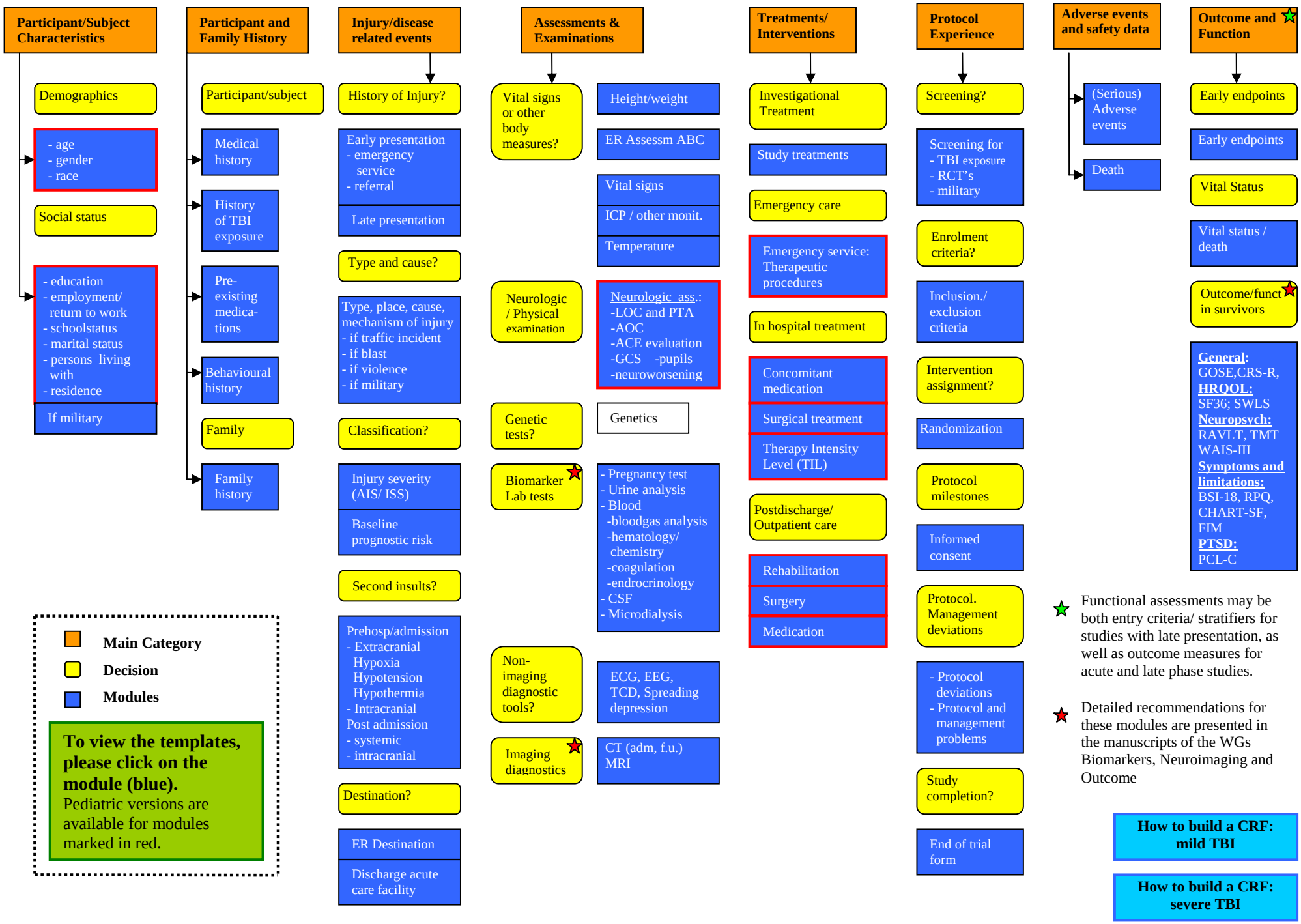
Participant/Subject Characteristics
Demographics
- age
- gender
- race
Social status
- education
- employment/ return to work
- schoolstatus
- marital status
- persons living with
- residence
If military
Participant and Family History
Participant/subject
Medical history
History of TBI exposure
Pre-existing medica-tions
Behavioural history
Family
Family history
Injury/disease related events
History of Injury?
Early presentation
- emergency service
- referral
Late presentation
Type and cause?
Type, place, cause, mechanism of injury
- if traffic incident
- if blast
- if violence
- if military
Classification?
Injury severity (AIS/ ISS)
Baseline prognostic risk
Second insults?
Prehosp/admission
- Extracranial
Hypoxia
Hypotension
Hypothermia
- Intracranial
Post admission
- systemic
- intracranial
Destination?
ER Destination
Discharge acute care facility
Assessments & Examinations
Vital signs or other body measures?
Height/weight
ER Assessm ABC
Vital signs
ICP / other monit.
Temperature
Neurologic / Physical examination
Neurologic ass.:
-LOC and PTA
-AOC
-ACE evaluation
-GCS -pupils
-neuroworsening
Genetic tests?
Genetics
Biomarker Lab tests
- Pregnancy test
- Urine analysis
- Blood
-bloodgas analysis
-hematology/ chemistry
-coagulation
-endrocrinology
- CSF
- Microdialysis
Non-imaging diagnostic tools?
ECG, EEG, TCD, Spreading depression
Imaging diagnostics
CT (adm, f.u.)
MRI
Treatments/ Interventions
Investigational Treatment
Study treatments
Emergency care
Emergency service: Therapeutic procedures
In hospital treatment
Concomitant medication
Surgical treatment
Therapy Intensity Level (TIL)
Postdischarge/ Outpatient care
Rehabilitation
Surgery
Medication
Protocol Experience
Screening?
Screening for
- TBI exposure
- RCT's
- military
Enrolment criteria?
Inclusion./ exclusion criteria
Intervention assignment?
Randomization
Protocol milestones
Informed consent
Protocol. Management deviations
- Protocol deviations
- Protocol and management problems
Study completion?
End of trial form
Adverse events and safety data
(Serious) Adverse events
Death
Outcome and Function
Early endpoints
Early endpoints
Vital Status
Vital status / death
Outcome/funct in survivors
General:
GOSE,CRS-R,
HRQOL:
SF36; SWLS
Neuropsych:
RAVLT, TMT
WAIS-III
Symptoms and limitations:
BSI-18, RPQ,
CHART-SF,
FIM
PTSD:
PCL-C
Main Category
Decision
Modules
To view the templates, please click on the module (blue).
Pediatric versions are available for modules marked in red.
Functional assessments may be both entry criteria/ stratifiers for studies with late presentation, as well as outcome measures for acute and late phase studies.
Detailed recommendations for these modules are presented in the manuscripts of the WGs Biomarkers, Neuroimaging and Outcome
How to build a CRF: mild TBI
How to build a CRF: severe TBI