

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	