User Manual

User Manual and General Instructions for researchers finding CENTER-TBI data in Mica and Opal

Version number	Purpose/Change	Author	Date
1.0	Initial draft, proof reading, extended draft, testing, finalization	Merijn Driessen, LUMC Judith Manniën, LUMC Eva Timmermans, LUMC Véronique De Keyser, UZA	Between 24-08-2021 and 09-03-2022
1.1	Revision by Mica/Opal test-users	Francesca Graziano, UNIMIB Véronique De Keyser, UZA Merijn Driessen, LUMC	Between 20-04-2022 and 20-06-2022
2.0	Changes for update to Mica 5.0, use of R token added.	Merijn Driessen, LUMC, Kristel Schaap, LUMC	13-10-2022
3.0	Updated procedures for access to data files and imaging data; added info regarding exports and token expiration; creating views removed.	Richard Wissels, LUMC, Kristel Schaap, LUMC, Véronique De Keyser, UZA	03-04-2025
4.0	Changes for update to Mica 6.0.1 and Opal 5.1.2	Richard Wissels, LUMC	13-05-2025
4.1	Updated explanation of use of OpalR API; added release notes of releases 3.1 and 3.2; Updated information on login into Opal/Mica; Various minor adjustments	Lars van der Burg, LUMC	20-01-2026

Contents

1 Introduction

The CENTER-TBI study data were collected in 69 sites in Europe, Israel, India, and Australia.

- The **CENTER-TBI (Europe and Israel)** dataset is composed of two parts:
  - The CENTER-TBI Registry (n= 22 782)
  - The CENTER-TBI Core (n= 4 509)

- The **OzENTER (Australia)** dataset is composed of one part:
  - The OzENTER Core (n= 198)

- The **CINTER-TBI India** dataset is composed of two parts:
  - The CINTER-TBI India Registry (n= 3 904)
  - The CINTER-TBI India Core (n= 1 046)

The *Registry dataset* serves to validate and generalize results of the Core dataset. All datasets were collected using the same e-CRF and the same inclusion criteria. The Australian and Indian dataset are more limited than the European dataset. For logistic reasons, not all variables from CENTER-TBI have been captured in the dataset of Australia and India.

This is a non-exhaustive list of data that was not or less captured in Australia:

- only ICU stratum (no ER or ADM stratum)
- only CT scans in acute phase (no MRI substudy)
- no lab sampling performed
- only waiver of consent, no confirmation of consent
- no registration of other studies, other registries or associated trials
- no physician concern recorded in TIL
- only 6 and 12month outcome
- only GOSE and SF-12 performed as outcome assessments (at 6/12 month only)

  → this means: no capture of follow up surgical data, follow up medications, follow up rehab data, follow up socio-economic data, …

This is a non-exhaustive list of data that was not or less captured in CINTER (India):

- only CT scans in acute phase (no MRI substudy)
- no lab sampling performed
- no registration of ICD codes
- no brain monitoring
- only 3 and 6 month outcome
- only questionnaires performed as outcome assessments (at 3/6 month)
- Structured Reporting of CT scans not performed (yet)

For *the Core dataset*, sites were able to participate in one or more of the three strata that are differentiated according to care path:

- Patients seen in the Emergency Room and discharged [ER]
- Patients primarily admitted to the hospital ward (non-ICU) [Adm]
- Patients primarily admitted to the ICU [ICU]

Important remark: the stratum is allocated at presentation based on planned care paths. However, possibility exist that a patient allocated to for example the ER stratum, was still admitted to WARD or ICU in a later stage of his care path due to worsening.

In addition, a number of sub-studies were performed: some patients received extensive MRI imaging and some patients received High Resolution monitoring. Inclusion in these sub-studies was centre specific.

Patients in the Core dataset had extensive follow up assessments that could go up to 2 years after enrolment. The type and timepoints of follow up assessments depend on the strata and sub-studies (see below overview).

Type A: questionnaires only	**Type B: questionnaires + neuropsychological assessment**
- Participant Q A - GOSE questionnaire - GOSE interview - SF12 - SF36 - Qolibri - PCL-5 - RPQ - PHQ-9 - GAD-7	- Participant Q A - GOSE questionnaire - GOSE interview - SF12 - SF36 - Qolibri - PCL-5 - RPQ - PHQ-9 - GAD-7 - Participant Q B - GOAT - RAVLT - TMT + RAVLT - Mobility - CRS-R

	2-3 wks	**3 months**	**6 months**	**12 months**	**24 months**
ER non MR*	A	A	B		
ER MR*	B	B	B		
Adm non MR*		A	B	A	
Adm MR*	A	A	B	B	B
ICU non MR*		A	B	A	
ICU MR*		A	B	B	B

*non MR: patient did not receive extensive MRI imaging / MR: patient did receive extensive MRI imaging
See previous table for A (type A) and B (type B) specifications

The overall time points of assessments and investigations differentiated by stratum and sub-studies is presented below. **You can find an interactive version of this table on the last page of this document**.

CENTER-TBI Core Data Collection : Guide to timing of assessments and investigations differentiated by stratum + Early MR imaging + Ultra early MR + External completion studies

CORE DATA | MR | Ultra Early MR | HR ICU | Extended Coagulation

TIME POINT		Day 1 (Adm)*	Post-op	Day 2	Day 3	Day 4	Day 5	2-3 Week	3 Month	6 Month	12 Month	24 Month
ER STRATUM: 1800												
Clinical data : on presentation/discharge ER and at time of follow-up												
Blood Sampling	Routine hospital	All										
	Biomarkers	All						MR Sites	MR Sites[2]			
	Genetics	All										
	ROTEM/TEG[3]	ROTEM/TEG[3]										
MRI (only MR sites)		Ultra early MR						MR Sites	MR Sites[2]			
Outcome Measures	Neuropsych							MR Sites	MR Sites[2]	All		
	Questionnaires							All	All(F2F)	All		
ADMISSION STRATUM: 1800												
Clinical data : on presentation, day 1-7, day 10, day 14, day 21 and day 28 unless discharge earlier												
Blood Sampling	Routine hospital	All										
	Biomarkers	All						MR Sites		All	MR Sites	MR Sites
	Genetics	All										
	Ext. Coag[3]	Ext. Coag[3]										
MRI (only MR sites)		Ultra early MR						MR Sites		MR Sites	MR Sites	MR Sites
Outcome Measures	Neuropsych									All	MR Sites	MR Sites
	Questionnaires							MR Sites	All	All	All	MR Sites
ICU STRATUM: 1800												
Clinical data : on presentation, day 1-7, day 10, day 14, day 21 and day 28 unless discharge earlier												
Blood Sampling	Routine hospital	All		All	All	All	All					
	Biomarkers	All		All	HR ICU	HR ICU	HR ICU	MR Sites		All	MR Sites	MR Sites
	Genetics	All										
	Ext. Coag[3]	Ext. Coag[3]	Ext. Coag[3]	Ext. Coag[3]								
MRI (only MR sites)		Ultra early MR						MR Sites		MR Sites	MR Sites	MR Sites
Outcome Measures	Neuropsych									All	MR Sites	MR Sites
	Questionnaires								All	All	All	MR Sites

Day 1 = Defined as day of Admission; in most cases this will be the same as day of injury, but in some (those patients presenting in the evening) it may be the next day.
Day 2 = Day after Admission
HR ICU: only sites participating in the HR ICU sub-study
[2] Initially target all patients scanned at 2-3 weeks, may later be restricted to only those with an abnormal MR at 2-3 weeks
[3] only sites participating in the extended coagulation sub-study

2 Understanding e-CRF, forms and variables

As the CENTER-TBI data consists of a large number of variables (over 2500 clinical variables alone), it is important to have an understanding about the overall structure of the e-CRF, the different data collection forms, and the associated variables in order to identify the relevant variables and export them.

The main structure of the e-CRF consists of data related to:

- The patient type, injury, and enrolment
- The pre-hospital and presentation status
- Additional Ward or ICU data (depending on the type of patient)
- Additional MRI or HR ICU data (depending on the sub-studies performed)
- Transitions of care
- Treatment (labs, medication, surgery)
- Outcome assessments

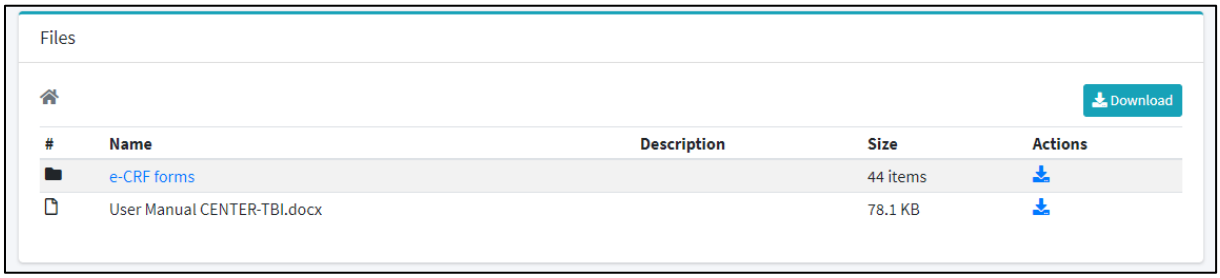
More details can be found in the study protocol: Maas et al. Collaborative European NeuroTrauma Effectiveness Research in Traumatic Brain Injury (CENTER-TBI), *Neurosurgery. 2015 Jan;76(1):67-80* doi: 10.1227/NEU.0000000000000575

The categories/domains used in the data collection regrouping variables are:

Domain/Dataset	**Details**
AIS	Abbreviated Injury Scale details
Biomarkers	Metadata and results from biomarkers samples
Brainmonitoring	Metadata from ICU files
CTMRI	Imaging CT/MRI details, contains data in session/experiment level. We recommend however using “Imaging” domain.
CentralHaemostasis	Metadata and results from Central Haemostasis samples
DailyTIL	Daily Therapy Intensity Level
Genetics	Metadata from genetics samples
Imaging	Imaging details, CTMRI domain contains data in session/experiment level, whereas Imaging domain has data in scan level. This also contains metadata from scans including header and QC information and structured reporting
InjuryHx	Injury details including details coming from Cause of injury, ER therapy and discharge, ER arrival status, Second insults, Neurological assessments and Behavioral history
Labs	Lab values coming from ICU, ER and Admission labs.
LabSampling	Blood sampling data collection details
FollowUp	Patient follow up details coming from Unscheduled follow up, Follow up appointments, ER Therapy and discharge, Hospital discharge forms
Hospital	Hospital discharge and ICU monitoring details
HourlyValues	Vitals measured every second hour
HourlyMeasurements	Hourly values in long format with datetime

MedHx	Medical History prior to the accident
Medication	Therapies and medications during the hospital stay
Meds	Medication during the hospital stay
Outcomes	Outcomes details coming from Follow up appointments, Outcome Assessments, Rivermead RPQ, Rivermead Assessment RPQ, GOSE Structured Interview, GOSE Questionnaire, QoLIBRIOS, QoLIBRI, GAD-7 Anxiety, PCL5, PHQ9 Depression, SF12, SF36, TMT RAVLT, 10m Walk & Timed Up and Go, JFK CRSR
PriorMeds	Medical History prior to the accident
Subject	Patient details coming from Informed Consent, Demographics and Socioeconomic Status, ER therapy and discharge, Hospital Discharge, Vitals Target Dates, Neurological Assessments, Follow up appointments
Surgeries	Surgery details
SurgeriesCranial	Cranial surgery details
SurgeriesExtraCranial	Extracranial surgery details
TransitionsOfCare	Transition of care and ward admission details
Vitals	Daily Vitals, GCS, Four Score, Second Insults details

Find here the overall tree structure of the eCRF with the link to each eCRF form: Annex 8. Or click on the following link or the image to access the individual e-CRF forms in Mica. Access the e-CRF forms (at the bottom of the webpage; see screenshot below).



Read the " Annex 1: Imaging" of this manual for more details on specifically the imaging data, outcome data, HR ICU data and biomarkers data.

3 Data anonymization

The CENTER-TBI data is anonymized, the images are de-faced and the variables are associated with individual patients based on the Global Unique Personal Identifier (GUPI). As part of the anonymization, the following elements are modified or not available.

- Site identifier - Not available; however an anonymized site code is available.
- Country - Not available.
- Dates - Date of Injury of all the subjects are made to 1st January 1970 and other dates are shifted relative to the date of injury.
- Free text - all of the identifiable information were either modified or removed.

4 Baseline derived variables

As baseline and for risk adjustment we recommend using the following variables:

- InjuryHx.PupilsBaselineDerived
- InjuryHx.GCSScoreBaselineDerived
- InjuryHx.GCSMotorBaselineDerived

For outcome, we recommend using:

- Subject.GOSE6monthEndpointDerived

For predictive modelling, the imputed variable might be preferred (see annex 3):

- Subject.DerivedImputed180DaysGOSE

5 Data access requests

For data access requests, submit a study plan proposal on the CENTER-TBI website: https://www.center-tbi.eu/data. The following data access routes are available:

- **OPAL**: Access to data tables and variables in Opal . See chapters 6 to 9.
- **XNAT**: Imaging Nifti files in XNAT. See Annex 1 .
- **Personal file transfer**: Separate data files that are not stored in Opal or XNAT can be requested and will be transferred by the user in person. These files are listed in the table below

Data files	file format(s)	number of files
Metabolomics	mzML	25
Genotype data	vcf, txt	23 VCF files & 23 statistics files
High resolution data of vital parameters	hdf5	284
Imaging DICOM header files	json	Available on request
Imaging QC results	json	Available on request
Imaging Bval	bval	Available on request
Imaging Bvec	bvec	Available on request
Imaging CT Quantitative analysis (icobrain icometrix)	csv, pdf	2
Biomarker results ABCDx Cytokines	csv	2
Biomarker results ABCDx GFAP & IL10	csv	1

6 About Mica and Opal

Mica and Opal are part of the OBiBa open source software suite.

Mica is an online data portal that includes the study catalogue and a searchable variable dictionary giving insight into the CENTER-TBI dataset. It also provides additional information on the study goals, design and participants.

The data dictionary, available in Mica and through the CENTER-TBI website, provides:

- A description of each variable, including measurement methods, unit type and entity type (i.e. level on which the variable was measured).
- The option groups / look-up values.
- The location in the e-CRF.
- A link to the e-CRF's.
- Any relevant remarks concerning the curation of variables.
- Frequency tables giving some orientating insight into the availability and distributions of the data (see also annex 6).

Opal is the data warehouse where you can view datasets, download the data to your preferred format or import the data into your local R session using the Opal API and the special R package (OpalR). Because of its integration with R, complex statistical analysis and reports can be performed in R without having to access the Opal user interface and without having to store a dataset from Opal onto your local pc storage.

7 Mica

The Mica environment is an online data catalog and portal to provide insight into the CENTER-TBI dataset. It has a direct connection to the Opal data warehouse. You can find the CENTER-TBI Mica portal at https://mica-ctbi.clinicalresearch.nl/.

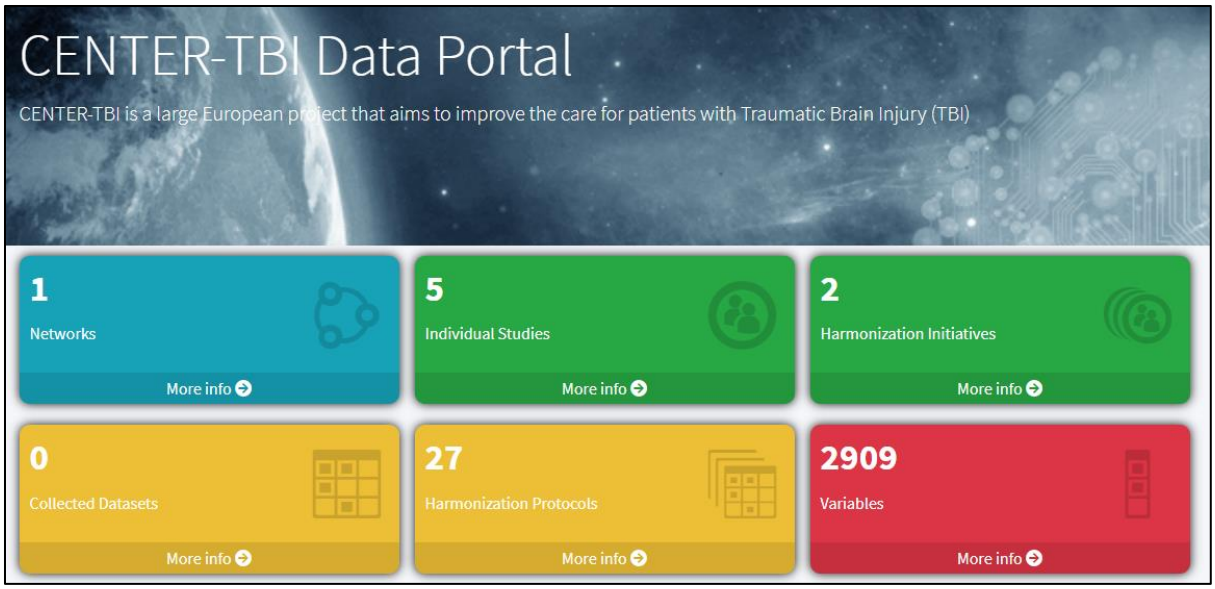
7.1 Login

You do not need to login to enter the Mica portal or to request variables.

