

EVICR.net Activities – Update

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). Its aim is 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 European platform for clinical research in ophthalmology and a useful industry resource in the development of new drugs and medical devices. At present, EVICR.net has 92 member centres from 19 European countries.

The 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 Harmonisation – Good Clinical Practice Guidelines (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 the quality, transparency and optimal use of clinical research data, and
- to communicate the challenges and opportunities raised by clinical research in ophthalmology to patients and citizens.

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 EVICR.net and cover the following main areas of research: AMD and Retinal Dystrophies; Diabetic Retinopathy and Retinal Vascular Diseases; Glaucoma; Anterior Segment, and Reading Centres.

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. The Coordinating Centre is responsible for the coordination of investigator-driven clinical trials (IDCTs). 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 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
Finland	1
France	12
Germany	15
Greece	1
Ireland	1
Israel	3
Italy	10
Poland	1
Portugal	8
Slovakia	1
Slovenia	1
Spain	13
Sweden	1
Switzerland	3
The Netherlands	4
United Kingdom	10
Total	92

Table 2. Multinational clinical research studies (2010–2014)

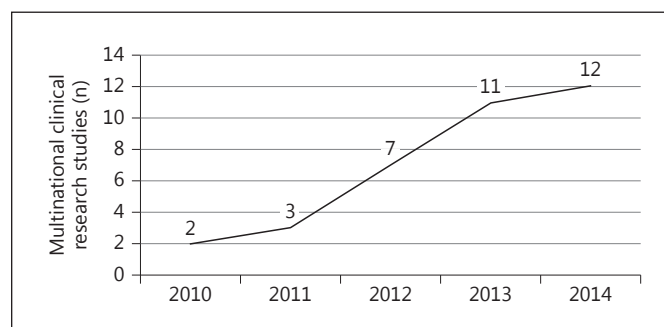
Year	IDCTs			Industry registries	Total
	no funding	EU funding	industry grant		
2010	2	–	–	–	2
2011	2	1	–	–	3
2012	2	2	1	2	7
2013	2	3	3	3	11
2014	2	3	4	3	12

9th Annual Members Meeting

To celebrate the EVICR.net 10th anniversary, its 9th Annual Members Meeting took place in Coimbra, Portugal at the Coordinating Centre, AIBILI, on November 16–18, 2014. The meeting was attended by 108 participants from Member Centres (table 1; fig. 1), CROs and Industry Advisory Board Members. The 2015 EVICR.net annual meeting will take place in Rome, Italy, on November 26–27.

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 submit abstracts for IDCTs to the Coordinating Centre in order to be evaluated by a specific Expert Committee.

**Fig. 1.** Number of members per country.**Fig. 2.** Number of multinational clinical research studies.

If approved they will have access to support in coordinating and implementing the IDCT. Also EVICR.net members have the opportunity to participate in IDCTs developed by the network or in industry studies.

Multinational Clinical Research Studies (2010–2014)

EVICR.net IDCTs have been growing in the last years, giving the opportunity for investigators to perform multinational clinical research of high quality (in compliance with ICH-GCP Guidelines) assuming that the rights, safety and wellbeing 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. In 2014, EVICR.net had 12 ongoing multinational clinical research studies, of which 3 are European Union-funded (table 2; fig. 2). During 2014 three clinical trials finished the clinical phase and are now in the final report and publication phase.

Table 3. Multinational clinical research studies per ophthalmology subspecialty (January 2015)

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 ATLANTIC ^b	EUROCONDOR ^a PROTEUS ^b ARTES ^b	STRONG ^a SPORT ^b	
Registries (industry)		POLARIS IRISS		
Total (n = 9)	2	5	2	0

^a EU-funded. ^b Industry grant.

Multinational Clinical Research Studies per Ophthalmology Subspecialty (January 2015) (table 3)

AMD and Retinal Dystrophies

Clinical Trials

(1) Eur-USH – European Young Investigators Network for Usher Syndrome. EU-funded project. ClinicalTrials.gov No. NCT01954953.

(2) ATLANTIC – A randomized, double-masked, sham-controlled phase 4 study of the efficacy, safety and tolerability of intravitreal aflibercept monotherapy compared to aflibercept with adjunctive photodynamic therapy in patients with polypoid choroidal vasculopathy. IDCT grant from Bayer.

Diabetic Retinopathy and Retinal Vascular Diseases

Clinical Trials

(1) 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. EU-funded project. EudraCT No. 2012-001200-38; ClinicalTrials.gov No. NCT01726075.

(2) PROTEUS – Prospective, randomized, multicentre, open-label, phase II/III study to assess efficacy and safety of ranibizumab 0.5 mg intravitreal injections plus panretinal photocoagulation versus and panretinal photocoagulation in monotherapy in the treatment of patients with high-risk proliferative diabetic retinopathy. IDCT grant from Novartis. EudraCT No. 2013-003640-23; ClinicalTrials.gov No. NCT01941329.

(3) ARTES – A collaborative retrospective trial on the efficacy and safety of intravitreal dexamethasone implant (Ozurdex) in patients with diabetic macular oedema. IDCT grant from Allergan. ClinicalTrials.gov No. NCT02121197.

Registries

(1) 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.

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

Glaucoma

Clinical Trials

(1) STRONG – European Consortium for the Study of a Topical Treatment of Neovascular Glaucoma. EU-funded project.

