

## Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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## Inclusion and exclusion criteria

### Inclusion criteria

- Type 2 diabetes
- HbA<sub>1c</sub> ≥7.0 %
- **OR** HbA<sub>1c</sub> <7.0 % and current insulin treatment corresponding to ≥20 U/day of basal insulin
- Current treatment with one or more oral or injectable antidiabetic agents
- Age ≥50 years at screening and at least one of the following conditions:
  - Prior myocardial infarction
  - Prior stroke or prior TIA
  - Prior coronary, carotid or peripheral arterial revascularization
  - >50% stenosis on angiography or other imaging of coronary, carotid or lower-extremity artery
  - History of symptomatic coronary heart disease documented by positive exercise stress test or any cardiac imaging, or unstable angina pectoris with ECG changes
  - Asymptomatic cardiac ischemia documented by positive nuclear imaging test or exercise test or dobutamine stress echo
  - Chronic heart failure NYHA class II–III
  - Chronic kidney disease corresponding to estimated glomerular filtration rate 30–59 mL/min/1.73m<sup>2</sup> per CKD-EPI
- **OR** Age ≥60 years at screening and at least one of the following risk factors:
  - Microalbuminuria or proteinuria
  - Hypertension and left ventricular hypertrophy by ECG or imaging
  - Left ventricular systolic and diastolic dysfunction by imaging
  - Ankle/brachial index <0.9

### Exclusion criteria

- An acute coronary or cerebrovascular event in the previous 60 days
- Planned coronary, carotid or peripheral artery revascularization
- Chronic heart failure NYHA class IV
- Current hemodialysis or peritoneal dialysis or eGFR <30 mL/min/1.73 m<sup>2</sup> per CKD-EPI
- End-stage liver disease, defined as the presence of acute or chronic liver disease and recent history of one or more of the following: ascites, encephalopathy, variceal bleeding, bilirubin ≥2.0 mg/dL, albumin level ≤3.5 g/dL, prothrombin time ≥4 seconds prolonged, international normalized ratio ≥1.7 or prior liver transplant
- Known or suspected hypersensitivity to trial products or related products
- Female of child-bearing potential who is pregnant, breast-feeding or intends to become pregnant, or is not using adequate contraceptive methods as required by local law or practice
- Expected simultaneous participation in any other clinical trial of an investigational medicinal product. Participation in a clinical trial with stent(s) is allowed
- Receipt of any investigational medicinal product within 30 days before randomization. Brazil: Receipt of any investigational medicinal product within 1 year before randomization unless there is a direct benefit to the patient at the investigator's discretion
- Current or past (within the last 5 years) malignant neoplasms (except basal cell and squamous cell skin carcinoma)
- Any condition that, in the investigator's opinion, would make the patient unable to adhere to the initial trial visit schedule and procedures

## Clinical event definitions

Acute coronary syndrome	Acute coronary syndrome conditions include ST-elevation acute myocardial infarction (STEMI), non-ST elevation acute myocardial infarction (NSTEMI), and unstable angina pectoris (UAP) requiring hospitalization.
Myocardial infarction (subcategory of acute coronary syndrome)	<ul style="list-style-type: none"> <li>• The term acute myocardial infarction (AMI) should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia.</li> <li>• Under these conditions, any one of the following criteria meets the diagnosis for AMI:             <ul style="list-style-type: none"> <li>○ Detection of a rise and/or fall of cardiac biomarker values [preferably cardiac troponin (cTn)] with at least one value above the 99th percentile upper reference limit (URL) and with at least one of the following:                 <ul style="list-style-type: none"> <li>– Symptoms of ischemia.</li> <li>– New or presumed new significant ST-segment–T wave (ST–T) changes or new left bundle branch block (LBBB).</li> <li>– Development of pathological Q waves in the electrocardiogram (ECG).</li> <li>– Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.</li> <li>– Identification of an intracoronary thrombus by angiography or autopsy.</li> </ul> </li> <li>○ Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB but death occurred before cardiac biomarkers were obtained, or before cardiac biomarker values would be increased.</li> <li>○ Percutaneous coronary intervention (PCI)-related MI is arbitrarily defined by elevation of cTn values (&gt;5 x 99th percentile URL) in patients with normal baseline values (≤99th percentile URL) or a rise of cTn values &gt;20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischemia or (ii) new ischemic ECG changes or (iii) angiographic findings consistent with a procedural complication or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required.</li> <li>○ Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarker values with at least one value above the 99th percentile URL.</li> </ul> </li> <li>• Coronary artery bypass grafting (CABG)-related MI is arbitrarily defined by elevation of cardiac biomarker values (&gt;10 x 99th percentile URL) in patients with normal baseline cTn values (≤99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality</li> </ul>



	<p>The totality of the clinical, electrocardiographic, and cardiac biomarker information should be considered to determine whether or not an AMI has occurred. Specifically, timing and trends in cardiac biomarkers and electrocardiographic information require careful analysis. The adjudication of AMI should also take into account the clinical setting in which the event occurs. AMI may be adjudicated for an event that has characteristics of an AMI but which does not meet the strict definition because biomarker or electrocardiographic results are not available.</p> <p><b>Biomarker elevations</b></p> <p>For cardiac biomarkers, laboratories should report an upper reference limit (URL). If the 99th percentile of the upper reference limit (URL) from the respective laboratory performing the assay is not available, then the URL the laboratory uses to diagnose myocardial infarction (decision limit) should be used. In general, troponins are preferred and take precedence over creatine kinase (CK)-MB when both biomarkers are available. CK-MB should be used if troponins are not available, and total CK may be used in the absence of CK-MB and troponin.</p> <p>Silent myocardial infarction: Silent MI is defined by the following: Asymptomatic patients who develop new pathologic Q-wave criteria for MI detected during routine ECG follow-up, or reveal evidence of MI by cardiac imaging that cannot be directly attributed to a coronary revascularization procedure, should be termed ‘silent MI’. The diagnosis of a new silent Q-wave MI should be confirmed by a repeat ECG or by an imaging study and by focused questioning about potential interim ischemic symptoms.</p>
Acute myocardial infarction categorization	<p>Since the prognostic significance of different types of myocardial infarctions (e.g., periprocedural myocardial infarction vs. spontaneous myocardial infarction) may be different, all AMI events will be categorized by subtype as outlined below and further described in the third Universal Definition for Myocardial Infarction referenced below.</p> <ul style="list-style-type: none"> <li>• Type 1: Spontaneous MI related to ischemia due to a primary coronary event such as plaque fissuring or rupturing.</li> <li>• Type 2: MI secondary to ischemia due to imbalance between oxygen demand and supplies, e.g., coronary spasm.</li> <li>• Type 3: Sudden cardiac death with symptoms of myocardial ischemia, accompanied by new ST elevation or LBBB, or verified coronary thrombus by angiography, but death occurring before blood samples could be obtained.</li> </ul>

	<ul style="list-style-type: none"> <li>• Type 4a: MI associated with percutaneous coronary intervention (PCI).</li> <li>• Type 4b: Stent thrombosis documented by angiography or autopsy.</li> <li>• Type 4c: Thrombosis not documented but restenosis is found by angiography or autopsy with no other obvious cause.</li> <li>• Type 5: MI associated with CABG</li> </ul>
<p>Unstable angina pectoris requiring hospitalization (subcategory of acute coronary syndrome)</p>	<p>Unstable angina pectoris requiring hospitalization is defined as:</p> <ol style="list-style-type: none"> <li>1. Ischemic discomfort (angina, or symptoms thought to be equivalent) <math>\geq 10</math> minutes in duration occurring <ul style="list-style-type: none"> <li>• at rest, or</li> <li>• in an accelerating pattern with frequent episodes associated with progressively decreased exercise capacity.</li> </ul> </li> </ol> <p>AND</p> <ol style="list-style-type: none"> <li>2. Prompting an unscheduled hospitalization within 24 hours of the most recent symptoms. Hospitalization is defined as an admission to an inpatient unit or a visit to an emergency department that results in at least a 24-hour stay (or a change in calendar date if the hospital admission or discharge times are not available).</li> </ol> <p>AND</p> <ol style="list-style-type: none"> <li>3. At least one of the following: <ol style="list-style-type: none"> <li>a. New or worsening ST or T wave changes on resting ECG (in the absence of confounders, such as LBBB or LVH) transient ST elevation (duration <math>&lt;20</math> minutes).  New ST elevation at the J point in two contiguous leads with the cut-points: <math>\geq 0.1</math> mV in all leads other than leads V2–V3 where the following cut-points apply: <math>\geq 0.2</math> mV in men <math>\geq 40</math> years (<math>\geq 0.25</math> mV in men <math>&lt;40</math> years) or <math>\geq 0.15</math> mV in women.  ST depression and T-wave changes: New horizontal or down-sloping ST depression <math>\geq 0.05</math> mV in two contiguous leads and/or new T inversion <math>\geq 0.3</math> mV in two contiguous leads with prominent R wave or R/S ratio <math>&gt;1</math>.</li> <li>b. Definite evidence of inducible myocardial ischemia as demonstrated by:  an early positive exercise stress test, defined as ST elevation or <math>\geq 2</math> mm ST depression prior to 5 metabolic equivalents of tasks (METs)  OR  stress echocardiography (reversible wall motion abnormality)  OR  myocardial scintigraphy (reversible perfusion defect),  OR</li> </ol> </li> </ol>

