Header Text:	
Visit:	**Form:** Acute Coronary Syndrome Adjudication
Form Version: 27-Apr-2018 14:01	**Form Status:**
Site No:	**Site Name:**
Subject No:xxxxxx2	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Complete the Adjudication form for adverse events fulfilling criteria as an Acute Coronary Syndrome and collect copies of all of the below source documents and deliver them to the adjudication supplier as soon as possible.

1.	Seq. No.	
2.	Adverse event number(s) related to Acute Coronary Syndrome	
3.	Hospital Records (incl. Admission Notes, Emergency Room Notes, History and Physical examination findings)	
4.	ECG tracings (prior to event, during event, and following event resolution)	
5.	Cardiac biomarkers (troponin, CK-MB including units, date, time, and reference ranges)	
6.	Invasive Procedure reports (cardiac catheterisation, percutaneous coronary intervention, CABG)	
7.	Cardiology Consultation report	
8.	Imaging reports (MRI, CTA, echocardiogram, Nuclear Medicine etc.)	

Header Text:		
Visit:		**Form:** Acute Coronary Syndrome Adjudication
Form Version: 27-Apr-2018 14:01		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

9.	Procedure reports (stress tests and angiography etc.)	
10.	Discharge Summary (when not available, a clinical description of the event)	
11.	Other relevant information to document the Acute Coronary Syndrome (acute myocardial infarction or hospitalisation for unstable angina pectoris) event	
12.	Investigator clinical narrative *If all of the above documents are unable to obtain or not applicable, please create an investigator clinical narrative.* *Please refer to the Event Adjudication Site Manual for further instructions on creating an investigator clinical narrative*	

Header Text:		
Visit:		**Form:** Acute Coronary Syndrome Adjudication
Form Version: 27-Apr-2018 14:01		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

13.	Estimated date when all pending documents will be delivered to the adjudication supplier	Please specify date: ☐ / ☐ / ☐

Header Text:		
Visit:		**Form:** Acute Gallbladder Disease
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Instructions to Investigator: Complete an Acute Gallbladder Disease CRF for each Adverse Event of biliary colic, cholecystitis and other forms of acute gallbladder disease

1.	Acute Gallbladder Disease event number	☐
2.	Related adverse event number	☐
3.	Did the subject have any signs/symptoms present during the course of the event? *(If this was an incidental finding due to other examinations/health checks, tick no)*	○ Yes ☐ Abdominal pain ☐ Right upper quadrant ☐ Epigastric ☐ Other ☐ Nausea ☐ Vomiting ☐ Fever ☐ Jaundice/Icterus ☐ Murphy's sign ☐ Other ○ No

Header Text:		
Visit:		**Form:** Acute Gallbladder Disease
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

4.	Was imaging performed?	○ No ○ Yes ☐ Ultrasound ☐ CT scan ☐ MRI ☐ Endoscopic retrograde cholangiopancreatogram (ERCP) ☐ Other Primary indication for imaging ○ Suspicion of pancreatitis ○ Suspicion of gallbladder disease (including gallstones and cholecystitis) ○ Unspecific GI symptoms ○ Other Was imaging abnormal? ○ No ○ Yes ☐ Gallstone(s) in the gallbladder ☐ Gallstone(s) in the common bile duct ☐ Obstructive gallstone ☐ Imaging findings suspicious for acute cholecystitis ☐ Dilated common bile duct ☐ Other Specify: ○ Unknown

Header Text:		
Visit:		**Form:** Acute Gallbladder Disease
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

5.	Was any treatment(s) given for this condition? *Update concomitant medication as relevant*	○ No ○ Yes ☐ Antibiotics ☐ I.V. fluids ☐ Cholecystectomy ○ Elective surgery ○ Urgent surgery ☐ Endoscopic retrograde cholangiopancreatogram (ERCP) ☐ Shock wave lithotripsy ☐ Medication to dissolve stones ☐ Other
6.	Were there any relevant risk/confounding factors identified? *Medical events that the subject has experienced in the past should be recorded on the Medical History form*	○ No ○ Yes ☐ Family history of gallstones ☐ Prior experience of similar pain ☐ Gastric bypass surgery ☐ Disease in the terminal ileum (e.g. Crohn's disease) ☐ Resection of the terminal ileum ☐ Rapid weight loss ☐ Other ○ Unknown

Header Text:		
Visit:		**Form:** Acute Pancreatitis
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Acute pancreatitis event number	☐
2.	Related adverse event number	☐
3.	Did the subject have significant upper abdominal pain?	○ No ○ Yes
4.	Were other signs/symptoms present during the course of the event?	○ No ○ Yes ☐ Nausea ☐ Vomiting ☐ Fever ☐ Other ○ Unknown

Laboratory Tests

Provide available results at time of diagnosis, unless otherwise specified in the table below.

