European Reference Network
for rare or low prevalence complex diseases

Network Hepatological Diseases (ERN RARE-LIVER)

Statutes of the

European Reference Network on Hepatological Diseases

(ERN RARE-LIVER)

1. Name and Character of the Network

The network shall be known as the European Reference Network on Hepatological Diseases (hereinafter referred to as ERN RARE-LIVER). 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 is English.

2. Objectives

The main objective of ERN RARE-LIVER is to **improve the care of patients with rare liver diseases** throughout European Union Member States. Additionally, ERN RARE-LIVER will contribute to the **advancement of scientific knowledge in the field of rare liver diseases**.

3. Principles and membership

Principles

The principles of work organization, membership and objectives are set by the European Commission (EC). ERN RARE-LIVER seeks close collaboration with the respective adult and paediatric hepatology societies (EASL and ESPGHAN). All members and partners of ERN RARE-LIVER are required to adhere to the objectives and tasks of the network as outlined in these statutes, including active participation in meetings, Clinical Patient Management System (CPMS) case conferences and registries (R-Liver).

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 Partner. This also applies to individual external experts. Appointment requires approval by the ERN coordinator and the Management Board (MB), and is finalized by the members at the annual meetings.

Each HCP chooses a representative and a deputy who are the main contact points and 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 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 International Liver Congress (ILC), or at the ESPGHAN Annual Meeting); each member or 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) Contribute patient data to the registries of ERN RARE-LIVER; each member or partner HCP should contribute to at least one of the ERN registries, all of its newly presenting patients from that respective disease/disease group 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. Organization 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 organization of ERN RARE-LIVER and reporting to EU authorities.

The work of the coordinator is supported by the ERN office and the ERN MB. The MB is led by the coordinator, who appoints - upon recommendations from the membership - experts in disease areas, cross-sectional topic leads, representatives of EASL and ESPGHAN, and two patient representatives. The MB should reflect the spectrum of ERN RARE-LIVER such as paediatrics, adult hepatology and basic science. Appointment to the MB is for three years, re-appointment is possible.

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 sharing agreement of ERN RARE-LIVER, this will have to be governed by independent Material or Data Sharing Agreements signed by the involved parties. For the retrospective and also the prospective collection of clinical data in registries, a data sharing agreement 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 Data Sharing Agreement). 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 to be carried out within ERN RARE-LIVER after approval by the MB. For each project, a PI should be clearly identifiable, who carries the overall responsibility. Upon prior approval by the MB, Registry Data may also be provided to any other body provided they serve the objectives of the ERN RARE-LIVER. HCPs will be notified of any upcoming data transfers. A HCP's data will be included in the data transfer only after they have provided consent for the transfer of their own data.

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. Position statements and clinical practice guidelines generated with or using data from the registries of ERN RARE-LIVER (e.g. R-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 MUST be submitted to the MB at least 4 weeks prior to submission for approval of authors' list and scientific content (full length publication). Other publications affiliated with ERN RARE-LIVER must be forwarded to the ERN office upon acceptance by the journal.
2. Any contest or conflict between investigators on authorship issues should be submitted to the MB. Conflicts between investigators and the MB should be solved with the help of outside advisers agreed upon by both parties.

3. Members of ERN RARE-LIVER are encouraged to add "European Reference Network on Hepatological Diseases (ERN RARE-LIVER)" as an additional affiliation on publications on rare liver disease topics.

Authorship rules for ERN RARE-LIVER papers: The author list of papers with contribution of the ERN RARE-LIVER (e.g. with data from registries or position papers) 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 an 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").
- If a publication is about both a VALDIG and an ERN study, the following statement should be added after the authors' list in the publication: "on behalf of ERN RARE-LIVER; a study of VALDIG, an EASL consortium".

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.