EUCROF
European CRO Federation

ENCePP Plenary Meeting
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EUCROF expectations
for the revision of Code of Conduct

Dr. Xavier Fournie

Co-Chair PV Working Group, EUCROF

Dr. Giovanni Fiori

Chair Late Phase Working Group, EUCROF

EUCROF - Mission

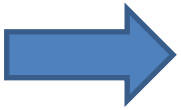
- EUCROF is a
  - **Non-profit** organization
  - Founded in **2005**
  - Representing the interests of **350+** CROs in **23** Countries, and **25.000+** Employees in Europe
  - Towards:
    - Regulatory bodies
    - Pharmaceutical, biotech, medical device industry
    - Healthcare related industry within the field of clinical research
    - Patients associations
- EUCROF's goal is to promote Good Clinical Research by improving the knowledge, competence and skills of member CROs

EUCROF – 10 Working Groups

Working Group	Chair / Co-Chair
Clinical Trials Legislation	Dagmar Chase
Communication	Christophe Golenvaux
Education and Training	Antoinette van DIJK
Innovative Medicines	Astrid Pañeda Rodriguez
Late Phase	Giovanni Fiori
Medical Devices	Ayse Burcu Cehreli
New Technologies	Yoani Matsakis/Alan Yeomans
Paediatrics	Martine Dehlinger-Kremer/ Alex Cvetkovic Muntañola
Pharmacovigilance	Nicolas Tsiakkas / Xavier Fournie
Early Phase	Simon Hutchings

EUCROF expectations for CoC

- Most of NI-PAS funded by Industry are subcontracted to CROs, especially studies based on prospective primary data collection
- Several CROs are registered as Research Centres in ENCePP network; some of them are active members of ENCePP WGs
- CROs are involved and provide expertise in all phases of PAS:
  - protocol design; site recruitment/set-up; monitoring and data management; data analysis; study report; PV; publications, etc.
- CRO insight is frequently solicited by Industry for PAS: they are playing a paramount role in the actual adoption, dissemination and operationalization of Code of Conduct and other ENCePP guidelines/principles, especially towards non-EU study sponsors.



As an essential stakeholder, CROs voice and vision should legitimately be considered

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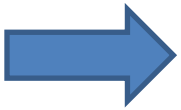
EUCROF perspectives on CoC

- Where CROs are sitting in the current Code of Conduct?
- Having no interest in study outcomes, CROs should be considered a trustworthy third party, acting to reinforce independency/transparency of the studies
- They should play a valuable role of interface between Principal Investigator and Industry staff, especially after protocol development
- As a consequence, the forthcoming revision of the Code of Conduct should include clarifications about the positioning of CROs



EUCROF (through their LP and PV WGs) will provide consolidated review and suggestions for the revision of CoC

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Thank you for your Attention