5.	Test	
	Test done?	○ Yes ○ No ○ Unknown
	Sample collection date	☐ / ☐ / ☐
	Result	☐ ☐
	Reference range *Use same units for reference range as the reported result*	Lower normal limit: ☐ Upper normal limit: ☐

Header Text:		
Visit:		**Form:** Acute Pancreatitis
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

6.	Was imaging performed?	○ No ○ Yes ☐ Ultrasound ☐ CT scan ☐ MRI ☐ Other Was imaging consistent with presence of gallstones? ○ No ○ Yes Was imaging consistent with acute pancreatitis? ○ No ○ Yes ☐ Obstructive gallstone ☐ Dilated common bile duct ☐ Peri-pancreatic fluid ☐ Oedematous or interstitial pancreatitis ☐ Necrotising pancreatitis ☐ Other Was imaging consistent with chronic pancreatitis? ○ No ○ Yes ☐ Calcification of pancreas ☐ Atrophy of the pancreas ☐ Dilatation of pancreatic ducts ☐ Pseudocysts ☐ Other ○ Unknown

Header Text:		
Visit:		**Form:** Acute Pancreatitis
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

7.	Were any acute complications present during the course of the event?	○ No ○ Yes ☐ Sepsis ☐ Gastrointestinal haemorrhage ☐ Respiratory failure requiring ventilation ☐ Renal failure requiring dialysis ☐ Other ○ Unknown
8.	What treatment(s) did the subject receive for this condition? *Standard treatment: e.g. pain killers, antibiotics, hospitalisation*	○ None ○ Standard treatment ○ Intensive care treatment ○ Other ○ Unknown
9.	Were there any relevant risk/confounding factors identified? *Medical events that the subject has experienced in the past should be recorded on the Medical History form*	○ No ○ Yes ☐ Prior history of pancreatitis ☐ Acute ☐ Chronic ☐ History of gallstones ☐ Alcohol consumption ☐ Family history of pancreatitis ☐ Hyper-triglyceridemia ☐ Tumour ☐ Trauma to the pancreas (incl. endoscopic retrograde cholangiopancreatography (ERCP)) ☐ Previous abdominal trauma (e.g. traffic accident) ☐ Hyper-calcaemia ☐ Other ○ Unknown

Header Text:		
Visit:		**Form:** Acute Pancreatitis Event Adjudication
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Complete the Adjudication form for adverse events fulfilling criteria as Acute Pancreatitis and collect copies of all of the below source documents and deliver them to the adjudication supplier as soon as possible.

1.	Seq. No.	
2.	Adverse event number(s) related to Acute Pancreatitis	
3.	Hospital Records (incl. Admission Notes, Emergency Room Notes, History and Physical examination findings)	
4.	Relevant laboratory findings (lipase, amylase, AST, ALT, ALP and bilirubin) date, time and reference ranges	
5.	Imaging description (ultrasound, CT or MRI scan)	
6.	Gastroenterologist Consultation notes and clinical description	
7.	Discharge Summary (when not available, a clinical description of the event)	
8.	Other relevant information to document the Acute Pancreatitis event	

Header Text:		
Visit:		**Form:** Acute Pancreatitis Event Adjudication
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

9.	Investigator clinical narrative *If all of the above documents are unable to obtain or not applicable, please create an investigator clinical narrative.* *Please refer to the Event Adjudication Site Manual for further instructions on creating an investigator clinical narrative*	
10.	Estimated date when all pending documents will be delivered to the adjudication supplier	Please specify date: [ ] / [ ] / [ ]

Header Text:		
Visit:		**Form:** Acute Renal Failure
Form Version: 27-Apr-2018 13:58		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

1.	Acute Renal failure number	
2.	Related adverse event number	
3.	How did this event present itself?	○ New onset of macroalbuminuria ○ Doubling of serum creatinine level from baseline and creatinine clearance per eGFR <= 45 mL/min/1.73m^2 ○ Acute Kidney Injury (AKI) ☐ Increase in serum creatinine >= 0.3 mg/dL within 48 hours ☐ Increase in serum creatinine to >= 1.5 times baseline within 7 days ☐ Urine volume < 0.5mL/kg/h for 6 hours ○ The need for dialysis - in the absence of an acute reversible condition ○ Other Specify:

Relevant laboratory tests (performed to confirm the event and/or its outcome)
Fill in results of any other relevant laboratory tests which have been performed. If multiple tests were done for the same parameter, list those you find most relevant to illustrate the clinical picture or dynamics of the condition (i.e. highest value seen, increase over time etc.)

