CERTAIN-LI Cooperative EuRopeanPaediatric Transpl-Ant INitiative LIver

Register
"Liver transplantation in childhood and adolescence"

Founded and operated on behalf of the Society for Pediatric Gastroenterology and Nutrition (GPGE)

Statute and Rules of Procedure

Version dated 03.11.2014

1. Preamble

The Cooperative **EuRopean** Paediatric TransplAnt Initiative Liver (CERTAIN-LI) registry was founded by the study group "Liver Transplantation in Children and Adolescents of the Society for Pediatric Gastroenterology and Nutrition (GPGE)" on behalf of the GPGE. The registry is intended to support and enable scientific evaluations and quality assurance in the field of pediatric liver transplantation. To this end, relevant data from as many pediatric liver transplant recipients as possible in Europe - especially in the area of the GPGE (Germany, Austria, Switzerland) and associated or other specialist societies interested in cooperation - are to be recorded on a regular basis.

2. Goals and tasks

The main objective of the CERTAIN-LI registry is to regularly collect clinical data on as many pediatric liver transplant patients as possible within the GPGE and associated professional societies in Europe. The aim is to contribute to academic research and quality assurance in this field.

3. Members and committees

3.1 Members / participating centers

Any center in Europe that cares for pediatric liver transplant patients can contribute data to the registry. Every center that contributes data to the registry is a member of CERTAIN-LI. Members are obliged to enter data regularly and carefully.

Members of CERTAIN-LI can receive an up-to-date database extract of the data they have contributed at any time. If a member wishes to carry out evaluations with the available overall data, the approval of the Steering Committee is required.

Compliance with data protection regulations is the responsibility of the member.

3.2 Member Assembly

A CERTAIN-LI Member Assembly is held once or twice a year as part of the GPGE annual meeting and/or as part of the meeting of the "Study Group on Liver Transplantation in Children and Adolescents".

The Member Assembly decides on all essential organizational and strategic matters of the CERTAIN-LI registry. The members are bound by the decisions of the Member Assembly

insofar as membership of the register is affected. The Registry Center is bound by the decisions of the Member Assembly.

The Member Assembly must vote at least once a year on the following points:

1) Approval of the minutes of the last Member Assembly
2) Support of the Steering Committee
3) Support of the Registry Center
4) Amendments to the Articles of Association and Rules of Procedure
5) Discussion and decision on pending requests for data evaluations

Each member (center) sends up to three representatives with voting rights to the Member Assembly of Members at its own discretion. Each member (center) is entitled to send further non-voting participants to the Member Assembly.

Votes require the specified majority in each case. If a required majority is not expressly specified, a simple majority of the voting members present at the Member Assembly shall apply.

Unless otherwise specified, all votes are taken publicly by a show of hands.

The Member Assemblies are organized by the Registry Center.

Minutes are kept of the Member Assembly. The minutes are prepared by the Registry Center and made available to the members. The minutes shall be deemed provisionally accepted if the Registry Center does not receive an explicit, reasoned objection from a member two weeks after publication. The reasons must also explain why the minutes should not be provisionally accepted until the next Member Assembly. Final acceptance is approved by a simple majority of the members entitled to vote at the next Member Assembly.

3.3 Steering Committee

The CERTAIN-LI Steering Committee consists of one member from each participating center that has actively submitted patient data to the registry in the 12 months prior to the respective meeting. Each center appoints this member independently. The Chairman of the GPGE's Liver Transplantation Working Group, his deputy and a representative of the Registry Center are members of the Steering Committee by virtue of their office. In the event of a vote equality, the vote of the Registry Center decides.

The task of the Steering Committee is to continuously safeguard the interests of the CERTAIN-LI registry. This includes, in particular, deciding on applications submitted for the evaluation of extracts from the overall database. Applications for the evaluation of data

are discussed and decided at the Member Assembly if possible; in the case of urgent applications, decisions are made using a voting system provided by the Registry Center. The decision must be justified by the members of the Steering Committee at the Member Assembly if necessary.

