Supplementary Data

Table S1 – Baseline concomitant diseases and lipidaemia (FAS-M12; n=793)

Characteristic	**FAS-M12**	**N**
Concomitant diseases		
Vascular disorders, n [%]	575 [72.5]	793
Nervous system disorders, n [%]	316 [39.8]	793
Renal and urinary disorders, n [%]	75 [9.5]	793
Eye disorders, n [%]	34 [4.3]	793
Cardiac disorders, n [%]	143 [18.0]	793
Endocrine disorders, n [%]	42 [5.3]	793
Metabolism and nutrition disorders, n [%]	212 [26.7]	793
Lipidaemia		
Triglycerides [mg/dL]	200.8±96.0	502
Total cholesterol [mg/dL]	193.0±48.9	565
HDL cholesterol [mg/dL]	48.8±21.1	516
LDL cholesterol [mg/dL]	116.6±42.2	514

Data shown as mean ± standard deviation, if not otherwise specified; FAS-M12, full analysis set of patients with month 12 data available

Supplementary Data

Table S2 – Baseline characteristics, main combinations of baseline OAD treatment – subgoups by previous basal insulin treatment (FAS-M12; n=793)

	Previous basal insulin			
	Gla-100 N=370	IDeg N=60	IDet N=105	NPH N=166
Baseline characteristics				
Age [years]	65.0±11.2	63.5±9.7	64.7±11.3	65.1±9.1
Diabetes duration [years]	11.5±6.3	11.7±6.2	12.3±7.1	13.1±8.2
Gender m/f [%]†	56.5/43.5	51.7/48.3	54.3/45.7	62.7/37.3
BMI [kg/m²]	31.6±5.5	32.0±6.3	31.7±6.3	32.4±5.8
BMI < 30/≥ 30 kg/m² [%]†	43.6/56.4	39.3/60.7	46.5/53.5	40.1/59.9
Height [cm]	170.5±9.3	169.3±9.7	170.7±8.8	171.0±9.5
Weight [kg]	92.3±18.5	93.6±22.3	92.4±18.5	94.8±19.3
FPG [mg/dL]	163.4±40.9	168.5±33.0	174.5±42.0	181.6±45.7
FPG [mmol/L]	9.08±2.27	9.36±1.83	9.69±2.33	10.09±2.54
HbA_{1c} [%]	8.2±0.8	8.2±0.8	8.3±0.7	8.3±0.8
Individual target HbA_{1c} [%]	7.0±0.5	7.2±0.8	7.0±0.5	7.1±0.5
OAD treatment combinations [%]‡,¶				
Metformin + DPP-4i	24.6	21.7	26.7	28.9
Metformin monotherapy	20.0	23.3	25.7	18.7
DPP-4i monotherapy	7.3	6.7	5.7	7.2
Metformin + SU	4.1	1.7	3.8	4.2
Metformin + SGLT2i	3.8	1.7	2.9	4.2
Metformin + SU + DPP-4i	1.1	-	3.8	3.0
Metformin + SU + SGLT2i	-	-	-	1.2
Metformin + SGLT2i + DPP-4i	3.0	-	2.9	3.0
SGLT2i monotherapy	1.4	1.7	-	1.8
SU monotherapy	4.1	-	3.8	1.8
SU + DPP-4i	1.1	-	2.9	3.0
Others§	29.5	43.2	21.8	23.0

Data are shown as mean ± standard deviation, unless otherwise specified; for N=92 no documentation of their previous basal insulin is available; † excluding „unknown/missing“ data; ‡ percentage of patients including “unknown/missing data”; § Others, other combinations or unknown; BMI, body mass index; DPP-4i, dipeptidyl peptidase-4 inhibitor; FAS-M12, full analysis set of patients with month 12 data available; FPG, fasting plasma glucose; Gla-100, insulin glargine 100 U/mL; IDeg, insulin degludec; IDet, insulin detemir; NPH, neutral protamine Hagedorn insulin; OAD, oral antidiabetic drug; SGLT2i, sodium-glucose cotransporter-2 inhibitor; SU, sulfonylurea

Supplementary Data

Table S3 – Four-point SMPG profiles at baseline and changes to month 6 and month 12 after switching the previous BI to Gla-300 (FAS-M12; n=793)

Timepoint	Baseline		Change to month 6		P value	Change to month 12		P value
	mean±SD	N	mean±SD	N		mean±SD	N	
Morning preprandial [mg/dL]	160.9±39.9	142	-27.4±37.3	99	<0.0001	-30.4±46.6	93	<0.0001
Morning 2 h postprandial [mg/dL]	186.8±56.3	117	-36.0±54.2	75	<0.0001	-38.1±56.8	72	<0.0001
Lunch 2 h postprandial [mg/dL]	178.7±53.7	127	-23.5±58.8	76	0.0008	-22.0±67.7	76	0.0058
Dinner 2 h postprandial [mg/dL]	183.5±54.2	131	-15.8±52.5	85	0.0068	-25.6±53.2	85	<0.0001

