Clinical research in ophthalmology

Cecília Martinho, Daniel Fernandes and José Cunha-Vaz of the European Network of Clinical Research in Ophthalmology explain the importance of clinical research for eye care...

Ophthalmology is, presently, the second market after oncology with more investment in new drugs. Many ophthalmic drugs and solutions are being developed to respond to ophthalmic patient needs.

There is a clear need for clinical research and development of new drugs, solutions and treatments to improve eye care. Investigator-Driven Clinical Trials (IDCTs) are, usually, performed at a national level but not multinational as investigators need to assume responsibilities of the sponsor. EVICR.net coordinates clinical research in ophthalmology at European level and providing all the necessary support for IDCTs.

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 harmonised 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 optimise the use of diagnostic, prevention and treatment strategies in ophthalmology.

At present, EVICR.net has 97 clinical research centres members from 19 European countries. EVICR.net coordinating centre is located at AIBILI in Coimbra, Portugal.

EVICR.net is a platform for clinical research in ophthalmology and a useful Industry resource in the process of developing new drugs and medical devices in ophthalmology. Its main objective is to facilitate multinational IDCTs across the European Union. EVICR.net promotes all aspects of clinical research in ophthalmology following ICH GCP guidelines; coordi-

nates training activities for its members; promotes quality, transparency and optimal use of clinical research data and informs patients and citizens of the challenges and opportunities raised by clinical research community in ophthalmology.

Regarding its organisation, the Steering Committee is responsible for the activities of the EVICR.net and the coordinating centre, AIBILI, is the contact point for the members and industry when performing ophthalmological clinical research in Europe.

The Network has 5 expert committees that have a fundamental role in the scientific evaluation of EVICR.net studies and activities, covering the following main areas of research: age-related macular degeneration and retinal dystrophies; diabetic retinopathy and retinal vascular diseases; glaucoma; anterior segment; and reading centres. The Network has also 2 transversal sections that work together with the expert committees, when applicable: medical devices and rare diseases.

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 for coordination and implementation of the IDCT. EVICR.net members are invited to participate in IDCTs developed by the Network or in industry-sponsored studies.

The number of multinational IDCTs within the EVICR.net has been growing steadily in the last years. In 2014 EVICR.net had 12 ongoing multinational clinical research studies of which 3 are funded by the EU research programmes. These studies are in the following areas: 3 in age-related macular degeneration and retinal dystrophies, 6 in diabetic retinopathy and retinal vascular diseases, 2 in glaucoma and 1 in the anterior segment. Advantages of multinational clinical research coordinated by EVICR.net include: larger sample size and shorter recruitment periods and in full compliance with ICH-GCP guidelines which is guaranteed by the support of the coordinating centre.

EVICR.net has developed a Quality System for its members compliant with ICH-GCP guidelines with 9 Organisational SOPs. All EVICR.net clinical site members agree to adopt or adapt these SOPs in their centres which will be checked before they are certified as sites of excellence. The implementation of this system will give a common standard way of working when performing multinational 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 research. These SOPs are also made available to our members.

In parallel, EVICR.net has developed 22 organisational SOPs for the reading centres so they can work as a network of reading centres in order to be able to have the capacity to respond to the industry needs for grading ophthalmological images in a standardise way with the most novel equipment. EVICR.net with its coordinating centre at AIBILI provides the supporting services needed to develop and implement IDCTs compliant with ICH-GCP guidelines at a multinational level which investigators alone are not able to do on their own. This way EVICR.net contributes to the development and improvement of diagnostic, prevention and treatment strategies for better patient care. ■

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