STARRT-AKI Data Management

Full Study Name:	STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre, Randomized, Controlled Trial
Short Study Name:	STARRT-AKI
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1. INTRODUCTION

The purpose of this document is to outline the measures taken by the Lead PIs and the Central Coordinating Centre for the STARRT-AKI study to ensure that the data collected for the trial is accurate and complete. This document will provide an overview of the three different methods utilized to ensure data quality and completeness with details on the objective of each of these methods and the specific activities performed.

a. Data management reports run on a periodic basis by central coordination team
b. Remote monitoring activities
c. Site Investigator closeout statement

2. DATA MANAGEMENT REPORTS

2.1 Objective of the Data Management Reports

This section provides a list of study-specific data management reports that are run periodically by the Data Manager and Project Lead to ensure data quality and completeness. The data quality checks described throughout this section are intended to look for:

a. Missing data
b. Inconsistent data (i.e. inconsistent information entered between two separate forms)
c. Data outliers
d. Protocol violations

Section 2.2 (2.1.1-2.1.15) outlines the details of each of the study-specific reports, along with the variables checked, report description, and frequency of each data quality check.

2.2 List of Data Management Reports

2.2.1 Eligibility Criteria

Variables: Inclusion criteria (1-4iii); exclusion criteria (1-10); according to the screening criteria entered, is the patient fully eligible for the trial?

Description: This check is performed to ensure that the eligibility criteria form is completed correctly for all patients randomized into the trial.
Manual and automated queries are raised if:

- Response to an inclusion criteria is *No*
  Note: an exception to this is inclusion criteria 4, where only one of the criteria 4i-iii need to be met
- Response to an exclusion criteria is *Yes*

Frequency: Ongoing: Manual checks are performed on an ongoing basis by the Data Manager prior to locking the data for each patient
3 months: Project Lead runs J review data listing report to identify any data

entry errors that might have been missed by Data Manager during the manual check

Checked by: Data Manager, Project Lead

2.2.2 Informed Consent

Variables: Was consent ultimately obtained from the patient to continue participation in STARRT-AKI post-randomization?

Description: For patients that are randomized using a deferred/delayed consent model or SDM consent model, this check ensures that:

- appropriate measures were taken to obtain patient's consent to continue participation in the study post-randomization; and
- if the site was unable to obtain patient's consent post-randomization, an appropriate reason is entered on the database for not obtaining patient's consent

Frequency: Reviewed as needed once patient's final outcome is entered

Checked by: Data Manager

2.2.3 Randomization

Variables: Do you wish to randomize this patient into the study?; Is this patient randomized in the PLUS study; Randomization group; Local randomization date and time

Description: The following checks are performed on the randomization form to ensure that it was completed correctly and that patient was randomized into the trial:

- *Do you wish to randomize this patient into the study?* is answered as *Yes*
- *Is this patient randomized in the PLUS study?* is NOT left blank and is answered using the appropriate radio button options
- *Local date and time of randomization* is entered for sites that are NOT located in the eastern time zone, and the time entered is consistent with the randomization date and time auto-generated by RAVE

Frequency: Ongoing: Manual checks are performed on an ongoing basis by Data Manager prior to locking each patient

3 months: Project Lead runs J review data listing report to identify any data entry errors that might have been missed by Data Manager during manual check

Checked by: Data Manager, Project Lead

2.2.4 Sequence of Events

Variables: ICU admission date and time; provisional eligibility date and time; full eligibility date and time; informed consent date and time; randomization date and time; RRT initiation date and time

Description: This report ensures that the study procedures were carried out in the following order:

- ICU admission → provisional eligibility → full eligibility → informed consent → randomization → RRT initiation

Report has been programmed using SAS Function and flags patient IDs where the sequence of events described above did not occur in the appropriate order.

- For example, the report will flag if a patient has an *ICU admission date and*

time which falls AFTER the *eligibility date and time* or an *RRT initiation date which* falls BEFORE the patient was declared fully eligible or randomized into the study

Note: Study Coordinators at some sites have stated that at times they work simultaneously between assessing patient's eligibility and obtaining consent, as such we often find the consent date and time falls a few minutes prior to eligibility date and time. In such cases, manual queries are raised to confirm that the date and time entered is correct and these queries are closed upon receipt of confirmation from the site.

