Long-Term Effects of Empagliflozin in Patients with Chronic Kidney Disease

The EMPA-KIDNEY Collaborative Group

Supplementary Appendix

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Supplementary Methods

EMPA-KIDNEY definitions of end-stage kidney disease and approaches to verification of deaths using medical notes (clinical adjudication)

(A) END-STAGE KIDNEY DISEASE (ESKD)

Definition

According to the main trial Protocol, the definition of ESKD includes:

i. Initiation of maintenance dialysis;
ii. Receipt of a kidney transplant.

Initiation of maintenance dialysis

At each visit, information was sought about initiation of dialysis. When reporting dialysis, investigators are asked to provide the date dialysis started and:

i. Confirm whether dialysis is ongoing or was temporary (and if only temporary, the reason for stopping). In general, ongoing dialysis is considered as maintenance dialysis if it is required for ≥90 days. Note that death within 90 days of starting dialysis is a special situation.[1]
ii. Confirm the type of dialysis (peritoneal dialysis or hemodialysis).

Receipt of a kidney transplant

At each visit, information was sought about kidney transplantation. When reporting receipt of a kidney transplant, investigators are asked to confirm the date of the procedure.

(B) DEATHS

Approach to adjudication

All reported deaths were reviewed and medical notes sought from Local Clinical Centers (LCCs). Blinded clinicians based at, or overseen by, the Central Coordinating Office in Oxford provide the final adjudication. These clinicians may include, but will not necessarily be, nephrologists or cardiologists. They work under the guidance of senior clinical trialists with extensive experience of adjudicating many thousands of such events (including ESKD, cardiovascular events, and death) in previous large-scale trials in similar populations.

Adjudication procedures in the post-trial follow-up period were identical to those from the active trial period. In making their final decisions, clinicians review the additional information collected from the LCCs as well as other potentially relevant information recorded during study Follow-up visits. SOP 9b: Adjudication Procedures details a quality control process where an initial random sample of first events assessed by each adjudicator are to be reviewed.

i. All reported deaths were required to be adjudicated to confirm:
    a. The date of death
    b. The cause of death

ii. Deaths are to be coded using MedDRA Preferred Terms. They are categorized to facilitate the protocol-specified analyses as follows:

[1] During adjudication of a death, a central clinician adjudicator may note the start of dialysis therapy. The adjudicator is required to provide an opinion on whether the dialysis would have been likely to be required long-term (i.e. renal recovery to be independent of dialysis is unlikely) or only temporarily (i.e. dialysis was started for acute kidney injury and recovery would have been expected had the participant not died within 90 days of starting dialysis).

Cardiovascular death		
Cardiac	Coronary heart disease	Myocardial infarction
		Other coronary heart disease
	Other cardiac disease	Specific cardiac causes, including non-ischemic heart failure
		Sudden cardiac death
Stroke	Hemorrhagic	
	Ischemic	Ischemic stroke (+/- hemorrhagic transformation)
	Undetermined	
Other cardiovascular	Specific other causes (not listed above)	(e.g. pulmonary embolism, ruptured aortic aneurysm)
Presumed cardiovascular	Unexplained death	
Non-cardiovascular death		
Medical	Renal	Death due to chronic kidney disease stage G5 (kidney failure)
	Infection (incl. Covid-19)	
	Cancer	
	Other medical	
Non-medical	External	Trauma

Cardiovascular death definitions

Cardiovascular death includes deaths due to any of the following categories: cardiac, stroke, other cardiovascular and presumed cardiovascular (see table above).

Myocardial infarction death
Death due to acute myocardial infarction (MI) refers to a death within 30 days after a MI related to consequences seen immediately after the MI, such as progressive congestive heart failure, inadequate cardiac output, or recalcitrant arrhythmia. This includes:

i. Deaths due to either acute MI; and
ii. Deaths due to surgical and non-surgical investigations and procedures to treat acute MI or a complication thereof.

Deaths occurring within 30 days after a MI should be attributed to MI unless there was a clear alternative cause.

Supporting evidence
To confirm death from MI there should be evidence of myocardial necrosis plus at least one other piece of supporting information, and no other likely diagnosis:

i. Evidence of myocardial necrosis from:
   a. Raised cardiac biomarker results compatible with acute myocardial necrosis (after taking into consideration the potential effects of chronic kidney disease [CKD] on such biomarkers); or
   b. Autopsy with MI or coronary thrombus of an age consistent with the clinical presentation.

ii. Other supporting information:
   a. Relevant presentation:
      1. Symptoms of ischemia; or
      2. Death
   b. ECG evidence of:
      1. New ischemia; or
      2. Development of pathological Q waves
   c. Cardiac imaging demonstrating new myocardial defect or evidence of acute coronary occlusion.

Other coronary heart disease death
Death due to other coronary disease includes cardiac causes of death that are believed related to coronary atherosclerosis. This includes:

i. Deaths that are related to angina (e.g. death following admission with unstable angina), chronic ischemia (including ischemic cardiomyopathy), and late complications of MI (after 30 days);
ii. Deaths due to surgical and non-surgical investigations and procedures for coronary artery disease (other than as treatments for acute MI); and
iii. Deaths which are believed to be due to coronary atherosclerosis, with autopsy findings of coronary artery disease but without a lesion of an age corresponding to the clinical presentation.

In all cases, deaths due to MI as defined above should be excluded.

Other cardiac disease death (including sudden cardiac death)
Death due to other cardiac disease includes:

i. Deaths that are likely to be due to specific cardiac disorders (e.g. valvular heart disease, non-ischemic cardiomyopathy, primary arrhythmia); and
ii. Deaths due to surgical and non-surgical investigations and procedures for other cardiac disease (other than for coronary artery disease);
iii. Deaths that are sudden and believed likely to be due to cardiac disease, but no definite cardiac cause described above has been identified are sudden cardiac deaths (MedDRA Preferred Term: “Sudden

cardiac death" [10049418]). These include witnessed sudden deaths with or without new or worsening of cardiac symptoms, and unwitnessed deaths in a participant who was seen to be alive and clinically well within 72 hours of being found dead without any evidence of another cardiovascular or a non-cardiovascular cause.

Other cardiac death excludes deaths thought to be due to coronary heart disease (including MI). In some cases, there may be evidence of both coronary heart disease and other cardiac disease (e.g. coronary atherosclerosis in a patient with aortic stenosis). In such cases, the available evidence (e.g. clinical presentation, eye-witness reports, clinical investigations, autopsy findings) should be used to determine the pathology that most likely led to death.

Stroke death

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. Death due to stroke refers to a death which results from:

i. An inexorable decline in the condition of the patient following stroke (typically, but not always within 30 days of the initial event); or
ii. A complication of the stroke (e.g. infection, complication of intervention or procedure); or
iii. Withdrawal of other therapies because of concerns relating to the poor prognosis associated with the stroke (e.g. withdrawal of dialysis).

Wherever possible, stroke subtype (e.g. hemorrhagic, ischemic or undetermined) should be differentiated.

Hemorrhagic stroke

Hemorrhagic stroke is defined as a stroke caused by a non-traumatic intraparenchymal, intraventricular, or subarachnoid hemorrhage.

