Statutes of the

European Reference Network on Hepatological Diseases

(ERN RARE-LIVER)

1. Name and Character of the Network

The European Reference Network on Hepatological Diseases (hereinafter referred to as ERN RARE-LIVER) is an international, government-endorsed and EU accredited, non-profit network of experts and patient representatives in the field of rare liver diseases. The official language of the network is English.

2. Objectives

The main objective of ERN RARE-LIVER is to improve the care of patients with rare, complex and difficult to treat liver diseases throughout the European Union Member States. The network also aims to the advancement of scientific knowledge and to facilitate research in the field of rare liver diseases.

3. Principles and Membership

Principles

The framework of work organisation and membership is established by the European Commission (EC). ERN RARE-LIVER seeks to foster collaboration with the adult and paediatric hepatology societies (EASL and ESPGHAN). All members and partners are required to uphold the network's objectives and tasks defined in these statutes, including active participation in meetings, the use of the Clinical Patient Management System (CPMS) and the R-LIVER registry.

Membership, Affiliated Partners and Collaborative Partners

ERN RARE-LIVER members are healthcare providers (HCP), i.e. hospitals and academic institutions, nominated by their respective health ministries, approved by the EC, and appointed by the Board of Member States (BoMS). In countries without an ERN RARE-LIVER member, an Affiliated Partner can be appointed by the EC after approval by the network coordinator and the BoMS.

In addition, further centres interested in participating in and willing to support the network objectives, and fulfilling the criteria defined in the Collaborative Partnership form of the ERN RARE-LIVER can be granted Collaborative Partnership status. Appointment requires approval by the ERN coordinator and the Management Board (MB), and finalised by the members meetings. In addition, individual External Experts and Registry Partners may be appointed by the ERN coordinator.

Each HCP chooses a representative and a deputy as the main contact points. The HCP representatives are responsible for securing fulfilment of ERN tasks (see section 4). HCP representatives remain in office until replacement is appointed by the HCP and communicated to the ERN office and the EC.

4. Tasks

The principal tasks of the ERN RARE-LIVER to achieve the aforementioned objectives are:

i. Improve the care of patients with rare, complex and difficult to treat liver diseases;

ii. Represent expertise in rare liver diseases within EASL and ESPGHAN, to the wider medical community and to the general public, including position statements and guidelines;
iii. Hold at least one full annual meeting, as well as one short meeting during one of the main European liver conferences (EASL and ESPGHAN Annual Meeting); at least one representative from each member or affiliated partner HCP is expected to attend;
iv. Provide expert advice through the CPMS platform to physicians within and outside of ERN RARE-LIVER and contribute own cases; each member or partner HCP should have at least 2 active CPMS users and contribute upon request;
v. Each member or partner HCP should contribute patient data to the R-LIVER registry of ERN RARE-LIVER, including the follow-ups as agreed upon;
vi. Fulfil the requirements of the EC for monitoring and reporting, such as the number of new patients seen and diagnosed, number of publications, clinical trials, training activities etc., as set by the EC;
vii. Identify and define unmet needs in care and research.

5. Organisation and structure

ERN RARE-LIVER is led by a coordinator appointed by the EC. The coordinator leads the ERN RARE-LIVER office, which is responsible for the organisation of ERN RARE-LIVER and reporting to EU authorities.

The work of the coordinator is supported by a management board. Members of the management board are appointed by the coordinator and should include cross-sectional topic leads, the registry coordinator, one representative of EASL and ESPGHAN respectively and two patient representatives. The management board should reflect the spectrum of ERN RARE-LIVER such as paediatric and adult hepatology as well as basic science. Appointment to the management board is for three years, re-appointment is possible.

Furthermore, ERN RARE-LIVER has a Data Access Committee (DAC) appointed by the management board. DAC is led by the registry coordinator of the ERN. Members of the DAC constitute two clinicians from each expert disease working group represented in the registry, two patient representatives, one data manager and a project manager. The DAC coordinates the access to R-LIVER data that complies with the aims of ERN RARE-LIVER. The DAC has agreed on a specific statute.

Major decisions require voting by all members of ERN RARE-LIVER, either at the members' assembly, or via online voting. Major decisions include the admission of new members, the expulsion of members, and amendments of these statutes. Decisions are taken by simple majority. Each member has a single vote.