	<p>MRI (myocardial perfusion deficit under pharmacologic stress), and believed to be responsible for the myocardial ischemic symptoms/signs.</p> <p>c. Angiographic evidence of new or worse <math>\geq 70\%</math> lesion and/or thrombus in an epicardial coronary artery that is believed to be responsible for the myocardial ischemic symptoms/signs.</p> <p>d. Need for coronary revascularization procedure (PCI or CABG) for the presumed culprit lesion(s). This criterion would be fulfilled if revascularization was undertaken during the unscheduled hospitalization, or subsequent to transfer to another institution without interceding home discharge.</p> <p>AND</p> <p>4. Negative cardiac biomarkers and no evidence of acute MI.</p>
Stroke	<p>Stroke is defined as an acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. An event will only meet the criteria for a stroke if:</p> <ul style="list-style-type: none"> <li>• Symptoms are present for more than 24 hours</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• Imaging evidence consistent with stroke is identified in a patient with neurological symptoms present for less than 24 hours</li> </ul>
Classification of stroke	<p>A. Ischemic stroke Ischemic stroke is defined as an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue. Hemorrhage may be a consequence of ischemic stroke. In this situation, the stroke is an ischemic stroke with hemorrhagic transformation and not a hemorrhagic stroke.</p> <p>B. Hemorrhagic stroke Hemorrhagic stroke is defined as an acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal, intraventricular, or subarachnoid hemorrhage. Subdural hematomas are intracranial hemorrhagic events and not strokes.</p> <p>C. Undetermined stroke Undetermined stroke is defined as an acute episode of focal or global neurological dysfunction caused by presumed brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction but with insufficient information to allow categorization as A or B.</p> <p>Stroke is documented by imaging (e.g., CT or MRI scan). Evidence obtained from autopsy can also confirm the diagnosis. Findings on lumbar puncture can also be supportive to the diagnosis.</p>
Fatal event	<p>Causes of death events will initially be identified as either “Known” or “Unknown”.</p> <p>If classified as “Unknown”, the event will be considered a CV death and no further adjudication of the event will be performed.</p>

	<p>If “Known” is selected, the Adjudicator will then be prompted to rate the likelihood that the death can be classified as a CV-related death event, by making one of the following selections for CV-related death:</p> <ol style="list-style-type: none"><li>1. Documented</li><li>2. Probable/Possible, or</li><li>3. Unlikely</li></ol> <p>If “Documented” or “Probable/Possible” is selected, the death event will be classified as CV related and the adjudicator will be asked to indicate the cause of cardiovascular death from the list below:</p> <ul style="list-style-type: none"><li>• Sudden cardiac death</li><li>• Acute MI</li><li>• Heart failure</li><li>• Cerebrovascular event</li><li>• Cardiovascular procedures</li><li>• Cardiovascular hemorrhage</li><li>• Other CV causes</li></ul> <p>If “Unlikely” is selected, the adjudicator will be asked to indicate the cause of death from the list below:</p> <ul style="list-style-type: none"><li>• Pulmonary causes</li><li>• Renal causes</li><li>• Gastrointestinal (GI) causes</li><li>• Hepatobiliary causes</li><li>• Pancreatic causes</li><li>• Infection (including sepsis)</li><li>• Non-infectious (e.g., systemic inflammatory response syndrome [SIRS])</li><li>• Hemorrhage that is neither cardiovascular bleeding or stroke</li><li>• Non-CV procedure or surgery</li><li>• Trauma</li><li>• Suicide</li><li>• Non-prescription drug reaction or overdose</li><li>• Prescription drug reaction or overdose</li><li>• Neurological (non-cardiovascular)</li><li>• Malignancy</li></ul>
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	<ul style="list-style-type: none"><li>• Other non-cardiovascular</li></ul>
Severe hypoglycemia	An episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. Plasma glucose values may not be available during an event, but neurological recovery following the return of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration.

## **Interim analysis data access management plan**

Access to the unblinded data output and results was limited to an external independent statistics group at Statistics Collaborative Inc., the interim reporting team at Novo Nordisk (which consisted of 12 employees), the independent external data monitoring committee, a small IT team and designated medical writers. The interim reporting team had no further participation in the conduct of the ongoing trial, were physically separated from all other employees and worked on a separate secured network.

The unblinded data seen by this team were restricted to the snapshot of cardiovascular, hypoglycemic and adverse events only, and baseline characteristics data collected until the interim database lock.

The following groups of individuals did not have access to the interim data: the DEVOTE Steering Committee, the Event Adjudication Committee, trial investigators; the Novo Nordisk DEVOTE operational team; or the Novo Nordisk Executive Management team.

## Rationale for the 1.3 and 1.8 thresholds

The 2008 FDA “*Guidance for Industry. Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes*” stipulates the need to establish cardiovascular safety prior to approval of a new therapy.<sup>1</sup> For a new therapy to be considered approvable, the data need to show that the upper bound of the two-sided 95% confidence interval for the hazard ratio is <1.8. If it is between 1.3 and 1.8, and the overall risk–benefit analysis supports approval, a post-marketing trial generally will be necessary to specifically confirm cardiovascular safety. If the data demonstrate that the upper bound of the two-sided 95% confidence interval for the hazard ratio is <1.3 and the overall risk–benefit analysis supports approval, a post-marketing trial is not necessary.

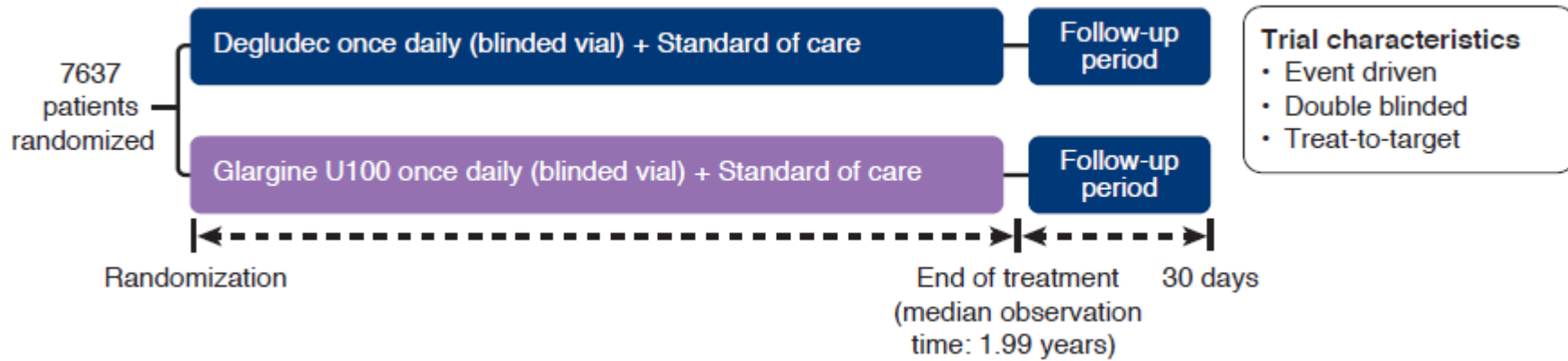
Further to the above guidance, it was discussed at the FDA Confidentiality Of Interim Results In Cardiovascular Outcome Safety Trials public hearing in 2014 that a cardiovascular trial should be designed to rule out the 1.3 margin, but the interim analysis, if conducted, should serve as the basis of determining whether or not the 1.8 margin is ruled out.<sup>2</sup>

It is based on this guidance from the FDA that the two thresholds were used for DEVOTE.