Ischemic stroke

For the purposes of analysis, ischemic stroke will include all of the following:

i. Ischemic stroke, which is defined as a stroke caused by an infarction of central nervous system tissue; or
ii. Ischemic stroke with hemorrhagic transformation, which is defined as ischemic stroke with evidence of subsequent hemorrhage into an area of previous infarction.

Undetermined stroke

Undetermined stroke is defined as a stroke of unknown/unconfirmed pathological type, i.e. a stroke for which it is unclear whether there is an ischemic or hemorrhagic cause because imaging was not performed or the result is not available.

Exclusions

The following conditions are not to be included in the definition of stroke:

i. Severe prolonged hypoglycemia resulting in neurological deficits;
ii. Trauma;
iii. Any subdural or extradural hematoma;
iv. Findings on CT scans (done for any reason) that do not correlate with a clinical episode;
v. Transient ischemic attacks and related syndromes (with symptoms lasting <24 hours and not leading to death, unless there is clear evidence of new infarction on cranial imaging); and
vi. Non-cardiovascular pathologies (e.g. tumor, degenerative disorders).

Other cardiovascular death

Other cardiovascular death includes:

i. Deaths due to other cardiovascular causes (e.g. pulmonary embolism, primary pulmonary hypertension, ruptured aortic aneurysm, limb ischemia); and

ii. Deaths due to surgical and non-surgical investigations and procedures for other cardiovascular disease (including peripheral arterial revascularization procedures such as peripheral bypass grafting, endarterectomy, arterectomy, embolectomy, and angioplasty).

Unexplained death

i. Deaths for which no cause can be determined in a CKD population are often from cardiovascular causes, and are to be considered presumed cardiovascular deaths.[2]
ii. Deaths which are unexplained are those with no evidence of an alternative cardiovascular or non-cardiovascular cause of death (excluding sudden cardiac death – see Section 3.2.3). This would include deaths for which the cause of death is medically unclear (despite adequate supporting documentation) as well as those for which there is inadequate documentation (despite best efforts). [For example, a death for which there is no information beyond "found dead at home" or "patient died", despite efforts to obtain further details (e.g. medical records, witness report) may be adjudicated as unexplained death.]

Non-cardiovascular death definitions

Non-cardiovascular death includes deaths due to any of the following categories: renal, infection, cancer, other medical and non-medical. Discussion with a Principal Investigator is encouraged for difficult cases. This may be particularly important if there is uncertainty as to whether a cardiovascular or a non-cardiovascular disease was the predominant cause of death.

Renal death

Evidence of renal death requires:

i. Evidence of CKD stage 5 (i.e. eGFR <15 mL/min/1.73m^2 [and usually <10 mL/min/1.73m^2] or ESKD); AND
ii. Evidence of:
    a. Conservative management of ESKD: the patient or their representatives had decided that, despite a clinical need, kidney failure replacement therapy [KFRT] was not to be provided. This includes progression to ESKD before KFRT can be provided; OR
    b. Withdrawal from KFRT: the patient or their representative has chosen to discontinue KFRT (e.g. personal choice, intolerant of dialysis therapy); AND

    No evidence that other major pathology led: (a) to death, or (b) to the decision to withdraw from KFRT (e.g. cancer or stroke), or (c) made dialysis infeasible. Such deaths should be ascribed to the underlying condition.

Infection death

i. Infection should be coded as the cause of death if:
    - death results directly from the infection;
    - death results from a complication of the infection (e.g. acute kidney injury).
ii. Infection should <u>not</u> be coded as the cause of death if the criteria for renal death, cancer death or any type of cardiovascular death are met (e.g. death resulting from pneumonia occurring 2 weeks after a stroke would be coded as a stroke death).

Cancer death

The underlying cause of cancer should be coded as the cause of death if death results:

- Directly from the cancer; or
- From a complication of the cancer or its treatment (e.g. infection / surgery / chemotherapy / radiotherapy); or
- From withdrawal of other therapies (including dialysis) because of concerns relating to the poor prognosis associated with the cancer.

[2] As recommended by Standardized Data Collection for Cardiovascular Trials Initiative (SCTI) Cardiovascular and Stroke Endpoint Definitions for Clinical Trials.

Cancer causes of death are to be categorized by site (e.g. primary organ of origin). Cancer deaths may arise from cancers that were present prior to randomization or which developed subsequently. These two scenarios are to be distinguished in the adjudication process, but if this distinction is not possible (e.g. due to lack of sufficiently detailed documentation) then the cancer will be assumed to have developed after randomization.

Other specific medical causes of death

i. The available evidence should be used to determine the most likely cause of death.
ii. Other medical causes of death should not be coded as the cause of death if the criteria for renal death, infection death, cancer death or any type of cardiovascular death are met.
iii. Acute kidney injury, ketoacidosis and liver causes of death should be adjudicated in line with the specific safety outcome definitions (see Supplementary appendix to N Engl J Med 2023;388: 117-127)
iv. Deaths due to surgical and non-surgical investigations and procedures for non-vascular diseases (e.g. bowel resection for Crohn's disease) should be attributed to the underlying disease for which the investigation or procedure was carried out.

Non-medical death

Non-medical death is defined as any death that is thought to be due to a non-medical ("external") cause. Not only are such deaths uncommon in most clinical trials, but they are generally unlikely to be affected by study treatments. Examples include suicide, homicide, road traffic accident, house fire, electrocution, war and natural disaster.

Supplementary Statistical Methods
(including handling and analysis of estimated GFR measurements)

An estimated GFR was sought in each 6 monthly post-trial follow-up period. Local clinic center staff were trained to record the latest outpatient result in the period. Local outpatient measurements of creatinine instead of measurements during hospitalizations were requested as these are most reflective of the participant's usual kidney function. Local creatinine results could be collected from outpatient clinic visits, general practitioner/primary care practitioner visits, or hospitalization visits (as a last resort).

Time-to-first event analyses

All statistical analysis methods were pre-specified in Data Analysis Plans. Estimated GFR was calculated from locally measured creatinine using the race-adjusted 2009 CKD-EPI formula. If multiple estimated GFR measurements were available in any one follow-up period, then the estimated GFR closest to the middle of the window was automatically selected. This ensures only a single estimated GFR measurement was selected in each follow-up window, minimizing any bias that could be introduced by any difference in frequency of creatinine measurement between groups. If there are two estimated GFRs recorded in the last follow-up period, the last of these estimated GFRs was included in analyses irrespective of whether or not it is the estimated GFR closest to the middle of the follow-up window. This could result in two estimated GFRs in the last follow-up period.

For the sustained ≥40% estimated GFR decline from randomization, and for the sustained estimated GFR below 10 mL/min/1.73m^2 components of the kidney disease progression composite outcome, confirmation of "sustained" required values on two consecutive estimated GFR measurements at least 30 days apart, or was assumed if it was the last estimated GFR value before death, withdrawal of consent, or the end of a participant's follow-up. There was no imputation for missing creatinine values in time-to-first event analyses.

In the primary analyses of the entire follow-up period (active and post-trial periods combined), the analyses from the reported results for the active trial's primary outcome using centrally measured estimated GFR were carried over. A sensitivity analysis using only local estimated GFR measurements collected throughout the entire trial follow-up period was pre-specified and conducted. This analysis did not differentiate the active versus post-trial periods (i.e. in this sensitivity analysis, estimated GFR values at the last scheduled active trial visit were not designated as the "last scheduled visit" for the purposes of "sustained" definitions unless the participant did not enter the post-trial follow-up period in which case it was the participant's actual last visit). A second sensitivity analysis limited all data to those centres participating in post-trial follow-up.

