EUCROF
European CRO Federation

POLCRO – EUCROF Meeting

19th May 2014
Warsaw

Dr. Stefano Marini, MD
EUCROF President European Contract Research Organization Federation
Medical Scientific Advisor to TFS Trial Form Support

Topics

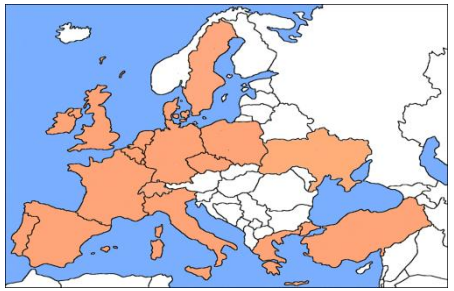
- **EUCROF Members**

- **Accomplishments**
  - Administrative
  - Visibility
  - Education
  - Communication
  - Internal / external / internal + external
  - Working Groups

- **Outlook**

EUCROF Members

- EUCROF is a non-profit organisation founded on 2005
- Member are legal entities registered in at least one European Country:
  - Associations of CROs, or
  - Private companies working in Clinical Research Services



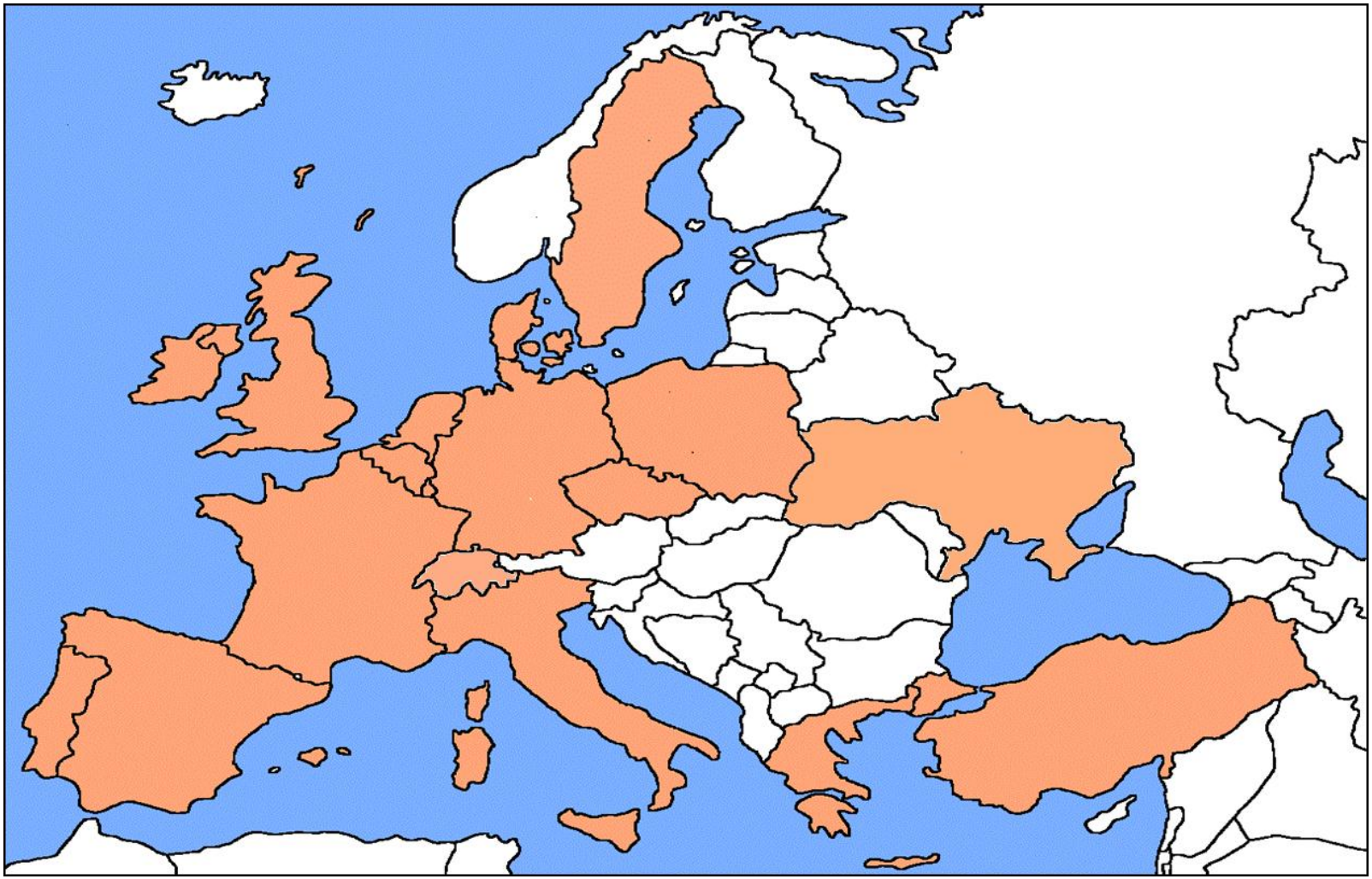
National Association	Country	No. CROs
1. ACRO-CZ	Czech Republic	18
2. ACRON	The Netherlands	40
3. AECIC	Spain	30
4. AFCROS	France	48
5. AICRO	Italy	13
6. ASCRO	Sweden	7
7. BeCRO	Belgium	29
8. BVMA	Germany	39
9. CCRA	United Kingdom	36
10. HACRO	Greece	10
11. SAKDER	Turkey	26