4.	Assessment index number	
	Sample collection date	/ /

Header Text:		
Visit:		**Form:** Acute Renal Failure
Form Version: 27-Apr-2018 13:58		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

4. (Cont.)	Description of test	○ Blood urea nitrogen (BUN) ○ Serum creatinine ○ GFR by Cr-EDTA clearance ○ eGFR ○ MDRD method ○ CKD method ○ Cockroft-Gault formula ○ 24-hour urine creatinine clearance ○ Urine albumin ○ Random spot urine sample ○ First morning urine sample ○ Timed urine collection: ☐ hours ○ Urine protein ○ Random spot urine sample ○ First morning urine sample ○ Timed urine collection: ☐ hours ○ Urinary albumin/creatinine ratio (ACR) ○ Erythrocytes (urine dipstick) ○ Leukocytes (urine dipstick) ○ Albumin (urine dipstick)
	Result of Test *If numeric result: use same unit for reference range as the reported result.*	○ Numeric result ☐ ○ Unit ☐ ○ Other unit, specify: ☐ Lower normal limit: ☐ Upper normal limit: ☐ ○ Non-numeric result ☐

Header Text:	
Visit:	**Form:** Acute Renal Failure
Form Version: 27-Apr-2018 13:58	**Form Status:**
Site No:	**Site Name:**
Subject No:	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

Other relevant information (that confirms this event and/or its outcome, e.g. clearance methods)

5.	Sequence number	
	Date of information	/ /
	Additional information on event	

6.	Has the subject received any nephrotoxic agents within the last 3 months? *Update concomitant medication as relevant*	○ No ○ Yes ☐ Aminoglycoside(s) Specify: ☐ Nonsteroidal anti-inflammatory drug(s) (NSAIDs) Specify: ☐ IV contrast Specify: ☐ Initiation of a RAS blockade Specify: ☐ Other drug(s) potentially affecting urinary protein excretion or renal function Specify: ○ Unknown

Header Text:		
Visit:		**Form:** Acute Renal Failure
Form Version: 27-Apr-2018 13:58		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

7.	Was there evidence or suspicion of conditions which could explain or have contributed to the event? *Medical events that the subject has experienced in the past should be recorded on the Medical History form*	○ No ○ Yes ☐ Acute urinary tract infection ☐ Chronic urinary tract infection ☐ Post-renal obstructive disease ☐ Hypertension ☐ Recent decrease in renal perfusion due to volume depletion, decreased cardiac output or hypotension ☐ Progression of chronic renal impairment/nephropathy ☐ Primary glomerulonephritis ☐ Systemic autoimmune disease ☐ Recent streptococcal infection ☐ Renal artery stenosis ☐ Renal vein thrombosis ☐ Other Specify: ○ Unknown
8.	Was the diagnosis supported by imaging? *Renal angio-imaging e.g. angiography, angio-CT, angio-MRI*	○ No ○ Yes ☐ Ultrasound ☐ CT scan ☐ Renal angio-imaging ☐ Other Specify: ○ Unknown
9.	Was the diagnosis based on a kidney biopsy?	○ No ○ Yes Summary of histology results ○ Unknown
10.	Is there any family history of renal disease?	○ No ○ Yes Specify: ○ Unknown

Header Text:		
Visit:		**Form:** Adverse Events
Form Version: 27-Apr-2018 13:57		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Adverse event number	
2.	Onset date of adverse event	/ /
3.	Adverse event diagnosis (if known) or sign/symptom *Report only one sign/symptom per AE form*	
Please refer to the protocol for detailed instructions on reporting requirements and timelines for Serious Adverse Events (SAEs).		
4.	Is the adverse event serious? *If Yes, complete a SIF form.*	○ No ○ Yes Seriousness criteria: Death ○ No ○ Yes Was an autopsy performed/planned? ○ No ○ Yes Life-threatening ○ No ○ Yes In-patient hospitalisation/prolongation of existing hospitalisation ○ No ○ Yes Date of admission: / / Date of discharge: / / Persistent or significant disability/incapacity ○ No ○ Yes Congenital anomaly/birth defect ○ No ○ Yes Important medical event ○ No ○ Yes
5.	Severity	○ Mild ○ Moderate ○ Severe

Header Text:		
Visit:		**Form:** Adverse Events
Form Version: 27-Apr-2018 13:57		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

6.	Outcome of adverse event *If the adverse event has fatal outcome or if the sequelae meets a seriousness criterion, the adverse event must be reported as a serious adverse event by also completing a SIF form*	○ Recovered/resolved Date: [ ] / [ ] / [ ] ○ Recovering/resolving Date: [ ] / [ ] / [ ] ○ Recovered/resolved with sequelae Date: [ ] / [ ] / [ ] Describe sequelae [ ] ○ Not recovered/not resolved ○ Fatal Date: [ ] / [ ] / [ ] ○ Unknown
7.	Does this adverse event match one of the adverse event categories defined in the protocol? *AE categories refer to AEs requiring additional data collection or events for adjudication.* *If one of the AE categories is chosen, additional information is to be provided in dedicated form(s)*	○ No ○ Yes ○ Medication error ○ Acute coronary syndrome ○ Acute myocardial infarction ○ Hospitalisation for unstable angina pectoris ○ Cerebrovascular event ○ Stroke ○ Transient ischaemic attack ○ Heart failure ○ Heart failure hospitalisation ○ Urgent heart failure visit ○ Coronary artery revascularisation ○ Acute pancreatitis ○ Acute gallbladder disease ○ Malignant neoplasms ○ Hepatic event ○ Acute renal failure ○ Diabetic retinopathy

Header Text:	
Visit:	**Form:** Adverse Events
Form Version: 27-Apr-2018 13:57	**Form Status:**
Site No:	**Site Name:**
Subject No:	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