Estimates of absolute benefits

Absolute benefits per 1000 participants allocated empagliflozin at given time points were calculated from differences in Kaplan-Meier curves between allocated groups at those time points.

Mathematically, if there had been no off-treatment effect of empagliflozin post-trial, absolute benefits would be observed to diminish from the end of the active trial period. This is expected as: let $S_i(t)$ denote the survival function in each allocated group at time t. The difference in the survival curves between the allocated groups at the end of the active period (2.5 years) is denoted by $d = S_1(2.5) - S_2(2.5)$. Due to the beneficial effects of active drug, there will be a separation of the curves at the end of the active trial, with a larger proportion of patients still event free in the empagliflozin group. In the post-trial period, we would expect the proportion of patients still event free in each group to reduce by a factor of $(100-x_i)/100$ each year, where x_i is the hazard rate in arm i. Therefore, n years after the end of the active trial period, the survival function in arm i will be $S_i(2.5)*((100-x_i)/100)^n$. When the post-trial hazard ratio is 1.0, the hazard rates in each arm are identical (i.e. $x_i=x$). In this scenario, the difference

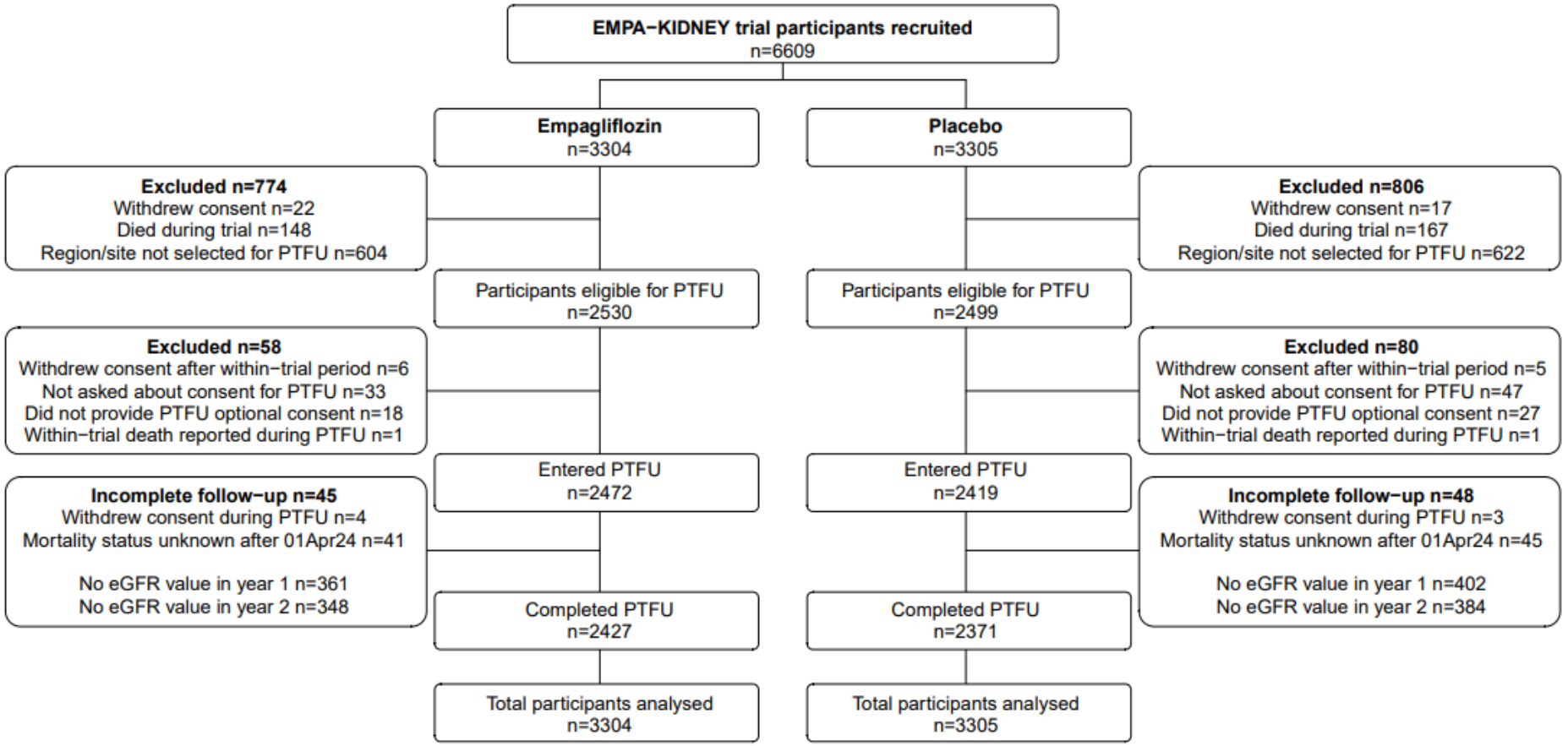
in the survival curves n years after the end of the active trial period would be $S_1(2.5)*((100-x)/100)^n - S_2(2.5)*((100-x)/100)^n = (S_1(2.5)- S_2(2.5))*((100-x)/100)^n = d*((100-x)/100)^n$. Hence, we would expect the absolute benefit observed at the end of the trial period to have diminished by a factor of (100-x)/100 for each year of post-trial follow-up in the absence of any additional off-treatment effect of study drug.

Mixed model repeated measures (MMRM) approach

Linear MMRM analyses were used to estimate mean estimated GFR by treatment allocation at each scheduled follow-up visit (and these values are shown in Figure S6). These models were adjusted for baseline estimated GFR (as a continuous variable), age, sex, prior diabetes, urinary albumin-to-creatinine ratio, and region (all in the same categories used in the minimization process), treatment allocation, follow-up time point and the interaction between baseline estimated GFR and follow-up time point. A further interaction term between treatment allocation and follow-up time point was then included in order to enable separate estimation of mean estimated GFR at each follow-up time point for each treatment arm, conditional on the other factors in the model. These models assume that any missing estimated GFR values can be predicted by the non-missing estimated GFR data for other individuals together with the other covariates in the model (i.e. that they are 'missing at random').

