Ensuring professional guarantees, roles and processes in the operation of clinical registries and databases for the study of European MultiPartner IPF Registry

A. Basic Provisions

1. These rules apply solely to non-interventional clinical research projects, especially retrospectively collected data in diagnostic and clinical databases and observational studies.
2. The project is headed by the Steering Committee, composed of representatives of all participating countries. A representative of a participating country (usually the head of the biggest or initiating workplace in given country qualified person) becomes a member of the Steering Committee no later than upon the commencement of the collection of data from the given country/workplace.
3. Representatives of the centres act in the position of investigators/data managers within projects, i.e. persons responsible for the accuracy of data entered.
4. The Steering Committee is headed by the Principal investigator of the project (head of the Steering Committee), who is elected by the members of the Steering Committee. Head of the Steering Committee is an important scientific personality capable of identifying and promoting the strategic objectives of the project and raising funds for them. The Principal investigator's task is primarily to coordinate and manage the project as a whole; the use of the data collected in the registry for any purpose must always be approved by the Steering Committee of the project.
5. Clinical registries and observational studies only collect pseudonymised and anonymised data that does not allow any direct or indirect identification of the patient. Members of the project team are not permitted to identify the identity of persons. The only person or entity that has the potential capability to identify the patient/data subject is the person or entity that entered the data into the registry.
6. The registry (primary database of the project) collects pseudonymised data that are subsequently anonymised for further scientific analysis. Since the pseudonymised data are considered to be personal data, the project management must be adapted in accordance with applicable legislation, including informed consents of the data subjects. The informed consent of the subject must clearly indicate that the subject has received information that some of the subject's data will be entered into the registry (albeit in anonymised or pseudnonimised form) and processed in the Registry operated by Masaryk University.
7. The registry itself, database and software tools, including software for reporting or on-line reporting, are the intellectual property of Masaryk University (MU) as the project operator and IT guarantee. Representatives of centres or investigators may be co-authors in the development of the relevant tools. Unless expressly agreed otherwise, Masaryk University is the producer of the database.
8. Within the projects, IT tools and services are covered in the form of jointly received grants, donations or sponsorships; they are not charged to individual centres or hospitals. The access of centres to these tools and services is equal and does not depend on the number of their records in the database.

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9. The producer of the database and project IT facilities within the meaning of paragraph 7 is Masaryk University.
10. Data collected in the databases of clinical registries and observational studies is seen in the project as part of the medical records of individual clinical centres. These centres are therefore the administrator and holder of primary data; MU acts as a data processor. Primary data may be handled only with the explicit consent of all centres. Secondary data (i.e. information that MU obtains by statistical processing of primary data) will not be published or commercially exploited without the consent of individual centres. The rules set out in Sections B and C must be followed.

B. Rules of professional guarantee, securing and operational of projects

1. The technological solution and settings of ICT tools for the project are based on the approval and decision of the project's Steering Committee. The producer and provider of the technological solution are the Institute of Biostatistics and Analyses at the Faculty of Medicine, Masaryk University (from now on referred to as IBA FM MU).
2. The data entered by healthcare facilities is centralized on IBA FM MU servers. The IBA FM MU is obliged to provide the necessary security facilities. Depending on the circumstances, separate agreements between the Faculty of Medicine of Masaryk University and individual healthcare facilities regarding the security and operational aspects of their cooperation may be concluded. IBA FM MU always offers parallel localization to the centres of data entered by them in the local database kept by the relevant clinical workplace.
3. The participating clinical centre has unlimited access to its data throughout the project and may archive it in parallel in their local databases. Clinical centres have the right to withdraw from the project at any time.
4. IBA FM MU must ensure that the records of the clinical centres cannot be reviewed mutually by the parties. Each investigator has full access only to their own data, except for the leading expert guarantee who can review data of all participating centres and individual members of the Steering Committee who can review data of participating centres in given country. In addition to participating centres and IBA FM MU, no other entity has access to the project data.
5. The use of overall project data is conditional upon approval of the leading expert guarantee and members of the Steering Committee (individual clinical centres do not provide the consent). The outputs on the country level, the approval of a member of the Steering Committee of given country and further the approval of participating clinical centres in the given country is required.
6. Entries in the project databases can only be used for analyses that have been duly approved. Specifically, there are the following modes of analysis and output preparation:
    - Joint outputs of the project as a whole. The Steering Committee decides on joint outputs and they are subject to approval by the leading expert guarantee of the project and approval of each member in the Steering Committee.
    - Joint outputs on the country level. Outputs are decided by a member of the Steering Committee of given country, but any clinical centre of given country can submit a proposal for data output. The outputs are conditional upon the approval of a member of Steering Committee in the given country and with the express consent of the participating clinical centres.
    - Data analysis for individual centres. At centres level, analysis will not be processed. Clinical centre may request data export to be provided to them.

