Developing an international network for clinical research in Ophthalmology: European Vision Institute Clinical Research Network (EVICR.net)

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Summary

There is a well-identified need for patient-oriented clinical research and this can only be achieved by creating active collaboration between academic centres with competence for clinical research, following GCP Guidelines and supported by an infrastructure that provides appropriate management of clinical trials at a realistic cost.

The EVICR.net (European Vision Institute Clinical Research Network) is a legal entity established as an independent European Economic Interest Grouping (EEIG) in accordance with the Council Regulation (EEC) n.º 2137/85 and was built and developed to function as the necessary structure to perform clinical research in Ophthalmology in the European Union according to ICH GCP Guidelines and European Directives. The association with ECRIN-IA opens new perspectives in the areas of Medical Devices and Rare Diseases.

Keywords

Clinical Research; Clinical Trials; Ophthalmology; Retina; Glaucoma; Ocular Surface; Cornea; Eye – Anterior Segment; Reading Centres.

Medical research is the basis for optimal patient treatment in hospitals and healthcare throughout the world. Translational research brings the ideas from basic research into clinical patient-oriented research and vice-versa. Clinical patient-oriented research involves testing new discoveries in the clinic by carrying out carefully controlled investigations on patients – known as clinical trials. This includes testing not only new drugs, but also new methods, devices, imaging and surgical procedures.

For Europe it is necessary to perform European Union wide patient-oriented research, with priorities set by patient needs. Such an approach would reduce fragmentation and duplication of research in Europe and provide a means for carrying out high-quality, multinational clinical studies. Efficient patient-oriented research re-

quires both specialized competences and a supporting infrastructure. Such research is performed in academic medical centres and university hospitals. However, at present, there is a clear need for infrastructures that provide support for the development of Investigator-Driven Clinical Trials (IDCT), database management, quality assurance, monitoring and regulatory affairs.

It is therefore crucial to create an appropriate environment such as networking to perform multi-national, large scale IDCT based on correctly powered scale as these type of studies have a greater potential to change clinical management.

Clinical investigators often lack the expertise needed to plan all the necessary resources, requirements and agreements before starting a clinical trial.

Networking and the development of excellent administrative support are needed developments for patient-oriented clinical research. In Ophthalmology the example set by the Diabetic Retinopathy Clinical Research Network (DRCR.net) in the USA was followed and EVICR.net (European Vision Institute Clinical Research Network, EEIG) was created in Europe.

The EVICR.net is a platform for clinical trial research in Ophthalmology in Europe to support investigator-driven clinical trials as well as an Industry resource in the development of new drugs and medical devices.

The Network was established in 2004 and since 2010 EVICR.net is a legal entity established as a European Economic Interest Grouping (EEIG) in accordance with the Council Regulation (EEC) # 2137/85.

The Network has a centralized infrastructure located at Association for Innovation and Biomedical Research on Light and Image (AIBILI), Coimbra, Portugal that functions as the Coordinating Centre with contract research organization functions necessary for the management of multicenter clinical trials in ophthalmology.

The main aims and objectives of EVICR.net are:

To guarantee a high level of quality and excellence in ophthalmology clinical research performed by members according to ICH GCP Guidelines; to promote multicenter clinical research trials within the European Union; To coordinate training activities for its members; To serve as a resource for Industry in performing clinical research in Ophthalmology

In order to become a member, a Clinical Site (CS) must apply to the Network and fulfil basic requirements such as dedicated space to perform clinical trials, qualified and experienced personnel, experience of multicentric clinical trials and to agree to implement organizational Standard Operating Procedures (SOPs) according to ICH GCP Guidelines. Each Clinical Site will be submitted to an On-Site Evaluation Visit performed by independent auditors according to the Network procedures in order to become a certified member of EVICR.net. The certification is valid for 2 years and the clinical site may under go recertification process for renewal.

At present the EVICR.net has 76 Centres members from 16 European Countries that are either certified or in the process of certification.

