



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).

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.

EVICR.net is an independent European Economic Interest Grouping (EEIG) in accordance with the European Union Council Regulation (EEC) No. 2137/85 and the Coordinating Centre is AIBILI located in Coimbra, Portugal.

At present, EVICR.net has 78 centre members from 16 European countries.

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 ICH GCP Guidelines
- To promote multicenter 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

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 Coor-

dinator of each Expert Committee and the CEO of the Management Board.

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: AMD and Retinal Dystrophies; Diabetic Retinopathy; Glaucoma; Cornea, Cataract and Refractive Surgery; Ocular Surface and Inflammation; and Reading Centres.

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, Novartis, Pfizer, Santen and Théa.

The *Coordinating Centre*, AIBILI, is located in Coimbra, Portugal, and is the contact point for the members and industry when performing ophthalmological clinical research in Europe with dedicated personnel. 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.

Recent Developments

7th Annual Members Meeting

The 7th EVICR.net Annual Members Meeting took place on October 11–12, 2012, in Nice, France, during the EVER 2012 Congress. EVICR.net was responsible for organizing the Clinical Trials and Epidemiology session of the EVER congress which was divided in: Clinical Trials in Glaucoma, Anterior Segment and Ocular Surface; Clinical Trials in Diabetic Retinopathy and Retinal Vascular Diseases; Clinical Trials in AMD and Rare Diseases; and Reading Centres.

For the first time there were presentations from industry representatives sharing projects and experiences in an open way. All members were able to participate in the different scientific sessions as they did not occur simultaneously.

Table 1. Clinical Trials and Registries

Status	AMD and Retinal Dystrophies	Diabetic Retinopathy	Glaucoma	Anterior Segment, Cataract and Ref. Surgery	Ocular Surface and Inflammation
Ongoing	USH, E-RARE ¹ LHON*	RET-2010-002 ² EUROCONDOR ^{1,2} POLARIS PROTEUS*	STRONG ^{1,2}	CCRS-2010-01	
Total	2	4	1	1	–
Pending funding	GEOGRAPHIC ATROPHY STARCLIN		European glaucoma diagnosis and management	IOL Biobank NEWEYE	
Total	2	0	1	2	–

¹ EU funded. ² Involving Reading Centres. * Under negotiation.

Clinical Trials and Registries

The EVICR.net Coordinating Centre assumes the leadership of coordination and management of investigator-driven clinical trials (IDCTs) and epidemiological studies 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 and if approved they will have access to support in coordinating and implementing the study.

Some major developments have been accomplished since we have started our activities in 2004. We have at the moment 8 ongoing clinical trials of which 3 are European Union-funded projects (table 1).

AMD and Retinal Dystrophies

Clinical Trials

- USH – E-RARE – European Young Investigators Network for Usher syndrome
EU funding approved.
- GEOGRAPHIC ATROPHY – High-resolution spectral-domain OCT imaging in geographic atrophy associated with age-related macular degeneration
Approved by the AMD Expert Committee. Currently looking for financial support.
- STARCLIN – Phenotyping and disease progression in Starardt macular dystrophy using fundus autofluorescence imaging
Application submitted for EU funding.

Registries

- LHON – Leber's Hereditary Optic Neuropathy
Under negotiation with the sponsor (Santhera).

Diabetic Retinopathy

Clinical Trials

- RET-2010-02 – Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using non-invasive procedures
ClinicalTrials.gov Identifier: NCT01145599. Study ongoing. 19 centres recruited 375 patients.
- EUROCONDOR – Neurodegeneration as an early event in the pathogenesis of diabetic retinopathy: a multicentric, prospective, phase II-III, double-blind randomized controlled trial to assess the efficacy of neuroprotective drugs administered topically to prevent or arrest diabetic retinopathy
EudraCT No.: 2012-001200-38. Project ongoing with EU funding (2012-2016). Clinical trial initiated on December 2012.
- 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 and PRP in monotherapy in the treatment of patients with high risk proliferative diabetic retinopathy
Industry grant (Novartis).

Registries

- POLARIS – A prospective non-interventional study to assess the effectiveness of existing anti-vascular endothelial growth factor (anti-VEGF) treatment regimens in patients with diabetic macular edema (DME) with central involvement
Industry sponsored (BAYER).

Glaucoma

Clinical Trials

- STRONG – Early onset of neovascular glaucoma Project ongoing with EU funding (2012–2016).
- The European Glaucoma Diagnosis and Management Trial IDCT
Abstract under evaluation by the Glaucoma Expert Committee.

