



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

The EVICR.net – European Vision Institute Clinical Research Network – 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 trial research in ophthalmology in Europe and aims to be a much-needed structure to support investigator-initiated clinical trials and to serve as an industry resource in order to promote the 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.

Each clinical site must apply to belong to the Network and fulfill basic requirements such as dedicate space to perform clinical trials, have qualified and experienced personnel, experience with multicentric clinical trials and agree to implement organizational SOPs according to ICH GCP Guidelines. Each clinical site in order to become a certified member of EVICR.net will be submitted to an On-Site Evaluation Visit performed by independent auditors according to the Network procedures.

The Network has a centralized infrastructure located at AIBILI, Coimbra, Portugal, which functions as the Coordinating Center with CRO functions necessary for the management of multicenter clinical trials.

At present, EVICR.net has 70 center members from 16 European countries that are either fully certified or in the process of certification.

## Aims and Objectives

The main aims and objectives of EVICR.net are:

- To guarantee a high level of quality and excellence in the clinical research collaborative work performed by members according to ICH GCP Guidelines
- To promote investigator-initiated 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.

## Organization

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 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: Retina (Age-Related Macular Degeneration and Retinal Dystrophies and Diabetic Retinopathy); Glaucoma; Cornea, Cataract and Refractive Surgery; Ocular Surface and Inflammation; and Reading Centers.

Each Expert Committee supervises a Scientific Section. Each clinical site will nominate one representative for each area of interest and expertise: Retina (Age-Related Macular Degeneration and Retinal Dystrophies and Diabetic Retinopathy); Glaucoma; Cornea, Cataract and Refractive Surgery; Ocular Surface and Inflammation; and Reading Centers. This representative will be part of the chosen Scientific Section. Each Scientific Section will vote every three years for the Coordinator which will be the representative of the Scientific Section in the Steering Committee.

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 for the activities of EVICR.net.

## Network Recent Developments

### *EVICR.net as an Independent Organization*

Following on the decision taken by the Steering Committee Meeting held in Mainz, Germany, on November 16, 2009, the EVICR.net – European Vision Institute Clinical Research Network, EEIG – is now established as a European Economic Interest Grouping, independent from the European Vision Institute but keeping scientific links with it.

### *EVICR.net Elections*

The Coordinators of the Expert Committees will be elected by their respective Scientific Sections at the next Annual Members Meeting in London, UK, on November 15 and 16, 2010. Therefore it is essential that each clinical site nominates a representative to

be able to participate/vote in each Scientific Section. For reasons of continuity, the Chairman will only be elected 1 year later, in 2011. This one-year interval between elections for the Coordinators of the Expert Committees and that of the Chairman will be maintained in the future.

#### *Investigator-Initiated Clinical Trials*

The Management Board at AIBILI, Coimbra, Portugal, assumes the leadership of coordination and management of investigator-driven clinical trials (IDCT) and epidemiological studies across Europe through the Network.

#### Retina

- *Title.* Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using non-invasive procedures
- *Principal Investigator.* J. Cunha-Vaz (Coimbra, Portugal)
- *Writing Committee.* J. Cunha-Vaz, C. Lobo, F. Bandello, P. Massin and S. Harding
- *Status.* Protocol, CRF and ICF approved. Initiation of the study expected in July after the signature of the participating centers of the protocol commitment. 25 have declared interest.

#### Cornea, Cataract and Refractive Surgery

- *Title.* Benchmarking and modeling human ocular biometry to assess the quality of vision in the European population (Project Gullstrand)
- *Principal Investigators.* J. Rozema and M.J. Tassignon (Antwerp, Belgium)
- *Writing Committee.* J. Rozema, L. Bataille and M. Larsen
- *Status.* Protocol, CRF and ICF in final stages of approval. Initiation expected in July.

An IDCT flowchart has been elaborated by the Coordinating Center for submission of IDCTs synopsis by investigators. For more information please contact Rita Fernandes via the following e-mail [anarf@aibili.pt](mailto:anarf@aibili.pt).

#### *Funding – European Union Research Programme*

In order to obtain funding for the Network, the Management Board prepared a proposal for European Union funding. A concerted effort was done with 17 EVICR.net members (from 11 countries) to contact their national representatives. The proposed title of this proposal is: ‘Structuring translational research on degenerative vision diseases of old-age between clinical research centers in Europe’. This call is expected to open in 2011.

#### *5th EVICR.net Annual Members Meeting*

The 5th EVICR.net Annual Members Meeting will take place on November 15 and 16, 2010, in London, UK. For more information please send an e-mail to [ssimoes@aibili.pt](mailto:ssimoes@aibili.pt). The General Assembly with elections of Expert Committee Coordinators will take place on November 15 as well as present the status of the EVICR.net investigator-driven clinical trials.

#### *Alliances and Partnerships*

Preferred alliances with other independent CROs for clinical site certification were established with AppleTree and Eurotrials.