EVICR.net was invited to participate in the ECRIN-IA (European Clinical Research Infrastructure Network - Integrating Activity) project funded by EU Commission, specifically to collaborate in the Medical Devices area. There is need for mapping of EU medical devices research centres and networks; collection of data on regulatory and ethical requirements on Medical Devices studies; development of common standards for quality assurance and monitoring; develop methodology and guidelines.

Organization of EVICR.net

The supreme organ of the Network is the General Assembly that consists of all EVICR.net members.

The EVICR.net has a Steering Committee that 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 Coordinators of each Expert Committee and the Chief Executive Officer (CEO).

Presently the Steering Committee is formed by Jose Sahel (CS 6), José Cunha-Vaz (CS 1), Esther Hoffmann (CS 2), Jorge Alió (CS 7), Joaquim Murta (CS 70), Tunde Peto (CS 10) and Cecília Martinho, CEO.

The Steering Committee is supported by Expert Committees that have a fundamental role in the scientific organization of EVICR.net and cover the following main areas of research: Age-Related Macular Degeneration and Retinal Dystrophies; Diabetic Retinopathy; Glaucoma; Cornea, Cataract and Refractive Surgery; Ocular Surface and Inflammation; and Reading Centers.

Each Expert Committee supervises a Scientific Section with the participation of the subspecialty representatives from each EVICR.net Clinical Site Member. Each Clinical Site nominates one representative for each area of interest and expertise. This representative will be part of the chosen Scientific Section.

The Coordinating Centre of EVICR.net is located in Portugal, at AIBILI in the Coimbra Coordinating Centre for Clinical Research (4C), a structure qualified to support Investigator-Driven and/or Industry-Sponsored Clinical Trials by providing the following services: protocol design and statistical planning; elaboration of the necessary documents for the submission of the clinical trial; coordination and implementation of the clinical trial; monitoring; quality control; data management; statistical analysis; periodical reports to the sponsor and/or regulatory authorities; final clinical trial report; and publication support.

The EVICR.net is prepared to provide a cohesive network of Certified Clinical Centres in Ophthalmology with harmonized procedures (SOPs), quality control and qualified personnel. This provides an environment that will help achieve high recruitment rates.

Investigator-Driven Clinical Trials through the Network (IDCTs)

Presently there are two observational IDCTs ongoing, one in Retina and another in Cornea, Cataract and Refractive Surgery. The first interventional study, EURO-CONDOR (European Consortium for the Early Treatment of Diabetic Retinopathy) has been funded by the European Union.

Future perspectives

EVICR.net has gone through a process of consolidation and its membership has increased steadily. The initiation of its first three Investigator-Driven Clinical Trials is clearly an important step forward.

It is felt that funding from the European Union Health Research Programmes

will create the appropriate basis for future growth and development of the Network. The same has happened with the DRCR.net in the USA, which increase markedly its activity and success when regular funding from the National Institute of Health became available.

The perspectives that are now opened with the association with ECRIN-IA in the Areas of Rare Diseases and Medical Devices for European Union funding are extremely promising for the development of this speciality-oriented clinical research network.

The EVICR.net is considered by its members as a much-needed tool to address the goal of more innovative patient-oriented research with expected positive results in improved health care in the European Union.

Executive summary

- Clinical patient-oriented research involves testing new discoveries in the clinic by carrying out carefully controlled investigations on patients – known as clinical trials.
- Efficient patient-oriented research requires both specialized competences and a supporting infrastructure and networking.
- Clinical investigators often lack the expertise needed to plan all the necessary resources, requirements and agreements before starting a clinical trial.
- The EVICR.net is a platform for ophthalmology clinical trial research in Europe and aims to be a much needed structure to support investigator-driven clinical trials as well as an Industry resource in the development of new drugs and medical devices.
- At present the EVICR.net has 76 Centres members from 16 European countries that are either certified or in the process of certification.[1]

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Authors Disclosure

The authors have no conflicts of interest to declare.