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

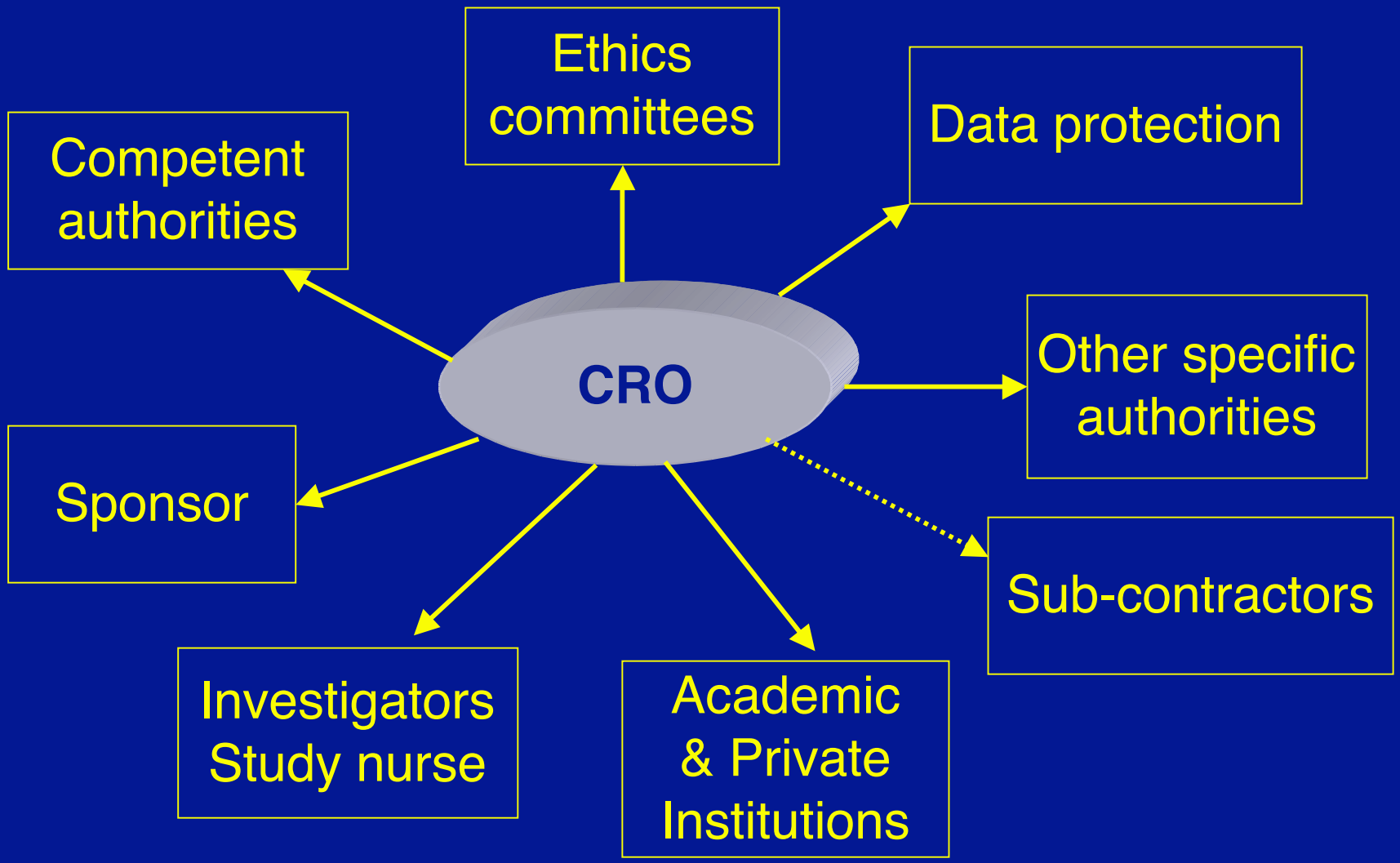
Two objectives

Minimize the risks

&

Optimize the drug development

The CRO is the key link in a clinical study


Ethics committees
Competent authorities
Data protection
CRO
Other specific authorities
Sponsor
Sub-contractors
Investigators Study nurse
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.