## **Network Members**

At the moment there are 70 clinical trial site members from 16 European countries. 23 other clinical trial sites have expressed interest in becoming members of EVICR.net.

Present status of the members (2010/07/12):

- 31 certified
- 8 already re-certified
- 31 in certification process

## **Expert Committees**

### *Technical SOPs – Present Status*

Expert Committee	SOPs finalized	SOPs in preparation
Retina	6	2
Glaucoma	4	7
Cornea, cataract and refractive surgery	9	3
Ocular surface and inflammation	6	9

In the future, these technical SOPs will be made accessible to the members on our website. These technical SOPs are an added value of our network and will be promoted to industry.

## **Reading Centers**

Two new SOPs for Reading Centers No. ECR 2220 – ‘Equipment (Basic Procedures for Maintenance, Calibration, etc.)’ and No. ECR 2221 – ‘Control of Infrastructures (General Housekeeping, Pest and Rodent Monitoring, etc.)’ have been issued.

The revision of the Reading Centers’ SOPs in order to include the new name and logo of the Network will be done progressively and with the help of the Coordinating Center.

## **Training Courses**

A Reading Center course is planned to take place during the Annual Members Meeting in London, UK, on November 16, 2010.

## **Next Meetings – 2010**

- EVICR.net Retina Section, EURETINA, Paris, France, September 3
- EVICR.net Cornea Section, ESCRS, Paris, France, September 4–8
- EVICR.net Glaucoma Section, EGS, Madrid, Spain, September 12–17
- EVICR.net Ocular Surface and Inflammation Section, EVER, Crete, Greece, October 6–9
- 5th EVICR.net Members Meeting, London, UK, November 15, 16

## European Network of Clinical Research in Ophthalmology

### Chairman

José Cunha-Vaz, MD, PhD

### Steering Committee

José Cunha-Vaz, MD, PhD

Jose Sahel, MD, PhD

Norbert Pfeiffer, MD, PhD

Jorge Alió, MD, PhD

Philippe Kestelyn, MD, PhD

Tunde Peto, MD, PhD, FHCO, FHCD

Cecília Martinho, BSc

### Expert Committees

#### Retina

AMD and Retinal Dystrophies

Diabetic Retinopathy

#### Glaucoma

Cornea, Cataract and Refractive Surgery

Ocular Surface and Inflammation

Reading Centers

### EVICR.net

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Website: [www.evicr.net](http://www.evicr.net)

### List of Clinical Sites (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: University Hospital Antwerp, 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

#### 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: Groupe Hospitalier Pellegrin, Unité Médicale Segment Postérieur, Service Ophthalmologie, Bordeaux

#### Germany

CS No. 2: University Medical Center, Johannes Gutenberg University, Department of Ophthalmology, Mainz

CS No. 5: Faculty of Medicine Mannheim, 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 Bochum, Center for Vision Science, Bochum

CS No. 47: Staedtisches Klinikum 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

#### Greece

CS No. 57: University of Crete, Institute of Vision and Optics (IVO), Crete

#### 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: University of Milan, Luigi Sacco Hospital, Department of Ophthalmology, Milan

CS No. 36: Catholic University, Institute of Ophthalmology, Rome

CS No. 37: Sezione di Oftalmologia, Dipartimento di Scienze Otorino-Odonto-Oftalmologiche e Cervico Facciali, Parma

CS No. 39: University of Padova, Department of Ophthalmology, Center for Clinical Trials, Padova

CS No. 46: Policlinico di Monza, Clinica Oculistica, Monza

CS No. 50: University of Udine, Department of Ophthalmology, Udine

- CS No. 63: University of Chieti-Pescara, Excellence Eye Research Center, Center for Excellence on Ageing, 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
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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, Centre for Clinical Trials, Coimbra  
CS No. 28: Instituto de Oftalmologia Dr. Gama Pinto, Lisbon  
CS No. 32: Porto Medical School – Hospital S. João, Department of Ophthalmology, Porto  
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
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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: VISSUM – Instituto Oftalmológico de 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
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- CS No. 51: Fundación Oftalmológica del Mediterráneo, Valencia  
CS No. 52: University Hospital Josep Trueta Of Girona, Department of Ophthalmology, Girona
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*Switzerland*

- CS No. 22: Inselspital, University of Bern, Department of Ophthalmology, Bern  
CS No. 49: Jules Gonin Eye Hospital, 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
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*United Kingdom*

- CS No. 10: Moorfields Eye Hospital NHS Trust, Clinical Trials Unit and Reading Centre, London  
CS No. 35: Queen's University, Institute of Clinical Science, Royal Victoria Hospital Ophthalmology and Vision Science Research Center, 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, Liverpool  
CS No. 66: Frimley Park Hospital NHS Foundation Trust, Clinical Trials Unit – Ophthalmology Treatment Centre, Camberley  
CS No. 68: Heart of England NHS Trust, Ophthalmic Research Unit, Birmingham  
CS No. 69: King's College Hospital, University of London, Laser and Retinal Research Unit, London
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