### References

1. US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). *Guidance for Industry: Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes*. December 2008. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071627.pdf>
2. U.S. Food & Drug Administration (FDA). *Confidentiality Of Interim Results In Cardiovascular Outcome Safety Trials*. Public Hearing. August 2014. <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM436369.pdf>

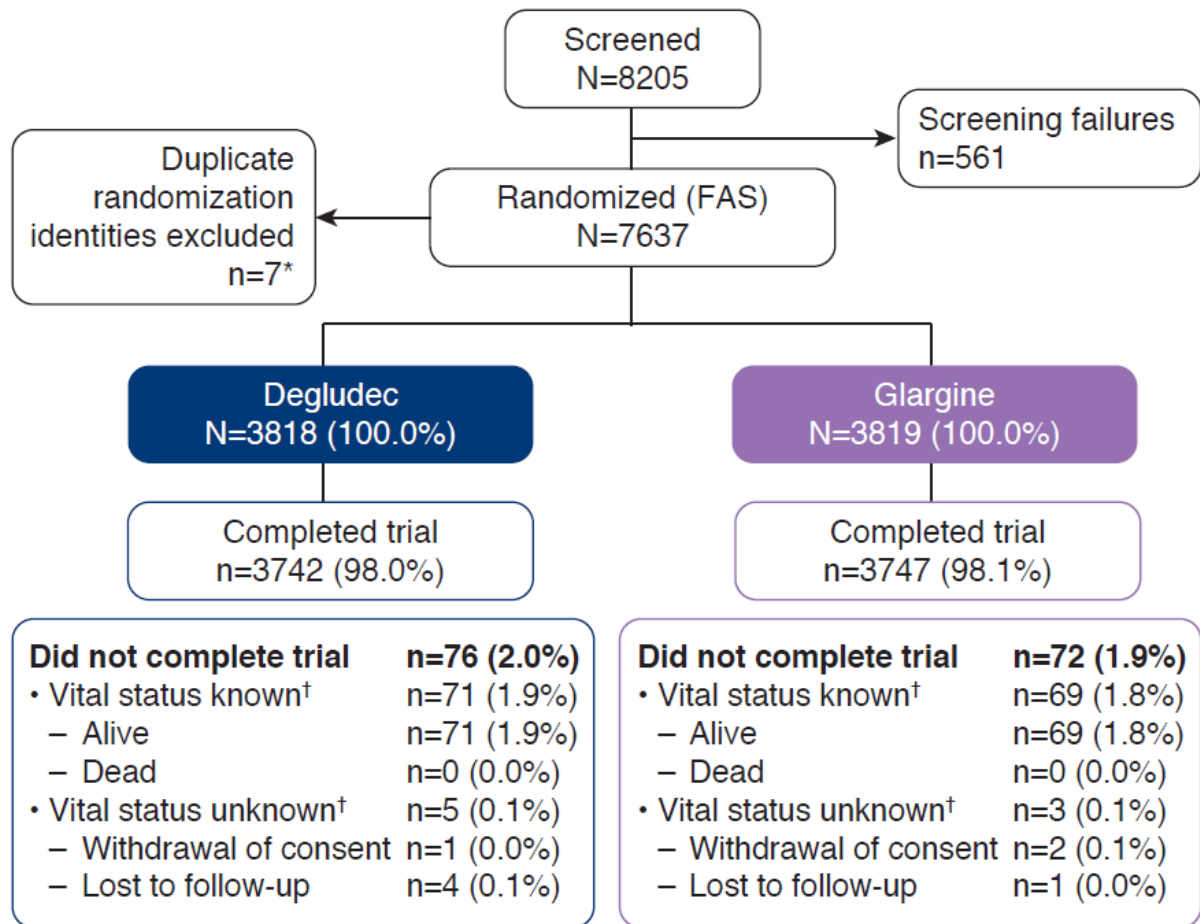
**Figure S1:** Trial design



U100, 100 units/mL.



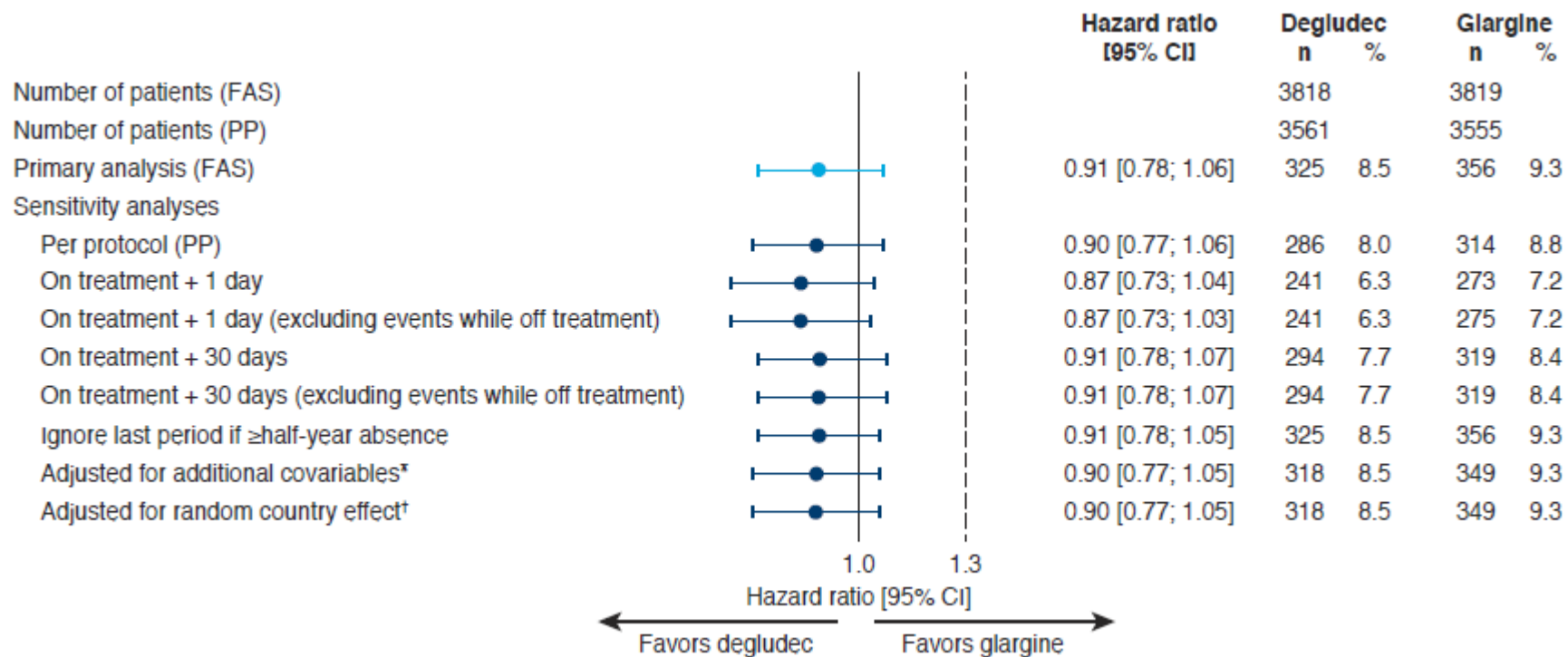
**Figure S2:** Patient disposition



Completed trial: follow-up visit completed or died during trial. Full analysis set: all randomized patients.

\*7644 patients were randomized in total. Of these, seven patients were randomized at two different sites. Data from the second site were not included in the full analysis set. †Status during trial closure: from the first patient's follow-up visit (29 Jun 2016) to the actual last patient/last visit (16 Oct 2016). FAS, full analysis set.

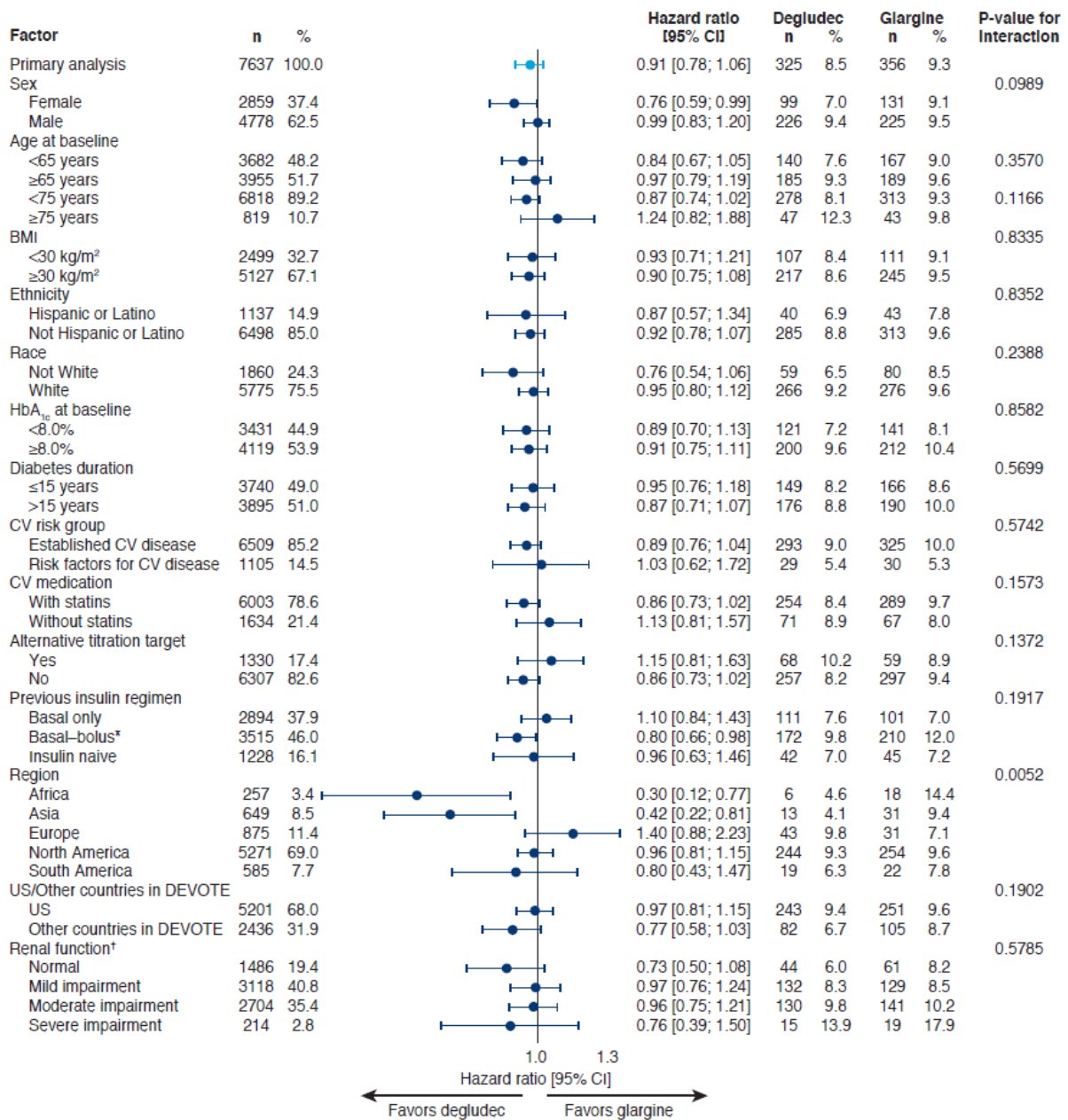
**Figure S3:** Major adverse cardiovascular event sensitivity analyses