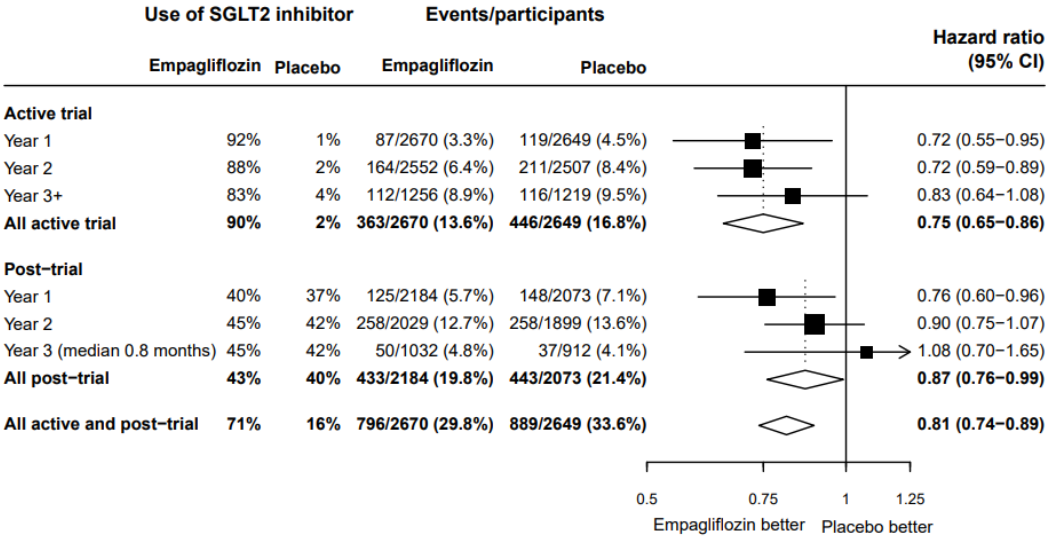
Supplementary Figures

Figure S1. CONSORT participant flowchart for active and post−trial follow-up periods (PTFU)



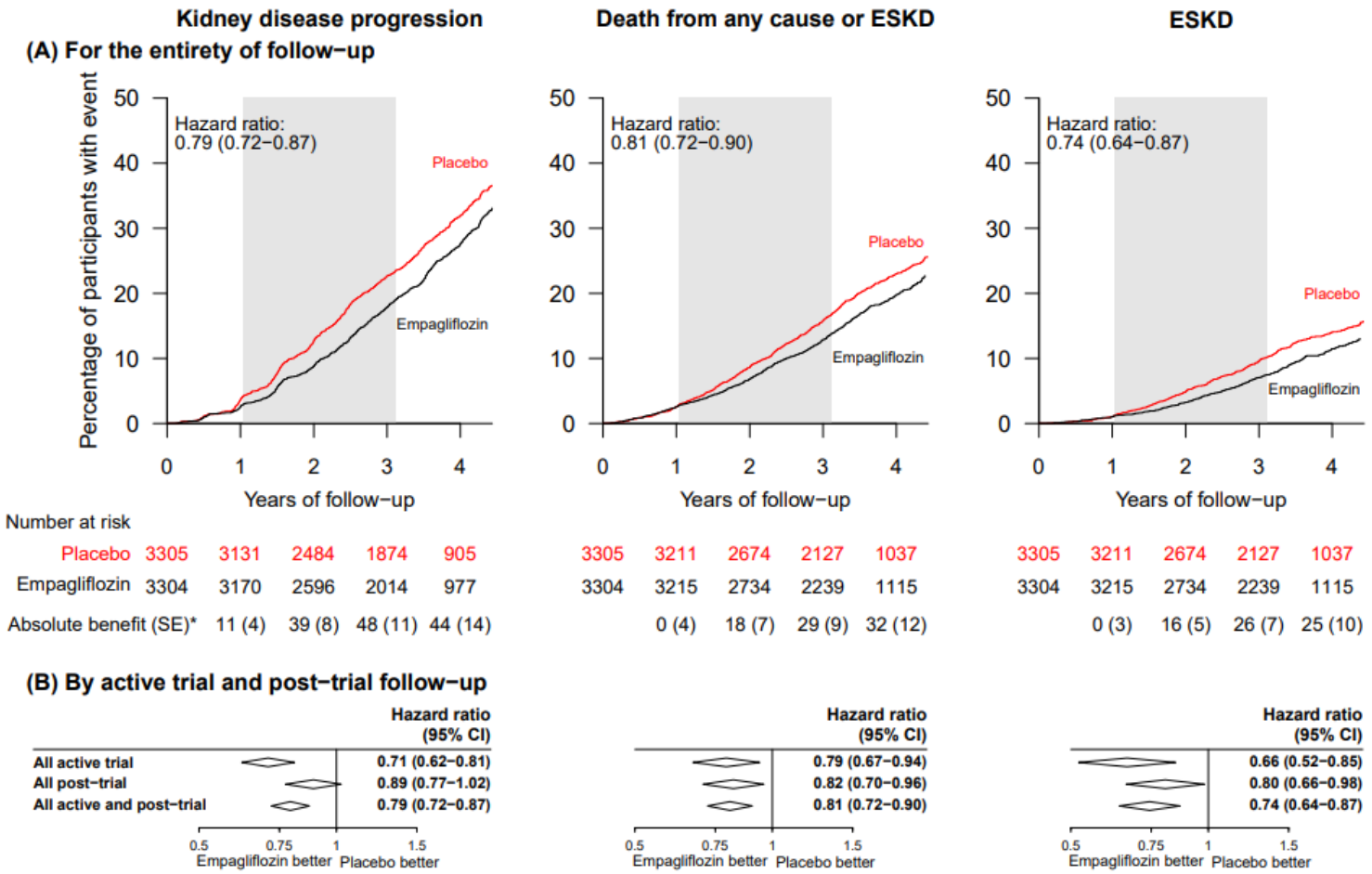
Proportions of participants entering PTFU were: Empagliflozin group: 2472/3304 (74.8%) and placebo group 2419/3305 (73.2%).

Figure S2: Effect of allocation to empagliflozin on progression of kidney disease or death from cardiovascular causes, restricted to sites that contributed to post-trial follow-up (sensitivity analysis)



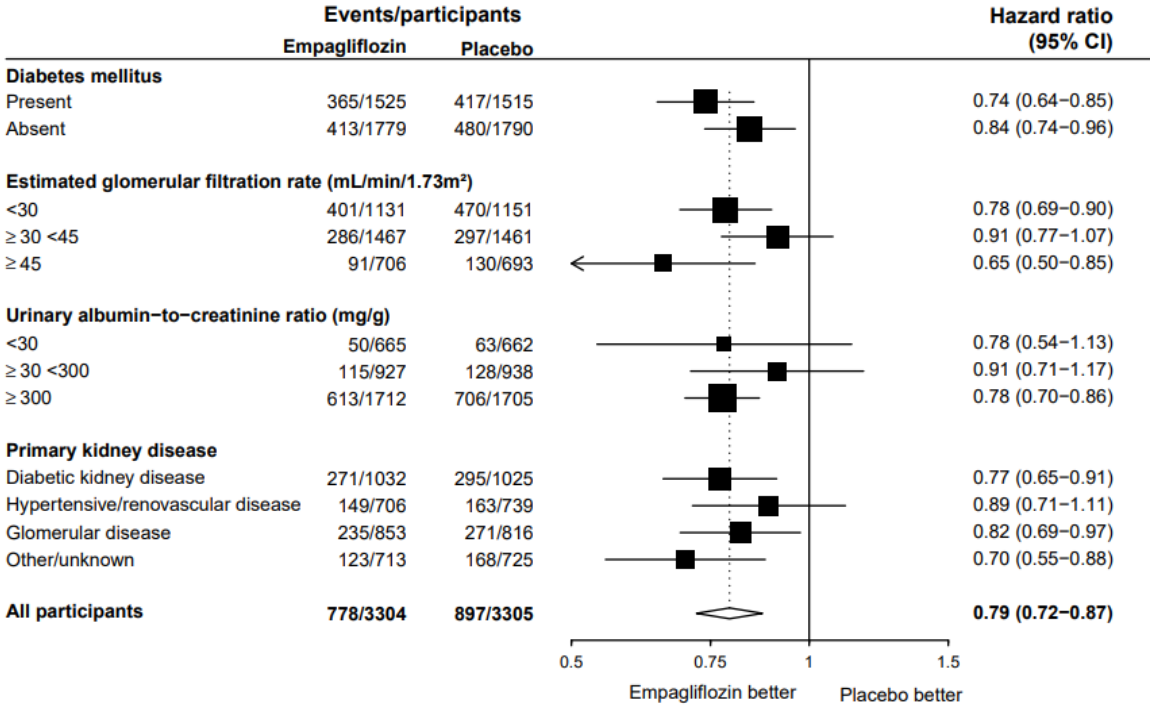
Presented analyses carry over the main results of the trial's primary outcome (i.e. any estimated glomerular filtration rate [eGFR] based outcome recorded at the active trial period's Final Follow−up Visit without a confirmatory result are still accepted as "sustained" despite the availability of local eGFR measurements in the post−trial period). Use of SGLT2 inhibitor defined in Table 2 and average use calculated as per Figure 1B with weights proportional to the total person years at risk in each year. Denominators are the number of participants still at risk of a first primary outcome at the start of the risk period.

