

## 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
- Anti-diabetic drug naïve or treated with one or more oral anti-diabetic drugs or treated with human NPH insulin or long-acting insulin analogue or premixed insulin, alone or in combination with OAD(s)
- Glycated hemoglobin  $\geq 7.0\%$
- Prior cardiovascular disease cohort: age  $\geq 50$  and  $\geq 1$  of the following criteria:
  - Prior MI
  - Prior stroke or TIA
  - Prior coronary, carotid or peripheral arterial revascularization
  - $>50\%$  stenosis of coronary, carotid, or lower extremity arteries
  - History of symptomatic CHD documented by positive exercise stress test or any cardiac imaging or unstable angina with ECG changes
  - Asymptomatic cardiac ischemia documented by positive nuclear imaging test, exercise test or dobutamine stress echo
  - Chronic heart failure NYHA class II-III
  - Chronic renal failure:
    - eGFR  $<60$  mL/min/ $1.73\text{m}^2$  (Modification of Diet in Renal Disease formula)
    - eGFR  $<60$  mL/min (Cockcroft-Gault formula)
- No Prior cardiovascular disease group: Age  $\geq 60$  y and  $\geq 1$  of the following criteria:
  - Microalbuminuria or proteinuria
  - Hypertension and left ventricular hypertrophy by ECG or imaging
  - Left ventricular systolic or diastolic dysfunction by imaging
  - Ankle-brachial index  $<0.9$

### **Exclusion criteria**

- Type 1 diabetes
- Calcitonin  $\geq 50$  ng/L
- Use of a GLP-1 receptor agonist (exenatide, liraglutide or other) or pramlintide or any DPP-4 inhibitor within the 3 months prior to screening
- Use of insulin other than human NPH insulin or long-acting insulin analogue or premixed insulin within 3 months prior to screening. Short-term use of other insulin during this period in connection with intercurrent illness is allowed, at Investigator's discretion
- Acute decompensation of glycemic control
- Acute coronary or cerebrovascular event in the previous 14 days
- Currently planned coronary, carotid, or peripheral artery revascularization
- Chronic heart failure (NYHA class IV)
- Current continuous renal replacement therapy
- End-stage liver disease
- History of solid organ transplant or awaiting solid organ transplant
- Malignant neoplasm
- Family or personal history of multiple endocrine neoplasia type 2 or familial medullary thyroid carcinoma
- Personal history of non-familial medullary thyroid carcinoma



## Clinical event definitions.

Acute Coronary Syndrome	<p>Acute Coronary Syndrome (ACS) conditions range from unstable angina pectoris (UAP) to non-ST elevation myocardial infarction (MI) (NSTEMI— subendocardial or nontransmural) and ST elevation MI (STEMI—transmural).</p> <p>Criteria for STEMI: New ST segment elevation is present in 2 or more contiguous leads on the 12-lead ECG.</p> <p>Criteria for NSTEMI: ST segment elevation is absent in 2 or more contiguous leads on the 12-lead ECG.</p> <p>In patients with abnormal biomarkers, it is recognized that lesser ECG abnormalities may represent an ischemic response and may be accepted under the category of abnormal ECG findings.</p>
Acute Myocardial Infarction (Subcategory of ACS)	<p>The term “MI” should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. MI may be adjudicated for an event that has characteristics of a MI but which does not meet the strict definition because biomarker or electrocardiographic results are not available.</p> <p>MI is diagnosed based on any of the following criteria, based on the redefinitions suggested by the ESC (European Society of Cardiology)/ACCF (American College of Cardiology Foundation)/AHA (American Heart Association)/WHF (World Heart Federation) task force.</p> <p>Under these conditions, any one of the following criteria meets the diagnosis for AMI:</p> <p>Spontaneous MI: Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least 1 value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least 1 of the following:</p> <p>Symptoms of ischemia</p> <p>ECG changes indicative of new ischemia (new ST-T changes or new</p>

	<p>left bundle branch block [LBBB])</p> <p>Development of pathological Q waves in the ECG</p> <p>Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality</p> <p>CK-MB and troponin are preferred, but CK may be used in the absence of CKMB and troponin.</p> <p>Sudden, Unexpected Cardiac Death: Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation, or new LBBB, and/or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.</p> <p>Percutaneous Coronary Intervention-Related Myocardial Infarction: For percutaneous coronary interventions (PCI) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 3x 99th percentile URL have been designated as defining PCI-related MI. A subtype related to a documented stent thrombosis is recognized. If the cardiac biomarker is elevated prior to PCI, a <math>\geq 20\%</math> increase of the value in the second cardiac biomarker sample within 24 hours of the PCI and documentation that cardiac biomarker values were decreasing (two samples at least 6 hours apart) prior to the suspected recurrent MI is also consistent with PCI-related myocardial infarction. Symptoms of cardiac ischemia are not required.</p> <p>Coronary Artery Bypass Grafting-Related Myocardial Infarction: For coronary artery bypass grafting (CABG) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 5 <math>\times</math> 99th percentile URL plus either new pathological Q waves or new LBBB, or angiographically</p>
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	<p>documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related MI. If the cardiac biomarker is elevated prior to CABG, a <math>\geq 20\%</math> increase of the value in the second cardiac biomarker sample within 72 hours of CABG and documentation that cardiac biomarker values were decreasing (two samples at least 6 hours apart) prior to the suspected recurrent MI plus either new pathological Q waves in at least 2 contiguous leads on the electrocardiogram or new LBBB, angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium is consistent with a periprocedural myocardial infarction after CABG. Symptoms of cardiac ischemia are not required.</p> <p>Silent Myocardial Infarction: Silent MI is defined by the following:</p> <ol style="list-style-type: none"> <li>1. No evidence of acute myocardial infarction</li> </ol> <p>AND</p> <ol style="list-style-type: none"> <li>2. Any one of the following criteria:</li> </ol> <p>New pathological Q-waves. A confirmatory ECG is recommended if there have been no clinical symptoms or history of myocardial infarction.</p> <p>Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a nonischemic cause.</p> <p>Autopsy evidence of a healed or healing MI.</p>
Clinical Classification of Different Types of MI	<p>For EAC adjudication the following classifications of MI will be identified. In addition to classification, the EAC Adjudicators will identify ranges of URL values.</p> <p>Type 1: Spontaneous MI related to ischemia due to a primary coronary event such as plaque fissuring or rupturing.</p> <p>Type 2: MI secondary to ischemia due to imbalance between oxygen demand and supplies, eg. coronary spasm.</p> <p>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.</p> <p>Type 4a: MI associated with PCI; 4b: stent thrombosis documented by angiography or autopsy</p>

	Type 5: MI associated with CABG.
Unstable Angina Pectoris Requiring Hospitalization (Subcategory of ACS)	<p>UAP is defined as cardiac ischemic events that do not fulfill the criteria of acute MI (NSTEMI or STEMI). If neither of these conditions is present by the criteria above in the MI sections of this document, then UAP may be present. The symptoms in UAP are often of shorter duration and/or are relapsing and represent a significant worsening of the patient's baseline symptoms to an extent as being the primary cause of unplanned hospitalization. For UAP to be present, NSTEMI and STEMI cannot be present.</p> <p>Severe recurrent ischemia (UAP) is defined as ischemic discomfort or equivalent meeting the following criteria in the absence of MI criteria:</p> <ol style="list-style-type: none"> <li>1. No elevation in cardiac biomarkers (cardiac biomarkers are negative for myocardial necrosis)</li> </ol> <p>AND</p> <ol style="list-style-type: none"> <li>2. Clinical presentation lasting at least 10 minutes at rest, or repeated episodes at rest lasting <math>\geq 5</math> minutes, or an accelerating pattern of ischemic discomfort (episodes that are more frequent, severe, longer in duration, and precipitated by minimal exertion), considered to be myocardial ischemia upon final diagnosis.</li> </ol> <p>Rest angina or New-onset (&lt; 2 months) severe angina (Canadian Cardiovascular Society Grading Scale* (or CCS classification system) classification severity <math>\geq</math> III) or Increasing angina (in intensity, duration, and/or frequency) with an increase in severity of at least 1 CCS class to at least CCS class III</p> <p>AND</p> <ol style="list-style-type: none"> <li>3. At least one of the following additional criteria for coronary artery disease and/or ischemia:</li> </ol> <p>New or worsening ST or T wave changes on ECG. ECG changes should satisfy the following criteria for acute myocardial ischemia in the absence of LVH and LBBB:</p> <p>ST elevation</p> <p>New transient (known to be &lt; 20 minutes) ST elevation at the J-point in two contiguous leads with the cut-off points: <math>\geq 0.2</math> mV in men or <math>\geq 0.15</math> mV in women in leads V2 -V3 and/or <math>\geq 0.1</math> mV in other leads</p>

