	2	4	1	2.6667	0.4083	17.4153	0.4857	0.1667	0.0062	4.5148	0.4167	-0.2650	1.0000
				USA	37	18	38	5	3.6973	1.5315	8.9259	0.0011	0.1599	0.0511	0.5002	0.3549	0.1613	0.5485
Last Visit (LOCF)																		
	Valproate Us	20 mg/kg	0.3836	N	29	16	30	4	4.1379	1.5694	10.9102	0.0009	0.1250	0.0347	0.4505	0.4184	0.2003	0.6365
				Y	11	4	12	2	2.1818	0.4931	9.6538	0.3707	0.3500	0.0496	2.4673	0.1970	-0.1570	0.5509
Last Visit (LOCF)																		
	Lamotrigine l	20 mg/kg	0.1871	N	23	13	28	3	5.2754	1.7080	16.2936	0.0007	0.0923	0.0216	0.3951	0.4581	0.2253	0.6908
				Y	17	7	14	3	1.9216	0.6067	6.0856	0.2802	0.3896	0.0786	1.9313	0.1975	-0.1202	0.5152
Last Visit (LOCF)																		
	Levetiracetar	20 mg/kg	0.5366	N	26	12	24	2	5.5385	1.3790	22.2436	0.0041	0.1061	0.0206	0.5468	0.3782	0.1570	0.5994
				Y	14	8	18	4	2.5714	0.9689	6.8247	0.0683	0.2143	0.0462	0.9942	0.3492	0.0266	0.6718
Last Visit (LOCF)																		
	Rufinamide l	20 mg/kg	0.5852	N	27	14	31	4	4.0185	1.5019	10.7517	0.0018	0.1376	0.0377	0.5014	0.3895	0.1671	0.6119
				Y	13	6	11	2	2.5385	0.6359	10.1335	0.2108	0.2593	0.0395	1.7000	0.2797	-0.0744	0.6338
Last Visit (LOCF)																		
	Baseline Droj	20 mg/kg	0.4292	<=45	17	8	6	1	2.8235	0.4400	18.1173	0.3401	0.2250	0.0215	2.3564	0.3039	-0.0772	0.6850
				>45 to <=110	15	6	20	3	2.6667	0.7924	8.9739	0.1292	0.2647	0.0532	1.3166	0.2500	-0.0432	0.5432
				>110	8	6	16	2	6.0000	1.5450	23.3007	0.0047	0.0476	0.0054	0.4216	0.6250	0.2840	0.9660
Last Visit (LOCF)																		
	Current AEDs:	20 mg/kg	0.4423	<3	8	6	6	1	4.5000	0.7194	28.1474	0.1026	0.0667	0.0046	0.9702	0.5833	0.1603	1.0000
				>=3	32	14	36	5	3.1500	1.2765	7.7733	0.0077	0.2074	0.0641	0.6713	0.2986	0.0929	0.5043
Last Visit (LOCF)																		
	Prior AEDs	20 mg/kg	0.7717	<6	23	12	22	3	3.8261	1.2458	11.7504	0.0106	0.1447	0.0334	0.6276	0.3854	0.1359	0.6349
				>=6	17	8	20	3	3.1373	0.9847	9.9948	0.0689	0.1985	0.0420	0.9387	0.3206	0.0364	0.6048

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

**Adhoc Table: GWEP1423 Any AE (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
				N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.0948	2-5 years	5	4	7	6	0.9231	0.5223	1.6313	1.0000
			6-11 years	15	15	18	10	1.7530	1.1587	2.6521	0.0036
			12-17 years	9	9	11	7	1.5200	0.9588	2.4096	0.0941
			18-55 years	12	11	7	7	0.9436	0.7235	1.2307	1.0000
Sex	20 mg/kg	0.6809	F	20	19	21	16	1.2469	0.9620	1.6161	0.1836
			M	21	20	22	14	1.4966	1.0759	2.0818	0.0212
Region	20 mg/kg	0.5982	REST OF THE WORLD	2	1	5	1	2.5000	0.2676	23.3593	1.0000
			USA	39	38	38	29	1.2767	1.0619	1.5351	0.0068
Valproate Use	20 mg/kg	0.3578	N	29	27	31	23	1.2482	0.9872	1.5783	0.0817
			Y	12	12	12	7	1.6667	1.0333	2.6882	0.0373
Lamotrigine Use	20 mg/kg	0.9928	N	24	23	29	21	1.3234	1.0414	1.6818	0.0306
			Y	17	16	14	9	1.4641	0.9734	2.2019	0.0671
Levetiracetam Use	20 mg/kg	0.0962	N	27	27	25	17	1.4592	1.1111	1.9163	0.0014
			Y	14	12	18	13	1.1728	0.8138	1.6903	0.4264
Rufinamide Use	20 mg/kg	0.6717	N	29	27	31	19	1.5043	1.1170	2.0258	0.0052
			Y	12	12	12	11	1.0870	0.8685	1.3604	1.0000
Baseline Drop Seizure Frequency	20 mg/kg	0.5137	<=45	19	18	6	3	1.8500	0.8728	3.9213	0.0312
			>45 to <=110	14	14	21	16	1.2889	0.9949	1.6698	0.0689
			>110	8	7	16	11	1.2319	0.7935	1.9124	0.6214
Current AEDs	20 mg/kg	0.7904	<3	8	8	7	6	1.1624	0.8040	1.6806	0.4667
			>=3	33	31	36	24	1.3992	1.0909	1.7945	0.0064
Prior AEDs	20 mg/kg	0.9713	<6	24	23	23	17	1.2891	0.9908	1.6772	0.0479
			>=6	17	16	20	13	1.4259	1.0070	2.0192	0.0481

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table: GWEP1423 Maximal AE Mild (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
				N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.2698	2-5 years	5	1	7	3	0.4667	0.0664	3.2821	0.5758
			6-11 years	15	4	18	7	0.6857	0.2474	1.9009	0.7120
			12-17 years	9	5	11	3	2.0370	0.6592	6.2943	0.3618
			18-55 years	12	1	7	2	0.2917	0.0319	2.6643	0.5232
Sex	20 mg/kg	0.3193	F	20	7	21	7	1.0500	0.4488	2.4567	1.0000
			M	21	4	22	8	0.5238	0.1850	1.4830	0.3102
Region	20 mg/kg	0.9457	REST OF THE WORLD	2	0	5	1	0.6667	0.0372	11.9356	1.0000
			USA	39	11	38	14	0.7733	0.4094	1.4606	0.4716
Valproate Use	20 mg/kg	0.0312	N	29	7	31	14	0.5345	0.2518	1.1347	0.1094
			Y	12	4	12	1	4.0000	0.5201	30.7623	0.3168
Lamotrigine Use	20 mg/kg	0.5172	N	24	6	29	11	0.6591	0.2860	1.5188	0.3838
			Y	17	5	14	4	1.0294	0.3398	3.1183	1.0000
Levetiracetam Use	20 mg/kg	0.1884	N	27	9	25	8	1.0417	0.4767	2.2763	1.0000
			Y	14	2	18	7	0.3673	0.0899	1.5012	0.2349
Rufinamide Use	20 mg/kg	0.6080	N	29	8	31	10	0.8552	0.3921	1.8650	0.7817
			Y	12	3	12	5	0.6000	0.1831	1.9660	0.6668
Baseline Drop Seizure Frequency	20 mg/kg	0.7380	<=45	19	2	6	0	1.7500	0.0952	32.1827	1.0000
			>45 to <=110	14	5	21	9	0.8491	0.3740	1.9276	0.7366
			>110	8	4	16	6	1.3077	0.5371	3.1840	0.6734
Current AEDs	20 mg/kg	0.6859	<3	8	3	7	4	0.6563	0.2183	1.9732	0.6193
			>=3	33	8	36	11	0.7934	0.3642	1.7284	0.5997
Prior AEDs	20 mg/kg	0.5799	<6	24	7	23	10	0.6708	0.3080	1.4610	0.3715
			>=6	17	4	20	5	0.9412	0.2996	2.9571	1.0000

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table: GWEP1423 Maximal AE Moderate (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
		p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.0349	2-5 years	5	2	7	2	1.3333	0.3297	5.3929	1.0000
			6-11 years	15	9	18	3	3.2232	1.1514	9.0230	0.0143
			12-17 years	9	0	11	4	0.1333	0.0081	2.1896	0.0941
			18-55 years	12	9	7	5	1.0629	0.5999	1.8832	1.0000
Sex	20 mg/kg	0.9939	F	20	11	21	8	1.4438	0.7358	2.8330	0.3543
			M	21	9	22	6	1.5714	0.6768	3.6485	0.3475
Region	20 mg/kg	0.2929	REST OF THE WORLD	2	1	5	0	6.0000	0.3351	107.4202	0.2857
			USA	39	19	38	14	1.3112	0.7818	2.1991	0.3594
Valproate Use	20 mg/kg	0.1372	N	29	15	31	8	2.0043	1.0026	4.0070	0.0624
			Y	12	5	12	6	0.8333	0.3469	2.0021	1.0000
Lamotrigine Use	20 mg/kg	0.7253	N	24	12	29	9	1.6111	0.8210	3.1615	0.2590
			Y	17	8	14	5	1.3176	0.5548	3.1292	0.7168
Levetiracetam Use	20 mg/kg	0.9845	N	27	14	25	9	1.4403	0.7620	2.7223	0.2781
			Y	14	6	18	5	1.5429	0.5910	4.0276	0.4651
Rufinamide Use	20 mg/kg	0.9885	N	29	12	31	8	1.6034	0.7669	3.3524	0.2749
			Y	12	8	12	6	1.3333	0.6668	2.6661	0.6802
Baseline Drop Seizure Frequency	20 mg/kg	0.8442	<=45	19	11	6	3	1.1579	0.4768	2.8120	1.0000
			>45 to <=110	14	7	21	7	1.5000	0.6739	3.3388	0.4830
			>110	8	2	16	4	1.0000	0.2299	4.3491	1.0000
Current AEDs	20 mg/kg	0.8134	<3	8	4	7	2	1.7500	0.4487	6.8247	0.6084
			>=3	33	16	36	12	1.4545	0.8139	2.5994	0.2280
Prior AEDs	20 mg/kg	0.7011	<6	24	11	23	6	1.7569	0.7786	3.9648	0.2270
			>=6	17	9	20	8	1.3235	0.6577	2.6633	0.5174

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table: GWEP1423 Any SAE (subgroups) (Safety Analysis Set, Patients Taking Clobazam)**

Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
		p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.7605	2-5 years	5	2	7	1	2.2222	0.3958	12.4777	0.5227
			6-11 years	15	5	18	0	13.0625	0.7804	218.6309	0.0127
			12-17 years	9	3	11	1	2.8000	0.5020	15.6179	0.2848
			18-55 years	12	2	7	0	3.0769	0.1683	56.2472	0.5088
Sex	20 mg/kg	0.1790	F	20	5	21	2	2.3048	0.5855	9.0720	0.2379
			M	21	7	22	0	15.6818	0.9513	258.5032	0.0036
Valproate Use	20 mg/kg	0.3549	N	29	7	31	2	3.2000	0.8363	12.2441	0.0756
			Y	12	5	12	0	11.0000	0.6749	179.2926	0.0373
Lamotrigine Use	20 mg/kg	0.9827	N	24	9	29	2	4.5600	1.2576	16.5343	0.0145
			Y	17	3	14	0	5.8333	0.3265	104.2157	0.2323
Levetiracetam Use	20 mg/kg	0.3263	N	27	7	25	0	13.9286	0.8365	231.9321	0.0102
			Y	14	5	18	2	2.7867	0.7348	10.5676	0.1948
Rufinamide Use	20 mg/kg	0.6560	N	29	11	31	2	4.9067	1.3727	17.5382	0.0043
			Y	12	1	12	0	3.0000	0.1342	67.0557	1.0000
Baseline Drop Seizure Frequency	20 mg/kg	0.9581	<=45	19	6	6	0	4.5500	0.2924	70.7936	0.2778
			>45 to <=110	14	4	21	1	4.4000	0.7821	24.7545	0.1336
			>110	8	2	16	1	3.1481	0.4920	20.1423	0.2490
Current AEDs	20 mg/kg	0.6422	<3	8	1	7	0	2.6667	0.1256	56.6255	1.0000
			>=3	33	11	36	2	5.0059	1.3835	18.1128	0.0046
Prior AEDs	20 mg/kg	0.3566	<6	24	4	23	1	2.8800	0.4950	16.7556	0.3475
			>=6	17	8	20	1	6.6111	1.3115	33.3258	0.0055
Region	20 mg/kg	0.6158	REST OF THE WORLD	2	0	5	0	2.0000	0.0511	78.2496	-
			USA	39	12	38	2	4.8750	1.3496	17.6088	0.0063

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

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**Adhoc Table:** GWEP1414 Total Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio			Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Total Seizures <=25pct																		
Age Group	10 mg/kg	0.5787	2-5 years		4	4	9	5	1.8000	1.0034	3.2289	0.2280	-	-	-	0.4444	0.1198	0.7691
				6-11 years	14	10	24	9	1.9048	1.0312	3.5183	0.0911	4.1667	1.0032	17.3050	0.3393	0.0335	0.6451
				12-17 years	7	5	20	13	1.0989	0.6225	1.9398	1.0000	1.3462	0.2055	8.8194	0.0643	-0.3303	0.4589
				18-55 years	12	8	23	10	1.5333	0.8297	2.8337	0.2890	2.6000	0.6062	11.1518	0.2319	-0.1031	0.5668
Sex	10 mg/kg	0.2853	F		21	16	32	13	1.8755	1.1578	3.0379	0.0133	4.6769	1.3708	15.9564	0.3557	0.1064	0.6049
				M	16	11	44	24	1.2604	0.8228	1.9308	0.3857	1.8333	0.5454	6.1622	0.1420	-0.1286	0.4127
Region	10 mg/kg	0.2486	REST OF THE WORLD		1	0	14	5	-	-	-	1.0000	-	-	-	-0.3571	-0.6081	-0.1061
				USA	36	27	62	32	1.4531	1.0700	1.9734	0.0319	2.8125	1.1389	6.9453	0.2339	0.0455	0.4222
Valproate Use	10 mg/kg	0.7378	N		30	21	46	20	1.6100	1.0746	2.4121	0.0339	3.0333	1.1448	8.0376	0.2652	0.0475	0.4830
				Y	7	6	30	17	1.5126	0.9789	2.3373	0.2173	4.5882	0.4900	42.9601	0.2905	-0.0236	0.6045
Lamotrigine Use	10 mg/kg	0.7371	N		27	20	51	27	1.3992	0.9942	1.9691	0.0905	2.5397	0.9145	7.0527	0.2113	-0.0034	0.4260
				Y	10	7	25	10	1.7500	0.9334	3.2812	0.1464	3.5000	0.7271	16.8480	0.3000	-0.0429	0.6429
Levetiracetam Use	10 mg/kg	0.0717	N		28	18	53	25	1.3629	0.9165	2.0265	0.1658	2.0160	0.7855	5.1741	0.1712	-0.0515	0.3938
				Y	9	9	23	12	1.9167	1.2960	2.8345	0.0131	-	-	-	0.4783	0.2741	0.6824
Rufinamide Use	10 mg/kg	0.5675	N		25	19	56	27	1.5763	1.1113	2.2359	0.0284	3.4012	1.1820	9.7874	0.2779	0.0654	0.4904
				Y	12	8	20	10	1.3333	0.7366	2.4135	0.4709	2.0000	0.4525	8.8407	0.1667	-0.1785	0.5119
Current AEDs	10 mg/kg	0.7627	<3		12	9	25	14	1.3393	0.8313	2.1577	0.3065	2.3571	0.5121	10.8502	0.1900	-0.1229	0.5029
				>=3	25	18	51	23	1.5965	1.0818	2.3561	0.0308	3.1304	1.1146	8.7920	0.2690	0.0462	0.4918
Prior AEDs	10 mg/kg	0.7267	<6		16	13	31	20	1.2594	0.8861	1.7898	0.3211	2.3833	0.5562	10.2122	0.1673	-0.0875	0.4222
				>=6	21	14	45	17	1.7647	1.0901	2.8568	0.0364	3.2941	1.1084	9.7897	0.2889	0.0425	0.5353
Baseline Drop Seizure Frequency	10 mg/kg	0.4539	<=55		12	7	22	11	1.1667	0.6182	2.2016	0.7289	1.4000	0.3385	5.7902	0.0833	-0.2652	0.4318
				>55 to <=125	11	9	32	16	1.6364	1.0491	2.5525	0.0856	4.5000	0.8374	24.1834	0.3182	0.0319	0.6045
				>125	14	11	22	10	1.7286	1.0141	2.9463	0.0833	4.4000	0.9549	20.2740	0.3312	0.0320	0.6303
Age Group	20 mg/kg	0.3407	2-5 years		5	5	9	5	1.8000	1.0034	3.2289	0.2208	-	-	-	0.4444	0.1198	0.7691
				6-11 years	11	9	24	9	2.1818	1.2133	3.9235	0.0275	7.5000	1.3153	42.7655	0.4432	0.1441	0.7423
				12-17 years	7	7	20	13	1.5385	1.1154	2.1220	0.1369	-	-	-	0.3500	0.1410	0.5590
				18-55 years	13	8	23	10	1.4154	0.7509	2.6679	0.4887	2.0800	0.5188	8.3389	0.1806	-0.1525	0.5137
Sex	20 mg/kg	0.6059	F		15	12	32	13	1.9692	1.2072	3.2124	0.0146	5.8462	1.3733	24.8866	0.3938	0.1293	0.6582
				M	21	17	44	24	1.4841	1.0561	2.0857	0.0548	3.5417	1.0245	12.2429	0.2641	0.0408	0.4873
Region	20 mg/kg	0.6497	REST OF THE WORLD		5	4	14	5	2.2400	0.9785	5.1280	0.1409	7.2000	0.6220	83.3415	0.4429	0.0117	0.8740
				USA	31	25	62	32	1.5625	1.1618	2.1015	0.0073	3.9063	1.4075	10.8413	0.2903	0.1037	0.4769
Valproate Use	20 mg/kg	0.7076	N		26	20	46	20	1.7692	1.1967	2.6158	0.0072	4.3333	1.4677	12.7942	0.3344	0.1182	0.5507
				Y	10	9	30	17	1.5882	1.0916	2.3108	0.0696	6.8824	0.7714	61.4062	0.3333	0.0764	0.5903
Lamotrigine Use	20 mg/kg	0.9900	N		24	20	51	27	1.5741	1.1492	2.1560	0.0120	4.4444	1.3304	14.8470	0.3039	0.1014	0.5064
				Y	12	9	25	10	1.8750	1.0491	3.3511	0.0789	4.5000	0.9723	20.8270	0.3500	0.0387	0.6613
Levetiracetam Use	20 mg/kg	0.9437	N		24	19	53	25	1.6783	1.1814	2.3844	0.0124	4.2560	1.3844	13.0844	0.3200	0.1091	0.5308
				Y	12	10	23	12	1.5972	1.0023	2.5453	0.1390	4.5833	0.8170	25.7136	0.3116	0.0181	0.6051
Rufinamide Use	20 mg/kg	0.7802	N		27	22	56	27	1.6900	1.2203	2.3404	0.0044	4.7259	1.5677	14.2468	0.3327	0.1362	0.5291
				Y	9	7	20	10	1.5556	0.8882	2.7243	0.2341	3.5000	0.5789	21.1608	0.2778	-0.0712	0.6268
Current AEDs	20 mg/kg	0.2082	<3		8	8	25	14	1.7857	1.2616	2.5276	0.0313	-	-	-	0.4400	0.2454	0.6346
				>=3	28	21	51	23	1.6630	1.1479	2.4094	0.0172	3.6522	1.3199	10.1060	0.2990	0.0884	0.5097

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Prior AEDs	20 mg/kg	0.3235 <6	19	18	31	20	1.4684	1.1079	1.9463	0.0182	9.9000	1.1603	84.4705	0.3022	0.1061	0.4983
		>=6	17	11	45	17	1.7128	1.0248	2.8628	0.0861	3.0196	0.9437	9.6615	0.2693	0.0016	0.5370
Baseline Drop Seizure Frequency	20 mg/kg	0.7744 <=55	15	13	22	11	1.7333	1.0914	2.7529	0.0353	6.5000	1.1789	35.8392	0.3667	0.0960	0.6373
		>55 to <=125	11	9	32	16	1.6364	1.0491	2.5525	0.0856	4.5000	0.8374	24.1834	0.3182	0.0319	0.6045
		>125	10	7	22	10	1.5400	0.8353	2.8391	0.2654	2.8000	0.5700	13.7540	0.2455	-0.1066	0.5975
Total Seizures <=50pct																
Age Group	10 mg/kg	0.6363 2-5 years	4	2	9	3	1.5000	0.3901	5.7680	1.0000	2.0000	0.1814	22.0564	0.1667	-0.4121	0.7454
		6-11 years	14	8	24	3	4.5714	1.4451	14.4608	0.0076	9.3333	1.8704	46.5732	0.4464	0.1554	0.7375
		12-17 years	7	3	20	2	4.2857	0.8929	20.5702	0.0913	6.7500	0.8335	54.6632	0.3286	-0.0609	0.7180
		18-55 years	12	5	23	1	9.5833	1.2581	72.9990	0.0118	15.7143	1.5608	158.2111	0.3732	0.0821	0.6643
Sex	10 mg/kg	0.4823 F	21	12	32	4	4.5714	1.7009	12.2867	0.0008	9.3333	2.4000	36.2964	0.4464	0.2057	0.6871
		M	16	6	44	5	3.3000	1.1667	9.3343	0.0528	4.6800	1.1831	18.5135	0.2614	0.0063	0.5164
Region	10 mg/kg	- REST OF THE WORLD	1	0	14	0	-	-	-	-	-	-	-	-	-	-
		USA	36	18	62	9	3.4444	1.7333	6.8447	0.0003	5.8889	2.2495	15.4163	0.3548	0.1695	0.5402
Valproate Use	10 mg/kg	0.2014 N	30	13	46	6	3.3222	1.4186	7.7805	0.0057	5.0980	1.6609	15.6481	0.3029	0.1006	0.5052
		Y	7	5	30	3	7.1429	2.2140	23.0442	0.0023	22.5000	2.9617	170.9325	0.6143	0.2628	0.9657
Lamotrigine Use	10 mg/kg	0.6370 N	27	13	51	5	4.9111	1.9574	12.3220	0.0004	8.5429	2.5928	28.1470	0.3834	0.1781	0.5888
		Y	10	5	25	4	3.1250	1.0494	9.3063	0.0814	5.2500	1.0214	26.9844	0.3400	-0.0016	0.6816
Levetiracetam Use	10 mg/kg	0.6861 N	28	11	53	4	5.2054	1.8238	14.8568	0.0016	7.9265	2.2251	28.2367	0.3174	0.1230	0.5118
		Y	9	7	23	5	3.5778	1.5285	8.3743	0.0057	12.6000	1.9659	80.7567	0.5604	0.2407	0.8801
Rufinamide Use	10 mg/kg	0.7932 N	25	15	56	8	4.2000	2.0506	8.6024	<.0001	9.0000	3.0089	26.9202	0.4571	0.2444	0.6699
		Y	12	3	20	1	5.0000	0.5842	42.7971	0.1361	6.3333	0.5756	69.6820	0.2000	-0.0630	0.4630
Current AEDs	10 mg/kg	0.9869 <3	12	7	25	4	3.6458	1.3179	10.0857	0.0183	7.3500	1.5313	35.2778	0.4233	0.1096	0.7371
		>=3	25	11	51	5	4.4880	1.7485	11.5193	0.0018	7.2286	2.1455	24.3543	0.3420	0.1310	0.5530
Prior AEDs	10 mg/kg	0.2928 <6	16	7	31	5	2.7125	1.0219	7.2003	0.0746	4.0444	1.0222	16.0020	0.2762	0.0008	0.5516
		>=6	21	11	45	4	5.8929	2.1240	16.3492	0.0002	11.2750	2.9613	42.9285	0.4349	0.2057	0.6641
Baseline Drop Seizure Frequency	10 mg/kg	0.0345 <=55	12	3	22	4	1.3750	0.3668	5.1545	0.6769	1.5000	0.2747	8.1894	0.0682	-0.2251	0.3614
		>55 to <=125	11	8	32	2	11.6364	2.8988	46.7106	<.0001	40.0000	5.6808	281.6485	0.6648	0.3885	0.9410
		>125	14	7	22	3	3.6667	1.1325	11.8714	0.0262	6.3333	1.2706	31.5677	0.3636	0.0650	0.6622
Age Group	20 mg/kg	0.1192 2-5 years	5	2	9	3	1.2000	0.2911	4.9465	1.0000	1.3333	0.1387	12.8180	0.0667	-0.4618	0.5951
		6-11 years	11	7	24	3	5.0909	1.6137	16.0605	0.0039	12.2500	2.1846	68.6923	0.5114	0.1978	0.8249
		12-17 years	7	6	20	2	8.5714	2.2240	33.0345	0.0006	54.0000	4.1241	707.0580	0.7571	0.4665	1.0000
		18-55 years	13	7	23	1	12.3846	1.7068	89.8645	0.0013	25.6667	2.6214	251.3033	0.4950	0.2115	0.7785
Sex	20 mg/kg	0.4278 F	15	11	32	4	5.8667	2.2325	15.4165	<.0001	19.2500	4.0797	90.8318	0.6083	0.3569	0.8598
		M	21	11	44	5	4.6095	1.8361	11.5722	0.0007	8.5800	2.4217	30.3990	0.4102	0.1769	0.6435
Region	20 mg/kg	0.0730 REST OF THE WORLD	5	4	14	0	-	-	-	0.0013	-	-	-	0.8000	0.4494	1.0000
		USA	31	18	62	9	4.0000	2.0385	7.8488	<.0001	8.1538	2.9874	22.2556	0.4355	0.2409	0.6301
Valproate Use	20 mg/kg	0.1803 N	26	14	46	6	4.1282	1.8061	9.4358	0.0003	7.7778	2.4539	24.6523	0.4080	0.1931	0.6229
		Y	10	8	30	3	8.0000	2.6172	24.4540	<.0001	36.0000	5.0942	254.4084	0.7000	0.4298	0.9702
Lamotrigine Use	20 mg/kg	0.4700 N	24	15	51	5	6.3750	2.6225	15.4970	<.0001	15.3333	4.4424	52.9247	0.5270	0.3168	0.7371
		Y	12	7	25	4	3.6458	1.3179	10.0857	0.0183	7.3500	1.5313	35.2778	0.4233	0.1096	0.7371
Levetiracetam Use	20 mg/kg	0.1687 N	24	15	53	4	8.2813	3.0712	22.3298	<.0001	20.4167	5.4971	75.8291	0.5495	0.3432	0.7559
		Y	12	7	23	5	2.6833	1.0790	6.6730	0.0587	5.0400	1.1065	22.9560	0.3659	0.0400	0.6919
Rufinamide Use	20 mg/kg	0.5257 N	27	17	56	8	4.4074	2.1804	8.9089	<.0001	10.2000	3.4576	30.0903	0.4868	0.2829	0.6907
		Y	9	5	20	1	11.1111	1.5072	81.9129	0.0055	23.7500	2.1490	262.4717	0.5056	0.1672	0.8440

