

ENROLMENT CRITERIA

ENROLCRIT = Enrolment criteria

1. CDE Variable	ENROLCRIT = enrolment criteria
2. CDE Definition	Enrolment criteria: inclusion and exclusion criteria specific to the study.
3. Recommended instrument for assessment	Clinical evaluation
4. Description of measure	Yes/No per criterium
5. Permissible values	Yes/No
6. Classification: Basic/Intermediate/Advanced	Identical
7. Procedure	All questions must be answered. Rigorous evaluation is required to determine if the patient meets the study specific criteria.
8. Comments/Special instructions:	<ul style="list-style-type: none"> - All questions on inclusion criteria should be answered as 'yes', and all questions on exclusion criteria as 'no' to qualify for enrolment in the study. - The criteria presented are only intended to present examples of enrolment criteria, commonly employed in TBI studies. Clearly, the choice of criteria is study specific, depending on the aim of the study.
9. Rationale/justification:	Enrolment criteria are motivated by clinical, ethical and safety considerations. Thus, patients unlikely to benefit from the treatment under investigation, those with other conditions which may confound treatment effects or outcome assessment, and those with an increased safety risk are generally excluded. Enrolment criteria serve to increase the chances for benefit, to decrease the risk exposure and to guarantee compliance with ethical regulations.
10. References:	

Recommended time for assessment:

Prior to entry to study.