Trial Product Details

Action taken to trial product:
Drug interrupted means temporary discontinuation of trial product.
Drug withdrawn means permanent discontinuation of trial product.
Technical complaint: *If the adverse event is related to a technical complaint remember to complete a Technical Complaint Form*

8.		
	Trial Product	○ Semaglutide / Semaglutide Placebo
	Was trial product given prior to AE onset?	○ Yes ○ No
	Causality	○ Probable ○ Possible ○ Unlikely
	Action taken to trial product	○ Drug interrupted ○ Drug withdrawn ○ Dose reduced ○ Dose increased ○ Dose not changed ○ Unknown ○ N/A
	Is the AE related to a technical complaint? If yes, fill in the Technical Complaint form.	○ No ○ Yes

Header Text:		
Visit:		**Form:** Body measurements
Form Version: 27-Apr-2018 13:57		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Body weight *(without shoes, on an empty bladder and only wearing light clothing)*	☐ ○ kg ○ lb
2.	Waist circumference *(In standing position)*	☐ ○ cm ○ in

Header Text:		
Visit:		**Form:** Body Measurements 1
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Height *(without shoes)*	☐ ○ cm ○ in
2.	Body weight *(without shoes, on an empty bladder and only wearing light clothing)*	☐ ○ kg ○ lb
3.	BMI (calculated)	☐ kg/m2
4.	Waist circumference *(In standing position)*	☐ ○ cm ○ in

Header Text:		
Visit:		**Form:** Body Measurements 3
Form Version: 27-Apr-2018 13:56		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Body weight *(Without shoes, on an empty bladder and only wearing light clothing)*	☐ ○ kg ○ lb

Header Text:		
Visit:		**Form:** Breast Neoplasms FU
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Please ensure to assess whether any information reported below should be reported as an AE.

1.	Has the subject had any imaging of the breast(s) performed since visit 1? *Imaging includes mammogram* If Yes, submit and then Add Entry to specify details below	○ No ○ Yes

If Yes is answered to the question above, fill in details below for each mammogram/other imaging modalities of the breast(s) performed since visit 1.

2.	Seq. No.	
	Date	/ /
	Reason for imaging of the breast(s) Imaging includes mammogram	○ As a part of a screening procedure (asymptomatic) ○ Diagnostic (to investigate a finding) ○ Surveillance (follow up on previous finding) ○ Other

Header Text:		
Visit:		**Form:** Breast Neoplasms FU
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

2. (Cont.)	Outcome *Any neoplasms that the subject has had diagnosed should be recorded on the Adverse Events form and for malignant neoplasms the Malignant Neoplasm form should be completed as well.* • *Normal is no signs of disease* • *Abnormal is signs suggesting neoplasia* • *Indeterminate: possible indication of dysplasia/abnormal growth* • *Other if another diagnosis is suspected*	○ Normal ○ Abnormal ○ Indeterminate ○ Other

Header Text:	
Visit:	**Form:** Breast Neoplasms FU
Form Version: 27-Apr-2018 13:58	**Form Status:**
Site No:	**Site Name:**
Subject No:	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Please ensure to assess whether any information reported below should be reported as an AE.

1.	Has the subject had any imaging of the breast(s) performed since visit 24? *Imaging includes mammogram* If Yes, submit and then Add Entry to specify details below	○ No ○ Yes

If Yes is answered to the question above, fill in details below for each mammogram/other imaging modalities of the breast(s) performed since visit 24.

2.	Seq. No.	
	Date	/ /
	Reason for imaging of the breast(s) *Imaging includes mammogram*	○ As a part of a screening procedure (asymptomatic) ○ Diagnostic (to investigate a finding) ○ Surveillance (follow up on previous finding) ○ Other

Header Text:		
Visit:		**Form:** Breast Neoplasms FU
Form Version: 27-Apr-2018 13:58		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

2. (Cont.)	Outcome *Any neoplasms that the subject has had diagnosed should be recorded on the Adverse Events form and for malignant neoplasms the Malignant Neoplasm form should be completed as well.* • *Normal is no signs of disease* • *Abnormal is signs suggesting neoplasia* • *Indeterminate: possible indication of dysplasia/abnormal growth* • *Other if another diagnosis is suspected*	○ Normal ○ Abnormal ○ Indeterminate ○ Other

Header Text:		
Visit:		**Form:** Case Book Sign Off
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Is the casebook ready for sign off?	☐

Header Text:		
Visit:		**Form:** Cerebrovascular Event Adjudication
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Complete the Adjudication form for adverse events fulfilling criteria as a Cerebrovascular event and collect copies of all of the below source documents and deliver them to the adjudication supplier as soon as possible.

