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 multinational clinical research in ophthalmology with the highest standards of quality. EVICR.net complies with 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.

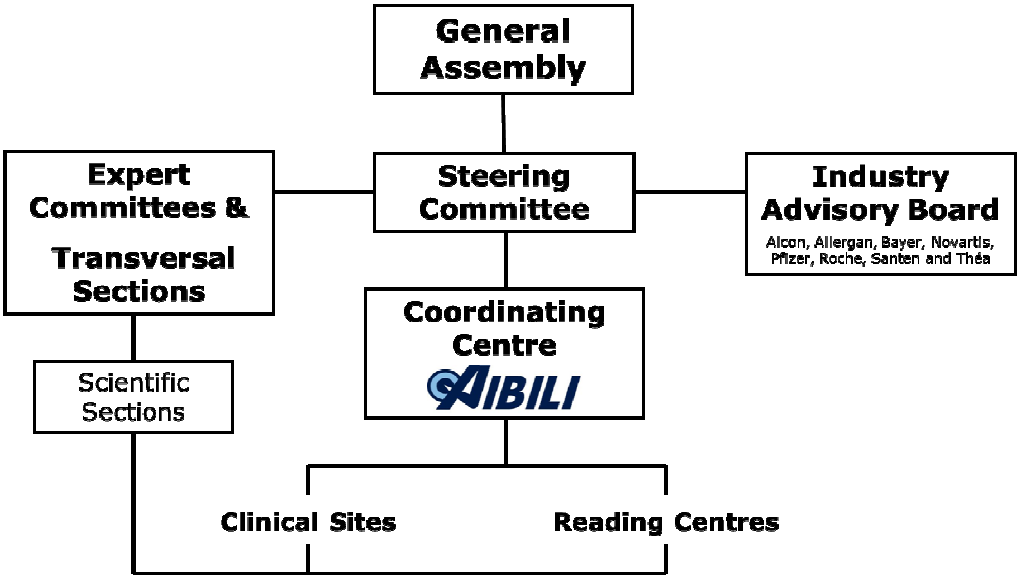
It is a platform for European multinational clinical research in Ophthalmology and a structure to support multinational Investigator Initiated Research (IIR). EVICR.net is also an Industry resource in order to promote the development of new drugs and medical devices through clinical research in ophthalmology.

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

The main **aims and objectives** of EVICR.net are to:

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

1.1. 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: the Chairman, the Coordinators of each Expert Committee, the Coordinators 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); Retinal Dystrophies; Diabetic Retinopathy and Vascular Diseases; Glaucoma; Anterior Segment and Ocular Surface, Inflammation, Dry-Eye & Allergies. There are also three Transversal Sections that work together with the Expert Committees, when applicable: Medical Devices, Rare Diseases and Reading Centres.

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.

1.2. Advantages of being a member of EVICR.net

- Participation in subspecialty Scientific Sections: AMD; Retinal Dystrophies; Diabetic Retinopathy and Vascular Diseases; Glaucoma; Anterior Segment and Ocular Surface, Inflammation, Dry-Eye & Allergies;
- Receive for free the EVICR.net organisational SOPs and become a certified Clinical Site;
- Support for multinational Investigator-Initiated Research;
- Opportunity to participate in new clinical research studies;
- Support for EU Clinical Research applications;
- Access to training and certification of personnel;
- Promotion of your Clinical Research Centre as member of EVICR.net;
- Networking with other European and USA Networks.

2. How to become a member

2.1. Requirements to become a member

In order to apply for membership, the Clinical Site should have:

- Supporting Facilities namely available clinical research area and basic Electronic Data Capture: computer and internet access.
- Human Resources namely qualified and experienced personnel (eg: ophthalmologists, technicians / study coordinators / nurses).
- Scientific record in peer reviewed international journals.
- Experience of multinational clinical studies.
- Agree to implement organisational SOPs according to ICH GCP Guidelines.

2.2. Membership Application

The Clinical Site needs to 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

The EVICR.net Coordinating Centre sends to the Clinical Site the Membership Application form and a Confidentiality Agreement that will have to be returned dully filled in. If the application is successful, the Coordinating Centre will send information on how to perform the payment of the application fee (500 €).

The Clinical Site will only become a member after the payment of the application fee.

3. Certification

Taking into consideration that the aim of EVICR.net is to be a network of certified Clinical Sites, certification of the Clinical Site is crucial. If the Clinical Site does not apply or obtain the certification it will be identified as an Associate Clinical Site of EVICR.net.

After becoming a Member, the Clinical Site (CS) receives a Certification Questionnaire and the EVICR.net Organisational SOPs for free to be implemented by the CS. The CS returns the Questionnaire filled in. EVICR.net CC analyses it and informs the CS on the decisions and actions that need to be implemented by the CS with the support of EVICR.net CC. The CS adopts/harmonises the 6 organisational SOPs with the help of EVICR.net CC. EVICR.net has also a training webinar regarding this matter (Webinar #3 – SOPs – quality and certification) available online.

As soon as this process is concluded the Clinical Site is ready to be Certified.

For this the Clinical Site (CS) signs the "Statement: Rights and Obligations as a Certified member of EVICR.net" and pays the certification fee of:

- 1.000€, if CS is already certified by a Quality Standard (e.g. ISO 9001, etc).
- 1.500€, if CS is not certified by a Quality Standard.

The Certificate is issued and is valid for a period of 4 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 being used.

4. Re-Certification

Before the Certificate expires, the Clinical Site receives a letter with a questionnaire which should be completed and returned to EVICR.net Coordinating Centre (CC) in order to renew the certification.

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

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". No fees are charged for the Re-Certification. A Certificate is issued for a period of 4 years.

5. Summary of Financial Obligations

5.1. To become a Member - Application fee: 500€

5.2. Annual Membership

Membership fee is 1.500€ and will be due only in the years following the acceptance of the Clinical Site membership application (e.g. Application in 2017; Membership Fee: 2018, 2019, …). The annual Membership fee of 1.500€ will be reduced to 500€ until the Clinical Site participates in an EVICR.net study. Thereafter the annual Membership fee will always be 1.500€.

5.3. Certification fee

Certification fee:

- 1.000€, if CS is already certified by a Quality Standard (e.g. ISO9001, etc).
- 1.500€, if CS is not certified by a Quality Standard. If needed, an Evaluation Visit to the CS may take place and the CS will also have to support the travel and accommodation expenses of this visit.

Certificate is valid for 4 years and the Re-Certification process is free of charge.

5.4. 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