Local CROs

1. Portugal
2. Poland
3. Ireland
4. Denmark
5. Switzerland
6. Ukraine

TOTAL: 293 Companies, 17 Countries , over 16.000 employees

EUCROF Members
Geographic Presence May - 2014



EUCROF Members
Potential Full Members to Come

- **Poland:**

the Polish

Association has been founded in Q3 2012

- **POLCRO**

- **Ireland:**

the Irish

Association to be founded soon

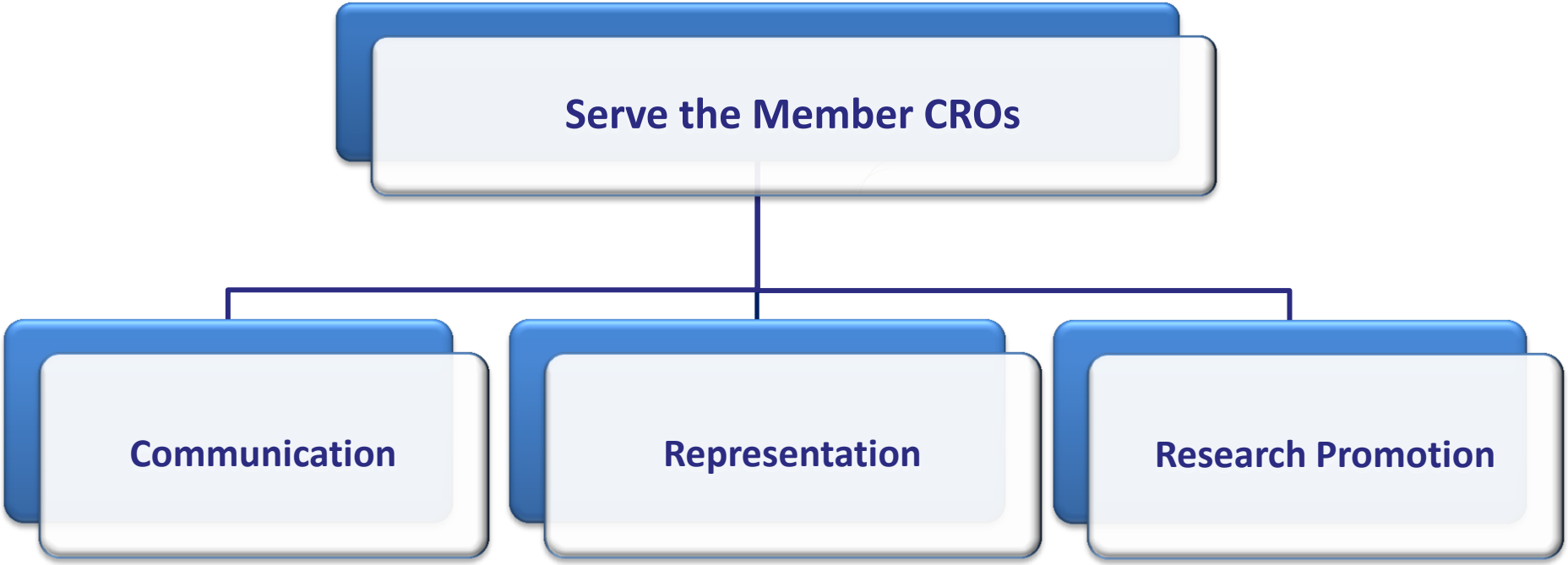
- **CRPI**

Objectives

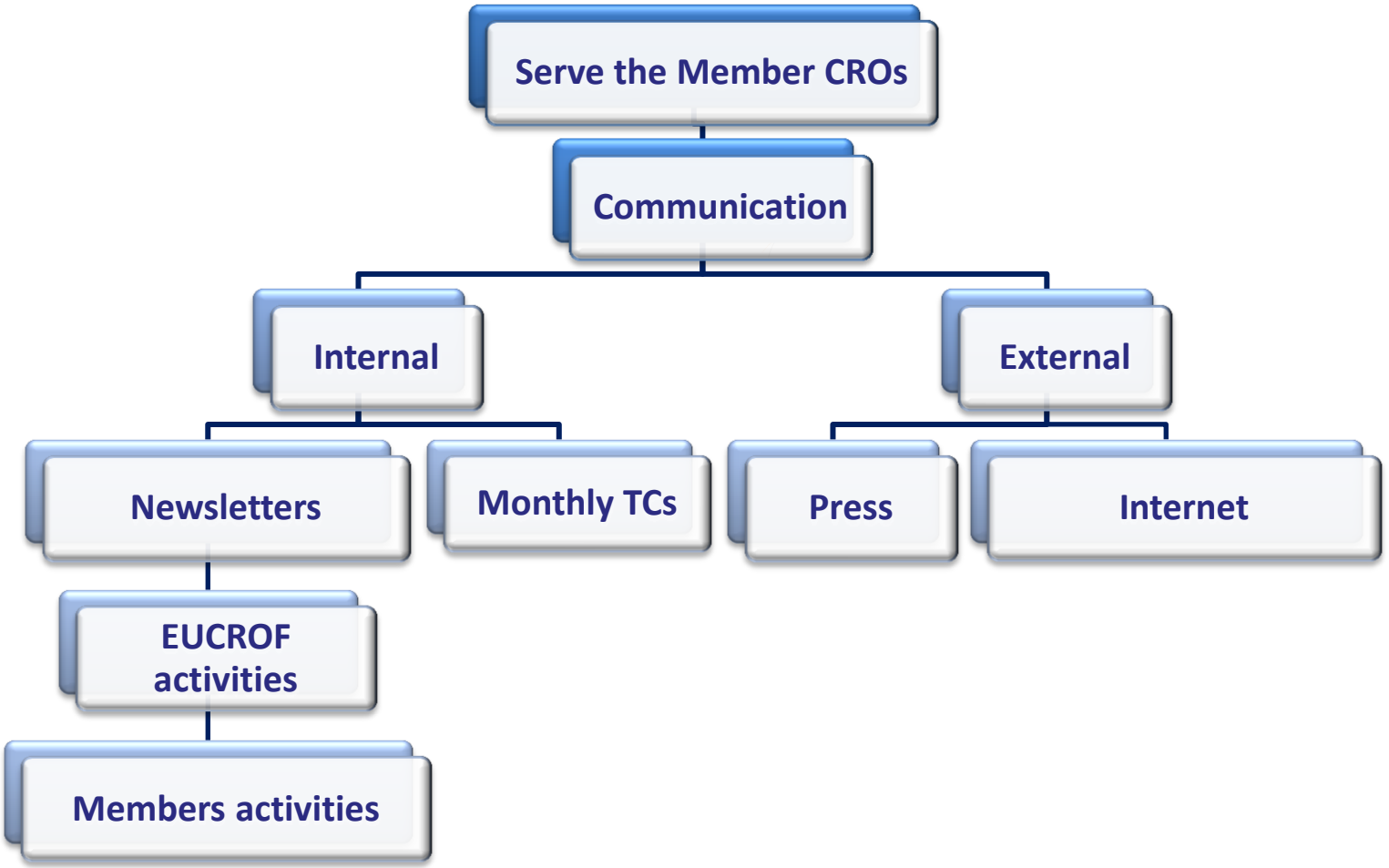
- Promote the **quality of clinical research**;
- **Promote outsourcing to CROs attitude** by improving knowledge, competence/expertise and skills of professionals within CROs in Europe;
- **Represent and support CROs** towards Regulatory Bodies, pharmaceutical, biotech, medical device and other healthcare related industry as well as medical, patients and affiliated research community, within the field of clinical research;
- Exchange relevant information and **networking between Members**;
- **Extend CRO representation** to all European territory.

