ARVO MEETING 2015
- Posters from two EVICR.net IDCTS

The EVICR.net has been represented at ARVO 2015 with abstracts of EVICR.net multinational investigator-driven clinical trials ECR-RET-2010-02 – RET02 and ECR-RET-2011-03 - EUROCONDOR.

- Meetings
Meetings of the Steering Committee and Industry Advisory Board took place on May 5, 2015.

10th EVICR.net ANNUAL MEMBERS MEETING

The 10th Members Meeting will take place on November 26-27, 2015 in Rome, Italy. The Preliminary Programme is now available at EVICR.net website. The registration form and practical information will be sent soon to all members.

NEW MEMBERS
The Network as now 97 Clinical Sites from 19 European countries.
Welcome to the New EVICR.net Members:
- CS nº 100: Meir Medical Center, Kfar-Saba, Israel
- CS nº 101: ALM-Oftalmolaser, Lisbon, Portugal
- CS nº 102: Instituto Português de Microcirurgia Ocular (IMO), Lisbon, Portugal
- CS nº 103: Serviço de Oftalmologia, Hospital de Braga, Braga, Portugal
- CS nº 104: Centro de Investigação, Serviço de Oftalmologia, Centro Hospitalar de Leiria E.P.E., Leiria, Portugal
- CS nº 105: Unidad Clinica de Retina – Servicio de Oftalmologia, Complejo Hospitalario Universitario de Albacete, Spain
1. CLINICAL TRIALS AND REGISTRIES (STATUS)
EVICR.net had in 2014, 12 ongoing multinational clinical research studies of which three are European Union funded. During 2014 three clinical trials finished the clinical phase and are now in the final report and publication phase.

<table>
<thead>
<tr>
<th>Year</th>
<th>IDCTs</th>
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<th>EU Funding</th>
<th>Industry Grant</th>
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Multinational Clinical Research Studies per Ophthalmology Subspecialty (May 2015)

1.1 AMD and Retinal Dystrophies
1.1.1 Ongoing Clinical Trials and Registries
   The study is under regulatory submission in 15 Clinical Sites. Ongoing.
   - Project extension - a first stage application to an E-Rare call for the project extension was submitted and approved. A full proposal is being prepared to be submitted before June 2, 2015.

   Contracting with the Clinical Sites. Ongoing.

1.1.2 Looking for funding
1. AMD1 - Geographic Atrophy - High-resolution spectral-domain OCT imaging in Geographic Atrophy associated with age-related macular degeneration – CI: F. Holz (CS 15)
   Looking for funding.

2. AMD7 - DRIVER - Early treatment of AMD patients with choroidal neovascularization: Biomarkers of treatment efficacy, biomarkers of conversion to wet AMD – CI: Rufino Silva (CS 82).
   Looking for funding.

1.2. Diabetic Retinopathy and Retinal Vascular Diseases
1.2.1 Ongoing Clinical Trials and Registries
1. DR1 - ECR-RET-2010-02 – RET02 - Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using non-invasive procedures – CI: J. Cunha-Vaz (CS 1).
   CI preparing Final Report expected to be concluded during 2015.

3. **DR5 - ECR-RET-2013-05 - 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 - CI: J. Figueira (CS 1). IDCT grant from Novartis. LPLV expected: March 2016. Ongoing.


1.2.2 **Looking for funding**

1. **DR7 - Study of the Efficacy and Safety of Aflibercept Compared With Ranibizumab in Subjects With Macular Edema Secondary to Branch Retinal Vein Occlusion** - CI: S. Younis (CS 84). Looking for funding.

1.3 **Glaucoma**

1.3.1 **Ongoing Clinical Trials**


1.3.2 **Looking for funding**

1. **G2 - The European Glaucoma Diagnosis and Management Questionnaire** - CI: E. Hoffmann (CS 2). Looking for funding.

1.4 **Anterior Segment**

1.4.1 **Ongoing Clinical Trials**


1.4.2 **Applying for funding**

1. **C6 - The Retrospective Keratoconus Progression Study** - CI: J. Rozema (CS 12). A grant application for Horizon 2020 (K-PROTECT) was submitted on 20/04/2015. Feedback expected in November 2015.

1.4.3 **Looking for funding**

1. **C3 - European IOL Biobank** - CI: J. Alió (CS 7) and M.J.Tassignon (CS 12). A grant application for ESCRs Clinical Research Awards was submitted on 28/05/2015. Looking for funding.
Looking for funding.

