

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.

Table 1. Number of members per country

Austria	2
Belgium	3
Denmark	2
France	8
Germany	15
Greece	2
Ireland	1
Israel	1
Italy	10
Poland	1
Portugal	7
Slovakia	1
Slovenia	1
Spain	9
Switzerland	3
The Netherlands	4
United Kingdom	10
Total	80

**Fig. 1.** Number of members per country.

8th Annual Members Meeting

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.

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

Year	IDCTs			Industry registries	Total
	no funding	EU funding	industry grant		
2010	2	–	–	–	2
2011	2	1	–	–	3
2012	2	2	1	2	7
2013	2	3	3	3	11

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).

AMD and Retinal Dystrophies

Clinical Trials

Eur-USH: European Young Investigators Network for Usher Syndrome. EU-funded project. ClinicalTrials.gov No. NCT01954953.

Registries

LHON: A registry on Leber's Hereditary Optic Neuropathy. Sponsor: Santhera. ClinicalTrials.gov No. NCT01892943.

Diabetic Retinopathy and Retinal Vascular Diseases

Clinical Trials

ECR-RET-2010-02: Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using noninvasive procedures. ClinicalTrials.gov No. NCT01145599.

EUROCONDOR: 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.

Table 3. Multinational clinical research studies per ophthalmology subspecialty

Ongoing clinical research	Area of subspecialty			
	AMD and retinal dystrophies	diabetic retinopathy and retinal vascular diseases	glaucoma	anterior segment
Clinical trials (IDCTs)	Eur-USH ^a	RET-2010-02 EUROCONDOR ^a PROTEUS ^b ARTES ^b	STRONG ^a SPORT ^b	CCR-2010-01
Registries (industry)	LHON	POLARIS IRISS		
Total (n = 11)	2	6	2	1

^a EU-funded. ^b Industry grant.

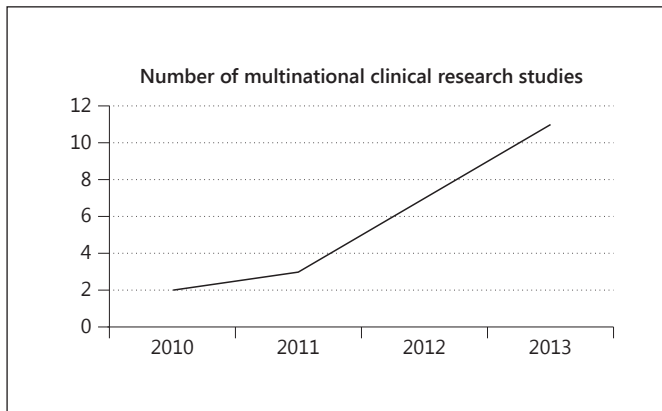


Fig. 2. Number of multinational clinical research studies.

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.

ARTES: A collaborative retrospective trial on the efficacy and safety of intravitreal dexamethasone implant (Ozurdex) in patients with diabetic macular edema. IDCT grant from Allergan.

Registries

POLARIS: A noninterventional study in patients with diabetic macular edema with central involvement to assess the effectiveness of existing anti-vascular endothelial growth factor treatment regimens. Sponsor: Bayer. ClinicalTrials.gov No. NCT01771081.

IRISS: An open-label registry study of the safety of Iluvien® (fluocinolone acetonide 190 µg intravitreal implant in applicator). Sponsor: Alimera. ClinicalTrials.gov No. NCT01998412.

Glaucoma

Clinical Trials

STRONG: European consortium for the Study of a Topical Treatment of Neovascular Glaucoma. EU-funded project. EudraCT 2014-000239-18.

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.

Standard Operating Procedures

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).

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
- Diabetic Retinopathy and Retinal Vascular Diseases Expert Committee during EURETINA, London, UK: September 11–14
- Glaucoma 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

Ingeborg 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)

Contacts

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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'Ophthalmologie, 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 Ophthalmologie Pédiatrique, Amiens

CS No. 61: CHU Pellegrin, Service Ophthalmologie, Bordeaux

CS No. 86: Clinique Ophthalmologique, 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

- CS No. 44: University Eye Clinic, Center for Vision Science, Bochum
CS No. 54: University of Düsseldorf, Department of Ophthalmology, Düsseldorf
CS No. 55: Eye Centre Spreebogen, Berlin
CS No. 56: University of Heidelberg, International Vision Correction Research Centre (IVCRC), Heidelberg
CS No. 59: Johann Wolfgang Goethe-University Frankfurt, Department of Ophthalmology, Frankfurt
CS No. 65: Justus-Liebig-University-Giessen, Department of Ophthalmology, Giessen
CS No. 77: Universität zu Köln, Zentrum für Augenheilkunde, Köln

Greece

- CS No. 57: University of Crete, Institute of Vision and Optics (IVO), Crete
CS No. 71: Laboratory of Research and Clinical Applications in Ophthalmology, Aristotle Univ. of Thessaloniki, A'Department of Ophthalmology, AHEPA Univ. Hospital, Thessaloniki