\*Fixed-effect covariables include: investigational medicinal product, sex, region, baseline age, smoking status at baseline, diabetes duration at baseline, cardiovascular risk, insulin-naïve at baseline and renal function eGFR at baseline; †Includes country plus \*; Ignore last period if ≥half-year absence: in case of no patient-site contact for a six month period prior to follow-up visit the patient is censored at last contact prior to follow-up.

CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; FAS, full analysis set; n, number of patients; PP, per protocol; %, proportion of patients.

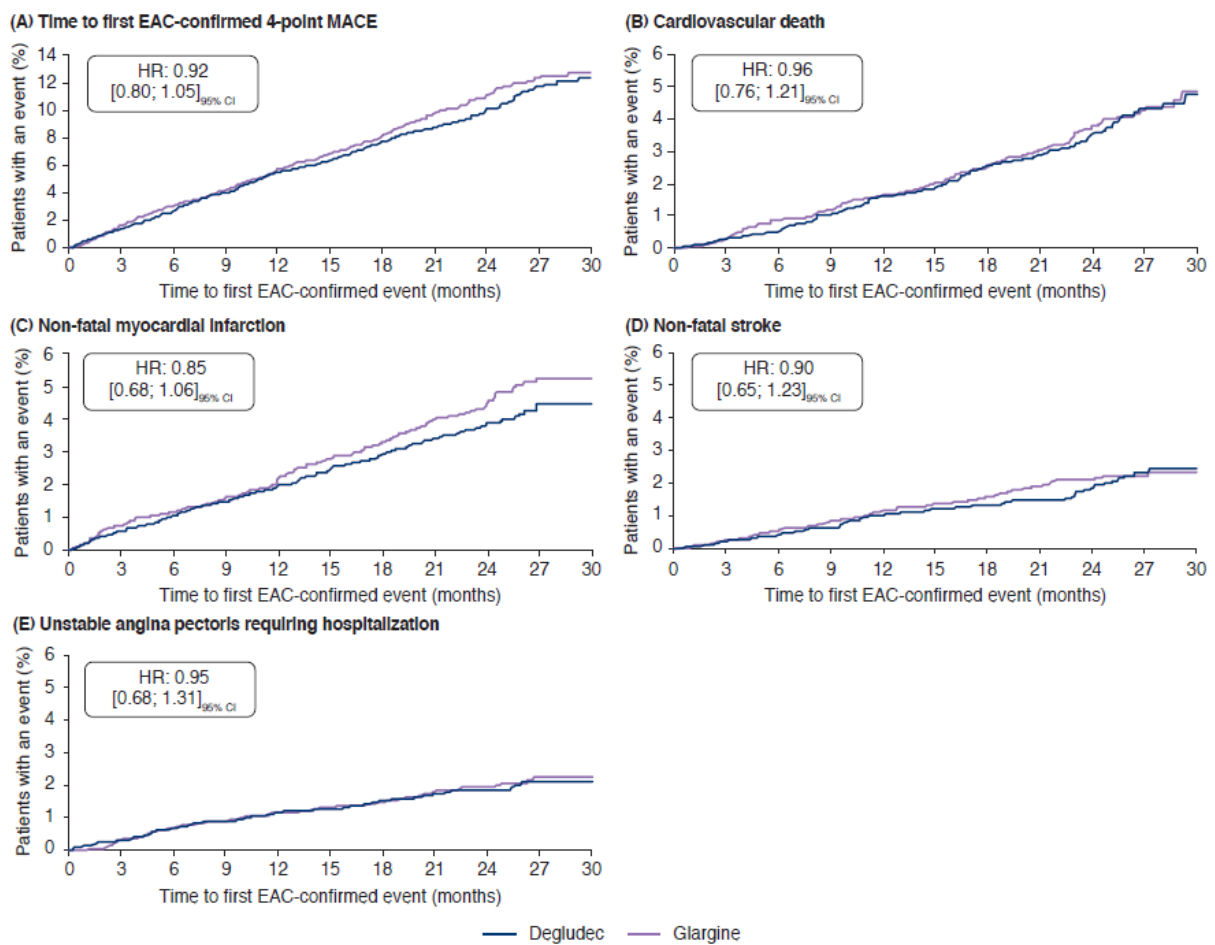
**Figure S4: Major adverse cardiovascular events subgroup analyses**



\*Includes basal-bolus, bolus only and premix; †As per CKD-EPI.

BMI, body mass index; CI, confidence interval; CKD-EPI, chronic kidney disease epidemiology collaboration; CV, cardiovascular; n, number of patients; US, United States; %, proportion of patients.

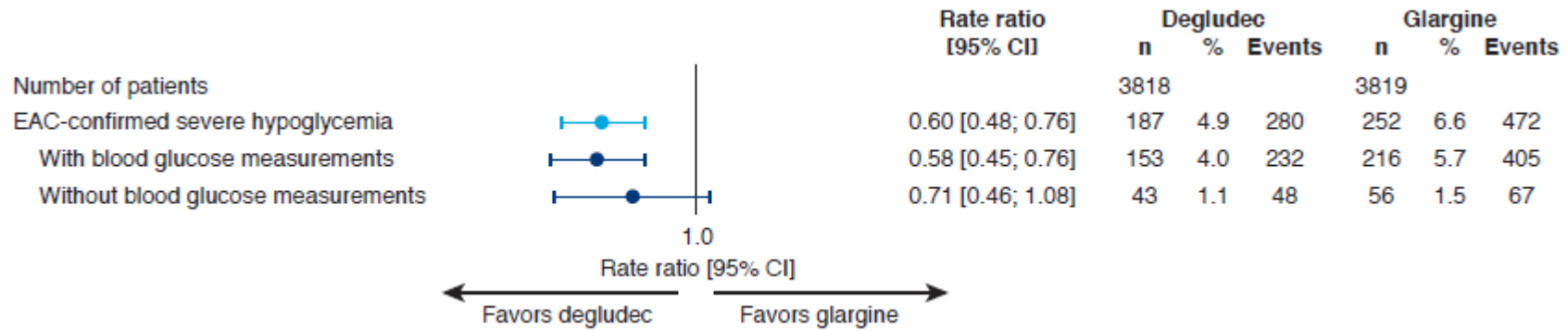
**Figure S5:** Time to first Event Adjudication Committee-confirmed 4-point major adverse cardiovascular event and individual components



Full analysis set (all randomized patients); Kaplan–Meier plots of time to EAC-confirmed cardiovascular events. Cox regression analysis accounting for treatment. Analysis includes events between randomization date and follow-up date. Patients without an event are censored at the time of last contact (phone or visit).