SMBG, self-measured blood glucose; BI, basal insulin; FAS-M12, full analysis set of patients with month 12 data available; SD, standard deviation; Gla-300, insulin glargine 300 U/mL

Supplementary Data

Table S4 – Final daily doses of previous BI, and Gla-300 start and final dose (month 12) after switching previous BI to Gla-300, stratified by previous BI (FAS-M12; n=793)

	Previous basal insulin in a BOT regimen							
	Gla-100 (n=370)	**N**	**IDeg (n=60)**	**N**	**IDet (n=105)**	**N**	**NPH (n=166)**	**N**
Last dose previous BI [U/d]	30.2±16.0	366	32.3±21.2	60	27.8±12.5	104	24.6±15.3	166
Start dose Gla-300 [U/d]	30.8±15.5	369	32.6±21.6	60	25.8±11.1	105	22.7±12.4	165
Final dose Gla-300 [U/d]	35.9±20.7	364	37.2±25.1	60	33.0±16.8	103	28.4±15.3	164

BI, basal insulin; BOT, basal insulin supported oral therapy; FAS-M12, full analysis set of patients with month 12 data available; SD, standard deviation; Gla-100, insulin glargine 100 U/mL; Gla-300, insulin glargine 300 U/mL; IDeg, insulin degludec; IDet, insulin detemir. Previous BI was unknown for n=92 study participants.

Table S5 – Final daily doses per kg bodyweight of previous BI, and Gla-300 start and final dose (month 12) after switching previous BI to Gla-300, stratified by previous BI (FAS-M12; n=793)

	Previous basal insulin in a BOT regimen							
	Gla-100 (n=370)	**N**	**IDeg (n=60)**	**N**	**IDet (n=105)**	**N**	**NPH (n=166)**	**N**
Last dose prev. BI [U/kg*d]	0.33±0.18	351	0.34±0.19	59	0.31±0.14	99	0.26±0.16	166
Start dose Gla-300 [U/kg*d]	0.34±0.16	353	0.34±0.19	59	0.29±0.12	105	0.24±0.13	165
Final dose Gla-300 [U/kg*d]	0.41±0.23	356	0.39±0.21	59	0.36±0.17	100	0.32±0.22	164

BI, basal insulin; BOT, basal insulin supported oral therapy; FAS-M12, full analysis set of patients with month 12 data available; prev., previous; SD, standard deviation; U/kg*d, units per kg body weight per day; Gla-100, insulin glargine 100 U/mL; Gla-300, insulin glargine 300 U/mL; IDeg, insulin degludec; IDet, insulin detemir. Previous BI was unknown for n=92 study participants.

Supplementary Data

Table S6 – Adverse events and serious adverse events (SAS; n=1,603)

Characteristic	SAS
Adverse events (AEs)	
Overall, n [%]	146 [9.1]
AEs considered possibly related to the use of Gla-300 by investigator or sponsor, n [%]	29 [1.8]
Serious adverse events (SAEs)	
Overall, n [%]	26 [1.6]
Most common reported SAEs:	
General disorders and administration site conditions, [%]	[0.4]
Nervous system disorders, [%]	[0.4]
Related SAEs:	2 [0.1]
Hyperglycaemia, dizziness (one patient)	
Hypoglycaemia, palpitations, confusional state, hyperhidrosis (one patient)	
Fatal adverse events (fatal AEs)*	
Overall, n [%]	5 [0.3]
MedDRA PT terms per patient:	
Acute myocardial infarction, condition aggravated, traumatic intracranial haemorrhage (one patient)	
Multiple organ dysfunction syndrome (one patient)	
Organ failure (one patient)	
Sudden cardiac death (one patient)	
Cerebrovascular accident (one patient)	

AE, adverse event; MedDRA PT, Medical Dictionary for Regulatory Activities Preferred Term; SAE, serious adverse event; SAS, safety analysis set; Gla-300, insulin glargine 300 U/mL; n, number of patients

* None of the fatal AEs were considered associated with Gla-300 by the reporter or the sponsor.

