THE ROLE OF THE CROs IN OPHTHALMOLOGY DRUG DEVELOPMENT IN EUROPE

P-P. Elena, N. Clerget
CLIROPHTHA, La Gaude, France
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 trial-related duties and functions” (ICH E6 §1.20)
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
Two objectives

Minimize the risks &

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

- Competent authorities
- Sponsor
- Investigators
- Study nurse
- Ethics committees
- Data protection
- Other specific authorities
- Sub-contractors
- Academic & Private Institutions
Main activities outsourced by the pharmaceutical, medical devices & biotechnology companies (1/2)

- 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.
CLIROPHTHA & APPLETREE
TWO CROs SPECIALISED IN
OPHTHALMOLOGY
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<th>CLIROPHTHA</th>
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<tbody>
<tr>
<td>Foundation</td>
<td>1994</td>
<td>2003</td>
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<tr>
<td>Location</td>
<td>France</td>
<td>Switzerland</td>
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<tr>
<td>Area of work</td>
<td>Europe, North Africa</td>
<td>German speaking Europe, UK, USA, Central and Eastern Europe, Greece, Turkey</td>
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<tr>
<td>Nb of studies</td>
<td>67</td>
<td>11</td>
</tr>
<tr>
<td>Nb of subjects/patients</td>
<td>8,978</td>
<td>1,123</td>
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<tr>
<td>Nb of clinical sites</td>
<td>1,315</td>
<td>96</td>
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Distribution of Clirophtha studies by therapeutic area (in %)

- Glaucoma: 42%
- Dry eye: 23%
- Infection: 17%
- Inflammation: 4%
- Others (ARMD...): 14%
- Others: 23%
Advantages of a CRO dedicated to ophthalmology (1/2)

- Privileged network of leading opinion investigators in ophthalmology.
- Partnership with the European Vision Institute.
- Partnership with academic University.
- Knowledge of the routine practice in ophthalmology.
- Impact on the drug development timeline by accelerating the process of recruiting and enrolling patients.

⇒ Pragmatic approach of the management of the clinical trials in ophthalmology
Following (2/2)

- Privileged relationship with the CA in charge of the ophthalmology subspecialty.
- Specific medical writing in ophthalmology for the study design, the protocol and the clinical report.

⇒ Improvement of our expertise via innovative and dedicated solutions to each clinical trial
Our add value to the investigational clinical site (1/4)

✓ 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.
Evaluation visit of the clinical sites according to EVI.CT SE requirements.

Clinical site
- A team
- Specific medical practices
- A specific environment
- A philosophy

Homogenisation of the work

Follow-up and recommendations

Certification Site of excellence

Quality

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The role of the CROs in ophthalmology drug development in Europe
Pierre-Paul ELENA
www.clirophtha.com
info@clirophtha.com

www.appletree-ag.com
Info@appletree-ag.ch