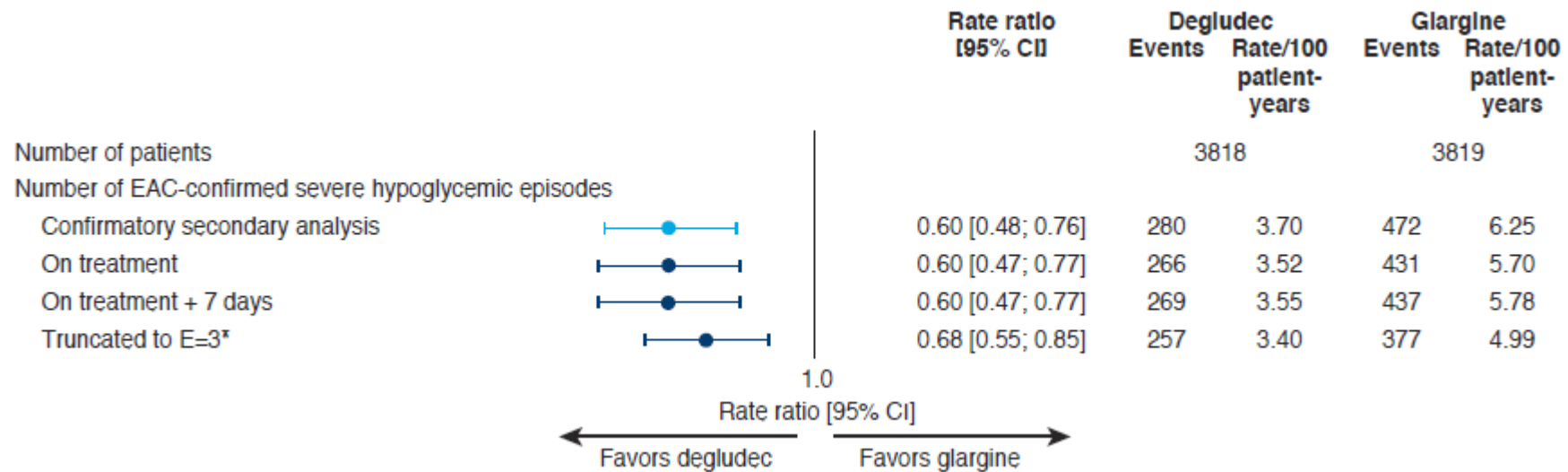
CI, confidence interval; EAC, Event Adjudication Committee; HR, hazard ratio; MACE, major adverse cardiovascular event.

**Figure S6:** Severe hypoglycemic events with and without blood glucose measurements



CI, confidence interval; EAC, Event Adjudication Committee; n, number of patients; %, proportion of patients.

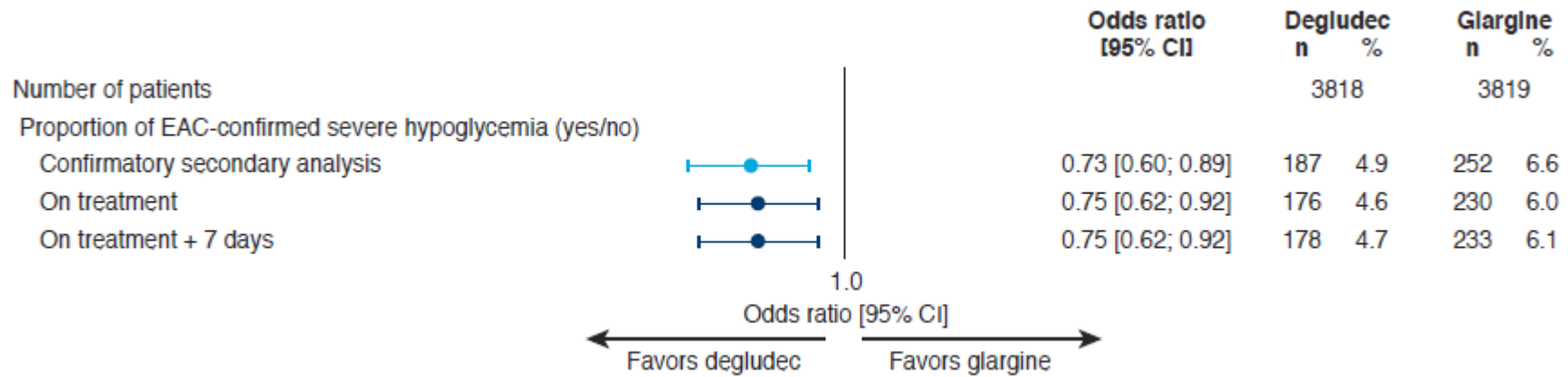
**Figure S7:** Severe hypoglycemia on-treatment sensitivity analyses



\*>3 episodes truncated to 3 episodes. Full analysis set (all randomized patients); negative binomial regression model with log-link function and the logarithm of the duration of the observation time (primary analysis) or exposure time (sensitivity analyses) as offset.

CI, confidence interval; EAC, Event Adjudication Committee.

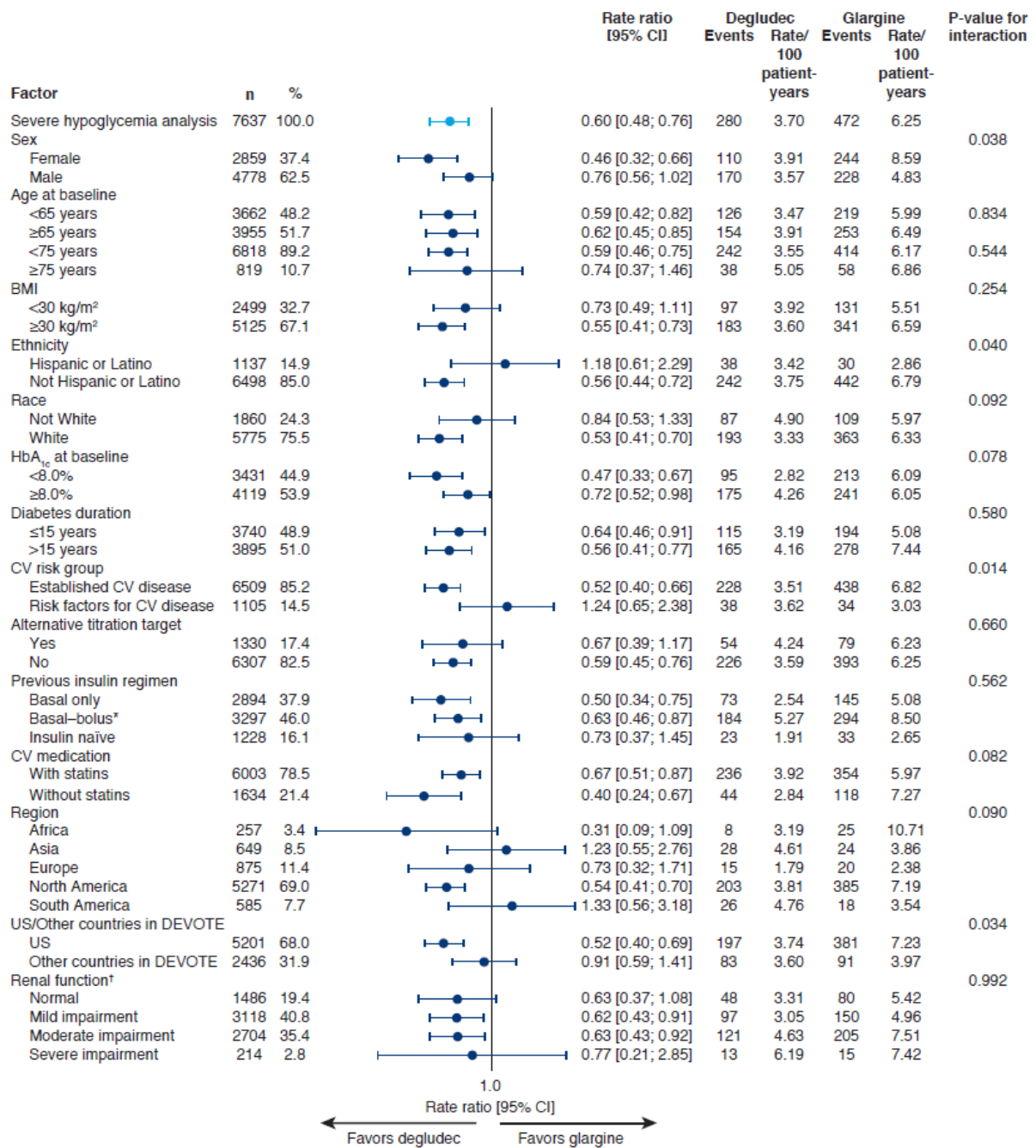
**Figure S8:** Incidence of severe hypoglycemia on-treatment sensitivity analyses



Full analysis set (all randomized patients); logistic regression model with treatment (degludec vs. glargine) as a fixed factor.

CI, confidence interval; EAC, Event Adjudication Committee; n, number of patients; %, proportion of patients.

**Figure S9:** Incidence of severe hypoglycemia subgroup analyses

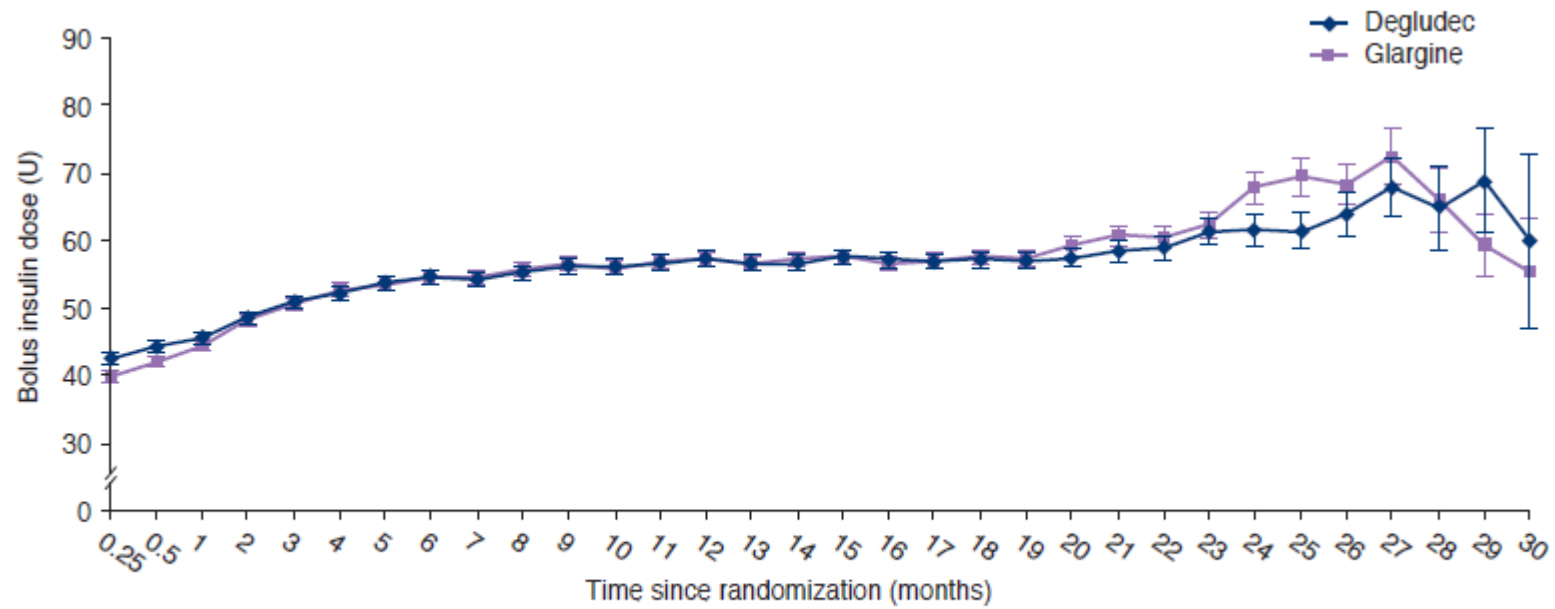


\*Includes basal-bolus, bolus only and premix; †As per CKD-EPI.

BMI, body mass index; CI, confidence interval; CKD-EPI, chronic kidney disease epidemiology collaboration; CV, cardiovascular; n, number of patients; US, United States; %, proportion of patients.



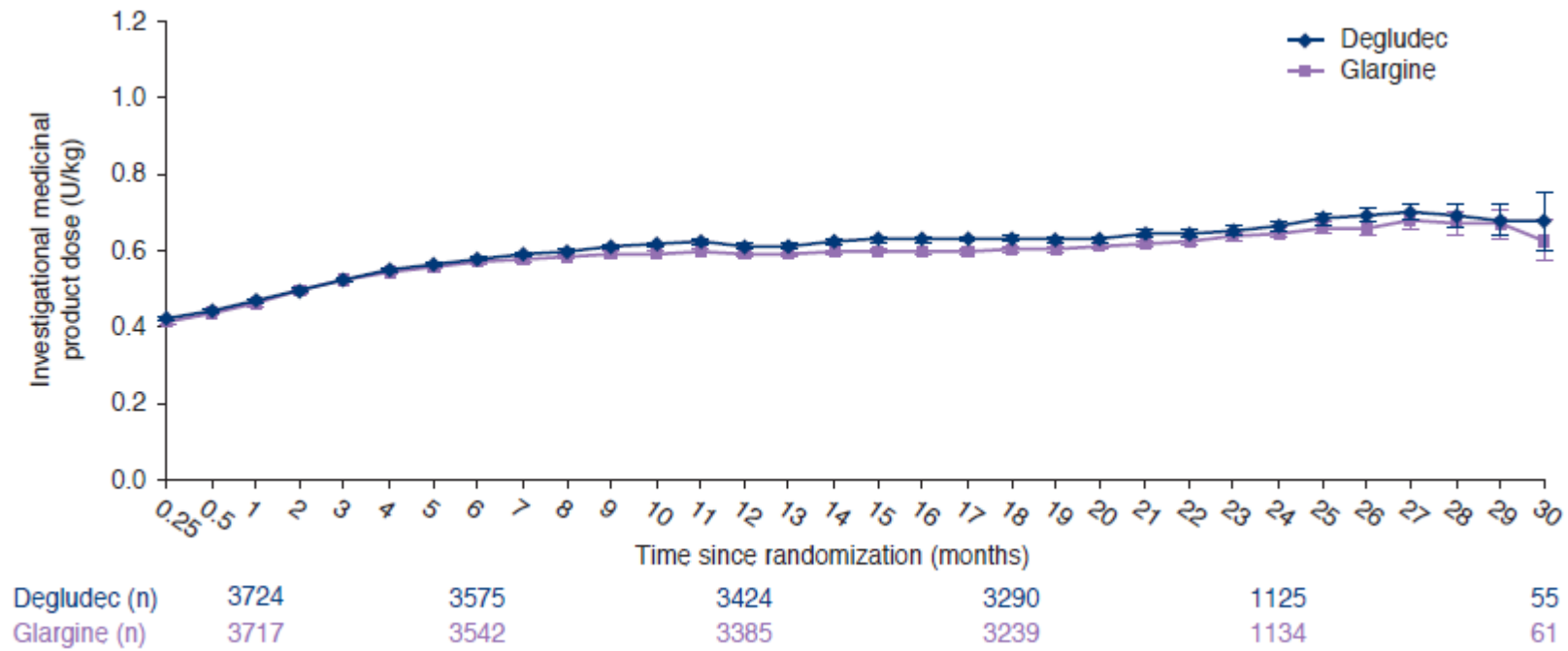
**Figure S10:** Daily bolus insulin dose over time (units)



Degludec (n)	1785	1858	1856	1859	645	29
Glargine (n)	1804	1890	1919	1895	658	33

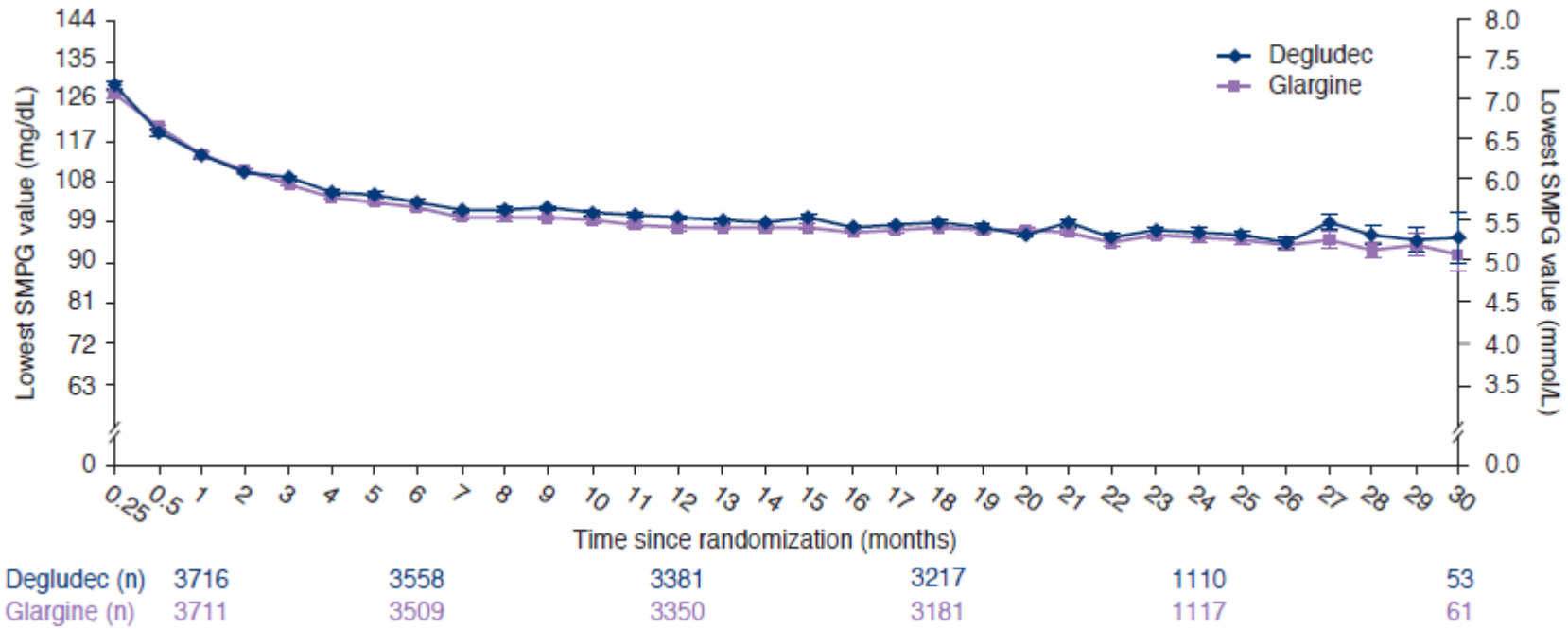
Full analysis set (all randomized patients). n, number of patients.