Cornea, Cataract and Refractive Surgery

Clinical Trials

- CCRS-2010-01 – Project Gullstrand – European Project for the Determination of Average Biometric Values of Human Eyes
ClinicalTrials.gov Identifier: NCT01173614. Study ongoing. 10 centres are recruiting.
- CCRS-03 – IOL Biobank
Application submitted to ESCRS for funding.
- NEWEYE – New autologous regenerative ocular therapies based on controlling differentiation in adult human stem cells
Application submitted for EU funding.

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 centres 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 investigator-driven or industry-driven clinical trials. These SOPs are also made available to our members.

In parallel EVICR.net has developed 22 organizational SOPs for the Reading Centres with the aim of establishing a network of Reading Centres able to have the capacity to respond to the industry needs for grading ophthalmological images in a standardized way with the most novel equipments.

Clinical Site Certification

At the moment we have 50 clinical sites certified of which 37 are re-certified (more than 2 years certificate).

ECRIN – European Clinical Research Infrastructure Network

EVICR.net is participating in the ECRIN – Integrating Activities project – specifically in the WorkPackage dedicated to medical devices. EVICR.net, as a disease-oriented network, was invited to participate in ECRIN, a European clinical research network that will soon become an ERIC – European Research Infrastructure Consortium. The ECRIN-IA has launched a call for multinational IDCTs in the areas of medical devices, rare disease and nutrition.

Alliances and Partnerships

EVICR.net has established preferred alliances with two CROs, AppleTree, Switzerland, and Eurotrials, Portugal, for the clinical site certification process, when an independent evaluation visit is necessary for the clinical sites that are not ISO 9001 certified.

Next Meetings – 2013

- EVICR.net AMD and Diabetic Retinopathy Expert Committees, during ARVO 2013, Seattle, USA, May 5–9
- EVICR.net Cornea Cataract and Ref. Surgery and Ocular Surf. Inflamm. Expert Committees, during ESCRS 2013, Amsterdam, The Netherlands, October 5–9
- EVICR.net Glaucoma Expert Committee, during SOE 2013, Copenhagen, Denmark, June 8–11
- 8th EVICR.net Members Meeting, during EVER 2013, Nice, France, September 18–21

EVICR.net – A Disease-Oriented Clinical Research Network Fits into the EU Research Programme

The disease-oriented clinical research networks are being called to perform a central role in the support of the recent emphasis on clinical research assessment by the European Union Research Framework Programme.

The development of ECRIN and EATRIS (European Infrastructure for Translational Medicine) into ERIC in the context of the ESFRI (European Strategy Forum on Research Infrastructures) concept welcome disease-oriented clinical research networks such as EVICR.net.

EVICR.net – European Network of Clinical Research in Ophthalmology

Chairman

Jose Sahel, MD, PhD

Steering Committee

Jose Sahel, MD, PhD: Chairman and AMD and Retinal Dys-trophies Expert Committee Coordinator

José Cunha-Vaz, MD, PhD: Diabetic Retinopathy Expert Committee Coordinator

Esther Hoffmann, MD, PhD: Glaucoma Expert Committee Coordinator

Jorge Alió, MD, PhD: Cornea, Cataract and Refractive Surgery Expert Committee Coordinator

Joaquim Murta, MD, PhD: Ocular Surface and Inflammation Expert Committee Coordinator

Tunde Peto, MD, PhD, FHCO, FHCD: Reading Centres Expert Committee Coordinator

Cecília Martinho, BSc: CEO

Contacts

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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

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. 45: Hôpital Purpan, Service d'Ophthalmologie, Toulouse

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

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. 47: Clinical Centre Karlsruhe, Department of Ophthalmology, Karlsruhe

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: University of Bari, Department of Ophthalmology and Otolaryngology, Bari
CS No. 67: University Vita Salute – Scientific Institute of San Raffaele, Department of Ophthalmology, Milan
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Poland

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

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

- CS No. 4: IOBA – Instituto Universitario Oftalmobiología Aplicada, Valladolid
CS No. 7: Visum 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 Oftalmológica del Mediterráneo, 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
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Switzerland

- CS No. 22: Inselspital, University of Bern, Department of Ophthalmology, Bern
CS No. 49: Jules Gonin Eye Hospital, Fondation Asile des Aveugles, Lausanne
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The Netherlands

- CS No. 17: University Medical Centre St Radboud, Ophthalmic Trial Centre Nijmegen, 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
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United Kingdom

- CS No. 10: Moorfields Eye Hospital NHS Foundation Trust, Clinical Trial Unit, 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, Gloucestershire
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, Surrey
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. 72: Torbay Hospital Eye Department, Devon
CS No. 79: Clinical Trials Unit, Oxford Eye Hospital, Oxford
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