THE ROLE OF THE CROs IN OPHTHALMOLOGY DRUG DEVELOPMENT IN EUROPE

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✓ What is a Contract Research Organisation (CRO)?
✓ Why CROs are needed?
✓ What are the main activities outsourced to CROs by the Sponsor?
✓ What are the advantages of a CRO dedicated to ophthalmology in Europe?
✓ Clirophtha AppleTree
✓ What is our add value to the european investigational site?
What is a Contract Research Organisation (CRO)?
“A person or an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of the sponsor’s clinical trial-related duties and functions” (ICH E6 §1.20)
Why CROs are needed?
The complexity of a clinical trial

- Therapeutic expertise
- Interactions with the competent authorities division for the drug development strategy
- Strategic regulatory submission to the Competent Authorities and the Ethics Committees
- Medical writing
- Regulatory survey in each country
- Knowledge of the routine practice
- Discussion with the leading-opinion leaders
- Selection of the investigators
- Management of the clinical sites
- Evaluation of the subjects recruitment
- Evaluation of the risks
- Anticipating the obstacles
- Respect of the deadlines
The Sponsor has two objectives

Minimize the risks

&

Optimize the drug development
The CRO is the key link in a clinical study because
The role of the CROs in ophthalmology drug development in Europe

- Competent authorities
- Sponsor
- Investigators
  - Study nurse
- Academic & Private Institutions
- Ethics committees
- Data protection
- Other specific authorities
- Sub-contractors
What are the main activities outsourced to CROs by the Sponsor?
Consulting on drug development (risk evaluation)
Feasibility of the Study
Regulatory submission to the competent authorities (CA) & the Ethics committees (EC)
Review of the Investigational Medicinal Product Dossier (IMPD)
Selection of the investigators
✓ Management of the monitoring activities
✓ Management of fees for investigators and hospitals
✓ Audits of the clinical sites
✓ Data management & Statistics
✓ Medical writing
What are the advantages of a CRO dedicated to ophthalmology in Europe?
Privileged European network of leading opinion investigators in ophthalmology

Partnership with the European Vision Institute

Partnership with European academic universities

Knowledge of the European routine practice in ophthalmology

Impact on the drug development timeline by accelerating the process of recruiting and enrolling patients in Europe

Privileged relationship with the European CA in charge of the ophthalmology subspecialty

Specific medical writing in ophthalmology for the study design, the protocol and the clinical report

Pragmatic approach of the European management of the clinical trials in ophthalmology
CLIROPHTHA & APPLETREE are two European CROs specialized in ophthalmology.

Member of:
AFCROs
EUCROF
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<td>Nb of studies</td>
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<td>Nb of subjects/patients</td>
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<td>Nb of clinical sites</td>
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The role of the CROs in ophthalmology drug development in Europe

March 30, 2006
Distribution by therapeutic area (in %)

- Glaucoma: 42%
- Dry eye: 23%
- Infection: 17%
- Inflammation: 4%
- Others (ARMD...): 14%

March 30, 2006

The role of the CROs in ophthalmology drug development in Europe
What is our add value to the European investigational site?
Qualified personnel in ophthalmology

Adaptability to the Good Clinical Practice (GCP)
using our specific overview and knowledge of the
ophthalmology routine practice

**Best credibility and adapted actions related to the management of the clinical trial**
Dedicated CROs to ophthalmology

Pharmaceutical Companies

Ophthalmologists

Same Language

Common view of the Clinical trials
In partnership with the European Vision Institute, we support the investigational clinical sites which decide to obtain the EVI.CT.SE certification.
Clinical site

- A team
- Specific medical practices
- A specific environment
- A philosophy
Evaluation visit of the clinical sites according to EVI.CT SE requirements.

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Homogenisation of the work
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Clinical site

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A philosophy

Homogenisation of the work

Follow-up and recommendations
Evaluation visit of the clinical sites according to EVI.CT SE requirements.

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Increase in Quality

Homogenisation of the work

Follow-up and recommendations

Certification Site of excellence

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Site of excellence

Follow-up and recommendations

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