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)?
- ✓ 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

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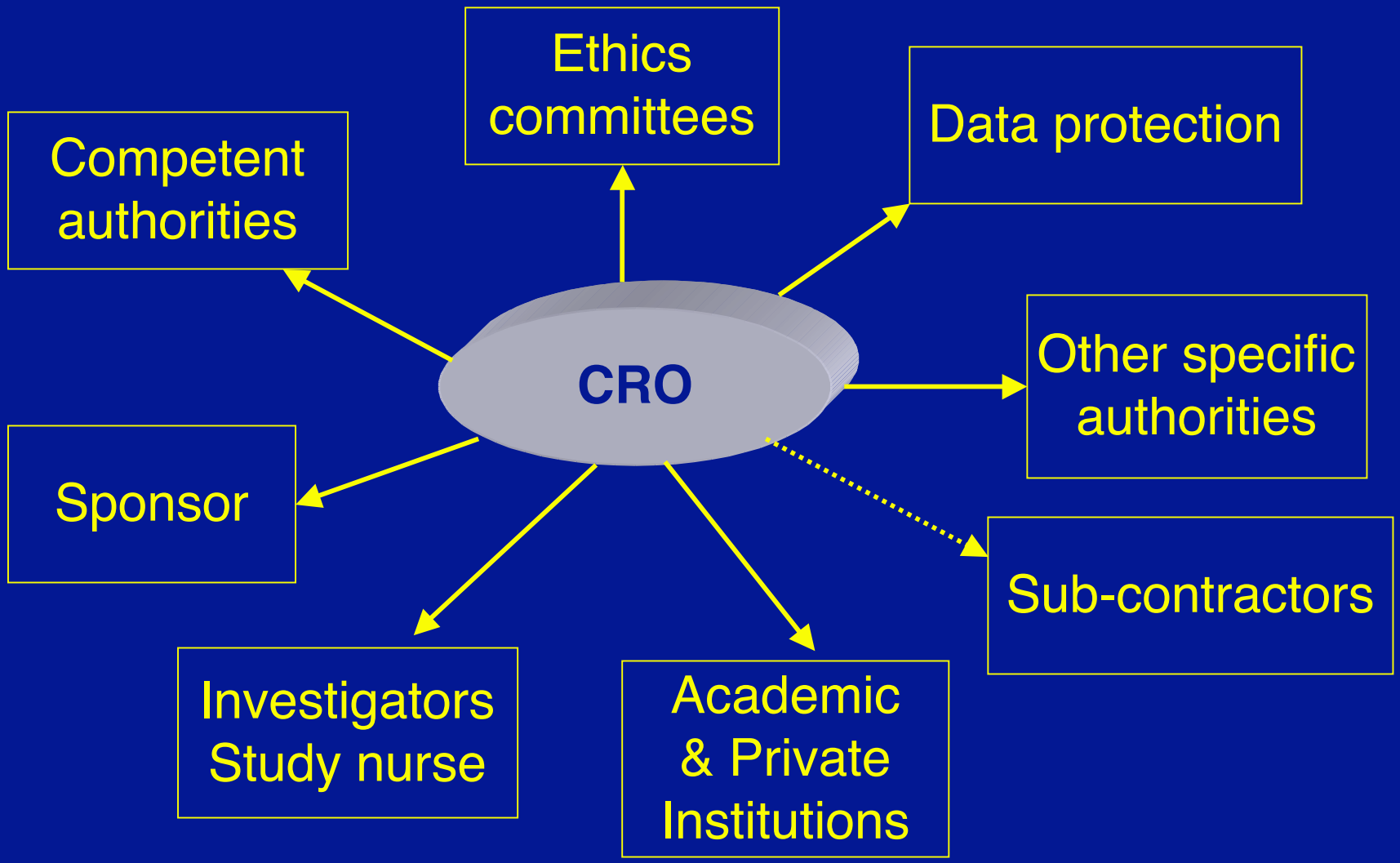
Optimize the drug development

The CRO is the key link in a clinical study because


Ethics committees
Competent authorities
Data protection
CRO
Other specific authorities
Sponsor
Sub-contractors
Investigators Study nurse
Academic & Private Institutions

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

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- ✓ 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**