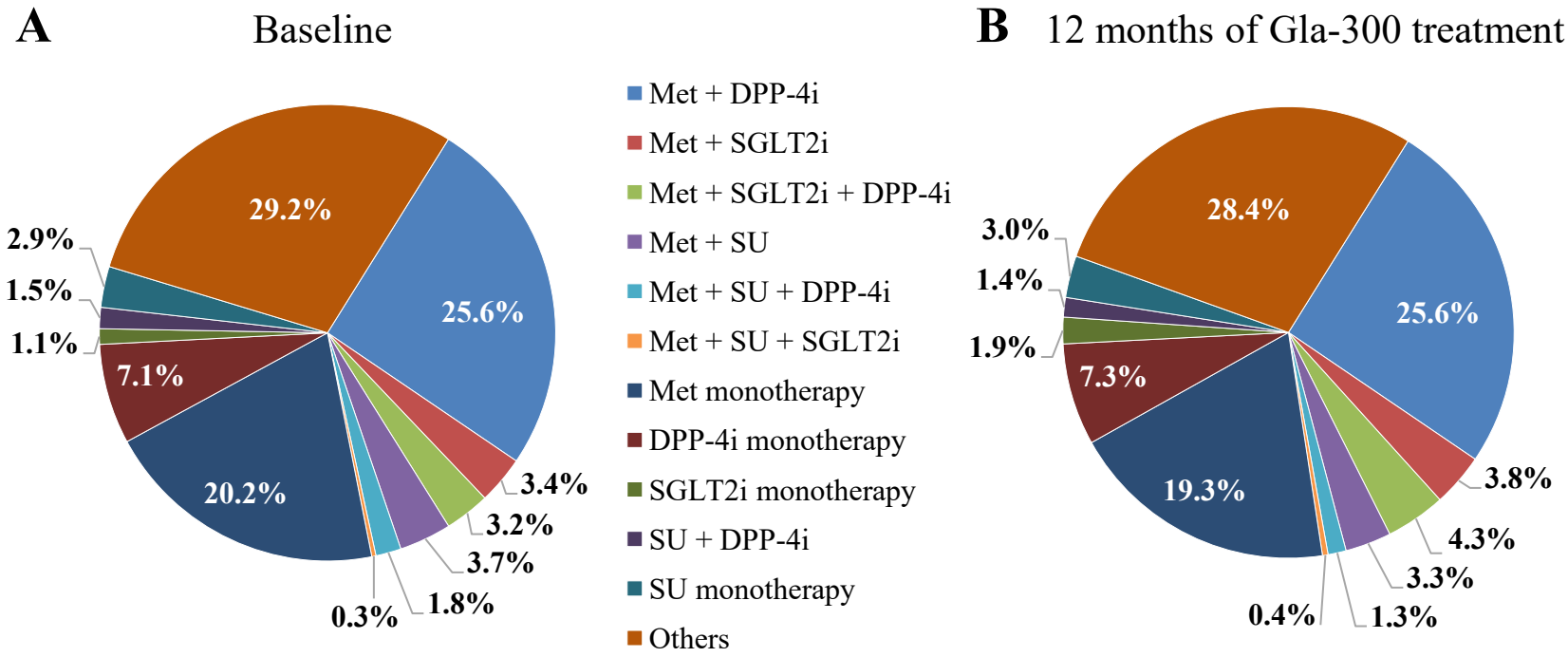

Figure S1 – Most often used combinations of oral antidiabetic drugs at baseline (A) and after 12 months of Gla-300 treatment (B) (FAS-M12; n=793); denominator for the percentages is the number of patients in the analysis set, i. e. percentage of patients including "unknown/missing data"; Others, other combinations or unknown; DPP-4i, dipeptidyl peptidase-4 inhibitor; FAS-M12, full analysis set of patients with month 12 data available; Gla-300, insulin glargine 300 U/mL; Met, metformin; SGLT2i, sodium-glucose cotransporter-2 inhibitor; SU, sulfonylurea.

