

Clinical Trials Symposium

11 October 2019, Bucharest

“EUCROF, the European CRO Federation ”

Dr. Martine Dehlinger-Kremer
President, EUCROF

EUCROF - Mission

- EUCROF is a legal non-profit entity representing the interests of CROs 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 Clinical Research by improving the knowledge, competence and skills of CROs

EUCROF – A Representative Organisation at European Level

- Non-profit organisation founded on 2005
- Members & Associate Mbs: legal entities registered in Europe
- Partners: legal entities registered outside Europe

MEMBERS : National Associations

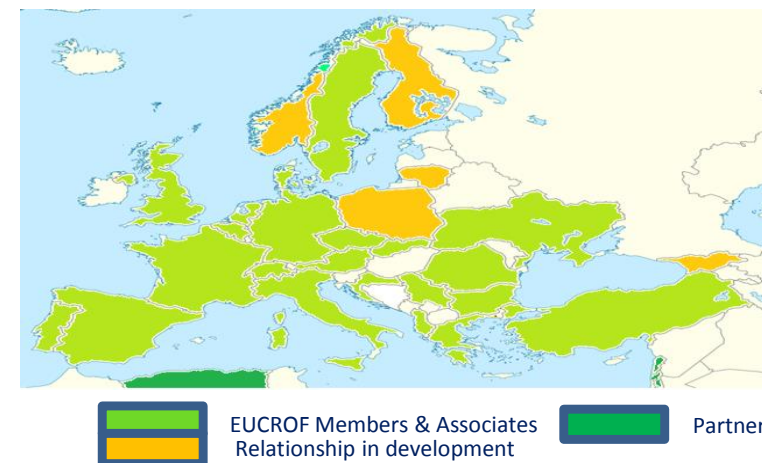
1. ACCSCR	Romania	12
2. ACRO-CZ	Czech Republic	19
3. ACRON	The Netherlands	45
4. AECIC	Spain	22
5. AFCROs	France	82
6. AICRO	Italy	24
7. BeCRO	Belgium	30
8. BVMA	Germany	41
8. CCRA	United Kingdom	31
10. HACRO	Greece	13
11. SAKDER	Turkey	24
12. SACROP	Slovakia	18

Associate Members

1. Albania
2. Austria
3. Bulgaria
4. Croatia
5. Denmark
6. Portugal
7. Serbia
8. Spain
9. Sweden
10. Switzerland
11. Ukraine
12. United Kingdom (2)