EUCROF is a non-profit organisation.

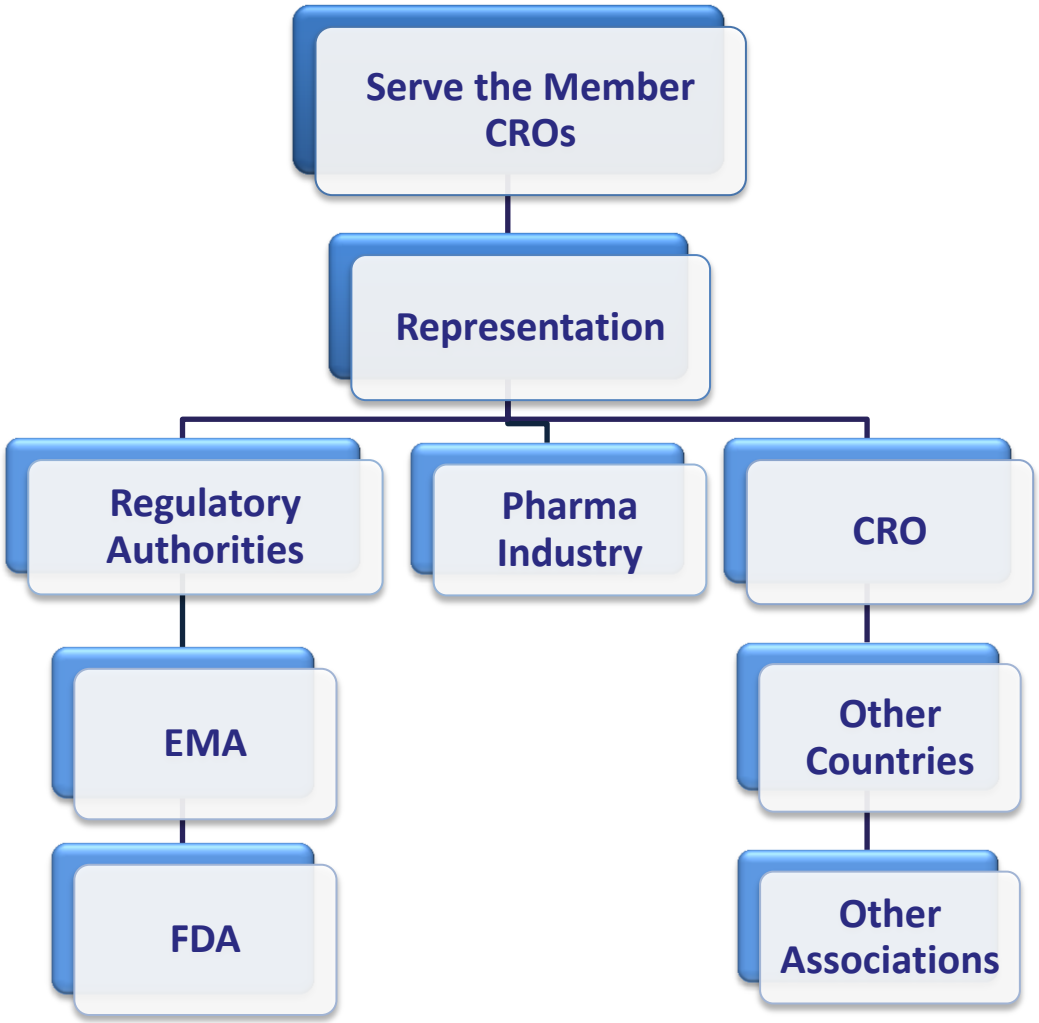
EUCROF Objectives



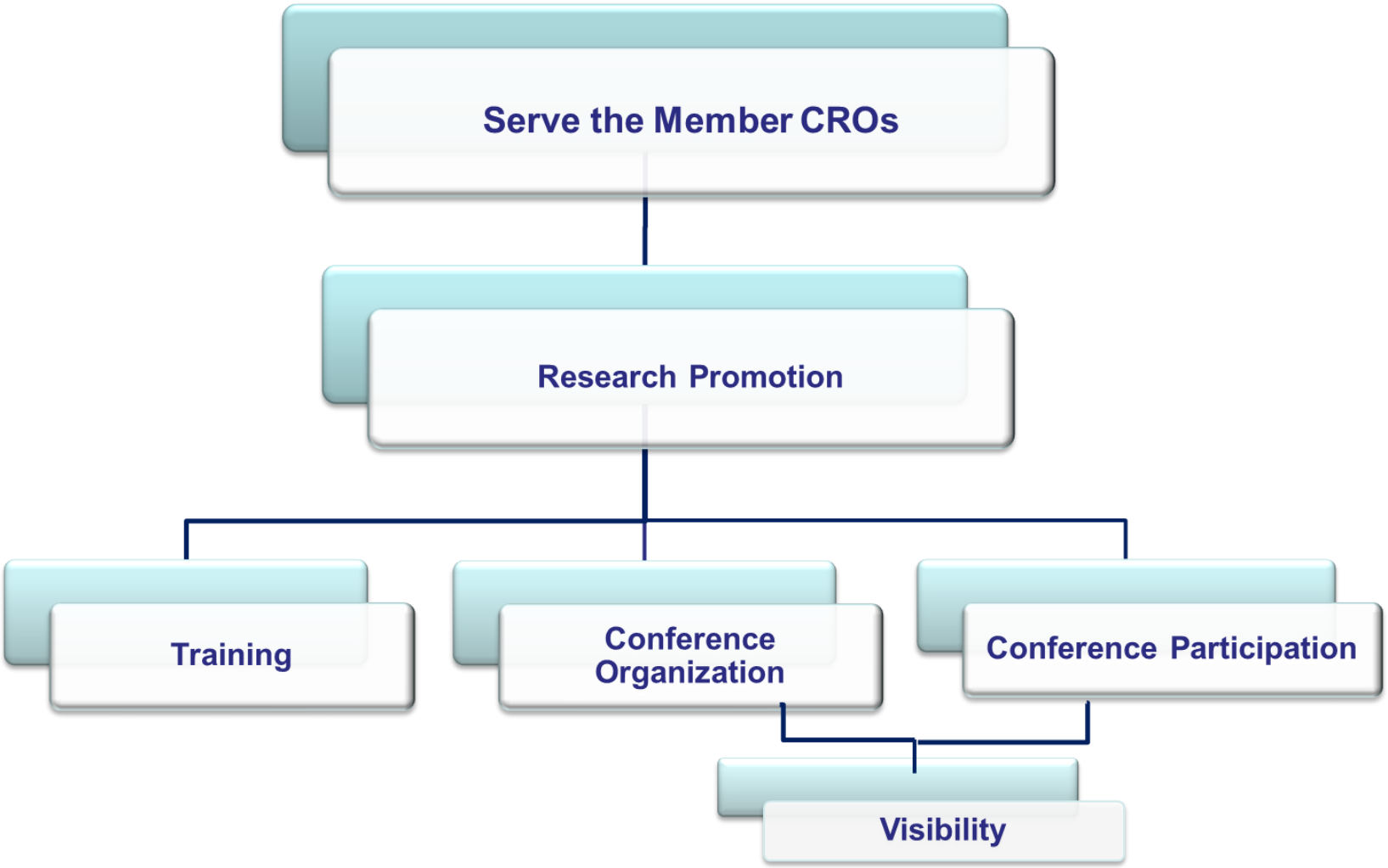
EUCROF Objectives



EUCROF Objectives



EUCROF Objectives



Accomplishments: Administrative

- SOPs made effective on 15 March 2013
  - Quality Statement
  - Master SOP
  - Establishment, Operation and Termination of EUCROF Working Groups
  - EUCROF Communication and Handling of Presentations and Other Documents
  - EUCROF Publications and Abstracts
- SOP Index
- Glossary

Accomplishments: Administrative

- **Finance**
  - **Tax advisor selected**
  - **Tax declaration generated for former years**
  - **Significant growth of bank movements**