Frequency: Monthly

Checked by: Data Manager, Project Lead

2.2.5 Daily Data

Variables: Last date of daily assessment; ICU discharge date; date of death

Description: This report is programmed to ensure that the daily data was collected as per the timeline specified in the study protocol. As per the protocol, daily data should be collected for 14 days post-randomization **OR** until the patient has been discharged from the study ICU (whichever comes first). As such, checks are performed on the variables listed above to ensure that:

- If a patient is alive at ICU discharge and is discharged within 14 days post-randomization, their *last date of daily assessment* is the same as *ICU discharge date*
- If a patient is deceased prior to ICU discharge and within 14 days post-randomization, their *last date of daily assessment* is the same as the *date of death*

This report has been programmed using SAS Function

Frequency: Monthly

Checked by: Data Manager, Project Lead

2.2.6 Protocol Violations related to RRT Initiation

Variables: Full eligibility date and time; RRT initiation date and time

Description: As per the study protocol, RRT initiation must take place within a specified time interval from full eligibility confirmation depending on which group the patient was randomized to.

- Accelerated randomization group: Report flags patients that: a) do not have an *RRT initiation date and time* entered and b) have an *RRT initiation date and time* entered which is AFTER 12 hours from *full eligibility date and time*
- Standard randomization group: Report flags patients that have an *RRT initiation date and time* entered which is within 12 hours from *full eligibility date and time*

This report is programmed using a Python code.

Frequency: Monthly

Checked by: Project Lead

2.2.7 Protocol Violations regarding timing of RRT Initiation Form

Variables: Was RRT initiated within the specified time intervals mandated by the protocol?
Description: Manual check is performed to ensure that the protocol violations form is completed ONLY for patients that are flagged in the above mentioned report (2.6) and appropriate reasoning is entered on the database where a protocol violation related to timing of RRT initiation has occurred.
Frequency: Monthly
Checked by: Data Manager, Project Lead

2.2.8 Protocol Violations related to Randomization

Variables: Full eligibility date and time; Randomization date and time; Local randomization date and time
Description: As per the study protocol, randomization must take place within 12 hours from full eligibility confirmation. This report flags patients that have a *randomization date and time* which is 12 hours AFTER the *full eligibility date and time*.
This report is programmed using a Python code.
Frequency: Monthly
Checked by: Project Lead

2.2.9 Hospital Discharge Data

Variables: RRT and vascular access (daily data); Date of last RRT in hospital
Description: For patients that are discharged from the ICU and hospital on the same day and within 14 days post-randomization, this manual check ensures that the *date of last RRT in hospital* entered is consistent with RRT and vascular access information entered in daily data.
Frequency: Manual check performed on an ongoing basis by Data Manager
Checked by: Data Manager

2.2.10 Resource Utilization through Day 28 & Hospital Re-Admissions

Variables: Was patient re-admitted to hospital between day 28 and day 90?
Description:
- For patients that are deceased between day 28 and day 90 and were not re-admitted to the hospital in between day 28 and day 90, this manual check ensures that the patient is NOT indicated to have been re-admitted to hospital.
- For patients that are alive and are indicated to have been re-admitted to hospital between day 28 and day 90, this manual check ensures that data is entered in Hospital Re-admissions form to ensure consistency.

Frequency: Manual check performed on an ongoing basis by Data Manager
Checked by: Data Manager

2.2.11 Resource Utilization through Day 28 & ICU Discharge Data/ICU Re-Admissions

Variables: Number of ICU days; ICU Discharge Date; Was patient re-admitted to ICU?
Description:
- For patients that are alive at ICU discharge and were not re-admitted to ICU during the index hospitalization, this check ensures that the difference between ICU discharge date and randomization date is aligned with the

number of ICU days entered
- A difference of 1 day is acceptable in this scenario given that sites may have calculated the number of ICU days based on local cutoffs for counting ICU days

Frequency: Manual check performed on an ongoing basis by Data Manager; J review reports generated to identify any errors that may have been missed during ongoing review

Checked by: Data Manager

2.1.12 Resource Utilization through Day 28

Variables: Number of ICU days; Number of Mechanical Ventilation Days; Number of Vasoactive Therapy Days; Death Date

Description:
- For patients that are deceased within 28 days from randomization, this check ensures that the number of days entered in resource utilization through day 28 form does NOT exceed the difference between the death date and randomization date

Frequency: Report ran prior to database lock for final check

Checked by: Data Manager

2.2.13 Adverse Events

Variables: Adverse event onset date; How was the event related to study procedures?

