

SUPPLEMENTARY TABLE S3. HYPOGLYCEMIC EVENTS AT ANY TIME (24 h) AND DURING THE NIGHT (00:00–05:59 h) IN THE FLEXIBLE-DOSING AND FIXED-DOSING GROUPS FOR THE POOLED EDITION 1 AND EDITION 2 SUBSTUDIES (SAFETY POPULATION)

	<i>At any time (24 h)</i>		<i>Nocturnal (00:00–05:59 h)</i>	
	<i>Flexible dosing (n=100)</i>	<i>Fixed dosing (n=96)</i>	<i>Flexible dosing (n=100)</i>	<i>Fixed dosing (n=96)</i>
Total participant-years	24.82	23.57	24.82	23.57
Confirmed (≤ 70 mg/dL [≤ 3.9 mmol/L]) or severe hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	47 (47.0)	53 (55.2)	21 (21.0)	22 (22.9)
Relative risk (95% CI) ^a	0.85 (0.65–1.11)		0.91 (0.54–1.55)	
Events [<i>n</i> (events per participant-year)]	259 (10.44)	349 (14.81)	57 (2.30)	46 (1.95)
Rate ratio (95% CI) ^b	0.71 (0.43–1.16)		1.18 (0.51–2.70)	
Confirmed (< 54 mg/dL [< 3.0 mmol/L]) or severe hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	17 (17.0)	20 (20.8)	8 (8.0)	9 (9.4)
Relative risk (95% CI) ^a	0.81 (0.46–1.44)		0.85 (0.34–2.12)	
Events [<i>n</i> (events per participant-year)]	42 (1.69)	57 (2.42)	15 (0.60)	11 (0.47)
Rate ratio (95% CI) ^b	0.70 (0.31–1.56)		1.30 (0.39–4.26)	
Documented symptomatic hypoglycemia (≤ 70 mg/dL [≤ 3.9 mmol/L])				
Participants with ≥ 1 event [<i>n</i> (%)]	28 (28.0)	36 (37.5)	16 (16.0)	15 (15.6)
Relative risk (95% CI) ^a	0.74 (0.50–1.12)		1.02 (0.53–1.95)	
Events [<i>n</i> (events per participant-year)]	149 (6.00)	172 (7.30)	41 (1.65)	29 (1.23)
Rate ratio (95% CI) ^b	0.82 (0.45–1.52)		1.34 (0.52–3.47)	
Documented symptomatic hypoglycemia (< 54 mg/dL [< 3.0 mmol/L])				
Participants with ≥ 1 event [<i>n</i> (%)]	15 (15.0)	16 (16.7)	7 (7.0)	7 (7.3)
Relative risk (95% CI) ^a	0.90 (0.47–1.70)		0.96 (0.35–2.64)	
Events [<i>n</i> (events per participant-year)]	39 (1.57)	37 (1.57)	14 (0.56)	9 (0.38)
Rate ratio (95% CI) ^b	1.00 (0.44–2.28)		1.48 (0.39–5.61)	
Severe hypoglycemia ^c				
Participants with ≥ 1 event [<i>n</i> (%)]	0 (0)	1 (1.0)	0 (0)	1 (1.0)
Events [<i>n</i> (events per participant-year)]	0 (0)	1 (0.04)	0 (0)	1 (0.04)
Any hypoglycemia				
Participants with ≥ 1 event [<i>n</i> (%)]	48 (48.0)	53 (55.2)	22 (22.0)	22 (22.9)
Relative risk (95% CI) ^a	0.87 (0.66–1.13)		0.96 (0.57–1.61)	
Events [<i>n</i> (events per participant-year)]	266 (10.72)	358 (15.19)	58 (2.34)	46 (1.95)
Rate ratio (95% CI) ^b	0.71 (0.43–1.16)		1.20 (0.53–2.73)	

^aRelative risk of participants experiencing one or more hypoglycemic event for flexible-dosing intervals versus fixed-dosing intervals.

^bRate ratio of annualized hypoglycemic event rates for flexible-dosing intervals versus fixed-dosing intervals.

^cRelative risk and rate ratio not estimated owing to low numbers.

CI, confidence interval.