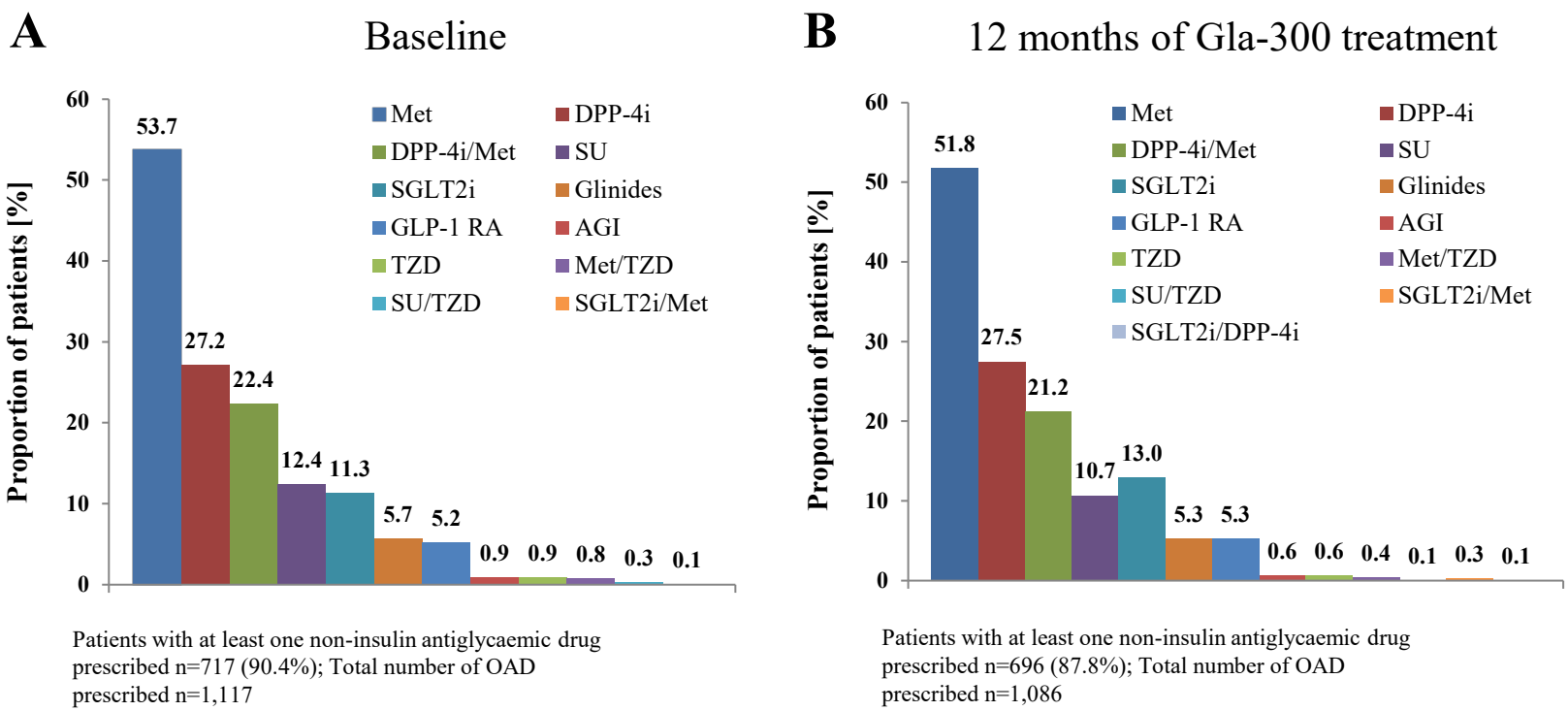

Figure S2 – Most often prescribed non-insulin antiglycaemic drugs and fix ratio drug combinations (A) at baseline and (B) after 12 months of Gla-300 treatment (FAS-M12; n=721); AGI, alpha glucosidase inhibitor; DPP-4i, dipeptidyl peptidase-4 inhibitor; FAS-M12, full analysis set of patients with month 12 data available; Gla-300, insulin glargine 300 U/mL; GLP-1 RA, glucagon-like peptide-1 receptor agonist; Met, metformin; SGLT2i, sodium-glucose cotransporter-2 inhibitor; SU, sulfonylurea, TZD, tiazolidinedione.