Accomplishments: Visibility

- **EUCROF Conference, Paris:**
  02-04 February 2015

- **Late Phase Research/Real-World Data, Dublin:**
  22-23 May 2014

- **DIA Europe, Amsterdam:**
  ✓ **EUCROF General Assembly 04 – 06 March 2013**

- **3rd Conference of Clinical Research, Paris:**
  31 January 2014

Accomplishments: Visibility

- **EUCROF / RIPPS / EMA Conference:**
  18 April 2013
  Methodological Approaches to overcome the challenges of Drug Evaluation in Children

- **EUCROF Conference in Brussels:**
  7 – 9 October 2013

- **Publications: "Collaborations with Patients Organizations" (Stefano) Nordic Life Science, review 02 2013, pag. 38**

Accomplishments: Visibility - Summary

- 02/03-12-2013 EMA meeting on “risk based quality management in clinical trials with interested parties “, London
- 07/09 -10-2013 EUCROF Conference, Brussels
- 30/06 - 06/07 2013 Biopharmaceutical R&D and CRO Conference
- 27/28-06-2013, 6° Forum Scientifique de Pharmaco-épidémiologie, Paris
- 27-06-2013, Enpr-EMA meeting, London
- 18-04-2013 Pediatric WG Symposium, London (EUCROF Pediatric WG and EMA)
- 06/08-03-2013 Late Phase Research/Real-World Data, Amsterdam (EUCROF Late Phase Chair Giovanni Fiori)
- 04/06-03-2013 DIA Europe, Amsterdam, Presentation Pediatric WG

www.eucrof.eu

EUCROF/RIPPS/EMA Conference

Methodological Approaches to Overcome the Challenges of Drug Evaluation in Children

London - 18 April 2013

The EU paediatric regulation entered into force in 2007 in order to facilitate the development of medicinal products in children and to limit the extent of off-label prescriptions.

There is an apparent paradox in evaluating medicinal products in children. Clearly, clinical studies in children need to be performed in order to be able to prescribe evidence-based safe and effective medicines, however for ethical reasons, children must be protected as much as possible from the invasiveness of individual procedures and from the risks of exposure of the patients involved to investigational medicinal products.

As a consequence, an ongoing consideration of these issues focuses on rendering such paediatric studies more feasible while looking for ways to circumvent the difficulties and at the same time, respecting ethical requirements. Among these different ways, innovative methodologies for study design are of growing importance importance e.g. PK and PKV PD studies using a population approach, modeling, simulation and extrapolation, adaptive dose-finding and phase III studies, use of sound and appropriate methodology for observational studies.

The aim of this conference is to establish the current level of use and PDCO recommendations for the use of innovative methodologies in the evaluation of medicinal products in children, to delineate their potential benefit and to define the conditions of their validity.

This one-day conference is aimed at professionals involved in the evaluation and development of medicinal products in children such as manufacturers, regulators, modellers, biostatisticians, investigators, co-investigators, physicians, study nurses, coordinators, regulatory affairs and clinical operations personnel.

Faculty

Amparo Alamany Pozuelo - Paediatric Working Group European CRO Federation (EUCROF) & ITTI, Spain
Martin Chalumeau, MD, PhD - Paediatrician, Necker Hospital, APHP, Paris Descartes University, Inserm, France
Martina Dehlinger-Kremer, PhD - Chair Paediatric Working Group European CRO Federation (EUCROF) & KPS Research, Germany
Pierangelo Gallatti, MD - Paediatric Working Group European CRO Federation (EUCROF) & Pierrel Research, Italy
Lamiae Grimaldi-Bensouda, PharmD, MSc, PhD, LA - SSR Research, France
Lutz O Harnisch, MD - Clinical Pharmacometrics, Pfizer Global Research & Development, UK
Efthymios Manolis, PharmD, M Sc - Scientific Advisor, European Medicines Agency (EMA), UK
Dairine McIntosh, PhD - Paediatric Working Group European CRO Federation (EUCROF) & McIntosh Scientific Advice Services Ltd, UK
Gérard Nguyen Duc Long, Rett Syndrome Europe, France
Frank Pétavy, Biostatistician, European Medicines Agency (EMA), UK
Gérard Pons, MD, PhD - Pharmacologist, Paediatrician, Professor of Clinical Pharmacology - University Paris Descartes, Head Clinical Pharmacology, Inserm UMR 663, CEA, France. Paediatric Committee, EMA, UK, IRDMD – AMEM, President RIPPS, France
Agnes Saint-Raymond, MD - Head of Sector Human Medicines Special Areas, European Medicines Agency (EMA), UK
Peter Thall, PhD - Biostatistic, UT M.D. Anderson Cancer Center, USA
John Whitehead, PhD - Head Department Mathematics and Statistics, Lancaster University, UK