7.2 The Mica environment

On the CENTER-TBI Mica homepage you can see the main building blocks of Mica:

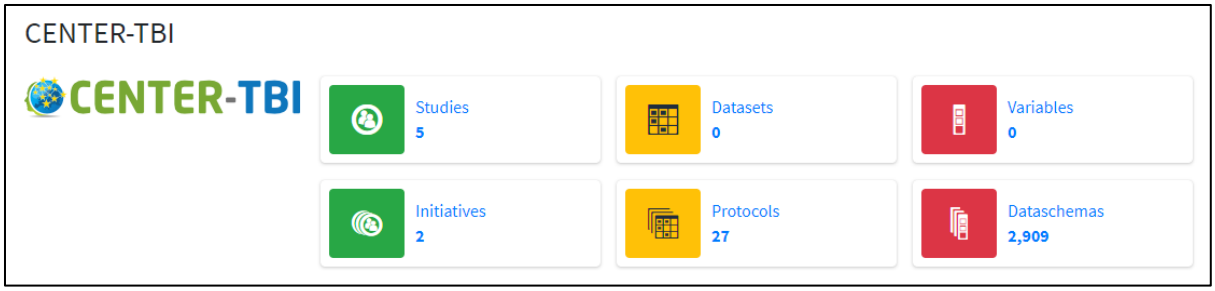
- Networks,
- Studies and Initiatives,
- Datasets and Protocols (=corresponding to the domains described in chapter 2) and
- Variables.



7.2.1 Networks, Studies, Initiatives, Protocols and Variables

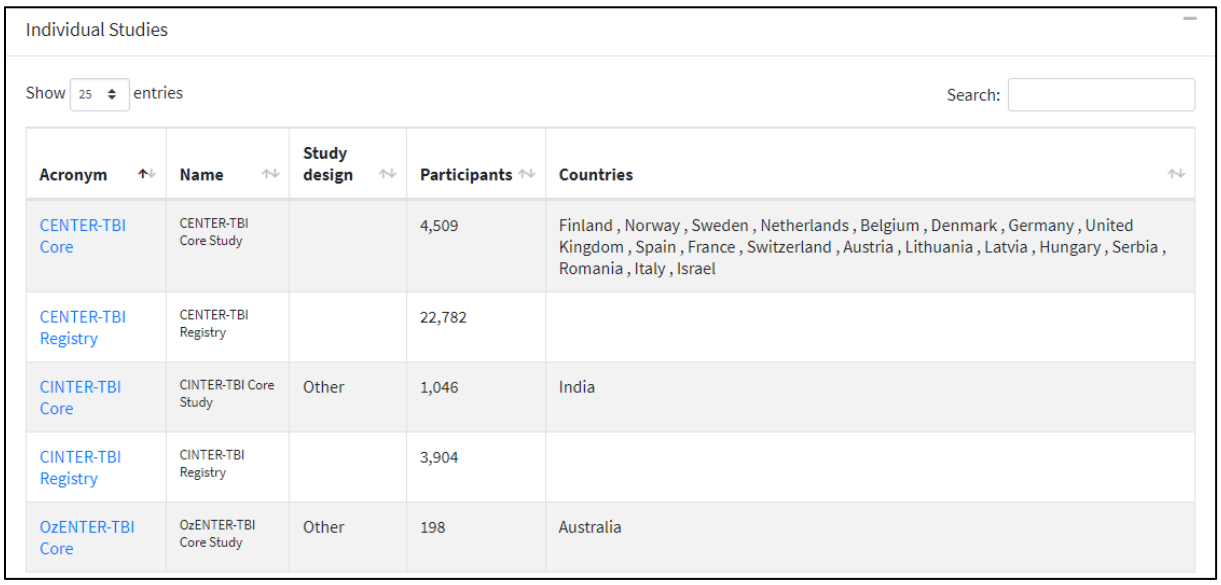
The network is the overarching umbrella that houses the various studies. By clicking on networks, you can find the CENTER-TBI network. Click on 'Read more' to navigate to the network page.

The network page shows an overview of the number of studies, initiatives, datasets, protocols and variables within the CENTER-TBI network.



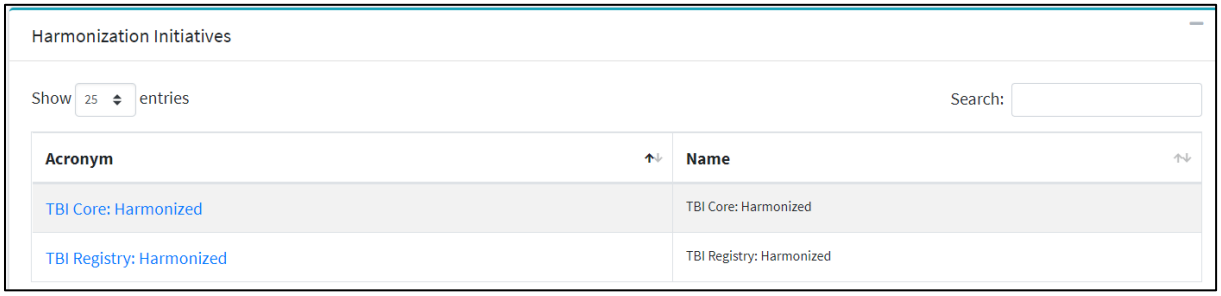
The network currently holds 5 individual studies: CENTER-TBI Core, CENTER-TBI Registry, OzENTER Core, CINTER Core and CINTER Registry. By clicking on one of these studies, you will be taken to the study-specific page.

The study pages of the individual studies show information on the study details, including study design, the timeline, the number of participants and availability of data.

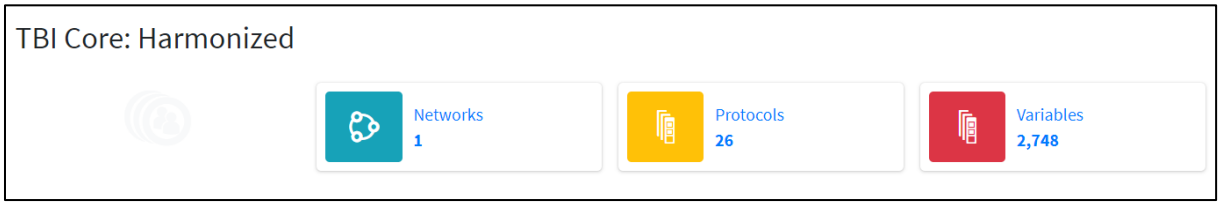


Note that the individual study pages do not include information about the actual datasets and collected variables; you can find these in the Harmonized Initiatives.

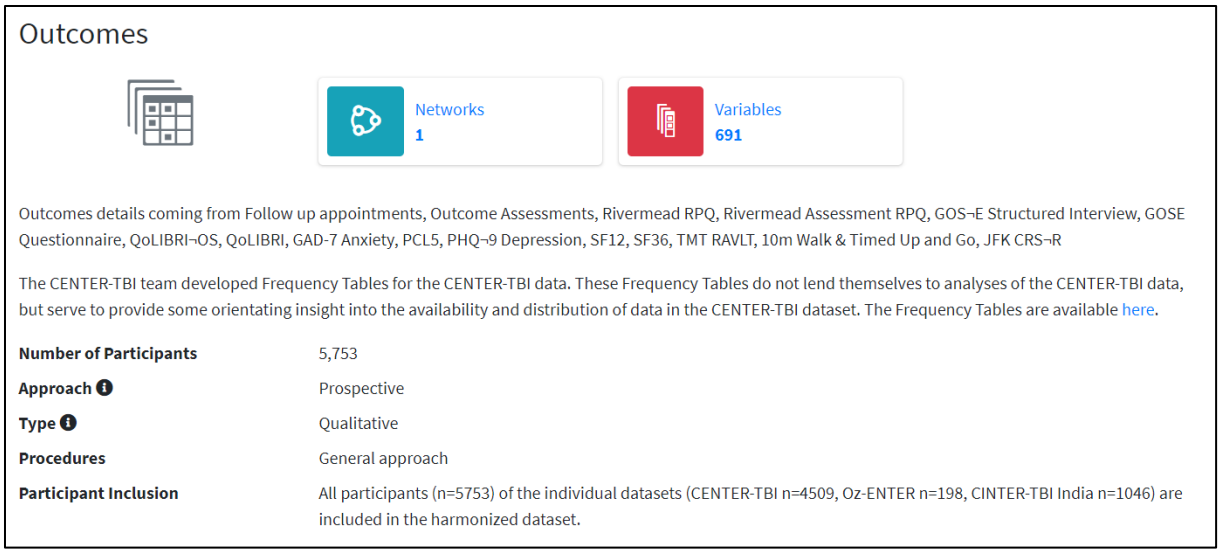
The Center-TBI network contains 2 overarching Harmonized Initiatives: 'TBI Core: Harmonized' and 'TBI Registry: Harmonized'. You can find these at the bottom of the Network page, under 'Harmonization Initiatives', or on the homepage behind the green box.



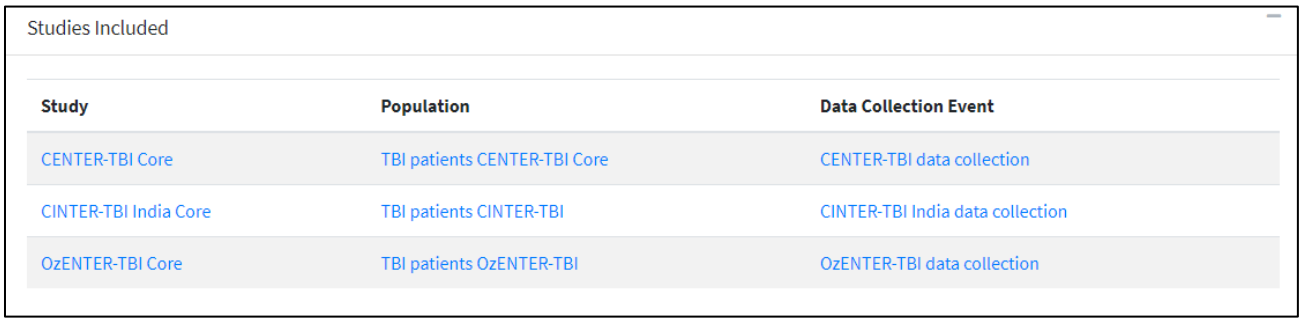
To see the specific datasets or variables that belong to the Center-TBI studies, select one of the Harmonization Initiatives and click on the icons for Protocols or Variables. This will guide you to the search environment, where all protocols and variables are listed.



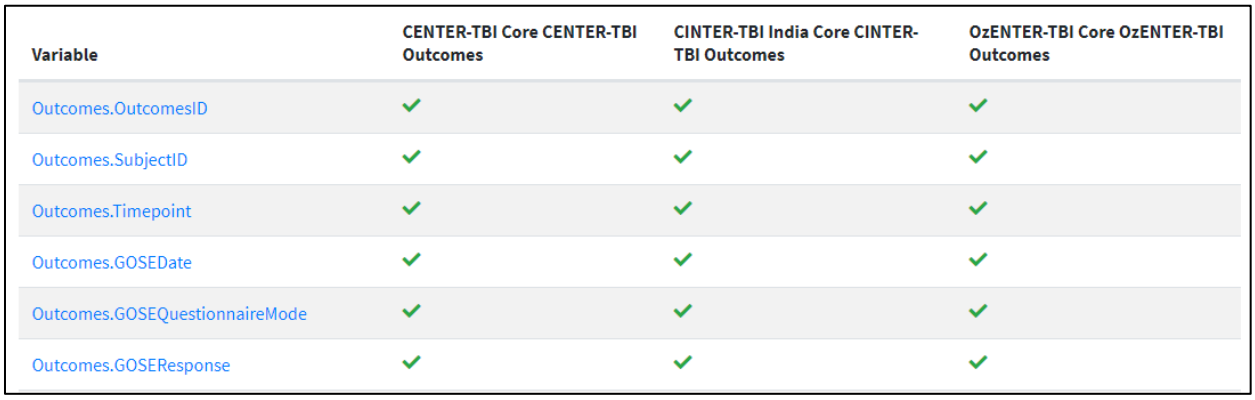
The protocols are equal to the data tables that belong to each study (see also domains described in Chapter 2). Clicking on a protocol shows information on the contents of the dataset and shows the number of variables that make up de dataset. An example of a dataset ('Outcomes') can be seen in the following figure:



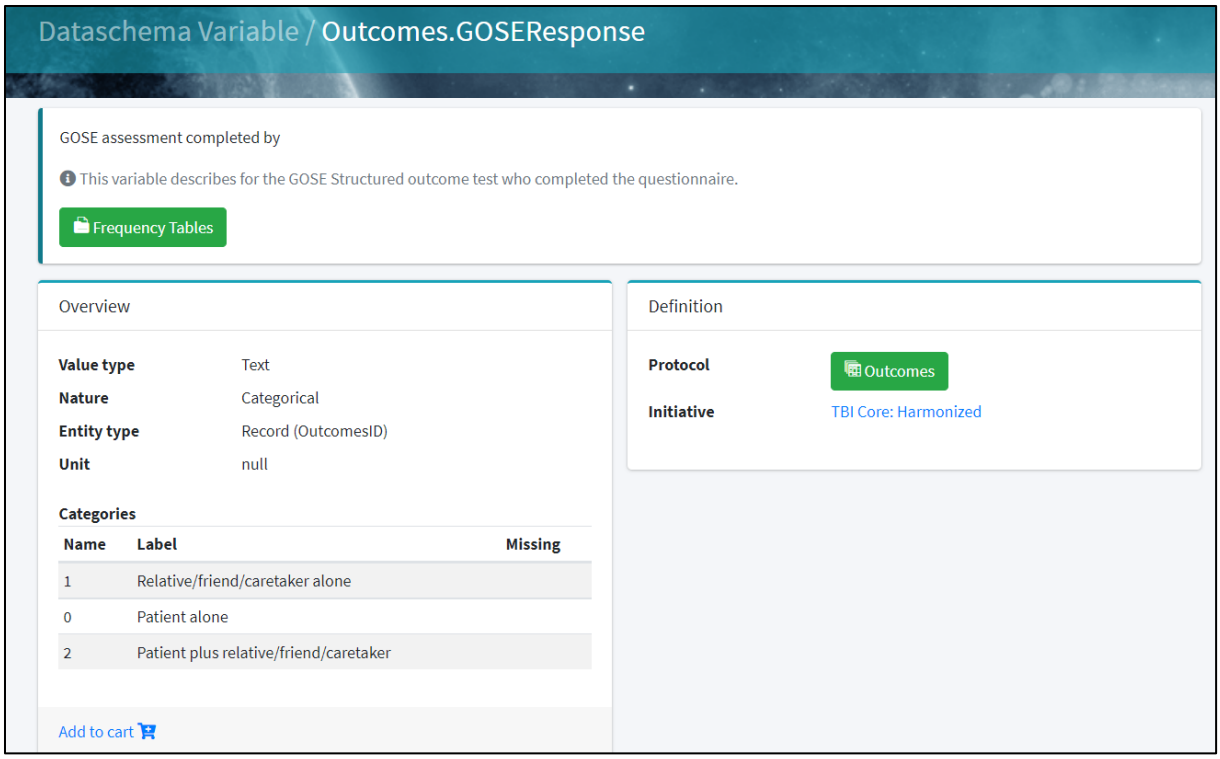
The studies for which this dataset has been harmonized can be found under 'Studies Included' (under each "Dataset"). Here you can click on the study, population or data collection event for more information on the included studies.



At the bottom of the protocol page you can find an overview of the harmonization. It shows which variables in this protocol are available from the different included studies. Some variables will only be available in the CENTER-TBI study, since they were not collected in CINTER-TBI India and OzENTER-TBI. This overview can also be downloaded by clicking the download button.

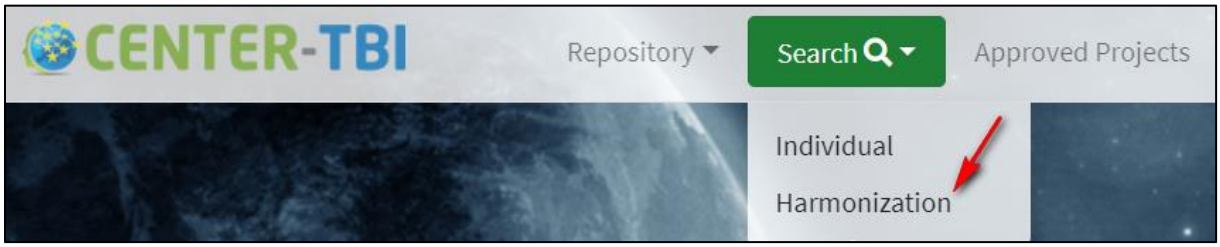


The protocol page also includes a list the variables collected in this protocol. If you click on one of the variables in the list, you will be directed to an overview page for the selected variable, providing you with extra insight into its metadata, based on the CENTER_TBI data dictionary.

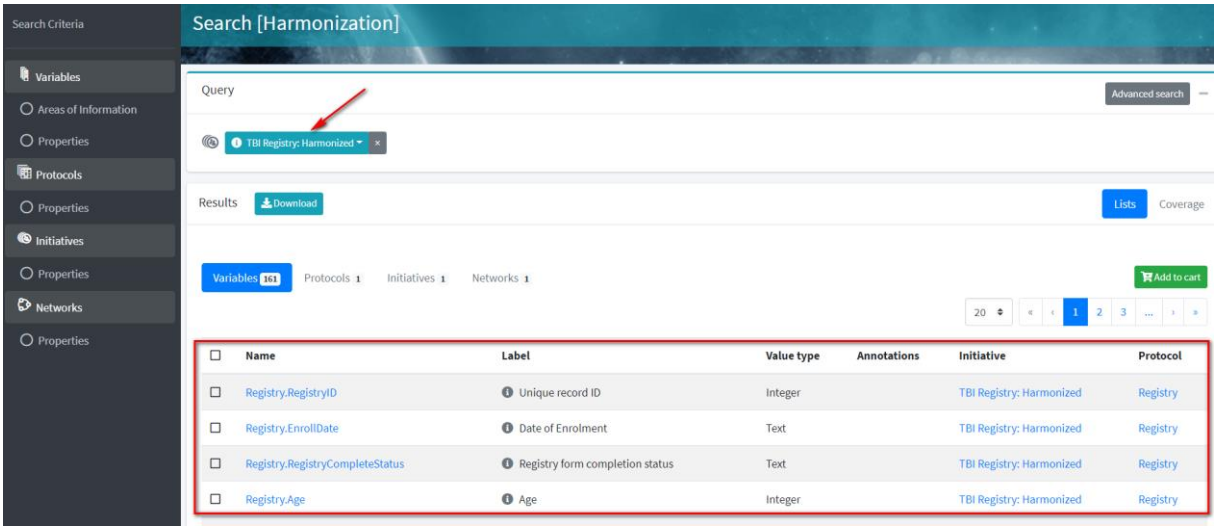


7.3 The Mica search environment

To search for variables or protocols, click on the green Search button on the top of the screen and select 'Harmonization'.



You can also get to the search environment if you click on the red 'Variables' box on the Mica homepage or another page. Depending on where you do this, the search environment will automatically filter for that selection. For instance, when you are in the 'TBI Registry: Harmonized' project and click on the red 'Variables' box, the search environment will automatically list all variables within TBI Registry:

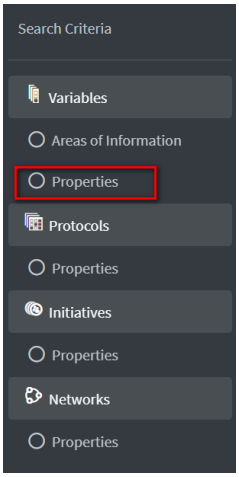


Clicking on any of the shown search results (highlighted in the red box above) will take you back out of the search environment and to the page of your selected variable, protocol or harmonization initiative.

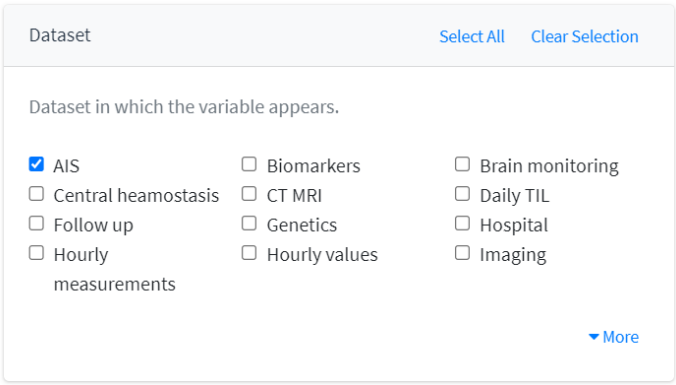
7.3.1 Searching within the search environment

The search environment gives you the ability to search for specific Harmonization Initiatives, datasets (here named Harmonization Protocols) or variables. When searching within the search environment, make sure that you select the right level. For instance, when you want to search variables, you need to select the 'Variables' button.

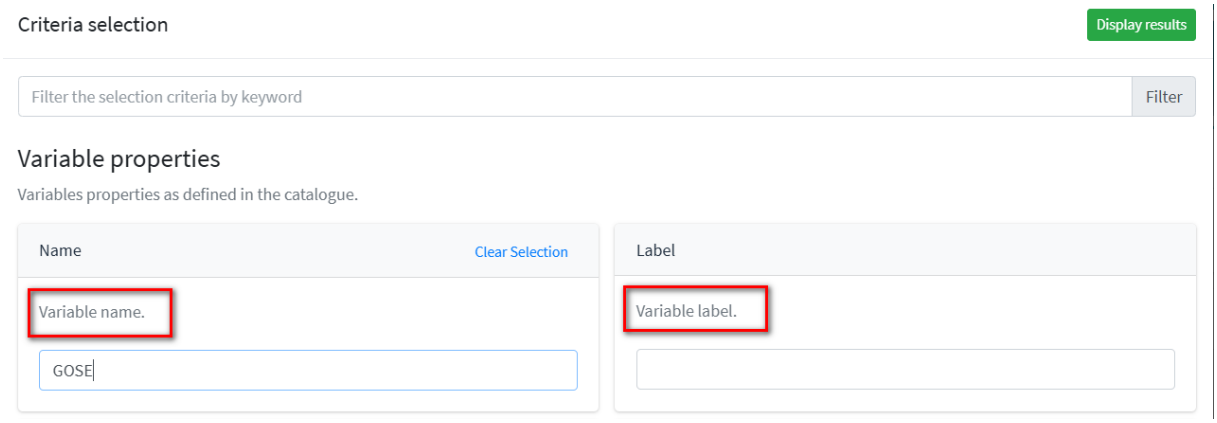
By making use of the properties buttons in the search criteria menu on the left, you can narrow down your search.



For instance, when you click on *Properties* under *Variables*, you can narrow down your selection by Study, Dataset or data type or search for parts of the variable name or variable label.
For example, by selecting the Dataset AIS, it will show only the available variables within the AIS table.

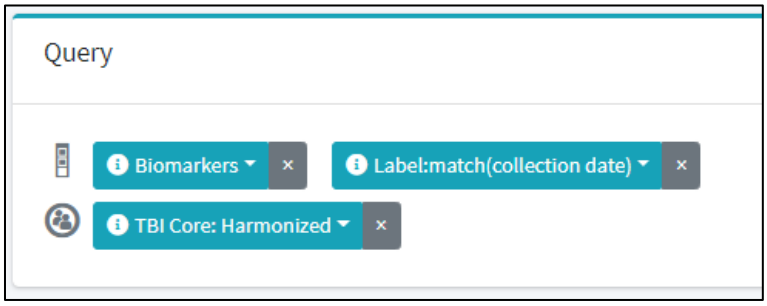


You can also search for specific variables, using (part of) the variable name or label.



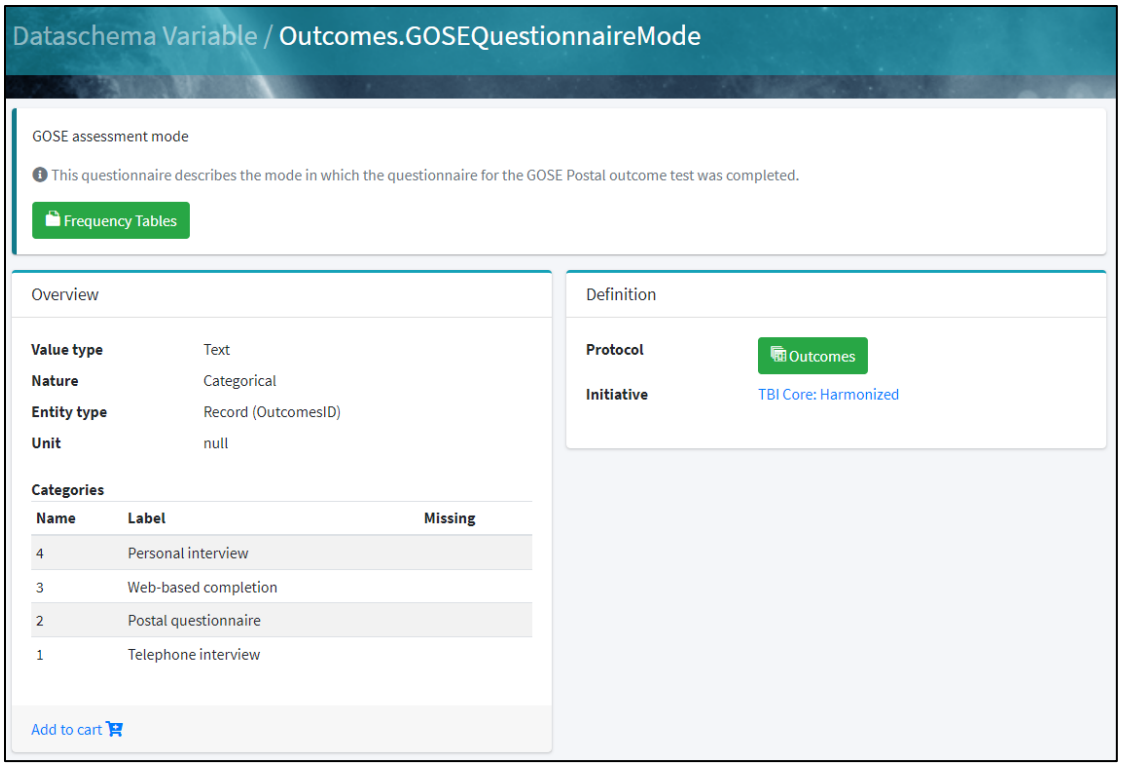
After specifying your selection, click 'Display results' on the top right of the window.

By using a combination of variable names/labels and studies or datasets, you will always be able to find the correct variable. The selection criteria that you chose will be shown at the top, under 'Query'.



By clicking on the criteria, you open a small menu where you can always alter your criteria, and further specify the request. By clicking the crosses, you can quickly remove unwanted criteria.

Once you have found your chosen variable, you can click on the name to be directed to an overview page for the selected variable, providing you with extra insight into its metadata, based on the CENTER_TBI data dictionary.

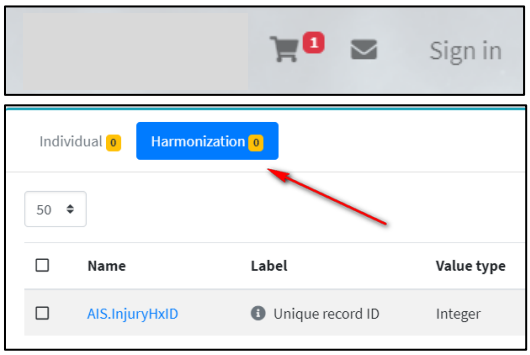


8 Data access requests and shopping cart in Mica

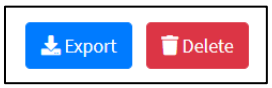
External researchers who are not part of the Center-TBI collaboration, can request access to variables in Opal required for their research proposal. In the Mica catalogue they can search for relevant variables (as described in the previous chapter) and select these for their data access request, as described below.

By clicking 'add to cart' in Mica, either on the variable page or within the search environment, you can add a variable to your shopping cart. You can also select multiple variables within the search environment, and then click on the green 'add to cart' icon in the top right:

You can see which variables are currently in your shopping cart by clicking the 'cart' icon in the top row and go to 'Harmonization' to see the items listed:



The variables in your shopping cart can be downloaded as a zip file, by clicking the 'Export' button on the shopping cart page. The zip file contains multiple csv files.



Attach the original, unchanged zip file to your data access request, to clarify the variables that you would like to request. For further information about data access requests, see **(https://www.center-tbi.eu/data)**.

9 Opal

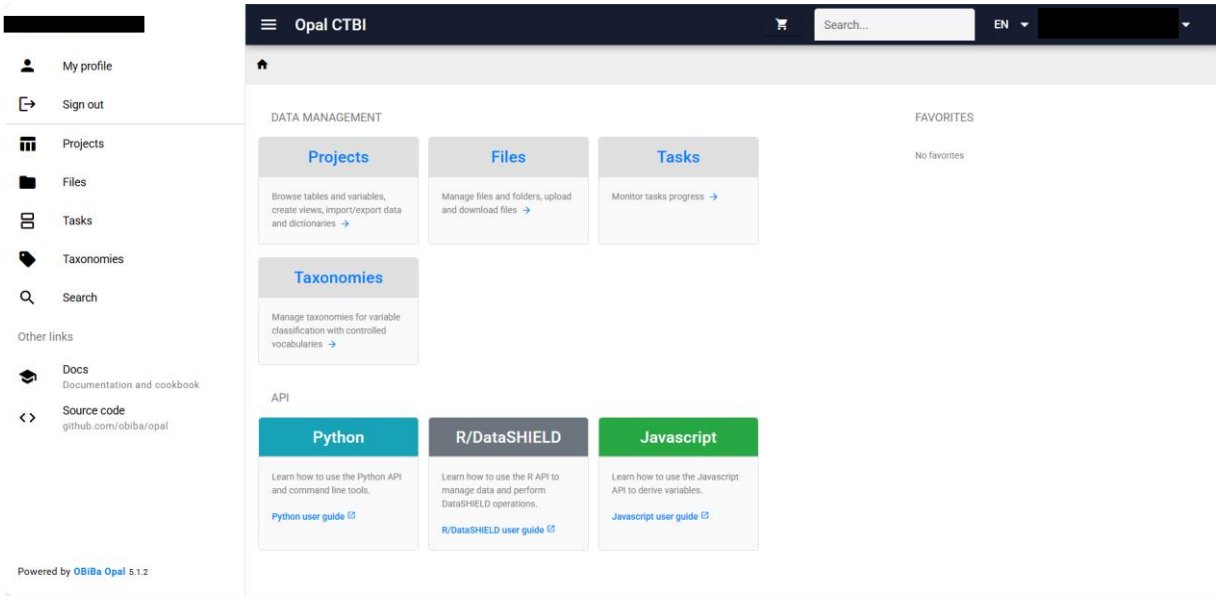
Opal is the core data warehouse application of OBiBa software stacks that provides all the necessary tools to import, validate, derive, query, report, analyze and export data. Because of its integration with R, complex statistical analysis and reports can be performed within Opal as well. Further user guides of Opal are available here.

9.1 Sign up

Before you can access the data in Opal, you need to create an account. Once your data access request has been approved you will get details about your account.

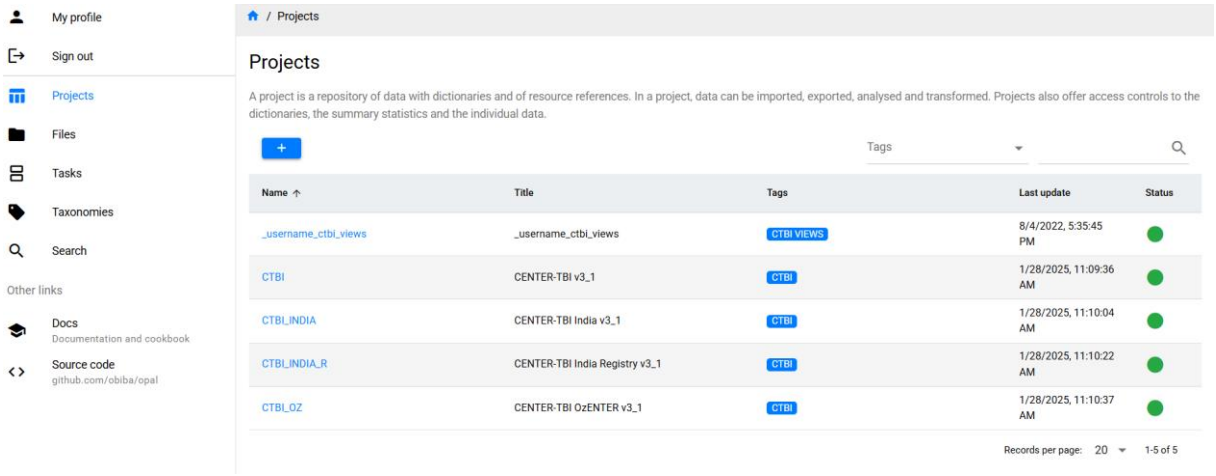
9.2 The Opal environment

Upon opening Opal, you start on the dashboard page. From the dashboard you can navigate to your datasets, search specific tables or variables, and manage files within the Opal environment.