	<p>ST depression and T-wave changes</p> <p>New horizontal or down-sloping ST depression <math>\geq 0.05</math> mV in two contiguous leads; and/or T inversion <math>\geq 0.1</math> mV in two contiguous leads with prominent R wave or R/S ratio <math>&gt; 1</math>.</p> <p>Evidence of ischemia on stress testing with cardiac imaging</p> <p>Evidence of ischemia on stress testing without cardiac imaging but with angiographic evidence of <math>\geq 70\%</math> lesion and/or thrombus in an epicardial coronary artery or initiation/increased dosing of antianginal therapy.</p> <p>Angiographic evidence of <math>\geq 70\%</math> lesion and/or thrombus in an epicardial coronary artery</p> <p>AND</p> <p>4. Requiring an unscheduled visit to a healthcare facility and overnight admission (does not include chest pain observation units). During adjudication, it should then be noted if the event required:</p> <p>Hospitalization (including an overnight stay on an inpatient unit) within 48 hours of the most recent symptoms.</p> <p>Coronary revascularization during an unscheduled visit to a healthcare facility or during an unplanned (or prolonged) hospitalization for the symptoms.</p>
Heart Failure Requiring Hospitalization	<p>Heart failure (HF) requiring hospitalization is defined as an event that meets the following criteria:</p> <p>1. Requires hospitalization defined as an admission to an inpatient unit or a visit to an emergency department that results in at least a 12 hour stay (or a date change if the time of admission/discharge is not available).</p> <p>AND</p> <p>2. Clinical manifestations of heart failure including at least one of the following: New or worsening dyspnea, orthopnea, paroxysmal nocturnal dyspnea, edema, pulmonary basilar crackles, jugular venous distension, new or worsening third heart sound or gallop rhythm, or radiological evidence of worsening heart failure.</p> <p>AND</p> <p>Additional/Increased therapy, initiation of intravenous diuretic, inotrope, or vasodilator therapy, up titration of intravenous</p>

	<p>therapy, if already on therapy, initiation of mechanical or surgical intervention (mechanical circulatory support, heart transplantation or ventricular pacing to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure, or biomarker results (e.g., brain natriuretic peptide) consistent with congestive heart failure will be supportive of this diagnosis.</p>
Cerebrovascular Events (Stroke, TIA)	<p>Stroke is an acute episode of neurological dysfunction attributed to a vascular cause and determined to not be due to a readily identifiable cause, such as a tumor or seizure with residual symptoms at least 24 hours after onset, or leading to death.</p> <p>Stroke is documented by imaging (eg, 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> <p>Ischemic cerebrovascular events lasting less than 24 hours will not be considered stroke and will be considered transient ischemic attacks, and will be identified as such in the eCRF.</p> <p>Micro-hemorrhages are defined as rounded &lt;5-10 mm foci of susceptibility artifact on gradient-echo (T2*) MRI sequences. These appear hypointense without signal characteristics of acute or subacute hemorrhage and are distinct from other causes of signal loss on gradient echo (T2*) MRI sequences (e.g. vascular flow voids, leptomeningeal hemosiderosis, or non-hemorrhagic subcortical mineralization). (NB: When found in the setting of acute or subacute stroke symptoms, hemosiderin alone [micro-hemorrhages] without MR signal changes consistent with acute or subacute stroke should be considered incidental and not the cause of the stroke symptoms.) While data pertaining to the occurrence of micro-hemorrhages will be collected as exploratory data, the occurrence of micro-hemorrhage will not be included in the primary endpoint.</p>
Classification of Cerebrovascular Events (Stroke, TIA)	<p>A. Transient Ischemic Attack: Transient ischemic attack (TIA) is defined as a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction.</p> <p>B. Ischemic Stroke: Ischemic stroke is defined as an acute episode</p>

	<p>of focal cerebral, spinal, or retinal dysfunction caused by an infarction of central nervous system tissue that results from a thrombus or embolus impairing central nervous system perfusion (not due to hemorrhage) and is documented by imaging. Evidence of ischemic stroke obtained from autopsy can also confirm the diagnosis. Findings on lumbar puncture can be supportive to the diagnosis.</p> <p>C. Hemorrhagic stroke: Hemorrhagic stroke is defined as an acute episode of focal or global cerebral, spinal, or retinal dysfunction caused by a nontraumatic intraparenchymal, intraventricular, or subarachnoid hemorrhage with documentation of cerebral hemorrhage on imaging (eg, CT or MRI scan), ie, intraparenchymal, intraparenchymal with penetration into the ventricles, intraventricular, or subarachnoidal hemorrhage. Subdural and epidural bleedings are not included. Evidence of hemorrhagic stroke obtained from autopsy can also confirm the diagnosis. Findings on lumbar puncture can be supportive to the diagnosis.</p> <p>D. Undetermined Stroke: Undetermined stroke is defined as a stroke with insufficient information to allow categorization as B or C.</p> <p>Stroke Disability: Stroke disability should be classified using the modified Rankin Scale.</p>
Coronary Revascularization	<p>Percutaneous Coronary Intervention (PCI): Placement of an angioplasty guide wire, balloon, or other device (e.g., stent, atherectomy catheter, brachytherapy delivery device, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization. In the assessment of the severity of coronary lesions with the use of intravascular ultrasound, CFR, or FFR, insertion of a guide wire will NOT be considered PCI.</p> <p>Coronary Artery Bypass Grafting (CABG): Surgical placement of an artery, vein, or other conduit that connects the aorta or one of its branches (e.g., internal mammary artery) to a coronary artery</p>

	distal to a coronary stenosis.
Death	<p>Mortality from CV Causes: CV mortality includes sudden cardiac death, death due to acute myocardial infarction, death due to heart failure, death due to stroke, and death due to other cardiovascular causes, as well as deaths for which there was no clearly documented non-vascular cause.</p> <p>Sudden Cardiac Death: refers to death that occurs unexpectedly in a previously stable patient and includes the following deaths:</p> <ul style="list-style-type: none"> <li>a. Witnessed and instantaneous without new or worsening symptoms</li> <li>b. Witnessed within 60 minutes of the onset of new or worsening cardiac symptoms</li> <li>c. Witnessed and attributed to an identified arrhythmia (eg, captured on an ECG recording or witnessed on a monitor by either a medic or paramedic)</li> <li>d. Subjects unsuccessfully resuscitated from cardiac arrest or successfully resuscitated from cardiac arrest but who die within 24 hours without identification of a non-cardiac etiology</li> <li>e. Unwitnessed death or other causes of death (information regarding the patient's clinical status within the week preceding death should be provided)</li> </ul> <p>Death due to Acute MI: death occurring up to 30 days after a documented acute MI (verified either by the diagnostic criteria outlined for acute MI or by autopsy findings showing recent MI or recent coronary thrombus) and where there is no conclusive evidence of another cause of death. If death occurs before biochemical confirmation of myocardial necrosis can be obtained, adjudication should be based on clinical presentation and ECG evidence.</p> <p>Death due to a MI that occurs as a direct consequence of a cardiovascular investigation/procedure/operation will be classified as death due to other cardiovascular cause.</p> <p>Death due to Heart Failure or Cardiogenic Shock : refers to death occurring in the context of clinically worsening symptoms and/or</p>