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Current AEDs	20 mg/kg	0.8284 <3	8	6	25	4	4.6875	1.7536	12.5302	0.0040	15.7500	2.2984	107.9304	0.5900	0.2573	0.9227
		>=3	28	16	51	5	5.8286	2.3885	14.2233	<.0001	12.2667	3.7382	40.2523	0.4734	0.2727	0.6740
Prior AEDs	20 mg/kg	0.6420 <6	19	14	31	5	4.5684	1.9594	10.6513	<.0001	14.5600	3.5921	59.0168	0.5756	0.3390	0.8121
		>=6	17	8	45	4	5.2941	1.8293	15.3212	0.0018	9.1111	2.2459	36.9615	0.3817	0.1303	0.6331
Baseline Drop Seizure Frequency	20 mg/kg	0.5238 <=55	15	10	22	4	3.6667	1.4097	9.5373	0.0052	9.0000	1.9582	41.3643	0.4848	0.1969	0.7727
		>55 to <=125	11	7	32	2	10.1818	2.4752	41.8839	0.0003	26.2500	3.9806	173.1073	0.5739	0.2775	0.8703
		>125	10	5	22	3	3.6667	1.0818	12.4279	0.0722	6.3333	1.1143	35.9967	0.3636	0.0222	0.7051
Total Seizures <=75pct																
Age Group	10 mg/kg	0.2486 2-5 years	4	0	9	1	-	-	-	1.0000	-	-	-	-0.1111	-0.3164	0.0942
		6-11 years	14	1	24	1	1.7143	0.1161	25.3124	1.0000	1.7692	0.1019	30.7093	0.0298	-0.1271	0.1866
		12-17 years	7	2	20	0	-	-	-	0.0598	-	-	-	0.2857	-0.0489	0.6204
		18-55 years	12	3	23	1	5.7500	0.6679	49.5043	0.1061	7.3333	0.6704	80.2214	0.2065	-0.0523	0.4653
Sex	10 mg/kg	0.7214 F	21	4	32	2	3.0476	0.6118	15.1805	0.1995	3.5294	0.5842	21.3227	0.1280	-0.0597	0.3157
		M	16	2	44	1	5.5000	0.5345	56.6002	0.1707	6.1429	0.5170	72.9919	0.1023	-0.0657	0.2702
Region	10 mg/kg	- REST OF THE WORLD	1	0	14	0	-	-	-	-	-	-	-	-	-	-
		USA	36	6	62	3	3.4444	0.9168	12.9412	0.0710	3.9333	0.9190	16.8341	0.1183	-0.0147	0.2512
Valproate Use	10 mg/kg	0.4176 N	30	5	46	1	7.6667	0.9415	62.4314	0.0327	9.0000	0.9952	81.3872	0.1449	0.0051	0.2848
		Y	7	1	30	2	2.1429	0.2247	20.4343	0.4775	2.3333	0.1809	30.1013	0.0762	-0.1980	0.3504
Lamotrigine Use	10 mg/kg	0.6804 N	27	2	51	1	3.7778	0.3586	39.7986	0.2738	4.0000	0.3459	46.2605	0.0545	-0.0514	0.1603
		Y	10	4	25	2	5.0000	1.0818	23.1089	0.0428	7.6667	1.1234	52.3207	0.3200	-0.0017	0.6417
Levetiracetam Use	10 mg/kg	0.9116 N	28	3	53	1	5.6786	0.6190	52.0947	0.1167	6.2400	0.6176	63.0466	0.0883	-0.0320	0.2086
		Y	9	3	23	2	3.8333	0.7626	19.2685	0.1206	5.2500	0.7062	39.0294	0.2464	-0.0824	0.5752
Rufinamide Use	10 mg/kg	0.5306 N	25	5	56	3	3.7333	0.9664	14.4225	0.0993	4.4167	0.9650	20.2135	0.1464	-0.0211	0.3139
		Y	12	1	20	0	-	-	-	0.3750	-	-	-	0.0833	-0.0730	0.2397
Current AEDs	10 mg/kg	0.5381 <3	12	1	25	1	2.0833	0.1421	30.5374	1.0000	2.1818	0.1247	38.1819	0.0433	-0.1309	0.2176
		>=3	25	5	51	2	5.1000	1.0627	24.4760	0.0353	6.1250	1.0964	34.2161	0.1608	-0.0048	0.3264
Prior AEDs	10 mg/kg	0.6069 <6	16	3	31	2	2.9063	0.5393	15.6624	0.3202	3.3462	0.4980	22.4851	0.1230	-0.0869	0.3329
		>=6	21	3	45	1	6.4286	0.7101	58.1981	0.0913	7.3333	0.7145	75.2708	0.1206	-0.0351	0.2764
Baseline Drop Seizure Frequency	10 mg/kg	0.4661 <=55	12	2	22	2	1.8333	0.2943	11.4220	0.6015	2.0000	0.2445	16.3622	0.0758	-0.1669	0.3184
		>55 to <=125	11	2	32	1	5.8182	0.5830	58.0684	0.1560	6.8889	0.5584	84.9842	0.1506	-0.0852	0.3863
		>125	14	2	22	0	-	-	-	0.1444	-	-	-	0.1429	-0.0404	0.3262
Age Group	20 mg/kg	0.7558 2-5 years	5	2	9	1	3.6000	0.4248	30.5085	0.5055	5.3333	0.3434	82.8274	0.2889	-0.1871	0.7649
		6-11 years	11	2	24	1	4.3636	0.4410	43.1735	0.2269	5.1111	0.4108	63.5950	0.1402	-0.1014	0.3817
		12-17 years	7	2	20	0	-	-	-	0.0598	-	-	-	0.2857	-0.0489	0.6204
		18-55 years	13	4	23	1	7.0769	0.8814	56.8229	0.0470	9.7778	0.9566	99.9434	0.2642	-0.0002	0.5286
Sex	20 mg/kg	0.2221 F	15	3	32	2	3.2000	0.5959	17.1834	0.3088	3.7500	0.5551	25.3326	0.1375	-0.0816	0.3566
		M	21	7	44	1	14.6667	1.9267	111.6487	0.0011	21.5000	2.4295	190.2639	0.3106	0.1042	0.5170
Region	20 mg/kg	0.1352 REST OF THE WORLD	5	3	14	0	-	-	-	0.0103	-	-	-	0.6000	0.1706	1.0000
		USA	31	7	62	3	4.6667	1.2950	16.8170	0.0143	5.7361	1.3681	24.0494	0.1774	0.0208	0.3340
Valproate Use	20 mg/kg	0.8551 N	26	5	46	1	8.8462	1.0914	71.6983	0.0208	10.7143	1.1770	97.5346	0.1706	0.0133	0.3278
		Y	10	5	30	2	7.5000	1.7151	32.7961	0.0062	14.0000	2.1025	93.2213	0.4333	0.1108	0.7558
Lamotrigine Use	20 mg/kg	0.4619 N	24	6	51	1	12.7500	1.6240	100.1021	0.0036	16.6667	1.8756	148.1002	0.2304	0.0530	0.4078
		Y	12	4	25	2	4.1667	0.8830	19.6616	0.0728	5.7500	0.8788	37.6215	0.2533	-0.0338	0.5405
Levetiracetam Use	20 mg/kg	0.0817 N	24	8	53	1	17.6667	2.3385	133.4640	0.0002	26.0000	3.0194	223.8872	0.3145	0.1223	0.5066
		Y	12	2	23	2	1.9167	0.3070	11.9660	0.5941	2.1000	0.2572	17.1430	0.0797	-0.1605	0.3200



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Rufinamide Use	20 mg/kg	0.5996 N Y	27	9	56	3	6.2222	1.8310	21.1453	0.0015	8.8333	2.1527	36.2465	0.2798	0.0924	0.4671	
			9	1	20	0	-	-	-	-	0.3103	-	-	-	0.1111	-0.0942	0.3164
Current AEDs	20 mg/kg	0.3891 <3 >=3	8	4	25	1	12.5000	1.6228	96.2831	0.0076	24.0000	2.1054	273.5874	0.4600	0.1051	0.8149	
			28	6	51	2	5.4643	1.1803	25.2974	0.0208	6.6818	1.2484	35.7619	0.1751	0.0140	0.3361	
Prior AEDs	20 mg/kg	0.6273 <6 >=6	19	6	31	2	4.8947	1.0977	21.8262	0.0412	6.6923	1.1878	37.7057	0.2513	0.0251	0.4775	
			17	4	45	1	10.5882	1.2721	88.1307	0.0175	13.5385	1.3890	131.9617	0.2131	0.0069	0.4193	
Baseline Drop Seizure Frequency	20 mg/kg	0.1418 <=55 >55 to <=125 >125	15	3	22	2	2.2000	0.4164	11.6225	0.3773	2.5000	0.3640	17.1725	0.1091	-0.1263	0.3445	
			11	2	32	1	5.8182	0.5830	58.0684	0.1560	6.8889	0.5584	84.9842	0.1506	-0.0852	0.3863	
			10	5	22	0	-	-	-	0.0013	-	-	-	-	0.5000	0.1901	0.8099
Total Seizures > Opct																	
Age Group	10 mg/kg	0.1288 2-5 years 6-11 years 12-17 years 18-55 years	4	0	9	3	-	-	-	0.4965	-	-	-	-	-0.3333	-0.6413	-0.0254
			14	1	24	9	0.1905	0.0269	1.3496	0.0594	7.8000	0.8682	70.0736	-0.3036	-0.5396	-0.0675	
			7	0	20	4	-	-	-	0.5453	-	-	-	-	-0.2000	-0.3753	-0.0247
			12	3	23	4	1.4375	0.3824	5.4042	0.6697	0.6316	0.1161	3.4368	0.0761	-0.2138	0.3659	
Sex	10 mg/kg	0.2664 F M	21	2	32	12	0.2540	0.0631	1.0218	0.0290	5.7000	1.1243	28.8978	-0.2798	-0.4893	-0.0702	
			16	2	44	8	0.6875	0.1629	2.9016	0.7154	1.5556	0.2934	8.2463	-0.0568	-0.2549	0.1413	
Region	10 mg/kg	0.6439 REST OF THE WORLD USA	1	0	14	5	-	-	-	1.0000	-	-	-	-0.3571	-0.6081	-0.1061	
			36	4	62	15	0.4593	0.1650	1.2782	0.1841	2.5532	0.7760	8.4001	-0.1308	-0.2788	0.0172	
Valproate Use	10 mg/kg	0.4348 N Y	30	4	46	14	0.4381	0.1593	1.2047	0.1043	2.8438	0.8347	9.6882	-0.1710	-0.3512	0.0092	
			7	0	30	6	-	-	-	0.5709	-	-	-	-	-0.2000	-0.3431	-0.0569
Lamotrigine Use	10 mg/kg	0.9626 N Y	27	3	51	14	0.4048	0.1273	1.2865	0.1491	3.0270	0.7858	11.6604	-0.1634	-0.3338	0.0071	
			10	1	25	6	0.4167	0.0572	3.0357	0.6445	2.8421	0.2964	27.2549	-0.1400	-0.3902	0.1102	
Levetiracetam Use	10 mg/kg	0.1879 N Y	28	4	53	13	0.5824	0.2094	1.6197	0.3926	1.9500	0.5702	6.6688	-0.1024	-0.2763	0.0714	
			9	0	23	7	-	-	-	0.1492	-	-	-	-	-0.3043	-0.4924	-0.1163
Rufinamide Use	10 mg/kg	0.6226 N Y	25	3	56	14	0.4800	0.1513	1.5226	0.2444	2.4444	0.6341	9.4239	-0.1300	-0.3006	0.0406	
			12	1	20	6	0.2778	0.0379	2.0369	0.2117	4.7143	0.4922	45.1546	-0.2167	-0.4712	0.0379	
Current AEDs	10 mg/kg	0.9376 <3 >=3	12	1	25	5	0.4167	0.0545	3.1843	0.6409	2.7500	0.2842	26.6075	-0.1167	-0.3381	0.1048	
			25	3	51	15	0.4080	0.1300	1.2802	0.1501	3.0556	0.7935	11.7665	-0.1741	-0.3526	0.0044	
Prior AEDs	10 mg/kg	0.3715 <6 >=6	16	1	31	9	0.2153	0.0298	1.5529	0.1307	6.1364	0.7022	53.6215	-0.2278	-0.4268	-0.0288	
			21	3	45	11	0.5844	0.1820	1.8770	0.5204	1.9412	0.4794	7.8609	-0.1016	-0.2969	0.0938	
Baseline Drop Seizure Frequency	10 mg/kg	0.9194 <=55 >55 to <=125 >125	12	1	22	5	0.3667	0.0482	2.7878	0.3891	3.2353	0.3319	31.5372	-0.1439	-0.3787	0.0908	
			11	1	32	6	0.4848	0.0654	3.5937	0.6563	2.3077	0.2459	21.6576	-0.0966	-0.3137	0.1205	
			14	2	22	9	0.3492	0.0880	1.3851	0.1419	4.1538	0.7428	23.2295	-0.2662	-0.5416	0.0091	
Age Group	20 mg/kg	0.4874 2-5 years 6-11 years 12-17 years 18-55 years	5	0	9	3	-	-	-	0.2582	-	-	-	-	-0.3333	-0.6413	-0.0254
			11	2	24	9	0.4848	0.1250	1.8812	0.4354	2.7000	0.4735	15.3956	-0.1932	-0.4923	0.1059	
			7	0	20	4	-	-	-	0.5453	-	-	-	-	-0.2000	-0.3753	-0.0247
			13	2	23	4	0.8846	0.1868	4.1895	1.0000	1.1579	0.1816	7.3839	-0.0201	-0.2700	0.2299	
Sex	20 mg/kg	0.6048 F M	15	2	32	12	0.3556	0.0908	1.3930	0.1698	3.9000	0.7477	20.3437	-0.2417	-0.4819	-0.0014	
			21	2	44	8	0.5238	0.1217	2.2548	0.4793	2.1111	0.4070	10.9502	-0.0866	-0.2561	0.0830	
Region	20 mg/kg	0.2861 REST OF THE WORLD USA	5	0	14	5	-	-	-	0.2565	-	-	-	-0.3571	-0.6081	-0.1061	
			31	4	62	15	0.5333	0.1932	1.4719	0.2783	2.1543	0.6487	7.1538	-0.1129	-0.2719	0.0461	
Valproate Use	20 mg/kg	0.32 N Y	26	4	46	14	0.5055	0.1856	1.3765	0.2567	2.4063	0.6986	8.2876	-0.1505	-0.3426	0.0416	
			10	0	30	6	-	-	-	0.3074	-	-	-	-	-0.2000	-0.3431	-0.0569
Lamotrigine Use	20 mg/kg	0.8391 N Y	24	3	51	14	0.4554	0.1444	1.4362	0.2370	2.6486	0.6818	10.2894	-0.1495	-0.3298	0.0308	
			12	1	25	6	0.3472	0.0469	2.5707	0.3891	3.4737	0.3685	32.7425	-0.1567	-0.3858	0.0724	

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Levetiracetam Use	20 mg/kg	0.6822 N Y	24	2	53	13	0.3397	0.0831	1.3894	0.1264	3.5750	0.7386	17.3042	-0.1619	-0.3221	-0.0018
			12	2	23	7	0.5476	0.1340	2.2385	0.4496	2.1875	0.3768	12.7008	-0.1377	-0.4202	0.1448
Rufinamide Use	20 mg/kg	0.8526 N Y	27	3	56	14	0.4444	0.1394	1.4168	0.2446	2.6667	0.6955	10.2252	-0.1389	-0.3029	0.0252
			9	1	20	6	0.3704	0.0519	2.6436	0.3816	3.4286	0.3478	33.7991	-0.1889	-0.4761	0.0983
Current AEDs	20 mg/kg	0.3804 <3 >=3	8	0	25	5	-	-	-	0.3023	-	-	-	-0.2000	-0.3568	-0.0432
			28	4	51	15	0.4857	0.1783	1.3229	0.1732	2.5000	0.7396	8.4500	-0.1513	-0.3314	0.0288
Prior AEDs	20 mg/kg	0.2126 <6 >=6	19	1	31	9	0.1813	0.0249	1.3202	0.0674	7.3636	0.8510	63.7139	-0.2377	-0.4264	-0.0490
			17	3	45	11	0.7219	0.2290	2.2759	0.7389	1.5098	0.3649	6.2477	-0.0680	-0.2884	0.1525
Baseline Drop Seizure Frequency	20 mg/kg	0.9345 <=55 >55 to <=125 >125	15	1	22	5	0.2933	0.0380	2.2656	0.3682	4.1176	0.4294	39.4817	-0.1606	-0.3765	0.0553
			11	1	32	6	0.4848	0.0654	3.5937	0.6563	2.3077	0.2459	21.6576	-0.0966	-0.3137	0.1205
			10	2	22	9	0.4889	0.1283	1.8624	0.4250	2.7692	0.4730	16.2134	-0.2091	-0.5311	0.1129

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1414 Convulsive Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio			Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Convulsive Seizures <=25pct	Age Group	10 mg/kg	0.7451	2-5 years	4	4	9	5	1.8000	1.0034	3.2289	0.2280	-	-	-	0.4444	0.1198	0.7691
				6-11 years	14	10	24	8	2.1429	1.1124	4.1280	0.0424	5.0000	1.1883	21.0389	0.3810	0.0784	0.6836
				12-17 years	7	6	20	11	1.5584	0.9466	2.5659	0.2040	4.9091	0.4956	48.6216	0.3071	-0.0316	0.6459
				18-55 years	12	7	23	8	1.6771	0.8033	3.5013	0.2825	2.6250	0.6263	11.0015	0.2355	-0.1046	0.5756
Sex	10 mg/kg	0.5855	F	21	16	32	13	1.8755	1.1578	3.0379	0.0133	4.6769	1.3708	15.9564	0.3557	0.1064	0.6049	
			M	16	11	44	19	1.5921	0.9918	2.5558	0.1432	2.8947	0.8599	9.7446	0.2557	-0.0145	0.5259	
Region	10 mg/kg	0.1841	REST OF THE WORLD	1	0	14	5	-	-	-	1.0000	-	-	-	-0.3571	-0.6081	-0.1061	
			USA	36	27	62	27	1.7222	1.2253	2.4207	0.0032	3.8889	1.5714	9.6243	0.3145	0.1268	0.5022	
Valproate Use	10 mg/kg	0.3717	N	30	21	46	20	1.6100	1.0746	2.4121	0.0339	3.0333	1.1448	8.0376	0.2652	0.0475	0.4830	
			Y	7	6	30	12	2.1429	1.2582	3.6496	0.0422	9.0000	0.9586	84.4954	0.4571	0.1442	0.7701	
Lamotrigine Use	10 mg/kg	0.739	N	27	20	51	21	1.7989	1.2098	2.6750	0.0084	4.0816	1.4636	11.3826	0.3290	0.1155	0.5424	
			Y	10	7	25	11	1.5909	0.8730	2.8993	0.2642	2.9697	0.6202	14.2197	0.2600	-0.0843	0.6043	
Levetiracetam Use	10 mg/kg	0.0876	N	28	18	53	21	1.6224	1.0533	2.4992	0.0392	2.7429	1.0619	7.0849	0.2466	0.0256	0.4676	
			Y	9	9	23	11	2.0909	1.3644	3.2042	0.0117	-	-	-	0.5217	0.3176	0.7259	
Rufinamide Use	10 mg/kg	0.5631	N	25	18	56	25	1.6128	1.1023	2.3597	0.0304	3.1886	1.1501	8.8398	0.2736	0.0546	0.4925	
			Y	12	9	20	7	2.1429	1.0848	4.2329	0.0659	5.5714	1.1278	27.5230	0.4000	0.0779	0.7221	
Current AEDs	10 mg/kg	0.8282	<3	12	9	25	12	1.5625	0.9265	2.6352	0.1657	3.2500	0.7079	14.9210	0.2700	-0.0436	0.5836	
			>=3	25	18	51	20	1.8360	1.2062	2.7947	0.0138	3.9857	1.4111	11.2579	0.3278	0.1066	0.5490	
Prior AEDs	10 mg/kg	0.4284	<6	16	12	31	17	1.3676	0.8926	2.0955	0.2185	2.4706	0.6505	9.3834	0.2016	-0.0735	0.4768	
			>=6	21	15	45	15	2.1429	1.3077	3.5114	0.0072	5.0000	1.6126	15.5028	0.3810	0.1437	0.6182	
Baseline Drop Seizure Frequency	10 mg/kg	0.6722	<=55	12	8	22	10	1.4667	0.7986	2.6938	0.2966	2.4000	0.5549	10.3811	0.2121	-0.1262	0.5504	
			>55 to <=125	11	9	32	13	2.0140	1.2178	3.3306	0.0339	6.5769	1.2175	35.5290	0.4119	0.1275	0.6964	
			>125	14	10	22	9	1.7460	0.9567	3.1867	0.0967	3.6111	0.8576	15.2056	0.3052	-0.0082	0.6186	
Age Group	20 mg/kg	0.6626	2-5 years	5	4	9	5	1.4400	0.6936	2.9894	0.5804	3.2000	0.2485	41.2079	0.2444	-0.2334	0.7223	
			6-11 years	11	7	24	8	1.9091	0.9284	3.9256	0.1440	3.5000	0.7863	15.5784	0.3030	-0.0381	0.6442	
			12-17 years	7	7	20	11	1.8182	1.2231	2.7027	0.0593	-	-	-	0.4500	0.2320	0.6680	
			18-55 years	13	10	23	8	2.2115	1.1733	4.1686	0.0354	6.2500	1.3272	29.4316	0.4214	0.1208	0.7220	
Sex	20 mg/kg	0.7294	F	15	12	32	13	1.9692	1.2072	3.2124	0.0146	5.8462	1.3733	24.8866	0.3938	0.1293	0.6582	
			M	21	16	44	19	1.7644	1.1654	2.6714	0.0169	4.2105	1.3094	13.5392	0.3301	0.0964	0.5638	
Region	20 mg/kg	0.719	REST OF THE WORLD	5	4	14	5	2.2400	0.9785	5.1280	0.1409	7.2000	0.6220	83.3415	0.4429	0.0117	0.8740	
			USA	31	24	62	27	1.7778	1.2638	2.5008	0.0022	4.4444	1.6676	11.8449	0.3387	0.1466	0.5308	
Valproate Use	20 mg/kg	0.263	N	26	19	46	20	1.6808	1.1225	2.5168	0.0259	3.5286	1.2417	10.0272	0.2960	0.0733	0.5187	
			Y	10	9	30	12	2.2500	1.3860	3.6526	0.0094	13.5000	1.5089	120.7831	0.5000	0.2445	0.7555	
Lamotrigine Use	20 mg/kg	0.2438	N	24	17	51	21	1.7202	1.1342	2.6091	0.0253	3.4694	1.2238	9.8351	0.2966	0.0700	0.5231	
			Y	12	11	25	11	2.0833	1.2969	3.3466	0.0106	14.0000	1.5603	125.6132	0.4767	0.2270	0.7263	
Levetiracetam Use	20 mg/kg	0.1899	N	24	20	53	21	2.1032	1.4420	3.0676	0.0005	7.6190	2.2802	25.4586	0.4371	0.2382	0.6360	
			Y	12	8	23	11	1.3939	0.7765	2.5022	0.4759	2.1818	0.5105	9.3251	0.1884	-0.1475	0.5243	
Rufinamide Use	20 mg/kg	0.2655	N	27	23	56	25	1.9081	1.3699	2.6578	0.0007	7.1300	2.1793	23.3272	0.4054	0.2186	0.5923	
			Y	9	5	20	7	1.5873	0.6883	3.6605	0.4223	2.3214	0.4668	11.5446	0.2056	-0.1806	0.5917	
Current AEDs	20 mg/kg	0.1591	<3	8	8	25	12	2.0833	1.3854	3.1329	0.0116	-	-	-	0.5200	0.3242	0.7158	

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		>=3	28	20	51	20	1.8214	1.2036	2.7563	0.0093	3.8750	1.4340	10.4714	0.3221	0.1078	0.5365
Prior AEDs	20 mg/kg	0.5236 <6	19	17	31	17	1.6316	1.1443	2.3263	0.0134	7.0000	1.3757	35.6193	0.3463	0.1233	0.5694
		>=6	17	11	45	15	1.9412	1.1287	3.3384	0.0423	3.6667	1.1357	11.8378	0.3137	0.0481	0.5794
Baseline Drop Seizure Frequency	20 mg/kg	0.9451 <=55	15	12	22	10	1.7600	1.0432	2.9693	0.0471	4.8000	1.0517	21.9068	0.3455	0.0552	0.6357
		>55 to <=125	11	8	32	13	1.7902	1.0292	3.1139	0.0883	3.8974	0.8672	17.5157	0.3210	0.0076	0.6344
		>125	10	8	22	9	1.9556	1.0839	3.5283	0.0605	5.7778	0.9868	33.8280	0.3909	0.0689	0.7129
Convulsive Seizures <=50pct Age Group	10 mg/kg	0.5672 2-5 years	4	2	9	2	2.2500	0.4697	10.7784	0.5301	3.5000	0.2838	43.1606	0.2778	-0.2825	0.8380
		6-11 years	14	8	24	4	3.4286	1.2575	9.3482	0.0144	6.6667	1.4763	30.1059	0.4048	0.1057	0.7038
		12-17 years	7	4	20	1	11.4286	1.5234	85.7385	0.0089	25.3333	2.0652	310.7566	0.5214	0.1426	0.9003
		18-55 years	12	4	23	3	2.5556	0.6798	9.6075	0.1999	3.3333	0.6048	18.3707	0.2029	-0.0972	0.5030
Sex	10 mg/kg	0.6099 F	21	11	32	6	2.7937	1.2199	6.3974	0.0161	4.7667	1.3885	16.3640	0.3363	0.0835	0.5891
		M	16	7	44	4	4.8125	1.6228	14.2720	0.0051	7.7778	1.8697	32.3546	0.3466	0.0891	0.6041
Region	10 mg/kg	0.5205 REST OF THE WORLD	1	0	14	1	-	-	-	1.0000	-	-	-	-0.0714	-0.2063	0.0635
		USA	36	18	62	9	3.4444	1.7333	6.8447	0.0003	5.8889	2.2495	15.4163	0.3548	0.1695	0.5402
Valproate Use	10 mg/kg	0.0352 N	30	12	46	7	2.6286	1.1684	5.9133	0.0284	3.7143	1.2530	11.0104	0.2478	0.0441	0.4516
		Y	7	6	30	3	8.5714	2.8099	26.1471	0.0002	54.0000	4.7544	613.3247	0.7571	0.4766	1.0000
Lamotrigine Use	10 mg/kg	0.4513 N	27	13	51	5	4.9111	1.9574	12.3220	0.0004	8.5429	2.5928	28.1470	0.3834	0.1781	0.5888
		Y	10	5	25	5	2.5000	0.9203	6.7916	0.1068	4.0000	0.8238	19.4232	0.3000	-0.0473	0.6473
Levetiracetam Use	10 mg/kg	1 N	28	12	53	5	4.5429	1.7792	11.5996	0.0010	7.2000	2.1974	23.5918	0.3342	0.1348	0.5337
		Y	9	6	23	5	3.0667	1.2436	7.5624	0.0350	7.2000	1.3105	39.5567	0.4493	0.0982	0.8004
Rufinamide Use	10 mg/kg	0.7846 N	25	14	56	9	3.4844	1.7441	6.9614	0.0004	6.6465	2.2934	19.2618	0.3993	0.1822	0.6163
		Y	12	4	20	1	6.6667	0.8403	52.8925	0.0531	9.5000	0.9134	98.8028	0.2833	0.0000	0.5666
Current AEDs	10 mg/kg	0.7961 <3	12	7	25	5	2.9167	1.1643	7.3064	0.0292	5.6000	1.2382	25.3273	0.3833	0.0633	0.7033
		>=3	25	11	51	5	4.4880	1.7485	11.5193	0.0018	7.2286	2.1455	24.3543	0.3420	0.1310	0.5530
Prior AEDs	10 mg/kg	0.0246 <6	16	6	31	7	1.6607	0.6696	4.1188	0.3177	2.0571	0.5515	7.6740	0.1492	-0.1300	0.4284
		>=6	21	12	45	3	8.5714	2.7025	27.1858	<.0001	18.6667	4.3540	80.0286	0.5048	0.2809	0.7286
Baseline Drop Seizure Frequency	10 mg/kg	0.0335 <=55	12	4	22	6	1.2222	0.4270	3.4983	0.7139	1.3333	0.2906	6.1173	0.0606	-0.2646	0.3858
		>55 to <=125	11	7	32	2	10.1818	2.4752	41.8839	0.0003	26.2500	3.9806	173.1073	0.5739	0.2775	0.8703
		>125	14	7	22	2	5.5000	1.3275	22.7871	0.0144	10.0000	1.6667	59.9993	0.4091	0.1209	0.6972
Age Group	20 mg/kg	0.2844 2-5 years	5	2	9	2	1.8000	0.3538	9.1572	0.5804	2.3333	0.2157	25.2450	0.1778	-0.3303	0.6859
		6-11 years	11	5	24	4	2.7273	0.9040	8.2281	0.1026	4.1667	0.8410	20.6439	0.2879	-0.0420	0.6177
		12-17 years	7	5	20	1	14.2857	1.9983	102.1264	0.0014	47.5000	3.5466	636.1708	0.6643	0.3163	1.0000
		18-55 years	13	8	23	3	4.7179	1.5098	14.7426	0.0064	10.6667	2.0494	55.5164	0.4849	0.1868	0.7831
Sex	20 mg/kg	0.306 F	15	8	32	6	2.8444	1.2004	6.7402	0.0370	4.9524	1.2865	19.0642	0.3458	0.0594	0.6322
		M	21	12	44	4	6.2857	2.3006	17.1739	<.0001	13.3333	3.4812	51.0679	0.4805	0.2525	0.7086
Region	20 mg/kg	0.173 REST OF THE WORLD	5	4	14	1	11.2000	1.6113	77.8485	0.0061	52.0000	2.6155	1033.8271	0.7286	0.3529	1.0000
		USA	31	16	62	9	3.5556	1.7770	7.1141	0.0003	6.2815	2.3160	17.0364	0.3710	0.1744	0.5675
Valproate Use	20 mg/kg	0.2154 N	26	13	46	7	3.2857	1.5017	7.1889	0.0025	5.5714	1.8310	16.9527	0.3478	0.1294	0.5663
		Y	10	7	30	3	7.0000	2.2217	22.0552	0.0006	21.0000	3.4597	127.4674	0.6000	0.2964	0.9036
Lamotrigine Use	20 mg/kg	0.8896 N	24	12	51	5	5.1000	2.0252	12.8435	0.0002	9.2000	2.7121	31.2087	0.4020	0.1859	0.6180
		Y	12	8	25	5	3.3333	1.3824	8.0377	0.0097	8.0000	1.6989	37.6725	0.4667	0.1573	0.7761
Levetiracetam Use	20 mg/kg	0.1808 N	24	14	53	5	6.1833	2.5138	15.2097	<.0001	13.4400	3.9381	45.8684	0.4890	0.2766	0.7014
		Y	12	6	23	5	2.3000	0.8807	6.0063	0.1297	3.6000	0.8000	16.1997	0.2826	-0.0467	0.6119

