## Fluid-TRIPS Protocol Summary of Changes Document

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Old Document | Fluid-TRIPS, Protocol No. GI-CCT300413 Version 1.0 17th January 2014

<table>
<thead>
<tr>
<th>Section</th>
<th>Existing Text as per Protocol Version 1</th>
<th>Revised Text as per Protocol Version 2</th>
<th>Reason/ Justification of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cover page and Header on pages 2-16</td>
<td>Version 1.0 dated 17th January 2014</td>
<td>Version 2.0 dated 24th February 2014</td>
<td>Administration – update protocol version number</td>
</tr>
<tr>
<td>Table of contents</td>
<td>-</td>
<td>-</td>
<td>Updated to match document numbering</td>
</tr>
<tr>
<td>5.4.2 Individual patient data</td>
<td>-</td>
<td>-</td>
<td>Amended to be inline with the CRF version 1.0 dated 12th February 2014</td>
</tr>
<tr>
<td>8.2 Data recording and document</td>
<td>-</td>
<td>-</td>
<td>Administration – Grammar corrected</td>
</tr>
</tbody>
</table>

### 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

### 8.2 Data recording and document

- De-identified data will be entered by each participating site
- Each participating site will enter de-identified data
| 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** |