EVICR.net – European Vision Institute Clinical Research Network, EEIG

The European Vision Institute Clinical Research Network – EVICR.net – 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 harmonized 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 optimize the use of diagnostic, prevention and treatment strategies in ophthalmology.

It is a platform for clinical research in ophthalmology in Europe and a useful industry resource in the process of development of new drugs and medical devices. At present, EVICR.net has 80 Member Centres from 17 European countries.

EVICR.net Coordinating Centre is located at AIBILI in Coimbra, Portugal.

Aims and Objectives

The main aims and objectives of EVICR.net are:

- To guarantee a high level of quality and excellence in ophthalmology clinical research performed by its members according to International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines
- To promote multinational clinical research within the European Union
- To coordinate training activities for its members
- To serve as a resource for industry in performing clinical research in ophthalmology
- To promote quality, transparency and optimal use of clinical research data
- To communicate with patients and citizens about the challenges and opportunities raised by clinical research in ophthalmology.

Organization

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

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 and the CEO of the Coordinating Centre.

The Expert Committees have a fundamental role in the scientific organization of the 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 Centers.

There are also two 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 collaborations with industry. The Industry Advisory Board is composed of individuals or representatives of companies who have given support to the activities of EVICR.net and at the moment is composed by Alcon, Allergan, Bayer, Novartis, Pfizer, Santen and Théa.

The Coordinating Centre, AIBILI, is the contact point for the members and industry when performing ophthalmological clinical research in Europe. Annually the Coordinating Centre updates the EVICR.net Research Resources Directory where all members have their resources listed: staff, equipment and facilities as well as their scientific areas of clinical research and the five most relevant publications. All members have access to a restricted area in the website that is also kept updated by the Coordinating Centre. The Coordinating Centre is responsible for the certification of EVICR.net Clinical Site Members.
The 8th EVICR.net Annual Members Meeting took place in Paris, France, on October 14–15, 2013. The meeting was attended by 100 participants from Member Centres, CROs and Industry Advisory Board Members (table 1, fig. 1).

Elections for the Expert Committees took place in the Scientific Sections that resulted in the new composition of Expert Committees. A new Scientific Section designated as Anterior Segment has emerged from the fusion of the Cornea, Cataract and Refractive Surgery and Ocular Surface and Inflammation Expert Committees. Two Transversal Sections were created, Medical Devices and Rare Diseases, that will address evaluation of investigator-driven clinical trials (IDCTs) in association with the Expert Committees.

Presentations from industry representatives sharing projects and experiences in an open way also took place. The EVICR.net annual meeting will take place in Coimbra, Portugal, on November 17–18.

### Clinical Trials and Registries

The EVICR.net Coordinating Centre assumes the leadership of coordination and management of IDCTs in ophthalmology across Europe through the Network. EVICR.net Members have the opportunity to participate in IDCTs within the Network as well as to submit abstracts for IDCTs to the Coordinating Centre in order to be evaluated by a specific Expert Committee. If approved they will have access to support in coordinating and implementing the IDCT (table 2, fig. 2).

EVICR.net IDCTs have been growing in the last years, giving the opportunity for investigators to perform multinational clinical research of high quality (compliant with ICH-GCP Guidelines) assuming that the rights, safety and well-being of the trial subjects are protected and that the clinical data are credible. EVICR.net has contributed to the improvement of diagnostic, prevention and treatment strategies in ophthalmology. EVICR.net has at the moment 11 ongoing multinational clinical research studies of which 3 are European Union-funded (table 3).

<table>
<thead>
<tr>
<th>Year</th>
<th>IDCTs</th>
<th>Industry</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no funding</td>
<td>EU funding</td>
<td>registrys</td>
</tr>
<tr>
<td>2010</td>
<td>2</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>2011</td>
<td>2</td>
<td>1</td>
<td>–</td>
</tr>
<tr>
<td>2012</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2013</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

### Table 1. Number of members per country

<table>
<thead>
<tr>
<th>Country</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>2</td>
</tr>
<tr>
<td>Belgium</td>
<td>3</td>
</tr>
<tr>
<td>Denmark</td>
<td>2</td>
</tr>
<tr>
<td>France</td>
<td>8</td>
</tr>
<tr>
<td>Germany</td>
<td>15</td>
</tr>
<tr>
<td>Greece</td>
<td>2</td>
</tr>
<tr>
<td>Ireland</td>
<td>1</td>
</tr>
<tr>
<td>Israel</td>
<td>1</td>
</tr>
<tr>
<td>Italy</td>
<td>10</td>
</tr>
<tr>
<td>Poland</td>
<td>1</td>
</tr>
<tr>
<td>Portugal</td>
<td>7</td>
</tr>
<tr>
<td>Slovakia</td>
<td>1</td>
</tr>
<tr>
<td>Slovenia</td>
<td>1</td>
</tr>
<tr>
<td>Spain</td>
<td>9</td>
</tr>
<tr>
<td>Switzerland</td>
<td>3</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>4</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>80</td>
</tr>
</tbody>
</table>

