**Primary data source**

**Protocol:** The Stress Ulcer Prophylaxis in the Intensive Care Unit (SUP-ICU) trial

**Department:**

**Hospital:**

**Investigator:**

|  |  |
| --- | --- |
| Data | Primary data source |
| Patient history |  |
| Participant ID | eCRF |
| Vital signs |  |
| Vasopressor/inotrope |  |
| Nutrition |  |
| Red blood cells |  |
| Other medication |  |
| Laboratory tests |  |
| Mechanical ventilation |  |
| Renal replacement therapy |  |
| Incidents |  |
| Vital status |  |
| Imaging |  |

Investigator (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Primary Data Source**

The primary data source list is used by the Good clinical practice (GCP) monitors in order to check that entered data are correct. The primary data source refers to the source/place where the data first appears (original data capture). Data sources must be listed for all data in the eCRF in the primary data source list above prior to inclusion of the first patient. Data may have more than one data source. In that case all sources should be listed. The superior sources should be listed first in case the data differs between sources.

The Primary Data Source List must be signed by the local investigator before initiating the trial and filed in “Site Master File”. If the list is updated during the trial, please remember to place the new list in the Site Master File.

**Examples of data**

Previous diseases, inclusion/exclusion criteria, randomisation number, date of visit, clinical examination, ECG, blood pressure, laboratory tests, drugs, side-effects, etc.

**Examples of sources from which data are captured - electronic or hard-copy documents**

Analysis print, ECG-print, electronic medical record, e-CRF, nurse notes, X-ray memorandum etc.

Describe the source as specific as possible.