Figure S3: Effect of allocation to empagliflozin on secondary outcomes over the entirety of follow-up



*Absolute difference in number of events per 1000 patients allocated to receive empagliflozin during the active trial period. A panels provide the KM-plots for the secondary outcomes for the entire follow-up period (active and post-trial periods combined). By contrast, B panels displays the hazard ratios in those originally allocated empagliflozin versus those originally allocated placebo separately for (a) the active trial, and (b) the post-trial period during which time no participant took study drug but some were started on non-trial SGLT2i (not necessarily empagliflozin). Presented analyses carry over the main results of the trial's primary outcome.

Figure S4: Effect of allocation to empagliflozin on progression of kidney disease over the entirety of follow-up by key pre−specified subgroups



Entirety of follow-up is the active and post-trial periods combined. Presented analyses carry over the main results of the trial's primary outcome from its active period.

Figure S5: Effect of allocation to empagliflozin on cause−specific mortality over the entirety of follow-up

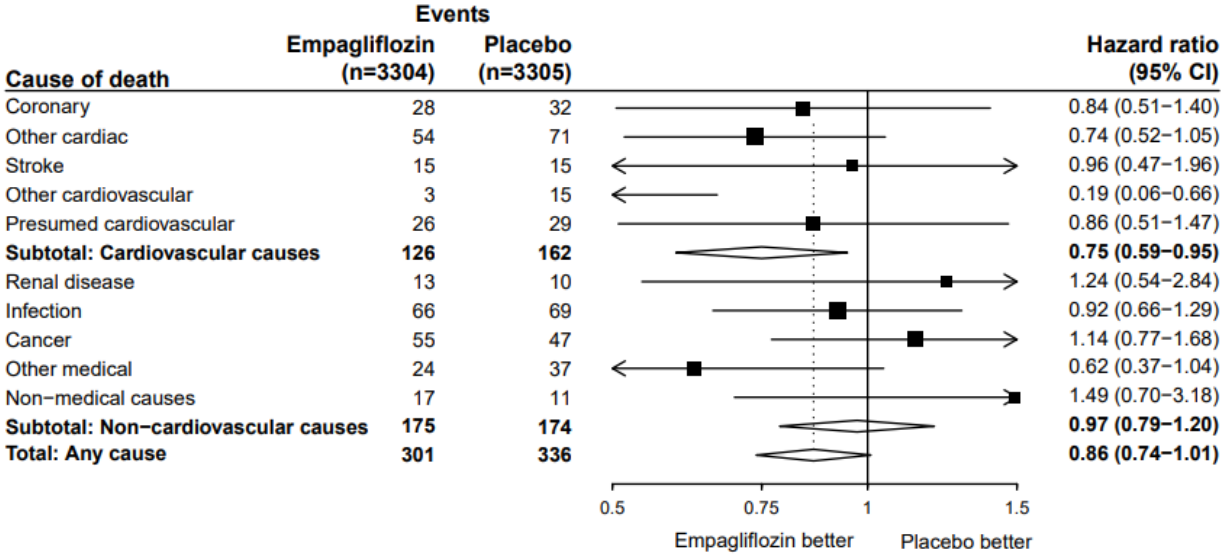
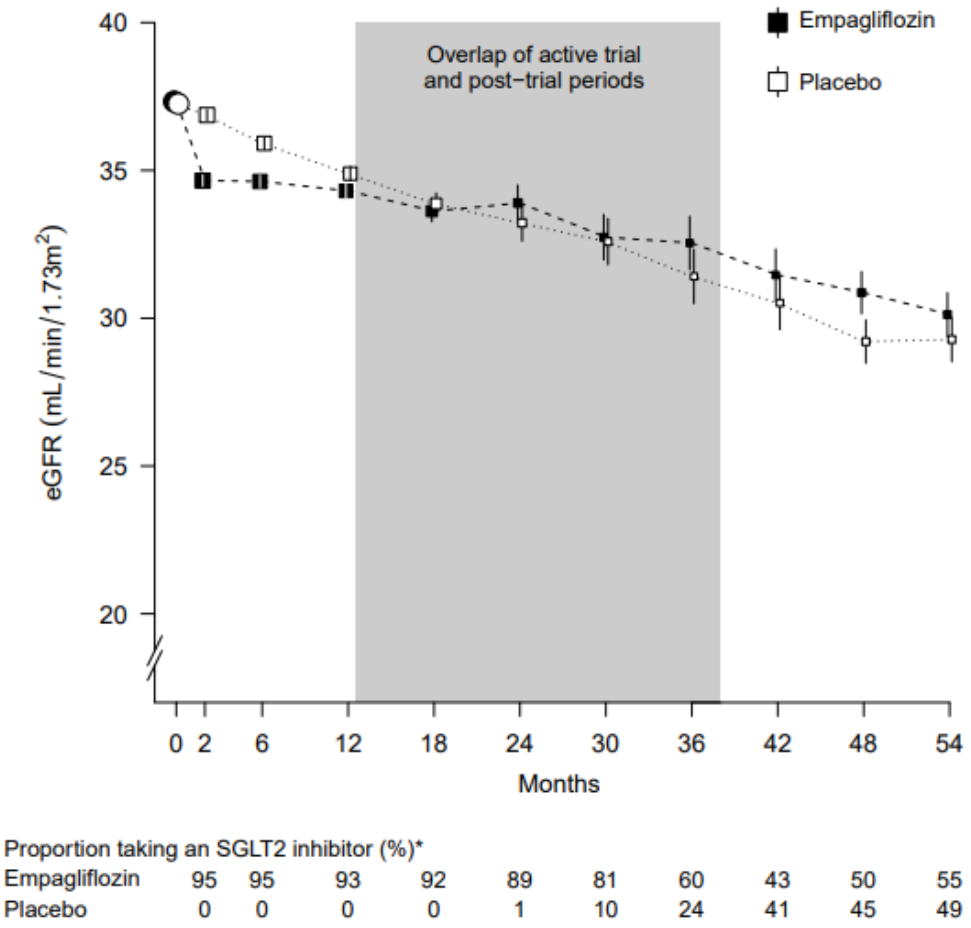