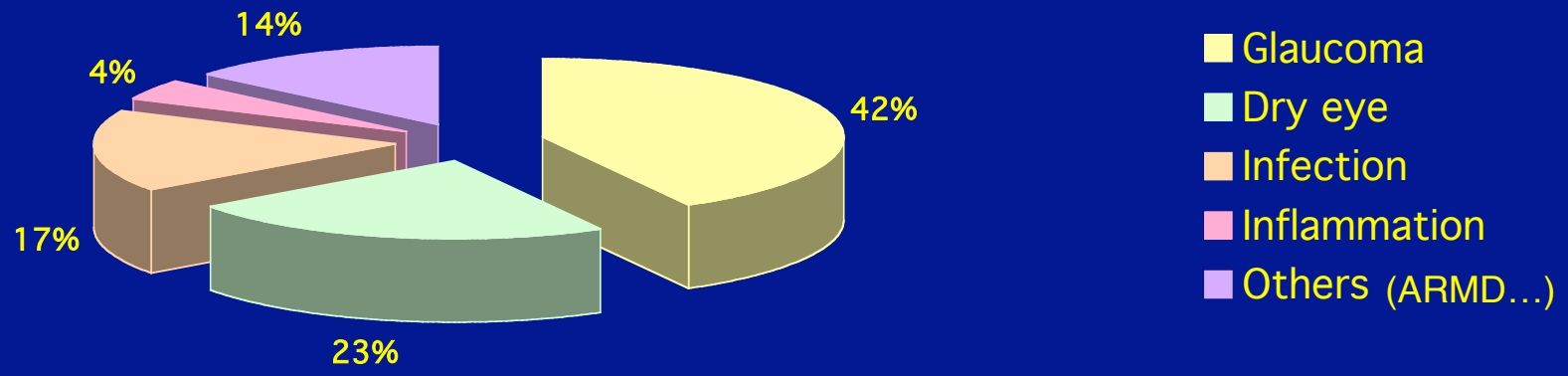
CLIROPHTHA & APPLETREE are two european CROs specialized in ophthalmology

Member of:
AFCROs
EUCROF

	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 by therapeutic area (in %)



What is our add value to the european investigational site ?

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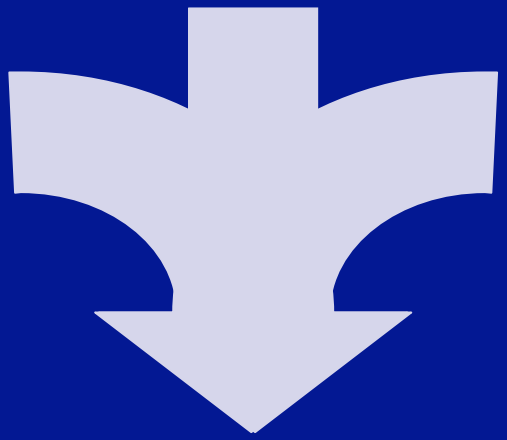
- ✓ Qualified personnel in ophthalmology
- ✓ Adaptability to the Good Clinical Practice (GCP) using our specific overview and knowledge of the ophthalmology routine practice