**Figure S11:** Daily basal insulin dose over time (units/kg)



Full analysis set (all randomized patients). n, number of patients.

**Figure S12:** Pre-breakfast self-measured plasma glucose over time



Full analysis set (all randomized patients). n, number of patients; SMPG, self-measured plasma glucose.

**Table S1:** Titration algorithms

<b>Lowest of three pre-breakfast SMPG values</b>		<b>Basal insulin adjustment</b>
<b>mg/dL</b>	<b>mmol/L</b>	<b>Units</b>
<71	<4.0	-2
71-90	4.0-5.0	0
91-126	5.1-7.0	+2
>126	>7.0	+4
<b>Lowest of three pre-prandial or bedtime SMPG values</b>		<b>Bolus insulin adjustment</b>
<b>mg/dL</b>	<b>mmol/L</b>	<b>Units</b>
<71	<4.0	-2
71-126	4.0-7.0	0
>126	>7.0	+2

SMPG, self-measured plasma glucose.

**Table S2:** Baseline characteristics

	<b>Degludec n=3818</b>	<b>Glargine n=3819</b>
Age (years)	64.9 ± 7.3	65.0 ± 7.5
Patients aged ≥75 years	381 (10.0)	438 (11.5)
Men	2396 (62.8)	2382 (62.4)
Ethnicity		
Hispanic or Latino	582 (15.2)	555 (14.5)
Race		
White	2903 (76.0)	2872 (75.2)
Black or African American	401 (10.5)	431 (11.3)
Asian	391 (10.2)	385 (10.1)
Other	123 (3.2)	131 (3.4)
Region		
North America	2625 (68.8)	2646 (69.3)
Europe	438 (11.5)	437 (11.4)
South America	304 (8.0)	281 (7.4)
India	168 (4.4)	189 (4.9)
Asia excluding India	151 (4.0)	141 (3.7)
Africa	132 (3.5)	125 (3.3)
Diabetes duration (years)	16.6 ± 8.8	16.2 ± 8.9
Smoking status		
Current	431 (11.3)	421 (11.0)
Previous	1696 (44.4)	1657 (43.4)
Never	1690 (44.3)	1740 (45.6)

Renal status		
Normal renal function (eGFR $\geq$ 90 mL/min/1.73m <sup>2</sup> per CKD-EPI)	740 (19.4)	746 (19.5)
Mild renal impairment (eGFR 60–89 mL/min/1.73m <sup>2</sup> per CKD-EPI)	1596 (41.8)	1522 (39.9)
Moderate renal impairment (eGFR 30–59 mL/min/1.73m <sup>2</sup> per CKD-EPI)	1321 (34.6)	1383 (36.2)
Severe renal impairment (eGFR $<$ 30 mL/min/1.73m <sup>2</sup> per CKD-EPI)	108 (2.8)	106 (2.8)
Trial eligibility stratum		
Age $\geq$ 50 years and established cardiovascular or chronic kidney disease†	3265 (85.5)	3244 (84.9)
Established chronic kidney disease only	525 (16.1)	510 (15.7)
Established cardiovascular disease only	2068 (63.3)	2051 (63.2)
Established cardiovascular AND chronic kidney disease	672 (20.6)	683 (21.1)
Age $\geq$ 60 years and risk factors for cardiovascular disease‡	538 (14.1)	567 (14.8)
Alternative titration target		
Alternative titration target at baseline	665 (17.4)	665 (17.4)
Switched to alternative titration target after baseline	368 (9.6)	337 (8.8)
Antihyperglycemic treatment (excluding		

insulins)		
Metformin	2294 (60.1)	2270 (59.4)
Sulfonylurea	1118 (29.3)	1111 (29.1)
Alpha-glucosidase inhibitors	63 (1.7)	70 (1.8)
Thiazolidinedione	145 (3.8)	123 (3.2)
Dipeptidyl peptidase-4 inhibitors	463 (12.1)	480 (12.6)
Glucagon-like peptide-1 receptor agonists	300 (7.9)	304 (8.0)
Sodium-dependent glucose transporter-2 inhibitors	82 (2.1)	86 (2.3)
Others	50 (1.3)	68 (1.8)
Insulins		
Not on insulin at baseline	604 (15.8)	624 (16.3)
Basal insulin only	1454 (38.1)	1440 (37.7)
Basal–bolus insulin (including bolus-only and pre-mix)	1760 (46.1)	1755 (46.0)
Antihypertensive therapy*		
Beta-blockers	2210 (57.9)	2190 (57.3)
Calcium channel blockers	1214 (31.8)	1244 (32.6)
Angiotensin-converting enzyme inhibitors	1831 (48.0)	1796 (47.0)
Angiotensin receptor blockers	1289 (33.8)	1266 (33.2)
Others	402 (10.5)	375 (9.8)
Diuretics*		
Loop diuretics	856 (22.4)	882 (23.1)
Thiazides	887 (23.2)	855 (22.4)
Others	537 (14.1)	534 (14.0)

Lipid-modifying medications*		
Statins	3020 (79.1)	2982 (78.1)
Fibrates	425 (11.1)	426 (11.2)
Ezetimibe	175 (4.6)	171 (4.5)
Others	131 (3.4)	137 (3.6)
Platelet aggregation inhibitors*		
Acetylsalicylic acid	2501 (65.5)	2491 (65.2)
Others	910 (23.8)	887 (23.2)
Anti-thrombotic medication*	308 (8.1)	289 (7.6)
Body weight (lb)	211.8 ± 50.5	211.9 ± 50.4
Body weight [kg]	[96.1 ± 22.9]	[96.1 ± 22.9]
Body mass index (kg/m <sup>2</sup> )	33.6 ± 6.8	33.6 ± 6.8
Blood pressure (systolic/diastolic, mmHg)	135.4 ± 18.0/ 76.1 ± 10.3	135.7 ± 18.1/ 76.2 ± 10.4
Pulse (beats/minute)	72.9 ± 11.4	73.3 ± 11.3
Glycated hemoglobin (%)	8.4 ± 1.6	8.4 ± 1.7
[mmol/mol]	[68.7 ± 17.8]	[68.5 ± 18.3]
Fasting plasma glucose (mg/dL)	169.8 ± 70.3	173.5 ± 70.7
[mmol/L]	[9.4 ± 3.9]	[9.6 ± 3.9]
eGFR (mL/min/1.73m <sup>2</sup> ) based on CKD-EPI	68.1 ± 21.5	67.8 ± 21.6
Total cholesterol (mg/dL)	164.0 ± 47.2	166.2 ± 47.0
[mmol/L]	[4.3 ± 1.2]	[4.3 ± 1.2]
Low-density lipoprotein cholesterol (mg/dL)	84.8 ± 36.5	86.1 ± 36.5
[mmol/L]	[2.2 ± 0.9]	[2.2 ± 1.0]
High-density lipoprotein cholesterol (mg/dL)	44.2 ± 12.9	44.6 ± 12.8



[mmol/L]	[1.2 ± 0.3]	[1.2 ± 0.3]
Triglycerides (mg/dL)	183.0 ± 150.6	187.2 ± 169.3
[mmol/L]	[2.1 ± 1.7]	[2.1 ± 1.9]

Full analysis set (all randomized patients); Data listed are number (proportion [%]) or mean ± standard deviation. Percentage refers to the proportion of patients on degludec or glargine treatment.

\*Nine patients have missing initiation drug date; they are assumed to be on treatment at baseline.

†Patients with missing age information or age <50 years, but who fulfilled at least one of the inclusion criteria for established cardiovascular/chronic kidney disease were included.

‡Patients with missing age information and who only fulfilled the inclusion criteria for cardiovascular disease risk factors were not included.

CKD-EPI, chronic kidney disease epidemiology collaboration formula; eGFR, estimated glomerular filtration rate.