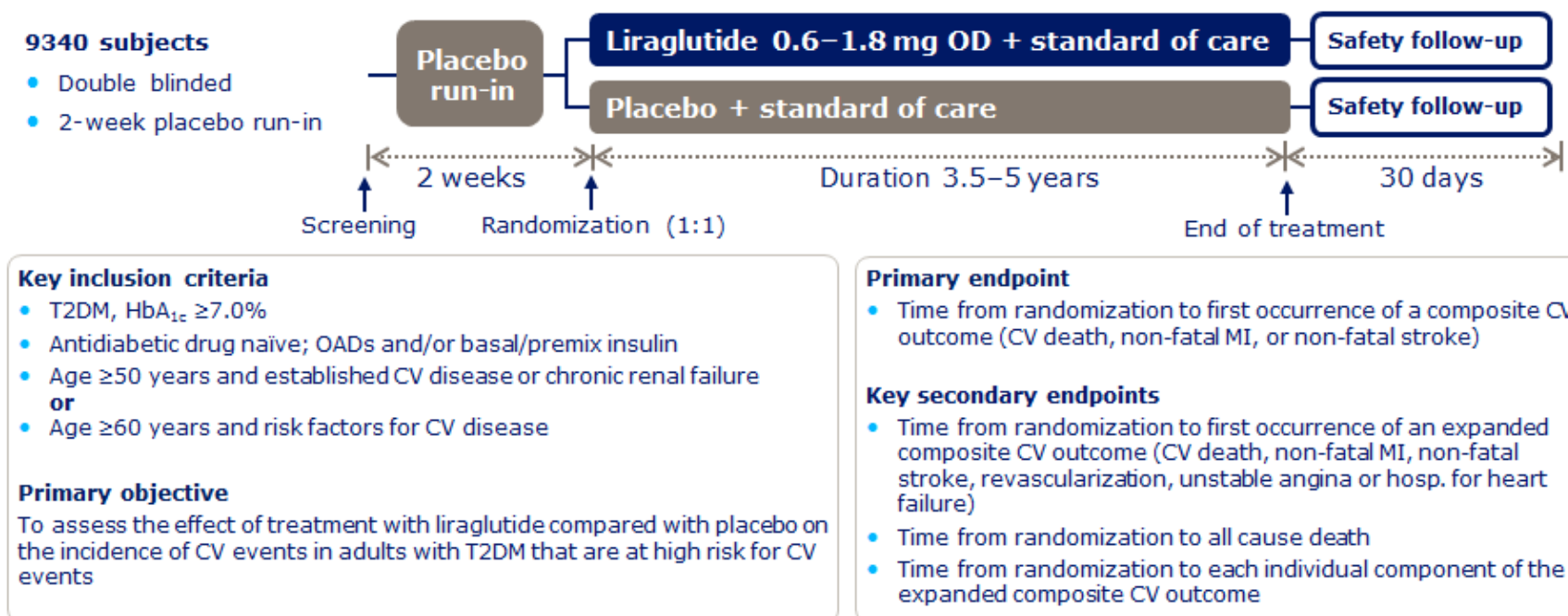
	<p>signs of heart failure without evidence of another cause of death. New or worsening signs and/or symptoms of congestive heart failure (CHF) include any of the following:</p> <ul style="list-style-type: none"> <li>a. New or increasing symptoms and/or signs of heart failure requiring the initiation of, or an increase in, treatment directed at heart failure or occurring in a patient already receiving maximal therapy for heart failure</li> <li>b. Heart failure symptoms or signs requiring continuous intravenous therapy or oxygen administration</li> <li>c. Confinement to bed predominantly due to heart failure symptoms</li> <li>d. Pulmonary edema sufficient to cause tachypnea and distress not occurring in the context of an acute MI or as the consequence of an arrhythmia occurring in the absence of worsening heart failure</li> <li>e. Cardiogenic shock not occurring in the context of an acute MI or as the consequence of an arrhythmia occurring in the absence of worsening heart failure. Cardiogenic shock is defined as systolic blood pressure (SBP) &lt; 90 mm Hg for greater than 1 hour, not responsive to fluid resuscitation and/or heart rate correction, and felt to be secondary to cardiac dysfunction and associated with at least one of the following signs of hypo-perfusion: Cool, clammy skin or Oliguria (urine output &lt; 30 mL/hour) or Altered sensorium or Cardiac index &lt; 2.2 L/min/m<sup>2</sup>.</li> </ul> <p>Cardiogenic shock can also be defined as SBP ≥ 90 mm Hg as a result of positive inotropic or vasopressor agents alone and/or with mechanical support in less than 1 hour. The outcome of cardiogenic shock will be based on CEC assessment and must occur after randomization. Episodes of cardiogenic shock occurring before and continuing after randomization will not be part of the study endpoint. This category will include sudden death occurring during an admission for worsening heart failure.</p> <p>Death due to Cerebrovascular Event: (intracranial hemorrhage or nonhemorrhagic stroke): refers to death occurring up to 30 days after a suspected stroke based on clinical signs and symptoms as well as neuroimaging and/or autopsy, and where there is no conclusive evidence of another cause of death. The FDA Stroke</p>
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	<p>Team Definition of Death due to Stroke can also refer to death occurring up to 30 days after a stroke that is either due to the stroke or caused by a complication of the stroke.</p> <p>Death due to Other Cardiovascular Causes: Death must be due to a fully documented cardiovascular cause not included in the above categories (eg, dysrhythmia, pulmonary embolism, or cardiovascular intervention).</p> <p>Non-Cardiovascular Death: Non-cardiovascular death is defined as any death not covered by cardiac death or vascular death and will be categorized into following groups: pulmonary causes, renal causes, gastrointestinal causes, infection (includes sepsis), non-infectious (e.g., systemic inflammatory response syndrome (SIRS)), malignancy (i.e., new malignancy, worsening of prior malignancy), hemorrhage- not intracranial, accidental/trauma, suicide, non-cardiovascular system organ failure (e.g., hepatic failure), non-cardiovascular surgery, other non-cardiovascular.</p> <p>Presumed Cardiovascular Death: All deaths not attributed to the categories of cardiovascular death and not attributed to a non-cardiovascular cause, are presumed cardiovascular deaths and as such are part of the cardiovascular mortality endpoint.</p> <p>Classification of Death Events: Causes of death events will be initially identified as either “Known” or “Unknown.” If classified as Unknown, no further adjudication of the event will be performed. If Known is selected, the Adjudicator will then be prompted to rate the likelihood that the death can be classified as a CV death event, by making one of the following selections for CV-Related Death: 1) Documented, 2) Probable/Possible, or 3) Unlikely. If “Documented” or “Probable/Possible” is selected, the death event will be classified as CV-related. If “Unlikely” is selected or if cause of death is not suspected to be CV related, the Adjudicator will rate the likelihood that the death event was a non-CV death event by making one of the following selections for Non-CV-Related Death: 1) Documented, 2) Probable/Possible, or 3) Unlikely. The definitions of classifications are as follows:</p>
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	<p>Documented— There is documented evidence for classification</p> <p>Probable/Possible— There is good reason and sufficient documentation and/or it is conceivable and cannot be dismissed</p> <p>Unlikely— The event is most likely related to an alternative cause other than a cardiovascular cause (eg, medical history relevant for cancer)</p> <p>For operational purposes, in case of doubt the EAC members are encouraged</p> <p>to consider the definitions at the end of this spectrum of definitions.</p>
Pancreatitis	<p>Pancreatitis is an inflammatory process of the pancreas.</p> <p>Two of following diagnostic criteria meets the diagnosis of acute pancreatitis: severe acute upper abdominal pain, elevated blood levels of pancreatic enzymes (lipase, amylase) 3xURL characteristic imaging finding (ultrasound, CT, MRI).</p> <p>Chronic pancreatitis will be defined by characteristic imaging finding (ultrasound, CT, MRI) with abnormal pancreatic function tests or characteristic histological findings.</p> <p>Events of acute pancreatitis will be further classified according to degree of severity based on revised Atlanta criteria:</p> <p>Mild acute pancreatitis (no organ failure and no local or systemic complications)</p> <p>Moderately severe acute pancreatitis (organ failure that resolves within 48 h (transient organ failure) and/or local or systemic complications without persistent organ failure)</p> <p>Severe acute pancreatitis (persistent organ failure (&gt;48 h) (single/multiple organs))</p>
Neoplasm	<p>Neoplasm is defined as an abnormal growth of tissue. All neoplasms will be captured.</p> <p>Neoplasms will be classified according to the tissue of origin, the organ system and to the malignancy status:</p>