Figure S6: Effect of allocation to empagliflozin on estimated glomerular filtration rate over the entirety of follow−up

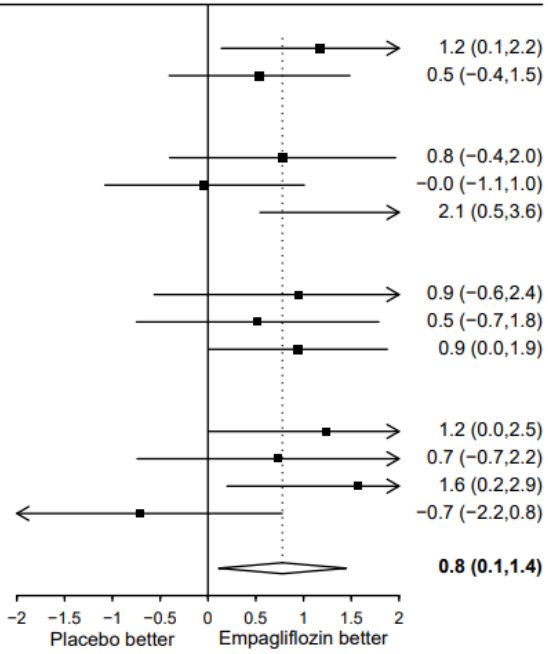


eGFR=estimated glomerular filtration rate. Plot of mean eGFR by time calculated from an MMRM model for the entirety of the trial with all analyses based on local creatinines (see supplementary statistical methods). The vertical lines indicate the 95% confidence intervals for the estimated means. The coordinates of the boxes are shifted slightly on the x axis to avoid overlap.

* Use of SGLT2 inhibitor based on reporting taking at least 80% of study drug or use of open-label SGLT2 inhibitor.

Figure S7: Effect of allocation to empagliflozin on absolute difference in mean estimated glomerular filtration rate at last local measurement by key pre−specified subgroups

	Mean baseline eGFR (mL/min/1.73m²)	Number with last local measurement	Median (IQR) follow−up, years	Mean eGFR at last local measurement (mL/min/1.73m²) Empagliflozin	Placebo	Difference (95% CI)
Diabetes						
Present	35.4	3026	3.5 (2.3−4.4)	30.3 (0.4)	29.2 (0.4)	1.2 (0.1,2.2)
Absent	38.9	3564	3.6 (3.1−4.4)	32.3 (0.3)	31.7 (0.3)	0.5 (−0.4,1.5)
Estimated glomerular filtration rate (mL per minute per 1.73m²)						
<30	24.9	2274	3.6 (2.6−4.4)	20.3 (0.4)	19.6 (0.4)	0.8 (−0.4,2.0)
≥ 30 <45	36.7	2917	3.6 (2.8−4.4)	31.1 (0.4)	31.1 (0.4)	−0.0 (−1.1,1.0)
≥ 45	58.7	1399	3.5 (2.3−4.2)	49.6 (0.5)	47.5 (0.5)	2.1 (0.5,3.6)
Urinary albumin−to−creatinine ratio (mg/g)						
<30	34.8	1321	3.6 (3.0−4.4)	34.6 (0.5)	33.6 (0.5)	0.9 (−0.6,2.4)
≥ 30 <300	36.2	1858	3.6 (2.5−4.4)	32.7 (0.5)	32.2 (0.5)	0.5 (−0.7,1.8)
≥ 300	38.9	3411	3.5 (2.4−4.3)	29.4 (0.3)	28.5 (0.3)	0.9 (0.0,1.9)
Primary kidney disease						
Diabetic kidney disease	35.4	2049	3.5 (2.3−4.4)	30.0 (0.4)	28.8 (0.4)	1.2 (0.0,2.5)
Hypertensive/renovascular disease	35.1	1439	3.6 (2.9−4.4)	30.5 (0.5)	29.8 (0.5)	0.7 (−0.7,2.2)
Glomerular disease	42.9	1668	3.6 (3.2−4.3)	33.9 (0.5)	32.3 (0.5)	1.6 (0.2,2.9)
Other/unknown	35.7	1434	3.6 (2.5−4.4)	31.2 (0.5)	31.9 (0.5)	−0.7 (−2.2,0.8)
All participants	**37.3**	**6590**	**3.6 (2.6−4.4)**	**31.4 (0.2)**	**30.6 (0.2)**	**0.8 (0.1,1.4)**



Last measurement defined as the last creatinine value recorded prior to death, end-stage kidney disease (i.e. date of commencement of maintenance dialysis or receipt of a kidney transplant), withdrawal of consent or end of follow-up. All analyses are based on local creatinine values.

Supplementary Tables

Table S1: Representativeness of study participants

Category	
Disease, problem, or condition under investigation	Chronic kidney disease (CKD) at risk of progression
Special considerations related to:	
Sex and gender	CKD affects men more than women, and the incidence (and prevalence) of kidney failure is greater in men than women.
Age	Prevalence of CKD increases steeply with age.
Race or ethnic group	The risks of developing CKD or its progression differ within countries by race and ethnicity. For example, Black, Hispanic and Native American people in the USA, Black and Asian people in the UK, and indigenous populations in Australia, Canada and South America are all at higher risk compared to the country's White population.
Geography	The crude prevalence of CKD varies globally from 2-15%, although this may in part be due to differences in methods of ascertainment. The causes of kidney disease vary substantially between countries. Diabetes causes between 10-55% of CKD; chronic glomerulonephritis causes between 5-40%. However, the cause of kidney disease is frequently unknown.
Other considerations	Previous large placebo-controlled trials of sodium glucose co-transporter-2 (SGLT2) inhibitors mainly recruited patients with type 2 diabetes and proteinuric CKD. Relatively few patients with CKD without diabetes were studied. The CREDENCE and SCORED trials exclusively studied patients with CKD with type 2 diabetes, and the DAPA-CKD trial in patients with proteinuric CKD studied 1398 patients without diabetes at baseline. Globally the majority of people with CKD have low levels of albuminuria (i.e. a urinary albumin-to-creatinine ratio less than 300 milligrams per gram) and do not have diabetes.
Overall representativeness of this trial	Participants in EMPA-KIDNEY were selected to have CKD at risk of progression, so do not represent the larger population of all people with CKD. Patients with polycystic kidney disease were excluded. Nevertheless, EMPA-KIDNEY included a wide range of patients with CKD, and the proportional effects of treatment are likely to be generalizable. Biologic sex (male or female) was reported by the participants and used to calculate estimate glomerular filtration rate. Gender was not reported. The participants in the present trial demonstrated an expected higher number of men than women. In the post-trial cohort, the proportion of Black patients overall was 4%, but among patients enrolled in post-trial follow-up in North America, 17% were Black and 17% were of Hispanic ethnicity. These are similar to the total population distribution of the United States. Causes of CKD, including diabetic kidney disease, were otherwise consistent with registry data where these were available from participating countries. EMPA-KIDNEY recruited patients from centres in Europe, North America and Asia. Post-trial follow-up did not include EMPA-KIDNEY participants from Japan. No patients were enrolled in Africa or Oceania.