**Table S3:** Concomitant antihyperglycemic and cardiovascular medications started after baseline and prevalent use at end of study

	After baseline				At end of study			
	Degludec		Glargine		Degludec		Glargine	
	n	%	n	%	n	%	n	%
<b>Antihyperglycemic medications</b>								
Metformin	117	3.1	115	3.0	2173	56.9	2155	56.4
Sulfonylureas	84	2.2	82	2.1	914	23.9	934	24.5
Alpha-glucosidase inhibitors	25	0.7	22	0.6	60	1.6	62	1.6
Thiazolidinediones	50	1.3	40	1.0	137	3.6	124	3.2
Dipeptidyl peptidase-4 inhibitors	122	3.2	136	3.6	432	11.3	466	12.2
Glucagon-like peptide-1 receptor agonists	151	4.0	118	3.1	322	8.4	306	8.0
Sodium-dependent glucose co-transporter-2 inhibitors	163	4.3	153	4.0	181	4.7	177	4.6
Others	28	0.7	19	0.5	53	1.4	59	1.5
<b>Cardiovascular medications</b>								
Antihypertensive therapies	731	19.1	734	19.2	3546	92.9	3543	92.8
Beta-blockers	205	5.4	205	5.4	2275	59.6	2263	59.3
Calcium channel blockers	266	7.0	273	7.1	1307	34.2	1305	34.2
Angiotensin-converting enzyme inhibitors	135	3.5	151	4.0	1738	45.5	1706	44.7
Angiotensin receptor blockers	159	4.2	168	4.4	1322	34.6	1307	34.2
Others	181	4.7	161	4.2	478	12.5	437	11.4
Diuretics	560	14.7	505	13.2	2013	52.7	2023	53.0
Loop diuretics	292	7.6	287	7.5	1011	26.5	1031	27.0
Thiazides	155	4.1	131	3.4	879	23.0	841	22.0
Others	242	6.3	191	5.0	617	16.2	589	15.4
Lipid-lowering drugs	284	7.4	289	7.6	3175	83.2	3141	82.2
Statins	181	4.7	181	4.7	3052	79.9	3008	78.8
Fibrates	56	1.5	57	1.5	417	10.9	422	11.1
Ezetimibe	33	0.9	34	0.9	174	4.6	187	4.9
Others	30	0.8	36	0.9	125	3.3	124	3.2
Platelet aggregation inhibitors	351	9.2	334	8.7	2817	73.8	2753	72.1
Acetylsalicylic acid	163	4.3	149	3.9	2554	66.9	2490	65.2
Others	238	6.2	227	5.9	987	25.9	948	24.8
Anti-thrombotic medications	330	8.6	355	9.3	381	10.0	362	9.5

Full analysis set (all randomized patients). n, number of patients; %, proportion of patients.

**Table S4:** Cardiovascular risk factors

<b>Change from baseline to month 24</b>	<b>Degludec</b>	<b>Glargine</b>
Body weight, lb [kg]	4.9 [2.2]	4.2 [1.9]
Body mass index, kg/m <sup>2</sup>	0.8	0.7
Systolic/diastolic blood pressure, mmHg	-1.1/-0.8	-0.0/-0.6
Pulse, beats/minute	-0.8	-0.7
Estimated glomerular filtration rate, ml/min/1.73m <sup>2</sup>	-2.4	-2.6
Total cholesterol, mg/dL [mmol/L]	-3.86 [-0.10]	-3.66 [-0.09]
High-density lipoprotein cholesterol, mg/dL [mmol/L]	-1.23 [-0.03]	-0.73 [-0.02]
Low-density lipoprotein cholesterol, mg/dL [mmol/L]	-0.98 [-0.03]	-1.09 [-0.03]
Triglycerides, mg/dL [mmol/L]	-9.22 [-0.10]	-12.21 [-0.14]

Full analysis set (all randomized patients). Values are mean.

**Table S5:** Malignant neoplasms by primary organ site

	Degludec		Glargine	
	n	%	n	%
Number of patients	3818		3819	
PYO	7568		7558	
Number of patients with events	93	2.4	99	2.6
Gastrointestinal other than colorectal	16	0.4	16	0.4
Genitourinary other than prostate	13	0.3	13	0.3
Lung and pleura	13	0.3	11	0.3
Colorectal	7	0.2	12	0.3
Prostate	11	0.3	10	0.3
Breast	9	0.2	10	0.3
Hematological malignancies	9	0.2	7	0.2
Gynecologic	8	0.2	5	0.1
Skin	5	0.1	6	0.2
Head and neck	4	0.1	3	0.1
Musculoskeletal	0	0.0	2	0.1
Unknown	0	0.0	4	0.1

Full analysis set (all randomized patients); neoplasms externally classified. Primary organ site was assessed by the external classifiers.

n, number of patients with events; PYO, patient-years of observation; %, proportion of patients with events.

**Table S6:** Serious adverse events by system organ class with frequencies  $\geq 1\%$

	Degludec				Glargine			
	n	%	E	R	n	%	E	R
All events	1473	38.6	3341	44.15	1517	39.7	3745	49.55
Cardiac disorders	579	15.2	873	11.54	616	16.1	972	12.86
Infections and infestations	367	9.6	501	6.62	394	10.3	549	7.26
Nervous system disorders	233	6.1	282	3.73	269	7.0	345	4.56
Gastrointestinal disorders	150	3.9	178	2.35	148	3.9	186	2.46
Metabolism and nutrition disorders	149	3.9	183	2.42	137	3.6	183	2.42
Renal and urinary disorders	144	3.8	171	2.26	172	4.5	210	2.78
Respiratory, thoracic and mediastinal disorders	148	3.9	194	2.56	172	4.5	241	3.19
Injury, poisoning and procedural complications	130	3.4	165	2.18	132	3.5	170	2.25
General disorders and administration-site conditions	122	3.2	130	1.72	142	3.7	158	2.09
Musculoskeletal and connective tissue disorders	118	3.1	134	1.77	118	3.1	134	1.77
Neoplasms benign, malignant and unspecified*	109	2.9	116	1.53	109	2.9	119	1.57
Hepatobiliary disorders	38	1.0	39	0.52	32	0.8	38	0.50
Psychiatric disorders	34	0.9	42	0.56	38	1.0	46	0.61
Blood and lymphatic system disorders	29	0.8	31	0.41	57	1.5	68	0.90

Full analysis set (all randomized patients). \*Including cysts and polyps.

E, number of events; n, number of patients with events; R, rate of events per 100 patient-years of observation; %, proportion of patients with events.

**Table S7:** Serious adverse events by preferred term with frequencies  $\geq 1\%$

	Degludec				Glargine			
	n	%	E	R	n	%	E	R
Number of patients	3818				3819			
PYO	7568				7558			
Number of patients with events	1473	38.6	3341	44.15	1517	39.7	3745	49.55
Atrial fibrillation	47	1.2	55	0.73	56	1.5	75	0.99
Acute myocardial infarction	98	2.6	111	1.47	115	3.0	123	1.63
Angina pectoris	36	0.9	37	0.49	48	1.3	53	0.70
Angina unstable	87	2.3	94	1.24	79	2.1	93	1.23
Coronary artery disease	80	2.1	85	1.12	89	2.3	91	1.20
Myocardial infarction	48	1.3	51	0.67	66	1.7	68	0.90
Cardiac failure congestive	134	3.5	177	2.34	143	3.7	206	2.73
Non-cardiac chest pain	47	1.2	48	0.63	54	1.4	63	0.83
Cellulitis	52	1.4	64	0.85	61	1.6	72	0.95
Pneumonia	90	2.4	99	1.31	90	2.4	102	1.35
Fall	54	1.4	57	0.75	55	1.4	59	0.78
Hypoglycemia	64	1.7	77	1.02	49	1.3	66	0.87
Ischemic stroke	43	1.1	44	0.58	45	1.2	50	0.66
Transient ischemic attack	28	0.7	29	0.38	42	1.1	44	0.58
Acute kidney injury	70	1.8	79	1.04	95	2.5	110	1.46
Chronic obstructive pulmonary disease	42	1.1	54	0.71	56	1.5	70	0.93

Full analysis set (all randomized patients); six and one of the reported hypoglycemic serious adverse events for degludec and glargine, respectively, were not categorized as severe hypoglycemia by the Event Adjudication Committee.

E, number of events; n, number of patients with events; PYO, patient-years of observation; R, rate of events per 100 patient-years of observation; %, proportion of patients with events.

**Table S8:** Critical symptoms of Event Adjudication Committee-confirmed severe hypoglycemic episodes by serious adverse event and preferred term

	Degludec				Glargine			
	n	%	E	R	n	%	E	R
Number of patients	3818				3819			
<b>All EAC-confirmed severe hypoglycemia</b>	187	4.9	280	3.70	252	6.6	472	6.25
Unconscious or in coma	54	1.4	60	0.79	63	1.6	75	0.99
Seizure	9	0.2	11	0.15	10	0.3	11	0.15
<b>Non-SAE</b>								
Unconscious or in coma	21	0.6	22	0.29	26	0.7	30	0.40
Seizure	2	0.1	2	0.03	4	0.1	4	0.05
<b>SAE (any PT)</b>								
Unconscious or in coma	35	0.9	38	0.50	40	1.0	45	0.60
Seizure	7	0.2	9	0.12	7	0.2	7	0.09
<b>SAE of 'hypoglycemia' (PT)</b>								
Unconscious or in coma	9	0.2	9	0.12	13	0.3	14	0.19
Seizure	0	0.0	0	0.00	3	0.1	3	0.04

Of the 752 EAC-confirmed severe hypoglycemic episodes, 136 were reported as a serious adverse event with the preferred term hypoglycemia: 71 events (60 patients) in the degludec group and 65 events (49 patients) in the glargine group. Based on hypoglycemic symptoms, as assessed by the EAC, including the more critical symptoms of unconsciousness/coma and seizure, this subset of events did not differ between the two groups, nor from all the EAC-confirmed severe hypoglycemic episodes.

E, number of events; EAC, Event Adjudication Committee; n, number of patients with events; PT, preferred term; R, rate of events per 100 patient-years of exposure; SAE, serious adverse event; %, proportion of patients with events.