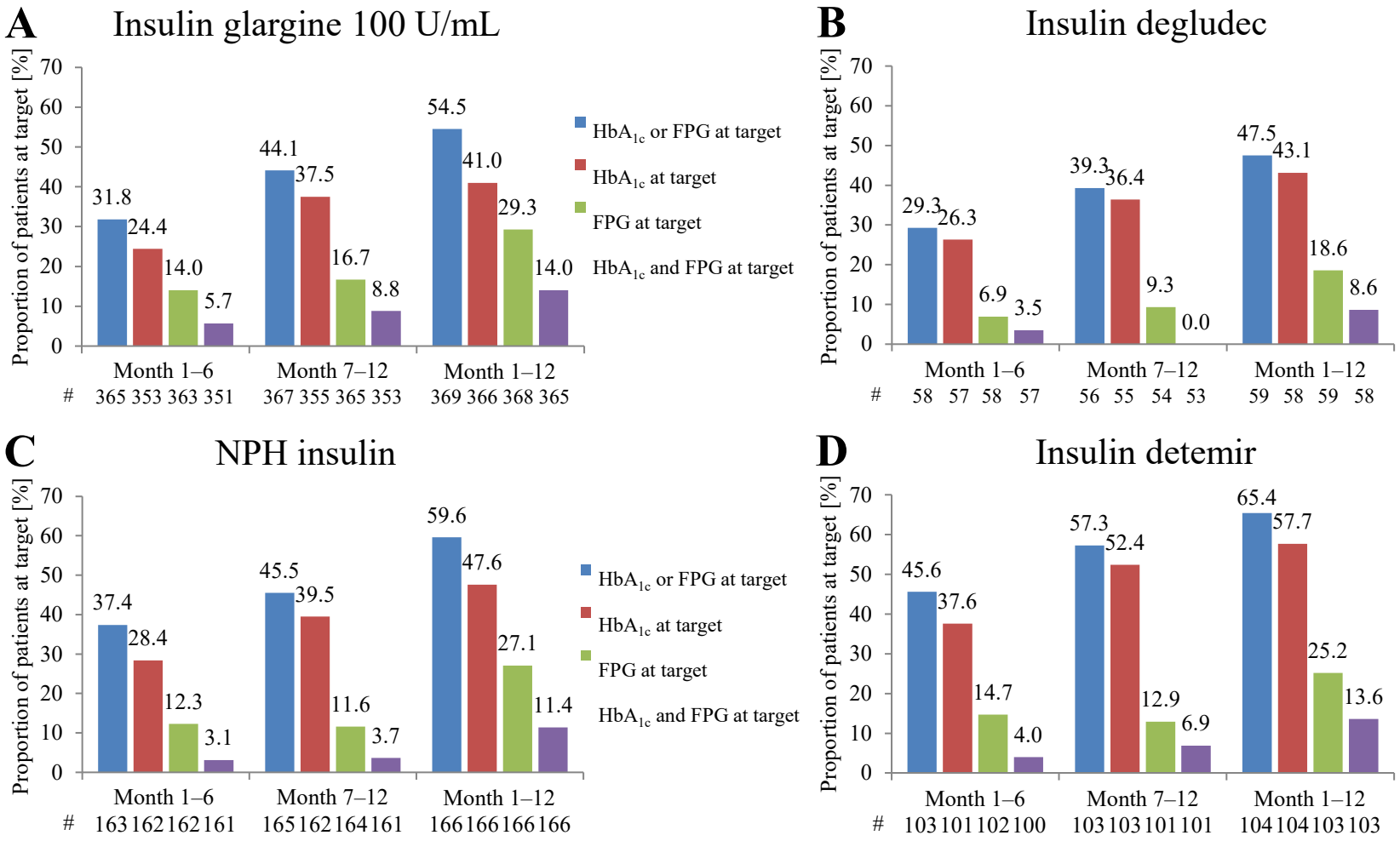

Figure S3 – FPG (≤ 110 mg/dL [≤ 6.1 mmol/L]) and HbA_{1c} (individual) target achievement after 1-6, 7-12 and 1-12 months of insulin glargine 300 U/mL treatment by previous basal insulin treatment (FAS-M12; n=793): (A) insulin glargine 100 U/mL (n=370), (B) insulin degludec (n=60), (C) NPH insulin (n=166) and (D) insulin detemir (n=105); #, number of patients with month 12 data available; FPG, fasting plasma glucose; post-hoc evaluation of 7-12 months: all patients with the respective parameter at target during this period were included, i.e. those in which target achievement occurred for the first time, was sustained from period 1-6 months or occurred for a second time after occurring and ending within period 1-6 months.

