Establishing registries

Content

I. General introduction

The University of Pécs Centre for Translational Medicine (UP CTM) wishes to provide all its partners, clinicians and basic researchers, the opportunity to establish registries. As a part of our service, we help and support to start new registries. This includes:

- statistical background
- IT development
- data management and data monitoring
- establishing patient clubs
- obtaining ethical licenses in Hungary
- assisting international distribution
- data processing
- research and publication assistance
- guarantee anonymity and data protection legislation contained in the
- ethics license
- confidentiality

  - only the data uploaders and approvers from the given institution can access the data, this other researchers cannot see.
  - the data uploaders and the approvers can see only their own data, although everyone can see the total number of patients in the registry
  - If someone has a research idea, she/he has to hand in a research plan to a relevant study group in the TM. The centers can decide if they would like to attend the research.

When establishing registries and launching trials, it is important that everyone should follow the chronological, ethical and monitoring steps that ensure proper operation and full compliance with both confidentiality and copyright rules.

II. Abbreviations, description, explanation, contact details

PI	Principal investigator	
SC	Strategic consultant	registries@tm-centre.org
PRC	Patient registry coordinator	registries@tm-centre.org
IT	IT	it@tm-centre.org
BIOS	Biostatistician group director	biostatistics@tm-centre.org
DMGD	Data management group director	datamanagement@tm-centre.org
EM	Ethical manager	ethics@tm-centre.org

PI - Principal investigator (given head of registry): The 'engine' of creating and maintaining a registry.

SC - **Strategic consultant** : Making decisions to start a registry.

PRC – Patient registry coordinator: Coordinates the tasks regarding the project's professional implementation

IT - **IT group director**: Creating, testing the online surface and interacting with the IT development team.

BIOS - **Biostatistician group director**: Creating a database from the registry, systematizing the data, preparing statistical analyzes, and keeping in contact.

DMGD - **Data management group director**: Describing the registry to clinical research administrators. distributing tasks, communication, check inbound data.

EM - **Ethical manager**: Know the process of ethical licensing, obtaining, forwarding the documentation required for the permit to the relevant authorities and keeping in contact.

III. Tasks of patient registry coordinator PRC

- Coordinate the tasks required for the professional implementation of the project and support the work of the professional leader.
- Coordinate the tasks/work between the professional attendants of the project.
- Efficiently and independently plans time, meets deadlines, initiates and follows through on tasks to ensure that goals and objectives specified for various programs are accomplished
- Coordinate the preparation of the professional and technical specifications on time and licensing the documentation related to project implementation.

- Preparation of professional consultations and discussions, assembling the documentation and providing information about the achievement of the results.

IV. Schedule for new registries

1. Determining the purpose of the registry, decision to start a registry.
The most important questions are:

1.1. Is the registry the most adequate way to achieve the aim?
1.2. Is the registry achievable? (financial and human resources)
1.3. Is this an acute or chronic registry?

PI+SC+PRC
Result: decision about the registry

2. The work starts with the principal investigator, collect the international registry questionnaires, EBM guidelines, cohort studies and set up the new registry's questionnaire and one short (approximately one page) summary about the aims (in English).
PI+PRC
Result:summary and questionnaire in English

3. Overview the completed questionnaire with different professional field, the final approval of the registry within CTM:
PI+SC+PRC+IT+BIOS+DMGD
Result: decision about the questionnaire and approve the registry

4. The Principal Investigator collates the registry with Hungarian and/or international colleagues. If there would be a major change then we should go back to point 3.
PI
Result: consensus

5. Translate the complete documentation into Hungarian, finalize the documents.
PI
Result: documentation in Hungarian

6. Parallel work:

6.1. PRC sends to ethical manager the whole documentation, who collaborates with the Principal Investigator in ethical licensing.
EM+PI. *PRC does not have to be involved in the conciliation (!)*
Result: TUKEB licence

6.2. IT launches the development. If there is a question, IT group leader should contact the PI.
IT+PI *PRC does not have to be involved in the conciliation (!)*
Result: eCRF

6.3. PI prepares detailed user guide in Hungarian and in English, DMGD and PRC supervise.
PI+DMGD+PRC
Result: User guide (user manual)

7. Testing the electronic case report form (eCRF).
   PI+IT+PRC
   Result: Finished eCRF

8. With the user guide a detailed local education should be provided to data managers.
   PI+DMGD+PRC
   Result: Qualified data uploaders

9. Organize patients involvement locally
   PI+DMGD

10. Involve national and international centers and start the education of them.
    PI+DMGD+PRC

11. Follow up and control quality of the registry monthly.
    DMGD+PRC
    Data upload has a four part quality check:
    1. check mark: Data upload by the administrator
    2. check mark: Local medical supervision and approval
    3. check mark: Approval by leading clinical research administrator, verification
    4. check mark: Approval and verification by Registry leader/Principal Investigator

12. Data analysis, research and publication.
    SC+PI+BIOS+IT+PRC

V. Collecting data

- In general, with one center, small-scale registries it is best to collect data in excel, while with multicentre, large-scale registries, it can be reasonable to create a separate, electronic surface (eCRF-electronic case report form).
- The collected data belongs to the patient. Whit the consent form signed, the patient allows the particular investigator to use their collected data.
- Every investigator can only see their own patient's data. There is an option where the whole database can be viewed, for this the investigator has to present a work plan to the particular study group, who considers and accepts it.The other investigators can allow to others to use the data collected by them. Only after this the collected data can be used to analysis, without personal patient informations.

VI. Publication rules

- Complete transparency.

- Researchers define the first and the last author, although UP CTM beside complete transparency- can name co-authors, who worked on the success of the registry.
- Acknowledgments should include the sponsors nominated by the UP CTM.

VI. Principal investigator obligations

Anyone who start a registry, must keep it under constant professional control, must take part in the approval of the forms, preferably close the forms as soon as possible (within one month). After an adequate sample size a publication should be made. The principal investigator should regularly participate in discussions at the Multidisciplinary Research Group (at least twice a year), where you can report on results and problems.

UP CTM should represent the uploaders' interests as well as the registry starters. The UP CTM is entitled to replace the principal investigator who does not perform his duties and replace it with a new researcher in agreement with the uploading centers.

If changes are made in the protocol, forms, etc. the requirements of the local ethical permission should be checked.