1.	Seq. No.	
2.	Adverse event number(s) related to Cerebrovascular event	
3.	Hospital Records (incl. Admission Notes, History and Emergency Room Records) and Physical examination	
4.	Brain imaging reports (Brain CT, Brain MRI, Carotid ultrasound, Cerebral angiography)	
5.	Neurological or neurosurgical consult notes	
6.	Discharge Summary (when not available, a clinical description of the event)	
7.	Lumbar puncture findings	
8.	Other relevant information to document the cerebrovascular event	

Header Text:		
Visit:		**Form:** Cerebrovascular Event Adjudication
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

9.	Investigator clinical narrative *If all of the above documents are unable to obtain or not applicable, please create an investigator clinical narrative.* *Please refer to the Event Adjudication Site Manual for further instructions on creating an investigator clinical narrative*	
10.	Estimated date when all pending documents will be delivered to the adjudication supplier	Please specify date: [ ] / [ ] / [ ]

Header Text:		
Visit:		**Form:** Childbearing Potential
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Is the subject of childbearing potential?	○ Yes ○ No

Header Text:		
Visit:		**Form:** Collection of Samples for Laboratory
Form Version: 27-Apr-2018 13:56		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Collect samples following the procedures detailed in the laboratory manual.

When results are received, sign and date all pages and file with the subjects notes. For all values outside the normal range, indicate on the lab report whether they are **Clinically Significant (CS) or Not Clinically Significant (NS).**

1.	Have all samples been taken? (Excluding biosamples for future analysis)	○ Yes ○ No, comment

Header Text:		
Visit:		**Form:** Collection of Samples for Laboratory
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Collect samples following the procedures detailed in the laboratory manual.

When results are received, sign and date all pages and file with the subjects notes. For all values outside the normal range, indicate on the lab report whether they are **Clinically Significant (CS) or Not Clinically Significant (NS).**

1.	Have all samples been taken? (Excluding biosamples for future analysis)	○ Yes ○ No, comment

Biosamples for future analysis

2.	Have biosamples for future analysis been taken?	○ Yes ○ No, comment:

Header Text:		
Visit:		**Form:** Colon Neoplasms FU
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Please ensure to assess whether any information reported below should be reported as an AE.

1.	Has the subject had an endoscopic examination of the colon performed since visit 1? If Yes, submit and then Add Entry to specify details below	○ No ○ Yes

If Yes is answered to the question above, fill in details below for each endoscopic examination performed since visit 1.

2.	Seq. No.	
	Reason for endoscopic examination of the colon	○ As a part of a screening procedure (asymptomatic) ○ Diagnostic (to investigate a finding) ○ Surveillance (follow up on previous finding) ○ Other

Header Text:		
Visit:		**Form:** Colon Neoplasms FU
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

2. (Cont.)	Outcome *Any neoplasms that the subject has had diagnosed should be recorded on the Adverse Events form, and if applicable Malignant Neoplasm form.* • *Normal is no signs of disease* • *Abnormal is signs suggesting neoplasia* • *Indeterminate: possible indication of dysplasia/abnormal growth* • *Other if another diagnosis is suspected*	○ Normal ○ Abnormal ○ Indeterminate ○ Other

Header Text:		
Visit:		**Form:** Colon Neoplasms FU
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Please ensure to assess whether any information reported below should be reported as an AE.

1.	Has the subject had an endoscopic examination of the colon performed since visit 24? If Yes, submit and then Add Entry to specify details below	○ No ○ Yes

If Yes is answered to the question above, fill in details below for each endoscopic examination performed since **visit 24**?

2.	Seq. No.	
	Reason for endoscopic examination of the colon	○ As a part of a screening procedure (asymptomatic) ○ Diagnostic (to investigate a finding) ○ Surveillance (follow up on previous finding) ○ Other

Header Text:		
Visit:		**Form:** Colon Neoplasms FU
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

2. (Cont.)	Outcome *Any neoplasms that the subject has had diagnosed should be recorded on the Adverse Events form, and if applicable Malignant Neoplasm form.* • *Normal is no signs of disease* • *Abnormal is signs suggesting neoplasia* • *Indeterminate: possible indication of dysplasia/abnormal growth* • *Other if another diagnosis is suspected*	○ Normal ○ Abnormal ○ Indeterminate ○ Other

Header Text:		
Visit:		**Form:** Comorbidities
Form Version: 27-Apr-2018 14:01		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

If response to any of the questions below is yes, remember to record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).

Does the subject currently have any of the following conditions/illnesses:

Cardiovascular and Metabolic Disorders		
1.	Dyslipidaemia	○ No ○ Yes ○ Unknown
2.	Hypertension	○ No ○ Yes ○ Unknown
3.	Coronary artery disease	○ No ○ Yes ○ Unknown
4.	Cerebrovascular disease	○ No ○ Yes ○ Unknown
5.	Obstructive sleep apnoea	○ No ○ Yes ○ Unknown
Reproductive system		
6.	Menstrual disorder (females only)	○ No ○ Yes ○ Unknown ○ N/A
7.	Polycystic Ovarian Syndrome (females only)	○ No ○ Yes ○ Unknown ○ N/A
8.	Involuntary impaired fertility/infertility (both males and females)	○ No ○ Yes ○ Unknown
Liver and kidney diseases		