Programme Committee

Amparo Alamany Pozuelo
Paediatric Working Group European CRO Federation (EUCROF) & ITTI, Spain
Agnes Saint-Raymond, MD
Head of Sector Human Medicines Special Areas, European Medicines Agency (EMA), UK
Martina Dehlinger-Kremer, PhD (Committee Chair)
Chair Paediatric Working Group European CRO Federation (EUCROF) & KPS Research, Germany
Gérard Pons, MD, PhD
Pharmacologist, Paediatrician, Professor of Clinical Pharmacology
University Paris Descartes, Head Clinical Pharmacology, Inserm UMR 663, CEA, France.
Paediatric Committee, EMA, UK, IRDMD – AMEM, President RIPPS, France

Organising Committee

Pierangelo Gallatti, MD - Paediatric Working Group European CRO Federation (EUCROF) & Pierrel Research, Italy
Patrice Gabort, MD - Paediatric Working Group European CRO Federation (EUCROF) & Quintiles, France
Milos Kalina - Paediatric Working Group European CRO Federation (EUCROF) & ITTI, Czech Republic
Dairine McIntosh, PhD (Committee Chair) - Paediatric Working Group European CRO Federation (EUCROF) & McIntosh Scientific Advice Services Ltd, UK
Karel Nicol - Bellpharm, RIPPS, France
Jean François Ouclet - RIPPS, France
Alexander Ovetchkin Mutanola, MD - Paediatric working Group European CRO Federation (EUCROF) & IMC, Spain
Michela Mazzoleni - Paediatric working Group European CRO Federation (EUCROF) & Medilinea, Italy

Co-organized by EUCROF European CRO Federation ripps

In partnership with EUROPEAN MEDICINES AGENCY

EUCROF European CRO Federation

EUCROF CONFERENCE

European CRO Federation

7-9 October 2013 Brussels, Belgium

www.eucrof-conference.eu

The future of Europe in the worldwide scene of Clinical Research

The European Federation of CROs is pleased to invite you to the forthcoming European Pharmaceutical Pre-Conference and Conference that will be held in Brussels.

This event will provide a unique opportunity to listen to worldwide expert speakers from Regional and National Authorities, Pharmaceutical Industry and global CROs and will be of interest to all actors engaged in clinical research, with a primary focus on the European region.

The aim of the Pre-Conference "Clinical Outsourcing: Converting Promise to Delivery" on 7 October 2013 is to provide a balanced interactive forum for representative "stakeholders" working in clinical research and development from pharmaceutical companies and outsourcing service providers. In 3 sessions, we will share information and insight from outsourcing practices and provide direction to strategic thinking on outsourcing for the future.

The main Conference on 8-9 October 2013 will address multiple facets of this highly evolving environment, considering how clinical research is responding to the global landscape, stressing the specific challenges and strengths which characterise the three main regions being the Americas, Europe and Asia.

A series of regulations and guidances will shortly reshape the clinical research landscape in Europe. Expert speakers will provide insight in the essential features of these new frameworks. We will review how the future Clinical Trial Regulation will transform access to Clinical Trials in Europe, also hearing from National Agencies and Ethic Committees preparing for this ambitious change. Risk based Quality Management will also be a point of focus, balancing expectations from the regulators and the perspective of Pharmaceutical Companies facing challenges on the implementation pathway.

We will critically assess how the fast changing digital technologies may offer opportunities for innovative ways of delivering Clinical Trials, considering inherent risks and challenges associated with them.

The Patient Associations will join this conference to highlight the most significant barriers to a prosperous clinical research.