Following (2/2)

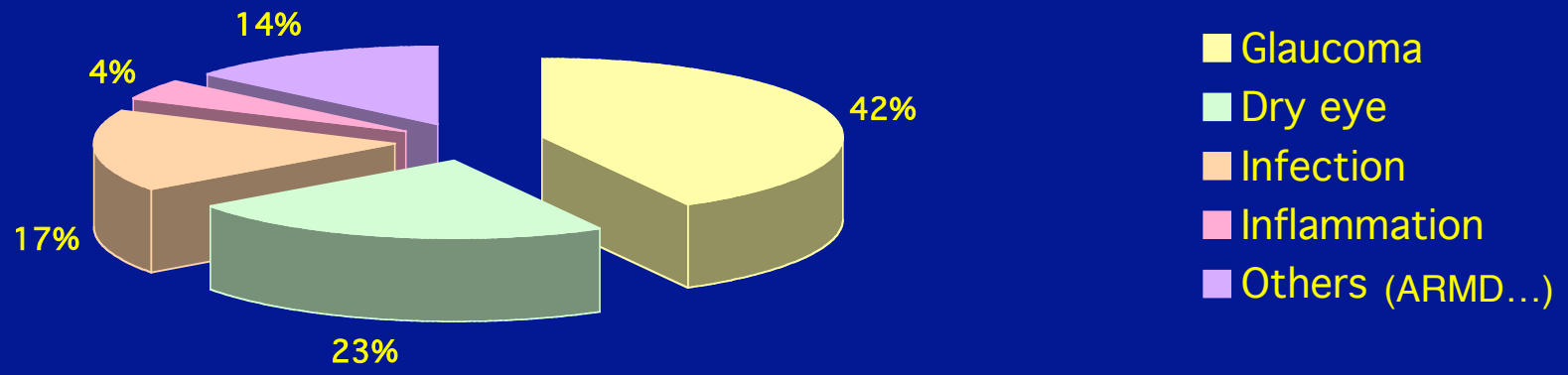
- ✓ Management of the monitoring activities.
- ✓ Management of fees for investigators and hospitals.
- ✓ Audits of the clinical sites.
- ✓ Data management & Statistics.
- ✓ Medical writing.

CLIROPHTHA & APPLETREE TWO CROs SPECIALISED IN OPHTHALMOLOGY

	CLIROPHTHA	APPLETREE
Foundation	1994	2003
Location	France	Switzerland
Area of work	Europe North Africa	German speaking Europe, UK, USA , Central and Eastern Europe, Greece, Turkey

	CLIROPHTHA	APPLETREE
Nb of studies	67	11
Nb of subjects/patients	8 978	1 123
Nb of clinical sites	1 315	96

Distribution of Clirophtha studies by therapeutic area (in %)



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)

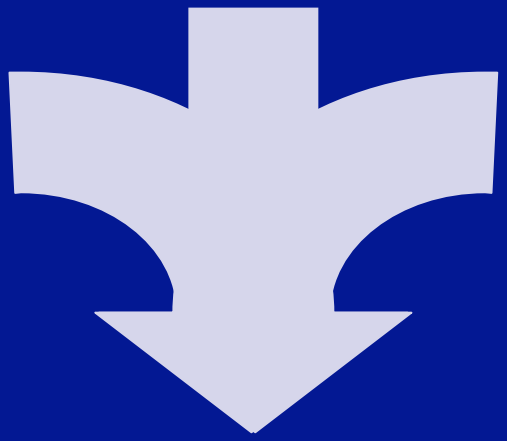
- ✓ Qualified personnel in ophthalmology.
- ✓ Adaptability to the Good Clinical Practice (GCP) using our specific overview and knowledge of the ophthalmology routine practice

⇨ **Best credibility and adapted actions related to the management of the clinical trial**

Following (2/4)

