

**Plan for data verification**

Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU)

**The trial’s EudraCT-number:** 2017-003829-15

**Level I:** Source Data Verification (SDV) of all the below mentioned data in the CRF for the first 3 included and totaling 10% in every center.

**Level II:** Selected data on every trial participant that is not selected for level I.

| **Data** | **CRF**  **Code/side** | **I** | **II** | **Comments** |
| --- | --- | --- | --- | --- |
| **Informed consent** |  | X | X | According to national regulations |
|  |  |  |  |  |
| **Inclusion criteria** | S2-S4 | X | X |  |
|  |  |  |  |  |
| **Exclusion criteria** | S5-S14 | X | X |  |
|  |  |  |  |  |
| **Baseline** | BL1-BL21 | X |  |  |
|  |  |  |  |  |
| **Day Form** | D1-D8 | X |  | The first 4 Day Forms are reviewed. |
|  |  |  |  |  |
| **Serious Adverse Reactions (SARs)** | SAR1-SAR8 | X | X | Level I: Patient files are reviewed for all day forms from inclusion to 24 hours after last administration or discharge from ICU.  Level II: Check off yes to SAR in CRF, SDV is to be performed in patient file and it is to be checked that the patient is no longer receiving trial medication |
|  |  |  |  |  |
| **Discharge and Readmission** | Discharge form | X |  |  |
|  |  |  |  |  |
| **Withdrawal** | W1-W3b | X |  |  |
|  |  |  |  |  |
| **90 Days Follow-up** | FU1-FU4 | X | X |  |