2. PUBLICATION AND DISSEMINATION OF EVICR.net STUDIES

Studies
- ECR-ICT-09 – LHON
  o Poster presented in the EVER 2014 Congress.
- ECR-RET-2010-02 – RET02
  o Poster presented in the ARVO 2014 Congress.
  o Poster presented in the ARVO 2015 Congress.
  o First publication submitted to IOVS on February/2015
  o Two other publications being written to submit to Ophthalmic Research.
- ECR-RET-2011-03 – EUROCONDOR
  o Poster presented in the ARVO 2014 Congress.
  o Poster presented in the ARVO 2015 Congress.
- ECR-GLC-2013-06 – SPORT
  o Poster presented in COPHy 2015
  o 1st paper: in preparation (expected to be ready for submission during May/2015 to Graefe's Archive).
- ECR-CIRS-2010-01 - Project Gullstrand
  o 1st paper: Accepted for publication (Cahier de Ophtalmologie, May 2013)
  o 2nd paper: Accepted for publication (Optometry and Vision Science, July/2014).
  o 3rd paper: Paper w/ CS 27 results (Leipzig, DE) was approved by the Anterior Segment Expert Committee and submitted to ACTA Ophthalmologica for publication (01/08/2014).

General
- Official Journal of EVICR.net - Ophthalmic Research
  o EVICR.net Update and Opening Words page were published (April/2015)
    http://www.evicr.net/downloads/file246_gb.pdf

3. INVESTIGATOR-DRIVEN CLINICAL TRIALS PROCESS
- The EVICR.net Coordinating Centre assumes the 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.
  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.
- The EVICR.net Investigator-Driven Clinical Trials Policies and the Investigator-Driven Clinical Trials process is available on our website.
- Instruction for applicants, template and flowcharts for development and implementation of IDCTs are available to the members in the EVICR.net website www.evicr.net. All abstracts should also identify the estimated financial costs needed for the proposed study (e-mail: evicrnet@aibil.pt).

4. TECHNICAL SOPs
The EVICR.net Expert Committee Coordinators have identified which technical SOPs of the respective subspecialty should be reviewed, deleted or written. The Coordinating Centre has started this revision process and contacted the authors of the SOPs that need to be reviewed.
5. REGULAR UPDATING OF EVICR.net CLINICAL SITES RESEARCH ACTIVITY
A questionnaire to enable the Coordinating Centre to give rapid replies to Industry as well as to identify the Clinical Sites that should be approached for specific investigator-driven clinical trials, representing more opportunities for new studies for the Clinical Sites was sent to all EVICR.net Clinical Sites.
The Coordinating Centre is collecting the replies and gathering the information.

6. RETINAL DYSTROPHIES DATABASE WORKSHOP
A Retinal Dystrophies database workshop is being organized under the AMD Expert Committee. The RD 5000 DB already exists and is being used in The Netherlands.
A Clinical Site questionnaire will be sent to the Sites after validation by the AMD EC in order to have an inventory of the existing local or national retinal dystrophies databases and the sizes of constituted cohorts and their extensions. We are counting on Clinical Sites participation.

7. SERVICES PROVIDED TO INDUSTRY
Allergan - Certification of Technicians for Refraction and Visual Acuity procedures
EVICR.net has signed agreements with Allergan for new studies that are being set up and that need BCVA technician’s certification through EVICR.net. 204 technicians have been certified since 2010.
EVICR.net has BCVA Certifiers for Allergan studies in France, Germany, Israel, Italy, Portugal, Spain and UK. We thank to all Clinical Sites involved in this service for their availability.

8. PROMOTION
International Congresses
EURETINA 2015 - An EVICR.net Session will be organized in Nice, France, on Friday, September 18, 2015 from 14:30 to 16:00. We are counting on your presence.

EVICR.net website
The website is the best way to promote the Network and also to communicate with our members. It is kept updated by the Coordinating Centre frequently. As a member, your Centre has received a password to give access to “Members Only” restricted area. If you have any questions please send us an e-mail to evicrnet@aibili.pt.
Please visit our website at www.evicr.net and give us feedback.

9. PARTNERSHIPS AND COLLABORATIONS
EVICR.net is participating in the ECRIN - Integrating Activities project, specifically in the WorkPackage dedicated to Medical Devices.
The ECRIN is an ERIC - European Research Infrastructure Consortium. 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 formalise this affiliation.

EXPERT COMMITTEE MEETINGS PLANNED FOR 2015

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<tr>
<th>AMD and Retinal Dystrophies</th>
<th>DR and Retinal Vascular Diseases</th>
<th>Glaucoma</th>
<th>Anterior Segment</th>
<th>Reading Centres</th>
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<tr>
<td>Coordinator: Prof. J. Sahel (CS 6)</td>
<td>Coordinator: Prof. J. Cunha-Vaz (CS 1)</td>
<td>Coordinator: Prof. I. Stalmans (CS 18)</td>
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## CLINICAL TRIALS AND REGISTRIES

### Ongoing Studies

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(a) EU funded  
(b) Industry Grant

### On Publication Stage

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### Looking for Funding

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(a) Submitted application for H2020 funding