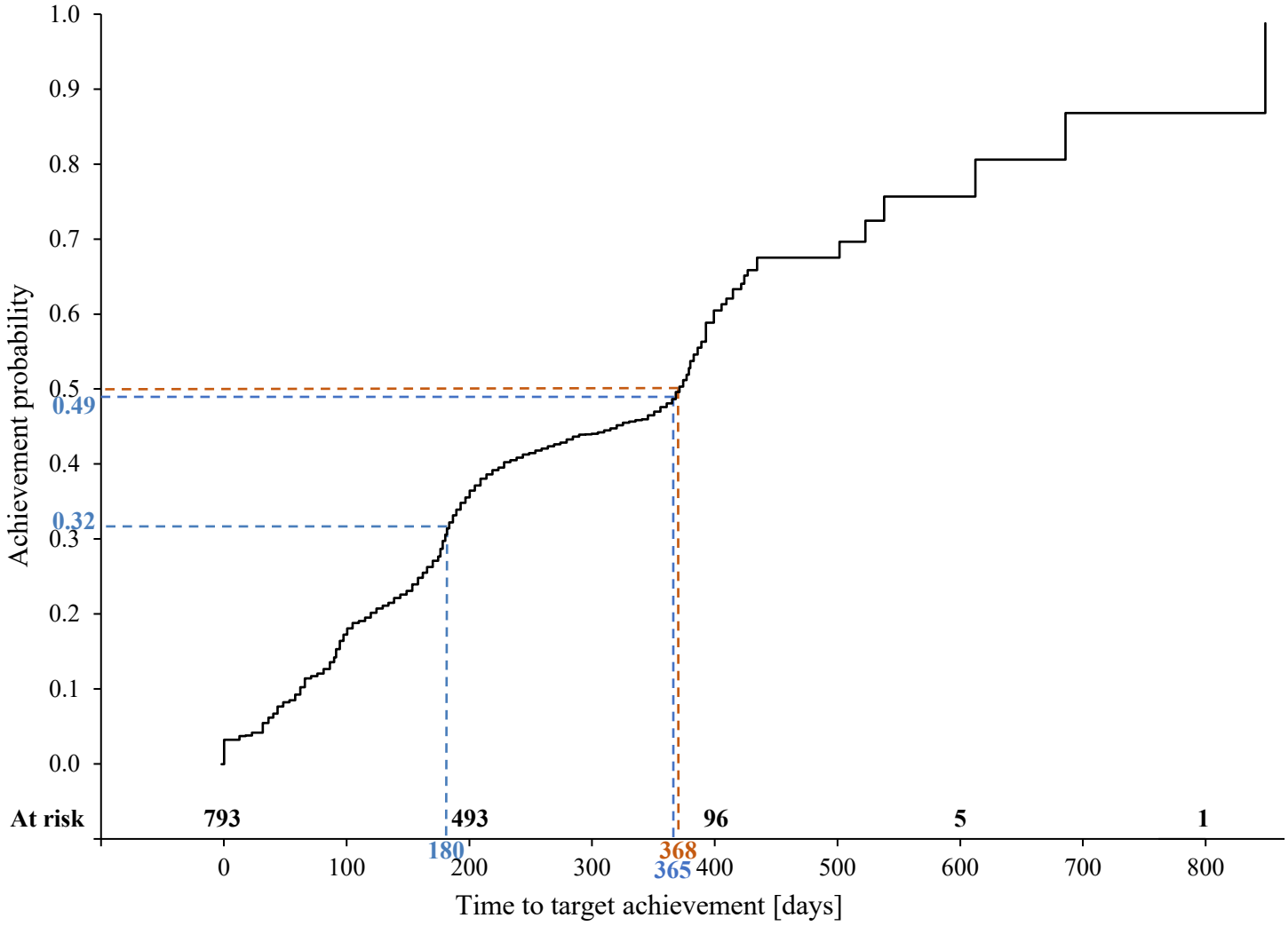

Figure S4A – Time to individualized HbA1c or FPG target achievement after switching the basal insulin in a BOT regimen to insulin glargine 300 U/mL (range 1 to 848 days); brown: median [95% CI] time to target achievement (368 [342; 379] days [12.3 months]); blue: Kaplan-Meier estimate [95% CI] for target achievement after 6 and 12 months, respectively (0.32 [0.29; 0.36] and 0.49 [0.45; 0.53]); FPG target, fasting plasma glucose ≤ 110 mg/dL (≤ 6.1 mmol/L); BOT, basal insulin supported oral therapy; CI, confidence interval

