

# Terms of Reference

ERN RARE-LIVER Patient Advocacy Group (ERN RARE-LIVER ePAG) [European Reference Networks](#) (ERNs) are virtual networks set up by the European Commission, involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. Each ERN is represented in an overarching 'Network Board'.

The ERN RARE-LIVER is dedicated to rare liver conditions and is governed by a Management Board which oversees a number of working groups: those that are disease-specific and those that span all rare liver diseases (transversal).

The following diagram shows the current structure of the ERN RARE-LIVER working groups.

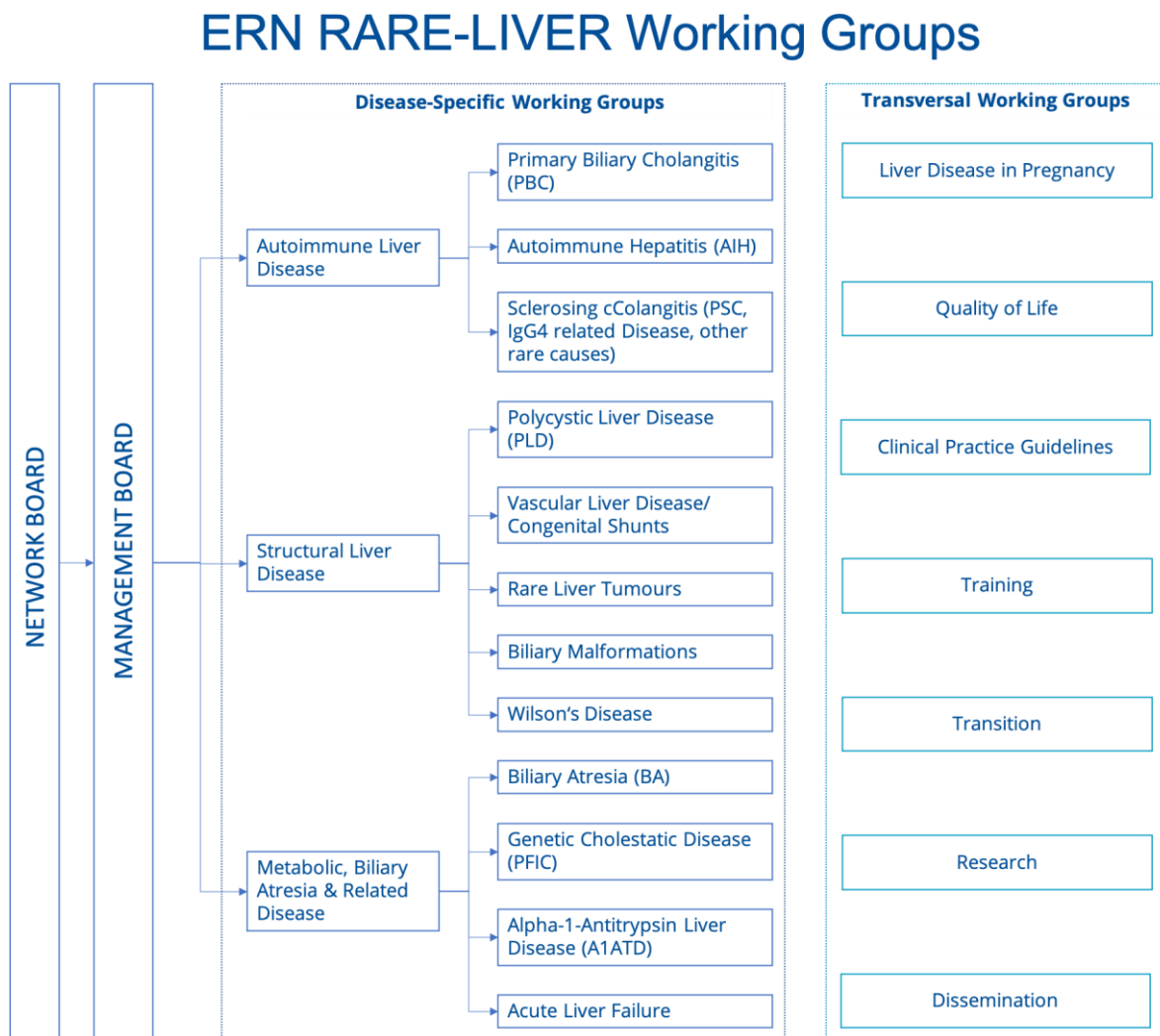


Figure 1. ERN RARE-LIVER Working Groups

## The ERN RARE-LIVER Patient Advocacy Group

According to the European Commission Expert Group (EUCERD), patients and patient representatives should play an active role in the decision-making process of the ERNs and be involved in structural and clinical network activities.