	<p>Benign</p> <p>Malignant</p> <p>Pre-malignant/Carcinoma in situ/borderline</p> <p>Unclassified</p>
Thyroid Disease Requiring Thyroidectomy and/or Thyroid Neoplasms	<p>All thyroid disease requiring thyroidectomy, including partial thyroidectomy (e.g. lobectomy, partial lobectomy) and all thyroid neoplasms will be adjudicated.</p> <p>Medullary carcinoma of the thyroid (MTC) is defined as a distinct thyroid carcinoma that originates in the calcitonin producing parafollicular C cells of the thyroid gland.</p> <p>Thyroid neoplasms deriving from the C cells will be classified according to the pathology report, as:</p> <p>C-cell hyperplasia</p> <p>Medullary microcarcinoma (carcinoma in situ)</p> <p>Medullary carcinoma.</p>
Nephropathy	<p>A new onset of persistent macroalbuminuria, or persistent doubling of serum creatinine level and creatinine clearance per MDRD <math>&lt;45 \text{ mL/min/1.73m}^2</math> , or the need for continuous renal-replacement therapy (in the absence of an acute reversible cause) or death due to renal disease.</p> <p>Macroalbuminuria is defined either as a 24 hour urine collection above 300 mg, or as an elevated ratio in a spot sample above 300 mg albumin / g creatinine.</p> <p>To confirm persistent macroalbuminuria or persistent doubling of serum creatinine, a confirmatory measurement should be performed.</p>
Diabetic Retinopathy	<p>Diabetic retinopathy defined as need for retinal photocoagulation or treatment with intravitreal agents or vitreous haemorrhage or diabetes-related-blindness (defined as Snellen visual acuity of 20/200 [6/60] or less or visual field of less than 20 degrees, in the better eye with best correction possible).</p>

Figure S1. Study design.



CV: cardiovascular; HbA<sub>1c</sub>: glycosylated hemoglobin; MI: myocardial infarction; OAD: oral antidiabetic drug; OD: once daily; T2DM: type 2 diabetes mellitus

Figure S2. Study subject disposition.