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Rufinamide Use	20 mg/kg	0.6013 N Y	27 9	16 4	56 20	9 1	3.6872 8.8889	1.8768 1.1498	7.2441 68.7187	0.0001 0.0223	7.5960 15.2000	2.6640 1.3754	21.6588 167.9819	0.4319 0.3944	0.2231 0.0560	0.6407 0.7328
Current AEDs	20 mg/kg	0.6638 <3 >=3	8 28	5 15	25 51	5 5	3.1250 5.4643	1.2084 2.2193	8.0814 13.4539	0.0362 <.0001	6.6667 10.6154	1.1764 3.2467	37.7811 34.7075	0.4250 0.4377	0.0547 0.2357	0.7953 0.6396
Prior AEDs	20 mg/kg	0.7844 <6 >=6	19 17	13 7	31 45	7 3	3.0301 6.1765	1.4751 1.8017	6.2241 21.1744	0.0025 0.0028	7.4286 9.8000	2.0604 2.1473	26.7824 44.7264	0.4584 0.3451	0.2028 0.1001	0.7140 0.5901
Baseline Drop Seizure Frequency	20 mg/kg	0.7451 <=55 >55 to <=125 >125	15 11 10	10 5 5	22 32 22	6 2 2	2.4444 7.2727 5.5000	1.1312 1.6393 1.2779	5.2821 32.2660 23.6719	0.0233 0.0076 0.0187	5.3333 12.5000 10.0000	1.2817 1.9471 1.4803	22.1919 80.2474 67.5536	0.3939 0.3920 0.4091	0.0914 0.0861 0.0767	0.6965 0.6980 0.7415
Convulsive Seizures <=75pct																
Age Group	10 mg/kg	0.1453 2-5 years 6-11 years 12-17 years 18-55 years	4 14 7 12	0 1 1 3	9 24 20 23	1 0 0 0	- - - -	- - - -	- - - -	1.0000 0.3684 0.2593 0.0336	- - - -	- - - -	- - - -	-0.1111 0.0714 0.1429 0.2500	-0.3164 -0.0635 -0.1164 0.0050	0.0942 0.2063 0.4021 0.4950
Sex	10 mg/kg	0.3647 F M	21 16	3 2	32 44	0 1	- 5.5000	- 0.5345	- 56.6002	0.0568 0.1707	- 6.1429	- 0.5170	- 72.9919	0.1429 0.1023	-0.0068 -0.0657	0.2925 0.2702
Region	10 mg/kg	. REST OF THE WORLD USA	1 36	0 5	14 62	0 1	- 8.6111	- 1.0467	- 70.8412	0.0241	9.8387	1.1010	87.9219	0.1228	0.0055	0.2400
Valproate Use	10 mg/kg	0.24 N Y	30 7	4 1	46 30	0 1	- 4.2857	- 0.3037	- 60.4725	0.0214 0.3468	- 4.8333	- 0.2639	- 88.5345	0.1333 0.1095	0.0117 -0.1575	0.2550 0.3766
Lamotrigine Use	10 mg/kg	0.0721 N Y	27 10	1 4	51 25	1 0	1.8889 -	0.1229 -	29.0280 -	1.0000 0.0040	1.9231 -	0.1155 -	32.0070 -	0.0174 0.4000	-0.0633 0.0964	0.0982 0.7036
Levetiracetam Use	10 mg/kg	0.5349 N Y	28 9	2 3	53 23	0 1	- 7.6667	- 0.9130	- 64.3807	0.1167 0.0572	- 11.0000	- 0.9621	- 125.7694	0.0714 0.2899	-0.0240 -0.0292	0.1668 0.6089
Rufinamide Use	10 mg/kg	. N Y	25 12	5 0	56 20	1 0	11.2000 -	1.3789 -	90.9717 -	0.0097	13.7500	1.5126	124.9888	0.1821	0.0216	0.3427
Current AEDs	10 mg/kg	. <3 >=3	12 25	0 5	25 51	0 1	- 10.2000	- 1.2578	- 82.7163	0.0132	12.5000	1.3729	113.8061	0.1804	0.0190	0.3417
Prior AEDs	10 mg/kg	0.4377 <6 >=6	16 21	3 2	31 45	1 0	5.8125 -	0.6562 -	51.4845 -	0.1075 0.0979	6.9231 -	0.6570 -	72.9480 -	0.1552 0.0952	-0.0459 -0.0303	0.3564 0.2208
Baseline Drop Seizure Frequency	10 mg/kg	0.6709 <=55 >55 to <=125 >125	12 11 14	1 2 2	22 32 22	0 1 0	- 5.8182 -	- 0.5830 -	- 58.0684 -	0.3529 0.1560 0.1444	- 6.8889 -	- 0.5584 -	- 84.9842 -	0.0833 0.1506 0.1429	-0.0730 -0.0852 -0.0404	0.2397 0.3863 0.3262
Age Group	20 mg/kg	0.1919 2-5 years 6-11 years 12-17 years 18-55 years	5 11 7 13	1 2 2 5	9 24 20 23	1 0 0 0	1.8000 - - -	0.1410 - - -	22.9864 - - -	1.0000 0.0924 0.0598 0.0034	2.0000 - - -	0.0976 - - -	41.0034 - - -	0.0889 0.1818 0.2857 0.3846	-0.3174 -0.0461 -0.0489 0.1202	0.4952 0.4097 0.6204 0.6491
Sex	20 mg/kg	0.5449 F M	15 21	3 7	32 44	0 1	- 14.6667	- 1.9267	- 111.6487	0.0281 0.0011	- 21.5000	- 2.4295	- 190.2639	0.2000 0.3106	-0.0024 0.1042	0.4024 0.5170
Region	20 mg/kg	0.3525 REST OF THE WORLD USA	5 31	3 7	14 62	0 1	- 14.0000	- 1.8015	- 108.8000	0.0103 0.0017	- 17.7917	- 2.0769	- 152.4114	0.6000 0.2097	0.1706 0.0592	1.0000 0.3602
Valproate Use	20 mg/kg	0.3654 N Y	26 10	6 4	46 30	0 1	- 12.0000	- 1.5125	- 95.2065	0.0015 0.0100	- 19.3333	- 1.8236	- 204.9724	0.2308 0.3667	0.0688 0.0563	0.3927 0.6770
Lamotrigine Use	20 mg/kg	0.3025 N Y	24 12	5 5	51 25	1 0	10.6250 -	1.3122 -	86.0311 -	0.0114 0.0018	13.1579 -	1.4419 -	120.0702 -	0.1887 0.4167	0.0219 0.1377	0.3556 0.6956

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Levetiracetam Use	20 mg/kg	0.0198 N Y	24	9	53	0	-	-	-	<.0001	-	-	-	0.3750	0.1813	0.5687
			12	1	23	1	1.9167	0.1311	28.0246	1.0000	2.0000	0.1140	35.0891	0.0399	-0.1373	0.2171
Rufinamide Use	20 mg/kg	0.7623 N Y	27	9	56	1	18.6667	2.4904	139.9159	0.0001	27.5000	3.2568	232.2052	0.3155	0.1343	0.4966
			9	1	20	0	-	-	-	0.3103	-	-	-	0.1111	-0.0942	0.3164
Current AEDs	20 mg/kg	0.2627 <3 >=3	8	4	25	0	-	-	-	0.0017	-	-	-	0.5000	0.1535	0.8465
			28	6	51	1	10.9286	1.3843	86.2786	0.0070	13.6364	1.5483	120.0993	0.1947	0.0380	0.3514
Prior AEDs	20 mg/kg	0.2564 <6 >=6	19	5	31	1	8.1579	1.0297	64.6304	0.0244	10.7143	1.1420	100.5213	0.2309	0.0234	0.4384
			17	5	45	0	-	-	-	0.0010	-	-	-	0.2941	0.0775	0.5107
Baseline Drop Seizure Frequency	20 mg/kg	0.3068 <=55 >55 to <=125 >125	15	4	22	0	-	-	-	0.0207	-	-	-	0.2667	0.0429	0.4905
			11	2	32	1	5.8182	0.5830	58.0684	0.1560	6.8889	0.5584	84.9842	0.1506	-0.0852	0.3863
			10	4	22	0	-	-	-	0.0058	-	-	-	0.4000	0.0964	0.7036
Convulsive Seizures >0pct Age Group	10 mg/kg	0.3064 2-5 years 6-11 years 12-17 years 18-55 years	4	0	9	1	-	-	-	1.0000	-	-	-	-0.1111	-0.3164	0.0942
			14	1	24	9	0.1905	0.0269	1.3496	0.0594	7.8000	0.8682	70.0736	-0.3036	-0.5396	-0.0675
			7	0	20	2	-	-	-	1.0000	-	-	-	-0.1000	-0.2315	0.0315
			12	5	23	9	1.0648	0.4590	2.4700	1.0000	0.9000	0.2174	3.7259	0.0254	-0.3176	0.3683
Sex	10 mg/kg	0.2523 F M	21	3	32	12	0.3810	0.1219	1.1901	0.1176	3.6000	0.8733	14.8396	-0.2321	-0.4569	-0.0073
			16	3	44	9	0.9167	0.2832	2.9674	1.0000	1.1143	0.2605	4.7668	-0.0170	-0.2424	0.2083
Region	10 mg/kg	0.648 REST OF THE WORLD USA	1 36	0 6	14 62	4 17	- 0.6078	- 0.2637	- 1.4012	1.0000 0.3232	- 1.8889	- 0.6683	- 5.3390	-0.2857 -0.1075	-0.5224 -0.2723	-0.0491 0.0572
Valproate Use	10 mg/kg	0.9371 N Y	30 7	5 1	46 30	13 8	0.5897 0.5357	0.2343 0.0794	1.4845 3.6146	0.2826 0.6563	1.9697 2.1818	0.6206 0.2262	6.2514 21.0425	-0.1159 -0.1238	-0.3023 -0.4275	0.0704 0.1799
Lamotrigine Use	10 mg/kg	0.5623 N Y	27 10	4 2	51 25	15 6	0.5037 0.8333	0.1854 0.2009	1.3684 3.4558	0.1778 1.0000	2.3958 1.2632	0.7068 0.2086	8.1211 7.6487	-0.1460 -0.0400	-0.3293 -0.3391	0.0373 0.2591
Levetiracetam Use	10 mg/kg	0.1694 N Y	28	6	53	15	0.7571	0.3306	1.7340	0.5995	1.4474	0.4902	4.2732	-0.0687	-0.2632	0.1257
			9	0	23	6	-	-	-	0.1499	-	-	-	-	-0.2609	-0.4403
Rufinamide Use	10 mg/kg	0.1423 N Y	25	5	56	13	0.8615	0.3443	2.1561	1.0000	1.2093	0.3792	3.8569	-0.0321	-0.2240	0.1597
			12	1	20	8	0.2083	0.0296	1.4669	0.1032	7.3333	0.7854	68.4759	-0.3167	-0.5823	-0.0511
Current AEDs	10 mg/kg	0.5639 <3 >=3	12	1	25	6	0.3472	0.0469	2.5707	0.3891	3.4737	0.3685	32.7425	-0.1567	-0.3858	0.0724
			25	5	51	15	0.6800	0.2787	1.6590	0.4224	1.6667	0.5276	5.2652	-0.0941	-0.2947	0.1064
Prior AEDs	10 mg/kg	0.7489 <6 >=6	16	2	31	8	0.4844	0.1162	2.0184	0.4568	2.4348	0.4511	13.1415	-0.1331	-0.3566	0.0905
			21	4	45	13	0.6593	0.2441	1.7811	0.5485	1.7266	0.4870	6.1214	-0.0984	-0.3123	0.1155
Baseline Drop Seizure Frequency	10 mg/kg	0.4101 <=55 >55 to <=125 >125	12	1	22	7	0.2619	0.0364	1.8850	0.2102	5.1333	0.5492	47.9822	-0.2348	-0.4845	0.0148
			11	2	32	5	1.1636	0.2623	5.1626	1.0000	0.8333	0.1371	5.0668	0.0256	-0.2348	0.2859
			14	3	22	9	0.5238	0.1706	1.6082	0.2925	2.5385	0.5477	11.7658	-0.1948	-0.4921	0.1025
Age Group	20 mg/kg	0.9195 2-5 years 6-11 years 12-17 years 18-55 years	5	0	9	1	-	-	-	1.0000	-	-	-	-0.1111	-0.3164	0.0942
			11	2	24	9	0.4848	0.1250	1.8812	0.4354	2.7000	0.4735	15.3956	-0.1932	-0.4923	0.1059
			7	0	20	2	-	-	-	1.0000	-	-	-	-0.1000	-0.2315	0.0315
			13	2	23	9	0.3932	0.0996	1.5518	0.2586	3.5357	0.6308	19.8187	-0.2375	-0.5172	0.0423
Sex	20 mg/kg	0.6923 F M	15	2	32	12	0.3556	0.0908	1.3930	0.1698	3.9000	0.7477	20.3437	-0.2417	-0.4819	-0.0014
			21	2	44	9	0.4656	0.1102	1.9677	0.4804	2.4429	0.4782	12.4780	-0.1093	-0.2824	0.0638
Region	20 mg/kg	0.3917 REST OF THE WORLD USA	5 31	0 4	14 62	4 17	- 0.4706	- 0.1731	- 1.2795	0.5304 0.1873	- 2.5500	- 0.7765	- 8.3746	-0.2857 -0.1452	-0.5224 -0.3072	-0.0491 0.0169

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Valproate Use	20 mg/kg	0.2186 N	26	4	46	13	0.5444	0.1978	1.4980	0.2600	2.1667	0.6247	7.5152	-0.1288	-0.3189	0.0614
		Y	10	0	30	8	-	-	-	0.1655	-	-	-	-0.2667	-0.4249	-0.1084
Lamotrigine Use	20 mg/kg	0.8958 N	24	3	51	15	0.4250	0.1358	1.3298	0.1505	2.9167	0.7551	11.2663	-0.1691	-0.3512	0.0129
		Y	12	1	25	6	0.3472	0.0469	2.5707	0.3891	3.4737	0.3685	32.7425	-0.1567	-0.3858	0.0724
Levetiracetam Use	20 mg/kg	0.4514 N	24	2	53	15	0.2944	0.0730	1.1873	0.0742	4.3421	0.9069	20.7888	-0.1997	-0.3638	-0.0356
		Y	12	2	23	6	0.6389	0.1514	2.6968	0.6855	1.7647	0.2974	10.4724	-0.0942	-0.3711	0.1827
Rufinamide Use	20 mg/kg	0.5531 N	27	3	56	13	0.4786	0.1488	1.5397	0.2440	2.4186	0.6263	9.3395	-0.1210	-0.2831	0.0411
		Y	9	1	20	8	0.2778	0.0406	1.9028	0.2012	5.3333	0.5548	51.2722	-0.2889	-0.5860	0.0082
Current AEDs	20 mg/kg	0.3284 <3	8	0	25	6	-	-	-	0.2964	-	-	-	-0.2400	-0.4074	-0.0726
		>=3	28	4	51	15	0.4857	0.1783	1.3229	0.1732	2.5000	0.7396	8.4500	-0.1513	-0.3314	0.0288
Prior AEDs	20 mg/kg	0.3538 <6	19	1	31	8	0.2039	0.0276	1.5053	0.1269	6.2609	0.7160	54.7483	-0.2054	-0.3893	-0.0216
		>=6	17	3	45	13	0.6109	0.1984	1.8808	0.5198	1.8958	0.4658	7.7166	-0.1124	-0.3369	0.1120
Baseline Drop Seizure Frequency	20 mg/kg	0.716 <=55	15	1	22	7	0.2095	0.0286	1.5326	0.1083	6.5333	0.7108	60.0506	-0.2515	-0.4835	-0.0195
		>55 to <=125	11	1	32	5	0.5818	0.0760	4.4514	1.0000	1.8519	0.1920	17.8588	-0.0653	-0.2767	0.1461
		>125	10	2	22	9	0.4889	0.1283	1.8624	0.4250	2.7692	0.4730	16.2134	-0.2091	-0.5311	0.1129

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1414 Non-Convulsive Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI		95% Upper CI	95% Lower CI	95% Upper CI
Non-Convulsive Seizures <=25pct	Age Group	10 mg/kg	0.0407	2-5 years	2	2	7	3	2.3333	0.9919	5.4887	0.4444	-	-	-	0.5714	0.2048	0.9380
				6-11 years	4	4	19	9	2.1111	1.3142	3.3912	0.1045	-	-	-	0.5263	0.3018	0.7508
				12-17 years	6	3	16	12	0.6667	0.2853	1.5577	0.3341	0.3333	0.0470	2.3664	-0.2500	-0.7029	0.2029
				18-55 years	9	8	18	10	1.6000	0.9966	2.5686	0.1925	6.4000	0.6564	62.4003	0.3333	0.0254	0.6413
Sex	10 mg/kg	0.1738	F		12	11	27	15	1.6500	1.1306	2.4081	0.0336	8.8000	0.9915	78.1066	0.3611	0.1170	0.6052
				M	9	6	33	19	1.1579	0.6701	2.0009	0.7164	1.4737	0.3133	6.9316	0.0909	-0.2602	0.4420
Region	10 mg/kg	0.3169	REST OF THE WORLD		1	0	11	3	-	-	-	1.0000	-	-	-	-0.2727	-0.5359	-0.0095
				USA	20	17	49	31	1.3435	1.0136	1.7809	0.0905	3.2903	0.8463	12.7923	0.2173	0.0107	0.4240
Valproate Use	10 mg/kg	0.545	N		16	13	38	19	1.6250	1.0941	2.4136	0.0391	4.3333	1.0609	17.7004	0.3125	0.0638	0.5612
				Y	5	4	22	15	1.1733	0.6955	1.9796	1.0000	1.8667	0.1749	19.9255	0.1182	-0.2828	0.5192
Lamotrigine Use	10 mg/kg	0.4501	N		14	11	43	26	1.2995	0.9020	1.8719	0.3355	2.3974	0.5822	9.8732	0.1811	-0.0788	0.4410
				Y	7	6	17	8	1.8214	1.0117	3.2791	0.1718	6.7500	0.6624	68.7793	0.3866	0.0351	0.7380
Levetiracetam Use	10 mg/kg	0.17	N		15	11	42	24	1.2833	0.8584	1.9186	0.3600	2.0625	0.5636	7.5477	0.1619	-0.1073	0.4311
				Y	6	6	18	10	1.8000	1.1908	2.7210	0.0664	-	-	-	0.4444	0.2149	0.6740
Rufinamide Use	10 mg/kg	0.235	N		15	13	44	24	1.5889	1.1367	2.2209	0.0326	5.4167	1.0908	26.8991	0.3212	0.0949	0.5476
				Y	6	4	16	10	1.0667	0.5397	2.1082	1.0000	1.2000	0.1663	8.6586	0.0417	-0.4039	0.4873
Current AEDs	10 mg/kg	0.2701	<3		6	4	20	12	1.1111	0.5689	2.1702	1.0000	1.3333	0.1957	9.0828	0.0667	-0.3674	0.5007
				>=3	15	13	40	22	1.5758	1.1177	2.2216	0.0565	5.3182	1.0590	26.7063	0.3167	0.0857	0.5477
Prior AEDs	10 mg/kg	0.0392	<6		7	4	24	15	0.9143	0.4484	1.8643	1.0000	0.8000	0.1447	4.4228	-0.0536	-0.4682	0.3610
				>=6	14	13	36	19	1.7594	1.2505	2.4754	0.0090	11.6316	1.3732	98.5274	0.4008	0.1891	0.6124
Baseline Drop Seizure Frequency	10 mg/kg	0.0315	<=55		8	4	20	12	0.8333	0.3820	1.8177	0.6908	0.6667	0.1281	3.4698	-0.1000	-0.5076	0.3076
				>55 to <=125	5	5	22	12	1.8333	1.2519	2.6848	0.1240	-	-	-	0.4545	0.2465	0.6626
				>125	8	8	18	10	1.8000	1.1908	2.7210	0.0308	-	-	-	0.4444	0.2149	0.6740
Age Group	20 mg/kg	0.6106	2-5 years		4	4	7	3	2.3333	0.9919	5.4887	0.1939	-	-	-	0.5714	0.2048	0.9380
				6-11 years	8	6	19	9	1.5833	0.8515	2.9440	0.2357	3.3333	0.5314	20.9107	0.2763	-0.0984	0.6511
				12-17 years	7	6	16	12	1.1429	0.7553	1.7292	1.0000	2.0000	0.1814	22.0564	0.1071	-0.2278	0.4421
				18-55 years	7	5	18	10	1.2857	0.6884	2.4013	0.6592	2.0000	0.3036	13.1731	0.1587	-0.2471	0.5646
Sex	20 mg/kg	0.2777	F		9	6	27	15	1.2000	0.6772	2.1263	0.7050	1.6000	0.3295	7.7693	0.1111	-0.2494	0.4716
				M	17	15	33	19	1.5325	1.0903	2.1541	0.0526	5.5263	1.0839	28.1753	0.3066	0.0788	0.5344
Region	20 mg/kg	0.665	REST OF THE WORLD		3	2	11	3	2.4444	0.6978	8.5627	0.5055	5.3333	0.3434	82.8274	0.3939	-0.2009	0.9888
				USA	23	19	49	31	1.3058	0.9829	1.7347	0.1100	2.7581	0.8104	9.3861	0.1934	-0.0120	0.3989
Valproate Use	20 mg/kg	0.1905	N		19	16	38	19	1.6842	1.1601	2.4452	0.0199	5.3333	1.3318	21.3574	0.3421	0.1137	0.5705
				Y	7	5	22	15	1.0476	0.6053	1.8133	1.0000	1.1667	0.1800	7.5636	0.0325	-0.3547	0.4196
Lamotrigine Use	20 mg/kg	0.1742	N		20	18	43	26	1.4885	1.1223	1.9742	0.0199	5.8846	1.2077	28.6732	0.2953	0.0988	0.4919
				Y	6	3	17	8	1.0625	0.4127	2.7357	1.0000	1.1250	0.1747	7.2430	0.0294	-0.4357	0.4946
Levetiracetam Use	20 mg/kg	0.0862	N		17	12	42	24	1.2353	0.8252	1.8492	0.3906	1.8000	0.5372	6.0308	0.1345	-0.1288	0.3977
				Y	9	9	18	10	1.8000	1.1908	2.7210	0.0258	-	-	-	0.4444	0.2149	0.6740
Rufinamide Use	20 mg/kg	0.2131	N		19	14	44	24	1.3509	0.9231	1.9768	0.1746	2.3333	0.7163	7.6013	0.1914	-0.0553	0.4381
				Y	7	7	16	10	1.6000	1.0947	2.3386	0.1243	-	-	-	0.3750	0.1378	0.6122
Current AEDs	20 mg/kg	0.9891	<3		6	5	20	12	1.3889	0.8373	2.3038	0.3798	3.3333	0.3256	34.1214	0.2333	-0.1341	0.6008



Dossier zur Nutzenbewertung - Modul 4B Anhang 4G

		>=3	20	16	40	22	1.4545	1.0191	2.0761	0.0881	3.2727	0.9280	11.5418	0.2500	0.0165	0.4835
Prior AEDs	20 mg/kg	0.9378 <6	12	10	24	15	1.3333	0.8937	1.9893	0.2681	3.0000	0.5326	16.8970	0.2083	-0.0780	0.4946
		>=6	14	11	36	19	1.4887	0.9853	2.2493	0.1183	3.2807	0.7816	13.7712	0.2579	-0.0119	0.5277
Baseline Drop Seizure Frequency	20 mg/kg	0.7702 <=55	11	9	20	12	1.3636	0.8665	2.1461	0.2617	3.0000	0.5088	17.6871	0.2182	-0.0949	0.5313
		>55 to <=125	8	7	22	12	1.6042	1.0099	2.5480	0.1987	5.8333	0.6105	55.7395	0.3295	0.0200	0.6391
		>125	7	5	18	10	1.2857	0.6884	2.4013	0.6592	2.0000	0.3036	13.1731	0.1587	-0.2471	0.5646
Non-Convulsive Seizures <=50pct																
Age Group	10 mg/kg	0.224 2-5 years	2	1	7	1	3.5000	0.3568	34.3311	0.4167	6.0000	0.1834	196.2798	0.3571	-0.3827	1.0000
		6-11 years	4	4	19	6	3.1667	1.6337	6.1383	0.0237	-	-	-	0.6842	0.4752	0.8932
		12-17 years	6	3	16	8	1.0000	0.3913	2.5555	1.0000	1.0000	0.1531	6.5308	0.0000	-0.4691	0.4691
		18-55 years	9	7	18	7	2.0000	1.0170	3.9330	0.1032	5.5000	0.8778	34.4609	0.3889	0.0361	0.7417
Sex	10 mg/kg	0.7345 F	12	9	27	10	2.0250	1.1221	3.6546	0.0407	5.1000	1.1129	23.3723	0.3796	0.0743	0.6849
		M	9	6	33	12	1.8333	0.9611	3.4973	0.1391	3.5000	0.7378	16.6035	0.3030	-0.0460	0.6520
Region	10 mg/kg	0.3667 REST OF THE WORLD	1	0	11	2	-	-	-	1.0000	-	-	-	-0.1818	-0.4097	0.0461
		USA	20	15	49	20	1.8375	1.2055	2.8009	0.0161	4.3500	1.3617	13.8961	0.3418	0.1074	0.5763
Valproate Use	10 mg/kg	0.8248 N	16	11	38	11	2.3750	1.3064	4.3177	0.0137	5.4000	1.5188	19.1992	0.3980	0.1290	0.6671
		Y	5	4	22	11	1.6000	0.8732	2.9316	0.3419	4.0000	0.3833	41.7442	0.3000	-0.1081	0.7081
Lamotrigine Use	10 mg/kg	0.9443 N	14	10	43	16	1.9196	1.1523	3.1981	0.0336	4.2188	1.1336	15.6998	0.3422	0.0649	0.6194
		Y	7	5	17	6	2.0238	0.9129	4.4866	0.1819	4.5833	0.6733	31.1983	0.3613	-0.0431	0.7658
Levetiracetam Use	10 mg/kg	0.1067 N	15	9	42	15	1.6800	0.9415	2.9979	0.1328	2.7000	0.8047	9.0594	0.2429	-0.0443	0.5300
		Y	6	6	18	7	2.5714	1.4410	4.5886	0.0162	-	-	-	0.6111	0.3859	0.8363
Rufinamide Use	10 mg/kg	0.0366 N	15	13	44	16	2.3833	1.5374	3.6947	0.0009	11.3750	2.2727	56.9319	0.5030	0.2799	0.7262
		Y	6	2	16	6	0.8889	0.2431	3.2499	1.0000	0.8333	0.1155	6.0129	-0.0417	-0.4873	0.4039
Current AEDs	10 mg/kg	0.6533 <3	6	4	20	8	1.6667	0.7641	3.6354	0.3652	3.0000	0.4404	20.4362	0.2667	-0.1674	0.7007
		>=3	15	11	40	14	2.0952	1.2444	3.5279	0.0156	5.1071	1.3698	19.0409	0.3833	0.1151	0.6515
Prior AEDs	10 mg/kg	0.037 <6	7	3	24	10	1.0286	0.3869	2.7341	1.0000	1.0500	0.1913	5.7635	0.0119	-0.4044	0.4282
		>=6	14	12	36	12	2.5714	1.5456	4.2782	0.0013	12.0000	2.3056	62.4560	0.5238	0.2844	0.7632
Baseline Drop Seizure Frequency	10 mg/kg	0.0272 <=55	8	4	20	11	0.9091	0.4092	2.0198	1.0000	0.8182	0.1584	4.2271	-0.0500	-0.4594	0.3594
		>55 to <=125	5	5	22	6	3.6667	1.8532	7.2547	0.0057	-	-	-	0.7273	0.5412	0.9134
		>125	8	6	18	5	2.7000	1.1592	6.2889	0.0384	7.8000	1.1621	52.3527	0.4722	0.1077	0.8367
Age Group	20 mg/kg	0.341 2-5 years	4	4	7	1	7.0000	1.1404	42.9692	0.0152	-	-	-	0.8571	0.5979	1.0000
		6-11 years	8	6	19	6	2.3750	1.0959	5.1468	0.0870	6.5000	1.0019	42.1718	0.4342	0.0685	0.7999
		12-17 years	7	5	16	8	1.4286	0.7252	2.8140	0.4050	2.5000	0.3701	16.8884	0.2143	-0.2005	0.6290
		18-55 years	7	5	18	7	1.8367	0.8720	3.8686	0.2016	3.9286	0.5912	26.1074	0.3254	-0.0780	0.7288
Sex	20 mg/kg	0.4203 F	9	6	27	10	1.8000	0.9167	3.5344	0.1461	3.4000	0.6927	16.6871	0.2963	-0.0615	0.6541
		M	17	14	33	12	2.2647	1.3707	3.7418	0.0028	8.1667	1.9455	34.2816	0.4599	0.2154	0.7044
Region	20 mg/kg	0.7266 REST OF THE WORLD	3	2	11	2	3.6667	0.8287	16.2238	0.1758	9.0000	0.5218	155.2422	0.4848	-0.0952	1.0000
		USA	23	18	49	20	1.9174	1.2852	2.8607	0.0049	5.2200	1.6646	16.3693	0.3744	0.1568	0.5921
Valproate Use	20 mg/kg	0.251 N	19	15	38	11	2.7273	1.5741	4.7251	0.0006	9.2045	2.4913	34.0077	0.5000	0.2668	0.7332
		Y	7	5	22	11	1.4286	0.7625	2.6764	0.4100	2.5000	0.3968	15.7493	0.2143	-0.1802	0.6088
Lamotrigine Use	20 mg/kg	0.1573 N	20	17	43	16	2.2844	1.4864	3.5107	0.0004	9.5625	2.4194	37.7956	0.4779	0.2649	0.6909
		Y	6	3	17	6	1.4167	0.5073	3.9559	0.6430	1.8333	0.2786	12.0661	0.1471	-0.3130	0.6071
Levetiracetam Use	20 mg/kg	0.411 N	17	12	42	15	1.9765	1.1884	3.2872	0.0214	4.3200	1.2762	14.6230	0.3487	0.0881	0.6093
		Y	9	8	18	7	2.2857	1.2253	4.2638	0.0192	12.5714	1.2799	123.4802	0.5000	0.1952	0.8048