The ERN RARE-LIVER Patient Advocacy Group provides patient representation in the ERN RARE-LIVER. It is made up of patient organisations that represent patients with rare liver diseases in Europe. 'Named Patient Representatives' from these groups are members of the ERN RARE-LIVER working groups shown in Figure 1. Two patient representatives are elected as 'Lead Patient Representatives'.

Figure 2 shows the roles of patient representatives in the ERN RARE-LIVER Patient Advocacy Group.

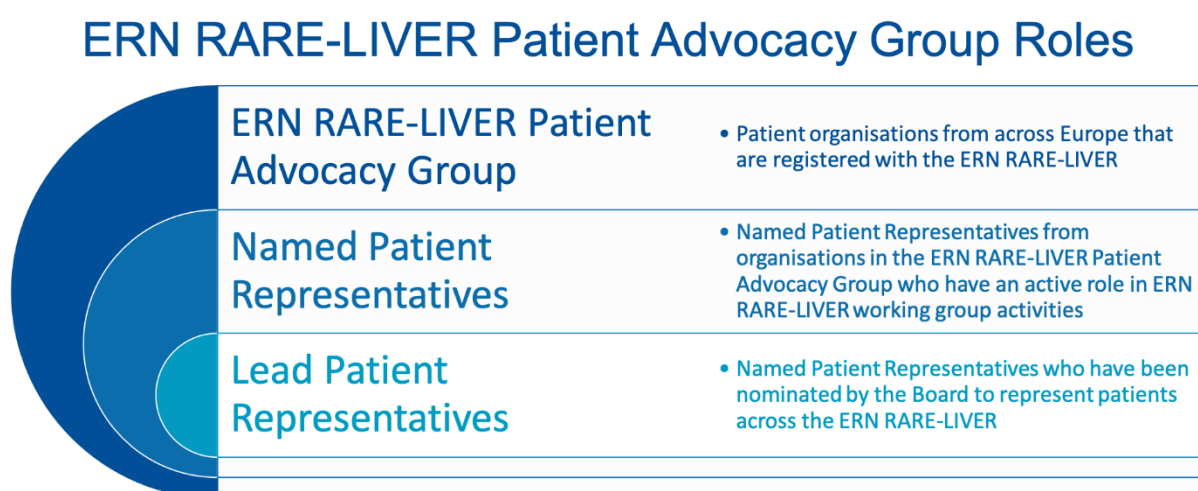


Figure 2. ERN RARE-LIVER Patient Advocacy Group Roles

### Patient Organisations

The patient organisations in the ERN RARE-LIVER Patient Advocacy Group include both members and non-members of EURORDIS.

Patient representatives from these patient organisations receive updates (such as including hearing about the latest ERN RARE-LIVER output, research, webinars and information for patients) and opportunities for ad hoc involvement in ERN RARE-LIVER activities (such as providing patient perspectives and disseminating information and surveys). They may occasionally be invited to join ERN RARE-LIVER working groups to help with specific, short-term projects.

### Named Patient Representatives

Named Patient Representatives are appointed from eligible patient organisations in the ERN RARE-LIVER Patient Advocacy Group. They

- provide support to the ERN RARE-LIVER on a voluntary basis and represent the interests of the wider patient community in ERN RARE-LIVER working groups;

- agree to adhere to the set of core values outlined in [the EURORDIS ePAG Constitution and Rules of Procedure \(Section 4\)](#);
- agree to declare any conflict of interest in the course of their work for the ERN RARE-LIVER Patient Advocacy Group, as outlined in the ERN RARE-LIVER Patient Advocacy Group Conflict of Interests Policy and Declaration (see Annex 1).
- may attend the ERN RARE-LIVER Annual Meeting. As per the grant agreement, funding is provided for patient representatives from the Management Board.

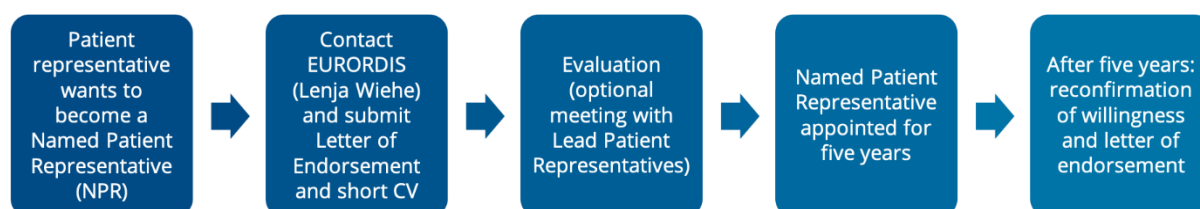
To be eligible, patient organisations must

- be members of the ERN RARE-LIVER Patient Advocacy Group;
- be governed by patients (at least the majority);
- be a not-for-profit or equivalent organisation;
- declare income from commercial companies (corporate income);
- must demonstrate that all decision-making is independent from any corporate income;
- declare all conflicts of interest in the ERN RARE-LIVER Patient Advocacy Group Declaration of Interests (both for the Named Patient Representative and for the patient organisation).

