EVICR.net and Steps for Membership

1. EVICR.net - What it is?

EVICR.net - European Vision Institute Clinical Research Network, EEIG is a network of European Ophthalmological Clinical Research Sites, dedicated to perform clinical research in ophthalmology with the highest standards of quality, following the European and International Directives for clinical research, according to harmonised Standard Operating Procedures (SOPs) in order to strengthen the capacity of the European Union to explore the determinants of ophthalmic diseases and to develop and optimise the use of diagnostic, prevention and treatment strategies in ophthalmology.

It is a platform for clinical trial research in Ophthalmology in Europe and a structure to support Investigator Initiated Research (IIR). EVICR.net is an Industry resource in order to promote the development of new drugs and medical devices in ophthalmology.

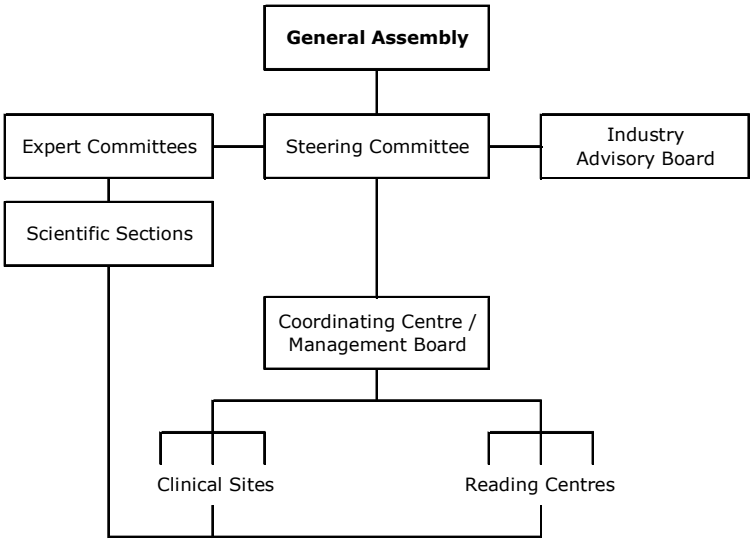
The **EVICR.net** is an European Economic Interest Grouping legally constituted in accordance with the Council Regulation (EEC) n.º 2137/85.

1.1. Aims and Objectives

The main aims and objectives of EVICR.net are:

- To guarantee a high level of quality and excellence in the multinational clinical research performed according to ICH GCP Guidelines
- To promote Investigator Initiated Research multinational clinical trials within the European Union
- To serve as a resource for Industry in performing clinical trials in Ophthalmology
- To coordinate training activities for its members
- To promote quality, transparency and optimal use of clinical research data
- To inform patients and citizens of the challenges and opportunities raised by clinical research in ophthalmology

1.2. Organisation & Structure



The **General Assembly** consists of all EVICR.net members and is the supreme organ of the Network. Each Clinical Site is represented at the General Assembly by one vote. The General Assembly is responsible for the governing statutes to regulate the day-to-day business.

The **Steering Committee** is responsible for the activities of the EVICR.net and acts as its decision-making body within the framework set by the General Assembly. The Steering Committee consists of up to seven representatives the Chairman, the Coordinator of each Expert Committee, the Coordinator of each Transversal Section and the CEO of the Management Board.

The Steering Committee is supported by **Expert Committees** that have a fundamental role in the scientific organisation of EVICR.net and cover the following main areas of research: Age-Related Macular Degeneration (AMD) and Retinal Dystrophies; Diabetic Retinopathy and Retinal Vascular Diseases; Glaucoma; Anterior Segment; and Reading Centres. There are also the following Transversal Sections that work together with the Expert Committees, when applicable: Medical Devices and Rare Diseases.

The Industry Advisory Board advises the Steering Committee in all matters of strategic relevance, particularly pertaining to collaborations with Industry. The Industry Advisory Board is composed of individuals or representatives of entities who have given support for the activities of EVICR.net.