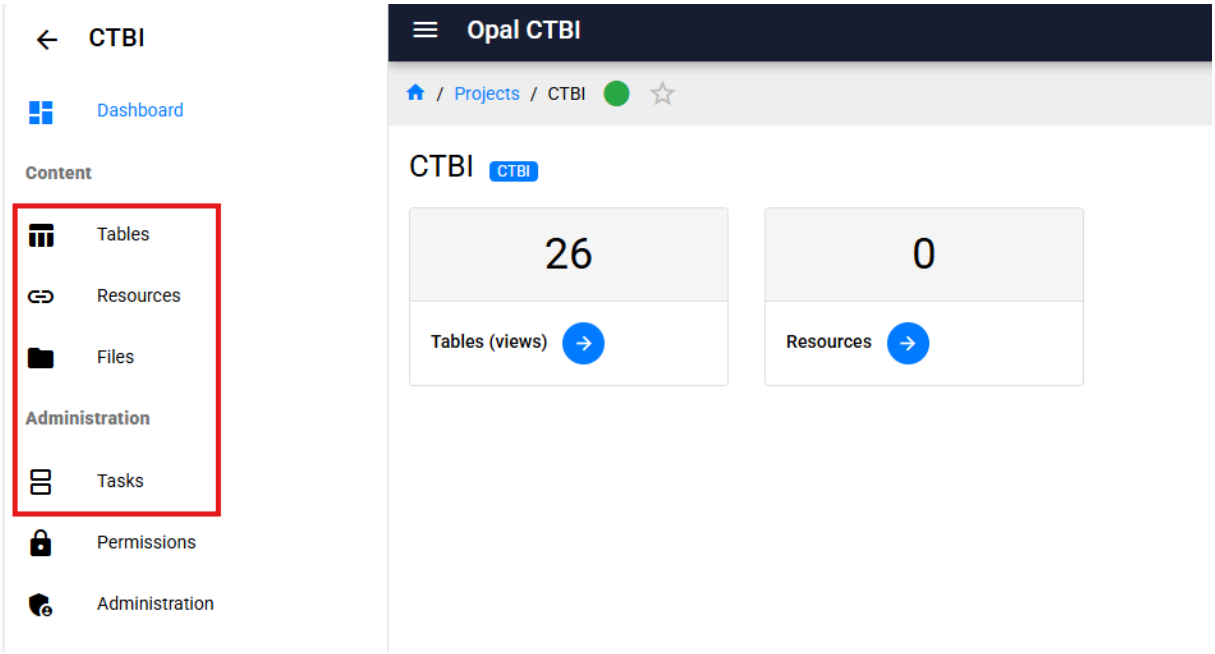


9.2.1 Exploring data in Opal

To get to the data, you can go to 'Projects' button, or click on 'Projects' in the side bar. This will guide you to the project section, where you can find the different datasets: CENTER-TBI Core, CENTER-TBI Registry, CINTER-TBI India Core, CINTER-TBI India Registry and OzENTER-TBI, or for external researchers: the views that have been created for your project.

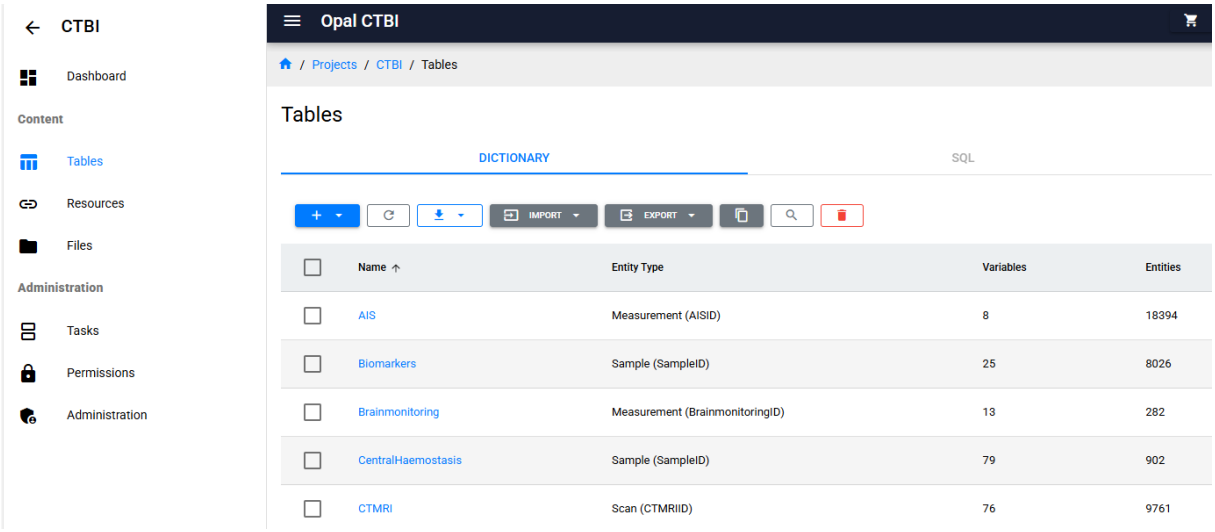


Clicking one of the projects will take you to the project Dashboard. The project dashboard gives an overview of the number of tables/views that are available within the project.



Using the options on the left side, you can navigate to different sections.

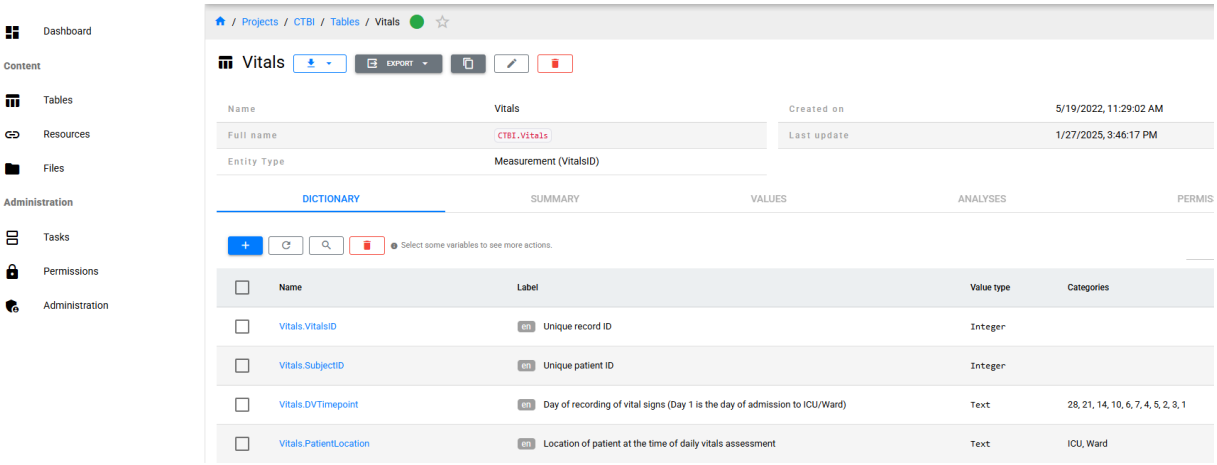
Tables directs you to the tables section within the project.



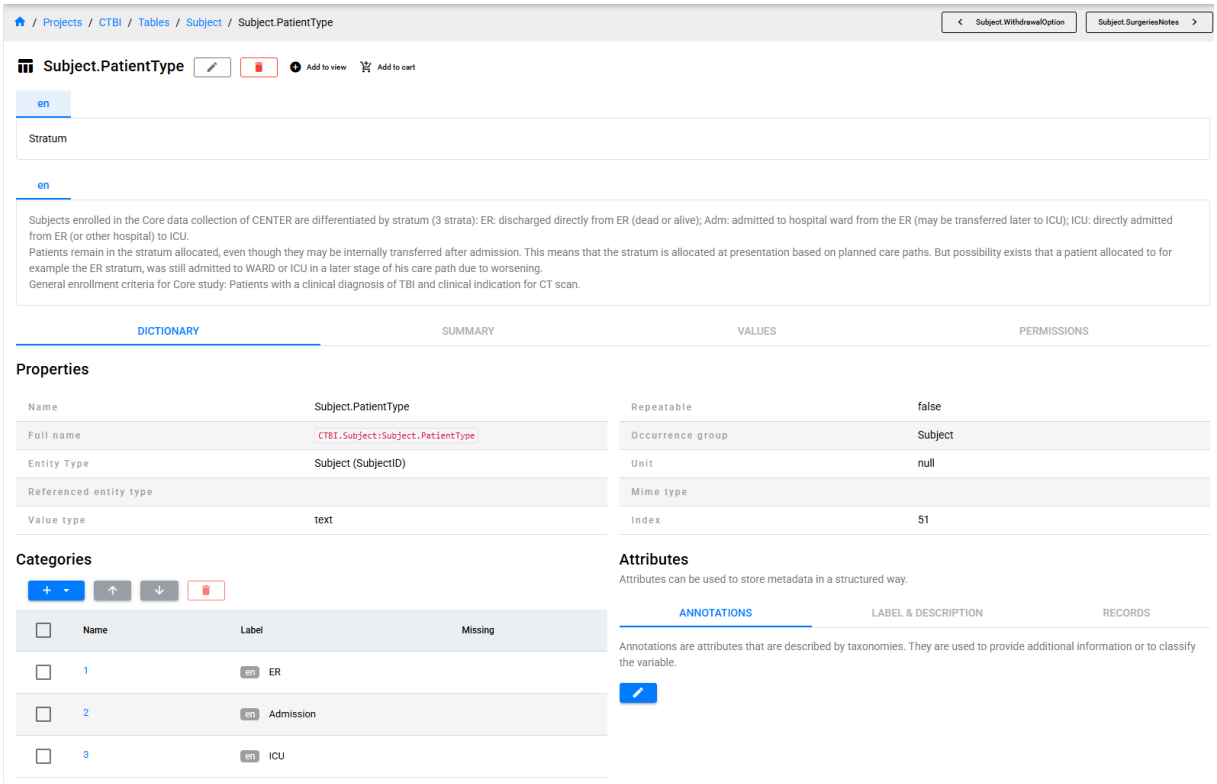
The overview also shows the number of variables and entities, which corresponds with the number of unique ID's. The column 'Entity Type' gives some insight into the nature of the ID's.

In the tables section you can click on the tables to navigate to a table. You can also select tables for export, or write SQL statements to make subsets of the data. More on how to use these options can be found in the export section of this manual.

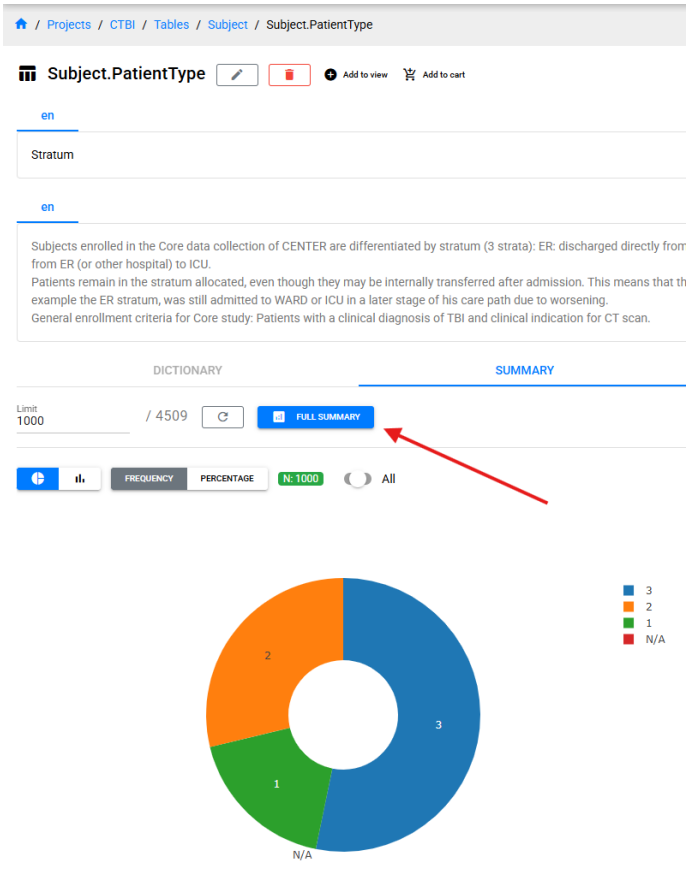
After clicking on a table, you will see an overview of all the variables in the table.
Table 'Vitals' (in the study 'CTBI'):



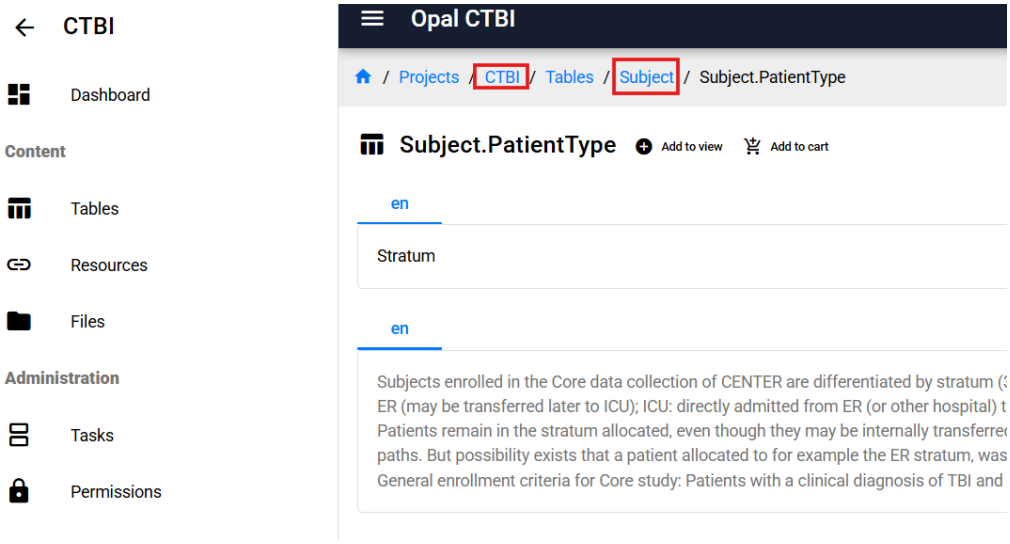
Here you can click on a variable to see more details, or select variables for creating views.
Variable 'Subject.PatientType' (in the table 'Subject', in the study 'CTBI'):



The ‘Summary’ tab gives an overview of the basis data descriptives, such as frequency diagrams and tables. !Note that by default Opal only shows the summary data based on the first 1000 records. Click on ‘Full Summary’ to see the summary of all records.



The 'Values' tab shows you a table of the data values for this specific variable. When you are looking at a specific variable, and you want to go back to the table view, click on the table name, *e.g.* "Subject". You can also use the "back" option in the browser. When you want to go back to the list of all the tables in the Project, you can click on "CTBI" in this example:



Files directs you to the files system, where you can find your downloaded files and extract them to your computer. Also see 'Exporting your data'.

9.3 Exporting your data

There are two ways of accessing the data in Opal for data analysis:

1. Use the Opal API to load data directly into R/Python.
2. Export the datafile in a separate file (.xlsx, .csv or another extension).

The recommended method is the first way, to load data into R/Python through a direct connection with Opal. With this way, there is no need to save a copy of the data locally and you can work with the most up to date version of the data.

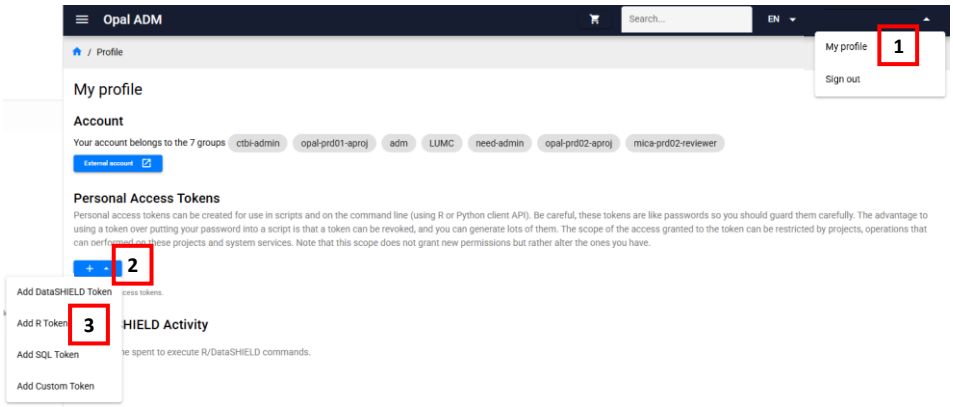
9.3.1 Loading data into R

Here the steps are explained to load data from Opal into R. R is widely used free statistical software that is available for Windows, MacOS and UNIX platforms. Here you can find more information on R and Rstudio (graphical interface around R).