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Rufinamide Use	20 mg/kg	0.1235 N Y	19 7	13 7	44 16	16 6	1.8816 2.6667	1.1457 1.4166	3.0901 5.0199	0.0277 0.0075	3.7917 -	1.2055 -	11.9255 -	0.3206 0.6250	0.0678 0.3878	0.5733 0.8622
Current AEDs	20 mg/kg	0.8234 <3 >=3	6 20	5 15	20 40	8 14	2.0833 2.1429	1.0929 1.3097	3.9712 3.5059	0.1602 0.0057	7.5000 5.5714	0.7327 1.6735	76.7732 18.5481	0.4333 0.4000	0.0659 0.1595	0.8008 0.6405
Prior AEDs	20 mg/kg	0.605 <6 >=6	12 14	9 11	24 36	10 12	1.8000 2.3571	1.0127 1.3779	3.1993 4.0323	0.0830 0.0053	4.2000 7.3333	0.9021 1.7158	19.5547 31.3426	0.3333 0.4524	0.0188 0.1880	0.6479 0.7168
Baseline Drop Seizure Frequency	20 mg/kg	0.4448 <=55 >55 to <=125 >125	11 8 7	9 7 4	20 22 18	11 6 5	1.4876 3.2083 2.0571	0.9164 1.5447 0.7697	2.4150 6.6636 5.4981	0.2409 0.0094 0.2049	3.6818 18.6667 3.4667	0.6288 1.8794 0.5629	21.5587 185.3994 21.3502	0.2682 0.6023 0.2937	-0.0472 0.3071 -0.1273	0.5836 0.8975 0.7146
Non-Convulsive Seizures <=75pct Age Group	10 mg/kg	0.6487 2-5 years 6-11 years 12-17 years 18-55 years	2 4 6 9	0 2 3 6	7 19 16 18	1 3 4 4	- 3.1667 2.0000 3.0000	- 0.7595 0.6230 1.1260	- 13.2037 6.4209 7.9932	1.0000 0.1937 0.3341 0.0393	- 5.3333 3.0000 7.0000	- 0.5264 0.4226 1.1848	- 54.0324 21.2972 41.3585	- 0.3421 0.2500 0.4444	-0.1429 -0.1746 -0.2029 0.0815	-0.4021 0.8588 0.7029 0.8074
Sex	10 mg/kg	0.7791 F M	12 9	7 4	27 33	6 6	2.6250 2.4444	1.1192 0.8742	6.1565 6.8353	0.0624 0.1805	4.9000 3.6000	1.1346 0.7381	21.1617 17.5596	0.3611 0.2626	0.0411 -0.0877	0.6811 0.6129
Region	10 mg/kg	. REST OF THE WORLD USA	1 20	0 11	11 49	0 12	2.2458 1.1942	4.2234 1.1942	0.0236 3.7685	1.2602 11.2698	0.3051 0.0560	0.5542				
Valproate Use	10 mg/kg	0.5583 N Y	16 5	8 3	38 22	5 7	3.8000 1.8857	1.4659 0.7355	9.8505 4.8345	0.0115 0.3261	6.6000 3.2143	1.6968 0.4343	25.6720 23.7867	0.3684 0.2818	0.1009 -0.1896	0.6360 0.7533
Lamotrigine Use	10 mg/kg	0.6794 N Y	14 7	7 4	43 17	7 5	3.0714 1.9429	1.3041 0.7316	7.2339 5.1595	0.0272 0.3564	5.1429 3.2000	1.3683 0.5161	19.3296 19.8415	0.3372 0.2773	0.0530 -0.1485	0.6214 0.7031
Levetiracetam Use	10 mg/kg	0.0878 N Y	15 6	6 5	42 18	9 3	1.8667 5.0000	0.7992 1.6757	4.3597 14.9193	0.1852 0.0069	2.4444 25.0000	0.6872 2.0953	8.6954 298.2870	0.1857 0.6667	-0.0915 0.3223	0.4630 1.0000
Rufinamide Use	10 mg/kg	0.2152 N Y	15 6	9 2	44 16	8 4	3.3000 1.3333	1.5577 0.3241	6.9913 5.4858	0.0061 1.0000	6.7500 1.5000	1.8654 0.1950	24.4250 11.5359	0.4182 0.0833	0.1453 -0.3494	0.6910 0.5161
Current AEDs	10 mg/kg	0.7635 <3 >=3	6 15	3 8	20 40	3 9	3.3333 2.3704	0.8951 1.1254	12.4132 4.9926	0.1119 0.0474	5.6667 3.9365	0.7541 1.1201	42.5801 13.8344	0.3500 0.3083	-0.0796 0.0246	0.7796 0.5920
Prior AEDs	10 mg/kg	0.0851 <6 >=6	7 14	3 8	24 36	8 4	1.2857 5.1429	0.4610 1.8373	3.5855 14.3953	0.6757 0.0016	1.5000 10.6667	0.2684 2.4196	8.3834 47.0234	0.0952 0.4603	-0.3170 0.1815	0.5075 0.7391
Baseline Drop Seizure Frequency	10 mg/kg	0.1417 <=55 >55 to <=125 >125	8 5 8	3 4 4	20 22 18	6 5 1	1.2500 3.5200 9.0000	0.4089 1.4507 1.1857	3.8209 8.5411 68.3130	1.0000 0.0297 0.0200	1.4000 13.6000 17.0000	0.2503 1.2245 1.4713	7.8297 151.0446 196.4257	0.0750 0.5727 0.4444	-0.3160 0.1808 0.0822	0.4660 0.9646 0.8067
Age Group	20 mg/kg	0.7322 2-5 years 6-11 years 12-17 years 18-55 years	4 8 7 7	3 4 5 3	7 19 16 18	1 3 4 4	5.2500 3.1667 2.8571 1.9286	0.7847 0.9087 1.0837 0.5717	35.1268 11.0350 7.5327 6.5064	0.0879 0.1445 0.0657 0.3554	18.0000 5.3333 7.5000 2.6250	0.8117 0.8344 1.0228 0.4069	399.1538 34.0916 54.9963 16.9349	0.6071 0.3421 0.4643 0.2063	0.1099 -0.0412 0.0680 -0.2075	1.0000 0.7254 0.8605 0.6202
Sex	20 mg/kg	0.7628 F M	9 17	6 9	27 33	6 6	3.0000 2.9118	1.2907 1.2429	6.9730 6.8213	0.0362 0.0209	7.0000 5.0625	1.3357 1.3799	36.6855 18.5725	0.4444 0.3476	0.0988 0.0763	0.7900 0.6189
Region	20 mg/kg	0.0958 REST OF THE WORLD USA	3 23	2 13	11 49	0 12	- 2.3080	- 1.2560	- 4.2410	0.0330 0.0156	- 4.0083	- 1.4019	- 11.4604	0.6667 0.3203	0.1332 0.0846	1.0000 0.5560
Valproate Use	20 mg/kg	0.2958 N Y	19 7	11 4	38 22	5 7	4.4000 1.7959	1.7847 0.7401	10.8478 4.3577	0.0011 0.3746	9.0750 2.8571	2.4505 0.4989	33.6079 16.3630	0.4474 0.2532	0.2007 -0.1618	0.6940 0.6683
Lamotrigine Use	20 mg/kg	0.0108 N Y	20 6	14 1	43 17	7 5	4.3000 0.5667	2.0597 0.0819	8.9769 3.9229	<.0001 1.0000	12.0000 0.4800	3.4276 0.0441	42.0118 5.2232	0.5372 -0.1275	0.3081 -0.4960	0.7664 0.2411

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Levetiracetam Use	20 mg/kg	0.8737 N	17	10	42	9	2.7451	1.3597	5.5419	0.0120	5.2381	1.5542	17.6535	0.3739	0.1091	0.6388	
		Y	9	5	18	3	3.3333	1.0173	10.9221	0.0721	6.2500	1.0259	38.0758	0.3889	0.0214	0.7564	
Rufinamide Use	20 mg/kg	0.7312 N	19	10	44	8	2.8947	1.3562	6.1785	0.0130	5.0000	1.5328	16.3096	0.3445	0.0927	0.5963	
		Y	7	5	16	4	2.8571	1.0837	7.5327	0.0657	7.5000	1.0228	54.9963	0.4643	0.0680	0.8605	
Current AEDs	20 mg/kg	0.4136 <3	6	4	20	3	4.4444	1.3564	14.5628	0.0278	11.3333	1.3953	92.0559	0.5167	0.1083	0.9250	
		>=3	20	11	40	9	2.4444	1.2157	4.9153	0.0194	4.2099	1.3305	13.3205	0.3250	0.0715	0.5785	
Prior AEDs	20 mg/kg	0.0123 <6	12	5	24	8	1.2500	0.5203	3.0032	0.7199	1.4286	0.3428	5.9538	0.0833	-0.2534	0.4200	
		>=6	14	10	36	4	6.4286	2.4090	17.1550	<.0001	20.0000	4.2144	94.9118	0.6032	0.3452	0.8611	
Baseline Drop Seizure Frequency	20 mg/kg	0.1685 <=55	11	5	20	6	1.5152	0.5971	3.8450	0.4524	1.9444	0.4235	8.9278	0.1545	-0.2017	0.5108	
		>55 to <=125	8	6	22	5	3.3000	1.3851	7.8625	0.0275	10.2000	1.5478	67.2166	0.5227	0.1753	0.8701	
		>125	7	4	18	1	10.2857	1.3783	76.7566	0.0123	22.6667	1.8391	279.3663	0.5159	0.1343	0.8974	
Non-Convulsive Seizures <=100pct Age Group	10 mg/kg	0.5503 2-5 years	2	0	7	0	-	-	-	-	-	-	-	-	-	-	
		6-11 years	4	0	19	0	-	-	-	-	-	-	-	-	-	-	
		12-17 years	6	0	16	1	-	-	-	1.0000	-	-	-	-	-0.0625	-0.1811	0.0561
		18-55 years	9	1	18	2	1.0000	0.1040	9.6135	1.0000	1.0000	0.0784	12.7568	0.0000	-0.2515	0.2515	
Sex	10 mg/kg	0.5873 F	12	1	27	2	1.1250	0.1126	11.2449	1.0000	1.1364	0.0930	13.8855	0.0093	-0.1757	0.1942	
		M	9	0	33	1	-	-	-	1.0000	-	-	-	-	-0.0303	-0.0888	0.0282
Region	10 mg/kg	. REST OF THE WORLD	1	0	11	0	-	-	-	-	-	-	-	-	-	-	
		USA	20	1	49	3	0.8167	0.0903	7.3897	1.0000	0.8070	0.0789	8.2567	-0.0112	-0.1280	0.1055	
Valproate Use	10 mg/kg	0.3483 N	16	1	38	1	2.3750	0.1581	35.6790	0.5087	2.4667	0.1447	42.0499	0.0362	-0.0929	0.1653	
		Y	5	0	22	2	-	-	-	1.0000	-	-	-	-	-0.0909	-0.2110	0.0292
Lamotrigine Use	10 mg/kg	0.4507 N	14	1	43	2	1.5357	0.1504	15.6811	1.0000	1.5769	0.1320	18.8342	0.0249	-0.1239	0.1738	
		Y	7	0	17	1	-	-	-	1.0000	-	-	-	-	-0.0588	-0.1707	0.0530
Levetiracetam Use	10 mg/kg	0.0368 N	15	0	42	3	-	-	-	0.5586	-	-	-	-0.0714	-0.1493	0.0065	
		Y	6	1	18	0	-	-	-	0.2500	-	-	-	-	0.1667	-0.1315	0.4649
Rufinamide Use	10 mg/kg	0.4769 N	15	1	44	2	1.4667	0.1430	15.0416	1.0000	1.5000	0.1262	17.8313	0.0212	-0.1192	0.1617	
		Y	6	0	16	1	-	-	-	1.0000	-	-	-	-	-0.0625	-0.1811	0.0561
Current AEDs	10 mg/kg	0.5376 <3	6	0	20	1	-	-	-	1.0000	-	-	-	-0.0500	-0.1455	0.0455	
		>=3	15	1	40	2	1.3333	0.1303	13.6486	1.0000	1.3571	0.1139	16.1644	0.0167	-0.1265	0.1598	
Prior AEDs	10 mg/kg	0.2874 <6	7	0	24	2	-	-	-	1.0000	-	-	-	-0.0833	-0.1939	0.0272	
		>=6	14	1	36	1	2.5714	0.1724	38.3460	0.4857	2.6923	0.1567	46.2643	0.0437	-0.1015	0.1888	
Baseline Drop Seizure Frequency	10 mg/kg	0.3756 <=55	8	0	20	1	-	-	-	1.0000	-	-	-	-0.0500	-0.1455	0.0455	
		>55 to <=125	5	1	22	2	2.2000	0.2449	19.7617	0.4735	2.5000	0.1803	34.6694	0.1091	-0.2615	0.4797	
		>125	8	0	18	0	-	-	-	-	-	-	-	-	-	-	
Age Group	20 mg/kg	0.4143 2-5 years	4	0	7	0	-	-	-	-	-	-	-	-	-	-	
		6-11 years	8	0	19	0	-	-	-	-	-	-	-	-	-	-	
		12-17 years	7	2	16	1	4.5714	0.4915	42.5177	0.2095	6.0000	0.4434	81.1960	0.2232	-0.1318	0.5783	
		18-55 years	7	1	18	2	1.2857	0.1374	12.0297	1.0000	1.3333	0.1013	17.5489	0.0317	-0.2654	0.3289	
Sex	20 mg/kg	0.7477 F	9	2	27	2	3.0000	0.4915	18.3124	0.2552	3.5714	0.4237	30.1025	0.1481	-0.1409	0.4372	
		M	17	1	33	1	1.9412	0.1292	29.1553	1.0000	2.0000	0.1173	34.0958	0.0285	-0.0977	0.1547	
Region	20 mg/kg	. REST OF THE WORLD	3	0	11	0	-	-	-	-	-	-	-	-	-	-	
		USA	23	3	49	3	2.1304	0.4652	9.7574	0.3762	2.3000	0.4269	12.3928	0.0692	-0.0839	0.2223	
Valproate Use	20 mg/kg	0.5944 N	19	2	38	1	4.0000	0.3867	41.3771	0.2552	4.3529	0.3689	51.3695	0.0789	-0.0681	0.2260	

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		Y	7	1	22	2	1.5714	0.1665	14.8309	1.0000	1.6667	0.1278	21.7324	0.0519	-0.2338	0.3377
Lamotrigine Use	20 mg/kg	0.3071 N	20	3	43	2	3.2250	0.5840	17.8085	0.3153	3.6176	0.5540	23.6231	0.1035	-0.0652	0.2722
		Y	6	0	17	1	-	-	-	1.0000	-	-	-	-0.0588	-0.1707	0.0530
Levetiracetam Use	20 mg/kg	0.314 N	17	2	42	3	1.6471	0.3014	8.9994	0.6199	1.7333	0.2630	11.4242	0.0462	-0.1256	0.2180
		Y	9	1	18	0	-	-	-	0.3333	-	-	-	0.1111	-0.0942	0.3164
Rufinamide Use	20 mg/kg	0.2488 N	19	3	44	2	3.4737	0.6306	19.1364	0.1563	3.9375	0.6011	25.7932	0.1124	-0.0627	0.2876
		Y	7	0	16	1	-	-	-	1.0000	-	-	-	-0.0625	-0.1811	0.0561
Current AEDs	20 mg/kg	0.3558 <3	6	0	20	1	-	-	-	1.0000	-	-	-	-0.0500	-0.1455	0.0455
		>=3	20	3	40	2	3.0000	0.5443	16.5336	0.3216	3.3529	0.5125	21.9377	0.1000	-0.0704	0.2704
Prior AEDs	20 mg/kg	0.9108 <6	12	2	24	2	2.0000	0.3197	12.5100	0.5877	2.2000	0.2700	17.9238	0.0833	-0.1548	0.3214
		>=6	14	1	36	1	2.5714	0.1724	38.3460	0.4857	2.6923	0.1567	46.2643	0.0437	-0.1015	0.1888
Baseline Drop Seizure Frequency	20 mg/kg	0.5506 <=55	11	2	20	1	3.6364	0.3701	35.7272	0.2814	4.2222	0.3370	52.9021	0.1318	-0.1153	0.3789
		>55 to <=125	8	1	22	2	1.3750	0.1435	13.1761	1.0000	1.4286	0.1115	18.2978	0.0341	-0.2247	0.2928
		>125	7	0	18	0	-	-	-	-	-	-	-	-	-	-
Non-Convulsive Seizures >0pct																
Age Group	10 mg/kg	0.5755 2-5 years	2	0	7	4	-	-	-	0.4444	-	-	-	-0.5714	-0.9380	-0.2048
		6-11 years	4	0	19	6	-	-	-	0.5392	-	-	-	-0.3158	-0.5248	-0.1068
		12-17 years	6	1	16	4	0.6667	0.0920	4.8298	1.0000	1.6667	0.1472	18.8744	-0.0833	-0.4493	0.2826
		18-55 years	9	1	18	3	0.6667	0.0803	5.5375	1.0000	1.6000	0.1422	18.0002	-0.0556	-0.3235	0.2124
Sex	10 mg/kg	0.8802 F	12	1	27	6	0.3750	0.0505	2.7843	0.4026	3.1429	0.3349	29.4972	-0.1389	-0.3603	0.0826
		M	9	1	33	11	0.3333	0.0494	2.2506	0.2475	4.0000	0.4427	36.1450	-0.2222	-0.4830	0.0386
Region	10 mg/kg	0.0612 REST OF THE WORLD	1	1	11	5	-	-	-	1.0000	-	-	-	0.5455	0.2512	0.8397
		USA	20	1	49	12	0.2042	0.0284	1.4678	0.0898	6.1622	0.7444	51.0137	-0.1949	-0.3486	-0.0412
Valproate Use	10 mg/kg	0.5037 N	16	2	38	12	0.3958	0.0998	1.5707	0.1872	3.2308	0.6318	16.5203	-0.1908	-0.4101	0.0285
		Y	5	0	22	5	-	-	-	0.5469	-	-	-	-0.2273	-0.4024	-0.0522
Lamotrigine Use	10 mg/kg	0.6634 N	14	1	43	12	0.2560	0.0365	1.7969	0.1520	5.0323	0.5919	42.7853	-0.2076	-0.3978	-0.0174
		Y	7	1	17	5	0.4857	0.0685	3.4424	0.6287	2.5000	0.2360	26.4803	-0.1513	-0.4891	0.1865
Levetiracetam Use	10 mg/kg	0.3692 N	15	2	42	12	0.4667	0.1179	1.8475	0.3118	2.6000	0.5082	13.3006	-0.1524	-0.3721	0.0673
		Y	6	0	18	5	1.3846	1.0397	1.8440	0.2801	-	-	-	-0.2778	-0.4847	-0.0709
Rufinamide Use	10 mg/kg	0.6034 N	15	1	44	12	0.2444	0.0346	1.7250	0.1515	5.2500	0.6211	44.3765	-0.2061	-0.3884	-0.0237
		Y	6	1	16	5	0.5333	0.0773	3.6787	0.6341	2.2727	0.2076	24.8822	-0.1458	-0.5207	0.2290
Current AEDs	10 mg/kg	0.5703 <3	6	1	20	6	0.5556	0.0822	3.7530	1.0000	2.1429	0.2043	22.4781	-0.1333	-0.4929	0.2262
		>=3	15	1	40	11	0.2424	0.0342	1.7197	0.1467	5.3103	0.6222	45.3243	-0.2083	-0.3956	-0.0210
Prior AEDs	10 mg/kg	0.0667 <6	7	2	24	7	0.9796	0.2599	3.6924	1.0000	1.0294	0.1601	6.6201	-0.0060	-0.3868	0.3749
		>=6	14	0	36	10	-	-	-	0.0445	-	-	-	-0.2778	-0.4241	-0.1315
Baseline Drop Seizure Frequency	10 mg/kg	0.1651 <=55	8	2	20	5	1.0000	0.2417	4.1377	1.0000	1.0000	0.1505	6.6426	0.0000	-0.3550	0.3550
		>55 to <=125	5	0	22	6	-	-	-	0.5552	-	-	-	-0.2727	-0.4588	-0.0866
		>125	8	0	18	6	-	-	-	0.1317	-	-	-	-0.3333	-0.5511	-0.1156
Age Group	20 mg/kg	0.1454 2-5 years	4	0	7	4	2.3333	0.9919	5.4887	0.1939	-	-	-	-0.5714	-0.9380	-0.2048
		6-11 years	8	2	19	6	0.7917	0.2010	3.1174	1.0000	1.3846	0.2134	8.9833	-0.0658	-0.4315	0.2999
		12-17 years	7	0	16	4	-	-	-	0.2727	-	-	-	-0.2500	-0.4622	-0.0378
		18-55 years	7	2	18	3	1.7143	0.3596	8.1722	0.5968	0.5000	0.0640	3.9059	0.1190	-0.2573	0.4954
Sex	20 mg/kg	0.2815 F	9	2	27	6	1.0000	0.2438	4.1014	1.0000	1.0000	0.1629	6.1385	0.0000	-0.3136	0.3136
		M	17	2	33	11	0.3529	0.0881	1.4147	0.1729	3.7500	0.7250	19.3971	-0.2157	-0.4378	0.0064

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Region	20 mg/kg	0.2489 REST OF THE WORLD	3	0	11	5	-	-	-	0.2582	-	-	-	-0.4545	-0.7488	-0.1603
		USA	23	4	49	12	0.7101	0.2567	1.9642	0.5603	1.5405	0.4372	5.4287	-0.0710	-0.2672	0.1252
Valproate Use	20 mg/kg	0.1780 N	19	2	38	12	0.3333	0.0829	1.3409	0.1089	3.9231	0.7787	19.7635	-0.2105	-0.4127	-0.0083
		Y	7	2	22	5	1.2571	0.3094	5.1082	1.0000	0.7353	0.1079	5.0113	0.0584	-0.3193	0.4361
Lamotrigine Use	20 mg/kg	0.2631 N	20	2	43	12	0.3583	0.0884	1.4528	0.1920	3.4839	0.6994	17.3539	-0.1791	-0.3668	0.0087
		Y	6	2	17	5	1.1333	0.2938	4.3723	1.0000	0.8333	0.1136	6.1107	0.0392	-0.3957	0.4742
Levetiracetam Use	20 mg/kg	0.1475 N	17	4	42	12	0.8235	0.3087	2.1972	0.7586	1.3000	0.3524	4.7958	-0.0504	-0.2940	0.1931
		Y	9	0	18	5	-	-	-	0.1358	-	-	-	-0.2778	-0.4847	-0.0709
Rufinamide Use	20 mg/kg	0.1766 N	19	4	44	12	0.7719	0.2853	2.0889	0.7566	1.4063	0.3882	5.0938	-0.0622	-0.2879	0.1635
		Y	7	0	16	5	-	-	-	0.2719	-	-	-	-0.3125	-0.5396	-0.0854
Current AEDs	20 mg/kg	0.9983 <3	6	1	20	6	0.5556	0.0822	3.7530	1.0000	2.1429	0.2043	22.4781	-0.1333	-0.4929	0.2262
		>=3	20	3	40	11	0.5455	0.1713	1.7370	0.3470	2.1494	0.5248	8.8041	-0.1250	-0.3339	0.0839
Prior AEDs	20 mg/kg	0.3826 <6	12	1	24	7	0.2857	0.0396	2.0640	0.2236	4.5294	0.4879	42.0524	-0.2083	-0.4482	0.0315
		>=6	14	3	36	10	0.7714	0.2485	2.3951	0.7344	1.4103	0.3242	6.1350	-0.0635	-0.3235	0.1965
Baseline Drop Seizure Frequency	20 mg/kg	0.7852 <=55	11	1	20	5	0.3636	0.0484	2.7331	0.3826	3.3333	0.3371	32.9588	-0.1591	-0.4138	0.0956
		>55 to <=125	8	1	22	6	0.4583	0.0648	3.2417	0.6378	2.6250	0.2643	26.0718	-0.1477	-0.4429	0.1475
		>125	7	2	18	6	0.8571	0.2242	3.2773	1.0000	1.2500	0.1850	8.4442	-0.0476	-0.4469	0.3517

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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Adhoc Table:		GWEP1414 CGIC Responder [VMI, MI, SI] (subgroups) (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)																	
Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference				
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI	
End of Treatment	Age Group	10 mg/kg	0.2078	2-5 years	4	3	9	4	1.6875	0.6699	4.2511	0.5594	0.2667	0.0195	3.6532	0.3056	-0.2287	0.8398	
				6-11 years	13	13	22	10	-	-	-	0.0009	-	-	-	0.5455	0.3374	0.7535	
				12-17 years	7	5	20	9	1.5873	0.8090	3.1144	0.3845	0.3273	0.0509	2.1054	0.2643	-0.1351	0.6637	
				18-55 years	11	7	19	9	1.3434	0.7004	2.5768	0.4664	0.5143	0.1121	2.3590	0.1627	-0.1996	0.5249	
Last Visit (LOCF)	Age Group	10 mg/kg	0.5324	2-5 years	4	3	9	4	1.6875	0.6699	4.2511	0.5594	0.2667	0.0195	3.6532	0.3056	-0.2287	0.8398	
				6-11 years	14	13	23	11	1.9416	1.2369	3.0477	0.0111	0.0705	0.0079	0.6315	0.4503	0.2056	0.6950	
				12-17 years	7	5	20	9	1.5873	0.8090	3.1144	0.3845	0.3273	0.0509	2.1054	0.2643	-0.1351	0.6637	
				18-55 years	12	7	23	9	1.4907	0.7411	2.9987	0.3110	0.4592	0.1109	1.9010	0.1920	-0.1509	0.5349	
End of Treatment	Sex	10 mg/kg	0.3079	F	20	17	31	13	2.0269	1.2882	3.1893	0.0033	0.1275	0.0308	0.5271	0.4306	0.1968	0.6644	
				M	15	11	39	19	1.5053	0.9659	2.3457	0.1331	0.3455	0.0936	1.2743	0.2462	-0.0271	0.5194	
Last Visit (LOCF)	Sex	10 mg/kg	0.3201	F	21	17	32	13	1.9927	1.2486	3.1801	0.0049	0.1610	0.0440	0.5894	0.4033	0.1642	0.6424	
				M	16	11	43	20	1.4781	0.9328	2.3421	0.1530	0.3953	0.1173	1.3323	0.2224	-0.0493	0.4941	
End of Treatment	Region	10 mg/kg	0.2879	REST OF THE WORLD	1	0	13	3	-	-	-	1.0000	-	-	-	-0.2308	-0.4598	-0.0017	
				USA	34	28	57	29	1.6187	1.2006	2.1823	0.0034	0.2219	0.0798	0.6175	0.3148	0.1324	0.4971	
Last Visit (LOCF)	Region	10 mg/kg	0.3517	REST OF THE WORLD	1	0	14	3	-	-	-	1.0000	-	-	-	-0.2143	-0.4292	0.0007	
				USA	36	28	61	30	1.5815	1.1609	2.1544	0.0059	0.2765	0.1088	0.7025	0.2860	0.1011	0.4709	
End of Treatment	Valproate Use	10 mg/kg	0.8419	N	29	23	44	18	1.9387	1.2985	2.8946	0.0016	0.1806	0.0613	0.5323	0.3840	0.1770	0.5910	
				Y	6	5	26	14	1.5476	0.9343	2.5635	0.3606	0.2333	0.0238	2.2842	0.2949	-0.0596	0.6493	
Last Visit (LOCF)	Valproate Use	10 mg/kg	0.4545	N	30	23	46	18	1.9593	1.2990	2.9550	0.0020	0.1957	0.0697	0.5495	0.3754	0.1685	0.5822	
				Y	7	5	29	15	1.3810	0.7687	2.4807	0.4264	0.4286	0.0712	2.5780	0.1970	-0.1838	0.5779	
End of Treatment	Lamotrigine Use	10 mg/kg	0.1671	N	26	22	47	20	1.9885	1.3729	2.8799	0.0005	0.1347	0.0401	0.4526	0.4206	0.2226	0.6186	
				Y	9	6	23	12	1.2778	0.6975	2.3409	0.6942	0.5455	0.1091	2.7271	0.1449	-0.2246	0.5144	
Last Visit (LOCF)	Lamotrigine Use	10 mg/kg	0.1608	N	27	22	50	21	1.9400	1.3373	2.8145	0.0015	0.1646	0.0536	0.5053	0.3948	0.1944	0.5953	
				Y	10	6	25	12	1.2500	0.6525	2.3945	0.7112	0.6154	0.1389	2.7270	0.1200	-0.2413	0.4813	
End of Treatment	Levetiracetam Use	10 mg/kg	0.3715	N	28	21	48	18	2.0000	1.3099	3.0537	0.0020	0.2000	0.0710	0.5636	0.3750	0.1641	0.5859	
				Y	7	7	22	14	-	-	-	0.1421	-	-	-	0.3636	0.1626	0.5646	
Last Visit (LOCF)	Levetiracetam Use	10 mg/kg	0.2847	N	28	21	52	18	2.1667	1.4088	3.3322	0.0009	0.1765	0.0631	0.4936	0.4038	0.1978	0.6099	
				Y	9	7	23	15	1.1926	0.7533	1.8880	0.6808	0.5357	0.0894	3.2101	0.1256	-0.2086	0.4598	
End of Treatment	Rufinamide Use	10 mg/kg	0.1569	N	23	20	52	23	1.9660	1.3940	2.7726	0.0008	0.1190	0.0314	0.4503	0.4273	0.2345	0.6200	
				Y	12	8	18	9	1.3333	0.7237	2.4567	0.4651	0.5000	0.1099	2.2739	0.1667	-0.1862	0.5195	
Last Visit (LOCF)	Rufinamide Use	10 mg/kg	0.3563	N	25	20	56	24	1.8667	1.3018	2.6766	0.0033	0.1875	0.0616	0.5711	0.3714	0.1680	0.5749	