1.3. Advantages of being a member of EVICR.net

- Receive for free the EVICR.net Required SOP Templates for Clinical Sites
- Obtain the status of a EVICR.net Certified Centre by implementing organisational SOPs and Quality Control (ICH GCP Guidelines compliant)
- Support for Investigator Initiated Research applications
- Support for EU Clinical Research applications
- Obtain regularly Industry contracts and in this way have a constant flow of income to keep well trained personnel
- Access to training and certification of personnel
- Participation in subspeciality Scientific Sections: AMD and Retinal Dystrophies; Diabetic Retinopathy and Retinal Vascular Diseases; Glaucoma; Anterior Segment and Reading Centres.
- Networking with other European and USA Networks

2. Requirements to become a member:

- Supporting resources: dedicated clinical trial area and electronic capture data infrastructure (ECD).
- Human resources: qualified and experienced personnel (ophthalmologists, technicians / trial coordinators / nurses).
- Scientific record in peer reviewed international journals
- Experience of multinational clinical trials.
- To agree to implement organisational SOPs according to ICH GCP Guidelines

3. How to become a member

3.1. Membership Application

3.1.1. Express intention to become a member by sending an e-mail to evicrnet@aibili.pt or by post to the following address: EVICR.net
AIBILI, Azinhaga de Santa Comba, Celas
3000-548 Coimbra
Portugal

3.1.2. The EVICR.net Coordinating Centre sends to the Clinical Site the application documents (a Confidentiality Agreement and Questionnaire) and all the necessary information to perform the payment of the application fee (500 €).

3.1.3. The Clinical Site will have to return the application documents filled in and pay the application fee to EVICR.net.

3.1.4. EVICR.net Coordinating Centre analyses the application and informs the Clinical Site on the membership decision (accepted/not accepted).

3.2 After becoming a Member, the Clinical Site receives for free the EVICR.net SOPs to be implemented by the Clinical Site.

- If the Clinical Site has already an ISO 9001 quality system implemented, the EVICR.net Coordinating Centre helps the Clinical Site to check if there are any relevant issues of the EVICR.net SOPs that need to be added in the Clinical Site SOPs. As soon as this SOP's harmonisation process is concluded the Clinical Site is ready to be Certified.
- If the Clinical Site does not have an ISO 9001 quality system implemented, the EVICR.net Coordinating Centre helps the Clinical Site to adopt the Clinical Site SOPs. Later, and when the Clinical Site consider appropriate, it will apply for an On-Site Evaluation Visit (audit). Then, and only then, the Clinical Site will have the costs of this On-Site Evaluation Visit (3.000€ + travel and stay expenses).

  After the On-Site Evaluation Visit takes place, the Clinical Site receives a Follow-Up Letter summarising all tasks performed and, if applicable, a detailed list of action points.

After all action points have been implemented, the Clinical Site is ready to be Certified.

4. Certification

The Clinical Site signs the "Statement: Rights and Obligations as a Certified member of EVICR.net" (which summarises the rights and obligations of a certified member of EVICR.net) and pays the certification entry fee (1.000€). The Certificate as an EVICR.net Clinical Site is issued for a period of 2 years.

3 months after the Certification, the EVICR.net asks for a proof of implementation of the adopted/harmonized SOPs, in order to confirm that they are used in its daily routine.

5. Re-Certification

No fees are charged for Re-Certification in order to reduce costs to the Clinical Site. No On-Site Evaluation Visit is performed during this process.

Before the Certificate expires, the Clinical Site receives a letter with a questionnaire which should be completed and returned to EVICR.net Coordinating Centre with the purpose of renewing the Certification.

The EVICR.net Coordinating Centre analyses the questionnaire, sends a Follow-Up Letter to the Clinical Site and, if applicable, with the necessary action points.

After implementing all action points, the Clinical Site is ready to be Re-Certified.

The Clinical Site signs the "Statement: Rights and Obligations as a Certified member of EVICR.net". A Certificate is issued for a period of 2 years.

6. Summary of Financial Obligations

6.1. To become a member

- Application fee: 500€

6.2. To become certified

- Audit / On-Site Evaluation Visit
    - Clinical Sites with ISO 9001 quality system implemented: no On-Site Evaluation Visit takes place
    - Clinical Sites with no ISO 9001 quality system implemented: 3.000€ + Travel and stay expenses for the CRO (to be negotiated between the Site and the CRO).
- Entry fee: 1.000€

Note: the Re-Certification process is free of charges

6.3. Annual Membership

- Annual Membership fee: 1.500€
- For members that have not yet participated in any clinical trial through EVICR.net a reduced fee of 500€ is charged annually.

6.4. Useful financial information

- EVICR.net bank account number:

  BPI
  Alameda Armando Gonçalves
  3000-059 Coimbra, Portugal
  IBAN: PT50 0010 0000 4441 5990 0016 7
  Swift: BBPIPTPL

- EVICR.net VAT number: PT 509 299 903