(2) SPORT – A randomized, 3-month, crossover, single-masked, investigator-led, multicentre trial on open-angle glaucoma or ocular hypertension patients. IDCT grant from Allergan. EudraCT 2013-003490-10; ClinicalTrials.gov No. NCT01975714.

Publications

AMD and Retinal Dystrophies

(1) ECR-ICT-09 – LHON – A registry on Leber's Hereditary Optic Neuropathy. Sponsor: Santhera. ClinicalTrials.gov No. NCT01892943.

- Poster presented at the EVER 2014 Congress.

Diabetic Retinopathy and Retinal Vascular Diseases

(1) ECR-RET-2010-02 – Identifying progression of retinal disease in eyes with non-proliferative diabetic retinopathy in diabetes type 2 using non-invasive procedures. ClinicalTrials.gov No. NCT01145599.

- Poster presented at the ARVO 2014 Congress.
- Poster accepted for the ARVO 2015 Congress.

(2) ECR-RET-2011-03 – 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. EU-funded project. EudraCT No. 2012-001200-38; ClinicalTrials.gov No. NCT01726075.

- Poster presented at the ARVO 2014 Congress.
- Poster accepted for the ARVO 2015 Congress.

Anterior Segment

(1) ECR-CCRS-2010-01 – Project Gullstrand – European project for the determination of average biometric values of human eyes. ClinicalTrials.gov No. NCT01173614.

- 1st paper: accepted for publication (*Cahiers d'Ophthalmologie*, May 2013).
- 2nd paper: accepted for publication (*Optometry and Vision Science*, July 2014).
- 3rd paper: paper with CS 27 results (Leipzig, DE) submitted to *Acta Ophthalmologica* for publication.

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 EVICR.net Clinical Sites Members agree to adopt or adapt these SOPs in their centres, which will be checked before they are certified as Sites of Excellence. An independent evaluation visit may occur before this certification.

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

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 Centres 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.

Clinical Sites Certification

At the moment we have 54 clinical sites certified, of which 46 are recertified (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. The ECRIN is a European Research Infrastructure Consortium (ERIC). EVICR.net has expressed its interest in becoming an Affiliate Partner of ECRIN-ERIC as EVICR.net is a disease-oriented network in ophthalmology for clinical research. Measures are being taken to formalize this affiliation.

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 inde-

pendent evaluation visit of the clinical sites. Collaborations are being established with other CROs in order to move forward multinational clinical research in ophthalmology.

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

Marie-José Tassignon, MD, PhD – Anterior Segment Expert Committee Coordinator

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

Jorge Alió, MD, PhD – Medical Devices Transversal Section Coordinator

Birgit Lorenz, MD, PhD – Rare Diseases Transversal Section Coordinator

Cecilia Martinho, BSc – CEO, Coordinating Centre (AIBILI)

Contacts

EVICR.net

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E-Mail evicrnet@aibili.pt, Website www.evicr.net

List of EVICR.net Members (per Country)

Austria (2)

CS No. 19: Medical University of Vienna, Department of Ophthalmology, Vienna

CS No. 83: Hommer Ophthalmology Institute, Vienna

Belgium (3)

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 (2)

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

CS No. 73: Odense University Hospital, Department of Ophthalmology, Odense

Finland (1)

CS No. 91: Department of Ophthalmology, Kuopio University Hospital, Kuopio

France (12)

- 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
 CS No. 92: Clinical Trial Unit, Department of Ophthalmology, CHU Nord, Aix-Marseille University, Marseille
 CS No. 93: Department of Ophthalmology, Centre Hospitalier Henri Duffaut, Avignon
 CS No. 97: Coscas Eye Clinic, Paris
 CS No. 99: Department of Ophthalmology, Croix-Rousse University Hospital, Lyon

Germany (16)

- 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 Eyetrail 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 (1)

- CS No. 71: Laboratory of Research and Clinical Applications in Ophthalmology, Aristotle Univ. of Thessaloniki, A'Department of Ophthalmology, AHEPA Univ. Hospital, Thessaloniki

Ireland (1)

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

Israel (2)

- CS No. 60: Tel Aviv Sourasky Medical Center, Department of Ophthalmology, Tel Aviv
 CS No. 88: Kaplan Medical Center, Ophthalmology Department, Rehovot
 CS No. 100: Meir Medical Center, Kfar-Saba

Italy (10)

- 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 Raffael, Department of Ophthalmology, Milan

Poland (1)

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

Portugal (8)

- 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
 CS No. 90: Serviço de Oftalmologia, Hospital de Vila Franca de Xira, Vila Franca de Xira

Slovakia (1)

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

Slovenia (1)

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

Spain (14)

- 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: Fundació 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
 CS No. 89: Ophthalmology Department, Dos de Maig Hospital, Barcelona
 CS No. 95: Instituto de Microcirugía Ocular, Barcelona
 CS No. 96: Ophthalmology Department, Hospital de LaPaz, Madrid
 CS No. 98: Servicio Oftalmología, Hospital Universitario y Politécnico de la Fe, Valencia

Switzerland (3)

- 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
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The Netherlands (4)

- CS No. 17: University Medical Centre St Radboud, Ophthalmic Trial Centre Nijmegen, Nijmegen
CS No. 25: Academic Medical Center, Department of Ophthalmology, Fe, Valencia
CS No. 40: Rotterdam Eye Hospital, Rotterdam
CS No. 76: University Eye Clinic, Maastricht
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United Kingdom (10)

- 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. 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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