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		Y	12	8	19	9	1.4074	0.7569	2.6169	0.4607	0.4500	0.1004	2.0178	0.1930	-0.1556	0.5416	
End of Treatment	Baseline Drop Seizure Frequency	10 mg/kg	0.6166 <=55	11	9	22	12	1.5000	0.9353	2.4056	0.2492	0.2667	0.0465	1.5299	0.2727	-0.0359	0.5813
			>55 to <=125	10	9	26	11	2.11273	1.2979	3.4867	0.0219	0.0815	0.0090	0.7410	0.4769	0.2111	0.7427
			>125	14	10	22	9	1.7460	0.9567	3.1867	0.0967	0.2769	0.0658	1.1661	0.3052	-0.0082	0.6186
Last Visit (LOCF)	Baseline Drop Seizure Frequency	10 mg/kg	0.6622 <=55	12	9	22	12	1.3750	0.8321	2.2720	0.2919	0.4000	0.0847	1.8901	0.2045	-0.1169	0.5260
			>55 to <=125	11	9	31	12	2.1136	1.2525	3.5668	0.0325	0.1404	0.0258	0.7637	0.4311	0.1459	0.7163
			>125	14	10	22	9	1.7460	0.9567	3.1867	0.0967	0.2769	0.0658	1.1661	0.3052	-0.0082	0.6186
End of Treatment	Current AEDs	10 mg/kg	0.2191 <3	12	11	23	10	2.1083	1.2836	3.4629	0.0097	0.0699	0.0077	0.6355	0.4819	0.2260	0.7378
			>=3	23	17	47	22	1.5791	1.0695	2.3314	0.0417	0.3106	0.1041	0.9265	0.2710	0.0418	0.5003
Last Visit (LOCF)	Current AEDs	10 mg/kg	0.1059 <3	12	11	25	10	2.2917	1.3768	3.8144	0.0042	0.0606	0.0067	0.5458	0.5167	0.2690	0.7643
			>=3	25	17	50	23	1.4783	0.9878	2.2122	0.0890	0.4009	0.1463	1.0981	0.2200	-0.0092	0.4492
End of Treatment	Prior AEDs	10 mg/kg	0.7700 <6	15	12	28	14	1.6000	1.0217	2.5057	0.1005	0.2500	0.0577	1.0831	0.3000	0.0256	0.5744
			>=6	20	16	42	18	1.8667	1.2360	2.8191	0.0071	0.1875	0.0535	0.6574	0.3714	0.1409	0.6019
Last Visit (LOCF)	Prior AEDs	10 mg/kg	0.6037 <6	16	12	30	15	1.5000	0.9506	2.3670	0.1261	0.3333	0.0874	1.2716	0.2500	-0.0275	0.5275
			>=6	21	16	45	18	1.9048	1.2386	2.9292	0.0083	0.2083	0.0648	0.6699	0.3619	0.1302	0.5936
End of Treatment	Age Group	20 mg/kg	0.2857 2-5 years	3	3	9	4	-	-	-	0.2045	-	-	-	0.5556	0.2309	0.8802
			6-11 years	10	6	22	10	1.3200	0.6672	2.6117	0.7043	0.5556	0.1217	2.5355	0.1455	-0.2226	0.5135
			12-17 years	6	6	20	9	-	-	-	0.0237	-	-	0.5500	0.3320	0.7680	
			18-55 years	13	10	19	9	1.6239	0.9279	2.8422	0.1469	0.2700	0.0560	1.3022	0.2955	-0.0252	0.6163
Last Visit (LOCF)	Age Group	20 mg/kg	0.2292 2-5 years	4	4	9	4	-	-	-	0.1049	-	-	-	0.5556	0.2309	0.8802
			6-11 years	11	7	23	11	1.3306	0.7173	2.4682	0.4768	0.5238	0.1197	2.2918	0.1581	-0.1919	0.5081
			12-17 years	7	7	20	9	-	-	-	0.0216	-	-	0.5500	0.3320	0.7680	
			18-55 years	13	10	23	9	1.9658	1.0894	3.5474	0.0411	0.1929	0.0414	0.8979	0.3779	0.0742	0.6816
End of Treatment	Sex	20 mg/kg	0.2399 F	14	9	31	13	1.5330	0.8676	2.7086	0.2078	0.4012	0.1088	1.4802	0.2235	-0.0817	0.5287
			M	18	16	39	19	1.8246	1.2716	2.6180	0.0039	0.1188	0.0240	0.5873	0.4017	0.1880	0.6155
Last Visit (LOCF)	Sex	20 mg/kg	0.1627 F	14	9	32	13	1.5824	0.8926	2.8055	0.2022	0.3801	0.1035	1.3963	0.2366	-0.0666	0.5398
			M	21	19	43	20	1.9452	1.3718	2.7584	0.0008	0.0915	0.0189	0.4424	0.4396	0.2447	0.6346
End of Treatment	Region	20 mg/kg	0.0557 REST OF THE WORLD	5	5	13	3	-	-	-	0.0065	-	-	-	0.7692	0.5402	0.9983
			USA	27	20	57	29	1.4559	1.0374	2.0433	0.0586	0.3625	0.1327	0.9906	0.2320	0.0218	0.4421
Last Visit (LOCF)	Region	20 mg/kg	0.0648 REST OF THE WORLD	5	5	14	3	-	-	-	0.0048	-	-	-	0.7857	0.5708	1.0000
			USA	30	23	61	30	1.5589	1.1291	2.1523	0.0140	0.2945	0.1101	0.7877	0.2749	0.0783	0.4714
End of Treatment	Valproate Use	20 mg/kg	0.1700 N	23	19	44	18	2.0193	1.3514	3.0173	0.0016	0.1457	0.0424	0.5008	0.4170	0.2046	0.6294
			Y	9	6	26	14	1.2381	0.6910	2.2182	0.7003	0.5833	0.1194	2.8490	0.1282	-0.2345	0.4909
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.1811 N	25	21	46	18	2.1467	1.4404	3.1991	0.0004	0.1224	0.0361	0.4157	0.4487	0.2473	0.6500
			Y	10	7	29	15	1.3533	0.7911	2.3152	0.4644	0.4592	0.0988	2.1337	0.1828	-0.1545	0.5200

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End of Treatment	Lamotrigine Use	20 mg/kg	0.9654 N Y	21 11	16 9	47 23	20 12	1.7905 1.5682	1.1891 0.9701	2.6960 2.5351	0.0170 0.1398	0.2315 0.2424	0.0727 0.0427	0.7375 1.3769	0.3364 0.2964	0.1058 -0.0095	0.5669 0.6024
Last Visit (LOCF)	Lamotrigine Use	20 mg/kg	0.9347 N Y	23 12	18 10	50 25	21 12	1.8634 1.7361	1.2610 1.0742	2.7535 2.8059	0.0053 0.0727	0.2011 0.1846	0.0644 0.0334	0.6283 1.0197	0.3626 0.3533	0.1455 0.0656	0.5797 0.6411
End of Treatment	Levetiracetam Use	20 mg/kg	0.3972 N Y	22 10	17 8	48 22	18 14	2.0606 1.2571	1.3407 0.8076	3.1671 1.9569	0.0041 0.4399	0.1765 0.4375	0.0556 0.0740	0.5605 2.5849	0.3977 0.1636	0.1754 -0.1555	0.6200 0.4828
Last Visit (LOCF)	Levetiracetam Use	20 mg/kg	0.2988 N Y	24 11	19 9	52 23	18 15	2.2870 1.2545	1.4934 0.8340	3.5025 1.8871	0.0004 0.4375	0.1393 0.4167	0.0446 0.0720	0.4351 2.4124	0.4455 0.1660	0.2379 -0.1337	0.6532 0.4657
End of Treatment	Rufinamide Use	20 mg/kg	0.8122 N Y	23 9	18 7	52 18	23 9	1.7694 1.5556	1.2178 0.8717	2.5707 2.7758	0.0110 0.2311	0.2203 0.2857	0.0710 0.0462	0.6833 1.7686	0.3403 0.2778	0.1243 -0.0788	0.5563 0.6343
Last Visit (LOCF)	Rufinamide Use	20 mg/kg	0.7362 N Y	26 9	21 7	56 19	24 9	1.8846 1.6420	1.3203 0.9114	2.6901 2.9583	0.0017 0.2232	0.1786 0.2571	0.0589 0.0420	0.5417 1.5732	0.3791 0.3041	0.1798 -0.0483	0.5785 0.6565
End of Treatment	Baseline Drop Seizure Frequency	20 mg/kg	0.5472 <=55 >55 to <=125 >125	13 11 8	12 7 6	22 26 22	12 11 9	1.6923 1.5041 1.8333	1.1203 0.7985 0.9647	2.5563 2.8334 3.4842	0.0270 0.2953 0.2148	0.1000 0.4190 0.2308	0.0110 0.0979 0.0377	0.9078 1.7938 1.4129	0.3776 0.2133 0.3409	0.1241 -0.1286 -0.0227	0.6311 0.5552 0.7046
Last Visit (LOCF)	Baseline Drop Seizure Frequency	20 mg/kg	0.5369 <=55 >55 to <=125 >125	15 11 9	14 7 7	22 31 22	12 12 9	1.7111 1.6439 1.9012	1.1416 0.8763 1.0313	2.5648 3.0839 3.5050	0.0136 0.1795 0.1134	0.0857 0.3609 0.1978	0.0095 0.0868 0.0331	0.7701 1.5010 1.1807	0.3879 0.2493 0.3687	0.1445 -0.0827 0.0281	0.6312 0.5812 0.7092
End of Treatment	Current AEDs	20 mg/kg	0.6751 <3 >=3	6 26	5 20	23 47	10 22	1.9167 1.6434	1.0651 1.1347	3.4491 2.3801	0.1686 0.0148	0.1538 0.2640	0.0154 0.0899	1.5343 0.7753	0.3986 0.3011	0.0380 0.0853	0.7591 0.5170
Last Visit (LOCF)	Current AEDs	20 mg/kg	0.5589 <3 >=3	7 28	6 22	25 50	10 23	2.1429 1.7081	1.2150 1.1950	3.7793 2.4414	0.0829 0.0081	0.1111 0.2323	0.0116 0.0805	1.0682 0.6707	0.4571 0.3257	0.1345 0.1203	0.7798 0.5311
End of Treatment	Prior AEDs	20 mg/kg	0.1077 <6 >=6	16 16	15 10	28 42	14 18	1.8750 1.4583	1.2677 0.8707	2.7732 2.4426	0.0034 0.2432	0.0667 0.4500	0.0077 0.1380	0.5755 1.4679	0.4375 0.1964	0.2176 -0.0841	0.6574 0.4769
Last Visit (LOCF)	Prior AEDs	20 mg/kg	0.0917 <6 >=6	19 16	18 10	30 45	15 18	1.8947 1.5625	1.3046 0.9274	2.7519 2.6325	0.0014 0.1508	0.0556 0.4000	0.0066 0.1236	0.4708 1.2950	0.4474 0.2250	0.2422 -0.0521	0.6525 0.5021

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

End of treatment = The date of last dose as recorded on the 'End of Treatment Study Outcome' CRF page (Visit 8: Day 99).

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.



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Adhoc Table		GWEP1414 CGIC Responder [VMI, MI] (subgroups) (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)																	
Analysis	Factor	Treatment	Interaction		Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference			
			p-value [1]	Factor Level	N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI		
End of Treatment	Age Group	10 mg/kg	0.8817	2-5 years	4	1	9	0	-	-	-	0.3077	-	-	-	0.2500	-0.1743	0.6743	
				6-11 years	13	6	22	3	3.3846	1.0149	11.2871	0.0505	0.1842	0.0359	0.9445	0.3252	0.0186	0.6318	
				12-17 years	7	4	20	3	3.8095	1.1194	12.9649	0.0496	0.1324	0.0191	0.9171	0.4214	0.0228	0.8200	
				18-55 years	11	5	19	3	2.8788	0.8468	9.7869	0.1040	0.2250	0.0406	1.2458	0.2967	-0.0402	0.6335	
Last Visit (LOCF)	Age Group	10 mg/kg	0.8846	2-5 years	4	1	9	0	-	-	-	0.3077	-	-	-	0.2500	-0.1743	0.6743	
				6-11 years	14	6	23	3	3.2857	0.9737	11.0879	0.0569	0.2000	0.0400	1.0008	0.2981	0.0046	0.5916	
				12-17 years	7	4	20	3	3.8095	1.1194	12.9649	0.0496	0.1324	0.0191	0.9171	0.4214	0.0228	0.8200	
				18-55 years	12	5	23	3	3.1944	0.9155	11.1459	0.0912	0.2100	0.0395	1.1158	0.2862	-0.0248	0.5973	
End of Treatment	Sex	10 mg/kg	0.8739	F	20	11	31	6	2.8417	1.2507	6.4562	0.0143	0.1964	0.0561	0.6874	0.3565	0.0978	0.6151	
				M	15	5	39	3	4.3333	1.1791	15.9259	0.0302	0.1667	0.0339	0.8203	0.2564	0.0036	0.5092	
Last Visit (LOCF)	Sex	10 mg/kg	0.8140	F	21	11	32	6	2.7937	1.2199	6.3974	0.0161	0.2098	0.0611	0.7202	0.3363	0.0835	0.5891	
				M	16	5	43	3	4.4792	1.2071	16.6212	0.0278	0.1650	0.0340	0.8005	0.2427	0.0032	0.4823	
End of Treatment	Region	10 mg/kg	0.5207	REST OF THE WORLD	1	0	13	1	-	-	-	1.0000	-	-	-	-0.0769	-0.2218	0.0679	
				USA	34	16	57	8	3.3529	1.6081	6.9909	0.0011	0.1837	0.0672	0.5023	0.3302	0.1398	0.5207	
Last Visit (LOCF)	Region	10 mg/kg	0.5403	REST OF THE WORLD	1	0	14	1	-	-	-	1.0000	-	-	-	-0.0714	-0.2063	0.0635	
				USA	36	16	61	8	3.3889	1.6136	7.1172	0.0012	0.1887	0.0699	0.5090	0.3133	0.1302	0.4964	
End of Treatment	Valproate Use	10 mg/kg	0.0462	N	29	15	44	4	5.6897	2.0966	15.4405	<.0001	0.0933	0.0265	0.3289	0.4263	0.2256	0.6271	
				Y	6	1	26	5	0.8667	0.1227	6.1216	1.0000	1.1905	0.1126	12.5852	-0.0256	-0.3601	0.3088	
Last Visit (LOCF)	Valproate Use	10 mg/kg	0.0405	N	30	15	46	4	5.7500	2.1101	15.6684	<.0001	0.0952	0.0273	0.3326	0.4130	0.2165	0.6096	
				Y	7	1	29	5	0.8286	0.1142	6.0134	1.0000	1.2500	0.1221	12.7955	-0.0296	-0.3230	0.2639	
End of Treatment	Lamotrigine Use	10 mg/kg	0.5470	N	26	12	47	5	4.3385	1.7173	10.9606	0.0011	0.1389	0.0416	0.4639	0.3552	0.1442	0.5661	
				Y	9	4	23	4	2.5556	0.8076	8.0863	0.1760	0.2632	0.0481	1.4410	0.2705	-0.0892	0.6302	
Last Visit (LOCF)	Lamotrigine Use	10 mg/kg	0.4876	N	27	12	50	5	4.4444	1.7494	11.2912	0.0011	0.1389	0.0420	0.4592	0.3444	0.1394	0.5495	
				Y	10	4	25	4	2.5000	0.7713	8.1033	0.1863	0.2857	0.0545	1.4974	0.2400	-0.0959	0.5759	
End of Treatment	Levetiracetam Use	10 mg/kg	0.0835	N	28	10	48	6	2.8571	1.1635	7.0164	0.0219	0.2571	0.0812	0.8145	0.2321	0.0315	0.4328	
				Y	7	6	22	3	6.2857	2.1044	18.7747	0.0011	0.0263	0.0023	0.3026	0.7208	0.4245	1.0000	
Last Visit (LOCF)	Levetiracetam Use	10 mg/kg	0.2997	N	28	10	52	6	3.0952	1.2561	7.6271	0.0174	0.2348	0.0744	0.7411	0.2418	0.0442	0.4393	
				Y	9	6	23	3	5.1111	1.6153	16.1726	0.0056	0.0750	0.0119	0.4732	0.5362	0.1989	0.8736	
End of Treatment	Rufinamide Use	10 mg/kg	0.0256	N	23	14	52	6	5.2754	2.3215	11.9875	<.0001	0.0839	0.0254	0.2767	0.4933	0.2758	0.7108	
				Y	12	2	18	3	1.0000	0.1953	5.1208	1.0000	1.0000	0.1409	7.0991	0.0000	-0.2722	0.2722	
Last Visit (LOCF)	Rufinamide Use	10 mg/kg	0.0376	N	25	14	56	6	5.2267	2.2743	12.0115	<.0001	0.0943	0.0296	0.3001	0.4529	0.2421	0.6636	

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		Y	12	2	19	3	1.0556	0.2054	5.4238	1.0000	0.9375	0.1326	6.6282	0.0088	-0.2583	0.2759	
End of Treatment	Baseline Drop Seizure Frequency	10 mg/kg	0.9562 <=55	11	6	22	3	4.0000	1.2268	13.0423	0.0334	0.1316	0.0240	0.7205	0.4091	0.0818	0.7364
			>55 to <=125	10	5	26	4	3.2500	1.0884	9.7048	0.0794	0.1818	0.0355	0.9322	0.3462	0.0066	0.6857
			>125	14	5	22	2	3.9286	0.8795	17.5481	0.0842	0.1800	0.0292	1.1096	0.2662	-0.0120	0.5445
Last Visit (LOCF)	Baseline Drop Seizure Frequency	10 mg/kg	0.9929 <=55	12	6	22	3	3.6667	1.1109	12.1028	0.0403	0.1579	0.0300	0.8323	0.3636	0.0465	0.6808
			>55 to <=125	11	5	31	4	3.5227	1.1488	10.8020	0.0376	0.1778	0.0364	0.8671	0.3255	0.0085	0.6425
			>125	14	5	22	2	3.9286	0.8795	17.5481	0.0842	0.1800	0.0292	1.1096	0.2662	-0.0120	0.5445
End of Treatment	Prior AEDs	10 mg/kg	0.6975 <6	15	7	28	3	4.3556	1.3141	14.4367	0.0192	0.1371	0.0285	0.6588	0.3595	0.0823	0.6368
			>=6	20	9	42	6	3.1500	1.2998	7.6337	0.0124	0.2037	0.0593	0.6998	0.3071	0.0648	0.5495
Last Visit (LOCF)	Prior AEDs	10 mg/kg	0.7188 <6	16	7	30	3	4.3750	1.3062	14.6535	0.0202	0.1429	0.0304	0.6722	0.3375	0.0718	0.6032
			>=6	21	9	45	6	3.2143	1.3150	7.8566	0.0120	0.2051	0.0606	0.6940	0.2952	0.0614	0.5290
End of Treatment	Current AEDs	10 mg/kg	0.0813 <3	12	9	23	3	5.7500	1.9052	17.3539	0.0005	0.0500	0.0084	0.2974	0.6196	0.3386	0.9006
			>=3	23	7	47	6	2.3841	0.9040	6.2870	0.1031	0.3345	0.0974	1.1490	0.1767	-0.0342	0.3876
Last Visit (LOCF)	Current AEDs	10 mg/kg	0.0589 <3	12	9	25	3	6.2500	2.0584	18.9770	0.0003	0.0455	0.0077	0.2691	0.6300	0.3539	0.9061
			>=3	25	7	50	6	2.3333	0.8766	6.2112	0.1095	0.3506	0.1035	1.1884	0.1600	-0.0377	0.3577
End of Treatment	Age Group	20 mg/kg	0.1358 2-5 years	3	1	9	0	-	-	-	0.2500	-	-	-	0.3333	-0.2001	0.8668
			6-11 years	10	3	22	3	2.2000	0.5344	9.0562	0.3461	0.3684	0.0597	2.2736	0.1636	-0.1545	0.4818
			12-17 years	6	6	20	3	-	-	-	0.0004	-	-	-	0.8500	0.6935	1.0000
			18-55 years	13	6	19	3	2.9231	0.8867	9.6365	0.1090	0.2188	0.0422	1.1346	0.3036	-0.0131	0.6204
Last Visit (LOCF)	Age Group	20 mg/kg	0.3179 2-5 years	4	1	9	0	-	-	-	0.3077	-	-	-	0.2500	-0.1743	0.6743
			6-11 years	11	3	23	3	2.0909	0.5004	8.7368	0.3627	0.4000	0.0662	2.4153	0.1423	-0.1547	0.4393
			12-17 years	7	6	20	3	5.7143	1.9285	16.9318	0.0017	0.0294	0.0025	0.3398	0.7071	0.4043	1.0000
			18-55 years	13	6	23	3	3.5385	1.0577	11.8373	0.0459	0.1750	0.0342	0.8945	0.3311	0.0272	0.6350
End of Treatment	Sex	20 mg/kg	0.5989 F	14	8	31	6	2.9524	1.2622	6.9060	0.0171	0.1800	0.0451	0.7181	0.3779	0.0837	0.6721
			M	18	8	39	3	5.7778	1.7339	19.2529	0.0024	0.1042	0.0232	0.4671	0.3675	0.1232	0.6118
Last Visit (LOCF)	Sex	20 mg/kg	0.7328 F	14	8	32	6	3.0476	1.2999	7.1450	0.0151	0.1731	0.0435	0.6890	0.3839	0.0915	0.6763
			M	21	8	43	3	5.4603	1.6120	18.4952	0.0038	0.1219	0.0281	0.5285	0.3112	0.0900	0.5324
End of Treatment	Region	20 mg/kg	0.1430 REST OF THE WORLD	5	4	13	1	10.4000	1.5044	71.8949	0.0077	0.0208	0.0010	0.4159	0.7231	0.3437	1.0000
			USA	27	12	57	8	3.1667	1.4684	6.8292	0.0050	0.2041	0.0703	0.5922	0.3041	0.0961	0.5121
Last Visit (LOCF)	Region	20 mg/kg	0.1094 REST OF THE WORLD	5	4	14	1	11.2000	1.6113	77.8485	0.0061	0.0192	0.0010	0.3823	0.7286	0.3529	1.0000
			USA	30	12	61	8	3.0500	1.3973	6.6572	0.0063	0.2264	0.0799	0.6420	0.2689	0.0742	0.4636
End of Treatment	Valproate Use	20 mg/kg	0.2684 N	23	12	44	4	5.7391	2.0840	15.8046	0.0002	0.0917	0.0246	0.3410	0.4308	0.2097	0.6519
			Y	9	4	26	5	2.3111	0.7893	6.7667	0.1916	0.2976	0.0579	1.5297	0.2521	-0.1061	0.6104
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.2859 N	25	12	46	4	5.5200	1.9876	15.3299	0.0003	0.1032	0.0284	0.3753	0.3930	0.1810	0.6051
			Y	10	4	29	5	2.3200	0.7715	6.9761	0.1970	0.3125	0.0637	1.5328	0.2276	-0.1057	0.5609

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End of Treatment	Lamotrigine Use	20 mg/kg	0.7927 N	21	9	47	5	4.0286	1.5354	10.5700	0.0070	0.1587	0.0447	0.5638	0.3222	0.0929	0.5515
			Y	11	7	23	4	3.6591	1.3509	9.9111	0.0160	0.1203	0.0235	0.6168	0.4625	0.1387	0.7862
Last Visit (LOCF)	Lamotrigine Use	20 mg/kg	0.8149 N	23	9	50	5	3.9130	1.4755	10.3776	0.0080	0.1728	0.0497	0.6014	0.2913	0.0752	0.5074
			Y	12	7	25	4	3.6458	1.3179	10.0857	0.0183	0.1361	0.0283	0.6530	0.4233	0.1096	0.7371
End of Treatment	Levetiracetam Use	20 mg/kg	0.5248 N	22	12	48	6	4.3636	1.8837	10.1085	0.0007	0.1190	0.0359	0.3946	0.4205	0.1923	0.6486
			Y	10	4	22	3	2.9333	0.8019	10.7306	0.1655	0.2368	0.0409	1.3710	0.2636	-0.0722	0.5994
Last Visit (LOCF)	Levetiracetam Use	20 mg/kg	0.5095 N	24	12	52	6	4.3333	1.8479	10.1619	0.0008	0.1304	0.0406	0.4194	0.3846	0.1665	0.6027
			Y	11	4	23	3	2.7879	0.7498	10.3659	0.1780	0.2625	0.0467	1.4759	0.2332	-0.0826	0.5490
End of Treatment	Rufinamide Use	20 mg/kg	0.0643 N	23	14	52	6	5.2754	2.3215	11.9875	<.0001	0.0839	0.0254	0.2767	0.4933	0.2758	0.7108
			Y	9	2	18	3	1.3333	0.2691	6.6061	1.0000	0.7000	0.0946	5.1802	0.0556	-0.2660	0.3771
Last Visit (LOCF)	Rufinamide Use	20 mg/kg	0.1041 N	26	14	56	6	5.0256	2.1791	11.5905	<.0001	0.1029	0.0327	0.3233	0.4313	0.2233	0.6394
			Y	9	2	19	3	1.4074	0.2831	6.9975	1.0000	0.6563	0.0890	4.8371	0.0643	-0.2529	0.3816
End of Treatment	Baseline Drop Seizure Frequency	20 mg/kg	0.8248 <=55	13	7	22	3	3.9487	1.2307	12.6698	0.0196	0.1353	0.0264	0.6939	0.4021	0.0955	0.7087
			>55 to <=125	11	5	26	4	2.9545	0.9739	8.9635	0.0912	0.2182	0.0443	1.0751	0.3007	-0.0246	0.6260
			>125	8	4	22	2	5.5000	1.2370	24.4548	0.0294	0.1000	0.0134	0.7451	0.4091	0.0424	0.7758
Last Visit (LOCF)	Baseline Drop Seizure Frequency	20 mg/kg	0.9522 <=55	15	7	22	3	3.4222	1.0488	11.1663	0.0563	0.1805	0.0370	0.8803	0.3303	0.0400	0.6207
			>55 to <=125	11	5	31	4	3.5227	1.1488	10.8020	0.0376	0.1778	0.0364	0.8671	0.3255	0.0085	0.6425
			>125	9	4	22	2	4.8889	1.0802	22.1274	0.0434	0.1250	0.0176	0.8874	0.3535	0.0074	0.6997
End of Treatment	Prior AEDs	20 mg/kg	0.1947 <6	16	10	28	3	5.8333	1.8757	18.1415	0.0005	0.0720	0.0150	0.3454	0.5179	0.2544	0.7813
			>=6	16	6	42	6	2.6250	0.9910	6.9533	0.0722	0.2778	0.0734	1.0513	0.2321	-0.0276	0.4919
Last Visit (LOCF)	Prior AEDs	20 mg/kg	0.3530 <6	19	10	30	3	5.2632	1.6579	16.7081	0.0020	0.1000	0.0224	0.4457	0.4263	0.1775	0.6752
			>=6	16	6	45	6	2.8125	1.0585	7.4732	0.0632	0.2564	0.0680	0.9674	0.2417	-0.0155	0.4988
End of Treatment	Current AEDs	20 mg/kg	0.4964 <3	6	4	23	3	5.1111	1.5436	16.9242	0.0180	0.0750	0.0093	0.6043	0.5362	0.1347	0.9378
			>=3	26	12	47	6	3.6154	1.5377	8.5004	0.0036	0.1707	0.0539	0.5406	0.3339	0.1198	0.5479
Last Visit (LOCF)	Current AEDs	20 mg/kg	0.6122 <3	7	4	25	3	4.7619	1.3776	16.4607	0.0258	0.1023	0.0150	0.6993	0.4514	0.0633	0.8395
			>=3	28	12	50	6	3.5714	1.5054	8.4729	0.0041	0.1818	0.0585	0.5656	0.3086	0.1043	0.5128

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

End of treatment = The date of last dose as recorded on the 'End of Treatment Study Outcome' CRF page (Visit 8: Day 99).