Table S2: Baseline characteristics at randomization for participants in post-trial follow-up (PTFU) and those not in PTFU

	Participants entering PTFU (n=4891)	Participants not known to have died at the end of active trial follow-up but did not enter PTFU (n=1362)
Demographics		
Age at randomization (years)	63 (14)	65 (13)
Sex		
Men	3227 (66%)	929 (68%)
Women	1664 (34%)	433 (32%)
Race		
White	3055 (62%)	554 (41%)
Black	178 (4%)	66 (5%)
Asian	1582 (32%)	725 (53%)
Mixed	20 (0%)	1 (0%)
Other	56 (1%)	16 (1%)
Prior disease		
Prior diabetes*	2107 (43%)	683 (50%)
Prior cardiovascular disease§	1280 (26%)	311 (23%)
Clinical measurements		
Systolic blood pressure (mmHg)	136.9 (18.3)	134.8 (17.3)
Diastolic blood pressure (mmHg)	78.6 (11.7)	77.6 (11.8)
Body mass index (kg/m²)	29.9 (6.6)	28.8 (7.0)
Laboratory measurements		
eGFR (mL/min/1.73m²)†		
Mean (SD)	36.9 (14.1)	40.5 (16.0)
<30	1711 (35%)	378 (28%)
≥30 to <45	2210 (45%)	575 (42%)
≥45	970 (20%)	409 (30%)
uACR (mg/g)†		
Geometric mean (approx SE)	213 (6)	276 (14)
Median (Q1-Q3)	317 (44-1063)	393 (81-1085)
<30	1030 (21%)	218 (16%)
≥30 to ≤300	1363 (28%)	380 (28%)
>300	2498 (51%)	764 (56%)
Concomitant medication use		
RAS inhibitor	4208 (86%)	1141 (84%)
Any diuretic	2080 (43%)	509 (37%)
Any lipid-lowering medication	3220 (66%)	878 (64%)
Cause of kidney disease		
Diabetic kidney disease	1404 (29%)	472 (35%)
Hypertensive/renovascular disease	1125 (23%)	247 (18%)
Glomerular disease	1306 (27%)	342 (25%)
Other/unknown	1056 (22%)	301 (22%)
5 year predicted kidney failure risk (%)		
Median (Q1-Q3)	10 (3-29)	7 (2-25)

Participants who died during the active trial period (n=317) or withdrew consent during the active trial period (n=39) not shown. Figures are n (%), mean (SD), geometric mean (approx SE) or median (Q1-Q3). eGFR=estimated glomerular filtration rate. uACR=urinary albumin-to-creatinine ratio. RAS=renin-angiotensin system. * Prior diabetes mellitus defined as participant-reported history of diabetes of any type, use of glucose-lowering medication or baseline HbA1c ≥48 mmol/mol at Randomization visit. § Defined as self-reported history of myocardial infarction, heart failure, stroke, transient ischemic attack, or peripheral arterial disease. † Uses central measurement taken at the randomization visit, or more recent local laboratory result before randomization. Those with missing data for BMI (n=15) not presented in relevant rows.

Table S3: Baseline characteristics at the last follow-up during the active trial treatment phase for participants entering post-trial follow-up (PTFU) and those not in PTFU and by use of SGLT2 inhibitors (SGLT2i) at the end of PTFU

	Characteristics of participants as they entered PTFU			Participants not known to have died at the end of active trial follow-up but did not enter PTFU (n=1362)
	Participants recorded as taking SGLT2i at last PTFU visit (n=2050)	Participants not recorded as taking SGLT2i at last PTFU visit (n=2841)	All participants (n=4891)	
Demographics				
Age (years)	65 (14)	64 (14)	65 (14)	67 (13)
Sex				
Men	1388 (68%)	1839 (65%)	3227 (66%)	929 (68%)
Women	662 (32%)	1002 (35%)	1664 (34%)	433 (32%)
Region				
Europe	1239 (60%)	1143 (40%)	2382 (49%)	111 (8%)
North America	424 (21%)	632 (22%)	1056 (22%)	539 (40%)
China or Malaysia	387 (19%)	1066 (38%)	1453 (30%)	124 (9%)
Japan	0 (0%)	0 (0%)	0 (0%)	588 (43%)
Race				
White	1491 (73%)	1564 (55%)	3055 (62%)	554 (41%)
Black	63 (3%)	115 (4%)	178 (4%)	66 (5%)
Asian	461 (22%)	1121 (39%)	1582 (32%)	725 (53%)
Mixed	11 (<1%)	9 (<1%)	20 (<1%)	1 (<1%)
Other	24 (1%)	32 (1%)	56 (1%)	16 (1%)
Prior disease				
Prior diabetes*	959 (47%)	1236 (44%)	2195 (45%)	706 (52%)
Prior cardiovascular disease§	600 (29%)	813 (29%)	1413 (29%)	342 (25%)
Clinical measurements				
Systolic blood pressure (mmHg)				
Mean (SD)	131.8 (18.0)	134.7 (19.0)	133.4 (18.6)	131.3 (17.3)
Missing	68 (3%)	269 (9%)	337 (7%)	158 (12%)
Diastolic blood pressure (mmHg)				
Mean (SD)	76.9 (11.4)	77.0 (12.3)	77.0 (11.9)	75.0 (11.1)
Missing	68 (3%)	269 (9%)	337 (7%)	158 (12%)
Body mass index (kg/m²)				
Mean (SD)	30.0 (6.5)	28.8 (6.4)	29.3 (6.5)	28.0 (7.0)
Missing	73 (4%)	272 (10%)	345 (7%)	160 (12%)
Laboratory measurements				
eGFR (mL/min/1.73m²)†				
Mean (SD)	35.2 (13.7)	30.9 (15.2)	32.8 (14.7)	36.0 (16.3)
On kidney failure replacement therapy	8 (<1%)	174 (6%)	182 (4%)	43 (3%)
<20	124 (6%)	580 (20%)	704 (14%)	170 (12%)
≥20 to <30	681 (33%)	761 (27%)	1442 (29%)	308 (23%)
≥30 to <45	858 (42%)	758 (27%)	1616 (33%)	408 (30%)
≥45	318 (16%)	341 (12%)	659 (13%)	285 (21%)
Missing	61 (3%)	227 (8%)	288 (6%)	148 (11%)
uACR (mg/g)†				
Geometric mean (approx SE)	249 (10)	313 (12)	283 (8)	356 (17)
Median (Q1-Q3)	320 (78-902)	391 (70-1232)	351 (73-1066)	445 (118-1204)
<30	237 (12%)	287 (10%)	524 (11%)	92 (7%)
≥30 to ≤300	639 (31%)	731 (26%)	1370 (28%)	364 (27%)
>300	911 (44%)	1201 (42%)	2112 (43%)	644 (47%)
Missing	255 (12%)	448 (16%)	703 (14%)	219 (16%)
Concomitant medication use				
RAS inhibitor	1775 (87%)	2137 (75%)	3912 (80%)	1087 (80%)
Any diuretic	497 (24%)	512 (18%)	1009 (21%)	264 (19%)
Any lipid-lowering medication	1460 (71%)	1893 (67%)	3353 (69%)	908 (67%)