⇨ **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

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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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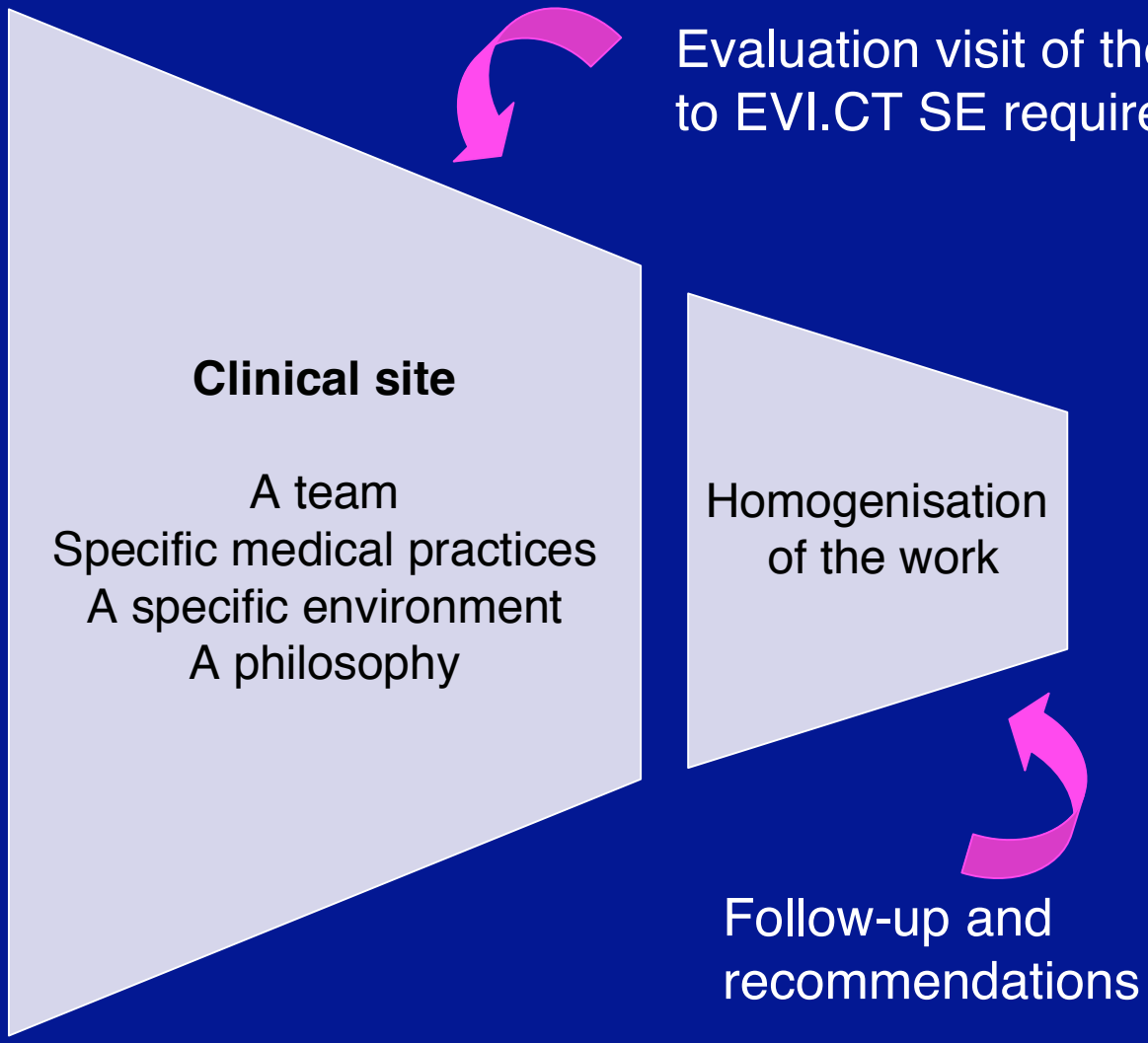
Homogenisation of the work

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



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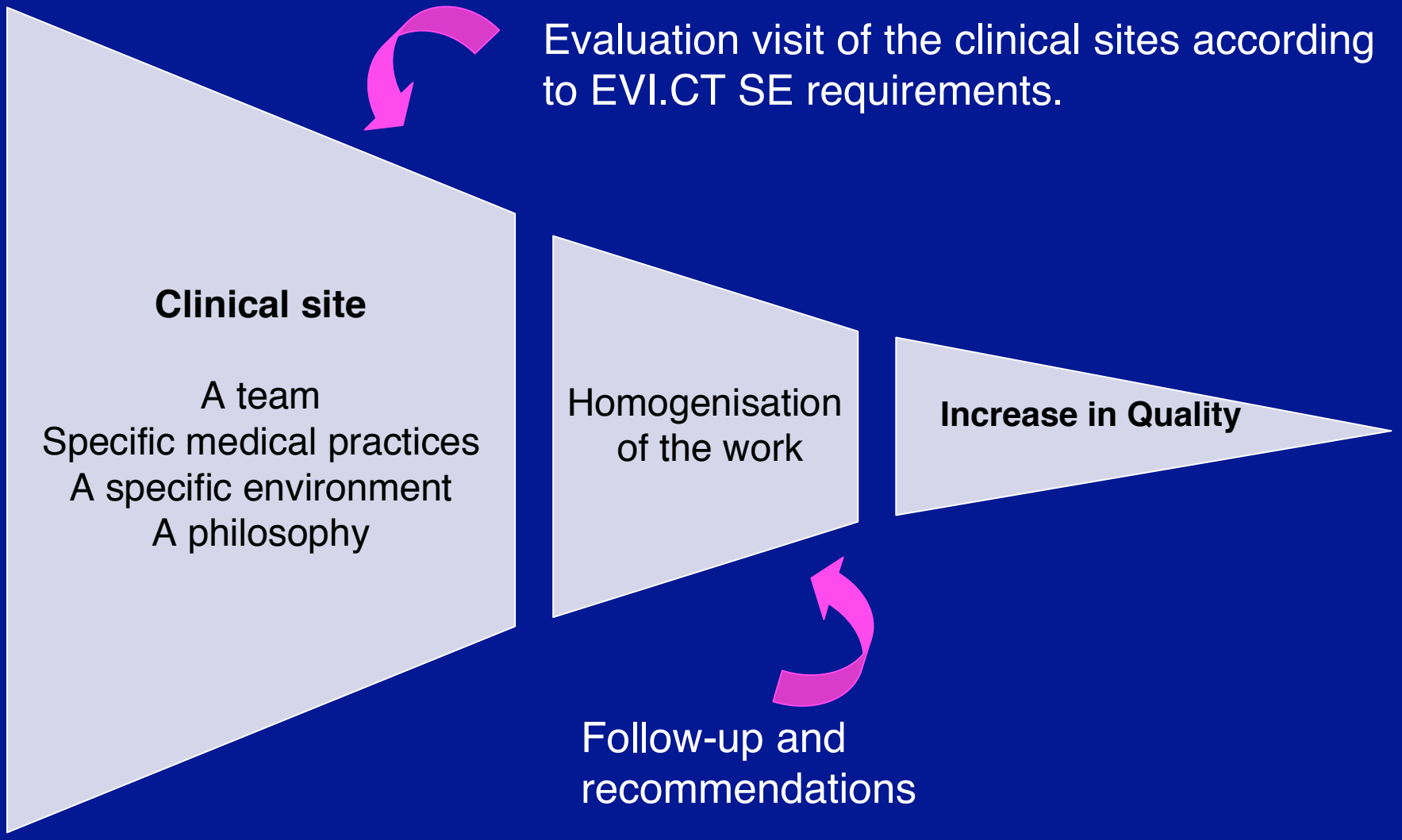