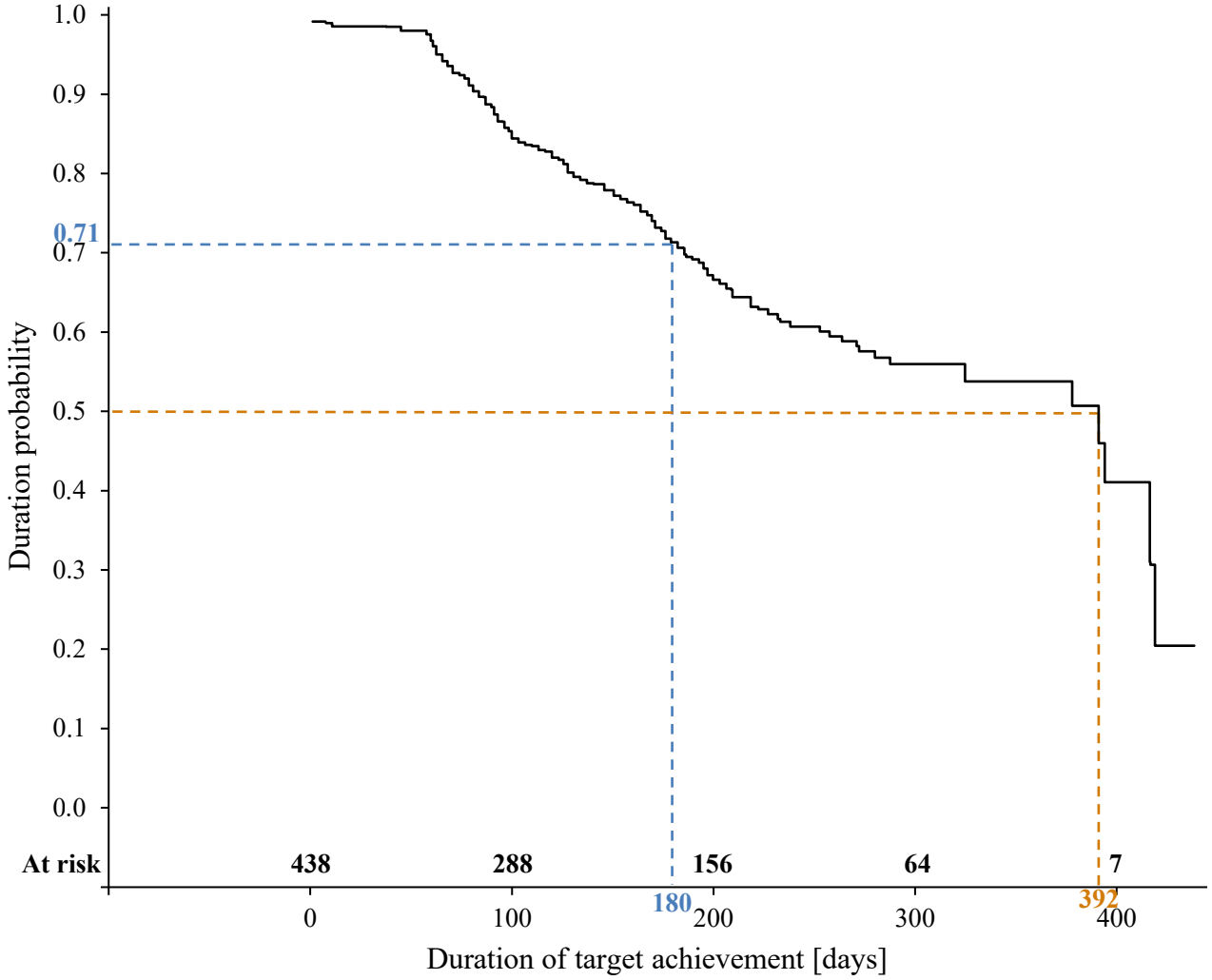

Figure S4B – Duration of individualized HbA1c or FPG target achievement under BOT with insulin glargine 300 U/mL (range 1 to 439 days). Of 438 FAS-M12 patients achieving this endpoint within 12 months, 30.1% reported an end of target achievement during the study, and 69.9% remained on target until study end. Brown: median [95% CI] time on target (392 [325; 418] days [13.1 months]); blue: Kaplan-Meier estimate [95% CI] for further duration on target after 6 months (180 days; 0.71 [0.66; 0.76]); FPG target, fasting plasma glucose ≤ 110 mg/dL (≤ 6.1 mmol/L); BOT, basal insulin supported oral therapy; CI, conficence interval

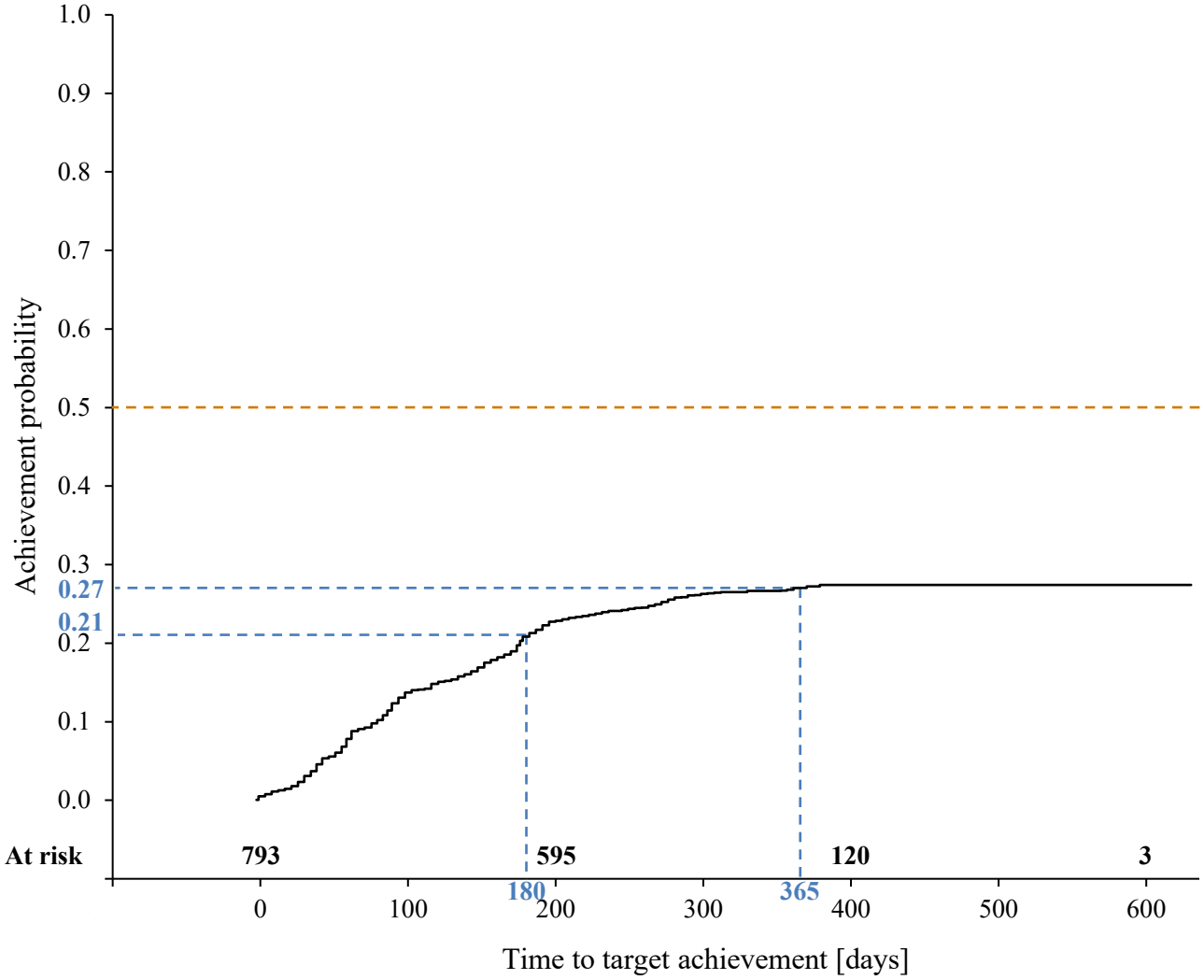

Figure S5A – Time to FPG target achievement after switching the basal insulin in a BOT regimen to insulin glargine 300 U/mL (range 1 to 644 days); brown: median time to target achievement not calculable (not reached within time of data collection, because less than 50% achieved this endpoint); blue: Kaplan-Meier estimate [95% CI] for target achievement after 6 and 12 months, respectively (0.21 [0.18; 0.24] and 0.27 [0.24; 0.30]); FPG target, fasting plasma glucose ≤ 110 mg/dL (≤ 6.1 mmol/L); BOT, basal insulin supported oral therapy