### Table 2. Multinational clinical research studies (2010–2013)

<table>
<thead>
<tr>
<th>AMD and Retinal Dystrophies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Trials</strong></td>
</tr>
<tr>
<td><strong>Eur-USH:</strong> European Young Investigators Network for Usher Syndrome. EU-funded project. ClinicalTrials.gov No. NCT01954953.</td>
</tr>
<tr>
<td><strong>Registries</strong></td>
</tr>
<tr>
<td><strong>LHON:</strong> A registry on Leber’s Hereditary Optic Neuropathy. Sponsor: Santhera. ClinicalTrials.gov No. NCT01892943.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diabetic Retinopathy and Retinal Vascular Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Trials</strong></td>
</tr>
<tr>
<td><strong>ECR-RET-2010-02:</strong> Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using noninvasive procedures. ClinicalTrials.gov No. NCT01145599.</td>
</tr>
<tr>
<td><strong>EUROCONDOR:</strong> Neurodegeneration as an early event in the pathogenesis of diabetic retinopathy: a multicenter, prospective, phase II/III, double-blind randomized controlled trial to assess the efficacy of neuroprotective drugs administered topically to prevent or arrest diabetic retinopathy. EU-funded project. EudraCT No. 2012-001200-38. ClinicalTrials.gov No. NCT01726075.</td>
</tr>
</tbody>
</table>

**Fig. 1.** Number of members per country.
PROTEUS: Prospective, randomized, multicenter, open label, phase II/III study to assess efficacy and safety of ranibizumab 0.5 mg intravitreal injections plus panretinal photocoagulation (PRP) versus PRP in monotherapy in the treatment of patients with high risk proliferative diabetic retinopathy. IDCT grant from Novartis. EudraCT No. 2013-003640-23.


Registries


Glucoma

Clinical Trials


SPORT: A randomized, 3 months’, crossover, single-masked, investigator-led, multicenter trial on open-angle glaucoma or ocular hypertension patients. IDCT grant from Allergan. EudraCT 2013-003490-10.

Anterior Segment

Clinical Trial

ECR-CCRS-2010-01: European project for the determination of average biometric values of human eyes. ClinicalTrials.gov No. NCT01173614.

EVICR.net has developed a quality system for its members compliant with ICH-GCP Guidelines. It provides for free to its members 9 Organizational SOPs. All our Clinical Site Members agree to adopt these SOPs in their centers, which will be checked before they are certified as Sites of Excellence.

The implementation of these 9 Organizational SOPs will permit the Clinical Sites to have a standard way of working and in compliance with ICH-GCP Guidelines when performing clinical trials.

EVICR.net has also developed 31 Technical SOPs for performing specific ophthalmic examinations or evaluations that can be used within the Network for clinical trials. These SOPs are also made available to our members.

In parallel, EVICR.net has developed 22 Organizational SOPs for the Reading Centres so they can work as a network of Reading Centers and be able to have the capacity to respond to the industry needs for grading ophthalmological images in a standardized way with the most novel equipment.

At the moment we have 53 Clinical Sites certified of which 43 are re-certified (more than 2 years’ certificate).

### Table 3. Multinational clinical research studies per ophthalmology subspecialty

<table>
<thead>
<tr>
<th>Ongoing clinical research</th>
<th>Area of subspecialty</th>
<th>diabetic retinopathy and retinal vascular diseases</th>
<th>glaucoma</th>
<th>anterior segment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials (IDCTs)</td>
<td>Eur-USH&lt;sup&gt;a&lt;/sup&gt;</td>
<td>RET-2010-02</td>
<td>STRONG&lt;sup&gt;a&lt;/sup&gt;</td>
<td>CCR-2010-01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EUROCONDOR&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PROTEUS&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTES&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registries (industry)</td>
<td>LHON</td>
<td>POLARIS</td>
<td>IRISS</td>
<td></td>
</tr>
<tr>
<td>Total (n = 11)</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

<sup>a</sup> EU-funded. <sup>b</sup> Industry grant.