6. Research Projects

As ERN RARE-LIVER is not a legal entity, all research projects will be run by and are the responsibility of individual principal investigators (PI) and their respective employer, the HCP constituting the ERN membership. The PI and co-authors hold ownership of intellectual property rights arising from ERN RARE-LIVER projects. Should any project need material or data sharing between the collaborating partners not covered by the Data Transfer Agreement (DTA) of ERN RARE-LIVER, this will have to be governed by independent Material or Data Sharing Agreement (DSA) signed by the involved parties. For the retrospective and also the prospective collection of clinical data in the R-LIVER registry, a DTA will have to be signed between the contributing centre and the site/PI storing and handling the data. Data collected will remain in the ownership of the HCP (as per the Registry DTA). Collaboration with established networks and study groups on rare diseases is encouraged and duplicate inclusion of patients into registries should be avoided.

Any member of the group can initiate scientific projects using registry data to be carried out within ERN RARE-LIVER after approval by the DAC. For each project, a PI should be clearly identifiable, who carries the overall responsibility. Upon prior approval by the DAC, registry data may also be shared with other entities, provided they align with the objectives of ERN RARE-LIVER. HCPs will be notified of any upcoming data extraction. A HCP's data will be included in the data extraction only after they have provided consent for the use of their own data. Publications using data of R-LIVER have to be approved by the DAC prior to submission and the MB be informed.

Authorship

The following rules relating to authorship, acknowledgements and sponsors for ERN RARE-LIVER are based on the 1991 Guidelines for the International Committee of Medical Editors (1), modified by a New England Journal of Medicine editorial and correspondence (2), and a Lancet editorial (3), and will be applied to the ERN RARE-LIVER publication plan.

1. Research projects generated by using R-LIVER data of ERN RARE-LIVER other than the centre's own data or any subset of data having been collected in a project officially affiliated with ERN RARE-LIVER, using ERN RARE-LIVER as a named author need to be submitted to the DAC at least 2 weeks prior to submission for quality control of the DAC process (full length publication). Other publications affiliated with ERN RARE-LIVER have to be forwarded to the ERN office upon acceptance by the journal.
2. Any conflict between investigators on authorship issues should be submitted to the DAC. In case of disagreement between investigators and the DAC, the issue is presented to the management board for a decision.
3. Authors from full members and affiliated partners of ERN RARE-LIVER should add to their ERN-related publications, position statements and clinical practice guidelines, "European Reference Network on Hepatological Diseases (ERN RARE-LIVER)" as affiliation additional to their institutional affiliation.
4. All position statements and clinical practice guidelines authored by ERN RARE-LIVER are to be approved by the management board for endorsement.

Authorship rules for ERN RARE-LIVER papers, position statements and clinical practice guidelines:
The author list of papers with contribution of the ERN RARE-LIVER will contain the following names, in order:

- The authors, who did the work, i.e., collected, generated and/or analysed the presented results and participated in the writing of the manuscript.
- The number of authorship slots and positions proportionate to the contribution to the project and production of the manuscript is the responsibility of the project PI.
- The ERN RARE-LIVER banner list, including a priori assigned number of representatives per contributing centre, for clinical contributions in order of decreasing number of patients included in the centre.
- Followed by 'on behalf of the ERN RARE-LIVER'. The ERN RARE-LIVER banner list should be circulated along with the manuscript to named authors and authors listed in the banner for confirmation of authorship.
- A publication will be considered related to the ERN RARE-LIVER, if it includes information about ERN RARE-LIVER itself or about diseases covered by ERN RARE-LIVER; if it involves as major contributors, at least two HCPs from two different Member States within the ERN RARE-LIVER, and if it acknowledges the ERN RARE-LIVER ("on behalf of the ERN RARE-LIVER").

Manuscripts on R-LIVER based data:

- Drafts should be sent to the ERN office at least two weeks before submitting to a journal.
- ERN office sends manuscript with a recommendation to the DAC members.

- DAC members have two weeks to veto or provide feedback if the manuscript does not comply with the approved data usage as stated in the DAC application.
- If a significant issue is identified, the ERN office will object to the publication and inform the management board.
- If no feedback is received from the ERN office within the given timeframe, the authors can assume the manuscript is approved.
- The management board will be notified only of the title of manuscripts running through DAC revision by the ERN office.

References:

1. International Committee of Medical Journal Editors. Style matters: Uniform requirements for manuscripts submitted to biomedical journals. BMJ 1991;302:338-41.
2. Kassirer JP, Angel M. On authorship and acknowledgments. N Engl J Med 1991;325:1510-2 and 1992; 326: 1084-8 (correspondence).
3. Oliver MF. AI, or the anonymity of authorship. Lancet 1995;345:668.

7. Amendments

These statutes have been agreed upon by all members of the ERN RARE-LIVER. Changes and amendments require the prior discussion in the membership and a majority vote of the full membership.