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1414 Any AE (subgroups) (Safety Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
	Age Group	10 mg/kg	0.6654	2-5 years	4	4	9	9	0.9474	0.6845	1.3111	0.7106 0.2834 0.2137
				6-11 years	13	10	24	16	1.1364	0.7518	1.7175	
				12-17 years	7	7	20	15	1.2702	0.9304	1.7341	
				18-55 years	11	10	23	15	1.3548	0.9402	1.9524	
	Sex	10 mg/kg	0.8413	F	19	17	32	23	1.2449	0.9541	1.6242	0.1761
				M	16	14	44	32	1.2031	0.9287	1.5587	0.3135
	Region	10 mg/kg	0.6743	REST OF THE WORLD	1	1	14	6	1.7308	0.6447	4.6462	0.4667
				USA	34	30	62	49	1.1091	0.9253	1.3294	0.4022
	Valproate Use	10 mg/kg	0.9204	N	28	25	46	34	1.2080	0.9749	1.4967	0.1425
				Y	7	6	30	21	1.2245	0.8353	1.7951	0.6471
	Lamotrigine Use	10 mg/kg	0.8902	N	27	24	51	38	1.1930	0.9683	1.4698	0.1552
				Y	8	7	25	17	1.2868	0.8840	1.8729	0.3939
	Levetiracetam Use	10 mg/kg	0.6713	N	27	24	53	37	1.2733	1.0201	1.5892	0.0938
				Y	8	7	23	18	1.1181	0.7965	1.5694	1.0000
	Rufinamide Use	10 mg/kg	0.9678	N	23	20	56	39	1.2486	0.9877	1.5785	0.1556
				Y	12	11	20	16	1.1458	0.8680	1.5126	0.6264
	Baseline Drop Seizure Frequency	10 mg/kg	0.0980	<=55	10	9	22	16	1.2039	0.8502	1.7045	0.3871
				>55 to <=125	11	11	32	20	1.5427	1.1527	2.0645	0.0195
				>125	14	11	22	19	0.9043	0.6511	1.2559	0.6582
	Current AEDs	10 mg/kg	0.9527	<3	11	10	25	19	1.1962	0.8961	1.5968	0.3999
				>=3	24	21	51	36	1.2396	0.9820	1.5647	0.1505
	Prior AEDs	10 mg/kg	0.7678	<6	16	14	31	23	1.1793	0.8929	1.5576	0.4568
				>=6	19	17	45	32	1.2582	0.9880	1.6024	0.1954
	Age Group	20 mg/kg	0.0978	2-5 years	5	4	9	9	0.7895	0.4869	1.2801	0.3571
				6-11 years	12	12	24	16	1.4569	1.0775	1.9698	0.0334
				12-17 years	7	6	20	15	1.1008	0.7239	1.6740	1.0000
				18-55 years	14	13	23	15	1.3935	0.9910	1.9597	0.1120
	Sex	20 mg/kg	0.4861	F	17	15	32	23	1.2276	0.9300	1.6205	0.2871
				M	21	20	44	32	1.3095	1.0672	1.6069	0.0463
	Region	20 mg/kg	0.3141	REST OF THE WORLD	5	3	14	6	1.4000	0.5485	3.5734	0.6285

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		USA	33	32	62	49	1.2270	1.0649	1.4137	0.0300
Valproate Use	20 mg/kg	0.1964 N	28	27	46	34	1.3046	1.0833	1.5711	0.0135
		Y	10	8	30	21	1.1429	0.7750	1.6854	0.6962
Lamotrigine Use	20 mg/kg	0.7243 N	24	22	51	38	1.2303	1.0065	1.5038	0.1227
		Y	14	13	25	17	1.3655	1.0059	1.8537	0.1189
Levetiracetam Use	20 mg/kg	0.7751 N	25	23	53	37	1.3178	1.0667	1.6281	0.0426
		Y	13	12	23	18	1.1795	0.9036	1.5397	0.3854
Rufinamide Use	20 mg/kg	0.7933 N	29	26	56	39	1.2747	1.0268	1.5824	0.0578
		Y	9	9	20	16	1.2091	0.9278	1.5756	0.2800
Baseline Drop Seizure Frequency	20 mg/kg	0.0907 <=55	17	16	22	16	1.2778	0.9543	1.7109	0.1125
		>55 to <=125	11	11	32	20	1.5427	1.1527	2.0645	0.0195
		>125	10	8	22	19	0.9114	0.6332	1.3120	0.6367
Current AEDs	20 mg/kg	0.5651 <3	9	8	25	19	1.1696	0.8500	1.6094	0.6445
		>=3	29	27	51	36	1.3190	1.0767	1.6158	0.0225
Prior AEDs	20 mg/kg	0.1211 <6	19	16	31	23	1.1234	0.8405	1.5015	0.4979
		>=6	19	19	45	32	1.3800	1.1309	1.6839	0.0067

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Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table:** GWEP1414 Maximal AE mild (subgroups) (Safety Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
	Age Group	10 mg/kg	0.1479	2-5 years	4	2	9	3	1.5000	0.3901	5.7680	1.0000
				6-11 years	13	5	24	14	0.6593	0.3064	1.4187	0.3133
				12-17 years	7	3	20	6	1.4286	0.4821	4.2329	0.6527
				18-55 years	11	1	23	11	0.1901	0.0280	1.2925	0.0527
	Sex	10 mg/kg	0.8277	F	19	7	32	16	0.7368	0.3721	1.4590	0.3984
				M	16	4	44	18	0.6111	0.2435	1.5334	0.3666
	Region	10 mg/kg	0.9841	REST OF THE WORLD	1	0	14	5	0.6818	0.0565	8.2309	1.0000
				USA	34	11	62	29	0.7017	0.4082	1.2063	0.1987
	Valproate Use	10 mg/kg	0.3600	N	28	10	46	21	0.7823	0.4343	1.4092	0.4708
				Y	7	1	30	13	0.3297	0.0513	2.1180	0.2173
	Lamotrigine Use	10 mg/kg	0.0300	N	27	11	51	21	0.9934	0.5736	1.7204	1.0000
				Y	8	0	25	13	0.1070	0.0071	1.6226	0.0116
	Levetiracetam Use	10 mg/kg	0.5041	N	27	10	53	26	0.7550	0.4299	1.3259	0.3490
				Y	8	1	23	8	0.3594	0.0529	2.4437	0.3791
	Rufinamide Use	10 mg/kg	0.8760	N	23	6	56	23	0.6352	0.2982	1.3528	0.3046
				Y	12	5	20	11	0.7576	0.3480	1.6494	0.7160
	Baseline Drop Seizure Frequency	10 mg/kg	0.3881	<=55	10	3	22	14	0.4714	0.1738	1.2790	0.1283
				>55 to <=125	11	4	32	11	1.0579	0.4230	2.6457	1.0000
				>125	14	4	22	9	0.6984	0.2651	1.8398	0.5013
	Current AEDs	10 mg/kg	0.1193	<3	11	7	25	14	1.1364	0.6453	2.0013	0.7288
				>=3	24	4	51	20	0.4250	0.1631	1.1073	0.0652
	Prior AEDs	10 mg/kg	0.5042	<6	16	4	31	14	0.5536	0.2177	1.4074	0.2185
				>=6	19	7	45	20	0.8289	0.4228	1.6253	0.7823
	Age Group	20 mg/kg	0.8468	2-5 years	5	2	9	3	1.2000	0.2911	4.9465	1.0000
				6-11 years	12	8	24	14	1.1429	0.6769	1.9297	0.7272
				12-17 years	7	2	20	6	0.9524	0.2471	3.6705	1.0000
				18-55 years	14	5	23	11	0.7468	0.3282	1.6993	0.5154
	Sex	20 mg/kg	0.4355	F	17	7	32	16	0.8235	0.4233	1.6021	0.7643
				M	21	10	44	18	1.1640	0.6569	2.0627	0.7893
	Region	20 mg/kg	0.5063	REST OF THE WORLD	5	1	14	5	0.5600	0.0847	3.7019	1.0000
				USA	33	16	62	29	1.0366	0.6671	1.6106	1.0000

Valproate Use	20 mg/kg	0.1407 N	28	15	46	21	1.1735	0.7354	1.8724	0.6325
		Y	10	2	30	13	0.4615	0.1251	1.7027	0.2686
Lamotrigine Use	20 mg/kg	0.5050 N	24	11	51	21	1.1131	0.6456	1.9192	0.8039
		Y	14	6	25	13	0.8242	0.4042	1.6806	0.7411
Levetiracetam Use	20 mg/kg	0.0585 N	25	9	53	26	0.7338	0.4067	1.3242	0.3343
		Y	13	8	23	8	1.7692	0.8737	3.5827	0.1691
Rufinamide Use	20 mg/kg	0.5146 N	29	11	56	23	0.9235	0.5268	1.6191	0.8193
		Y	9	6	20	11	1.2121	0.6594	2.2280	0.6942
Baseline Drop Seizure Frequency	20 mg/kg	0.8692 <=55	17	11	22	14	1.0168	0.6341	1.6306	1.0000
		>55 to <=125	11	3	32	11	0.7934	0.2702	2.3298	1.0000
		>125	10	3	22	9	0.7333	0.2511	2.1416	0.7026
Current AEDs	20 mg/kg	0.9060 <3	9	5	25	14	0.9921	0.5027	1.9579	1.0000
		>=3	29	12	51	20	1.0552	0.6077	1.8321	1.0000
Prior AEDs	20 mg/kg	0.1955 <6	19	11	31	14	1.2820	0.7430	2.2119	0.5607
		>=6	19	6	45	20	0.7105	0.3397	1.4864	0.4108

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Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

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**Adhoc Table:** GWEP1414 Maximal AE moderate (subgroups) (Safety Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
	Age Group	10 mg/kg		- 2-5 years	4	2	9	5	-	-	-	1.0000
				6-11 years	13	5	24	2	-	-	-	0.0723
				12-17 years	7	3	20	7	-	-	-	1.0000
				18-55 years	11	5	23	1	-	-	-	0.0082
	Sex	10 mg/kg	0.6341	F	19	7	32	6	1.9649	0.7745	4.9852	0.1919
				M	16	8	44	9	2.4444	1.1417	5.2338	0.0487
	Region	10 mg/kg	0.1568	REST OF THE WORLD	1	1	14	1	7.5000	1.3482	41.7224	0.1333
				USA	34	14	62	14	1.8000	0.9886	3.2774	0.0642
	Valproate Use	10 mg/kg	0.5013	N	28	11	46	9	2.0079	0.9530	4.2305	0.1040
				Y	7	4	30	6	2.8571	1.0927	7.4705	0.0688
	Lamotrigine Use	10 mg/kg	0.0804	N	27	10	51	12	1.5741	0.7835	3.1622	0.2902
				Y	8	5	25	3	5.2083	1.5853	17.1119	0.0099
	Levetiracetam Use	10 mg/kg	0.2156	N	27	11	53	6	3.5988	1.4924	8.6778	0.0038
				Y	8	4	23	9	1.2778	0.5406	3.0203	0.6894
	Rufinamide Use	10 mg/kg	0.3889	N	23	10	56	13	1.8729	0.9619	3.6468	0.1017
				Y	12	5	20	2	4.1667	0.9529	18.2201	0.0735
	Baseline Drop Seizure Frequency	10 mg/kg	0.0845	<=55	10	4	22	1	8.8000	1.1217	69.0356	0.0242
				>55 to <=125	11	6	32	6	2.9091	1.1819	7.1600	0.0468
				>125	14	5	22	8	0.9821	0.4017	2.4015	1.0000
	Current AEDs	10 mg/kg	0.4422	<3	11	2	25	3	1.5152	0.2931	7.8317	0.6309
				>=3	24	13	51	12	2.3021	1.2426	4.2650	0.0168
	Prior AEDs	10 mg/kg	0.7959	<6	16	7	31	7	1.9375	0.8228	4.5625	0.1823
				>=6	19	8	45	8	2.3684	1.0429	5.3789	0.0584
	Age Group	20 mg/kg		- 2-5 years	5	1	9	5	-	-	-	0.3007
				6-11 years	12	2	24	2	-	-	-	0.5877
				12-17 years	7	2	20	7	-	-	-	1.0000
				18-55 years	14	6	23	1	-	-	-	0.0070
	Sex	20 mg/kg	0.4735	F	17	6	32	6	1.8824	0.7159	4.9491	0.2962
				M	21	5	44	9	1.1640	0.4449	3.0453	0.7565
	Region	20 mg/kg		- REST OF THE WORLD	5	2	14	1	-	-	-	0.1548
				USA	33	9	62	14	-	-	-	0.6231



Valproate Use	20 mg/kg	0.9668 N	28	8	46	9	1.4603	0.6378	3.3437	0.4040
		Y	10	3	30	6	1.5000	0.4578	4.9150	0.6650
Lamotrigine Use	20 mg/kg	0.4392 N	24	7	51	12	1.2396	0.5592	2.7476	0.7765
		Y	14	4	25	3	2.3810	0.6195	9.1514	0.2251
Levetiracetam Use	20 mg/kg	0.0333 N	25	8	53	6	2.8267	1.0979	7.2773	0.0539
		Y	13	3	23	9	0.5897	0.1932	1.7997	0.4678
Rufinamide Use	20 mg/kg	0.2608 N	29	8	56	13	1.1883	0.5568	2.5360	0.7915
		Y	9	3	20	2	3.3333	0.6683	16.6254	0.2872
Baseline Drop Seizure Frequency	20 mg/kg	0.2775 <=55	17	3	22	1	3.8824	0.4420	34.1005	0.2998
		>55 to <=125	11	5	32	6	2.4242	0.9198	6.3896	0.1136
		>125	10	3	22	8	0.8250	0.2756	2.4693	1.0000
Current AEDs	20 mg/kg	0.7513 <3	9	2	25	3	1.8519	0.3669	9.3470	0.5908
		>=3	29	9	51	12	1.3190	0.6329	2.7487	0.5979
Prior AEDs	20 mg/kg	0.0034 <6	19	1	31	7	0.2331	0.0310	1.7500	0.1343
		>=6	19	10	45	8	2.9605	1.3853	6.3270	0.0071

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

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**Adhoc Table:** GWEP1423 Total Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference			
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI	95% Upper CI	Risk Difference	95% Lower CI	95% Upper CI
Total Seizures <=25pct																		
Age Group	20 mg/kg	0.4896	2-5 years	5	5	12	4	3.0000	1.3478	6.6776	0.0294	-	-	-	0.6667	0.3999	0.9334	
			6-11 years	16	14	27	13	1.8173	1.1786	2.8022	0.0206	7.5385	1.4293	39.7595	0.3935	0.1450	0.6421	
			12-17 years	9	7	18	7	2.0000	1.0170	3.9330	0.1032	5.5000	0.8778	34.4609	0.3889	0.0361	0.7417	
			18-55 years	12	8	28	11	1.6970	0.9221	3.1231	0.1698	3.0909	0.7473	12.7845	0.2738	-0.0485	0.5961	
Sex	20 mg/kg	0.1897	F	20	18	42	17	2.2235	1.4983	3.2998	0.0003	13.2353	2.7112	64.6103	0.4952	0.2969	0.6935	
			M	22	16	43	18	1.7374	1.1241	2.6852	0.0346	3.7037	1.2122	11.3159	0.3087	0.0712	0.5461	
Region	20 mg/kg	0.5239	REST OF THE WORLD	3	2	19	8	1.5833	0.6073	4.1280	0.5714	2.7500	0.2110	35.8381	0.2456	-0.3322	0.8234	
			USA	39	32	66	27	2.0057	1.4492	2.7759	<.0001	6.6032	2.5442	17.1377	0.4114	0.2424	0.5805	
Valproate Use	20 mg/kg	0.6788	N	30	25	52	22	1.9697	1.3805	2.8104	0.0004	6.8182	2.2546	20.6190	0.4103	0.2210	0.5995	
			Y	12	9	33	13	1.9038	1.1155	3.2494	0.0472	4.6154	1.0490	20.3059	0.3561	0.0597	0.6524	
Lamotrigine Use	20 mg/kg	0.4245	N	25	22	54	24	1.9800	1.4214	2.7582	0.0002	9.1667	2.4480	34.3252	0.4356	0.2517	0.6194	
			Y	17	12	31	11	1.9893	1.1304	3.5008	0.0337	4.3636	1.2174	15.6412	0.3510	0.0767	0.6254	
Levetiracetam Use	20 mg/kg	0.5580	N	28	23	50	19	2.1617	1.4578	3.2053	0.0003	7.5053	2.4412	23.0746	0.4414	0.2459	0.6369	
			Y	14	11	35	16	1.7188	1.0927	2.7035	0.0566	4.3542	1.0322	18.3673	0.3286	0.0576	0.5996	
Rufinamide Use	20 mg/kg	0.0403	N	29	21	64	27	1.7165	1.1924	2.4709	0.0079	3.5972	1.3863	9.3342	0.3023	0.0995	0.5050	
			Y	13	13	21	8	2.6250	1.5218	4.5281	0.0002	-	-	-	0.6190	0.4113	0.8267	
Baseline Drop Seizure Fre	20 mg/kg	0.4238	<=45	19	14	21	10	1.5474	0.9173	2.6103	0.1167	3.0800	0.8124	11.6769	0.2607	-0.0306	0.5519	
			>45 to <=110	15	13	35	13	2.3333	1.4518	3.7501	0.0018	11.0000	2.1359	56.6504	0.4952	0.2603	0.7302	
			>110	8	7	29	12	2.1146	1.2746	3.5081	0.0422	9.9167	1.0751	91.4692	0.4612	0.1703	0.7522	
Current AEDs	20 mg/kg	0.0681	<3	9	9	26	9	2.8889	1.7033	4.8996	0.0010	-	-	-	0.6538	0.4710	0.8367	
			>=3	33	25	59	26	1.7191	1.2160	2.4304	0.0044	3.9663	1.5376	10.2315	0.3169	0.1234	0.5104	
Prior AEDs	20 mg/kg	0.6486	<6	25	20	38	17	1.7882	1.1938	2.6787	0.0084	4.9412	1.5333	15.9229	0.3526	0.1300	0.5753	
			>=6	17	14	47	18	2.1503	1.4067	3.2871	0.0038	7.5185	1.8940	29.8459	0.4406	0.2122	0.6689	
Total Seizures <=50pct																		
Age Group	20 mg/kg	0.1681	2-5 years	5	4	12	2	4.8000	1.2582	18.3114	0.0276	20.0000	1.3908	287.6003	0.6333	0.2242	1.0000	
			6-11 years	16	9	27	8	1.8984	0.9201	3.9171	0.1128	3.0536	0.8426	11.0666	0.2662	-0.0317	0.5641	
			12-17 years	9	7	18	2	7.0000	1.8101	27.0697	0.0012	28.0000	3.2556	240.8139	0.6667	0.3587	0.9746	
			18-55 years	12	5	28	6	1.9444	0.7332	5.1566	0.2535	2.6190	0.6082	11.2788	0.2024	-0.1153	0.5200	
Sex	20 mg/kg	0.6372	F	20	11	42	9	2.5667	1.2723	5.1779	0.0183	4.4815	1.4210	14.1336	0.3357	0.0848	0.5866	
			M	22	14	43	9	3.0404	1.5695	5.8900	0.0010	6.6111	2.1192	20.6241	0.4271	0.1921	0.6620	
Region	20 mg/kg	0.8103	REST OF THE WORLD	3	2	19	4	3.1667	0.9706	10.3318	0.1688	7.5000	0.5343	105.2793	0.4561	-0.1079	1.0000	
			USA	39	23	66	14	2.7802	1.6306	4.7403	0.0001	5.3393	2.2389	12.7332	0.3776	0.1944	0.5608	
Valproate Use	20 mg/kg	0.2521	N	30	17	52	13	2.2667	1.2879	3.9892	0.0082	3.9231	1.5069	10.2131	0.3167	0.1038	0.5295	
			Y	12	8	33	5	4.4000	1.7870	10.8339	0.0017	11.2000	2.4211	51.8104	0.5152	0.2217	0.8086	
Lamotrigine Use	20 mg/kg	0.6513	N	25	16	54	14	2.4686	1.4411	4.2286	0.0024	5.0794	1.8343	14.0650	0.3807	0.1592	0.6022	
			Y	17	9	31	4	4.1029	1.4817	11.3610	0.0055	7.5938	1.8399	31.3416	0.4004	0.1354	0.6654	
Levetiracetam Use	20 mg/kg	0.6086	N	28	16	50	8	3.5714	1.7532	7.2752	0.0003	7.0000	2.4158	20.2833	0.4114	0.2018	0.6210	
			Y	14	9	35	10	2.2500	1.1707	4.3243	0.0273	4.5000	1.2064	16.7850	0.3571	0.0649	0.6494	

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Rufinamide Use	20 mg/kg	0.4510 N Y	29	17	64	15	2.5011	1.4603	4.2839	0.0018	4.6278	1.8106	11.8280	0.3518	0.1447	0.5590	
			13	8	21	3	4.3077	1.3882	13.3667	0.0078	9.6000	1.8326	50.2884	0.4725	0.1687	0.7764	
Baseline Drop Seizure Fre	20 mg/kg	0.3899 <=45 >45 to <=110 >110	19	10	21	6	1.8421	0.8281	4.0978	0.1965	2.7778	0.7520	10.2604	0.2406	-0.0556	0.5368	
			15	9	35	5	4.2000	1.6895	10.4408	0.0019	9.0000	2.2167	36.5413	0.4571	0.1835	0.7308	
			8	6	29	7	3.1071	1.4543	6.6386	0.0134	9.4286	1.5395	57.7444	0.5086	0.1706	0.8467	
Current AEDs	20 mg/kg	0.3553 <3 >=3	9	6	26	4	4.3333	1.5737	11.9325	0.0074	11.0000	1.9152	63.1778	0.5128	0.1751	0.8506	
			33	19	59	14	2.4264	1.4095	4.1770	0.0016	4.3622	1.7480	10.8862	0.3385	0.1379	0.5390	
Prior AEDs	20 mg/kg	0.7900 <6 >=6	25	15	38	9	2.5333	1.3168	4.8739	0.0073	4.8333	1.6166	14.4511	0.3632	0.1283	0.5980	
			17	10	47	9	3.0719	1.5112	6.2446	0.0043	6.0317	1.8011	20.2002	0.3967	0.1372	0.6563	
Total Seizures <=75pct																	
Age Group	20 mg/kg	0.1074 2-5 years 6-11 years 12-17 years 18-55 years	5	2	12	0	-	-	-	0.0735	-	-	-	0.4000	-0.0294	0.8294	
			16	7	27	4	2.9531	1.0216	8.5366	0.0679	4.4722	1.0489	19.0688	0.2894	0.0118	0.5669	
			9	6	18	1	12.0000	1.6904	85.1889	0.0017	34.0000	2.9426	392.8514	0.6111	0.2855	0.9368	
			12	0	28	1	-	-	-	1.0000	-	-	-	-	-0.0357	-0.1045	0.0330
Sex	20 mg/kg	0.3805 F M	20	5	42	3	3.5000	0.9269	13.2155	0.0984	4.3333	0.9195	20.4221	0.1786	-0.0266	0.3837	
			22	10	43	3	6.5152	1.9950	21.2772	0.0005	11.1111	2.6260	47.0137	0.3848	0.1632	0.6063	
Region	20 mg/kg	0.6108 REST OF THE WORLD USA	3	2	19	2	6.3333	1.3634	29.4196	0.0727	17.0000	1.0212	283.0115	0.5614	0.0104	1.0000	
			39	13	66	4	5.5000	1.9277	15.6921	0.0006	7.7500	2.3096	26.0053	0.2727	0.1140	0.4315	
Valproate Use	20 mg/kg	0.2165 N Y	30	10	52	5	3.4667	1.3077	9.1902	0.0153	4.7000	1.4238	15.5152	0.2372	0.0504	0.4239	
			12	5	33	1	13.7500	1.7828	106.0473	0.0033	22.8571	2.2973	227.4155	0.3864	0.1014	0.6714	
Lamotrigine Use	20 mg/kg	0.1557 N Y	25	11	54	3	7.9200	2.4208	25.9114	<.0001	13.3571	3.2711	54.5420	0.3844	0.1805	0.5884	
			17	4	31	3	2.4314	0.6147	9.6175	0.2256	2.8718	0.5598	14.7322	0.1385	-0.0884	0.3654	
Levetiracetam Use	20 mg/kg	0.5464 N Y	28	9	50	2	8.0357	1.8649	34.6244	0.0012	11.3684	2.2461	57.5409	0.2814	0.1001	0.4627	
			14	6	35	4	3.7500	1.2446	11.2987	0.0221	5.8125	1.3168	25.6575	0.3143	0.0345	0.5941	
Rufinamide Use	20 mg/kg	0.0816 N Y	29	9	64	6	3.3103	1.2993	8.4338	0.0139	4.3500	1.3756	13.7553	0.2166	0.0337	0.3995	
			13	6	21	0	-	-	-	0.0013	-	-	-	-	0.4615	0.1905	0.7325
Baseline Drop Seizure Fre	20 mg/kg	0.8390 <=45 >45 to <=110 >110	19	6	21	1	6.6316	0.8762	50.1916	0.0395	9.2308	0.9934	85.7751	0.2682	0.0402	0.4962	
			15	6	35	2	7.0000	1.5909	30.7997	0.0060	11.0000	1.8889	64.0569	0.3429	0.0833	0.6024	
			8	3	29	3	3.6250	0.8977	14.6388	0.1010	5.2000	0.8057	33.5600	0.2716	-0.0818	0.6249	
Current AEDs	20 mg/kg	0.1481 <3 >=3	9	5	26	1	14.4444	1.9378	107.6714	0.0021	31.2500	2.8564	341.8802	0.5171	0.1841	0.8500	
			33	10	59	5	3.5758	1.3349	9.5786	0.0159	4.6957	1.4440	15.2697	0.2183	0.0461	0.3904	
Prior AEDs	20 mg/kg	0.3922 <6 >=6	25	9	38	4	3.4200	1.1800	9.9126	0.0243	4.7813	1.2783	17.8838	0.2547	0.0428	0.4667	
			17	6	47	2	8.2941	1.8487	37.2122	0.0032	12.2727	2.1741	69.2795	0.3104	0.0760	0.5448	
Total Seizures >0pct																	
Age Group	20 mg/kg	0.8303 2-5 years 6-11 years 12-17 years 18-55 years	5	0	12	1	-	-	-	1.0000	-	-	-	-0.0833	-0.2397	0.0730	
			16	1	27	11	0.1534	0.0218	1.0799	0.0171	10.3125	1.1835	89.8620	-0.3449	-0.5649	-0.1249	
			9	0	18	5	-	-	-	0.1358	-	-	-	-	-0.2778	-0.4847	-0.0709
			12	1	28	8	0.2917	0.0408	2.0827	0.2332	4.4000	0.4850	39.9174	-0.2024	-0.4314	0.0266	
Sex	20 mg/kg	0.9060 F M	20	1	42	12	0.1750	0.0244	1.2540	0.0451	7.6000	0.9128	63.2780	-0.2357	-0.4024	-0.0690	
			22	1	43	13	0.1503	0.0210	1.0760	0.0238	9.1000	1.1044	74.9849	-0.2569	-0.4194	-0.0943	
Region	20 mg/kg	0.6163 REST OF THE WORLD USA	3	0	19	7	-	-	-	0.5227	-	-	-	-0.3684	-0.5853	-0.1515	
			39	2	66	18	0.1880	0.0461	0.7673	0.0047	6.9375	1.5135	31.7991	-0.2214	-0.3493	-0.0936	

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Valproate Use	20 mg/kg	0.2509 N	30	2	52	13	0.2667	0.0645	1.1024	0.0430	4.6667	0.9749	22.3384	-0.1833	-0.3310	-0.0356
		Y	12	0	33	12	-	-	-	0.0196	-	-	-	-0.3636	-0.5278	-0.1995
Lamotrigine Use	20 mg/kg	0.2052 N	25	0	54	13	-	-	-	0.0070	-	-	-	-0.2407	-0.3548	-0.1267
		Y	17	2	31	12	0.3039	0.0768	1.2022	0.0947	4.7368	0.9162	24.4902	-0.2694	-0.4994	-0.0395
Levetiracetam Use	20 mg/kg	0.7097 N	28	1	50	14	0.1276	0.0177	0.9195	0.0078	10.5000	1.2997	84.8253	-0.2443	-0.3865	-0.1021
		Y	14	1	35	11	0.2273	0.0323	1.5991	0.1391	5.9583	0.6902	51.4343	-0.2429	-0.4474	-0.0383
Rufinamide Use	20 mg/kg	0.2975 N	29	2	64	18	0.2452	0.0609	0.9879	0.0279	5.2826	1.1368	24.5479	-0.2123	-0.3559	-0.0686
		Y	13	0	21	7	-	-	-	0.0286	-	-	-	-0.3333	-0.5350	-0.1317
Baseline Drop Seizure Fre	20 mg/kg	0.8652 <=45	19	1	21	6	0.1842	0.0243	1.3942	0.0948	7.2000	0.7780	66.6339	-0.2331	-0.4508	-0.0153
		>45 to <=110	15	1	35	13	0.1795	0.0257	1.2514	0.0391	8.2727	0.9719	70.4180	-0.3048	-0.5086	-0.1009
		>110	8	0	29	6	-	-	-	0.3053	-	-	-	-0.2069	-0.3543	-0.0595
Current AEDs	20 mg/kg	0.3764 <3	9	0	26	9	1.5294	1.1563	2.0230	0.0742	-	-	-	-0.3462	-0.5290	-0.1633
		>=3	33	2	59	16	0.2235	0.0547	0.9125	0.0148	5.7674	1.2354	26.9244	-0.2106	-0.3502	-0.0710
Prior AEDs	20 mg/kg	0.0619 <6	25	0	38	13	-	-	-	0.0008	-	-	-	-0.3421	-0.4929	-0.1913
		>=6	17	2	47	12	0.4608	0.1147	1.8507	0.3188	2.5714	0.5117	12.9228	-0.1377	-0.3351	0.0598

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1423 Convulsive Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI		95% Upper CI	95% Lower CI	95% Upper CI
Convulsive Seizures <=25pct	Age Group	20 mg/kg	0.9888	2-5 years	5	4	12	5	1.9200	0.8626	4.2737	0.2941	5.6000	0.4720	66.4471	0.3833	-0.0647	0.8314
				6-11 years	16	12	27	12	1.6875	1.0156	2.8040	0.0644	3.7500	0.9600	14.6489	0.3056	0.0225	0.5887
				12-17 years	9	7	18	8	1.7500	0.9381	3.2644	0.2172	4.3750	0.7047	27.1611	0.3333	-0.0223	0.6890
				18-55 years	12	9	28	13	1.6154	0.9654	2.7030	0.1654	3.4615	0.7701	15.5596	0.2857	-0.0211	0.5925
	Sex	20 mg/kg	0.1360	F	20	17	42	17	2.1000	1.3932	3.1655	0.0011	8.3333	2.1105	32.9045	0.4452	0.2295	0.6609
				M	22	15	43	21	1.3961	0.9188	2.1215	0.1891	2.2449	0.7638	6.5983	0.1934	-0.0519	0.4388
	Region	20 mg/kg	0.9465	REST OF THE WORLD	3	2	19	7	1.8095	0.6701	4.8864	0.5442	3.4286	0.2611	45.0257	0.2982	-0.2776	0.8741
				USA	39	30	66	31	1.6377	1.2028	2.2299	0.0039	3.7634	1.5486	9.1462	0.2995	0.1207	0.4784
	Valproate Use	20 mg/kg	0.7735	N	30	23	52	25	1.5947	1.1298	2.2508	0.0192	3.5486	1.2978	9.7026	0.2859	0.0826	0.4892
				Y	12	9	33	13	1.9038	1.1155	3.2494	0.0472	4.6154	1.0490	20.3059	0.3561	0.0597	0.6524
	Lamotrigine Use	20 mg/kg	0.7882	N	25	21	54	28	1.6200	1.1897	2.2060	0.0066	4.8750	1.4756	16.1063	0.3215	0.1255	0.5175
				Y	17	11	31	10	2.0059	1.0799	3.7260	0.0383	3.8500	1.1057	13.4058	0.3245	0.0440	0.6050
	Levetiracetam Use	20 mg/kg	0.4622	N	28	21	50	18	2.0833	1.3593	3.1930	0.0019	5.3333	1.9001	14.9700	0.3900	0.1816	0.5984
				Y	14	11	35	20	1.3750	0.9250	2.0439	0.2024	2.7500	0.6506	11.6242	0.2143	-0.0560	0.4846
	Rufinamide Use	20 mg/kg	0.0436	N	29	20	64	31	1.4238	1.0019	2.0234	0.0757	2.3656	0.9362	5.9773	0.2053	-0.0029	0.4135
				Y	13	12	21	7	2.7692	1.4824	5.1730	0.0011	24.0000	2.5738	223.7903	0.5897	0.3415	0.8380
	Baseline Drop Seizure Frequency	20 mg/kg	0.0129	<=45	19	11	21	12	1.0132	0.5945	1.7267	1.0000	1.0313	0.2938	3.6194	0.0075	-0.2992	0.3142
				>45 to <=110	15	13	35	12	2.5278	1.5335	4.1666	0.0015	12.4583	2.4066	64.4946	0.5238	0.2907	0.7569
				>110	8	8	29	14	2.0714	1.4212	3.0191	0.0121	-	-	-	0.5172	0.3354	0.6991
Current AEDs	20 mg/kg	0.0959	<3	9	8	26	8	2.8889	1.5523	5.3762	0.0049	18.0000	1.9173	168.9908	0.5812	0.3099	0.8525	
			>=3	33	24	59	30	1.4303	1.0319	1.9825	0.0489	2.5778	1.0267	6.4719	0.2188	0.0204	0.4172	
Prior AEDs	20 mg/kg	0.9738	<6	25	19	38	17	1.6988	1.1202	2.5763	0.0195	3.9118	1.2781	11.9725	0.3126	0.0824	0.5429	
			>=6	17	13	47	21	1.7115	1.1322	2.5871	0.0453	4.0238	1.1419	14.1796	0.3179	0.0712	0.5646	
Convulsive Seizures <=50pct	Age Group	20 mg/kg	0.9030	2-5 years	5	4	12	4	2.4000	0.9638	5.9762	0.1312	8.0000	0.6577	97.3113	0.4667	0.0261	0.9072
				6-11 years	16	8	27	6	2.2500	0.9530	5.3123	0.0933	3.5000	0.9206	13.3065	0.2778	-0.0131	0.5687
				12-17 years	9	6	18	4	3.0000	1.1260	7.9932	0.0393	7.0000	1.1848	41.3585	0.4444	0.0815	0.8074
				18-55 years	12	5	28	4	2.9167	0.9445	9.0068	0.0968	4.2857	0.8995	20.4204	0.2738	-0.0338	0.5814
	Sex	20 mg/kg	0.6270	F	20	10	42	9	2.3333	1.1287	4.8237	0.0378	3.6667	1.1666	11.5248	0.2857	0.0339	0.5375
				M	22	13	43	9	2.8232	1.4345	5.5562	0.0048	5.4568	1.7743	16.7821	0.3816	0.1429	0.6203
	Region	20 mg/kg	0.4863	REST OF THE WORLD	3	2	19	3	4.2222	1.1382	15.6629	0.1169	10.6667	0.7178	158.5046	0.5088	-0.0493	1.0000
				USA	39	21	66	15	2.3692	1.3927	4.0306	0.0015	3.9667	1.6902	9.3093	0.3112	0.1249	0.4975
	Valproate Use	20 mg/kg	0.0290	N	30	15	52	15	1.7333	0.9931	3.0255	0.0624	2.4667	0.9695	6.2760	0.2115	-0.0057	0.4287
				Y	12	8	33	3	7.3333	2.3203	23.1766	0.0003	20.0000	3.6981	108.1647	0.5758	0.2916	0.8599
	Lamotrigine Use	20 mg/kg	0.6190	N	25	16	54	13	2.6585	1.5224	4.6424	0.0010	5.6068	2.0063	15.6686	0.3993	0.1792	0.6193
				Y	17	7	31	5	2.5529	0.9548	6.8257	0.0828	3.6400	0.9345	14.1788	0.2505	-0.0169	0.5179
	Levetiracetam Use	20 mg/kg	0.1648	N	28	15	50	6	4.4643	1.9544	10.1974	0.0001	8.4615	2.7306	26.2200	0.4157	0.2102	0.6212
				Y	14	8	35	12	1.6667	0.8743	3.1770	0.2008	2.5556	0.7192	9.0809	0.2286	-0.0746	0.5318
	Rufinamide Use	20 mg/kg	0.2949	N	29	15	64	15	2.2069	1.2538	3.8846	0.0091	3.5000	1.3809	8.8712	0.2829	0.0735	0.4923
				Y	13	8	21	3	4.3077	1.3882	13.3667	0.0078	9.6000	1.8326	50.2884	0.4725	0.1687	0.7764