### Fig. 2. Number of multinational clinical research studies.

![Number of multinational clinical research studies](image-url)
Collaboration with European Clinical Research Infrastructure Network (ECRIN)

EVICR.net is participating in the ECRIN Integrating Activities project, specifically in the WorkPackage dedicated to medical devices. ECRIN has become a European Research Infrastructure Consortium (ERIC) and has now its statutes published in the official journal of the EU (December 2013). The EVICR.net has started discussing its integration as an Affiliate Partner of ECRIN-ERIC an Organ-Specific Clinical Research Network, providing its expertise in clinical research in ophthalmology.

Alliances and Partnerships

EVICR.net has established preferred alliances with two CROs, AppleTree (Switzerland) and Eurotrials (Portugal), for the EVICR.net Clinical Site certification process, to perform an independent evaluation visit of the Clinical Sites. Collaborations are being established with other CROs to move forward multinational clinical research in ophthalmology.

Next Meetings – 2014

- Industry Advisory Board during ARVO, Orlando, USA: May 5
- Glaucome during European Glaucoma Society, Nice, France: June 7–11
- Anterior Segment Expert Committee during ESCRS, London, UK: September 13–17
- 9th EVICR.net Members Meeting Coimbra, Portugal: November 17–18

EVICR.net – European Network of Clinical Research in Ophthalmology

Chairman
Jose Sahel, MD, PhD

Steering Committee
Jose Sahel, MD, PhD – AMD and Retinal Dystrophies Expert Committee Coordinator
José Cunha-Vaz, MD, PhD – Diabetic Retinopathy and Retinal Vascular Diseases Expert Committee Coordinator
Ingemborg Stalmans, MD, PhD – Glaucoma Expert Committee Coordinator
Jorge Alió, MD, PhD – Anterior Segment Expert Committee Coordinator
Tunde Peto, MD, PhD, FHCO, FHCD – Reading Centres Expert Committee Coordinator
Marie-José Tassignon, MD, PhD – Medical Devices Transversal Section Coordinator

Birgit Lorenz, MD, PhD – Rare Diseases Transversal Section Coordinator
Cecilia Martinho, BSc – CEO, Coordinating Centre (AIBILI)

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Website www.evicr.net

List of EVICR.net Members (per Country)

Austria
CS No. 19: Medical University of Vienna, Department of Ophthalmology, Vienna
CS No. 83: Hommer Ophthalmology Institute, Vienna

Belgium
CS No. 8: Ghent University Hospital, Department of Ophthalmology, Ghent
CS No. 12: Antwerp University Hospital, Department of Ophthalmology, Antwerp
CS No. 18: University Hospital Leuven, Department of Ophthalmology, Leuven

Denmark
CS No. 30: Glostrup Hospital, Department of Ophthalmology, Copenhagen University, Glostrup
CS No. 73: Odense University Hospital, Department of Ophthalmology, Odense

France
CS No. 3: Centre Hospitalier Creteil, University Eye Clinic, Paris
CS No. 6: Centre National d’Ophthalmologie des Quinze-Vingts, Centre d’Investigation Clinique, Paris
CS No. 13: CHU Gabriel Montpied, Unité de Recherche Clinique, Service d’Ophtalmologie, Clermont-Ferrand
CS No. 14: Hôpital Lariboisière, Department of Ophthalmology, Paris
CS No. 42: University Hospital, CHU Dijon, Department of Ophthalmology, Dijon
CS No. 48: CLAIROP: Centre loco-régional d’Amiens pour l’Innovation et la Recherche en Ophtalmologie Pédiatrique, Amiens
CS No. 61: CHU Pellegrin, Service Ophtalmologie, Bordeaux
CS No. 86: Clinique Ophtalmologique, Centre Saint Victor, Centre Hospitalier Universitaire d’Amiens, Amiens

Germany
CS No. 2: University Medical Center, Johannes Gutenberg University, Department of Ophthalmology, Mainz
CS No. 5: Faculty of Medicine Mannheim of the Ruprecht-Karls-University Heidelberg, Department of Ophthalmology, Mannheim
CS No. 9: University Hospital Tuebingen (UKT), STZ Biomed & STZ Eyetrial at the Center for Ophthalmology, Tuebingen
CS No. 11: University Eye Hospital Munich, Munich
CS No. 15: University of Bonn, Department of Ophthalmology, Bonn
CS No. 21: University Medical Center Hamburg-Eppendorf, Department of Ophthalmology, Hamburg
CS No. 24: University of Freiburg, Department of Ophthalmology, Freiburg
CS No. 27: University Eye Hospital, Leipzig
CS No. 43: RWTH Aachen University, Department of Ophthalmology, Aachen

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