Description: Check to ensure that:
- The event entered is related to study procedures;
- The event entered occurred during the patient's ICU admission or within 14 days following randomization

Frequency: Monthly

Checked by: Data Manager

2.2.14 Day 90 Outcomes

Variables: Day 90 vital status (primary outcome)

Description: Check to ensure that the day 90 *vital status* is entered in correct field. This check is performed manually from the front end of the database by the Data Manager, as well as through J Review reports on Medidata RAVE

Frequency: Ongoing: Manual check is performed on an ongoing basis by the Data Manager
3 months: J review data listing report is run every 3 months by Project Lead for any errors that might have been missed during manual checks

Checked by: Data Manager, Project Lead

2.2.15 Study completion

Variables: Study completion date; day 90 vital status; date of death

Description: Check to ensure that the information entered for patient's completion of the study is consistent with the information entered on the day 90 outcome data:
- For patients that are alive: manual check is performed to ensure that the *study completion date* is consistent with day 90 window
- For patients that are deceased: manual check is performed to ensure

that the *study completion date* is consistent with *date of death*

- For patients who did not complete the full study follow up to 90 days (i.e. lost to follow up/consent withdrawal): manual check is performed to ensure that the information entered in study completion form is consistent with data entered in day 90 outcome. In addition, AHRC team (or Regional Coordinating Centre) also follows up with sites with respect to patients that are lost to follow up to ensure that necessary means to retrieve patients' vital status at day 90 are carried out.

Frequency: Ongoing: Manual check is performed on an ongoing basis by Data Manager
3 months or upon request by PIs/Sponsors: J review data listing report is run by Project Lead

Checked by: Data Manager

2.2.16 Retrospective Amendment of Full Eligibility

Variables: Retrospective amendment of eligibility criteria

Description: Project Lead runs data listing report through J review to identify any new patients that may have the retrospective amendment of eligibility criteria form completed.

Frequency: 3 months or upon request by PIs/Sponsors

Checked by: Project Lead

2.2.17 Pre-Randomization and RRT Initiation SOFA

Variables: SOFA scores at pre-randomization and RRT initiation; corresponding variables for each SOFA score component

Description:

- Individual components of each SOFA score are cross checked with corresponding variables in other parts of the database to ensure the score that was entered aligns with the instructions provided in Manual of Operations

Frequency: Report ran prior to database lock for a final check

Checked by: Project Lead and Data Manager

2.2.18 Outliers

Variables: CRRT dose; SOFA score at pre-randomization and RRT initiation

Description:

- SOFA Score: AHRC Statistician (blinded to outcome of the trial) has built a report to identify SOFA scores across sites that have a lower than expected variability in scores and/or have a mean which is out of line as compared to other sites
- CRRT dose: Project Lead runs a report through J review to identify any CRRT doses entered that may be too high or too low as compared to the remainder of CRRT doses entered for a particular patient

Frequency: Report ran prior to database lock for a final check

Checked by: Project Lead

2.3 Data Management Workflow and Query Resolution

Issues identified through the above mentioned reports (2.1.1-2.1.16) are handled as per the steps

described below:

a. Patient IDs with discrepancies identified through the reports/manual checks
   - If discrepancies are found via a report run by Project Lead, then concerns for that patient are provided to Data Manager along with discrepancies found
b. AHRC Data Manager raises a manual query on Medidata RAVE for the site to clarify the discrepancy
c. Sites are provided with a two week timeline for query resolution
d. For any queries that are not resolved within two weeks, open query reports are circulated to sites on a monthly basis and sites are asked to provide query resolution comments or make appropriate corrections to the data entered
e. Once query resolution comments are provided by the sites/appropriate changes are made to the data to correct any errors, Data Manager closes the query
   - *Note: For any issues/queries that require PI attention, Project Lead ensures appropriate communication with PIs prior to closure of queries*

3 REMOTE MONITORING PLAN

3.1 Objective of Remote Monitoring Plan

The purpose of this section is to outline the study-specific procedures related to remote monitoring and source data verification (SDV) for STARRT-AKI trial. This section on remote monitoring plan outlines:

a) the critical variables monitored (see 3.5)
b) methods utilized to identify potential data quality issues (see 3.3), and
c) the actions taken by central coordination team to reconcile any discrepancies in the data (see 3.4)

3.2 Remote Monitoring for STARRT-AKI

This is a multi-national clinical trial with 168 participating sites in 15 countries. Remote monitoring is performed in order to ensure that the data collected is comprehensive, accurate and collected according to the protocol and supporting operation documents (e.g. Manual of Operations). The purpose of the SDV is to ensure the following:

a) Patient meets the eligibility criteria for the study;
b) Patient has provided written informed consent to participate in the trial;
c) Complete and accurate data is entered onto the electronic Case Report Forms (eCRFs); and
d) All outcome events have been entered into the electronic CRFs and a copy of the de-identified source documents have been sent to the AHRC, as required. Original supporting documents should be maintained in the patient's file.

3.3 Remote Monitoring Activities

Remote monitoring is performed on participating sites in the trial which are located in the following countries: Austria, Canada, US, Belgium, Finland, France, Germany, Ireland, UK, Switzerland, Italy, Kenya and Brazil. This includes targeted SDV of eCRF data on 2 of the first 5 randomly selected patients randomized into the trial at each site, followed by a random sample of 10% of remaining patients (1 patient for each tranche of 10 patients 6-15, 16-25, etc). Only critical data variables which are programmed into Medidata RAVE eCRF system are source verified. A list of these variables can be found in section 3.5. Targeted SDV focuses on the data in the following key forms:

a) Eligibility criteria

b) *Informed consent*
c) *Randomization*
d) *Hospital and ICU Discharge Data*
e) *Index Hospitalization and Resource Utilization at Day 28*
f) *RRT Initiation Data*
g) *Day 90 Outcome Data*
h) *Adverse Events Details*

The AHRC Project Assistant provides sites with the SDV Tool, which is a one page document listing key variables for targeted SDV. Sites are asked to complete the SDV Tool and send it to the central coordination team, along with de-identified source documents for selected variables listed on the SDV Tool, using St. Michael Hospital's secure file transfer system. Appropriate instructions are provided to sites on how to complete the SDV tool, de-identify source documents, and send these documents to central coordination team using secure file transfer.

Upon receipt of the completed SDV Tool and appropriate source documents, the central coordination team reviews these documents to ensure that the data is consistent with the data entered on the eCRF. The review includes checking the eCRF entries on Medidata RAVE for accuracy and completeness against source documents. The AHRC maintains a monitoring log of all patients for whom source documents are requested, received, and verified. Variables are marked as "verified" in the monitoring log once the review is complete. Urgent issues are communicated on an ongoing basis as needed with the PIs/Sponsor.

If errors or inconsistencies are noted, a follow up email is sent to the site's Principal Investigator and Primary Study Coordinator. The follow up email includes a summary of the issues identified, outline of any corrective actions and/or request an explanation and a timeline for resolution.

3.4 Timeframe for Response

The monitoring follow up email to the sites includes a timeline within which the critical issues identified must be resolved, and if this requirement cannot be met, sites are instructed to notify the AHRC immediately. The central coordination team makes every effort to resolve issues with the Site Coordinator and Site Investigator in a timely manner.

3.5 SDV Variables

All the variables listed below are included in the SDV Tool. Sites monitored by the central coordination team are required to complete the SDV tool for all variables that are listed in this appendix. In addition, de-identified source documents will be collected from sites for selected variables as specified in the table below.

Form	Field/Variable	Source Document Required?
Eligibility criteria	○ Baseline creatinine ○ Last creatinine for screening ○ Screening urine output ○ Potassium	○ Yes

	○ Bicarbonate ○ eGFR value	
Informed Consent	○ Date and time of informed consent ○ Type of consent model used	○ No
Randomization	○ Date and Time of Randomization ○ Randomization arm	○ No
Baseline	○ Year of birth	○ No
Hospital and ICU Discharge Data	○ Hospital Admission date ○ Hospital discharge date ○ ICU admission date ○ ICU discharge date	○ Yes
Day 28 Resource Utilization Form	○ Number of ICU days ○ Number of hospital RRT days ○ Number of mechanical ventilation days ○ Number of vasoactive therapy days	○ No
RRT Initiation Data	○ RRT initiation date and time ○ Initial RRT modality ○ Reason for RRT initiation	○ Yes
Day 90 Outcome Data	○ Vital status at day 90 ○ Requirement for RRT at day 90 ○ Date of last RRT prior to day 90 ○ Date of sampling for creatinine and eGFR ○ Day 90 creatinine and eGFR ○ Date of sampling for urine albumin/urine creatinine ○ Day 90 urine albumin and urine creatinine ○ Date and cause of death	○ No
Adverse Event Details	○ Event type, even start and stop date, and relatedness of the event to the study procedures	○ Yes (for Serious Adverse Events only)

4 CLOSEOUT STATEMENT

4.1 Objective of Closeout Statement

The purpose of the Closeout Statement is to allow all sites to declare that all possible measures were taken to ensure data accuracy and consistency with data entry guidelines. This section outlines:

a. The email template sent to sites for ensuring data completeness and accuracy (see 4.2)
b. Closeout statement form sent to sites for Site Investigator sign off (see 4.3)
c. List of critical variables that sites are urged to check prior to closeout statement sign off (see

4.4).

4.2 Closeout Statement Email Sent to Sites

Below is the email template sent to sites with attachments including closeout statement form and list of critical variables to check:

Dear <insert Site Investigator name> and <insert site team name>,

As we approach the final stages of recruitment in STARRT-AKI, we are working diligently to ensure that trial data inputted into Medidata RAVE is both complete and accurate. The hard work that we have all invested in the trial will hopefully result in numerous important contributions to the literature that will impact on patient care. But to ensure that our contributions to the literature achieve the highest level of quality, data excellence is mandatory. In particular, we want to emphasize how crucial it is that all data are entered in a way that is consistent with the criteria outlined in the data manual. We are pleased to report that the "Source Data Verification" process- in which you have all participated- was extremely informative and highlighted the high quality of data entry across the trial. However, the source data verification process only assessed a limited number of data points for a handful of randomly selected patients at each site.

STARRT-AKI does not have the resources to perform on site monitoring so we rely heavily on individual sites to perform an internal review of their data practices. We would be grateful if you could review the manual of operations (you should have one in your files but we have attached the most recent version for your convenience in both English and French) and confirm that you and your site has entered all data elements in the manner described in the manual. If you feel this is not the case, we would deeply appreciate it if you could review your source documents (ie, the paper or electronic chart for participating patients) and feel free to re-enter the data for any element(s) that may have been entered incorrectly or that was reported as missing before. If data errors were made for patients whose data has been "locked", let us know and we will "unlock" the database to enable you to make these updates. Furthermore, we are attaching a list of "critical variables" that we believe are the most vital to our future analyses and which may be most susceptible to data entry errors. Please look at these especially carefully to confirm that your site has entered data for these variables in a manner that conforms to the data entry manual.

After the final patient is randomized into STARRT-AKI, all sites will be asked to "close out" the data for all the patients that they have recruited. At that point, we will ask the site investigator to sign the attached "Close-Out Form" which acknowledges that data entry was complete and consistent with the operations manual to the best of his/her team's ability. We recognize that recruiting patients into a trial such as STARRT-AKI and

the necessary data collection after patients are recruited is a lot of work. During these final critical months of the trial, we will be at your disposal at all times to assist you in any way possible with the data completion process. Our goal is a final dataset that is complete and reliable and we will invest whatever resources we can to help accomplish this.

Please don't hesitate to reach out to us at any time with any questions.

With best regards,

Nikita, Sydney, Ron and Sean

4.3 Closeout Statement Form

STARRT AKI

STARRT-AKI Site Investigator Closeout Statement

Study Title:	STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury
Site Name:	
Investigator Name:	
No. of patients randomized:	

Note: The PI signature on this form should be obtained after ALL patients randomized at the site have reached their Day 90 follow-up, and ALL the data for patients randomized at the site has been completed on Medidata RAVE.

I acknowledge that I have taken all possible measures to ensure the accuracy and completeness of the data entered for all patients randomized into the STARRT-AKI study at this site. Moreover, I have done the utmost to ensure that all data has been entered in a manner that is consistent with the criteria described in the Manual of Operations V4.0 [02 APR 2018] and according to Good Clinical Practice. Finally, I agree to fully assist in the clarification of any queries that might arise from trial monitoring in relation to any aspect of the STARRT-AKI trial.