	Characteristics of participants as they entered PTFU			Participants not known to have died at the end of active trial follow-up but did not enter PTFU (n=1362)
	Participants recorded as taking SGLT2i at last PTFU visit (n=2050)	Participants not recorded as taking SGLT2i at last PTFU visit (n=2841)	All participants (n=4891)	
Cause of kidney disease				
Diabetic kidney disease	583 (28%)	821 (29%)	1404 (29%)	472 (35%)
Hypertensive/renovascular disease	417 (20%)	708 (25%)	1125 (23%)	247 (18%)
Glomerular disease	604 (29%)	702 (25%)	1306 (27%)	342 (25%)
Other/unknown	446 (22%)	610 (21%)	1056 (22%)	301 (22%)
5 year predicted risk of kidney failure (%)‡				
Median (Q1-Q3) – overall	12 (5-30)	22 (5-63)	15 (5-45)	13 (3-41)
Median (Q1-Q3) – empagliflozin group	12 (5-28)	20 (5-61)	15 (5-42)	12 (3-28)
Median (Q1-Q3) – placebo group	12 (5-32)	23 (6-64)	16 (5-47)	14 (3-46)

Participants who died during the active trial period (n=317) or withdrew consent during the active trial period (n=39) not shown. Figures are n (%), mean (SD), geometric mean (approx SE) or median (Q1-Q3). eGFR=estimated glomerular filtration rate. uACR=urinary albumin-to-creatinine ratio. RAS=renin-angiotensin system.

* Prior diabetes mellitus defined as diabetes at randomization or incident diabetes reported during the trial. § Defined as self-reported history of myocardial infarction, heart failure, stroke, transient ischemic attack, or peripheral arterial disease, or incident myocardial infarction, heart failure, stroke, transient ischemic attack, or peripheral arterial disease reported during the active trial. † Uses central measurement taken at the final follow-up visit among those not on kidney replacement therapy at final follow-up visit. ‡ Not calculated for those already on kidney replacement therapy at final follow-up visit.

Median (Q1-Q3) 5-year predicted kidney failure risk (%) at randomization among those participants recorded as taking SGLT2i at last PTFU visit in empagilflozin group 7 (3-19) and placebo group 7 (2-17). Median (Q1-Q3) 5-year predicted kidney failure risk (%) at randomization among those participants who were not on an SGLT2i at last PTFU visit in empagilflozin group 13 (4-39) and placebo group 14 (4-42).

3 vs 4 participants allocated empagliflozin and placebo respectively were unblinded during the active trial period, and 15 vs 16 participants allocated empagliflozin and placebo respectively were unblinded prior to the end of PTFU.

Table S4: Use of RAS inhibitors and mineralocorticoid receptor antagonists over time

	Renin-angiotensin system inhibitor use		Mineralocorticoid receptor antagonist use	
	Empagliflozin	**Placebo**	**Empagliflozin**	**Placebo**
All participants	N=3304	N=3305	N=3304	N=3305
Active trial period				
12 months	2610/3164 (82%)	2608/3159 (83%)	195/3164 (6%)	233/3159 (7%)
24 months	1541/1884 (82%)	1545/1875 (82%)	119/1884 (6%)	147/1875 (8%)
36 months	273/326 (84%)	248/323 (77%)	19/326 (6%)	25/323 (8%)
Study average	82%	82%	6%	8%
Participants entering post-trial follow-up	N=2472	N=2419	N=2472	N=2419
Active trial period				
12 months	2025/2423 (84%)	1954/2363 (83%)	148/2423 (6%)	180/2363 (8%)
24 months	1220/1483 (82%)	1161/1417 (82%)	101/1483 (7%)	113/1417 (8%)
36 months	249/297 (84%)	225/289 (78%)	17/297 (6%)	24/289 (8%)
Study average	83%	82%	6%	8%
Post-trial period				
12 months	1525/2186 (70%)	1484/2147 (69%)	125/2186 (6%)	138/2147 (6%)
24 months	1582/2376 (67%)	1524/2312 (66%)	156/2376 (7%)	157/2312 (7%)
Study average	68%	68%	6%	7%

Active trial periods defined using 12, 24, and 36 months follow-up visit windows. Active trial period denominators are those known to be alive in each period. Post-trial periods defined using information nearest to 12 and 24 months since completion of active trial follow-up. Post-trial period denominators are those who joined post-trial follow-up, had a follow-up in the period and were known to be alive in the relevant period. Study average use calculated using weights proportional to the total person years at risk in each year.

Table S5: Effect of allocation to empagliflozin on components of primary outcome over the entirety of follow-up (i.e. combining active trial and post-trial follow-up periods)

	Empagliflozin (N=3304)		Placebo (N=3305)		
	Participants with event	**No. of events per 100 patient years**	**Participants with event**	**No. of events per 100 patient years**	**Hazard ratio (95% CI)**
Primary outcome: progression of kidney disease or death from CV causes	865 (26.2%)	8.4	1001 (30.3%)	10.0	0.79 (0.72-0.87)
End stage kidney disease (commencement of maintenance dialysis or receipt of kidney transplant)	296 (9.0%)	2.7	372 (11.3%)	3.5	0.74 (0.64-0.87)
Sustained decline in eGFR to <10ml/min/1.73m²	247 (7.5%)	2.2	300 (9.1%)	2.8	0.77 (0.65-0.91)
Renal death (i.e. death from kidney failure)	13 (0.4%)	0.1	10 (0.3%)	0.1	1.24 (0.54-2.84)
Sustained decline of ≥40% in eGFR from randomization	726 (22.0%)	7.0	828 (25.1%)	8.2	0.80 (0.72-0.88)
Death from cardiovascular cause	126 (3.8%)	1.1	162 (4.9%)	1.5	0.75 (0.59-0.95)

Presented analyses carry over the main results of the trial's primary outcome from the active trial period. A sensitivity analysis of the primary outcome analyses using only local estimated GFR measurements collected throughout the entire follow−up period which did not differentiate the active trial versus post−trial periods (i.e. the last locally−measured estimate GFR recorded during PTFU was considered to be a "sustained" decline) found: 842 (25.5%) vs 976 (29.5%); HR=0.79 (95% CI 0.72−0.86).

Table S6: Absolute benefits of allocation to empagliflozin on primary and secondary outcomes over the entirety of follow-up

	Absolute difference in number of events per 1000 patients allocated to empagliflozin			
	Kidney disease progression or CV death	**Kidney disease progression**	**Death from any cause or ESKD**	**ESKD**
Active trial period only				
End of year 1	12 (5)	11 (4)	0 (4)	0 (3)
End of year 2	43 (10)	42 (9)	19 (8)	17 (6)
End of active trial period (2.5 years)	57 (14)	56 (14)	25 (11)	26 (8)
Post-trial period only				
End of year 1	15 (8)	14 (7)	10 (7)	8 (6)
End of year 2	25 (13)	19 (13)	19 (10)	12 (9)
Active trial and post-trial periods combined				
End of year 1	12 (5)	11 (4)	0 (4)	0 (3)
End of year 2	41 (8)	39 (8)	18 (7)	16 (5)
End of year 3	52 (11)	48 (11)	29 (9)	26 (7)
End of year 4	45 (14)	44 (14)	32 (12)	25 (10)

CV=cardiovascular. ESKD=end-stage kidney disease (i.e. date of commencement of maintenance dialysis or receipt of a kidney transplant).