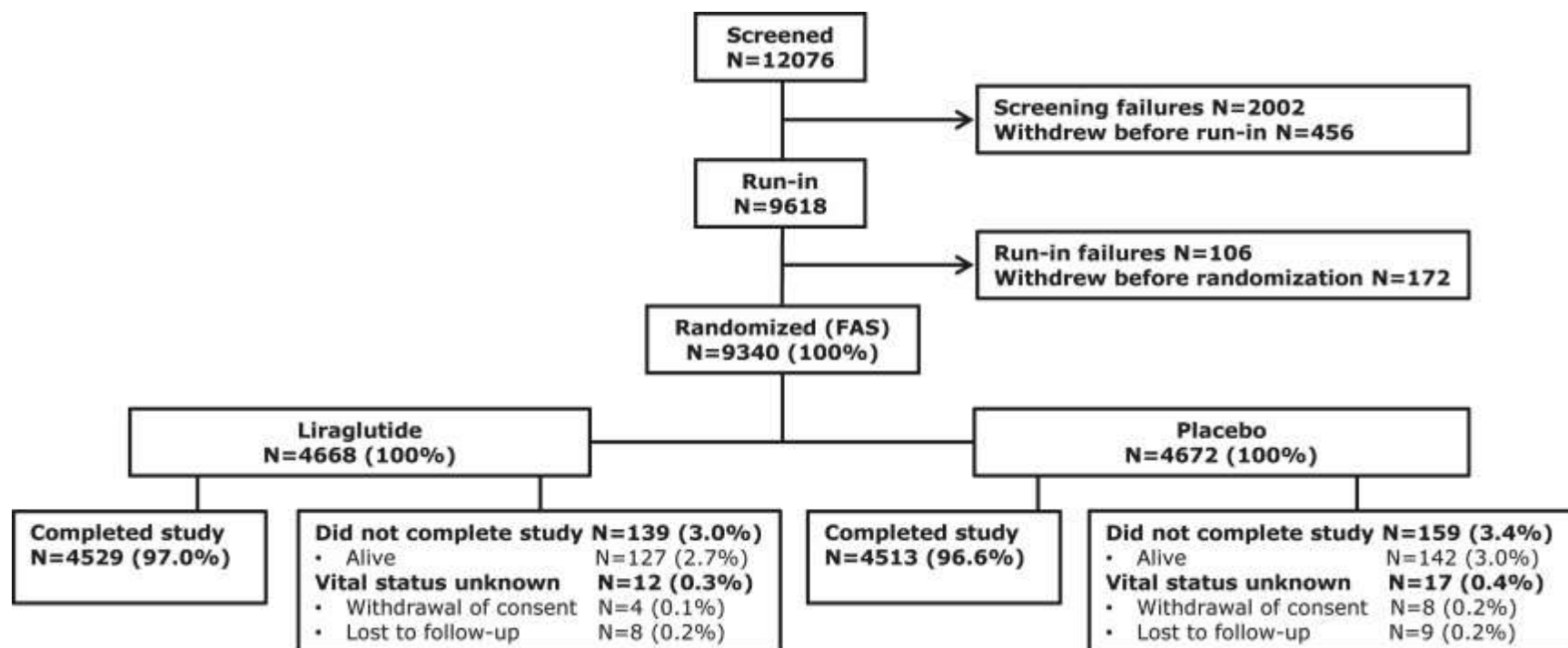
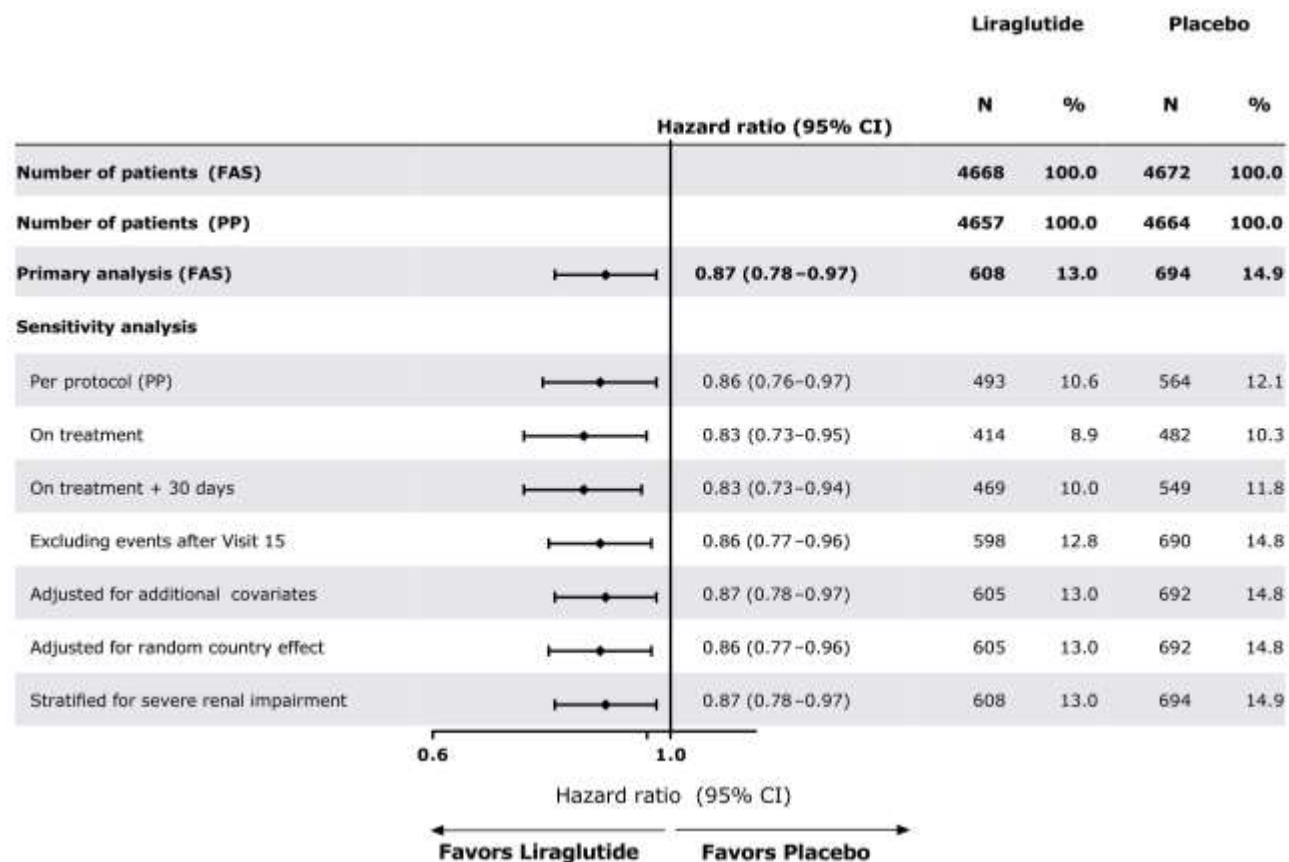
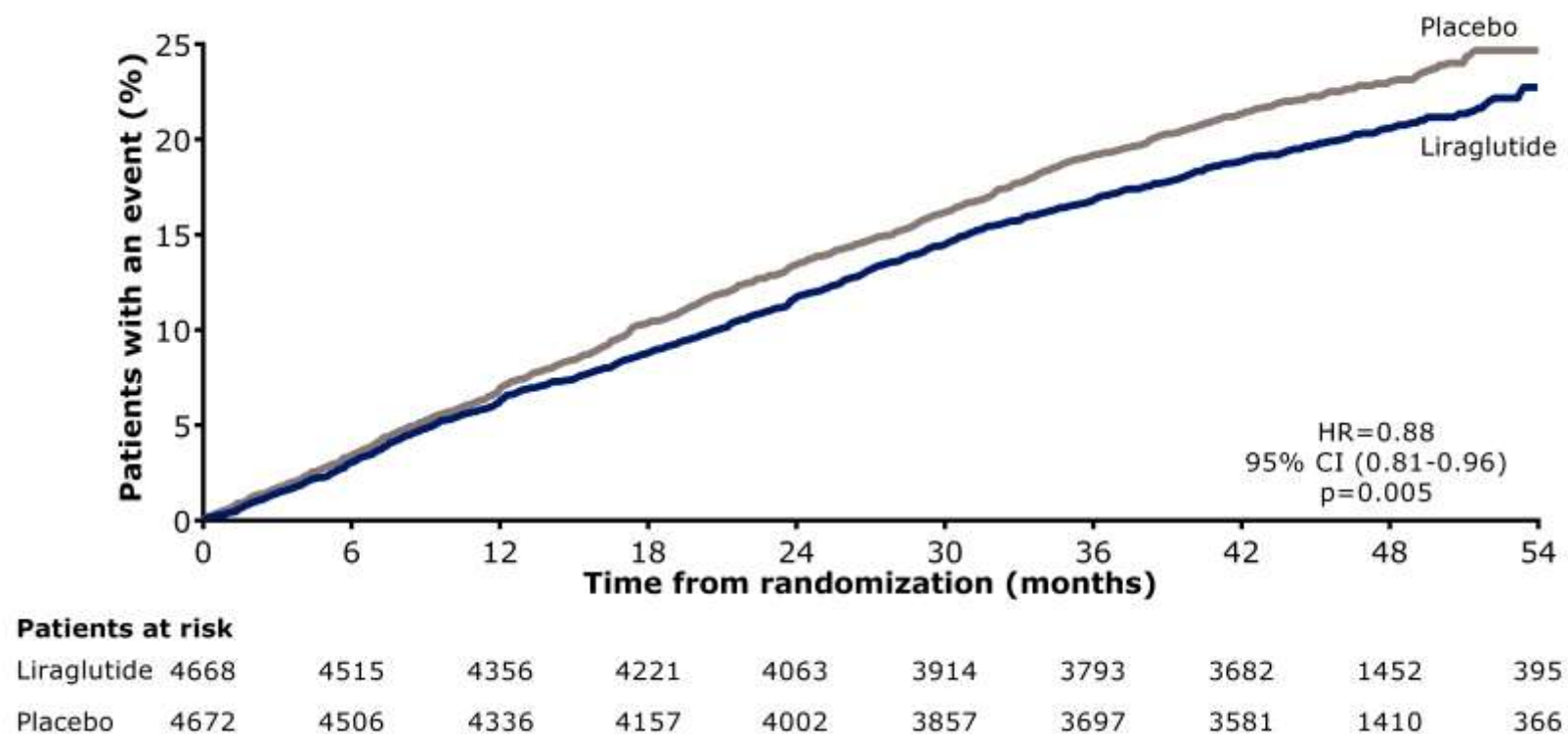


Figure S3. Magnitude of treatment effects of liraglutide on the primary composite outcome.



Sensitivity analyses of primary composite outcomes: 1) during randomized treatment and no more than an accumulated 120 day period of no treatment in a given patient (per protocol); 2) considering events occurring during randomized treatment only (on treatment); 3) considering events occurring during randomized treatment or no later than 30 days into an off-treatment period; 4) excluding events occurring between end-of-treatment (visit 15) and follow-up (visit 16); 5) adjusted for additional covariates (sex, region, baseline age, diabetes duration, prior cardiovascular events at baseline, anti-diabetes medications at baseline, smoking history, and estimated glomerular filtration rate); 6) adjusted for additional covariates with country as a random effect; and 7) stratified by estimated glomerular filtration rate <30 versus >30. All analyses performed using Cox proportional hazard regression with treatment as a fixed factor. FAS = full analysis set; PP = per protocol; CI = confidence interval.

