

Building your CRF

The data elements for TBI are contained in modules which are grouped together in categories. For example, the data elements 'age', 'gender' and 'race' are contained in the module 'demographics', under the category 'subject characteristics'. The structure of the common data elements (CDE) for TBI are consistent with the CDE's developed by NIH-NINDS and KAI (www.commondataelements.org) for use across different fields of neurological diseases. The structure of the CDE's is presented under the heading 'overview'. The data elements and modules are intended for use as 'building blocks' when designing your CRF. They offer optimal flexibility, as the level of detail required for data elements can vary greatly with the design and aim of a specific study. To this purpose, the modules are presented at three levels of detail: basic, intermediate and advanced, with the greatest level of detail in the advanced version. The coding of these versions is such that in every case the advanced version can be collapsed to the intermediate or basic versions, thus facilitating comparison and meta-analysis of individual patient data between studies. This approach was chosen as for example relatively simple observational studies or large pragmatic clinical trials would require much less detail than highly focused and complex phase II trials. The choice of data elements and level of detail will depend on the type of study. The modules were developed in a format suitable to both mild and more severe injuries, as also to civilian and military studies. A module with elements specific to pediatric TBI is presented separately.

The proposed modules contain all essential data elements for development of a CRF in TBI studies. The elements and modules can be used as 'plug in' elements and can be used multiple times in various sections of the CRF. For example, the module on 'Glasgow Coma Scale (GCS) and pupils' may be recorded only on admission, or also pre-hospital, as well as daily during the acute care phase.

The choice of elements and level of detail will depend on the type of study. In designing your CRF you can mix basic, intermediate and advanced versions of the different data elements according to the requirements of the study. We note that the data elements proposed are by no means all inclusive, and the option always remains open to include other elements when developing your CRF. We would however strongly advocate that the coding of variables contained in the modules is at least compatible with the proposed format.