

Data Verification plan

The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial

EudraCT number: 2018-000404-42

Level I: Systematic data verification of all data in the case report form. Applies to the first 3 trial participants and hereafter until a total of 10% of participants for each trial site has been monitored.

Level II: Selected data on all trial participants, who has not been selected for 'Level I'.

Data	eCRF Code	I	II	Comments
Informed consent		X	X	According to national regulations
Consent stated in medical record		X	X	According to national regulations
Inclusion criteria	S2-S5	X	X	
Exclusion criteria	S6-S10	X	X	
	S13	X		Stratification variable
Baseline	BL1-BL21	X		
Day Form	D1-D23	X		First 4 day forms: all data must be monitored. Every 10 th day form after the first 4 forms: - D1-D14 (fluid data) - D 15 and 15a-c (protocol violations)
Serious Adverse Reactions (SARs)	SAR1-SAR6	X*	X**	*Level I: Medical record will be examined all days from inclusion until 24 hours after last administration or ICU discharge. **Level II: Systematic data verification will be performed if a SAR is 'yes' and it will be controlled that a 'Note to file' with information from sponsor to investigator is archived in Trial Master File #13.
Discharge and Readmission	Discharge form	X		
Withdrawal	Withdrawal form	X		
90 Days Follow-up	90 day follow up form	X	X	