Site Principal Investigator Signature: _____

Date: _____

4.3 Critical Variables for final verification

Form	Variables
Eligibility Criteria Form (Form 1)	• Inclusion criteria 4 *Evidence of severe AKI based on at least ONE of the following: i) ≥2 fold increase in creatinine from baseline; ii) if current Cr is ≥ 354 µmol/L (4.0 mg/dL) with evidence of a minimum increase of at least 27 µmol/L (0.3 mg/dL) from the baseline Cr; or iii) Urine output < 6.0 mL/kg over the preceding 12 hours* • Exclusion criteria 1 *Potassium concentration > 5.5 mmol/L* • Exclusion criteria 2 *Bicarbonate concentration < 15 mmol/L*
Risk Factors (Form 6)	• Baseline serum creatinine (please refer to determining baseline Cr flowchart in Manual of Operations V4.0 [0APR2018] Page 12 English Version OR Manual of Operations V4.0 [0APR2018] Page 64 French Version) *µmol/L or mg/dL* • Has the patient met criteria for Sepsis in the preceding 72 hours? *Yes/No*
Pre-Randomization SOFA (Form 7)	• Total SOFA score *Calculated from the indivdual score of each component of SOFA including Respiration, Coagulation, Liver, Cardiovascular, CNS, Renal. Most extreme result in the 24 hours preceding randomization should be assigned for each component.*
Pre-Randomization Severity of Illness (Form 8)	• Mechanical ventilation or CPAP? *Yes/No*
Daily Data – RRT and Vascular Access (Form 10)	• Receiving RRT on study day? *Yes/No* • Was RRT initiated for the first time since randomization? *Yes/No* • RRT modality *IHD/SLED/CRRT*
RRT Initiation Data (Form 11)	• RRT initiation date and time *Date and time when first RRT was initiated since randomization* • Creatinine *µmol/L or mg/dL; last available result prior to first RRT initiation since randomization* • Urea *mmol/L or mg/dL; last available result prior to first RRT initiation since randomization*
Adverse Events (Form 12)	• Adverse event data (refer to page 57 of Manual of Operations V4.0 [0APR2018] English Version OR page 37 Manual of Operations V4.0 [0APR2018] French Version for details on reportable adverse events for this study)
Protocol Violations (Form 13)	• Protocol violations regarding the timing of RRT initiation *Was RRT initiated within the specified time intervals mandated by the protocol?*
ICU and Hospital Discharge Data (Form 14)	• Alive at ICU discharge? *Yes/No* • Date of ICU discharge

	• Was RRT administered in 7 days following ICU discharge? *Yes/No* • ICU re-admissions during index hospitalization? *Yes/No* • Date of last RRT in hospital (if applicable) • Last serum creatinine recorded in the hospital *µmol/L or mg/dL* • Date of last serum creatinine recorded in the hospital (if applicable) • Alive at hospital discharge? *Yes/No* • Date of hospital discharge (*if patient is alive at hospital discharge*) • Plan for further RRT at the time of hospital discharge? *Yes/No*
Resource Utilization at Day 28 (Form 15)	• Total number of ICU days • Total number of in-hospital RRT days • Number of mechanical ventilation days • Number of vasoactive therapy days • Was patient re-admitted to hospital following discharge from their index hospitalization?
Day 90 outcome (Form 16)	• Vital status at 90 days following randomization *Alive/Deceased* • Disposition at 90 days *Not applicable if patient is deceased prior to day 90 post-randomization* • Requirement for RRT at 90 days *Not applicable if patient is deceased prior to day 90 post-randomization* • Date of last RRT session *Not applicable if patient is deceased prior to day 90 post-randomization* • Day 90 serum creatinine *mmol/L or mg/dL; not applicable if patient is deceased prior to day 90 post-randomization* • Was patient re-admitted to hospital between day 28-day 90? *Not applicable if the patient was not discharged from prior hospitalization by day 90*
Death Details (Form 17)	• Date of death *If patient is deceased between randomization and day 90 post-randomization*
Study Completion (Form 19)	• Did the patient complete the full study up to 90 days? *Yes/No* • If not, reason for not completing the full study *Lost to follow up/consent withdrawal/other*