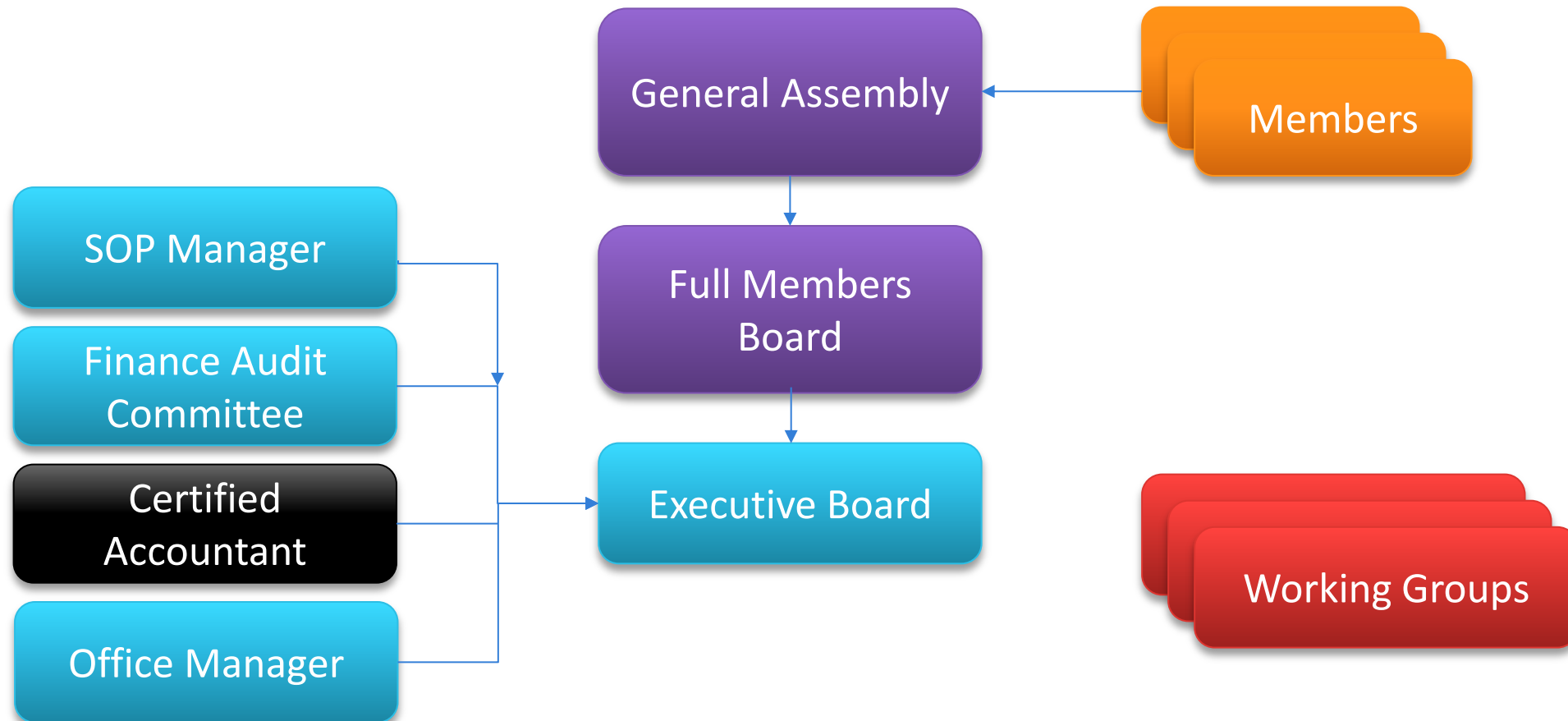
Partner Members

1. Algeria
2. Israel
3. Lebanon



- > 360 CROs
- > 25,000 employees
- 25 Countries
- > 300 CROs are SMEs

EUCROF – Organisation Structure



EUCROF – Organisation Process

Executive Board

- Elected, 2 years mandate
- Monthly meetings
- Proposes Policy / Coordinates / Day to day management
- 1 x half time permanent office manager
- Subcontracted accounting office

Full Member Board

- Every Member/Ass Mb/Partner Represented
- Decision Making – Votes (members only)
- Monthly meetings

General Assembly

- Decision Making - Votes
- Bi-annual meetings

Finance Audit Committee

Working Groups



President
Martine DEHLINGER-KREMER



Vice-President
Stefano MARINI



Secretary
Simon LEE



Treasurer
Yoanni Th. MATSAKIS



Member
Christophe GOLENVAUX

Ongoing Initiatives and some of recent Accomplishments (1/2)

- Participation to EMA Stakeholder Meetings and EMA Initiatives
 - EU Clinical Trial Information System (CTIS, previously Portal and Union Database)
 - Enpr-EMA, European Network of Paediatric Research
 - Pharmacovigilance
 - Telematic Group
 - GCP Inspection Working Group
 - EMA Regulatory Science to 2025 Strategy
- Collaboration with EMA
 - Member of ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) WG2, since February 2018: Representative is Xavier Fournie
 - Observer Member of Coordinating Group of Enpr-EMA (European Network of Paediatric Research) since April 2018: Representative is Martine Dehlinger-Kremer
- Collaborations with further stakeholders
 - DIA PV expert group - member of program committee of the 2019 European Forum for Qualified Persons in Pharmacovigilance (QPPVs)
 - EFPIA and LEEM - GDPR CoC
 - Association of CROs (ACRO) and Japanese CRO Association (JCROA)
- EU Clinical Trial Regulation No 536/2014
 - User Acceptance Testing off site & on site at EMA (started with 50 testers)
 - Product Owner and Back-up in the New Delivery System (0.25 FTE for Product Owner)

Ongoing Initiatives and some of recent Accomplishments(2/2)

- **GDPR - Establishment of a Code of Conduct for CROs**
 - CNIL is the supporting Data Protection Authority
 - Collaboration with Industry (EFPIA & LEEM), Patient Organisations, Ethics Committees
- **Publications**
 - “Pharmacovigilance (PV) in 2020: Boldly Shaping the Future” -Part I and II in Applied Clinical Trials in 2018
 - “Artificial Intelligence (AI) in Pharmacovigilance: do we really need it...?": to be published in DIA Journal soon
 - Article “Alternative approaches to generate clinical evidence for the paediatric population”, soon in European Journal Paediatric Research
- **Webinars & Trainings 2019**
 - 6 Webinars: 2 on GDPR, RBM, Statistics, Validation of Computerized Systems in GCP environment, Patients’ Centricity
 - F2F Training on “Successfully conducting paediatric clinical trials”, Madrid, 24 October 2019
- **Attendance at International Events**
 - 2018, 26 events: Presentations at 15 international conferences & Attendance of 11 stakeholders' meetings at EMA
 - 2019, 15 events: Presentations at 11 international conferences & Attendance of 4 stakeholders' meetings at EMA
- **European Conference on Clinical Research**
 - Organised every two years: 2020 in Amsterdam, 2022 in Madrid

EUCROF - Working Groups

Working Group	Chair / Co-Chair
Clinical Trials Legislation	Dagmar Chase
Communication	Christophe Golenvaux
Early Phase	Harry Therianos
Events and Training	Donato Bonifazi
Innovative Medicines	Dolores Pérez Méndez
Late Phase	Georgina Nock
Medical Devices	Ayse Burcu Cehreli
New Technologies	Alan Yeomans / Yoani Matsakis
Outsourcing Management	TBN
Paediatrics	Martine Dehlinger-Kremer
Patients' Associations	Hervé Servy
Pharmacovigilance	Nicolas Tsiakkas

EUCROF Conference

10 – 11. Feb 2020, Amsterdam, NL

EUCROF
European CRO Federation
15TH ANNIVERSARY
OF EUCROF

acron
25TH ANNIVERSARY
OF ACRON

BeCRO
10TH ANNIVERSARY
OF BeCRO



**Join us for
the 5th EUROPEAN CONFERENCE
ON CLINICAL RESEARCH
Amsterdam, the Netherlands
Spring 2020**

To show your interest in joining or for any questions please contact us at info@eucrof.eu



I am looking forward to
seeing you at the conference in Amsterdam!

www.eucrof-conference.eu



Thank You for Your Attention