Dedicated CROs to ophthalmology

Pharmaceutical Companies



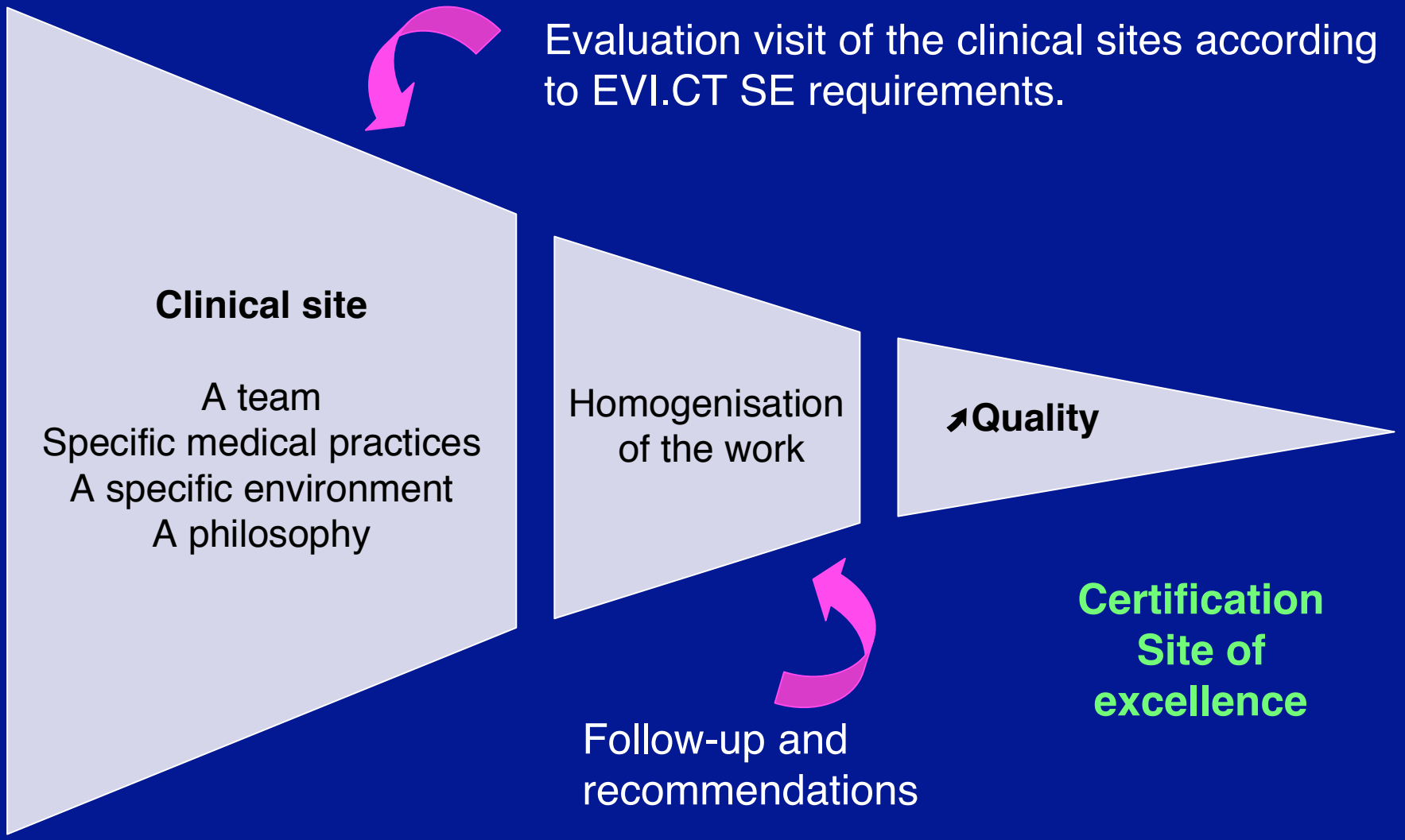
Ophthalmologists

Same Language
Common view of the Clinical trials

Following (3/4)

In partnership with the European Vision Institute, we support the investigational clinical sites which decide to obtain the EVI.CT.SE certification.

Following (4/4)



Pierre-Paul ELENA

www.clirophtha.com

info@clirophtha.com

www.appletree-ag.com

Info@appletree-ag.ch