Michèle Garot & Philippe Van der Hofstadt
Chairs of the EUCROF Conference 2013

Organisers

EUCROF
European CRO Federation

- ✓ Stefano Marini, President (Italy)
- ✓ Dagmar Chase, Vice-president (Germany)
- ✓ Amparo Alemany, Treasurer (Spain)
- ✓ Darina Hrdlickova, Secretary (Czech Republic)
- ✓ Christophe Golenvaux, Member (Belgium)

BeCRO

- ✓ Philippe Van der Hofstadt, President
- ✓ Michèle Garot, Vice President
- ✓ Julie De Wever, Secretary
- ✓ Sven Deferme, Training & Events

Programme Committee

- ✓ Dagmar Chase (BVMA, Germany)
- ✓ Martina Dahlinger-Kremer (BVMA, Germany)
- ✓ Izaak den Daas (ACRON, The Netherlands)
- ✓ Michèle Garot - Chair (BeCRO, Belgium)
- ✓ Darina Hrdlickova (ACRO-Cz, Czech Republic)
- ✓ Carmen Martinez (AECIC, Spain)
- ✓ Philippe Van der Hofstadt - Chair (BeCRO, Belgium)

famhp

With the contribution of Greet Musch and Kits tot Bonnarens, Federal Agency for Medicines and Health Products. FAMHP

Accomplishments: Education

- **Three free Webinars:**

  Medical Devices WG: Susanne Gerbl-Rieger CROMSOURCE

  Requirements for Clinical Investigations with Medical Devices - Clarity about the actual regulatory framework - basis to understand the future

Participants: 85

Germany:	37	Italy:	4
Belgium:	2	France:	11
Spain:	23	Sweden:	1
CZ:	3	Switzerland:	2
		Ukraine:	1
		Ireland:	1

Accomplishments: Education

- **Three free Webinars:**

Medical Devices WG: Judith Koehnen Theorem Clinical

EN ISO 14155:2011 - Good Clinical Practice for Medical Device Clinical Investigations

Participants:	**97**
Germany:	**32**
Belgium:	**11**
Spain:	**22**
Slovakia:	**3**
France:	**4**
Italy:	**10**
Turkey:	**5**
NL:	**1**
Greece:	**5**
Poland:	**1**
UK:	**3**

Accomplishments: Education

- **Three free Webinars:**

Medical Devices WG: Jochen Wegerer UL MDT

Safety Reporting in Clinical Investigations with Medical Devices

Participants: 91

Germany:	35
Belgium:	3
Spain:	19
Czech Republic:	16
France:	14
Italy:	5
Switzerland:	3
NL:	7
UK:	3

Accomplishments: Communication internal

- **Monthly TCs Executive Board (EB)**
- **Monthly TCs extended EB**
- **EUCROF Newsletter**

Accomplishments: Communication internal

- Face-to-Face Meetings
  - DIA Vienna: 25 March 2014
  - Executive Board Meeting in Rome: 25 June 2014
  - Annual Meeting: 1 - 2 December 2014 in Istanbul together with SAKDER

Accomplishments: Communication external

- **Article for JCROA 20th anniversary (president):**

“EUCROF perspective on the present and future of CRO world development”

- **Meeting with ACRO und JCROA in Brussels: 7 October 2013**

Accomplishments: Communication external

- **Visit to China (president) in 2013:**

- **Jinghai International Biopharma and BPO Investment Promotion Summit – Opening Speech – July 1st**
- **China Sourcing Summit in Hagzhou, "Clinical Trials and Outsourcing: General Trend Moving Toward East" - July 4**
- **International Biopharmaceutical CRO and CMO Forum in Suzhou – July 5**
- **China (Suzhou) Service Outsourcing Development and Investing – July 6**


2013中国（苏州）
创新发展投资
China (Suzhou)
Outsourcing Innovation
International Biopharmaceutic
CRO and CMO Forum
国际生物医药研发外包与协同生产高
2013 中国 · 苏州
Biopharmaceutical
CRO & CMO
Forum
Dagmar Chase
Stefano Marini
&
Darina Hrdlickova
Whoever has
Competence in
EUCROF
42 of 48
苏州市商务局
CoIP
中国 · 苏州 Suzhou China
2013中国（
创新发展投
China (Suzhou)
Outsourcing Innova

International Relations

Europe:

- Finland
- Norway
- Slovakia
- Russia
- Bulgaria
- Romania

MENA:	USA:	ASIA:	AUSTRALIA:	SOUTH AMERICA:
in progress	ACRO	CHINA (CROU) Japan (JCROA)	in progress	Brazil (ABRACRO) Argentina

Accomplishments: Communication internal and external

- EUCROF Website
- EUCROF Brochure
- EUCROF WG leaflets

EUCROF
European CRO Federation

EUCROF, