Committee), and whereindicated, requestors will be asked to develop scientific protocols for approval of secondary analyses. The potential to share data will be included in the participant Information and Consent Form.

20. Data Management:

(a) Data Storage

All clinical and laboratory data will be recorded in the CRF and stored with a unique serial number identifier.Data will be entered onto Open Clinica. Prof Maitland's team at KCH will enable CRF and database development. All data will be regularly backed up and backup copies stored both on and off site. Paper records will be archived in locked cabinets. These cabinets will have limited access with prior authorisation.

(b) Data Management and Statistical Analysis

The data will be examined for inconsistencies during the trial by the statistician and fed back to study sites for corrections following GCP procedures.

The primary analysis for the trial will describe baseline parameters (stratified by study stratum and arm), describe time to tolerate oral fluids/feeds and maintenance of normal fluid balance and time to discharge, and compare primary and secondary endpoints by trial arm. The primary analysis will be by intention to treat.The primary endpoint of 96-hour mortality will be compared between arms with a chi-squared test assuming unequal variances between the arms, and comparing the WHO SAM arm to the other two arms (WHO Plan C and Slow rehydration arm) combined.

A secondary analysis will be pair-wise comparisons of urine output using a t-test between each arm and thestandard of care (WHO SAM arm). The primary endpoint for the oral rehydration comparison of change in sodium at 24 hours will be analysed using normal linear regression, adjusting for baseline (measured at randomisation), with appropriate transformations if necessary.

The secondary endpoint of change in sodium at 24 hours from post-iv levels for those in stratum A will also use normal linear regression, adjusting for the value measured after the end of their iv rehydration. Changes in weight, MUAC and electrolytes will be analysed using normal linear regression (potentially on log- transformed data), and generalised estimating equations to jointly model changes during admission and at day-7. Analysis of adverse events, including mortality, evidence of pulmonary oedema and heart failure, will use time to event methods through day 28 counting in hospital death as a competing risk. Adverse events will also be summarised by body system. Analysis of perturbations of electrolyte abnormalities (severe hyponatraemia (<125mmols/L) or hypokalaemia (<2.5mol/L) will use time to event methods through day 7 counting in hospital death as a competing risk.

(C) Intellectual Property

Any Intellectual property rights that arise from the work will be safeguarded according to the KEMRI IPR Policy of 2015 and the Industrial Property Act of 2001, sections 32, 58 and 80. The scientific and intellectualcontributions of all persons involved in the research will be appropriately acknowledged in all publications and presentations arising from the work.