Header Text:		
Visit:		**Form:** Comorbidities
Form Version: 27-Apr-2018 14:01		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

9.	Non-Alcoholic Fatty Liver Disease	○ No ○ Yes ○ Unknown
10.	Non-Alcoholic Steatohepatitis (biopsy-confirmed)	○ No ○ Yes ○ Unknown
11.	Kidney disease	○ No ○ Yes ○ Unknown
12.	Obesity-related kidney disease (Based on proteinuria, glomerular hypertrophy and focal segmental glomerulosclerosis. Diabetic nephropathy or hypertensive nephrosclerosis must be excluded)	○ No ○ Yes ○ Unknown
Musculoskeletal system		
13.	Symptomatic osteoarthritis of the knee	○ No ○ Yes ○ Unknown
14.	Symptomatic osteoarthritis of the hip	○ No ○ Yes ○ Unknown
15.	Hyperuricaemia/Gout	○ No ○ Yes ○ Unknown
Other		

Header Text:		
Visit:		**Form:** Comorbidities
Form Version: 27-Apr-2018 14:01		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

16.	Currently treated with medication for thyroid disease	○ No ○ Yes ○ Unknown
17.	Asthma/Chronic Obstructive Pulmonary Disease	○ No ○ Yes ○ Unknown

Header Text:		
Visit:		**Form:** Concomitant Medication
Form Version: 27-Apr-2018 13:56		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Seq. No.	
2.	Generic or Trade name	
3.	Start date	/ /
4.	Continuing?	○ Yes ○ No, Stop date / /
5.	Rescue medication *(If rescue criteria of FPG value exceeding 15 mmol/L (270 mg/dL) is met)*	○ Yes ○ No
6.	Class of medication	○ Anti-hypertensives ○ Lipid lowering agents ○ Oral antidiabetic drug (OAD) ○ Other
7.	Total Daily Dose *This field is mandatory for anti-hypertensives, lipid-lowering drugs and, OADs*	Unit ○ mg ○ g ○ Other unit, specify:

Header Text:		
Visit:		**Form:** Concomitant Medication
Form Version: 27-Apr-2018 13:56		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

8.	Primary Indication *Remember to fill in/update in the Concomitant Illness/Medical History form, if applicable, or to fill in an Adverse Event form for which the concomitant medication is administered*	○ Adverse Event, enter Adverse Event no. ☐ ○ Medical History/Concomitant Illness, enter seq. no. ☐ ○ Diabetes history/diabetes complications ○ Other, specify: ☐

Header Text:		
Visit:		**Form:** Concomitant Specific Drug
Form Version: 27-Apr-2018 13:57		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID: NNXXXX-XXXX		
1.	Seq. No.	
2.	Generic or Trade name	
3.	Start date	/ /
4.	Continuing?	○ Yes ○ No, Stop date / /
5.	Total Daily Dose	Unit ○ mg ○ mL ○ ug ○ g ○ U ○ IU ○ Unit 1 ○ Unit 2 ○ Other unit, specify:

Header Text:	
Visit:	**Form:** Coronary Artery Revascularisation
Form Version: 27-Apr-2018 13:58	**Form Status:**
Site No:	**Site Name:**
Subject No:	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Complete the Adjudication form for adverse events fulfilling criteria as a Coronary Artery Revascularisation and collect copies of all of the below source documents and deliver them to the adjudication supplier as soon as possible.

1.	Seq. No.	
2.	Adverse event number(s) related to Coronary Artery Revascularisation	
3.	Procedure/Operative reports (cardiac catheterisation, percutaneous coronary intervention, CABG)	
4.	Hospital Records (incl. Admission Notes, Emergency Room Notes, History and Physical examination findings)	
5.	ECG Tracings (prior to procedure and following procedure)	
6.	Cardiac biomarkers (troponin, CK-MB including units, date, time, and reference ranges [prior to procedure and following procedure, if done])	
7.	Cardiology Consultation and Surgery Notes	
8.	Discharge Summary (when not available, a clinical description of the event)	

Header Text:		
Visit:		**Form:** Coronary Artery Revascularisation
Form Version: 27-Apr-2018 13:58		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

9.	Other relevant information to document coronary artery revascularisation	
10.	Investigator clinical narrative *If all of the above documents are unable to obtain or not applicable, please create an investigator clinical narrative.* *Please refer to the Event Adjudication Site Manual for further instructions on creating an investigator clinical narrative*	
11.	Estimated date when all pending documents will be delivered to the adjudication supplier	Please specify date: / /

Header Text:		
Visit:		**Form:** Death Event Adjudication
Form Version: 27-Apr-2018 13:59		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

8.	Investigator clinical narrative *If all of the above documents are unable to obtain or not applicable, please create an investigator clinical narrative.* *Please refer to the Event Adjudication Site Manual for further instructions on creating an investigator clinical narrative*	
9.	Estimated date when all pending documents will be delivered to the adjudication supplier	Please specify date: [ ] / [ ] / [ ]

Header Text:		
Visit:		**Form:** Diabetes History/Diabetes Complications
Form Version: 27-Apr-2018 13:55		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Diagnosis of Diabetes

Diabetes Mellitus should not be recorded as Medical History in the Medical History/Concomitant Illness form.

1.	Date of diagnosis of type 2 diabetes	/ /

Diabetes Complications
Has the subject been diagnosed with any of the following diabetes complications?

The below complications should not be recorded as Medical History in the Medical History/Concomitant Illness form.

Any other diabetes complications should be recorded in the Medical History/Concomitant Illness form.

2.	Diabetic retinopathy	○ No ○ Yes, Date of onset: / / Further description of the complication, if applicable:
3.	Diabetic neuropathy	○ No ○ Yes, Date of onset: / / Further description of the complication, if applicable:
4.	Diabetic nephropathy	○ No ○ Yes, Date of onset: / / Further description of the complication, if applicable:
5.	Macroangiopathy (including peripheral vascular disease)	○ No ○ Yes, Date of onset: / / Further description of the complication, if applicable:

Header Text:	
Visit:	**Form:** Diabetic Retinopathy
Form Version: 27-Apr-2018 14:03	**Form Status:**
Site No:	**Site Name:**
Subject No:	**Subject Initials:**
Generated By: CRFAdmin	**Generated Time (GMT):** 24-Mar-2020 18:39

5.	What treatment(s) did the subject receive for this event? *Update concomitant medication as relevant*	**Right eye** ☐ Observation (i.e. no treatment given) ☐ Focal laser treatment/photocoagulation for macular oedema ☐ Scatter laser treatment/panretinal photocoagulation (PRP) for proliferative diabetic retinopathy ☐ Anti-VEGF intravitreal agent ☐ Vitrectomy ☐ Other Specify: **Left eye** ☐ Observation (i.e. no treatment given) ☐ Focal laser treatment/photocoagulation for macular oedema ☐ Scatter laser treatment/panretinal photocoagulation (PRP) for proliferative diabetic retinopathy ☐ Anti-VEGF intravitreal agent ☐ Vitrectomy ☐ Other Specify:

Eye examination results

6.	Eye	○ Left Eye ○ Right Eye
	Diabetic retinopathy present? *If only microaneurysms, select 'No'*	○ No ○ Yes ○ Mild non-proliferative diabetic retinopathy ○ Moderate-severe non-proliferative diabetic retinopathy ○ Proliferative diabetic retinopathy

Header Text:		
Visit:		**Form:** Diabetic Retinopathy
Form Version: 27-Apr-2018 14:03		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

6. (Cont.)	Other condition(s) identified?	○ No ○ Yes ☐ Vitreous haemorrhage ☐ Traction retinal detachment ☐ Neovascular glaucoma ☐ Cataract ☐ Other eye disease Specify:
	Diabetic macular oedema present?	○ No ○ Yes ○ Unknown
	Best corrected visual acuity impaired	○ No ○ Yes Specify best corrected visual acuity: ○ Mildly impaired visual acuity (e.g. Snellen ≥ 6/12 [20/40]) ○ Moderately impaired visual acuity (e.g. Snellen < 6/12 [20/40]) ○ Severely impaired visual acuity (e.g. Snellen ≤ 6/60 [20/200]) ○ Unknown

Header Text:

Visit: **Form:** Diabetic Retinopathy History

Form Version: 27-Apr-2018 13:59 **Form Status:**

Site No: **Site Name:**

Subject No: **Subject Initials:**

Generated By: CRFAdmin **Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

1.	Eye	○ Right eye ○ Left eye
	Diabetic retinopathy	○ No ○ Yes
	Type of diabetic retinopathy	○ Nonproliferative ○ Proliferative ○ Unknown
	Has the subject had diabetic macular oedema?	○ No ○ Yes ○ Unknown
	Has any treatment been given for diabetic retinopathy?	☐ Laser treatment/photocoagulation ○ No ○ Yes ○ Unknown ☐ Intravitreal agents ○ No ○ Yes ○ Unknown ☐ Vitrectomy ○ No ○ Yes ○ Unknown ☐ Other ○ No ○ Yes, Specify ○ Unknown

Header Text:		
Visit:		**Form:** History of Gallbladder Disease
Form Version: 27-Apr-2018 14:02		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:

Any history of gallbladder disease other than listed below should be recorded on the Medical History form.