### Process for appointing Named Patient Representatives

If a member of the ERN RARE-LIVER Patient Advocacy Group wishes to become a Named Patient Representative, they must apply by submitting the following documents to EURORDIS:

- a letter of endorsement from their patient organisation
- a CV outlining their experience as a patient advocate
- a completed ERN RARE-LIVER Patient Advocacy Group Declaration of Interests (see Annex 1).



*Figure 3. Appointment of Named Patient Representatives*

EURORDIS will file the documentation (see Figure 3) and pass to the Lead Patient Representatives for evaluation. The Lead Patient Representatives are happy to arrange a meeting with the candidate and their organisation to discuss the role. If successful, the Named Patient Representative will be appointed for a five-year term. This mandate may be renewed by the Named Patient Representative reconfirming their willingness to continue and by presenting an up-to-date letter of endorsement from their patient organisation.

## Lead Patient Representatives

### The Lead Patient Representatives

- represent members of the ERN RARE-LIVER Patient Advocacy Group at ERN RARE-LIVER Management Board meetings for a two-year term;
- have voting power in the ERN RARE-LIVER Management Board meetings. If necessary, a proxy (chosen by the two Lead Patient Representatives) may attend and vote at the ERN RARE-LIVER Management Board meetings;
- must be based in the European Union or European Economic Area.

### Process for appointing Lead Patient Representatives

The Named Patient Representatives nominate and vote for two Lead Patient Representatives for a period of two years. Their mandate may be renewed annually thereafter with the agreement of Named Patient Representatives and the ERN RARE-LIVER Management Board.

### EASL Patient Representative

A rare liver disease patient representative from the [European Association for the Study of the Liver \(EASL\)](#) attends and votes in the ERN RARE-LIVER Management Board meetings. The EASL patient representative provides a link between ERN RARE-LIVER and EASL, mainly in respect of mutual communication and the exchange of information, with the objective of improving patient care.

## ERN RARE LIVER Patient Advocacy Group Aims

The purpose of Named Patient Representatives is to:

- represent the patient community to ensure that the needs of children and adults living with rare liver diseases are included in the discussions of the Management Board and in the strategic and operational delivery of the network.
- work with the ERN RARE-LIVER Management Board through the Lead Patient Representatives to improve access to high quality diagnosis, care and treatment of rare liver conditions.

The Named Patient Representatives will deliver these aims by:

- contributing to the development of patient information and resources;
- supporting improvements to healthcare by contributing to and driving initiatives to improve healthcare and equity of access to care for patients;
- disseminating information and communications to the ERN RARE-LIVER Patient Advocacy Group;
- contributing to the development of research priorities and ensure that they are informed by the needs of patients and families;
- providing advice on ethical issues in relation to areas such as the application of personal data rules, compliance with information consent and management of complaints;
- engaging with the relevant patient communities for disease-specific activities and projects;

- updating the ERN RARE-LIVER Patient Advocacy Group about activities via regular teleconferences and other communications.
- working to grow the representation and engagement of patients in the ERN RARE-LIVER.

## Responsibilities

The ERN RARE-LIVER Named Patient Representatives have an important role and mission in governance, ethical issues, care, research, service evaluation, and in the education of the ERN RARE-LIVER community including patients and families. In order to ensure that the ERN RARE-LIVER Named Patient Representatives provide quality recommendations and feedback that genuinely reflects patients' viewpoints, Named Patient Representatives commit to:

- representing the rare liver community on behalf of the community on behalf of and with the mandate of their community;
- conducting proper internal consultation with their respective patient organisations and with the Patient Advocacy Group to the best of their ability;
- sharing important news and sending a brief report of any ERN meeting attended to ERN RARE-LIVER, and in the newsletter to keep the patient community updated;
- informing ERN RARE-LIVER when representing ERN RARE-LIVER at a conference, workshop, or any meeting of public importance;
- declaring individual potential conflicts of interests as well as those of their patient organisation in formal meetings or activities.

## Operation

### Process for Joining

A patient organisation wishing to join the ERN RARE-LIVER Patient Advocacy Group should contact the Lead Patient Representatives in the first instance. The patient organisation will be asked to submit some basic information before it is passed to the ERN and EURORDIS for registration into the Patient Advocacy Group:

- Name of organisation
- Key contact person name and email
- Rare liver disease area(s) of interest
- What % of the governing board (or equivalent) is made up of patients
- Confirmation that the organisation is a non-profit

### Attendance of meetings and frequency of the meetings

EURORDIS will provide support and participate in meetings with ERN RARE-LIVER patient organisations.