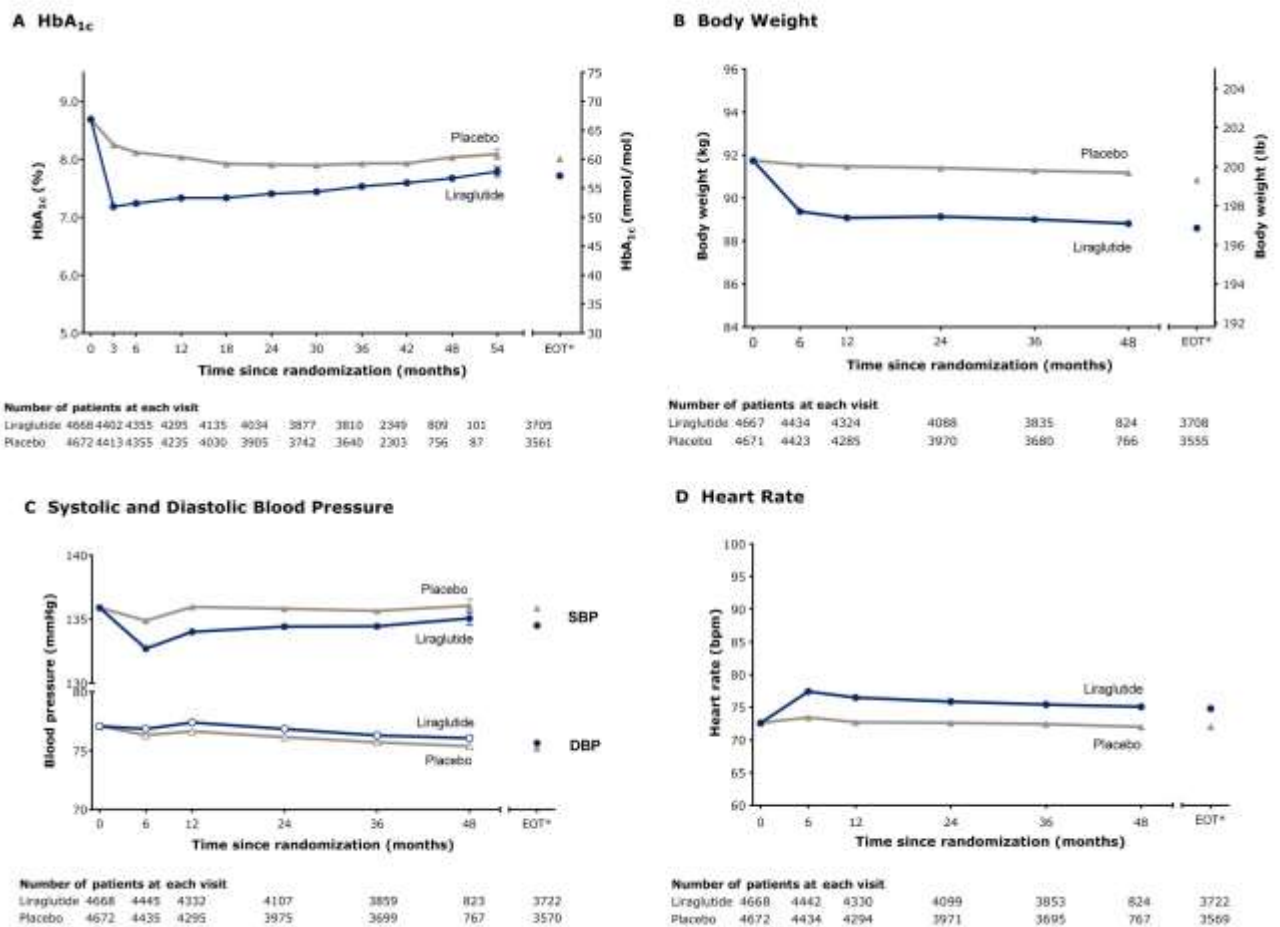
Figure S4. Time to first expanded composite cardiovascular outcome (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina pectoris or hospitalization for heart failure).



X-axis truncated at 54 months, since less than 10% of subjects had an observation time beyond 54 months.

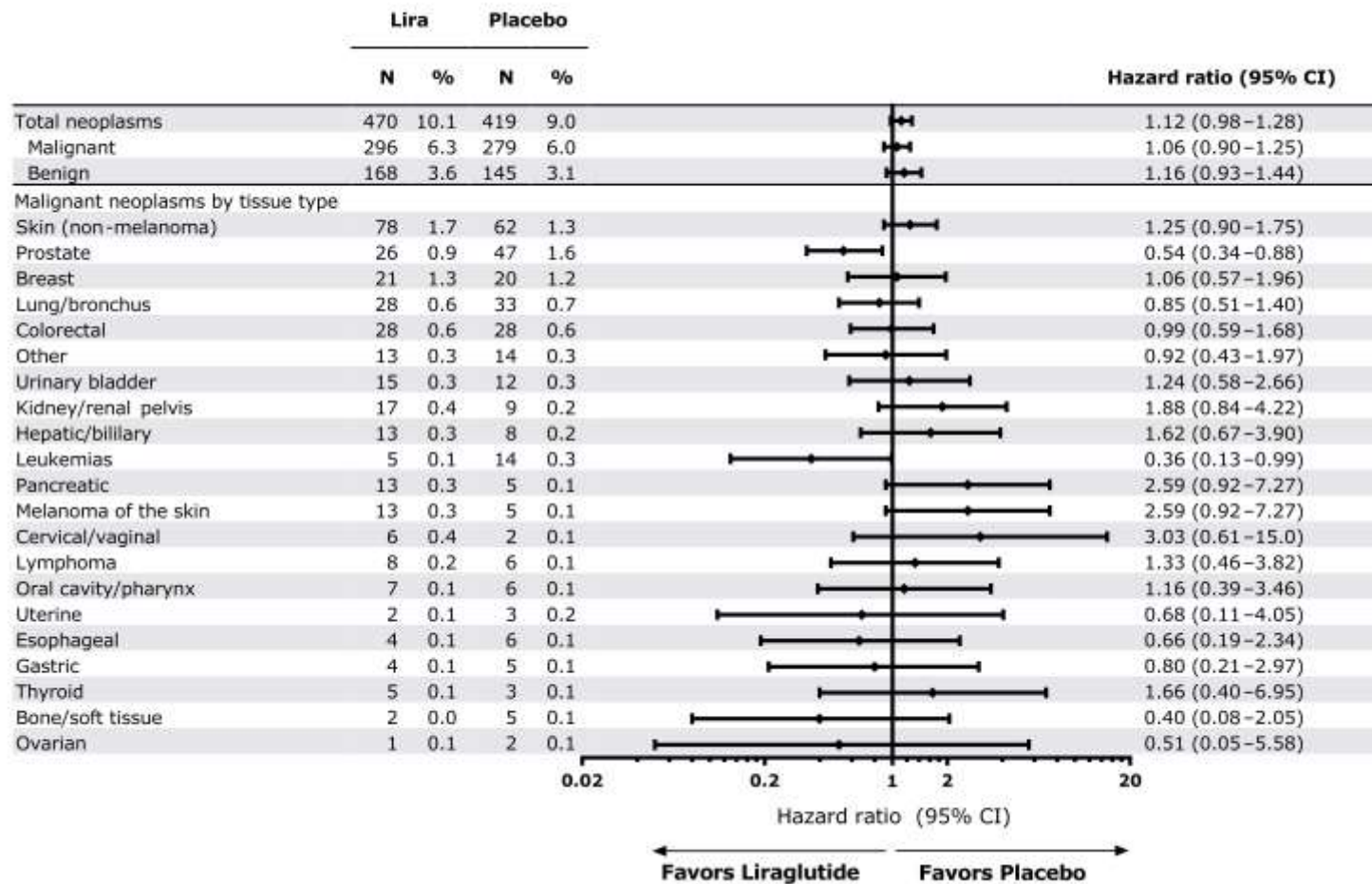


Figure S5. Estimated mean values from randomization to end of trial for: (A) glycated hemoglobin, (B) body weight, (C) blood pressure, and (D) heart rate.



HbA<sub>1c</sub> = glycated hemoglobin; EOT = end of trial; SBP = systolic blood pressure; DBP = diastolic blood pressure.

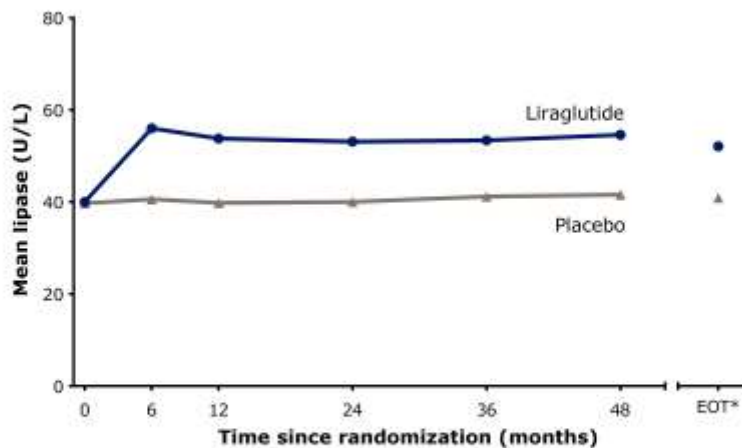
Figure S6. Neoplasms.