Ireland

- CS No. 31: Mater Vision Institute (MVI), Dublin

Israel

- CS No. 60: Tel Aviv Sourasky Medical Center, Department of Ophthalmology, Tel Aviv

Italy

- CS No. 16: University of Milan, Centre for Clinical Trials at San Paolo Hospital, Milan
CS No. 20: G. B. Bietti Foundation – IRCCS, Rome
CS No. 34: Luigi Sacco Hospital, University of Milan, Department of Ophthalmology, Milan
CS No. 36: Catholic University, Institute of Ophthalmology, Rome
CS No. 37: Dipartimento di Scienze Biomediche, Biotecnologiche e Transazionali S.Bi.Bi.T., Parma
CS No. 39: University of Padova, Department of Ophthalmology, Center for Clinical Trials, Padova
CS No. 50: University of Udine, Department of Ophthalmology, Udine
CS No. 63: University G. d'Annunzio of Chieti-Pescara, Excellence Eye Research Centre, Chieti
CS No. 64: Ophthalmic Clinic of the University of Bari, Bari
CS No. 67: University Vita Salute – Scientific Institute of San Raffael, Department of Ophthalmology, Milan

Poland

- CS No. 33: Poznan University of Medical Sciences, Department of Ophthalmology, Poznan

Portugal

- CS No. 1: AIBILI – Association for Innov. and Biom. Research on Light and Image, Coimbra
CS No. 28: Instituto de Oftalmologia Dr. Gama Pinto, Lisbon
CS No. 32: Oporto Medical School – Hospital S. João, Department of Ophthalmology, Oporto
CS No. 62: Centro Hospitalar de Lisboa Central, Centro de Investigação, Serviço de Oftalmologia, Lisbon
CS No. 70: University Hospital of Coimbra, Ophthalmology Department, Coimbra
CS No. 80: Instituto de Retina e Diabetes Ocular de Lisboa (IRL), Lisbon
CS No. 82: Espaço Médico de Coimbra, Coimbra

Slovakia

- CS No. 87: Department of Ophthalmology, Comenius University, Bratislava, Slovakia

Slovenia

- CS No. 23: University Medical Centre of Ljubljana, University Eye Hospital, Ljubljana

Spain

- CS No. 4: IOBA – Instituto Universitario Oftalmobiología Aplicada, Valladolid
CS No. 7: Vissum Corporación Oftalmológica Alicante, Alicante
CS No. 26: Centro de Oftalmología Barraquer, Barcelona
CS No. 38: Institut Català de Retina (ICR), Clinical Trial Unit, Barcelona
CS No. 41: Centro Médico Teknon, Institut de la Màcula i de la Retina, Barcelona
CS No. 51: Fundación para la Investigación Biomedica y Sanitaria (FISABIO), Oftalmología Médica, Valencia
CS No. 52: University Hospital Josep Trueta of Girona, Department of Ophthalmology, Girona
CS No. 74: Hospital Vall d'Hebrón, Department of Ophthalmology, Barcelona
CS No. 75: Vallés Oftalmologia Research, Barcelona
CS No. 78: Instituto Oftalmológico Fernandez-Vega, Oviedo

Switzerland

- CS No. 22: Inselspital, University of Bern, Department of Ophthalmology, Bern
CS No. 49: Jules Gonin Eye Hospital, Fondation Asile des Aveugles, Lausanne
CS No. 85: Clinical Research Centre Mémorial A. de Rothschild, Geneva

The Netherlands

- CS No. 17: Department of Ophthalmology, Radboud University Medical Centre, Nijmegen
CS No. 25: Academic Medical Center, Department of Ophthalmology, Amsterdam
CS No. 40: Rotterdam Eye Hospital, Rotterdam
CS No. 76: University Eye Clinic, Maastricht

United Kingdom

- CS No. 10: NIHR Moorfields Clinical Research Facility, Moorfields Eye Hospital, NHS Foundation Trust, London
CS No. 35: The Queen's University and Royal Group of Hospitals Trust, Ophthalmology and Vision Science, Belfast
CS No. 53: Gloucestershire Hospitals NHS Foundation Trust, Clinical Trials Unit, Department of Ophthalmology, Cheltenham
CS No. 58: Royal Liverpool University Hospital, Clinical Eye Research Centre, St. Paul's Eye Unit, Liverpool
CS No. 66: Frimley Park Hospital Foundation Trust, Ophthalmology Clinical Trials Unit, Frimley
CS No. 68: Heart of England NHS Trust, Ophthalmic Research Unit, Birmingham
CS No. 69: King's Health Partners, Laser and Retinal Research Unit, London
CS No. 79: Clinical Trials Unit, Oxford Eye Hospital, Oxford
CS No. 81: Royal Surrey County Hospital, NHS Foundation Trust, Ophthalmic Research Unit, Guildford
CS No. 84: ICORG, Imperial College Ophthalmologic Research Group, London

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