BASELINE RISK ASSESSMENT

BaseProgn = Baseline Risk Assessment

1. CDE Variable	BaseProgn = Baseline prognostic risk assessment
2. CDE Definition	The baseline prognostic risk assessment provides an estimate of outcome calculated with a prognostic model.
3. Recommended instrument for assessment	Multivariable prognostic model
4. Description of measure	Risk assessment for mortality or unfavourable outcome expressed as fraction or percentage.
5. Permissible values	0-100
6. Classification: Basic / Intermediate / Advanced	Basic/intermediate: 7 predictor model Advanced: 10 predictor model
7. Procedure	The prognostic risk assessment can be calculated by applying a prognostic model. We recommend models proposed by the IMPACT study group and the CRASH trial collaborators (www.tbi-impact.org and www.crash2.lsthm.ac.uk)

8. Comments / Special instructions:

The IMPACT prognostic models are intended for use in patients with moderate/severe TBI. The models proposed by the CRASH trial collaborators have also been developed and internally validated for mild TBI. The baseline risk assessment should be performed post stabilization but prior to any study intervention. We summarize the predictors as required for application of the IMPACT prognostic models.

- Age in years
- Presence or absence of hypoxia
- Presence or absence of hypotension
- Pupillary reactivity:
  - both pupils reactive
  - one non-reacting pupil
  - both pupils non-reactive
- CT classification
- Presence or absence of traumatic subarachnoid hemorrhage
- Qualifying motor score for study admission

The advanced version includes the following laboratory values: haemoglobin, glucose, prothrombine time.

Under the qualifying motor score for study admission we recommend to additionally document the time at which this assessment was performed and the conditions of assessment, e.g. whether any external factors may have influenced the assessment.

Although much of this information will already be contained elsewhere in the CRF, we consider it important to summarize it in the element on baseline risk assessment to ensure that all relevant information is available and codified in a format for entry into the prognostic model. The calculation of the prognostic risk can be performed during the analysis phase.

9. Rationale / justification:

TBI populations are characterized by substantial heterogeneity. This heterogeneity confounds comparison between studies and may also lead to imbalances between treatment groups in clinical trials. Characterization of populations is better performed by calculation of

the prognostic risk than by reporting characteristics individually. In clinical trials, the prognostic risk estimate can be used as one of the enrolment criteria (excluding patients with an extreme risk estimate), for purpose of stratification and in the analysis phase for covariate adjustment or assessing outcome in relation to initial prognostic risk (sliding dichotomy approach). We therefore consider calculation of baseline prognostic risk mandatory for all clinical studies on TBI.

10. References:

Steyerberg EW, Mushkudiani N, Perel P, et al. Predicting outcome after traumatic brain injury: development and international validation of prognostic scores based on admission characteristics. *PLoS Med*. Aug 2008;5(8):e165.

MRC CRASH Trial Collaborators. Predicting outcome after traumatic brain injury: practical prognostic models based on large cohort of international patients. *BMJ*. Feb 2008;336(7641):425-429.

Recommended time for assessment:
On admission after primary stabilization.