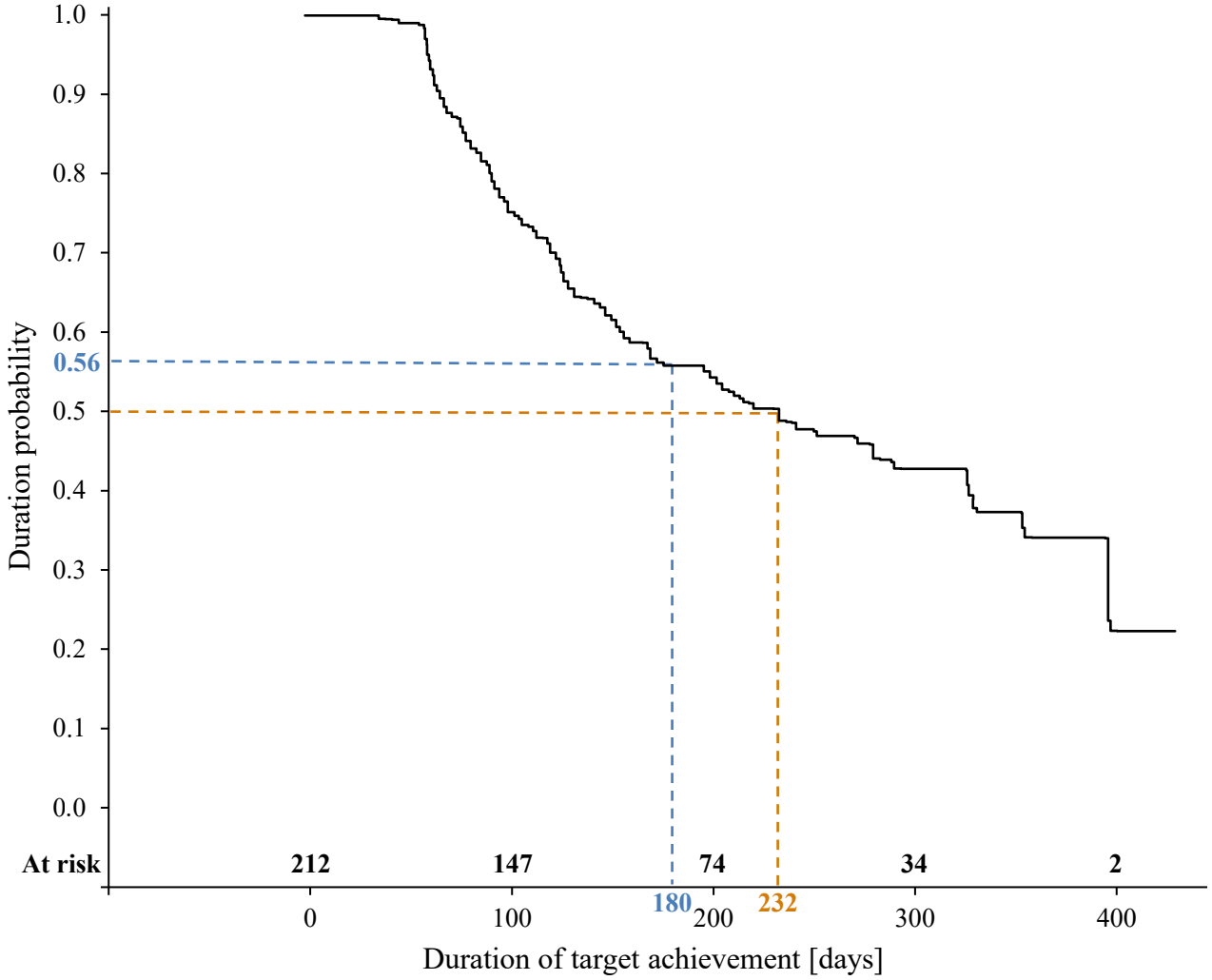

Figure S5B – Duration of FPG target achievement under BOT with insulin glargine 300 U/mL (range 1 to 427 days). Of 212 FAS-M12 patients achieving this endpoint within 12 months, 49.5% reported an end of target achievement during the study, and 50.5% remained on target until study end. Brown: median [95% CI] time on target (232 [170; 325] days [7.7 months]); blue: Kaplan-Meier estimate [95% CI] for further duration on target after 6 months (180 days; 0.56 [0.49; 0. 63]); FPG target, fasting plasma glucose ≤ 110 mg/dL (≤ 6.1 mmol/L); BOT, basal insulin supported oral therapy; CI, confidence interval