Cox proportional hazard regression model adjusted for treatment. N: number of subjects; %: proportion of subjects. Lira = liraglutide; CI = confidence interval.

Figure S7. Lipase and Amylase over time.

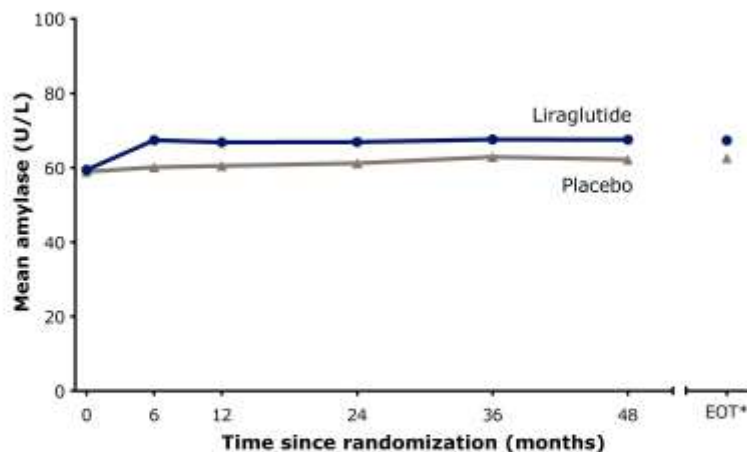
### A Lipase



#### Number of patients at each visit

Liraglutide	4578	4335	4273	4016	3800	808	3687
Placebo	4568	4340	4230	3891	3621	752	3552

### B Amylase



#### Number of patients at each visit

Liraglutide	4600	4361	4289	4038	3817	814	3716
Placebo	4590	4363	4242	3921	3642	758	3569

Observed geometric means for lipase (panel A) and amylase (panel B) from baseline to end of trial (EOT). There were 51.3 and 31.8 % of liraglutide- and placebo-treated patients who at some point during the trial had a lipase greater than or equal to the upper limit of normal (ULN). Similarly, for amylase there were 29.0 and 22.9 %, respectively. There were 8.3 and 5.3 % of liraglutide- and placebo-treated patients who at some point during the trial had a lipase greater than or equal to 3 times ULN. Similarly, for amylase there were 1.0 and 0.8 %, respectively. There were no stopping rules in the current study related to amylase or lipase levels. Patients with

pancreatitis (as determined by the investigator) were to stop treatment with liraglutide or placebo at the time of diagnosis as also described in the product information.

**Table S1. LEADER standard of care guidelines.**

	<b>Treatment / Guideline</b>
<b>Blood glucose</b>	HbA1c $\leq$ 7.0% (individualized depending on patient)  If >7.0%, additional HbA1c measurement after 3m. If HbA1c still >7.0%, treatment should be intensified to achieve target if appropriate
<b>Therapy</b>	Lifestyle modifications and metformin are considered foundational therapy in most countries  Add-on therapy: thiazolidinediones, sulfonylureas, alpha glucosidase inhibitors for intensification according to local labels (DPP-IV and other incretin-based therapies are not allowed)  Insulin therapy: should be based on local practice, including basal, basal/bolus, premix, and mealtime bolus
<b>Blood pressure</b>	Target: 130/80 mm Hg
<b>Antihypertensive therapy</b>	First line: ACE inhibitors or ARBs  Based on individual patient needs: Ca <sup>2+</sup> blockers, diuretics, others
<b>Lipids</b>	Target LDL: <100 mg/dL (<70 mg/dL in patients with previous cardiovascular events)  Statins: recommended for all patients  Second-line therapy: investigator discretion
<b>Antiplatelet therapy</b>	Aspirin or clopidogrel (if aspirin intolerant) for patients with prior cardiovascular events (MI, CVA, or revascularization)
<b>HbA1c: glycated hemoglobin; ACE: angiotensin converting enzyme; ARB: angiotensin receptor blockers; MI: myocardial infarction; CVA: cerebrovascular accident</b>	

**Table S2. Baseline characteristics.**

	<b>Liraglutide (N=4,668)</b>	<b>Placebo (N=4,672)</b>
Male sex	3011 (64.5)	2992 (64.0)
Age, years	64.2 $\pm$ 7.2	64.4 $\pm$ 7.2
Diabetes duration, years	12.8 $\pm$ 8.0	12.9 $\pm$ 8.1
<b>Geographic region</b>		
Europe	1639 (35.1)	1657 (35.5)
North America	1401 (30.0)	1446 (31.0)
Asia	360 (7.7)	351 (7.5)
Rest of the world	1268 (27.2)	1218 (26.1)
Glycated hemoglobin, %	8.7 $\pm$ 1.6	8.7 $\pm$ 1.5
BMI, kg/m <sup>2</sup>	32.5 $\pm$ 6.3	32.5 $\pm$ 6.3
Body weight, kg	91.9 $\pm$ 21.2	91.6 $\pm$ 20.8
Systolic blood pressure, mm Hg	135.9 $\pm$ 17.8	135.9 $\pm$ 17.7
Diastolic blood pressure, mm Hg	77.2 $\pm$ 10.3	77.0 $\pm$ 10.1
Heart failure <sup>a</sup>	835 (17.9)	832 (17.8)
<b>Established CVD (age <math>\geq</math>50)</b>	3831 (82.1)	3767 (80.6)
Prior myocardial infarction	1464 (31.4)	1400 (30.0)
Prior stroke or transient ischemic attack	730 (15.6)	777 (16.6)
Prior revascularization	1835 (39.3)	1803 (38.6)
>50% stenosis of coronary, carotid, or lower extremity arteries	1188 (25.4)	1191 (25.5)
Documented symptomatic CHD <sup>b</sup>	412 (8.8)	406 (8.7)
Documented asymptomatic cardiac ischemia <sup>c</sup>	1241 (26.6)	1231 (26.3)
Heart failure NYHA II – III	653 (14.0)	652 (14.0)
Chronic kidney disease <sup>d</sup>	1185 (25.4)	1122 (24.0)
<b>CVD risk factors (age <math>\geq</math>60 )</b>	837 (17.9)	905 (19.4)
Microalbuminuria or proteinuria	501 (10.7)	558 (11.9)
Hypertension and left ventricular hypertrophy	248 (5.3)	251 (5.4)
Left ventricular systolic or diastolic dysfunction	203 (4.3)	191 (4.1)
Ankle-brachial index <0.9	110 (2.4)	116 (2.5)
<b>Renal function</b>		
Normal (eGFR $\geq$ 90)	1620 (34.7)	1655 (35.4)
Mild impairment (eGFR 60–89)	1932 (41.4)	1975 (42.3)
Moderate impairment (eGFR 30–59)	999 (21.4)	935 (20.0)
Severe impairment (eGFR <30)	117 (2.5)	107 (2.3)

Full analysis set. Data are means  $\pm$  standard deviations or number of patients (percentage of either liraglutide-treated or placebo-treated group). Percentage data refer to proportion of patients. BMI = body mass index; CHD = coronary heart disease; CVD = cardiovascular disease; NYHA = New York Heart Association; eGFR = estimated glomerular filtration rate; ACE = angiotensin converting enzyme; ARB = angiotensin receptor blocker.

<sup>a</sup>NYHA class I, II and III.

<sup>b</sup>Documented CHD: documented by positive exercise stress test or any cardiac imaging or unstable angina with ECG changes.

<sup>c</sup>Documented asymptomatic ischemia: Documented by positive nuclear imaging test, exercise test or dobutamine stress echo

<sup>d</sup>eGFR <60 mL/min/1.73m<sup>2</sup> per Modification of Diet in Renal Disease formula or <60 mL/min/1.73m<sup>2</sup> per Cockcroft-Gault formula.

There were very few missing data; the maximum proportion of missing data was seen for “Diabetes duration” with 0.2% of subjects without information.

