The European Network for Clinical Research

EVICR.net – an important partner for drug development

COIMBRA - The EVICR.net (European Vision Institute Clinical Research Network) is a network of European ophthalmological clinical research sites, dedicated to perform clinical research with the highest standards of quality, following the European and international directives for clinical research according to harmonized Standard Operating Procedures (SOPs).

EVICR.net 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 be an industry resource in order to promote the development of new drugs and medical devices for the treatment of ophthalmic diseases.

EVICR.net is now an independent European Economic Interest Grouping (EEIG) in accordance with the Council Regulation (EEC) n.º 2137/85.

Each clinical trial site must apply to the network and fulfil basic requirements, namely have adequate infrastructure and equipment, qualified staff, experience in clinical trials, and agree to implement common organizational SOPs according to ICH GCP guidelines (International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use – guidelines for Good Clinical Practice).

Each clinical site in order to be a certified member of EVICR.net will be submitted to an on-site evaluation visit by independent auditors according to network procedures.

This network has an infrastructure for management of multicenter clinical trials located at AIBILI (Association for Innovation and Biomedical Research on Light and Image), Coimbra, Portugal.

Prof. Cunha-Vaz

Aims and objecives

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 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.

At present 70 centres in 16 European countries are members of EVICR.net, they are either certified already or in the process of certification.

Members per Country:

- Austria: Vienna (1)
- Belgium: Antwerp (1), Ghent (1), Leuven (1)
- Denmark: Glostrup (1)
- France: Amiens (1), Bordeaux (1), Clermond-Ferrand (1), Dijon (1), Paris (3), Toulouse (1)
- Germany: Aachen (1), Berlin (1), Bochum (1), Bonn (1), Düsseldorf (1), Frankfurt (1), Freiburg (1), Giessen (1), Hamburg (1), Heidelberg (1), Karlsruhe (1), Leipzig (1), Mainz (1), Mannheim (1), Munich (1), Tuebingen (1)
- Greece: Crete (1), Thessaloniki (1)
- Ireland: Dublin (1)
- Israel: Tel Aviv (1)
- Italy: Bari (1), Chieti (1), Milan (3), Monza (1), Padova (1), Parma (1), Rome (2), Udine (1)
- Poland: Poznan (1)
- Portugal: Coimbra (2), Lisbon (2), Porto (1)
- Slovenia: Ljubljana (1)
- Spain: Alicante (1), Barcelona (3), Girona (1), Santiago de Compostela (1), Valência (1), Valladolid (1)
- Switzerland: Bern (1), Lausanne (1)
- The Netherlands: Amsterdam (1), Nijmegen (1), Rotterdam (1)
- United Kingdom: Belfast (1), Celtenham (1), Liverpool (1), London (1), Solihull (1), Surrey (1)

Organization of EVICR.net

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 Management Structure is located at AIBILI, in Coimbra, Portugal.

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, diabetic retinopathy), glaucoma, cornea, cataract and refractive surgery, ocular surface and inflammation, reading centres.

Expert Committees

Each Expert Committee supervises a Scientific Section. Each Scientific Section will vote every three years for the coordinator which will be its representative of the Scientific Section in the Steering Committee.

Each clinical site will nominate one representative for each area of interest and expertise. This representative will be part of the chosen Scientific Section.

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 entities who have given support for the activities of EVICR.net. The EVICR.net is prepared to provide industry with a cohesive network of certified clinical centres with harmonized procedures (SOPs), quality control and qualified personnel. This offers an environment that will help achieving high recruitment rates. Furthermore the network may be also used by the industry for feasibility assessments and scientific advice on clinical trial design.

Partner in the process of drug development

This network of European clinical trial centres in ophthalmology was developed to become an important partner in the process of drug development in Europe. ■

Tue, 8 June 16.00 – 17.30 hrs

Session: Networking for clinical trial research in europe

Radio Tower Lounge 2

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Do you speak ocular tumour?

How using the 7th edition of the AJCC-UICC eye cancer staging system will save lives

NEW YORK – Standardised staging, multi-center cooperation and bio-informatics grids are important steps on a way for better patient care in ophthalmic oncology.

The AJCC-UICC Ophthalmic Oncology Task Force (OOTF) was composed of 45 eye cancer specialists from 11 countries (www.eyecancerbig.com/EyeCaBIG/The_AJCCUICC_Task_Force.html). [1-3] Over 5 years we worked together to create a universal eye cancer staging system. This was a joint effort of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC). In 2009, Springer published it as the AJCC, 7th edition staging system. The AJCC Manual is currently used as a standard by ophthalmic oncologists, pathologists, radiation oncologists, medical oncologists, pediatric oncologists, tumour registries and clinical cancer centers around the world. Already, 8 such collaborative multi-center studies will be presented at the World Ophthalmology Congress 2010 (WOC) in Berlin, Germany. Major ophthalmic journals, including the AJO, BJO, Archives, and OPRS have taken leadership roles in requiring its use in their instructions for authors. As part of the AJCC and UICC, it will also be employed by hundreds of professional organisations in over 103 countries and serves as a foundation for The Eye Cancer BIG (eyecancerbig.com) initiative.

Basic Concepts

1) What is made by the community will be used by the community.
2) An "ophthalmic oncology language" will allow us to compare outcomes.
3) Evidence-based medicine will be used to determine allocation of resources.
4) Bio-informatics can be used to improve and control eye cancer patient care.
5) There is power in numbers!

Do you speak our language?

Bio-informatics will change the way we practice medicine (e.g. cabig.nci.nih.gov). It will allow us to cope with the information explosion and subspecialisation that is moving medicine forward. Much less expensive than prospective-randomised clinical trials, bio-informatics grids (BIG) will allow researchers and clinicians to collect the massive amounts of information (data) needed to compare methods of diagnosis and treatment. It will allow statistically significant evidence-based conclusions and shed light on methods that do not work.

Bio-informatics grids link basic scientists, pathologists, epidemiologists and clinicians to determine evidence-based medical practices for common and rare diseases. However, it is rare diseases (e.g. eye cancer) where research funds are lacking and patients scarce that most need multi-center, multi-specialty cooperation. Lastly, consider that government-controlled health care systems increasingly require evidence-based proof to support diagnostic and therapeutic options.

There is power in numbers!

Multicenter collaborative studies will allow recruitment of large numbers of patients and/or clinical samples in shorter periods of time. They will avoid duplication of effort with lost resources and encourage cooperation among centers. Consider that singlecenter (even megacenter) studies are particularly vulnerable to selection bias, poor-quality data collection and analysis. Multicenter collaborative studies are more likely to be prospectively designed, higher quality and well funded. [4]

Example 1

What if in the year 2020, twenty ophthalmic oncology centers had been collecting standardised data from each and every patient encounter for 10 years. The best quality data was collected (derived from community designed electronic medical record [EMR entries). The best quality data, by an eye cancer specialist at the time of patient examination. What can be achieved?

References

1. Ophthalmic Sites. In Edge SB, Byrd DR, Compton CC, Fritz AG, Greene FL, Trotti A. Chapter 51: Malignant Melanoma of the Uvea. Ophthalmic Sites: Part X. The AJCC Cancer Staging Manual, 7th edition. New York, Springer 2009; 547-559.
2. FINGER PT; for the Members of the 7th Edition, AJCC-UICC Ophthalmic Oncology Task Force. The 7th edition AJCC staging system for eye cancer: An international language for ophthalmic oncology. Arch Pathol Lab Med 2009;133:1197-1198.
3. FINGER PT. Do you speak ocular tumor? Ophthalmology 2003;110(1):13-14.
4. HARBOUR JW. A transformation in ocular oncology. Arch Ophthalmol 2010;128(3):36-8.
5. DIENER-WEST M, REYNOLDS SM, AGUGLIARO DJ, et al. Development of metastatic disease after enrollment in the COMS trials for treatment of choroidal melanoma: Collaborative Ocular Melanoma Study Group Report No. 26. Arch Ophthalmol 2005;123:1639–1643.

1) 20,000 cases (a mean100 cases per year x 10 years x 20 centers = 20,000 cases). These would all be well described cases of choroidal melanoma, their diagnosis and treatment (with up to 10-year outcomes). By the year 2030, we could collect 40,000 cases and have 20,000 with a minimum follow up of 10 years. These numbers and data quality would be powerful and unparalleled. This data could be mined to compare methods of diagnosis and treatment.

Example 2

In treatment of metastatic choroidal melanoma, most patients in the USA are referred to a medical oncologist. They are offered no treatment, "standard chemotherapy," or inclusion in a research protocol. Lack of treatment typically offers 4-6 months of life, standard chemotherapy (still employed) often diminishes quality of life. Most failed research protocols are abandoned unpublished, only to be resurrected at another clinical center.

The largest published series of patients with metastatic choroidal melanoma is from the 16-year Collaborative Ocular Melanoma Study where 739 cases were described. However, this report contains no information about systemic performance scores, no mention of the number or size of metastatic tumours at diagnosis or results of treatment. [5] This number is just a fraction of the cases of metastatic choroidal melanoma found in the USA in one year.

Failure to collect the outcomes of patients treated for metastatic melanoma will doom our future patients to repetition of these failed treatments. In contrast, a BIG would record these treatments for collection, access and publication. It will make this information available to our patients for informed consent.

Summary

Standardised eye cancer staging is the foundation. It is time for ophthalmic oncology to evolve from megacenter to multi-center cooperation in the best interest of our patients. Bio-informatics offers the potential to improve our medical practice by determining evidence-based preferred diagnostic techniques and therapeutic options. This will not only help us shape the destiny of medical practice, it will save our patient's lives. ■

Tue, 8 June 16.00 – 17.30 hrs

Session: AJCC/UICC symposium: TNM based classification system for ocular oncology

Radio Tower Lounge 1

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