Meetings of the ERN RARE-LIVER Patient Advocacy Group will be decided on a case-by-case basis and the meetings will be held in English.

The Lead Patient Representatives and the EASL Patient Representative will meet with the ERN RARE-LIVER Project Manager/EURORDIS.



The Lead Patient Representatives/EASL Patient Representative will engage with the other Named Patient Representatives and report back on ERN RARE-LIVER activities and plans. The ERN RARE-LIVER Project Manager will be invited to these meetings for specific agenda items on a case-by-case basis.

### Decision-making and disputes

Decisions made by the ERN RARE-LIVER Named Patient Representatives are taken by consensus, but voting is possible if necessary. Where a consensus is not met, the Lead Patient Representatives and the EASL Patient Representative have the casting votes.

As outlined in Section 8 of the [EURORDIS ePAG Constitution and Rules of Procedure](#), if a dispute arises between patient representatives in the Patient Advocacy Group, they commit in good faith to try to take steps to resolve the dispute together, supported by EURORDIS. Confidentiality will be guaranteed in any mediation activity in which EURORDIS is requested to engage, however the ERN RARE-LIVER Coordinator will be informed on a confidential basis in all cases. If mediation is inconclusive and the circumstances are untenable, agreement will be reached on the appropriateness of termination of the relationship.

### Conflict of Interests

Named Patient Representatives must declare all conflicts of interest in the ERN RARE-LIVER Patient Advocacy Group Conflict of Interests Declaration.

### Contact

ERN RARE-LIVER office: [ern.rareliver@uke.de](mailto:ern.rareliver@uke.de)

EURORDIS: [lenja.wiehe@eurordis.org](mailto:lenja.wiehe@eurordis.org)

# Annex 1

## ERN RARE-LIVER Patient Advocacy Group Conflict of Interests Policy and Declaration

Named Patient Representatives should adhere to ethical criteria, be transparent, and avoid any conflict of interest in the course of their work for the ERN RARE-LIVER Patient Advocacy Group.

### Corporate Income

Corporate income is defined as any income received from a commercial organisation such as a pharmaceutical company or device company. This includes grants or contracts for projects, studies or research, scholarships, payments, stock options, materials and unrestricted donations or payments, personal fees and gifts.

Each Named Patient Representative shall declare corporate income received personally or by their Patient Organisation annually and whenever a change in interest occurs.

### Conflict of Interest

A conflict of interest can arise when

- total corporate income exceeds 50 % of the Patient Organisation's total annual income.
- income from a single commercial organisation exceeds 20% of the Patient Organisation's total annual income.

### Procedure

Where a conflict of interest arises, the Named Patient Representative will be excluded from all discussion and decision-making on related matters except in exceptional circumstances where non-conflicted Named Patient Representatives agree it is in the best interests of the patients represented by the ERN RARE-LIVER Patient Advocacy Group.

In all cases a note will be made of the nature of the conflict, the discussion of the matter and the action taken to manage the conflict.

## Patient Organisation

Name:

Is Patient Organisation a non-profit/charity?

Yes ☐ No ☐

Is the majority of the Patient Organisation Board or equivalent governed by patients and/or families?

Yes ☐ No ☐

If No, what proportion of the Board is made up of patients and/or families?

Has your Patient Organisation received Corporate Income in the last two years?

Yes ☐ No ☐

Does the total value of this Corporate Income exceed €10.000 (ten thousand Euros)?

Yes ☐ No ☐

If yes, please give details of all Corporate Income accepted in the last two years:

Commercial organisation	Purpose	Amount €	% of Patient Organisation total income for that financial year



## Named Patient Representative

Name:

Role in Patient Organisation:

Have you personally received Corporate Income in the last two years in the course of your role in the Patient Organisation?

Yes ☐ No ☐

Does the total value of this Corporate Income exceed €200 (two hundred Euros)?

Yes ☐ No ☐

If yes, please give details of all Corporate Income accepted in the last two years:

Commercial organisation	Purpose	Amount €

## Declaration

To the best of my knowledge, the above information is complete and correct at the time of making this declaration. I undertake to update as necessary the information provided, and to review the accuracy of the information on an annual basis. I give my consent for these details to be used for the purposes described in the ERN RARE-LIVER Patient Advocacy Group Conflict of Interests Policy and for no other purpose. The information provided in this declaration will not be shared publicly or outside of the ERN RARE-LIVER.

Name

Email address:

Date