There were no statistically significant differences. Continuous variables were tested using a Wilcoxon test; categorical variables were tested using a Pearson Chi-square test. Baseline concomitant medications are found in Supplementary Table S4 (significant difference in use of beta blockers at baseline: p=0.008).

**Table S3. Sensitivity analysis of the primary composite outcome by baseline renal status.**

	<b>Liraglutide</b>	<b>Placebo</b>	<b>Hazard Ratio</b>	<b>95% CI</b>
eGFR $\geq 60$ ml/min/1.73 m <sup>2</sup>	436 (12.3)	471 (13.0)	0.94	0.83-1.07
eGFR 30-59 ml/min/1.73 m <sup>2</sup>	147 (14.7)	197 (21.1)	0.67	0.54-0.83
eGFR $< 30$ ml/min/1.73 m <sup>2</sup>	25 (21.4)	26 (24.3)	0.89	0.51-1.54
Interaction p-value between treatment and factor: 0.03.				



**Table S4. Cardiovascular and anti-diabetes medications at baseline and during trial.**

	Baseline			Introduced during trial		
	Liraglutide (N=4668)	Placebo (N=4672)	p-value	Liraglutide (N=4668)	Placebo (N=4672)	p-value
<b>Cardiovascular medication</b>						
Antihypertensive therapy	4329 (92.7)	4303 (92.1)	0.25	1452 (31.1)	1584 (33.9)	0.004
Beta blockers	2652 (56.8)	2529 (54.1)	0.009	445 (9.5)	486 (10.4)	0.16
Calcium channel blockers	1538 (32.9)	1479 (31.7)	0.18	465 (10.0)	557 (11.9)	0.002
ACE inhibitors	2417 (51.8)	2350 (50.3)	0.15	331 (7.1)	375 (8.0)	0.09
Angiotensin receptor blockers	1488 (31.9)	1486 (31.8)	0.94	368 (7.9)	456 (9.8)	0.001
Renin inhibitors	42 (0.9)	40 (0.9)	0.82	5 (0.1)	9 (0.2)	0.29
Others	468 (10.0)	454 (9.7)	0.62	274 (5.9)	309 (6.6)	0.14
Diuretics	1953 (41.8)	1953 (41.8)	0.97	851 (18.2)	1025 (21.9)	<.001
Loop diuretics	824 (17.7)	837 (17.9)	0.74	484 (10.4)	572 (12.2)	0.004
Thiazides	829 (17.8)	788 (16.9)	0.25	216 (4.6)	293 (6.3)	<.001
Thiazide-like diuretics	325 (7.0)	355 (7.6)	0.24	125 (2.7)	156 (3.3)	0.06
Aldosterone antagonists	254 (5.4)	251 (5.4)	0.88	236 (5.1)	238 (5.1)	0.93
Lipid lowering drugs	3564 (76.3)	3515 (75.2)	0.21	667 (14.3)	738 (15.8)	0.04
Statins	3405 (72.9)	3336 (71.4)	0.10	439 (9.4)	520 (11.1)	0.006
Ezetimibe	165 (3.5)	169 (3.6)	0.83	68 (1.5)	73 (1.6)	0.68
Fibrates	412 (8.8)	432 (9.2)	0.48	172 (3.7)	164 (3.5)	0.65
Niacin	95 (2.0)	95 (2.0)	1.00	22 (0.5)	31 (0.7)	0.22
Other lipid lowering drugs	8 (0.2)	14 (0.3)	0.20	15 (0.3)	16 (0.3)	0.86
Platelet aggregation inhibitors	3205 (68.7)	3121 (66.8)	0.05	701 (15.0)	773 (16.5)	0.04
Acetylsalicylic acid (ASA)	2977 (63.8)	2899 (62.1)	0.08	378 (8.1)	423 (9.1)	0.10
Clopidogrel, Ticlopidine, Prasugrel, Ticagrelor	720 (15.4)	745 (15.9)	0.49	387 (8.3)	416 (8.9)	0.29

Other anti-thrombotic drugs	314 (6.7)	327 (7.0)	0.60	601 (12.9)	615 (13.2)	0.68
<b>Antihyperglycemic medication</b>	4113 (88.1)	4129 (88.4)	0.69	1012 (21.7)	3242 (29.1)	<.001
Metformin	3540 (75.8)	3604 (77.1)	0.14	249 (5.3)	299 (6.4)	0.03
SU	2370 (50.8)	2363 (50.6)	0.85	349 (7.5)	505 (10.8)	<.001
Alpha glucosidase inhibitors	139 (3.0)	123 (2.6)	0.31	83 (1.8)	146 (3.1)	<.001
TZD	296 (6.3)	279 (6.0)	0.46	99 (2.1)	160 (3.4)	<.001
DPP4 inhibitors	4 (<0.1)	2 (<0.1)	0.41	149 (3.2)	170 (3.6)	0.23
GLP1 receptor agonist	0 (0)	2 (<0.1)	0.16	87 (1.9)	139 (3.0)	<.001
SGLT2 inhibitors	N/A	N/A	N/A	100 (2.1)	130 (2.8)	0.046
Glinides	178 (3.8)	172 (3.7)	0.74	85 (1.8)	137 (2.9)	<.001
Other	0 (0)	1 (<0.1)	0.32	0 (0)	1 (<0.1)	0.32
Insulin treatment	2038 (43.7)	2131 (45.6)	0.06	1346 (28.8)	2019 (43.2)	<.001
Premix	445 (9.5)	463 (9.9)	0.54	282 ( 6.0)	440 (9.4)	<.001
Short acting	42 (0.9)	26 (0.6)	0.05	586 (12.6)	915 (19.6)	<.001
Intermediate acting	547 (11.7)	600 (12.8)	0.10	273 (5.8)	386 (8.3)	<.001
Long acting	1041 (22.3)	1077 (23.1)	0.39	619 (13.3)	940 (20.1)	<.001
Other insulins	23 (0.5)	14 (0.3)	0.14	31 (0.7)	43 (0.9)	0.16
No insulin treatment	2630 (56.3)	2541 (54.4)	0.06	1830 (39.2)	1343 (28.7)	<.001

Differences in use of cardiovascular and antihyperglycemic medications at baseline and during trial were tested using Pearson's Chi-square test.

Data are number of patients (percent of group). N/A: Not applicable as SGLT-2 inhibitors were not approved at baseline.

**Table S5. Additional pancreatic cancer data (number of subjects with an event).**

	<b>Liraglutide</b>	<b>Placebo</b>
Neoplasm adjudication	13	5
Neoplasm + death adjudication	13	9
MedDRA search in AE database (not adjudicated)	11	10

Analysis of pancreatic cancer was established using a 3-step independent process. First, all neoplasms were adjudicated by the Event Adjudication Committee (EAC), foremost by histology or cytology, to establish a tissue of origin. Eighteen neoplasms with the tissue of origin “pancreas” were identified by the EAC, 13 in the liraglutide group and 5 in the placebo group. Second, all deaths were adjudicated, with a diagnosis provided for all confirmed non-cardiovascular deaths using less stringent criteria, i.e., not requiring a pathological diagnosis for neoplasms. In this step, another four deaths were adjudicated as from malignancy related to pancreatic cancer, all in the placebo group. Third, based on investigator reports of adverse events and use of MedDRA SMQ search criteria, 21 subjects with pancreatic cancer were identified: 11 in the liraglutide group and 10 in the placebo group.

**Table S6. Severe hypoglycemia events by randomized treatment.**

<b>Treatment group</b>	<b>Number of severe hypoglycemia events</b>	<b>Number of participants experiencing that number of events</b>
Liraglutide	1	90
	2	12
	3	6
	4	3
	5	1
	10	1
	19	1
	Total	114
Placebo	1	119
	2	21
	3	5
	4	4
	5	2
	6	1
	47	1
	Total	153

The proportion of participants with one or more severe events (logistic regression adjusted for covariates): odds ratio = 0.75 [95% CI 0.59-0.97].