1.	Does the subject have a history of gallbladder disease?	○ No ○ Yes ☐ Cholelithiasis (gallstones in the gallbladder or in the bile ducts) Calendar year of most recent event? ____ ☐ Cholecystitis (inflammation of the gallbladder) Calendar year of most recent event? ____ ☐ Biliary colic/pain Calendar year of most recent event? ____ ☐ Other Calendar year of most recent event? ____ ○ Unknown
2.	Has a cholecystectomy been performed?	○ No ○ Yes ○ Unknown

APQS=AP Questionnaire

QSCAT=TB-CGHD-P

TB-CGHD-P *(Repeatable)*

Protocol	
Protocol [Protocol] **NOT SUBMITTED**	Code List: Protocol <Unspecified Protocol> [-9999] [redacted] [1]

Header	
Site Number [SiteCode]	Free Entry - Text **NOT SUBMITTED**
Site Number [DomainSiteCode]	Free Entry - Text **NOT SUBMITTED**
Subject ID [PatientID]	Free Entry - Text **NOT SUBMITTED**
Subject Initials [Initials]	Free Entry - Text **NOT SUBMITTED**

Form Level Data	
Report date [ReportDate]	Date **QSDTC**
Report start date and time [ReportStartDate]	DateTime
Comments are present in the audit trail when box is checked [HasComments]	Boolean **NOT SUBMITTED**
SitePad Report ID [SitePadReportID]	Free Entry - Integer **NOT SUBMITTED**

TBCGHDP	
In the past week, how much did you worry about: Causing your child pain when giving the injection - TBCGHD1L [TBCGHD1L] **QSORRES when QSTESTCD=TBCP0201**	Code List: TBCGHDP1 Not at all [0] A little [1] Somewhat [2] A lot [3] Extremely [4]
In the past week, how much did you worry about: Remembering to give the injection - TBCGHD2L [TBCGHD2L] **QSORRES when QSTESTCD=TBCP0202**	Code List: TBCGHDP1 Not at all [0] A little [1] Somewhat [2] A lot [3] Extremely [4]
In the past week, how much did you worry about: Doing the injection correctly - TBCGHD3L [TBCGHD3L] **QSORRES when QSTESTCD=TBCP0203**	Code List: TBCGHDP1 Not at all [0] A little [1] Somewhat [2] A lot [3] Extremely [4]
In the past week, how often did you feel: Frustrated with your child's behavior related to the injection - TBCGHD4L [TBCGHD4L] **QSORRES when QSTESTCD=TBCP0204**	Code List: TBCGHDP2 Never [0] Rarely [1] Sometimes [2] Often [3] All of the time [4]

TBCGHDP	
In the past week, how often did you feel: Sad about your child needing injections - TBCGH5L [TBCGHD5L] QSORRES when QSTESTCD=TBCP0205	Code List: TBCGHDP2 Never [0] Rarely [1] Sometimes [2] Often [3] All of the time [4]
In the past week, how often did your child's treatment interfere with your: Social life (for example going out in the evening) - TBCGHD6L [TBCGHD6L] QSORRES when QSTESTCD=TBCP0206	Code List: TBCGHDP2 Never [0] Rarely [1] Sometimes [2] Often [3] All of the time [4]
In the past week, how often did your child's treatment interfere with your: Travel plans and vacations - TBCGHD7L [TBCGHD7L] QSORRES when QSTESTCD=TBCP0207	Code List: TBCGHDP2 Never [0] Rarely [1] Sometimes [2] Often [3] All of the time [4]
In the past week, how often did your child's treatment interfere with your: Daily routine - TBCGHD8L [TBCGHD8L] QSORRES when QSTESTCD=TBCP0208	Code List: TBCGHDP2 Never [0] Rarely [1] Sometimes [2] Often [3] All of the time [4]
Respondent's role - RSPCAT1L [RSPCAT1L] NOT SUBMITTED	Code List: RSPCAT1L Caregiver [1] Subject [2]
Visit - VST1L [VST1L] NOT SUBMITTED	Code List: VST1L Visit 5 [10] Visit 7 [20]

Caregiver Submit	
Caregiver [IsCaregiver] NOT SUBMITTED	Boolean
LPA Role (LPARole) [LPARole] NOT SUBMITTED	Code List: LPARole Patient [0] Site User [1] Site Administrator [2] Caregiver [3]

LogPad/SitePad Performance	
Percentage of battery remaining [BatteryLevel]	Integer NOT SUBMITTED
Seconds of modem activity during previous transmission [ModemSeconds]	Free Entry - Integer NOT SUBMITTED
Device Identification [DeviceID]	Free Entry - Integer NOT SUBMITTED
Device version number [LPVersion]	Free Entry - Text NOT SUBMITTED
Device Start Time (in UTC)* *The LogPad Start Time indicates when the device that	DateTime NOT SUBMITTED

Header Text:		
Visit:		**Form:** Treatment Discontinuation Criteria
Form Version: 27-Apr-2018 14:00		**Form Status:**
Site No:		**Site Name:**
Subject No:		**Subject Initials:**
Generated By: CRFAdmin		**Generated Time (GMT):** 24-Mar-2020 18:39

Trial ID:		
1.	Did the subject fulfil any of the treatment discontinuation criteria?	○ No ◉ Yes Discontinuation of trial treatment due to: ☐ Included in the trial in violation of the inclusion and/or exclusion criteria and/or randomisation criteria ☐ Safety concern as judged by the investigator ☐ Calcitonin >/= 100 ng/L ☐ Suspicion of pancreatitis ☐ Pregnancy ☐ Intention of becoming pregnant ☐ Simultaneous participation in another clinical trial of an approved or non-approved investigational medicinal product