

SUPPLEMENTARY TABLE S4. HYPOGLYCEMIC EVENTS AT ANY TIME (24 H) AND DURING THE NIGHT (00:00–05:59 H) IN THE EDITION 1 SUBSTUDY (SAFETY POPULATION)

	<i>At any time (24 h)</i>		<i>Nocturnal (00:00–05:59 h)</i>	
	<i>Flexible dosing (n=56)</i>	<i>Fixed dosing (n=53)</i>	<i>Flexible dosing (n=56)</i>	<i>Fixed dosing (n=53)</i>
Total participant-years	13.82	13.15	13.82	13.15
Confirmed (≤ 70 mg/dL [≤ 3.9 mmol/L]) or severe hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	31 (55.4)	35 (66.0)	14 (25.0)	12 (22.6)
Events [<i>n</i> (events per participant-year)]	187 (13.53)	262 (19.92)	33 (2.39)	22 (1.67)
Confirmed (< 54 mg/dL [< 3.0 mmol/L]) or severe hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	13 (23.2)	15 (28.3)	4 (7.1)	7 (13.2)
Events [<i>n</i> (events per participant-year)]	30 (2.17)	47 (3.57)	10 (0.72)	8 (0.61)
Documented symptomatic hypoglycemia (≤ 70 mg/dL [≤ 3.9 mmol/L])				
Participants with ≥ 1 event [<i>n</i> (%)]	18 (32.1)	22 (41.5)	11 (19.6)	8 (15.1)
Events [<i>n</i> (events per participant-year)]	114 (8.25)	119 (9.05)	30 (2.17)	11 (0.84)
Documented symptomatic hypoglycemia (< 54 mg/dL [< 3.0 mmol/L])				
Participants with ≥ 1 event [<i>n</i> (%)]	11 (19.6)	11 (20.8)	3 (5.4)	5 (9.4)
Events [<i>n</i> (events per participant-year)]	28 (2.03)	27 (2.05)	9 (0.65)	6 (0.46)
Severe hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	0 (0)	1 (1.9)	0 (0)	1 (1.9)
Events [<i>n</i> (events per participant-year)]	0 (0)	1 (0.08)	0 (0)	1 (0.08)
Any hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	32 (57.1)	35 (66.0)	15 (26.8)	12 (22.6)
Events [<i>n</i> (events per participant-year)]	193 (13.97)	262 (19.92)	34 (2.46)	22 (1.67)