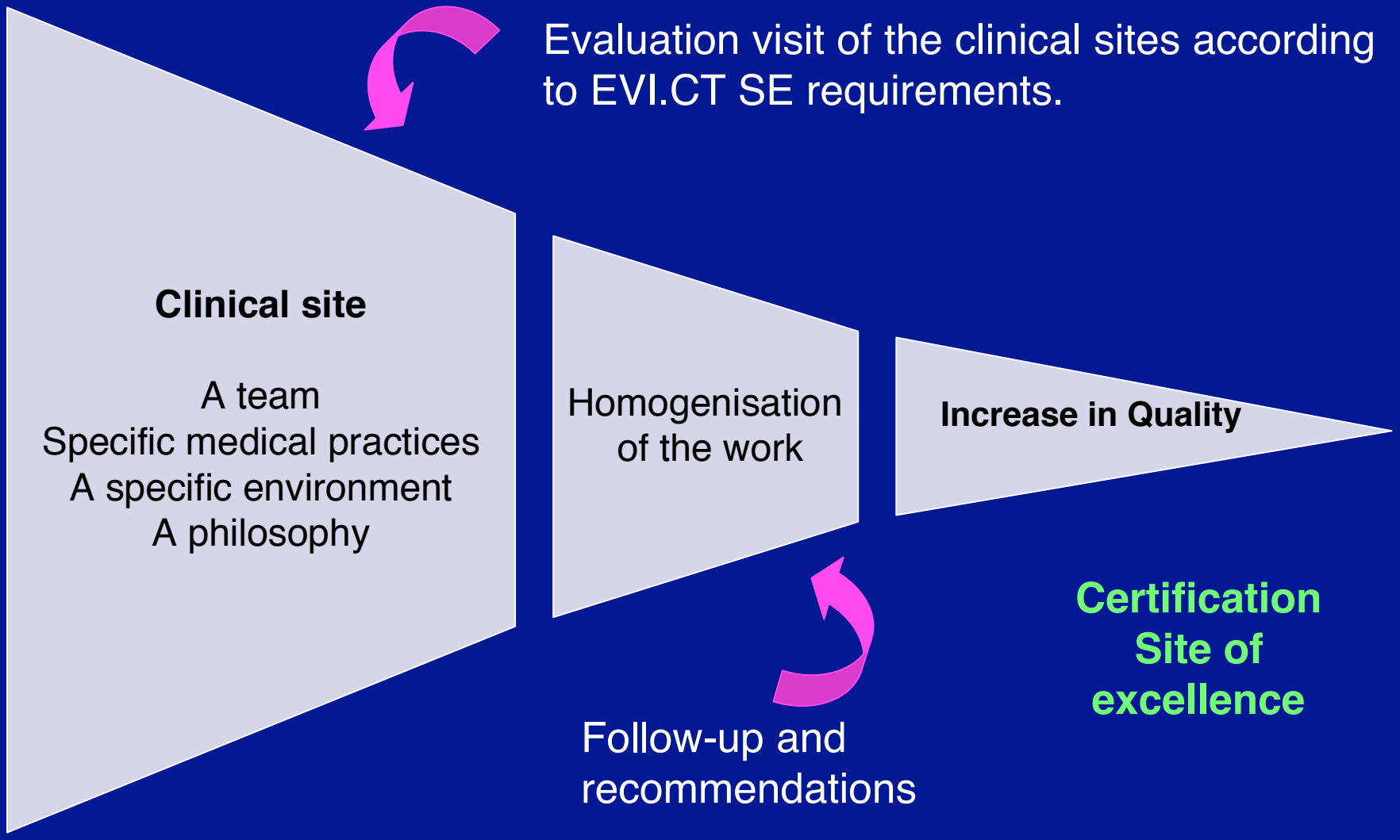
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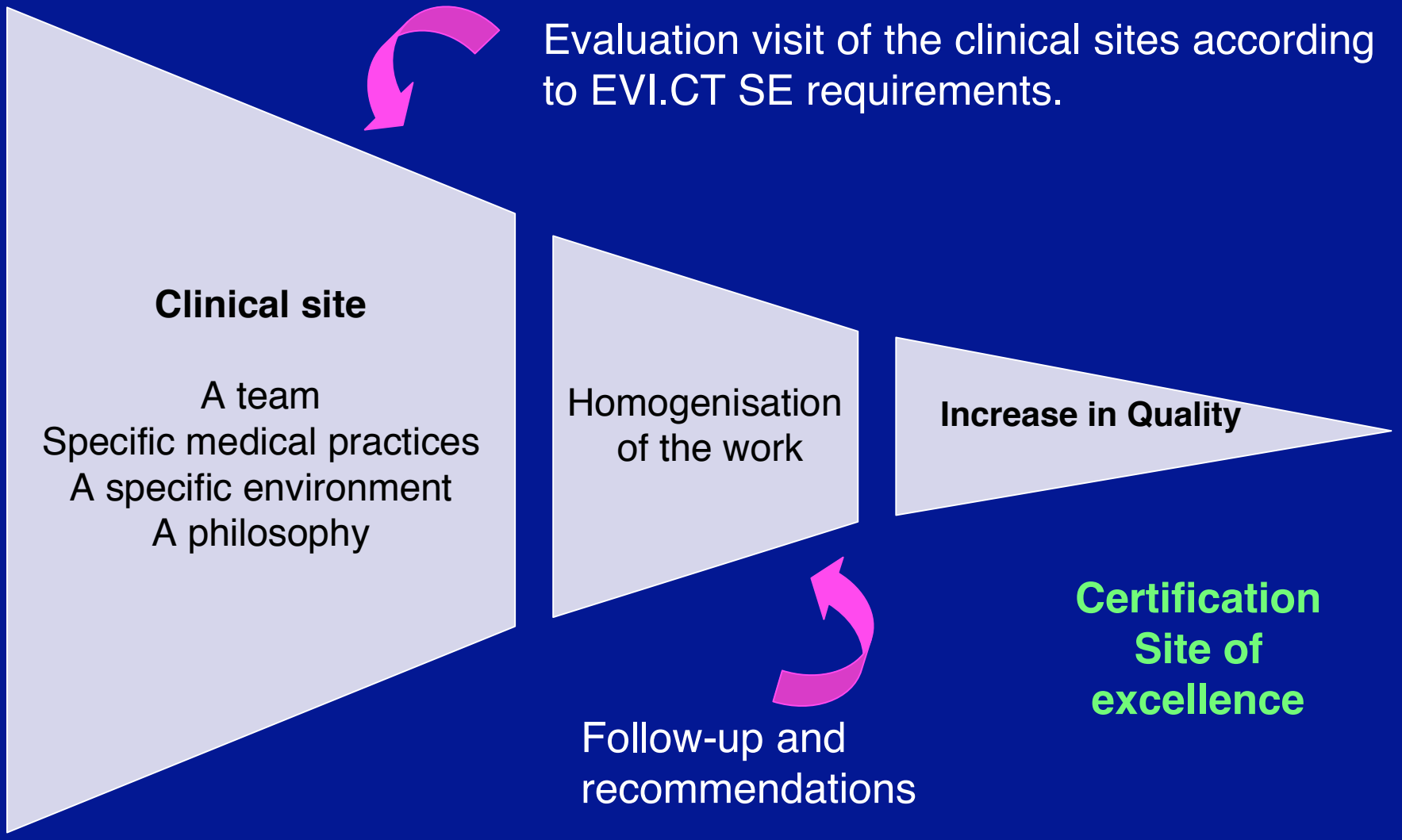
A philosophy
Homogenisation of the work
Increase in Quality
Certification Site of excellence
Follow-up and recommendations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Pierre-Paul ELENA

www.clirophtha.com

info@clirophtha.com

www.appletree-ag.com

Info@appletree-ag.ch