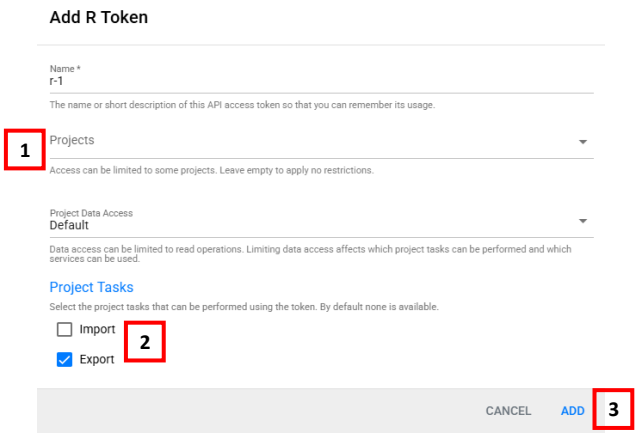
The required steps are also explained in the included Opal_user_manual_OpalR_API.Rmd. You can use this template to set-up the connection and get useful commands on how to incorporate the connection in your own script. The steps will also be discussed below.

9.3.1.1 Opal Personal Access Token (PAT)

For the Opal-R connection, you need to set-up a Personal Access Token (PAT) once in Opal. Click on your username followed by "My profile" (**[1]**). Click on the "+ v" under Personal Access Tokens (**[2]**) and on "Add R Token" (**[3]**).



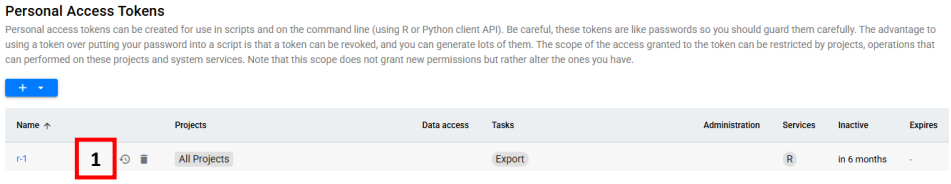
A new window pop-ups where you have to select some settings for your token. With projects you can set the projects for which the token is valid (**[1]**; leave empty so your token is usable for all available projects). Select export for project tasks, to be able to export data from Opal into R (**[2]**). Click ADD (**[3]**) to create the PAT.



An unique token pop-ups, copy it to your clipboard. With this token you can export data from Opal into R, and thus needs to be saved in a secure place. We advise to use the windows credential store via the *keyring* package.

9.3.1.2 Renew Opal token

You will then see that a token has been added to your account, where you can see the specified rights for this token. The Opal token will become inactive after 6 months. Once a token has become inactive, you will have to renew the token in your Opal profile (**[1]**; will only become visible when you hoover over it with your cursor).



9.3.1.3 *Keyring package*

The *keyring* package has functions with which it can access the system's credential store. With the following command you save your token under the name "token_name" in the credential store.

```
keyring::key set("token name")
```

A pop-up will appear, paste the token that has been created above and press OK. Your token is now saved in the credential store and with the following command you can retrieve it.

```
keyring::key get("token name")
```

See the included _Opal_R_connection.Rmd for a practical example.

When others get hold of your token they can also access your data. Therefore, never type or store your token directly in your R scripts, since scripts might be shared with other people or stored on shared spaces. Instead, save your token in the credential store and access it via the above command.

9.3.1.4 *Opal-R connection*

To interact with Opal, you need to use the *opalr* package. This package has a scala of functions that can be used to connect between Opal and R. To access Opal, you first need to set-up an Opal connection. This can be done with the following command.

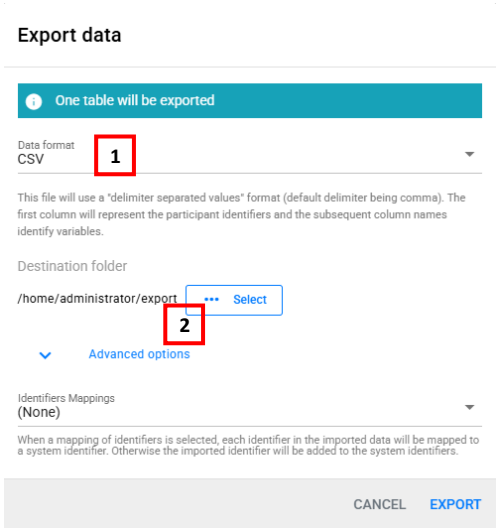
```
opal <- opalr::opal.login(url = "https://opal.clinicalresearch.nl",
token = keyring::key_get("token_name")
```

With this connection, you can access the datafile as follows.

```
datafile <- opalr::opal.table_get(opal = opal, project = "insert
name of the project", table = "insert name of the table")
```

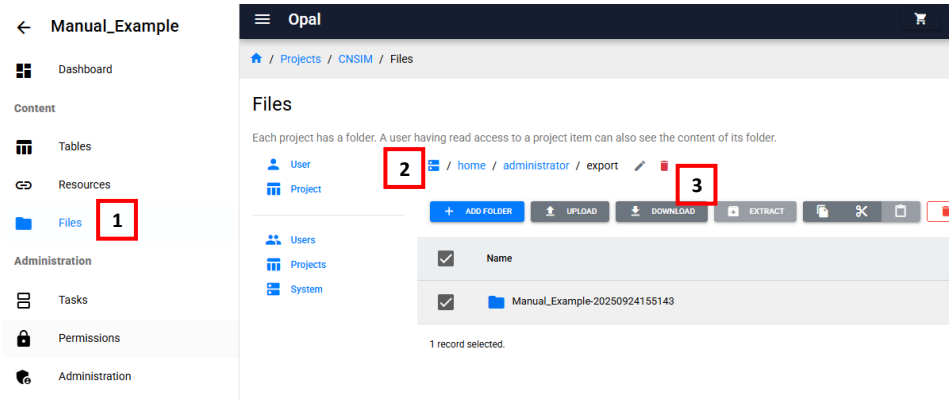
For further information on R statements that can be used see the opalr package documentation.

9.3.2 Export to separate file



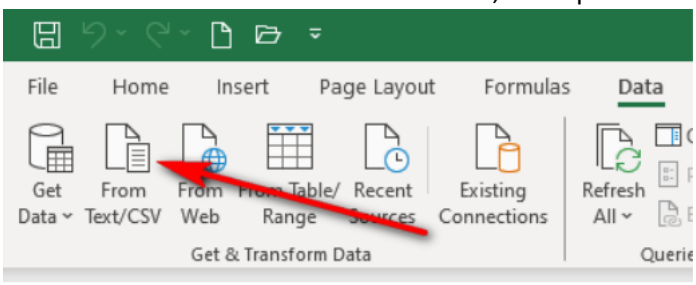
If you prefer not to work with R, it is also possible to export data from Opal into various formats, like csv or sav. With this export you make a local copy of the data, save this copy in a secure place and ensure that no unauthorized person can access it.

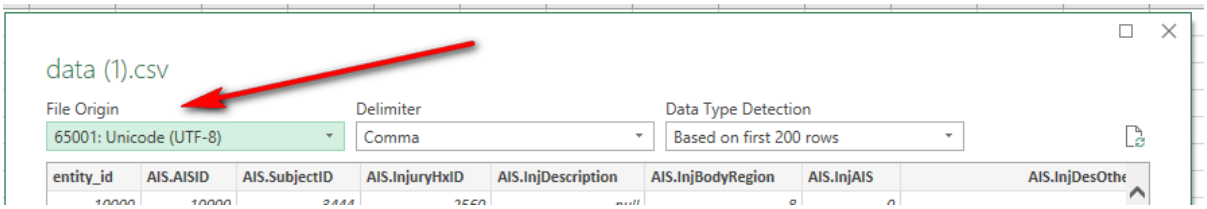
In the **table dashboard** you can use the export button (**[4]** in the picture above). A new window opens where you can select the required data format (**[1]**) and the folder in Opal where the file is saved (**[2]**, choose your personal export folder). From that place the file can be downloaded to your personal computer.
If you navigate to Files (**[1]**) you can find your own export folder. Navigate to the correct path (**[2]**) and you will find your export. After selecting the export you want you can download it (**[3]**). The file will stay available in your export folder for later use, until you delete it.



9.3.3 Special characters

Some tables will contain special characters, including Greek notations such as “µ” to describe units of volume, size or weight. If you wish to use these fields in your analyses, please make sure to choose the correct encoding (UTF-8) when reading in the exported files. For example, when reading in a downloaded CSV file into Microsoft Excel, first open Excel and then read in the CSV file as below

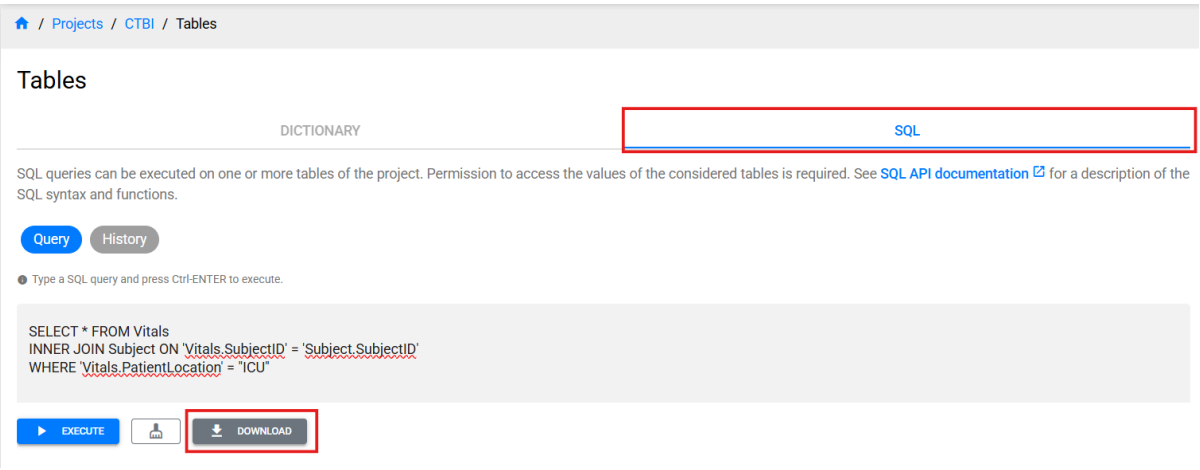




9.3.4 SQL selections

When making manual exports from Opal, it is also possible to use SQL statements to make selections in variables and records, commonly known as queries. In the ‘SQL’ tab, users can use standard SQL commands like SELECT, FROM and WHERE to make selections for the specific use-case. It is important to use backticks (`) around the names of table and variables within these query statements. The selection can be downloaded using the download button below the query. Creating joins between tables is also possible.

Beware that this should only be used if the user has experience with SQL, as it is easy to make mistakes leading to incorrect datasets.



9.4 Deletion of personal view projects

For external users outside the Center-TBI collaboration, a personal view project is created which contains views on the variables they requested for their research project.

Once a user account has been deactivated, their personal view project will be deleted 1 year after last login date.

10 Useful Links

CENTER-TBI website: https://www.center-tbi.eu/

Data Dictionary: https://datadictionary.center-tbi.eu/

GitLab Repository: https://git.center-tbi.eu

Data access & publication requests https://www.center-tbi.eu/data

Cantab manual: https://www.center-tbi.eu/manual/CANTAB-RS6-v20140728

11 Annex 1: Imaging data

The domain 'Imaging' contains all the imaging-related variables in the Opal tables. These include (meta-)data concerning the imaging files, such as scanner settings and scan datetime, but also information extracted from interpretation of the images.

The actual imaging scans are stored as Nifti files in XNAT, hosted on a server at the Leiden University Medical Center. XNAT is an open-source imaging informatics software platform developed by the Neuroinformatics Research group at Washington University, enabling access and viewing of the available Nifti scans. Access to the imaging files in XNAT can be requested via the Center-TBI office (see chapter 5, 'Data access requests').

In addition, access to the following imaging metadata files can be requested trough the Center-TBI office:

Data files	file format(s)
Imaging DICOM header files	json
Imaging QC results	json
Imaging Bval	bval
Imaging Bvec	bvec
Imaging CT Quantitative analysis (icobrain icometrix)	csv, pdf

By searching the domain 'Imaging' in Opal, you can access all the imaging-related variables in the Opal tables.

Variables in the Imaging table that contain the term 'URL' can be used to link the external files to the applicable data record: data file type	opal variable	variable content
Nifti files	Imaging.NiftiURL	XNAT URL per experiment (NB. multiple scans are possible per URL)
Snapshots	Imaging.SnapshotURL	"Can be found in XNAT under the specified scan session."
Thumbnails	Imaging.ThumbnailURL	"Can be found in XNAT under the specified scan session."
Dicom headers	Imaging.DicomHeaderURL	Filename
QC results	Imaging.QCResultsURL	Filename
Bval	Imaging.BvalURL	Filename incl folder structure (because file names are not unique)
Bvec	Imaging.BvecURL	Filename incl folder structure (because file

		names are not unique)

We recommend using the "**Imaging.**" domain primarily, since that domain combines all data from CTMRI and FollowUp together with the imaging Meta data.

The "Imaging.CRF…" variables combine imaging data extracted from the e-CRF, e.g. Imaging.CRFTimepoint = CTMRI.Timepoint + FollowUp.Timepoint.

Central Structured and Standardized Reporting was performed using the NINDS CDEs on all interpretable CT images. By searching "StructuredReporting" you can access this data.
An R code has been developed to help you extract into comprehensive tables the detailed structured reporting information from the Imaging.LesionData variable (JSON files). The code is available in the CENTER-TBI Gitlab. You will also find an interactive diagram of the 25 CDEs and their possible attributes on the CENTER-TBI Gitlab.

CT early is considered "**first CT**". When a Central review is not available this can be due to:

- Scan uninterpretable (wrong scans, bad quality, etc.)
- Scan not available/performed/uploaded

  Reasons for scan not being available included:
  - Scan performed in referring hospital and images not available
  - Pediatric patient and MR performed instead of CT (reducing radiation risk)
  - Patient too uncooperative to undergo scan, and no indication for sedation.

In order to obtain the reports for the initial CT scan, follow the next steps:

1) in Opal download Subject.Gupi, Imaging.ExperimentId, Imaging.Timepoint and your variables of interest;
2) select for unique values of Imaging.ExperimentId;
3) select for timepoint = CT early;
4) you should get 4221 CT early reports of which 4088 were interpretable and interpreted.

For the following list of experiment IDs, Nifti scans are not available. This can be due to the uninterpretability, Dicom missing, preprocessing failed, too few slices, slice increment inconsistency, spine scans uploaded, etc..

CTBI_E00720	CTBI_E10511	CTBI_E20497
CTBI_E00750	CTBI_E10515	CTBI_E21936
CTBI_E00806	CTBI_E10517	CTBI_E25935
CTBI_E01185	CTBI_E13350	CTBI_E27070
CTBI_E01568	CTBI_E13751	CTBI_E28374
CTBI_E02498	CTBI_E14440	CTBI_E29423
CTBI_E02714	CTBI_E15031	CTBI_E30197
CTBI_E04472	CTBI_E18183	CTBI_E32561
CTBI_E06282	CTBI_E18185	CTBI_E32569
CTBI_E06314	CTBI_E19049	CTBI_E41403
CTBI_E06316	CTBI_E19985	CTBI_E43223
CTBI_E06338	CTBI_E20029	CTBI_E43227
CTBI_E06358	CTBI_E20033	CTBI_E43231
CTBI_E07598	CTBI_E20035	CTBI_E43235
CTBI_E08970	CTBI_E20043	CTBI_E43239

CTBI_E43243
CTBI_E43247
CTBI_E43251
CTBI_E43255
CTBI_E43259
CTBI_E43263
CTBI_E43267
CTBI_E43271
CTBI_E43275
CTBI_E43279
CTBI_E43283
CTBI_E43287
CTBI_E43291
CTBI_E43295
CTBI_E43299
CTBI_E43303
CTBI_E43307
CTBI_E43311
CTBI_E43315
CTBI_E43319
CTBI_E43323
CTBI_E43327
CTBI_E43331
CTBI_E43335
CTBI_E43339
CTBI_E43343
CTBI_E43347
CTBI_E44845
CTBI_E45724
CTBI_E47528
CTBI_E54085
CTBI_E54687
CTBI_E56454
CTBI_E65876
CTBI_E65993
CTBI_E66128
CTBI_E66364
CTBI_E66384

For the following list of GUPI's there is no imaging data available because no images have been uploaded to the central repository:

2aKg329	3Mxj242	5hqa779	7CGC395	8rWe275
2aZc954	3nxp645	5hSR652	7DkP965	8swy254
2CwE756	3QtP966	5iBD359	7dKx492	8Tvi853
2CYR995	3rqp487	5iLF374	7dMi577	8xyJ537
2DLL573	3rth894	5JHf259	7FEV334	8Ypg329
2EeT899	3tPx998	5kgp479	7fzL326	8YQm799
2enN423	3Vzc963	5kGq874	7GjL839	9bkT239
2FXu462	3xYA486	5kxA247	7hBd367	9bPn863
2GBu796	3zCu247	5LXx254	7hQS673	9BQE783
2GEY763	4aiT765	5QpW899	7keL575	9ceB526
2gSm989	4arN655	5qyM254	7Ndj855	9frd568
2Hqs463	4cNx999	5uEp795	7ryW383	9gzj428
2LSz237	4CRz375	5xfa852	7TAg459	9hYZ524
2nEF378	4FmV422	5Xrg353	7TFQ763	9Khz638
2Njt548	4fVB478	5yeX796	7tjT299	9LSS688
2pjV364	4GiQ982	5zEy356	7Uig748	9NAk452
2qbz679	4hJR542	6Amc624	7UiY495	9qCk363
2Qjc754	4hWG766	6AQD757	7uXt263	9qsP965
2rCM426	4JAW268	6bJy778	7VDS928	9QwR739
2SiV997	4Jbh597	6CSJ667	7vzi267	9SzG278
2tYg498	4mrf549	6eVk586	7Xrc556	9TAP374
2UFb788	4pUb945	6ezY353	7yAV286	9tfK563
2uKc322	4qeX427	6HuM739	7ydN775	9thB794
2VdG646	4Qzq727	6itq446	7YeE448	9umj552
2xPq786	4rde674	6iYc665	7Zmp573	9UUC848
2yuc942	4RST279	6KNy732	7ZqT564	9UYd464
2ZFf733	4SnU954	6RLt465	8ahU997	9VdG934
2zUX287	4vnx935	6sqR823	8aYp777	9Wcr656
2Zzf943	5bDR966	6teA862	8bcT775	9WXx422
3bwd673	5btz622	6VmM865	8cdZ428	9xNa427
3Cen349	5BwA829	6Xtv852	8cZU858	9XtN928
3dsY975	5DPs832	6yeM346	8dAj689	9yPZ753
3dyu657	5Dzy536	6Yvw547	8fgS499	9zQx843
3gAJ693	5fWB355	6ywi954	8iga477	
3HCR796	5GXU253	6ZQE735	8kCf765	
3iUs972	5hDc979	6ZTC457	8PTs464	
3MiC879	5hPD942	7AcU632	8qdZ537	

12 Annex 2: High Resolution ICU data

By searching the domain ‘Brainmonitoring’, you can access all the High resolution ICU related variables.

To gain access to the HDF5 files themselves, a data access request can be made via the Center-TBI office. Once the request has been approved, a personal data transfer will be prepared and additional information will be provided on how to download the files.

Variable Brainmonitoring.HDF5URL in domain ‘Brainmonitoring’ contains the file names that could be used to link the data records in Opal and the HDF5 files belonging to each record.

13 Annex 3: Outcome data: GOSE scoring

There are four main sources for GOSE ratings in CENTER-TBI, summarized as follows:

(1) Clinician overall GOSE rating (*Outcomes.GOSEScore)*. Structured interviews for the GOSE were conducted face to face or by telephone with either the patient or another informant. Interviewers then assigned an overall rating. Occasionally a clinician rating may have been recorded without an interview, if contact was not possible, and there was sufficient information from other sources.

(2) Centrally assigned GOSE based on structured interview responses. Completed GOSE questionnaires were assigned a rating centrally on the basis of the responses recorded, as described above.

(3) GOSE self-report questionnaire scored centrally as already described. Questionnaires could be completed by patients alone, by patients with the help of carers, or by relatives / carers alone.

(4) Deaths assigned using date of death in the database. Central scoring added the outcome rating 'dead' to the composite GOSE variables when appropriate. 'Dead' is assigned if (a) the date of death occurs before the follow-up window for the timepoint has closed, (b) no other outcome has been assigned to the composite (from interview or self-report sources), (c) A follow-up is due at the timepoint per protocol.

Approaches to GOSE assessment used in CENTER-TBI were sufficiently well aligned to justify construction of composite and derived variables for use in subsequent analyses.
In Mica/Opal you will find the following available GOSE variables:

Outcomes.GOSEScore:
This GOSE Structured rating was assigned by the rater/interviewer at the time of the interview and entered in the e-CRF for a particular follow-up time-point, along with responses on the sections of the interview.

Outcomes.DerivedCompositeGOSE:
This GOSE rating is a derived composite score calculated from sources in the following order of precedence:.

(a) Central scoring based on GOSE interview questionnaires completed by investigators
(b) Central scoring based on GOSE self-report questionnaires completed by patients and/or carers
(c) Interviewer ratings for survivors, when neither the interview or self-report questionnaires have been completed
(d) From date of death or investigator recorded death

Subject.GOSE6monthEndpointDerived:
A six month GOSE endpoint that uses both observed ratings (i.e. *Outcomes.DerivedCompositeGOSE)* and imputed values (when the observed value was missing or outside the pre-specified time window (5-8 months))

Subject.DerivedImputed180DaysGOSE:
This variable contains a GOSE that has been imputed at exactly 180 days after injury. In this variable the observed values also were replaced by imputed values.

We recommend using **Subject.GOSE6monthEndpointDerived** for analyses. This variable conforms to conventional expectations that imputation is only used when observed values are not available.
For predictive modelling, the imputed variable **Subject.DerivedImputed180DaysGOSE** might be preferred. This variable takes advantage of smoothing accomplished by the imputation process, and avoids using a hybrid of observed and imputed values.

These variables have very similar values and the choice of which to use will have little in the way of practical implications. A MSM model has been used for imputation in both variables (see also https://www.liebertpub.com/doi/10.1089/neu.2019.6858).

Outcomes.GOSEScore and *Outcomes.DerivedCompositeGOSE* contain a higher number of missing values and are not being recommended for general-purpose use in subsequent analyses.
The GOSE was collected at 3 months and 6 months across all strata, and at 12 months in the admission and ICU strata. Depending on the strata and on the MRI sub-study the GOSE may have been collected in other subgroups at particular timepoints. The same rules and models have been applied for 3 month and 12 month outcome, leading to the following variables available in Mica/Opal:
Subject.GOSE3monthEndpointDerived
Subject.DerivedImputed90DaysGOSE
Subject.GOSE12monthEndpointDerived
Subject.DerivedImputed360DaysGOSE

GOSE scoring OzENTER (Australia) dataset:
GOSE was measured by either a postal questionnaire or a structured telephone interview by a trained assessor.

Subject.GOSE6monthEndpointDerived: does not include imputed values in the OzENTER data set. It equals the composite GOSE at 6 months.

GOSE scoring CINTER India dataset:
Outcomes.GOSEScore
For the 3 and 6 month GOSE scoring, the Indian investigators did not perform a structured interview (as was done in CENTER-TBI), since this was too time consuming for many patients. The investigator asked some general questions about quality of life and how the patient felt and then completed the GOSE questionnaire in the e-CRF based on their clinical judgement. Hence, the "Outcomes.GOSEScore" variable is a guided interview, in line with the original GOS approach, in which the clinician has a description of different GOS categories and, based on the information available, makes a judgement about the overall rating.

Outcomes.DerivedCompositeGOSE / Subject.GOSE6monthEndpointDerived:
Data entered in the Postal GOSE, is a copy of the interview GOSE – no postal questionnaires were performed.

As questionnaires were only interview based, no composite or derived variable is available for the Indian dataset, the variable "Outcomes.GOSEScore" should be used.

14 Annex 4: Outcome data: Cantab

Researchers who wish to understand the way that the CANTAB tests are administered and the outcomes are derived, should refer to the CANTAB Eclipse Test Administration Guide that is available through this link: https://www.center-tbi.eu/manual/CANTAB-RS6-v20140728.

The guide to modes and outcome measures that gives the key to the specific CENTER-TBI outcomes as recommended by Cambridge Cognition can be found below. There is some redundancy among these outcomes and researchers may want to be selective in their final choice of variables.

The main (confounding) covariates for these tests are age and education level, and particularly the former. These need considered in analyses.

The CANTAB outcomes can be skewed and/or have outliers, and depending on your analysis you may want to transform (e.g. Log10) and/or truncate variables or otherwise deal with these problems.

CANTAB: Guide to Modes and Outcome Measures for CENTER-TBI study

Cambridge Cognition. February 2016

Research - Cantab Research Suite

Attention Switching Task (AST)

Designed to assess: executive function that provides a measure of cued attentional set-shifting (cognitive flexibility)

Mode: *8d1-8d2-40d2a-8s-40sa-8s8d-40s40da*

Block	Number of Trials	Rule?	Practice or Assessed?	Feedback
1	8	Direction	Practice	Yes
2	8	Direction	Practice	Yes
3	40	Direction	Assessed	No
4	8	Side	Practice	Yes
5	40	Side	Assessed	No
6	16	Direction and Side	Practice	Yes
7	80	Direction and Side	Assessed	No

Duration: ~8 minutes

Key Outcome Measures	Definition
Median Switching cost	The difference between the median latency of response (from stimulus appearance to button press) during assessed blocks in which the rule is switching versus assessed blocks in which the rule remains constant. Calculated by subtracting the median latency of response during non-switching block(s) from the median latency of response during switching block(s). This measure is complex in sense. Close to zero indicates less variation in latencies across non-switch and switch trials. A positive score indicates that the subject responds more quickly in non-switching block(s).
Median Congruency cost	**The difference between the median latency of response (from stimulus appearance to button press) on the trials that were congruent versus the trials that were incongruent. Calculated by subtracting the median congruent latency (in ms) from the median incongruent latency. This measure is complex in sense.**

	Close to zero indicates less variation in latencies across congruent and incongruent trials. A positive score indicates that the subject is faster on congruent trials and a negative score indicates that the subject is faster on incongruent trials.
Median Reaction Latency	The median latency of response (from stimulus appearance to button press), calculated across all correct, assessed trials

Paired Associates Learning (PAL)

Designed to assess: episodic memory and visuospatial learning

Mode: *Clinical*

Stage	Number of Patterns	Number of Boxes	Practice or Assessed	Max Number of Attempts
1, 2	1	6	Assessed	10
3, 4	2	6	Assessed	10
5, 6	3	6	Assessed	10
7	6	6	Assessed	10
8	8	8	Assessed	10

Duration: ~10 minutes

Key Outcome Measures	Definition
Total errors (adjusted)	The number of times the subject chose the incorrect box for a stimulus on assessment problems but with an adjustment for the estimated number of errors they would have made on any problems, attempts & recalls they did not reach due to failing or aborting the test
First trial memory score	The number of correct box choices that were made on the first attempt during assessment problems.
Stages completed	The number of stages that the subject passed.

Reaction Time (RTI)

Designed to assess: reaction time, movement time and vigilance

Mode: *RTI TBI*

Stage	1 or 5 choice?	Practice or Assessed	Number of Trials	Max Trials Allowed
1 *(identical to stage 2 in Clinical mode)*	5-choice Touchscreen	Practice	12 trials (stage repeated if less than 5 out of 12 correct)	40
2 *(identical to stage 5 in Clinical mode)*	5-choice Press-pad	Assessed	8 trials (stage repeated if less than 5 out of 8 correct)	40

Duration: ~X minutes

Mode: *Clinical*

Stage	1 or 5 choice?	Practice or Assessed	Number of Trials	Max Trials Allowed
1	Simple	Practice	9 (stage repeated if less than 5 out of 9	18

	Touchscreen		correct)	
2	5-choice Touchscreen	Practice	12 (stage repeated if less than 5 out of 12 correct)	40
3	Simple Press-pad	Practice	9 (stage repeated if less than 5 out of 9 correct)	18
4	Simple Press-pad	Assessed	9 (stage repeated if less than 5 out of 9 correct)	18
5	5-choice Press-pad	Assessed	8 (stage repeated if less than 5 out of 8 correct)	40

Duration: ~6 minutes

Key Outcome Measures	Definition
Median 5-choice reaction time	The median duration between the onset of the stimulus and the time at which the subject released the button. Calculated for correct, assessed trials in which the stimulus could appear in any one of five locations
Median 5-choice movement time	The median time taken to touch the stimulus after the button has been released. Calculated for correct, assessed trials where stimuli could appear in any one of five locations

Rapid Visual Information Processing (RVP)

Designed to assess: sustained attention and concentration

Mode: *Clinical*

Stage	Target Sequence	Practice or Assessed
1	357	Practice
2	357	Practice
3	357	Practice
4	357; 246; 468	Practice
5	357; 246; 468	Assessed
6	357; 246; 468	Assessed
7	357; 246; 468	Assessed

Duration: ~7 minutes (1 minute per stage, 9 target sequences per minute)

Key Outcome Measures	Definition
A' prime	A' (A prime) is the signal detection measure of sensitivity to the target, regardless of response tendency (the expected range is 0.00 to 1.00; bad to good). In essence, this metric is a measure of how good the subject is at detecting target sequences
Median latency	The median response latency during assessment sequence blocks where the subject responded correctly

Stockings of Cambridge (SOC)

Designed to assess: spatial planning and spatial working memory

Mode: *Clinical*

Problem Number	Practice or Assessed?	Number of Trials	Min. number of Moves Required	'Too Many Moves'
1,2,3,4	Practice	4	1	3

5,6	Practice	2	2	5
7,8	Assessed	2	2	5
9,10	Assessed	2	3	7
11,12	Assessed	2	4	9
	Follow-phase	*The computer replicates the moves the subject made to complete the previous 8 problems, and the subject must simply follow the moves on screen*		
13,14	Practice	2	2	5
15,16	Assessed	2	4	9
17,18,19,20	Assessed	4	5	12
	Follow-phase	*The computer replicates the moves the subject made to complete the previous 8 problems, and the subject must simply follow the moves on screen*		

Duration: ~10 minutes

Mode: *Clinical-no follow*

Overall Stage	Practice or Assessed	Number of Trials	Number of Moves Required	'Too Many Moves'
1	Practice	4	1	n/a
-	Practice	2	2	n/a
2	Assessed	2	2	5
-	Assessed	2	3	7
-	Assessed	2	4	9
3	Practice	2	2	n/a
-	Assessed	2	4	9
-	Assessed	4	5	12

Duration: ~8 minutes

NB: use the Clinical mode if you want to look at thinking time as well as accuracy scores, whereas the Clinical-no follow mode should be used if you only want to look at accuracy scores and not latency scores

Key Outcome Measures	Definition
Problems solved in minimum moves	The number of times the subject has successfully completed a problem in the minimum possible number of moves
Initial thinking time ***(NB: Applicable to the Clinical mode only)***	The mean difference of the time taken to select the first ball in the solve problem phase and the time taken to select the first ball in the follow problem phase. For *n* move problems
Subsequent thinking time	The subject's mean speed of movement after the initial move has been made for *n* move problems

Spatial Working Memory (SWM)

Designed to assess: executive function and spatial working memory

Mode: *Clinical*

Stage	Number of Tokens	Number of Boxes	Practice or Assessed	Max Number of Inspections (per problem)
1				
2				
3				
4				

5				
6				
7				
8				
9				

Duration: ~5 minutes

Key Outcome Measures	Definition
Between errors	The total number of times the subject revisits a box in which a token has previously been found in the same problem (calculated for assessed problems only)
Strategy	For assessed problems with six boxes or more, the number of distinct boxes used by the subject to begin a new search for a token, within the same problem

15 Annex 5: Biomarkers and blood sampling data

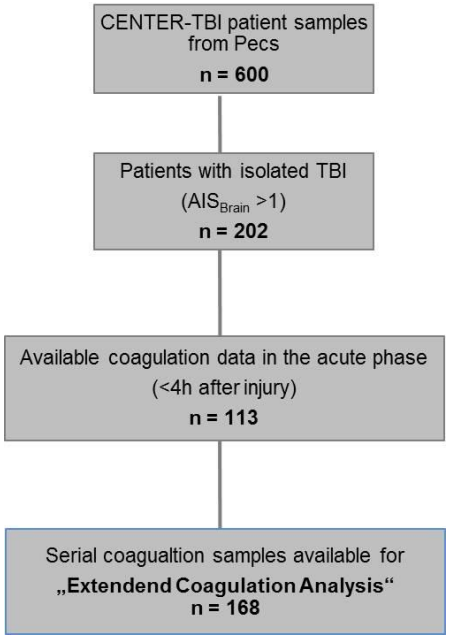
For all blood samples the curated Sample ID, collection date and time and freezer date and time, etc. has been uploaded to Mica/Opal.

We recommend using the "Biomarkers." domain, "CentralHaemostasis." domain and "Genetics." domain primarily (instead of the "labsampling."), as these contain the curated sample ID and curated collection/freezer dates and times.

