CHN66: SAMPLE AND LAB TEST COMPLETENESS

1.0 PURPOSE / INTRODUCTION:

1.1 Introduction:

Sample completeness is very critical for CHAIN project to derive meaningful conclusions from future data for publication. Sample completeness is a key determinant to the selection samples for cases and controls to be included in the planned lab assay analysis. Lab data forms an important component of the CHAIN study as this will be analyzed in relation to the clinical data to determine the causes of mortality in comparison to the controls. It is therefore of critical importance that sites focus on ensuring that they obtain all the sample types from participants at each time point.

Any challenges on sample collection must be reported to the clinical lead and the lab coordination for site support where possible. Sites must track their own internal performance on a weekly basis in reference to the Dash board.

1.2 **Purpose**

The purpose of this SOP is to give guidance on the acceptable percentage cut offs of sample and lab data completeness as a measure of site performance.

2.0 SCOPE / RESPONSIBILITY:

This SOP is applicable to all study clinicians, laboratory technicians and PIs in CHAIN study.

The Principal Investigator (through the study coordinator when applicable) retains the overall responsibility of implementation of these standard procedures.

The Study Laboratory Coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation. Please contact that the Study Laboratory Coordinator through your site coordinator.

3.0 ACCEPTABLE PERCENTAGE MONTHLY SAMPLE COMPLETENESS

Sample type in all time points	Minimum accepted completeness	Reduction in monthly performance that requires Flagging
Blood (Serum and Plasma)	95%	≥10%
Dry Blood spots	95%	≥10%
Whole Blood	95%	≥10%
CBC samples and test parameters	95%	≥10%

Clinical Chemistry samples and analytes	95%	≥10%
Rectal swabs	100	≥10%
Stool	85%	≥10%
Blood culture	95%	≥10%
PBMCs	90%	≥10%

4.0 LAB TESTS AND ACTIONS

Clinical chemistry and CBC requires 95 % completeness as well as complete lab results for each test parameter or analyte. No sites should miss the specified tests in the lab CRF as listed below at all time points. CBC is required in all the time points while clinical chemistry is collected at admission, discharge, deterioration, readmission and for all community participants. The expected tests are;

CBC

Complete blood count with differentials

Clinical chemistry

Total Calcium, Magnesium, Albumin, Total Bilirubin, Alkaline Phosphate, Inorganic Phosphate, ALT, Sodium, Potassium, Urea and Creatinine (UEC).

Specific actions

Lab data entry must be done on real time basis but not later than Friday every week. Each site must generate a monthly report on challenges faced on sample collection for review by clinical and lab management. All the sample and lab data reports will be generated based on data entered by sites in Red Cap. Any data not entered in the database in good time will not be included in the report and may show suboptimal performance by sites. It is therefore the responsibility of all the sites to ensure that the data in all the databases are up to date.

When a performance is flagged, it is the obligation of the site project coordinator or lab manager to notify the site PI, clinical lead (Priya Sukhtankar) and CHAIN lab manager (Caroline Tigoi) by email with details on the causes of the suboptimal performance and actions taken. Depending on the performance challenges further discussions might be initiated with the specific site.

Document history

Version	Author	Approved by	Dated
1.01 Sample and lab test completeness.	Caroline Tigoi	Robert Bandsma	31/07/2018

Site training record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM