Fluid-TRIPS
Protocol Summary of Changes Document

New Document	Fluid-TRIPS, Protocol No. GI-CCT300413 Version 2.0, 24th February 2014
Old Document	Fluid-TRIPS, Protocol No. GI-CCT300413 Version 1.0 17th January 2014

Section	Existing Text as per Protocol Version 1	Revised Text as per Protocol Version 2	Reason/ Justification of Change
Cover page and Header on pages 2-16	Version 1.0 dated 17th January 2014	Version 2.0 dated 24th February 2014	Administration – update protocol version number
Table of contents	-	-	Updated to match document numbering
5.4.2 Individual patient data	- ICU admission date and time - APACHE II - Prescriber details - Vasoconstrictor or inotropic agent infusion - ABP - Lab results (creatinine, bilirubin, platelets, base excess or deficit, lactate, serum albumin, INR, APTT) - Fluid input and output for the study day - Fluid balance	- ICU admission date - Severity of disease score - Prescriber characteristics - SOFA score – respiratory and cardiovascular only - Systolic and diastolic ABP - Lab results (creatinine, bilirubin, base excess or deficit, lactate, serum albumin) - Urine and fluid output previous complete hour - Fluid resuscitation infusion totals for the study day - Total daily fluid balance – input and output volumes	Amended to be inline with the CRF version 1.0 dated 12th February 2014
8.2 Data recording and document	De-identified data will be entered by each participating site	Each participating site will enter de-identified data	Administration – Grammar corrected

retention and 8.3 Data quality assurance	• Site specific • Custodians • Password protected • The data cleaning process will be overseen by the Fluid-TRIPS management committee	• Site-specific • Custodian • Password-protected • The Fluid-TRIPS management committee will oversee this data cleaning process.	
10 Project timeline	• July 2014 Finalise data collection • September 2014 All data entered and queries resolved • October 2014 Data analysis • December 2014 Final manuscript(s) submitted for publication	• Data collection day 4 • Data collection day 5 • Data collection day 6 • Data collection day 7 • November 2014 Finalise data collection • February 2015 All data entered and queries resolved • March 2015 Data analysis • June 2015 Final manuscript(s) submitted for publication	Additional study days added to allow for more sites to participate and allow flexibility in timeline for sites/regions to get regulatory approval. All milestones adjusted to accommodate the extra data collection days