In addition, for the biomarkers samples, the results of the following analyses were uploaded into Opal:

- ✓ Biomarkers.S100B
- ✓ Biomarkers.NSE
- ✓ Biomarkers.GFAP
- ✓ Biomarkers.UCH-L1
- ✓ Biomarkers.NFL
- ✓ Biomarkers.Tau

Concerning the extended coagulation analyses (CentralHaemostasis.), 600 patient samples from 9 sites were received. TBI patients with extracranial injuries and AIS Brain ≤1 were excluded, which gave a cohort of 202 patients, who had an isolated TBI. We focused on iTBI patients who received a coagulation test within the first 4 hours after TBI injury. In total, 113 iTBI had the information about early coagulation tests, together with serial blood collection samples, hence we achieved a sample number of 168 iTBI patients. Based on this iTBI cohort, an extended coagulation analysis was performed for which you will also find the results in Mica/Opal.



In addition to the data found in Mica/Opal, access can be requested to the following additional files through the Center-TBI office:

Data files	file format(s)	number of files
Biomarker results ABCDx Cytokines	csv	2
Biomarker results ABCDx GFAP & IL10	csv	1

16 Annex 6: Frequency tables

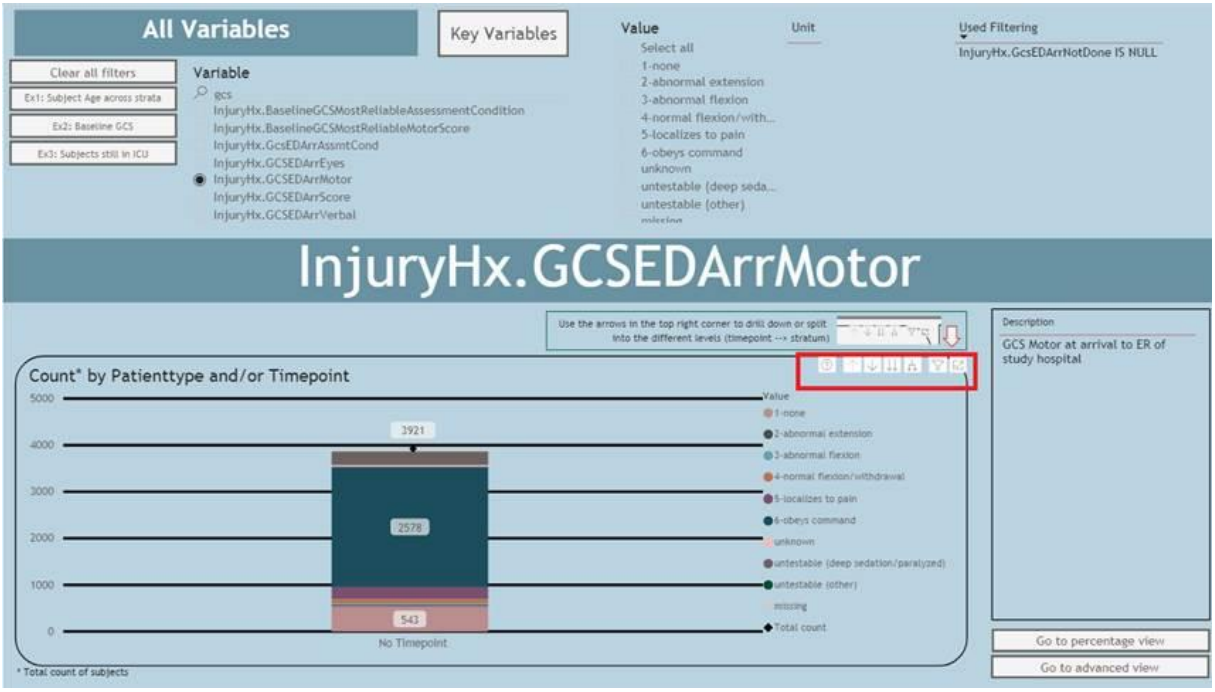
We have been developing Frequency Tables for the CENTER-TBI data. These Frequency Tables do not lend themselves to analyses of the CENTER-TBI data, but serve to provide some orientating insight into the availability and distribution of data in the CENTER-TBI dataset.

The Frequency Tables are available through the CENTER-TBI Data Dictionary: When you select a variable in the list of the Frequency Tables, the corresponding values, unit (if applicable) and frequency table will appear per patient type (ER, Admission, ICU).

In the upper right corner of the "all variables" view you will also see the rules used to establish missingness (as not all variables are applicable for all patients) under "Used Filtering" (when rules apply).

If you move your mouse to the top right corner of the table (underneath the green frame), arrows will appear (see screen shot) on which you can click to see the data per timepoint (for longitudinal data) or the total amount of data.

In the downright corner of the screen, you will see a button to go to the percentage view or advanced view. In the advanced view, you will find more parameters about this variable. You can click on them & select the ones that interest you.



17 Annex 7: Upload of statistical scripts for analyses to CENTER-TBI Gitlab

According to the data access and publication policies of CENTER-TBI, researchers are requested to save their final variable search and to upload the final statistical scripts used in preparation of CENTER-TBI manuscripts (please also see the SOP manual for data access and publication requests on the CENTER-TBI website (https://www.center-tbi.eu/data)).

Scripts are to be uploaded through the Publication Submission Approval: https://www.center-tbi.eu/data/publication

Save statistical scripts to Gitlab:
In addition, for CENTER-TBI researchers, there is the possibility to save their script on Gitlab. login to the script application on the website: https://www.center-tbi.eu/scripts/**.** (Use the same login credentials that are used to login to Extranet).

You will see on the left an "explorer" part where you can navigate through the folders to see the available shared-scripts and download scripts you would like to use.

Below the explorer part, you see an "upload form" where you can upload a new script (or several scripts) you would like to share. Make sure to mention the Study Plan number or Manuscript reference in the Notes section, together with a brief description. Once uploaded, your script will be reviewed and then released.

On the right part, you see the "info box" with text from the README file pertaining to the folder you open in the explorer part.

And below that you see the list of "latest uploads" with the status (approved or awaiting approval). When you have uploaded a script, you can see here if your script has been approved yet or is still awaiting approval.

18 Annex 8: Release notes for Opal releases

18.1 release 3.1 – 31-01-2025

18.1.1 Scope and summary

Center-TBI data in Opal originated from Neurobot version 3.0 and was imported into Opal in 2022. For the current release to version 3.1 in Opal, several changes were made to the data and dictionaries in the Opal tables. Also a new route for transfer of data files had been created.

18.1.1.1 Line break cleaning

The previous dictionaries contained several line breaks of non-HTML type, which resulted in Opal cutting off lines after the first line break ("\n") when updating data in tables or adding new variables to tables. All of these line breaks have been replaced by HTML line breaks. This will enable future data table updates in Opal by the LUMC Opal management team.

18.1.1.2 Non-UTF8 cleaning

After the initial import of the Center-TBI Neurobot data into Opal in 2022, non-UTF8 characters were present in the data and dictionaries, which resulted in several text fields with unreadable values (example, see screenshot below). These non-UTF8 characters have been replaced by corrected text values, as provided by the Center-TBI office.

Variable	Value
Labs.DLPlateletOtherUnit	X103/Ã□Â□Ã□Â¼L

18.1.1.3 Invisible character cleaning

All fields in data and dictionaries that were cleaned of non-UTF8 characters and linebreaks, have additionally been checked for invisible special characters that sometimes created new non-UTF8 characters in the Opal user interface or caused words to be glued together. In order to solve this, non-breaking spaces (U+00A0) have been replaced by regular spaces (U+0020). And the non-visable characters string terminator (U+009C), operating system command (U+009D) and soft hyphen (U+00AD) have been removed. These characters are not directly relevant for the interpretation of the text fields and have been cleaned in order to improve data handling in Opal.

18.1.1.4 New route for file exchange and XNAT server

In addition, the Center-TBI file server (https://files.center-tbi.eu/remote.php/webdav) has been closed for access, which means that files are no longer available for download via this server. In release 3.1 there are new ways of making files available: Imaging files are now available on an XNAT server of the Leiden University Medical Center. Access to this server can be requested at the Center-TBI office. All other files can be shared with a user via a safe transfer method, after sending a request to the Center-TBI office.

18.1.1.5 URL data cleaning

In response to the new file exchange routes described above, old URLs to Center-TBI file server (https://files.center-tbi.eu/remote.php/webdav) in Opal data tables have been replaced by new URLs to the XNAT server, or by file names and information about how files can be requested.

18.1.2 Changes in Opal

The following changes have been made to Opal tables:

1. Data updates (see Table 1):

a. Replace data text fields containing non-UTF8 with corrected values, as provided by the Center-TBI office.
b. In fields with non-UTF8 characters, also non-visible special characters that caused new non-UTF8 characters in Opal user interface have been removed or replaced by a regular space: non-breaking spaces (U+00A0), string terminator (U+009C), operating system command (U+009D), soft hyphen (U+00AD).
c. Imaging table: Replace old URLs to imaging files with new XNAT URLs or with file name, depending on file type. 280 old NIFTI URLs were replaced by 'NA', because no imaging file is available for that scan.
d. Brainmonitoring table: Replace old URL to HDF5 files with file name.

2. Dictionary updates (see Table 2):
   a. Replace dictionary fields containing non-UTF8 characters with corrected values, as provided by the Center-TBI office.
   b. Non-visible special characters that caused new non-UTF8 characters in Opal user interface have been removed or replaced by a regular space: non-breaking spaces (U+00A0), string terminator (U+009C), operating system command (U+009D), soft hyphen (U+00AD).
   c. Replace all line breaks ("\n") in dictionaries with HTML line breaks ("
").
   d. Update dictionary labels and descriptions for URL variables in tables "Imaging" and "Brainmonitoring".

Lists of all changes (per data point) can be requested at opal@lumc.nl.

Table 1: Data updates in Opal:

Opal project	**non-UTF8 characters replaced by UTF8 characters & non-visible special characters removed**	**Old URLs replaced by new URL or file name**
CTBI	**13 tables**: AIS CTMRI DailyTIL FollowUp Hospital Imaging InjuryHx Labs MedHx Medication Outcomes PriorMeds Subject	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.NiftiURL Imaging.BvalURL **Brainmonitoring table**: Brainmonitoring.HDF5URL
CTBI_R	*No changes*	*No changes*
CTBI_OZ	*No changes*	**Imaging table**: Imaging.DicomHeaderURL Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.NiftiURL
CTBI_INDIA	*No changes*	**Imaging table**: Imaging.DicomHeaderURL

		Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.NiftiURL
CTBI_INDIA_R	*No changes*	*No changes*

Table 2: Dictionary updates in Opal:

Opal project	**non-UTF8 characters replaced by UTF8 characters**	**linebreaks replaced with HTML linebreaks & non-visible special characters removed**	**Variable label changed**	**Variable description changed**
CTBI	**All tables**: done for all dictionary fields where applicable	**All tables**: done for all dictionary fields where applicable	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.BvalURL **Brainmonitoring table**: Brainmonitoring.HDF5URL	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.NiftiURL Imaging.BvalURL **Brainmonitoring table**: Brainmonitoring.HDF5URL
CTBI_R	*No changes*	**All tables**: done for all dictionary fields where applicable	*No changes*	*No changes*
CTBI_OZ	**All tables**: done for all dictionary fields where applicable	**All tables**: done for all dictionary fields where applicable	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.BvalURL	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.NiftiURL Imaging.BvalURL
CTBI_INDIA	**All tables**: done for all dictionary fields where applicable	**All tables**: done for all dictionary fields where applicable	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.BvalURL	**Imaging table**: Imaging.DicomHeaderURL Imaging.QCResultsURL Imaging.SnapshotURL Imaging.ThumbnailURL Imaging.BvecURL Imaging.NiftiURL Imaging.BvalURL
CTBI_INDIA_R	*No changes*	**All tables**: done for all dictionary fields where applicable	*No changes*	*No changes*

18.1.3 New route for file exchange

The following data files are now available to be requested via the Center-TBI office (Table 3). Once the request has been approved, the files will be transferred to the researcher via via a safe transfer method.

Table 3: Available data files

Data files	**file format(s)**	**number of files**
Metabolomics	mzML	25

Genotype data	vcf, txt	23 VCF files & 23 statistics files
High resolution data of vital parameters	hdf5	284
Imaging QC results	json	Available on request
Imaging Bval	bval	Available on request
Imaging Bvec	bvec	Available on request
Imaging CT Quantitative analysis (icobrain icometrix)	csv, pdf	2
Biomarker results ABCDx Cytokines	csv	2
Biomarker results ABCDx GFAP & IL10	csv	1

18.1.3.1 XNAT server

Imaging files in Nifti format are now available on an XNAT server of the Leiden University Medical Center. An account is required to log on to the web interface of the XNAT server. Access to this server can be requested at the Center-TBI office.

To access images in XNAT: copy the URL of imaging files in Opal's Imaging table and paste the URL into a web browser. This will take you to the corresponding image scan session in the XNAT web interface.

18.1.4 Impact for users

The impact level of the changes made in release 3.1 to the data tables in Opal, is estimated: **low**.

- Clean-up of non-UTF8 characters, non-visible characters and line breaks in the table dictionaries are esthetic changes;
- Clean-up of non-UTF8 characters and non-visible characters in the data are also esthetic: changes are made to text fields only and do not affect the meaning or interpretation of the data;
- Changes to data values and dictionaries of URLs in the Imaging and Brainmonitoring tables are made to administrative text fields only and will not affect the meaning or interpretation of the data.
- Users who have access to *views* on the Opal data: data in views will be automatically updated for the affected variables. However, dictionaries of views created before this release 3.1 will remain unchanged. In case a user wishes for the dictionaries of their existing views to be updated (mainly relevant if a view contains imaging or HDF5 URL variables), they can send a request for a manual dictionary update to adm@lumc.nl.

18.2 release 3.2 – 06-10-2025

18.2.1 Scope and summary

In January 2025 version 3.1 was released in Opal. For the current release to version 3.2 in Opal, several changes were made to the data and dictionaries in the Opal tables.

18.2.1.1 Major Extracranial Injury

The calculated variable MajorExtracranialInjuryDerived has been added to the InjuryHx table. This variable indicates whether there is an Abbreviated Injury Scale (AIS) of 3 or higher for one or more of the following domains: Face, ThoraxChest, ThoracicSpine, AbdomenPelvicContents, LumbarSpine, UpperExtremities, LowerExtremities, PelvicGridle, Externa, CervicalSpine.

18.2.1.2 Biomarker timepoint

A timepoint variable has been added to the biomarker table of the CTBI project, indicating at what timepoint the biomarker sample is collected after injury. The new variable contains the following options: acute (within 24 hours), subacute (between 1 and 10 days), 2-3 weeks (between 11 and 30 days), 3 months (between 31 days and 4.5 months), 6 months (between 4.5 and 9 months), 12 months (between 9 and 18 months) and 24 months (after 18 months).

18.2.1.3 Decompresive Craniectomy measurements

The post-operative CT scans of a subset of patients were reviewed to quantify the extent and characteristics of the decompressive craniectomy (DC) and its impact on intracranial structures. Eighteen DC variables were added to the Imaging table of the CTBI project that display different of these measurements.

18.2.1.4 Updating datafile and dictionary

Because the CENTER-TBI data is continuously analyzed, new information keeps being gathered. The values of various tables have been updated with this new information. This involves 5 variables from the biomarkers table (GFAP, UCH-L1, Tau, NFL and S100B), 2 variables from the Imaging table (Timepoint and CRFTimePoint) and 200 variables from the Outcomes table (DerivedCompositeGOSE, DerivedCompositeGOSEDaysPostInjury, SF12ScorePCS, SF12ScoreMCS, Derived_SF12ScorePCS, Derived_SF12ScoreMCS, SF36ScorePCS, SF36ScoreMCS and 192 CANTAB variables). Additionally, a number of minor fixes have been made to the datafile or the variable dictionary, to fix certain typos or inconsistencies in the data.

18.2.2 Changes in Opal

The following changes have been made to Opal tables:

Opal project	In release	Variables altered
CTBI	New variables	Biomarkers.Timepoint; InjuryHx.MajorExtracranialInjuryDerived; Imaging.SubduralHematomaAcuteLargestThicknessDerived & 18 Imaging.DC_... variables
	Updating values	Biomarkers.GFAP: Biomarkers.UCH_L1; Biomarkers.Tau; Biomarkers.NFL; Biomarkers.S100B; Imaging.Timepoint; Imaging. Imaging.CRFTimePoint; Outcomes.SF12ScorePCS;Outcomes.SF12ScoreMCS; Outcomes.Derived_SF12ScorePCS; Outcomes.Derived_SF12ScoreMCS; Outcomes.SF36ScorePCS; Outcomes.SF36ScoreMCS; Outcomes.DerivedCompositeGOSE; Outcomes.DerivedCompositeGOSEDaysPostInjury & 192 Outcomes.CANTAB variables
	Adjust typos or inconsistencies	Imaging.DicomHeaderURL, Imaging.ExperimentLabel & HourlyMeasurements.id
CTBI_R	Adjust typos or inconsistencies	Registry variable dictionary labels
CTBI_INDIA	New variables	InjuryHx.MajorExtracranialInjuryDerived
	Adjust typos or inconsistencies	Imaging.DicomHeaderURL & HourlyMeasurements.id

CTBI_INDIA_R	Adjust typos or inconsistencies	Registry variable dictionary labels
CTBI_OZ	New variables	InjuryHx.MajorExtracranialInjuryDerived
	Adjust typos or inconsistencies	Imaging.DicomHeaderURL & HourlyMeasurements.id

Lists of all changes (per data point) can be requested at opal@lumc.nl.

