Registry data retrieval and analysis protocol

If the researchers participating in the registry want to start their research work or want information about the quantity and quality of the uploaded data, they have the opportunity to do so through the Patient Registry Coordinator. In general, from a newly launched register the head of the registry (PI) is given the opportunity to write the first comprehensive publication. After that, any center can initiate a data analysis in which they formulate a research idea.

PI	Principal Investigator	
JI	Junior Investigator	
SC	Strategic Consultant	registries@tm-centre.org
PRC	Patient Registry Coordinator	registries@tm-centre.org
IT	Informatics Group	it@tm-centre.org
BIOS	Biostatistician group director	biostatistics@tm-centre.org
DMGD	Data Management Group Director	datamanagement@tm-centre.orgl

1. Indication of data retrieval request

For a data retrieval request, the Principal Investigator should contact the Registry Coordinator. Following the briefing, it is the lead researcher's responsibility to prepare a one-page research plan that details and justifies the purpose, hypotheses, primary endpoints, and lists of participating members. We definitely recommend the participation of a junior investigator (e.g. PhD student).

PI + PRC

Result: determination of the purpose of data analysis

2. Professional consultation

Presentation of the research plan and review and coordination of the data to be retrieved. This is one of the most important parts of the process, it definitely requires a detailed discussion. After all, thousands of data, sometimes millions of data, need to be retrieved thoughtfully, because if the analysis does not start in the right structure and data has to be retrieved and analyzed again, it can cause a lot of difficulties and often result in chaotic data tables. The definition of centers and co-authors, first / last author(s) is also part of this consultation.

PI + PRC + IT + STAT

Result: consensus

3. Notification of centers, request for permission for data analysis

Each center decides for itself whether to make its data available for research. In general, everyone tends to be positive, but they have the right to decide. Co-authorship criteria should be determined based on international guidelines in which our center assists the researcher initiating the study. Usually, collaboration partners are listed among the authors or in the acknowledgment.
PI + PRC
Result: determination of the number of participants

4. IT data retrieval

Data retrieval is possible only from data that has undergone 4-step quality control. No personal data (name, insurance number) can be retrieved, but age and sex can. The structure of data retrieval needs to be defined. This is greatly influenced by whether the registry from which the retrieval is made has an "acute" or "chronic" structure. The actual duration of the retrieval can be 1-2 days or even 1-2 weeks, depending on the complexity of the structure and the amount of data retrieved. The retrieved data table can be transmitted in the form of a password-protected excel spreadsheet or on a portable data storage.
PI + PRC + IT
Result: data table

5. Checking the quality of the data table

Random comparison of the retrieved data with the data in the registry. Checking the quality of the data table from a medical perspective.
PRC + DMGD
Result: cleaned data table

6. Professional control and statistical preparation

The data table is checked by the Principal Investigator from medical professional perspective. The Principal and Junior Investigators identify professional questions, group the data, and make comprehensive descriptive diagrams. Checks the quantity and quality of data. We provide professional guidance for this.
PI + JI + SC + PRC + AMV + STAT + IT
Result: professional questions, descriptive figures

7. Data grouping, determination of biological differences and preparation of descriptive statistics

Determination of differences between groups, preparation of preliminary figures.
PI + JI
Result: preliminary analysis

8. Preparation of a comparative statistical analysis

The Principal Investigator and the statistician agree on the analysis. The Principal Investigator sets up the hypotheses. Biostatistician examines the established hypotheses using statistical methods. The necessary figures must be agreed on in advance.

PI + SC + BIOS

Result: hypotheses and data table

9. Preparation of the article

Build up the structure of the article as the following. If additional data is needed to be retrieved, return to point 2.

1. Conclusion: collect the main results
2. Collection of Supplementary material (data quality table, center distribution, basic database)
3. Results, Methods
4. Introduction, Discussion

PI + JI + SC

Result: Publication