3.4 Registry Center

The CERTAIN-LI Registry Center has the following tasks:

1) The Registry Center in Heidelberg has the task of providing a database with a graphical user interface that can be accessed via the Internet. The database and the website must comply with all relevant laws and regulations. Furthermore, the database and the website must ensure international standards analogous to clinical trials, for example in accordance with Good Clinical Practice (GCP), as far as data entry is concerned. The functionality of the database is described in the specifications. The specifications are part of these statutes as an annex.
2) Upon request, the Registry shall provide members with the data of the respective center in structured form.
3) The Registry Center provides members with extracts from the entire database to enable scientific analysis if this has been approved by the Steering Committee or the Member Assembly. The Registry Center offers the possibility to take over parts of the evaluation.
4) The Registry Center prepares the Member Assemblys and draws up the provisional minutes.

3.5 Patronage

The CERTAIN-LI registry will appoint a patron who is able to sustainably promote the registry through his/her commitment to the cause of pediatric liver transplantation, his/her personal and public integrity and level of awareness.

4. Applications for the evaluation of data and publications

4.1 Applications for data analysis

The basis of every application for the evaluation of an extract from the complete database is a written project outline with the following content:

a) Title of the project
b) Background (rationale for the evaluation, own and third-party preliminary work)
c) Research question (formulated as a scientific hypothesis)
d) Method (statistical design)
e) Information on the persons involved
f) Information on the time frame
g) Information on the planned publication of the data (congresses, publication, authorship)

In principle, the outline should be formulated in such a way that it can clearly fulfill the requirements for acceptance as a scientific publication. The outline can be submitted at any time.

Scientific evaluations should primarily be formulated and coordinated by members. The Steering Committee decides on applications from external persons, institutions or pharmaceutical companies.

4.2 Evaluation of the project outlines

Proposals for new evaluations are presented as a project outline to the Steering Committee or the Member Assembly (either directly or following a decision by the Steering Committee on a proposal submitted to it). In the event of rejection, the applicant can apply for arbitration via the GPGE Board.

4.3 Accepted project outlines

Once the project outline has been accepted, the applicant must state within four weeks by when the results of the evaluations will be available and in what form. Once the project outline has been accepted, no second study on the same topic can be accepted. If the results are not available more than three months after the planned deadline, the project is deemed to have been abandoned and can be awarded to a new applicant. The previous applicant should make their preliminary work available to the new applicant or, if possible, cooperate with them.

The project is listed on the homepage with the planned timelines. The applicant receives a database excerpt containing the data – partly aggregrated – required for evaluations in accordance with the project outline.

4.4 Publication and authorship

In addition to quality assurance, publications and other scientific projects are to be supported by the CERTAIN-LI registry. The members declare their consent to the use of the data for publication purposes.

The authorship depends essentially on the type of publication (case studies, review articles, project evaluations) and the activity of the participants.

The treating clinics must always be involved in casuistic reports. The initiative can also come from the treating clinic. Review articles generally do not contain any new, i.e. unpublished results. Here, the lead author or senior author names the co-authors according to the components contributed.

As a general rule, the authors of a scientific publication should be those who have contributed significantly to the conception and planning or to the analysis and interpretation of the data and to the formulation of the manuscript and who have agreed to publication. Inclusion of documented patients in a study/project does not necessarily lead to co-authorship. In all publications dealing with study/project issues, all members will be listed in the addendum.

Regarding the order of authors, the first author is usually the person who wrote the manuscript. The study/project leader can claim the position of last author if he/she is not already the first author. If several study/project leaders are involved in a study, they agree on the last authorship according to the extent of their involvement. The other authors are named and ranked by the study/project leaders involved in the study/project. The corresponding author is usually the main project leader.

In the event of disagreements about authorship, the Steering Committee decides.

5 Miscellaneous, final conclusions

5.1 Changes of the Rules of Procedure / Statue

Changes regarding the Rules of Procedure are requested by the members and decided by the Member Assembly. Changes in the Statute require two-thirds of the votes of all present representatives eligible to vote.

5.2 Safeguarding clause

Should some of the rules of this statute/rules of procedure be invalid due to national or supranational laws/regulations, the other rules remain unaffected by this.

5.3 Effective date

These Articles of Association and Rules of Procedure enter into force provisionally on 01.03.2015: they enter into force definitively with the start of the register.