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Baseline Drop Seizure Frequency	20 mg/kg	0.5092 <=45	19	9	21	5	1.9895	0.8089	4.8933	0.1856	2.8800	0.7475	11.0965	0.2356	-0.0535	0.5247
		>45 to <=110	15	9	35	5	4.2000	1.6895	10.4408	0.0019	9.0000	2.2167	36.5413	0.4571	0.1835	0.7308
		>110	8	5	29	8	2.2656	1.0207	5.0291	0.0999	4.3750	0.8429	22.7073	0.3491	-0.0237	0.7220
Current AEDs	20 mg/kg	0.6269 <3	9	6	26	6	2.8889	1.2469	6.6930	0.0378	6.6667	1.2686	35.0351	0.4359	0.0879	0.7839
		>=3	33	17	59	12	2.5328	1.3848	4.6327	0.0044	4.1615	1.6393	10.5643	0.3118	0.1127	0.5108
Prior AEDs	20 mg/kg	0.7509 <6	25	13	38	8	2.4700	1.2002	5.0834	0.0148	4.0625	1.3438	12.2813	0.3095	0.0746	0.5443
		>=6	17	10	47	10	2.7647	1.4025	5.4499	0.0066	5.2857	1.6048	17.4096	0.3755	0.1139	0.6370
Convulsive Seizures <=75pct Age Group	20 mg/kg	0.0273 2-5 years	5	3	12	1	7.2000	0.9663	53.6481	0.0525	16.5000	1.0882	250.1761	0.5167	0.0597	0.9737
		6-11 years	16	3	27	3	1.6875	0.3857	7.3836	0.6546	1.8462	0.3251	10.4847	0.0764	-0.1486	0.3014
		12-17 years	9	6	18	0	-	-	-	0.0003	-	-	-	0.6667	0.3587	0.9746
		18-55 years	12	0	28	1	-	-	-	1.0000	-	-	-	-0.0357	-0.1045	0.0330
Sex	20 mg/kg	0.7815 F	20	6	42	3	4.2000	1.1683	15.0988	0.0255	5.5714	1.2253	25.3333	0.2286	0.0132	0.4440
		M	22	6	43	2	5.8636	1.2881	26.6920	0.0149	7.6875	1.4024	42.1399	0.2262	0.0298	0.4227
Region	20 mg/kg	0.6731 REST OF THE WORLD	3	1	19	2	3.1667	0.4001	25.0627	0.3708	4.2500	0.2553	70.7529	0.2281	-0.3229	0.7791
		USA	39	11	66	3	6.2051	1.8436	20.8854	0.0009	8.2500	2.1345	31.8872	0.2366	0.0867	0.3865
Valproate Use	20 mg/kg	0.3288 N	30	8	52	4	3.4667	1.1391	10.5500	0.0259	4.3636	1.1869	16.0434	0.1897	0.0157	0.3638
		Y	12	4	33	1	11.0000	1.3615	88.8744	0.0140	16.0000	1.5657	163.5012	0.3030	0.0300	0.5761
Lamotrigine Use	20 mg/kg	0.3474 N	25	9	54	3	6.4800	1.9177	21.8961	0.0011	9.5625	2.3062	39.6494	0.3044	0.1066	0.5023
		Y	17	3	31	2	2.7353	0.5054	14.8030	0.3306	3.1071	0.4650	20.7635	0.1120	-0.0888	0.3127
Levetiracetam Use	20 mg/kg	0.3630 N	28	6	50	3	3.5714	0.9671	13.1889	0.0631	4.2727	0.9770	18.6854	0.1543	-0.0113	0.3199
		Y	14	6	35	2	7.5000	1.7151	32.7961	0.0042	12.3750	2.0933	73.1587	0.3714	0.1010	0.6418
Rufinamide Use	20 mg/kg	0.1863 N	29	8	64	5	3.5310	1.2636	9.8671	0.0205	4.4952	1.3227	15.2768	0.1977	0.0223	0.3732
		Y	13	4	21	0	-	-	-	0.0154	-	-	-	0.3077	0.0568	0.5586
Baseline Drop Seizure Frequency	20 mg/kg	0.5199 <=45	19	5	21	0	-	-	-	0.0177	-	-	-	0.2632	0.0652	0.4612
		>45 to <=110	15	4	35	2	4.6667	0.9555	22.7917	0.0580	6.0000	0.9631	37.3811	0.2095	-0.0271	0.4462
		>110	8	3	29	3	3.6250	0.8977	14.6388	0.1010	5.2000	0.8057	33.5600	0.2716	-0.0818	0.6249
Current AEDs	20 mg/kg	0.5226 <3	9	3	26	1	8.6667	1.0274	73.1082	0.0441	12.5000	1.0980	142.3060	0.2949	-0.0219	0.6116
		>=3	33	9	59	4	4.0227	1.3417	12.0612	0.0112	5.1563	1.4456	18.3910	0.2049	0.0400	0.3699
Prior AEDs	20 mg/kg	0.9070 <6	25	7	38	2	5.3200	1.2011	23.5631	0.0230	7.0000	1.3174	37.1933	0.2274	0.0376	0.4172
		>=6	17	5	47	3	4.6078	1.2315	17.2405	0.0259	6.1111	1.2749	29.2927	0.2303	0.0027	0.4579
Convulsive Seizures >0pct Age Group	20 mg/kg	0.2759 2-5 years	5	1	12	2	1.2000	0.1381	10.4251	1.0000	0.8000	0.0556	11.5040	0.0333	-0.3758	0.4425
		6-11 years	16	2	27	9	0.3750	0.0923	1.5235	0.1657	3.5000	0.6498	18.8520	-0.2083	-0.4489	0.0322
		12-17 years	9	0	18	6	-	-	-	0.0707	-	-	-	-0.3333	-0.5511	-0.1156
		18-55 years	12	3	28	7	1.0000	0.3100	3.2262	1.0000	1.0000	0.2098	4.7671	0.0000	-0.2928	0.2928
Sex	20 mg/kg	0.8781 F	20	3	42	13	0.4846	0.1555	1.5105	0.2261	2.5402	0.6322	10.2071	-0.1595	-0.3694	0.0503
		M	22	3	43	11	0.5331	0.1657	1.7152	0.3492	2.1771	0.5384	8.8031	-0.1195	-0.3133	0.0744
Region	20 mg/kg	0.6180 REST OF THE WORLD	3	1	19	7	0.9048	0.1644	4.9782	1.0000	1.1667	0.0888	15.3213	-0.0351	-0.6109	0.5408
		USA	39	5	66	17	0.4977	0.1993	1.2430	0.1411	2.3592	0.7941	7.0089	-0.1294	-0.2782	0.0194
Valproate Use	20 mg/kg	0.5668 N	30	5	52	15	0.5778	0.2333	1.4309	0.2889	2.0270	0.6534	6.2888	-0.1218	-0.3033	0.0597
		Y	12	1	33	9	0.3056	0.0431	2.1638	0.2463	4.1250	0.4636	36.7020	-0.1894	-0.4074	0.0286
Lamotrigine Use	20 mg/kg	0.8303 N	25	2	54	11	0.3927	0.0940	1.6412	0.2083	2.9419	0.6003	14.4180	-0.1237	-0.2749	0.0275
		Y	17	4	31	13	0.5611	0.2166	1.4535	0.3441	2.3472	0.6218	8.8612	-0.1841	-0.4502	0.0821
Levetiracetam Use	20 mg/kg	0.6428 N	28	5	50	16	0.5580	0.2289	1.3606	0.1973	2.1647	0.6957	6.7353	-0.1414	-0.3334	0.0505

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		Y	14	1	35	8	0.3125	0.0430	2.2731	0.4146	3.8519	0.4347	34.1295	-0.1571	-0.3509	0.0366
Rufinamide Use	20 mg/kg	0.4562 N	29	5	64	18	0.6130	0.2522	1.4904	0.3089	1.8783	0.6209	5.6818	-0.1088	-0.2850	0.0673
		Y	13	1	21	6	0.2692	0.0364	1.9910	0.2100	4.8000	0.5064	45.4948	-0.2088	-0.4503	0.0327
Baseline Drop Seizure Frequency	20 mg/kg	0.0655 <=45	19	5	21	4	1.3816	0.4335	4.4032	0.7116	0.6588	0.1480	2.9320	0.0727	-0.1870	0.3323
		>45 to <=110	15	1	35	11	0.2121	0.0300	1.4995	0.0787	6.4167	0.7470	55.1199	-0.2476	-0.4466	-0.0487
		>110	8	0	29	9	-	-	-	0.1589	-	-	-	-0.3103	-0.4787	-0.1420
Current AEDs	20 mg/kg	0.5261 <3	9	1	26	9	0.3210	0.0470	2.1936	0.2346	4.2353	0.4553	39.4013	-0.2350	-0.5100	0.0399
		>=3	33	5	59	15	0.5960	0.2380	1.4926	0.3011	1.9091	0.6244	5.8367	-0.1027	-0.2680	0.0625
Prior AEDs	20 mg/kg	0.6087 <6	25	3	38	11	0.4145	0.1283	1.3391	0.1346	2.9877	0.7403	12.0576	-0.1695	-0.3619	0.0229
		>=6	17	3	47	13	0.6380	0.2069	1.9675	0.5248	1.7843	0.4395	7.2444	-0.1001	-0.3219	0.1217

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1423 Non-Convulsive Seizure Responder (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		Odds Ratio	95% Lower CI		95% Upper CI	95% Lower CI	95% Upper CI
Non-Convulsive Seizures <=25pct	Age Group	20 mg/kg	0.0631	2-5 years	4	4	10	3	3.3333	1.2933	8.5911	0.0699	-	-	-	0.7000	0.4160	0.9840
				6-11 years	14	11	20	10	1.5714	0.9374	2.6343	0.1529	3.6667	0.7794	17.2503	0.2857	-0.0212	0.5927
				12-17 years	9	9	15	6	2.5000	1.3451	4.6464	0.0068	-	-	-	0.6000	0.3521	0.8479
				18-55 years	8	5	22	13	1.0577	0.5580	2.0049	1.0000	1.1538	0.2184	6.0968	0.0341	-0.3593	0.4275
	Sex	20 mg/kg	0.8057	F	17	14	34	17	1.6471	1.1021	2.4614	0.0348	4.6667	1.1318	19.2414	0.3235	0.0764	0.5707
				M	18	15	33	15	1.8333	1.1961	2.8100	0.0160	6.0000	1.4556	24.7327	0.3788	0.1369	0.6207
	Region	20 mg/kg	0.6268	REST OF THE WORLD	2	2	15	9	1.6667	1.1026	2.5194	0.5147	-	-	-	0.4000	0.1521	0.6479
				USA	33	27	52	23	1.8498	1.3101	2.6119	0.0007	5.6739	2.0051	16.0558	0.3759	0.1874	0.5644
	Valproate Use	20 mg/kg	0.8143	N	24	20	41	21	1.6270	1.1486	2.3047	0.0156	4.7619	1.3837	16.3879	0.3211	0.1075	0.5348
				Y	11	9	26	11	1.9339	1.1403	3.2799	0.0365	6.1364	1.1006	34.2137	0.3951	0.0984	0.6918
	Lamotrigine Use	20 mg/kg	0.8638	N	21	17	42	18	1.8889	1.2583	2.8354	0.0066	5.6667	1.6253	19.7573	0.3810	0.1560	0.6059
				Y	14	12	25	14	1.5306	1.0178	2.3017	0.0826	4.7143	0.8677	25.6122	0.2971	0.0298	0.5645
	Levetiracetam Use	20 mg/kg	0.1472	N	24	21	42	18	2.0417	1.3955	2.9871	0.0006	9.3333	2.4067	36.1946	0.4464	0.2467	0.6462
				Y	11	8	25	14	1.2987	0.7864	2.1448	0.4672	2.0952	0.4473	9.8137	0.1673	-0.1600	0.4946
	Rufinamide Use	20 mg/kg	0.6169	N	27	22	49	24	1.6636	1.1869	2.3317	0.0070	4.5833	1.4940	14.0612	0.3250	0.1224	0.5277
				Y	8	7	18	8	1.9688	1.1033	3.5131	0.0838	8.7500	0.8841	86.6033	0.4306	0.1062	0.7549
	Baseline Drop Seizure Frequency	20 mg/kg	0.8852	<=45	16	13	17	9	1.5347	0.9251	2.5461	0.1411	3.8519	0.7968	18.6213	0.2831	-0.0217	0.5878
				>45 to <=110	11	9	27	11	2.0083	1.1780	3.4236	0.0327	6.5455	1.1794	36.3248	0.4108	0.1170	0.7045
				>110	8	7	23	12	1.6771	1.0473	2.6856	0.1082	6.4167	0.6768	60.8402	0.3533	0.0463	0.6602
	Current AEDs	20 mg/kg	0.1843	<3	8	8	20	10	2.0000	1.2903	3.1000	0.0251	-	-	-	0.5000	0.2809	0.7191
>=3				27	21	47	22	1.6616	1.1530	2.3946	0.0139	3.9773	1.3601	11.6307	0.3097	0.0977	0.5217	
Prior AEDs	20 mg/kg	0.2755	<6	19	15	25	14	1.4098	0.9282	2.1411	0.1985	2.9464	0.7589	11.4397	0.2295	-0.0379	0.4968	
			>=6	16	14	42	18	2.0417	1.3750	3.0315	0.0028	9.3333	1.8793	46.3525	0.4464	0.2258	0.6670	
Non-Convulsive Seizures <=50pct	Age Group	20 mg/kg	0.0242	2-5 years	4	4	10	2	5.0000	1.4475	17.2710	0.0150	-	-	-	0.8000	0.5521	1.0000
				6-11 years	14	9	20	9	1.4286	0.7668	2.6616	0.3151	2.2000	0.5404	8.9571	0.1929	-0.1396	0.5253
				12-17 years	9	7	15	4	2.9167	1.1752	7.2384	0.0327	9.6250	1.3776	67.2458	0.5111	0.1592	0.8630
				18-55 years	8	2	22	9	0.6111	0.1664	2.2447	0.6722	0.4815	0.0786	2.9479	-0.1591	-0.5227	0.2046
	Sex	20 mg/kg	0.4244	F	17	12	34	12	2.0000	1.1552	3.4627	0.0357	4.4000	1.2503	15.4844	0.3529	0.0833	0.6226
				M	18	10	33	12	1.5278	0.8285	2.8172	0.2416	2.1875	0.6794	7.0435	0.1919	-0.0903	0.4741
	Region	20 mg/kg	0.4534	REST OF THE WORLD	2	1	15	7	1.0714	0.2420	4.7434	1.0000	1.1429	0.0597	21.8701	0.0333	-0.7042	0.7708
				USA	33	21	52	17	1.9465	1.2196	3.1068	0.0072	3.6029	1.4418	9.0033	0.3094	0.1016	0.5173
	Valproate Use	20 mg/kg	0.2820	N	24	17	41	15	1.9361	1.2006	3.1221	0.0105	4.2095	1.4215	12.4657	0.3425	0.1084	0.5766
				Y	11	5	26	9	1.3131	0.5694	3.0282	0.7130	1.5741	0.3745	6.6154	0.1084	-0.2381	0.4548
	Lamotrigine Use	20 mg/kg	0.8774	N	21	14	42	16	1.7500	1.0721	2.8565	0.0598	3.2500	1.0813	9.7680	0.2857	0.0363	0.5352
				Y	14	8	25	8	1.7857	0.8609	3.7040	0.1791	2.8333	0.7334	10.9459	0.2514	-0.0658	0.5687
	Levetiracetam Use	20 mg/kg	0.5766	N	24	15	42	13	2.0192	1.1676	3.4921	0.0195	3.7179	1.2959	10.6670	0.3155	0.0766	0.5544
				Y	11	7	25	11	1.4463	0.7714	2.7117	0.4705	2.2273	0.5170	9.5943	0.1964	-0.1481	0.5409
	Rufinamide Use	20 mg/kg	0.4139	N	27	16	49	18	1.6132	0.9957	2.6136	0.0909	2.5051	0.9567	6.5596	0.2252	-0.0040	0.4545
				Y	8	6	18	6	2.2500	1.0459	4.8405	0.0895	6.0000	0.9187	39.1845	0.4167	0.0459	0.7874



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Baseline Drop Seizure Frequency	20 mg/kg	0.2774 <=45	16	8	17	7	1.2143	0.5734	2.5713	0.7319	1.4286	0.3608	5.6556	0.0882	-0.2505	0.4270
		>45 to <=110	11	7	27	7	2.4545	1.1269	5.3465	0.0607	5.0000	1.1157	22.4084	0.3771	0.0483	0.7059
		>110	8	7	23	10	2.0125	1.1792	3.4346	0.0454	9.1000	0.9576	86.4801	0.4402	0.1343	0.7461
Current AEDs	20 mg/kg	0.0131 <3	8	8	20	6	3.3333	1.7066	6.5106	0.0019	-	-	-	0.7000	0.4992	0.9008
		>=3	27	14	47	18	1.3539	0.8101	2.2628	0.3312	1.7350	0.6664	4.5176	0.1355	-0.0986	0.3697
Prior AEDs	20 mg/kg	0.7669 <6	19	12	25	10	1.5789	0.8750	2.8492	0.2231	2.5714	0.7528	8.7840	0.2316	-0.0581	0.5213
		>=6	16	10	42	14	1.8750	1.0584	3.3215	0.0723	3.3333	1.0057	11.0485	0.2917	0.0149	0.5684
Non-Convulsive Seizures <=-75pct Age Group	20 mg/kg	0.2543 2-5 years	4	0	10	1	-	-	-	1.0000	-	-	-	-0.1000	-0.2859	0.0859
		6-11 years	14	8	20	8	1.4286	0.7074	2.8848	0.4867	2.0000	0.5002	7.9969	0.1714	-0.1652	0.5080
		12-17 years	9	6	15	2	5.0000	1.2700	19.6850	0.0215	13.0000	1.7006	99.3750	0.5333	0.1806	0.8861
		18-55 years	8	2	22	4	1.3750	0.3092	6.1137	0.6452	1.5000	0.2172	10.3607	0.0682	-0.2724	0.4088
Sex	20 mg/kg	0.7249 F	17	8	34	7	2.2857	0.9960	5.2454	0.1007	3.4286	0.9685	12.1374	0.2647	-0.0087	0.5381
		M	18	8	33	8	1.8333	0.8287	4.0560	0.2070	2.5000	0.7351	8.5019	0.2020	-0.0701	0.4742
Region	20 mg/kg	0.9395 REST OF THE WORLD	2	1	15	4	1.8750	0.3710	9.4763	0.5147	2.7500	0.1371	55.1663	0.2333	-0.4949	0.9615
		USA	33	15	52	11	2.1488	1.1282	4.0924	0.0288	3.1061	1.1950	8.0733	0.2430	0.0401	0.4459
Valproate Use	20 mg/kg	0.7916 N	24	12	41	10	2.0500	1.0477	4.0110	0.0564	3.1000	1.0616	9.0521	0.2561	0.0167	0.4955
		Y	11	4	26	5	1.8909	0.6233	5.7366	0.4038	2.4000	0.5000	11.5193	0.1713	-0.1508	0.4934
Lamotrigine Use	20 mg/kg	0.3360 N	21	9	42	11	1.6364	0.8059	3.3226	0.2517	2.1136	0.7004	6.3788	0.1667	-0.0833	0.4166
		Y	14	7	25	4	3.1250	1.1048	8.8392	0.0331	5.2500	1.1750	23.4571	0.3400	0.0413	0.6387
Levetiracetam Use	20 mg/kg	0.5822 N	24	11	42	8	2.4063	1.1251	5.1462	0.0267	3.5962	1.1821	10.9405	0.2679	0.0358	0.4999
		Y	11	5	25	7	1.6234	0.6585	4.0022	0.4455	2.1429	0.4911	9.3510	0.1745	-0.1683	0.5174
Rufinamide Use	20 mg/kg	0.2057 N	27	11	49	12	1.6636	0.8514	3.2505	0.1926	2.1198	0.7747	5.8004	0.1625	-0.0585	0.3835
		Y	8	5	18	3	3.7500	1.1707	12.0117	0.0601	8.3333	1.2545	55.3551	0.4583	0.0813	0.8354
Baseline Drop Seizure Frequency	20 mg/kg	0.7424 <=45	16	6	17	3	2.1250	0.6361	7.0984	0.2587	2.8000	0.5619	13.9521	0.1985	-0.1000	0.4970
		>45 to <=110	11	6	27	5	2.9455	1.1305	7.6743	0.0471	5.2800	1.1394	24.4680	0.3603	0.0316	0.6890
		>110	8	4	23	7	1.6429	0.6492	4.1572	0.4055	2.2857	0.4407	11.8552	0.1957	-0.1986	0.5899
Current AEDs	20 mg/kg	0.0133 <3	8	6	20	2	7.5000	1.8976	29.6425	0.0018	27.0000	3.0926	235.7233	0.6500	0.3224	0.9776
		>=3	27	10	47	13	1.3390	0.6818	2.6299	0.4418	1.5385	0.5608	4.2209	0.0938	-0.1288	0.3163
Prior AEDs	20 mg/kg	0.4320 <6	19	9	25	8	1.4803	0.7046	3.1100	0.3588	1.9125	0.5581	6.5543	0.1537	-0.1359	0.4432
		>=6	16	7	42	7	2.6250	1.0940	6.2984	0.0433	3.8889	1.0831	13.9637	0.2708	0.0029	0.5388
Non-Convulsive Seizures <=-100pct Age Group	20 mg/kg	0.1378 2-5 years	4	0	10	0	-	-	-	-	-	-	-	-	-	-
		6-11 years	14	2	20	0	-	-	-	0.1622	-	-	-	0.1429	-0.0404	0.3262
		12-17 years	9	2	15	0	-	-	-	0.1304	-	-	-	0.2222	-0.0494	0.4938
		18-55 years	8	0	22	1	-	-	-	1.0000	-	-	-	-0.0455	-0.1325	0.0416
Sex	20 mg/kg	0.5783 F	17	1	34	0	-	-	-	0.3333	-	-	-	0.0588	-0.0530	0.1707
		M	18	3	33	1	5.5000	0.6161	49.0991	0.1200	6.4000	0.6135	66.7596	0.1364	-0.0455	0.3182
Region	20 mg/kg	. REST OF THE WORLD	2	0	15	0	-	-	-	0.0721	7.0345	0.7502	65.9594	0.1020	-0.0155	0.2194
		USA	33	4	52	1	6.3030	0.7361	53.9728	0.0721	7.0345	0.7502	65.9594	0.1020	-0.0155	0.2194
Valproate Use	20 mg/kg	0.2917 N	24	2	41	1	3.4167	0.3268	35.7186	0.5495	3.6364	0.3119	42.4008	0.0589	-0.0613	0.1792
		Y	11	2	26	0	-	-	-	0.0826	-	-	-	0.1818	-0.0461	0.4097
Lamotrigine Use	20 mg/kg	0.6044 N	21	3	42	1	6.0000	0.6637	54.2431	0.1038	6.8333	0.6648	70.2349	0.1190	-0.0376	0.2757
		Y	14	1	25	0	-	-	-	0.3590	-	-	-	0.0714	-0.0635	0.2063
Levetiracetam Use	20 mg/kg	0.3023 N	24	2	42	1	3.5000	0.3346	36.6071	0.5484	3.7273	0.3198	43.4401	0.0595	-0.0603	0.1793

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		Y	11	2	25	0	-	-	-	0.0873	-	-	-	0.1818	-0.0461	0.4097
Rufinamide Use	20 mg/kg	0.2970 N	27	2	49	1	3.6296	0.3448	38.2129	0.2863	3.8400	0.3318	44.4391	0.0537	-0.0528	0.1601
		Y	8	2	18	0	-	-	-	0.0862	-	-	-	0.2500	-0.0501	0.5501
Baseline Drop Seizure Frequency	20 mg/kg	0.7188 <=45	16	1	17	0	-	-	-	0.4848	-	-	-	0.0625	-0.0561	0.1811
		>45 to <=110	11	2	27	1	4.9091	0.4943	48.7589	0.1956	5.7778	0.4661	71.6156	0.1448	-0.0940	0.3836
		>110	8	1	23	0	-	-	-	0.2581	-	-	-	0.1250	-0.1042	0.3542
Current AEDs	20 mg/kg	0.5118 <3	8	1	20	0	-	-	-	0.2857	-	-	-	0.1250	-0.1042	0.3542
		>=3	27	3	47	1	5.2222	0.5711	47.7534	0.1347	5.7500	0.5671	58.2974	0.0898	-0.0357	0.2153
Prior AEDs	20 mg/kg	0.2535 <6	19	3	25	0	-	-	-	0.0732	-	-	-	0.1579	-0.0061	0.3219
		>=6	16	1	42	1	2.6250	0.1744	39.5047	0.4791	2.7333	0.1606	46.5127	0.0387	-0.0886	0.1659
Non-Convulsive Seizures >0pct																
Age Group	20 mg/kg	0.6106 2-5 years	4	0	10	4	-	-	-	0.2507	-	-	-	-0.4000	-0.7036	-0.0964
		6-11 years	14	1	20	8	0.1786	0.0251	1.2721	0.0504	8.6667	0.9394	79.9562	-0.3286	-0.5821	-0.0750
		12-17 years	9	0	15	6	-	-	-	0.0519	-	-	-	-0.4000	-0.6479	-0.1521
		18-55 years	8	1	22	7	0.3929	0.0569	2.7140	0.3911	3.2667	0.3344	31.9142	-0.1932	-0.4938	0.1075
Sex	20 mg/kg	0.7488 F	17	1	34	11	0.1818	0.0255	1.2941	0.0422	7.6522	0.8965	65.3160	-0.2647	-0.4577	-0.0717
		M	18	1	33	14	0.1310	0.0187	0.9165	0.0086	12.5263	1.4861	105.5830	-0.3687	-0.5678	-0.1696
Region	20 mg/kg	0.7457 REST OF THE WORLD	2	0	15	5	-	-	-	1.0000	-	-	-	-0.3333	-0.5719	-0.0948
		USA	33	2	52	20	0.1576	0.0394	0.6305	0.0008	9.6875	2.0869	44.9708	-0.3240	-0.4793	-0.1687
Valproate Use	20 mg/kg	0.8870 N	24	1	41	13	0.1314	0.0183	0.9429	0.0112	10.6786	1.2980	87.8515	-0.2754	-0.4387	-0.1121
		Y	11	1	26	12	0.1970	0.0290	1.3359	0.0574	8.5714	0.9540	77.0081	-0.3706	-0.6267	-0.1145
Lamotrigine Use	20 mg/kg	0.7352 N	21	1	42	16	0.1250	0.0178	0.8796	0.0058	12.3077	1.5031	100.7790	-0.3333	-0.5061	-0.1605
		Y	14	1	25	9	0.1984	0.0280	1.4081	0.0640	7.3125	0.8169	65.4548	-0.2886	-0.5201	-0.0570
Levetiracetam Use	20 mg/kg	0.0177 N	24	0	42	18	-	-	-	<.0001	-	-	-	-0.4286	-0.5782	-0.2789
		Y	11	2	25	7	0.6494	0.1597	2.6395	0.6896	1.7500	0.3000	10.2069	-0.0982	-0.3862	0.1898
Rufinamide Use	20 mg/kg	0.4151 N	27	2	49	18	0.2016	0.0506	0.8042	0.0061	7.2581	1.5359	34.2979	-0.2933	-0.4605	-0.1260
		Y	8	0	18	7	-	-	-	0.0622	-	-	-	-0.3889	-0.6141	-0.1637
Baseline Drop Seizure Frequency	20 mg/kg	0.2420 <=45	16	2	17	6	0.3542	0.0833	1.5059	0.2245	3.8182	0.6410	22.7443	-0.2279	-0.5070	0.0511
		>45 to <=110	11	0	27	14	-	-	-	0.0026	-	-	-	-0.5185	-0.7070	-0.3301
		>110	8	0	23	5	-	-	-	0.2912	-	-	-	-0.2174	-0.3860	-0.0488
Current AEDs	20 mg/kg	0.4606 <3	8	0	20	7	-	-	-	0.0749	-	-	-	-0.3500	-0.5590	-0.1410
		>=3	27	2	47	18	0.1934	0.0486	0.7704	0.0056	7.7586	1.6374	36.7642	-0.3089	-0.4794	-0.1384
Prior AEDs	20 mg/kg	0.1613 <6	19	0	25	9	-	-	-	0.0057	-	-	-	-0.3600	-0.5482	-0.1718
		>=6	16	2	42	16	0.3281	0.0849	1.2689	0.1101	4.3077	0.8635	21.4894	-0.2560	-0.4747	-0.0373