18.2.3 Impact for users

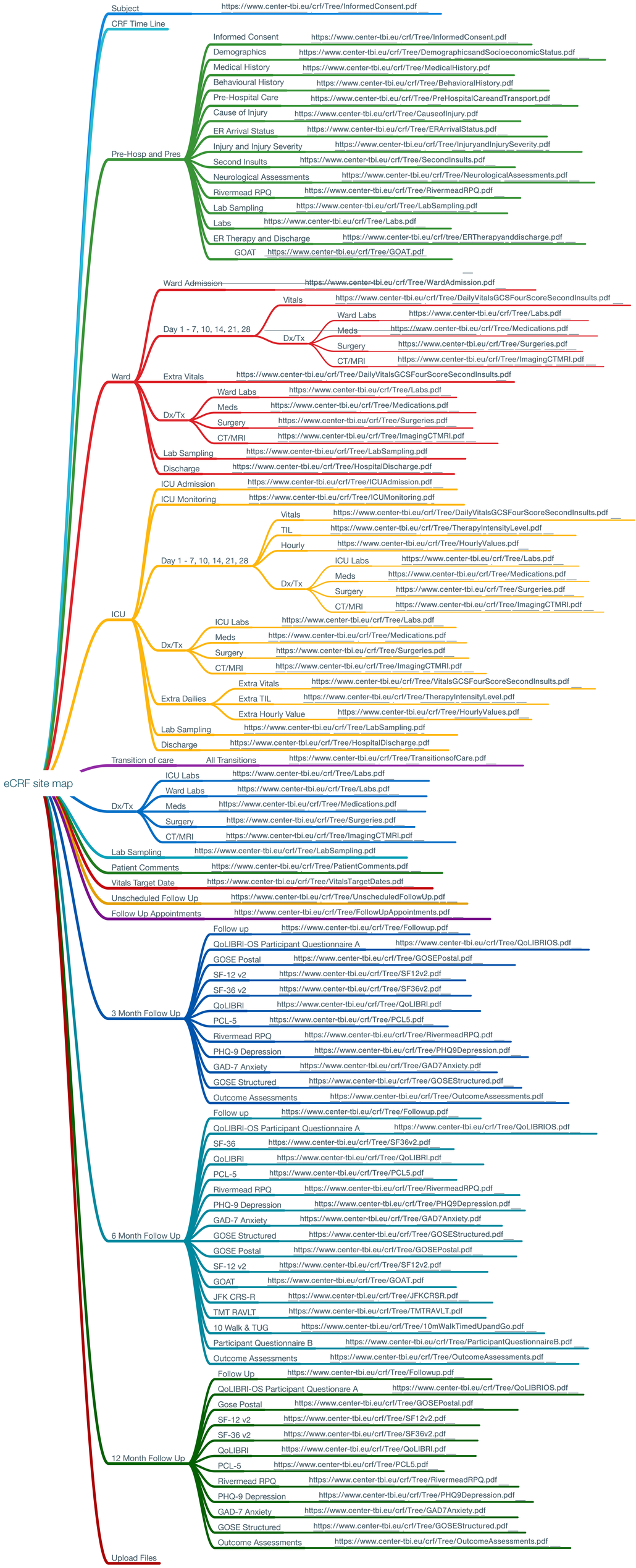
The impact level of the changes made in release 3.2 to the data tables in Opal, is estimated: **low**.

- Addition of new variables does not affect other variables, tables or old exports
- Updating values can alter values that were used in an analysis before. Updating affects in total 205 variables in two tables, but only affects a small subset of the records.
- Changes of the typos and inconsistencies in the data and dictionaries are mainly made to administrative text fields and will not affect the meaning or interpretation of the data. For some records the Imaging.ExperimentLabel is adjusted (capital vs lowercase letter mistakes), this can alter the recognition/binding of data.

Users who have access to *views* on the Opal data: data in views will be automatically updated for the affected variables. However, dictionaries of views created before this release 3.2 will remain unchanged. In case a user wishes for the dictionaries of their existing views to be updated, they can send a request for a manual dictionary update to opal@lumc.nl.

19 Annex 9: eCRF overview tree structure and linked forms

See next page.


eCRF site map
Subject
https://www.center-tbi.eu/crf/Tree/InformedConsent.pdf
CRF Time Line
Pre-Hosp and Pres
Informed Consent
https://www.center-tbi.eu/crf/Tree/InformedConsent.pdf
Demographics
https://www.center-tbi.eu/crf/Tree/DemographicsandSocioeconomicStatus.pdf
Medical History
https://www.center-tbi.eu/crf/Tree/MedicalHistory.pdf
Behavioural History
https://www.center-tbi.eu/crf/Tree/BehavioralHistory.pdf
Pre-Hospital Care
https://www.center-tbi.eu/crf/Tree/PreHospitalCareandTransport.pdf
Cause of Injury
https://www.center-tbi.eu/crf/Tree/CauseofInjury.pdf
ER Arrival Status
https://www.center-tbi.eu/crf/Tree/ERArrivalStatus.pdf
Injury and Injury Severity
https://www.center-tbi.eu/crf/Tree/InjuryandInjurySeverity.pdf
Second Insults
https://www.center-tbi.eu/crf/Tree/SecondInsults.pdf
Neurological Assessments
https://www.center-tbi.eu/crf/Tree/NeurologicalAssessments.pdf
Rivermead RPQ
https://www.center-tbi.eu/crf/Tree/RivermeadRPQ.pdf
Lab Sampling
https://www.center-tbi.eu/crf/Tree/LabSampling.pdf
Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
ER Therapy and Discharge
https://www.center-tbi.eu/crf/tree/ERTherapyanddischarge.pdf
GOAT
https://www.center-tbi.eu/crf/Tree/GOAT.pdf
Ward
Ward Admission
https://www.center-tbi.eu/crf/Tree/WardAdmission.pdf
Day 1 - 7, 10, 14, 21, 28
Vitals
https://www.center-tbi.eu/crf/Tree/DailyVitalsGCSFourScoreSecondInsults.pdf
Dx/Tx
Ward Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Meds
https://www.center-tbi.eu/crf/Tree/Medications.pdf
Surgery
https://www.center-tbi.eu/crf/Tree/Surgeries.pdf
CT/MRI
https://www.center-tbi.eu/crf/Tree/ImagingCTMRI.pdf
Extra Vitals
https://www.center-tbi.eu/crf/Tree/DailyVitalsGCSFourScoreSecondInsults.pdf
Dx/Tx
Ward Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Meds
https://www.center-tbi.eu/crf/Tree/Medications.pdf
Surgery
https://www.center-tbi.eu/crf/Tree/Surgeries.pdf
CT/MRI
https://www.center-tbi.eu/crf/Tree/ImagingCTMRI.pdf
Lab Sampling
https://www.center-tbi.eu/crf/Tree/LabSampling.pdf
Discharge
https://www.center-tbi.eu/crf/Tree/HospitalDischarge.pdf
ICU
ICU Admission
https://www.center-tbi.eu/crf/Tree/ICUAdmission.pdf
ICU Monitoring
https://www.center-tbi.eu/crf/Tree/ICUMonitoring.pdf
Day 1 - 7, 10, 14, 21, 28
Vitals
https://www.center-tbi.eu/crf/Tree/DailyVitalsGCSFourScoreSecondInsults.pdf
TIL
https://www.center-tbi.eu/crf/Tree/TherapyIntensityLevel.pdf
Hourly
https://www.center-tbi.eu/crf/Tree/HourlyValues.pdf
Dx/Tx
ICU Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Meds
https://www.center-tbi.eu/crf/Tree/Medications.pdf
Surgery
https://www.center-tbi.eu/crf/Tree/Surgeries.pdf
CT/MRI
https://www.center-tbi.eu/crf/Tree/ImagingCTMRI.pdf
Dx/Tx
ICU Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Meds
https://www.center-tbi.eu/crf/Tree/Medications.pdf
Surgery
https://www.center-tbi.eu/crf/Tree/Surgeries.pdf
CT/MRI
https://www.center-tbi.eu/crf/Tree/ImagingCTMRI.pdf
Extra Dailies
Extra Vitals
https://www.center-tbi.eu/crf/Tree/VitalsGCSFourScoreSecondInsults.pdf
Extra TIL
https://www.center-tbi.eu/crf/Tree/TherapyIntensityLevel.pdf
Extra Hourly Value
https://www.center-tbi.eu/crf/Tree/HourlyValues.pdf
Lab Sampling
https://www.center-tbi.eu/crf/Tree/LabSampling.pdf
Discharge
https://www.center-tbi.eu/crf/Tree/HospitalDischarge.pdf
Transition of care
All Transitions
https://www.center-tbi.eu/crf/Tree/TransitionsofCare.pdf
Dx/Tx
ICU Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Ward Labs
https://www.center-tbi.eu/crf/Tree/Labs.pdf
Meds
https://www.center-tbi.eu/crf/Tree/Medications.pdf
Surgery
https://www.center-tbi.eu/crf/Tree/Surgeries.pdf
CT/MRI
https://www.center-tbi.eu/crf/Tree/ImagingCTMRI.pdf
Lab Sampling
https://www.center-tbi.eu/crf/Tree/LabSampling.pdf
Patient Comments
https://www.center-tbi.eu/crf/Tree/PatientComments.pdf
Vitals Target Date
https://www.center-tbi.eu/crf/Tree/VitalsTargetDates.pdf
Unscheduled Follow Up
https://www.center-tbi.eu/crf/Tree/UnscheduledFollowUp.pdf
Follow Up Appointments
https://www.center-tbi.eu/crf/Tree/FollowUpAppointments.pdf
3 Month Follow Up
Follow up
https://www.center-tbi.eu/crf/Tree/Followup.pdf
QoLIBRI-OS Participant Questionnaire A
https://www.center-tbi.eu/crf/Tree/QoLIBRIOS.pdf
GOSE Postal
https://www.center-tbi.eu/crf/Tree/GOSEPostal.pdf
SF-12 v2
https://www.center-tbi.eu/crf/Tree/SF12v2.pdf
SF-36 v2
https://www.center-tbi.eu/crf/Tree/SF36v2.pdf
QoLIBRI
https://www.center-tbi.eu/crf/Tree/QoLIBRI.pdf
PCL-5
https://www.center-tbi.eu/crf/Tree/PCL5.pdf
Rivermead RPQ
https://www.center-tbi.eu/crf/Tree/RivermeadRPQ.pdf
PHQ-9 Depression
https://www.center-tbi.eu/crf/Tree/PHQ9Depression.pdf
GAD-7 Anxiety
https://www.center-tbi.eu/crf/Tree/GAD7Anxiety.pdf
GOSE Structured
https://www.center-tbi.eu/crf/Tree/GOSEStructured.pdf
Outcome Assessments
https://www.center-tbi.eu/crf/Tree/OutcomeAssessments.pdf
6 Month Follow Up
Follow up
https://www.center-tbi.eu/crf/Tree/Followup.pdf
QoLIBRI-OS Participant Questionnaire A
https://www.center-tbi.eu/crf/Tree/QoLIBRIOS.pdf
SF-36
https://www.center-tbi.eu/crf/Tree/SF36v2.pdf
QoLIBRI
https://www.center-tbi.eu/crf/Tree/QoLIBRI.pdf
PCL-5
https://www.center-tbi.eu/crf/Tree/PCL5.pdf
Rivermead RPQ
https://www.center-tbi.eu/crf/Tree/RivermeadRPQ.pdf
PHQ-9 Depression
https://www.center-tbi.eu/crf/Tree/PHQ9Depression.pdf
GAD-7 Anxiety
https://www.center-tbi.eu/crf/Tree/GAD7Anxiety.pdf
GOSE Structured
https://www.center-tbi.eu/crf/Tree/GOSEStructured.pdf
GOSE Postal
https://www.center-tbi.eu/crf/Tree/GOSEPostal.pdf
SF-12 v2
https://www.center-tbi.eu/crf/Tree/SF12v2.pdf
GOAT
https://www.center-tbi.eu/crf/Tree/GOAT.pdf
JFK CRS-R
https://www.center-tbi.eu/crf/Tree/JFKCRSR.pdf
TMT RAVLT
https://www.center-tbi.eu/crf/Tree/TMTRAVLT.pdf
10 Walk & TUG
https://www.center-tbi.eu/crf/Tree/10mWalkTimedUpandGo.pdf
Participant Questionnaire B
https://www.center-tbi.eu/crf/Tree/ParticipantQuestionnaireB.pdf
Outcome Assessments
https://www.center-tbi.eu/crf/Tree/OutcomeAssessments.pdf
12 Month Follow Up
Follow Up
https://www.center-tbi.eu/crf/Tree/Followup.pdf
QoLIBRI-OS Participant Questionare A
https://www.center-tbi.eu/crf/Tree/QoLIBRIOS.pdf
Gose Postal
https://www.center-tbi.eu/crf/Tree/GOSEPostal.pdf
SF-12 v2
https://www.center-tbi.eu/crf/Tree/SF12v2.pdf
SF-36 v2
https://www.center-tbi.eu/crf/Tree/SF36v2.pdf
QoLIBRI
https://www.center-tbi.eu/crf/Tree/QoLIBRI.pdf
PCL-5
https://www.center-tbi.eu/crf/Tree/PCL5.pdf
Rivermead RPQ
https://www.center-tbi.eu/crf/Tree/RivermeadRPQ.pdf
PHQ-9 Depression
https://www.center-tbi.eu/crf/Tree/PHQ9Depression.pdf
GAD-7 Anxiety
https://www.center-tbi.eu/crf/Tree/GAD7Anxiety.pdf
GOSE Structured
https://www.center-tbi.eu/crf/Tree/GOSEStructured.pdf
Outcome Assessments
https://www.center-tbi.eu/crf/Tree/OutcomeAssessments.pdf
Upload Files

Note:The interactive PDF may not work on all mobile devices

CENTER-TBI Core Data Collection : Guide to timing of assessments and investigations differentiated by stratum + Early MR imaging + Ultra early MR + External completion studies

CORE DATA

MR

Ultra Early MR

HR ICU

Extended Coagulation

TIME POINT		Day 1 (Adm)*	Post-op	Day 2	Day 3	Day 4	Day 5	2-3 Week	3 Month	6 Month	12 Month	24 Month
ER STRATUM: 1800												
Clinical data : on presentation/discharge ER and at time of follow-up												
Blood Sampling	**Routine hospital**	All										
	Biomarkers	All						MR Sites	MR Sites[2]			
	Genetics	All										
	ROTEM/TEG[3]	ROTEM/TEG[3]										
MRI (only MR sites)		Ultra early MR						MR Sites	MR Sites[2]			
Outcome Measures	**Neuropsych**							MR Sites	MR Sites[2]	All		
	Questionnaires							All	All(F2F)	All		
ADMISSION STRATUM: 1800												
Clinical data : on presentation, day 1-7, day 10, day 14, day 21 and day 28 unless discharge earlier												
Blood Sampling	**Routine hospital**	All										
	Biomarkers	All						MR Sites		All	MR Sites	MR Sites
	Genetics	All										
	Ext. Coag[3]	Ext. Coag[3]										
MRI (only MR sites)		Ultra early MR						MR Sites		MR Sites	MR Sites	MR Sites
Outcome Measures	**Neuropsych**									All	MR Sites	MR Sites
	Questionnaires							MR Sites	All	All	All	MR Sites
ICU STRATUM: 1800												
Clinical data : on presentation, day 1-7, day 10, day 14, day 21 and day 28 unless discharge earlier												
Blood Sampling	**Routine hospital**	All		All	All	All	All					
	Biomarkers	All		All	HR ICU	HR ICU	HR ICU	MR Sites		All	MR Sites	MR Sites
	Genetics	All										
	Ext. Coag[3]	Ext. Coag[3]	Ext. Coag[3]	Ext. Coag[3]								
MRI (only MR sites)		Ultra early MR						MR Sites		MR Sites	MR Sites	MR Sites
Outcome Measures	**Neuropsych**									All	MR Sites	MR Sites
	Questionnaires								All	All	All	MR Sites

Day 1 = Defined as day of Admission; in most cases this will be the same as day of injury, but in some (those patients presenting in the evening) it may be the next day.
Day 2 = Day after Admission
HR ICU: only sites participating in the HR ICU sub-study
[2] Initially target all patients scanned at 2-3 weeks, may later be restricted to only those with an abnormal MR at 2-3 weeks
[3] only sites participating in the extended coagulation sub-study