7. No analyses or summaries of internal data of the project may be carried out and presented without the express approval of the member of Steering Committee in one of the operating modes specified in the previous paragraph.
8. Representatives of the individual centres may make suggestions for certain analyses, and scientific or presentation outputs. Applications must be submitted to the Leading expert guarantee of the project who will have them discussed by the Steering Committee.
9. Primary project data must not be published or used for presentations. All outputs refer to processed, aggregated data.
10. A professional association operating in the area of the primary project objectives may provide professional patronage for the project and may express its opinions through the Leading expert guarantee of the project.

C. Procedures for the use of data in registries and observational studies, rules of communication

1. The organisation of project assumes that the common agenda and processing of applications are carried out during the Steering Committee meetings, in urgent matters also electronically or using video conferencing. The project's Steering Committee meets on regular basis for a meeting in person twice a year.
2. Suggestions for the use of project data and processing specific analyses may be submitted by any representative of the participating centres, a member of a professional association or an independent expert or expert team. Suggestions may come from outside the participating centres. Data from the project may be, with the consent of representatives of the centres, used for any form of academic and scientific work, especially conference presentations, posters, publications in domestic and foreign press, or electronic publications. Private companies, government authorities and health insurance companies may also request an analysis, for example for the purposes of obtaining population and regional data on a medicinal product. The content and scope of such a requested analysis (hereinafter referred to as the "output") must be in accordance with the report of the relevant project and must be justified by the requirements of administrative proceedings or inspection activities concerning the health services provided. The applicant or initiator of a specific output shall submit a brief written application to the Leading expert guarantee of the project, containing in particular:
    - Type of planned output and its purpose
    - Preliminary title of the final output
    - Hypothesis, specification of the analysis with defined group of patients, parameters, time intervals, groups, range of data etc.
    - Proposal for the main author of the work
    - Proposed forms of output (internal report, public publication, presentation,...).
3. The Leading expert guarantee of the project will ensure that the application will be discussed by members of the Steering Committee and delivers the final opinion to the applicant. Consent of members can be arranged through the "e-voting" feature that is part of the Registry. The Member of the Steering Committee shall then express agreement/disagreement with the provision of the data for the discussed purpose.
4. With this permission, the "applicant" officially asks IBA FM MU for an analysis; the output must be always available to the Leading expert guarantee and to all members of the Steering Committee who can then hand over the outputs to the clinical centres in the given country.

5. The actual processing of project data and publication of the project outputs are regulated by the agreed project protocol as well as by the usual rules for the proper publication of scientific results (professional opposition, approval of all co-authors, etc.).
6. The first author of the publication or scientific result is the initiator or the applicant of the output. Then the authors are listed according to their contribution to the particular study and output (e.g. for data acquisition, the authors are ordered according to number of patients in the particular analysis), followed by the responsible analyst(s) of IBA FM MU and the last given is the senior author. The final order of authors is always subject to their final approval before the output submission/publication.
7. If any of the members of Steering Committee expresses disagreement in the vote, this does not automatically imply the veto of the intent. In these cases, the Steering Committee will meet via teleconference and discuss the intentions with all members again. Strategic intentions allow the approval of an absolute majority of members of the Steering Committee

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