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported (-) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1423 CGIC Responder [VMI, MI, SI] (subgroups) (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI	
End of Treatment	Age Group	20 mg/kg	0.6103	2-5 years	4	4	12	3	-	-	-	0.0192	-	-	-	0.7500	0.5050	0.9950
6-11 years				15	11	27	8	2.4750	1.2837	4.7720	0.0099	0.1531	0.0373	0.6280	0.4370	0.1546	0.7194	
12-17 years				7	6	18	6	2.5714	1.2517	5.2824	0.0302	0.0833	0.0081	0.8589	0.5238	0.1852	0.8624	
18-55 years				10	8	27	12	1.8000	1.0666	3.0378	0.0726	0.2000	0.0356	1.1230	0.3556	0.0448	0.6664	
Last Visit (LOCF)	Age Group	20 mg/kg	0.6084	2-5 years	5	5	12	3	-	-	-	0.0090	-	-	-	0.7500	0.5050	0.9950
6-11 years				15	11	27	8	2.4750	1.2837	4.7720	0.0099	0.1531	0.0373	0.6280	0.4370	0.1546	0.7194	
12-17 years				9	7	18	6	2.3333	1.1124	4.8944	0.0461	0.1429	0.0224	0.9104	0.4444	0.0963	0.7926	
18-55 years				11	9	28	12	1.9091	1.1459	3.1805	0.0375	0.1667	0.0303	0.9171	0.3896	0.0971	0.6821	
End of Treatment	Sex	20 mg/kg	0.9190	F	19	15	42	13	2.5506	1.5349	4.2385	0.0007	0.1195	0.0332	0.4310	0.4799	0.2494	0.7105
M				17	14	42	16	2.1618	1.3868	3.3697	0.0034	0.1319	0.0327	0.5315	0.4426	0.2093	0.6758	
Last Visit (LOCF)	Sex	20 mg/kg	0.7601	F	20	16	42	13	2.5846	1.5644	4.2700	0.0004	0.1121	0.0313	0.4015	0.4905	0.2662	0.7147
M				20	16	43	16	2.1500	1.3766	3.3579	0.0025	0.1481	0.0421	0.5213	0.4279	0.2007	0.6551	
End of Treatment	Region	20 mg/kg	0.3688	REST OF THE WORLD	3	3	18	6	-	-	-	0.0632	-	-	-	0.6667	0.4489	0.8844
USA				33	26	66	23	2.2609	1.5548	3.2875	<.0001	0.1440	0.0543	0.3822	0.4394	0.2586	0.6201	
Last Visit (LOCF)	Region	20 mg/kg	0.3454	REST OF THE WORLD	3	3	19	6	-	-	-	0.0545	-	-	-	0.6842	0.4752	0.8932
USA				37	29	66	23	2.2491	1.5524	3.2586	<.0001	0.1476	0.0581	0.3748	0.4353	0.2598	0.6108	
End of Treatment	Valproate Use	20 mg/kg	0.2790	N	26	22	52	17	2.5882	1.6954	3.9512	<.0001	0.0883	0.0263	0.2970	0.5192	0.3308	0.7076
Y				10	7	32	12	1.8667	1.0204	3.4146	0.1435	0.2571	0.0557	1.1877	0.3250	-0.0049	0.6549	
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.4317	N	29	24	52	17	2.5314	1.6568	3.8678	<.0001	0.1012	0.0329	0.3115	0.5007	0.3132	0.6882
Y				11	8	33	12	2.0000	1.1215	3.5668	0.0777	0.2143	0.0476	0.9648	0.3636	0.0535	0.6738	
End of Treatment	Lamotrigine Use	20 mg/kg	0.5841	N	19	15	54	20	2.1316	1.4031	3.2382	0.0028	0.1569	0.0457	0.5385	0.4191	0.1951	0.6431
Y				17	14	30	9	2.7451	1.5228	4.9484	0.0008	0.0918	0.0211	0.3999	0.5235	0.2791	0.7679	
Last Visit (LOCF)	Lamotrigine Use	20 mg/kg	0.5098	N	23	18	54	20	2.1130	1.4036	3.1810	0.0012	0.1634	0.0526	0.5080	0.4122	0.2001	0.6244
Y				17	14	31	9	2.8366	1.5681	5.1312	0.0007	0.0877	0.0202	0.3807	0.5332	0.2916	0.7748	
End of Treatment	Levetiracetam Use	20 mg/kg	0.2096	N	24	20	50	14	2.9762	1.8432	4.8056	<.0001	0.0778	0.0225	0.2683	0.5533	0.3591	0.7475
Y				12	9	34	15	1.7000	1.0313	2.8023	0.0958	0.2632	0.0604	1.1464	0.3088	0.0124	0.6053	
Last Visit (LOCF)	Levetiracetam Use	20 mg/kg	0.1150	N	26	22	50	14	3.0220	1.8817	4.8532	<.0001	0.0707	0.0206	0.2422	0.5662	0.3798	0.7525
Y				14	10	35	15	1.6667	1.0048	2.7646	0.1137	0.3000	0.0786	1.1445	0.2857	-0.0022	0.5736	
End of Treatment	Rufinamide Use	20 mg/kg	0.3225	N	24	20	63	20	2.6250	1.7528	3.9312	<.0001	0.0930	0.0281	0.3081	0.5159	0.3276	0.7041
Y				12	9	21	9	1.7500	0.9680	3.1637	0.1451	0.2500	0.0522	1.1976	0.3214	-0.0023	0.6452	
Last Visit (LOCF)	Rufinamide Use	20 mg/kg	0.4216	N	27	22	64	20	2.6074	1.7383	3.9110	<.0001	0.1033	0.0342	0.3121	0.5023	0.3169	0.6877

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		Y	13	10	21	9	1.7949	1.0083	3.1951	0.0790	0.2250	0.0476	1.0632	0.3407	0.0288	0.6525
End of Treatment																
Baseline Drop Seizure Frequency	20 mg/kg	0.7004 <=45	14	11	20	9	1.7460	1.0009	3.0458	0.0791	0.2231	0.0473	1.0524	0.3357	0.0296	0.6419
		>45 to <=110	15	12	35	10	2.8000	1.5650	5.0096	0.0014	0.1000	0.0232	0.4316	0.5143	0.2625	0.7660
		>110	7	6	29	10	2.4857	1.3837	4.4653	0.0298	0.0877	0.0092	0.8333	0.5123	0.2007	0.8240
Last Visit (LOCF)																
Baseline Drop Seizure Frequency	20 mg/kg	0.6091 <=45	17	13	21	9	1.7843	1.0194	3.1233	0.0516	0.2308	0.0560	0.9502	0.3361	0.0438	0.6285
		>45 to <=110	15	12	35	10	2.8000	1.5650	5.0096	0.0014	0.1000	0.0232	0.4316	0.5143	0.2625	0.7660
		>110	8	7	29	10	2.5375	1.4409	4.4688	0.0140	0.0752	0.0081	0.6998	0.5302	0.2430	0.8173
End of Treatment																
Current AEDs	20 mg/kg	0.7273 <3	7	6	26	9	2.4762	1.3472	4.5514	0.0300	0.0882	0.0092	0.8506	0.5110	0.1938	0.8282
		>=3	29	23	58	20	2.3000	1.5410	3.4329	<.0001	0.1373	0.0481	0.3920	0.4483	0.2567	0.6398
Last Visit (LOCF)																
Current AEDs	20 mg/kg	0.6057 <3	8	7	26	9	2.5278	1.4017	4.5585	0.0145	0.0756	0.0080	0.7145	0.5288	0.2357	0.8220
		>=3	32	25	59	20	2.3047	1.5438	3.4407	<.0001	0.1436	0.0530	0.3890	0.4423	0.2549	0.6296
End of Treatment																
Prior AEDs	20 mg/kg	0.7027 <6	22	18	37	12	2.5227	1.5224	4.1804	0.0004	0.1067	0.0296	0.3850	0.4939	0.2731	0.7146
		>=6	14	11	47	17	2.1723	1.3603	3.4688	0.0067	0.1545	0.0378	0.6320	0.4240	0.1689	0.6791
Last Visit (LOCF)																
Prior AEDs	20 mg/kg	0.5236 <6	23	19	38	12	2.6159	1.5800	4.3310	0.0002	0.0972	0.0271	0.3484	0.5103	0.2962	0.7244
		>=6	17	13	47	17	2.1142	1.3315	3.3569	0.0054	0.1744	0.0490	0.6201	0.4030	0.1590	0.6470

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

End of treatment = The date of last dose as recorded on the 'End of Treatment Study Outcome' CRF page (Visit 8: Day 99).

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

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**Adhoc Table:** GWEP1423 CGIC Responder [VMI, MI] (subgroups) (ITT Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)	Odds Ratio		Risk Difference	Risk Difference		
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI		95% Lower CI	95% Upper CI	
End of Treatment	Age Group	20 mg/kg	0.2027	2-5 years	4	3	12	0	-	-	-	0.0071	-	-	-	0.7500	0.3257	1.0000
6-11 years				15	6	27	5	2.1600	0.7906	5.9013	0.1582	0.3409	0.0826	1.4072	0.2148	-0.0732	0.5028	
12-17 years				7	3	18	4	1.9286	0.5717	6.5064	0.3554	0.3810	0.0590	2.4577	0.2063	-0.2075	0.6202	
18-55 years				10	5	27	5	2.7000	0.9883	7.3767	0.0943	0.2273	0.0471	1.0975	0.3148	-0.0280	0.6576	
Last Visit (LOCF)	Age Group	20 mg/kg	0.1447	2-5 years	5	4	12	0	-	-	-	0.0021	-	-	-	0.8000	0.4494	1.0000
6-11 years				15	6	27	5	2.1600	0.7906	5.9013	0.1582	0.3409	0.0826	1.4072	0.2148	-0.0732	0.5028	
12-17 years				9	4	18	4	2.0000	0.6450	6.2011	0.3748	0.3571	0.0639	1.9974	0.2222	-0.1550	0.5994	
18-55 years				11	6	28	5	3.0545	1.1692	7.9797	0.0443	0.1812	0.0392	0.8374	0.3669	0.0402	0.6935	
End of Treatment	Sex	20 mg/kg	0.3667	F	19	10	42	6	3.6842	1.5671	8.6615	0.0036	0.1500	0.0431	0.5226	0.3835	0.1353	0.6317
M				17	7	42	8	2.1618	0.9300	5.0251	0.1026	0.3361	0.0977	1.1562	0.2213	-0.0411	0.4837	
Last Visit (LOCF)	Sex	20 mg/kg	0.4074	F	20	11	42	6	3.8500	1.6618	8.9198	0.0017	0.1364	0.0397	0.4684	0.4071	0.1648	0.6495
M				20	9	43	8	2.4188	1.0967	5.3345	0.0367	0.2794	0.0868	0.8990	0.2640	0.0168	0.5111	
End of Treatment	Region	20 mg/kg	0.5440	REST OF THE WORLD	3	2	18	3	4.0000	1.0829	14.7750	0.1278	0.1000	0.0067	1.4904	0.5000	-0.0605	1.0000
USA				33	15	66	11	2.7273	1.4148	5.2571	0.0034	0.2400	0.0935	0.6160	0.2879	0.0957	0.4801	
Last Visit (LOCF)	Region	20 mg/kg	0.5724	REST OF THE WORLD	3	2	19	3	4.2222	1.1382	15.6629	0.1169	0.0938	0.0063	1.3931	0.5088	-0.0493	1.0000
USA				37	18	66	11	2.9189	1.5500	5.4967	0.0011	0.2111	0.0847	0.5264	0.3198	0.1354	0.5043	
End of Treatment	Valproate Use	20 mg/kg	0.6297	N	26	14	52	10	2.8000	1.4457	5.4228	0.0036	0.2041	0.0725	0.5742	0.3462	0.1266	0.5657
Y				10	3	32	4	2.4000	0.6425	8.9647	0.3282	0.3333	0.0602	1.8445	0.1750	-0.1313	0.4813	
Last Visit (LOCF)	Valproate Use	20 mg/kg	0.8193	N	29	16	52	10	2.8690	1.5031	5.4762	0.0013	0.1935	0.0708	0.5288	0.3594	0.1491	0.5697
Y				11	4	33	4	3.0000	0.8979	10.0230	0.0919	0.2414	0.0481	1.2113	0.2424	-0.0629	0.5477	
End of Treatment	Lamotrigine Use	20 mg/kg	0.6110	N	19	10	54	9	3.1579	1.5169	6.5742	0.0048	0.1800	0.0570	0.5686	0.3596	0.1141	0.6052
Y				17	7	30	5	2.4706	0.9260	6.5917	0.0873	0.2857	0.0732	1.1154	0.2451	-0.0242	0.5144	
Last Visit (LOCF)	Lamotrigine Use	20 mg/kg	0.5139	N	23	13	54	9	3.3913	1.6911	6.8008	0.0008	0.1538	0.0516	0.4584	0.3986	0.1729	0.6242
Y				17	7	31	5	2.5529	0.9548	6.8257	0.0828	0.2747	0.0705	1.0701	0.2505	-0.0169	0.5179	
End of Treatment	Levetiracetam Use	20 mg/kg	0.5933	N	24	10	50	5	4.1667	1.6004	10.8478	0.0039	0.1556	0.0455	0.5320	0.3167	0.1026	0.5307
Y				12	7	34	9	2.2037	1.0551	4.6029	0.0769	0.2571	0.0649	1.0196	0.3186	0.0027	0.6345	
Last Visit (LOCF)	Levetiracetam Use	20 mg/kg	0.4417	N	26	12	50	5	4.6154	1.8221	11.6910	0.0009	0.1296	0.0389	0.4319	0.3615	0.1527	0.5704
Y				14	8	35	9	2.2222	1.0783	4.5796	0.0504	0.2596	0.0706	0.9544	0.3143	0.0174	0.6112	
End of Treatment	Rufinamide Use	20 mg/kg	0.5641	N	24	12	63	10	3.1500	1.5719	6.3126	0.0020	0.1887	0.0662	0.5377	0.3413	0.1218	0.5607
Y				12	5	21	4	2.1875	0.7230	6.6183	0.2303	0.3294	0.0677	1.6028	0.2262	-0.0994	0.5518	
Last Visit (LOCF)	Rufinamide Use	20 mg/kg	0.6186	N	27	14	64	10	3.3185	1.6889	6.5206	0.0006	0.1720	0.0625	0.4733	0.3623	0.1539	0.5707

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		Y	13	6	21	4	2.4231	0.8401	6.9892	0.1297	0.2745	0.0588	1.2820	0.2711	-0.0478	0.5899
End of Treatment																
Baseline Drop Seizure Frequency	20 mg/kg	0.6346 <=45	14	6	20	4	2.1429	0.7387	6.2159	0.2522	0.3333	0.0727	1.5293	0.2286	-0.0844	0.5415
		>45 to <=110	15	6	35	4	3.5000	1.1521	10.6330	0.0479	0.1935	0.0446	0.8391	0.2857	0.0163	0.5551
		>110	7	5	29	6	3.4524	1.4715	8.1001	0.0180	0.1043	0.0161	0.6769	0.5074	0.1417	0.8731
Last Visit (LOCF)																
Baseline Drop Seizure Frequency	20 mg/kg	0.6378 <=45	17	8	21	4	2.4706	0.8947	6.8220	0.0873	0.2647	0.0623	1.1249	0.2801	-0.0106	0.5708
		>45 to <=110	15	6	35	4	3.5000	1.1521	10.6330	0.0479	0.1935	0.0446	0.8391	0.2857	0.0163	0.5551
		>110	8	6	29	6	3.6250	1.6010	8.2077	0.0077	0.0870	0.0139	0.5449	0.5431	0.2088	0.8774
End of Treatment																
Current AEDs	20 mg/kg	0.2048 <3	7	5	26	4	4.6429	1.6810	12.8233	0.0086	0.0727	0.0103	0.5140	0.5604	0.1982	0.9227
		>=3	29	12	58	10	2.4000	1.1787	4.8866	0.0196	0.2951	0.1080	0.8064	0.2414	0.0375	0.4453
Last Visit (LOCF)																
Current AEDs	20 mg/kg	0.1757 <3	8	6	26	4	4.8750	1.8183	13.0706	0.0034	0.0606	0.0089	0.4144	0.5962	0.2656	0.9267
		>=3	32	14	59	10	2.5813	1.2973	5.1361	0.0115	0.2624	0.0990	0.6955	0.2680	0.0713	0.4648
End of Treatment																
Prior AEDs	20 mg/kg	0.4420 <6	22	11	37	5	3.7000	1.4804	9.2474	0.0052	0.1563	0.0443	0.5507	0.3649	0.1287	0.6011
		>=6	14	6	47	9	2.2381	0.9631	5.2008	0.0870	0.3158	0.0875	1.1402	0.2371	-0.0455	0.5197
Last Visit (LOCF)																
Prior AEDs	20 mg/kg	0.4592 <6	23	12	38	5	3.9652	1.6030	9.8087	0.0024	0.1389	0.0399	0.4831	0.3902	0.1594	0.6209
		>=6	17	8	47	9	2.4575	1.1331	5.3297	0.0511	0.2664	0.0804	0.8828	0.2791	0.0165	0.5417

LOCF = last observation carried forward; MI = much improved; VMI = very much improved; SI = slightly improved.

End of treatment = The date of last dose as recorded on the 'End of Treatment Study Outcome' CRF page (Visit 8: Day 99).

Last visit = Last visit is defined as the last scheduled visit (not including the end of taper or safety follow-up visits) at which a patient's last evaluation is performed.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] Results are not reported ( - ) when the event count in one study arm is 0.

**Adhoc Table:** GWEP1423 Any AE (subgroups) (Safety Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
	Age Group	20 mg/kg	0.2851	2-5 years	5	4	12	9	1.0263	0.5817	1.8106	1.0000
				6-11 years	15	15	27	18	1.4662	1.1085	1.9393	0.0160
				12-17 years	9	9	18	10	1.7190	1.1196	2.6395	0.0258
				18-55 years	12	11	28	22	1.1402	0.8642	1.5043	0.6521
	Sex	20 mg/kg	0.8932	F	20	19	42	28	1.4250	1.1251	1.8049	0.0238
				M	21	20	43	31	1.3210	1.0718	1.6283	0.0453
	Region	20 mg/kg	0.0893	REST OF THE USA	2 39	1 38	19 66	10 49	0.9500 1.3124	0.2228 1.1285	4.0502 1.5262	1.0000 0.0024
				N Y	29 12	27 12	52 33	37 22	1.2956 1.4530	1.0565 1.1161	1.5887 1.8915	0.0234 0.0225
	Valproate Us	20 mg/kg	0.5189	N	29	27	52	37	1.2956	1.0565	1.5887	0.0234
				Y	12	12	33	22	1.4530	1.1161	1.8915	0.0225
	Lamotrigine l	20 mg/kg	0.9973	N	24	23	54	39	1.3269	1.1025	1.5970	0.0168
				Y	17	16	31	20	1.4588	1.0950	1.9435	0.0354
	Levetiracetar	20 mg/kg	0.0872	N	27	27	51	35	1.4386	1.1874	1.7430	0.0007
				Y	14	12	34	24	1.1905	0.8701	1.6288	0.4651
	Rufinamide L	20 mg/kg	0.8367	N	29	27	63	42	1.3804	1.1246	1.6944	0.0084
				Y	12	12	22	17	1.2637	0.9807	1.6285	0.1366
	Baseline Droj	20 mg/kg	0.3756	<=45	19	18	21	15	1.3129	0.9746	1.7687	0.0948
				>45 to <=110	14	14	36	23	1.5220	1.1716	1.9772	0.0101
				>110	8	7	28	21	1.1240	0.7821	1.6155	0.6514
	Current AEDs	20 mg/kg	0.7274	<3	8	8	26	17	1.4571	1.0582	2.0065	0.0770
				>=3	33	31	59	42	1.3080	1.0838	1.5784	0.0140
	Prior AEDs	20 mg/kg	0.8756	<6	24	23	38	29	1.2557	1.0325	1.5273	0.0732
				>=6	17	16	47	30	1.4745	1.1531	1.8855	0.0253

Adverse events (AE) are coded using the Medical Dictionary for Regulatory Activities (MedDRA). Multiple entries for an individual under each system organ class/preferred term are only counted once. A TEAE is defined as an AE with a start date on or after the first dose of investigational medicinal product.

Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.

**Adhoc Table:** GWEP1423 Maximal AE Mild (subgroups) (Safety Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
	Age Group	20 mg/kg	0.0188	2-5 years	5	1	12	6	0.4000	0.0634	2.5239	0.3382
				6-11 years	15	4	27	13	0.5538	0.2194	1.3981	0.2072
				12-17 years	9	5	18	3	3.3333	1.0173	10.9221	0.0721
				18-55 years	12	1	28	10	0.2333	0.0335	1.6257	0.1244
	Sex	20 mg/kg	0.1595	F	20	7	42	14	1.0500	0.5037	2.1889	1.0000
				M	21	4	43	18	0.4550	0.1761	1.1760	0.0953
	Region	20 mg/kg	0.6812	REST OF THE USA	2	0	19	7	0.4444	0.0332	5.9409	0.5333
					39	11	66	25	0.7554	0.4248	1.3432	0.3960
	Valproate Us	20 mg/kg	0.3900	N	29	7	52	21	0.5977	0.2895	1.2339	0.1543
				Y	12	4	33	11	1.0000	0.3928	2.5456	1.0000
	Lamotrigine l	20 mg/kg	0.8579	N	24	6	54	20	0.6750	0.3109	1.4656	0.4356
				Y	17	5	31	12	0.7598	0.3217	1.7944	0.7531
	Levetiracetar	20 mg/kg	0.1595	N	27	9	51	18	0.9444	0.4930	1.8093	1.0000
				Y	14	2	34	14	0.3469	0.0904	1.3310	0.0983
	Rufinamide L	20 mg/kg	0.8241	N	29	8	63	25	0.6952	0.3580	1.3499	0.3504
				Y	12	3	22	7	0.7857	0.2475	2.4944	1.0000
	Baseline Droj	20 mg/kg	0.2868	<=45	19	2	21	7	0.3158	0.0745	1.3379	0.1328
				>45 to <=110	14	5	36	12	1.0714	0.4621	2.4844	1.0000
				>110	8	4	28	13	1.0769	0.4844	2.3945	1.0000
	Current AEDs	20 mg/kg	0.9051	<3	8	3	26	12	0.8125	0.3030	2.1784	1.0000
				>=3	33	8	59	20	0.7152	0.3549	1.4409	0.3579
	Prior AEDs	20 mg/kg	0.7657	<6	24	7	38	17	0.6520	0.3184	1.3349	0.2878
				>=6	17	4	47	15	0.7373	0.2842	1.9126	0.7576

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Table includes results for TEAEs where there are 10 or more subjects in at least one study arm within a subgroup.

[1] P-value from a test of interaction based upon a Breslow-Day test of homogeneity.

[2] When TEAE counts in both groups are non-zero, p-values are from Fisher's Exact tests. When the TEAE count in either subgroup is 0, relative risks and 95 % confidence intervals are calculated after adding 0.5 to the count in both groups, p-values are from Fisher's Exact tests based on the original data. Results are not reported ( - ) when the TEAE count in both groups is 0.



**Adhoc Table:** GWEP1423 Maximal AE moderate (subgroups) (Safety Analysis Set, Patients Taking CBD + Clobazam vs. All Placebos)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.0116	2-5 years	5	2	12	2	2.1667	0.5022	9.3482	0.5378	
				15	9	27	5	3.0227	1.2897	7.0847	0.0148	
				9	0	18	7	0.1267	0.0080	1.9981	0.0593	
				12	9	28	11	1.8428	1.0556	3.2171	0.0824	
Sex	20 mg/kg	0.6651	F	20	11	42	13	1.7769	0.9742	3.2410	0.0957	
			M	21	9	43	12	1.5357	0.7711	3.0586	0.2659	
Region	20 mg/kg	-	REST OF THE WORLD	2	1	19	3	-	-	-	0.3524	
			USA	39	19	66	22	-	-	-	0.1485	
Valproate Use	20 mg/kg	0.3993	N	29	15	52	14	1.9212	1.0872	3.3949	0.0317	
			Y	12	5	33	11	1.2500	0.5477	2.8530	0.7284	
Lamotrigine Use	20 mg/kg	0.8430	N	24	12	54	17	1.5882	0.9062	2.7837	0.1350	
			Y	17	8	31	8	1.8235	0.8348	3.9833	0.2014	
Levetiracetam Use	20 mg/kg	0.8817	N	27	14	51	17	1.5556	0.9140	2.6474	0.1461	
			Y	14	6	34	8	1.8214	0.7737	4.2879	0.2942	
Rufinamide Use	20 mg/kg	0.9455	N	29	12	63	15	1.7379	0.9361	3.2265	0.1381	
			Y	12	8	22	10	1.4667	0.7986	2.6938	0.2966	
Baseline Drop Seizure Frequency	20 mg/kg	0.6567	<=45	19	11	21	7	1.7368	0.8487	3.5546	0.2028	
			>45 to <=110	14	7	36	11	1.6364	0.7973	3.3583	0.3251	
			>110	8	2	28	7	1.0000	0.2564	3.8998	1.0000	
Current AEDs	20 mg/kg	0.3913	<3	8	4	26	5	2.6000	0.9106	7.4236	0.1648	
			>=3	33	16	59	20	1.4303	0.8670	2.3597	0.1879	
Prior AEDs	20 mg/kg	0.7588	<6	24	11	38	11	1.5833	0.8173	3.0674	0.2756	
			>=6	17	9	47	14	1.7773	0.9491	3.3281	0.1392	

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**Adhoc Table:** GWEP1423 Any SAE (subgroups) (Safety Analysis Set, Patients Taking Clobazam)

Analysis	Factor	Treatment	Interaction p-value [1]	Factor Level	Active		Placebo		Relative Risk [2]			p-value (vs. Placebo)
					N (total)	n (event)	N (total)	n (event)	Relative Risk	95% Lower CI	95% Upper CI	
Age Group	20 mg/kg	0.5463	2-5 years	5	2	12	1	3.6111	0.6101	21.3738	0.1912	
			6-11 years	15	5	27	0	19.2500	1.1370	325.9223	0.0035	
			12-17 years	9	3	18	1	4.4333	0.7683	25.5829	0.0933	
			18-55 years	12	2	28	2	2.2308	0.4386	11.3448	0.5698	
Sex	20 mg/kg	0.2330	F	20	5	42	3	3.5000	0.9269	13.2155	0.0984	
			M	21	7	43	1	14.3333	1.8838	109.0566	0.0012	
Region	20 mg/kg	0.9227	REST OF THE USA	2	0	19	0	6.6667	0.1604	277.1305	0.0013	
			USA	39	12	66	4	4.6528	1.7052	12.6956		
Valproate Us	20 mg/kg	0.0788	N	29	7	52	4	2.9444	1.0004	8.6661	0.0488	
			Y	12	5	33	0	28.7692	1.7086	484.4121	0.0006	
Lamotrigine l	20 mg/kg	0.6276	N	24	9	54	4	4.6444	1.6796	12.8428	0.0021	
			Y	17	3	31	0	12.4444	0.6804	227.6136	0.0393	
Levetiracetar	20 mg/kg	0.4056	N	27	7	51	1	13.2222	1.7146	101.9623	0.0020	
			Y	14	5	34	3	4.0476	1.1154	14.6888	0.0365	
Rufinamide L	20 mg/kg	0.8497	N	29	11	63	4	5.4519	2.0060	14.8169	0.0003	
			Y	12	1	22	0	5.3077	0.2326	121.1072	0.3529	
Baseline Droj	20 mg/kg	0.7139	<=45	19	6	21	2	3.3158	0.7585	14.4946	0.1202	
			>45 to <=110	14	4	36	1	10.2857	1.2563	84.2095	0.0180	
			>110	8	2	28	1	7.0000	0.7245	67.6351	0.1176	
Current AEDs	20 mg/kg	0.7702	<3	8	1	26	0	9.0000	0.4012	201.8765	0.2353	
			>=3	33	11	59	4	4.5098	1.6502	12.3244	0.0021	
Prior AEDs	20 mg/kg	0.6794	<6	24	4	38	1	6.3333	0.7520	53.3414	0.0690	
			>=6	17	8	47	3	7.3725	2.2086	24.6100	0.0006	

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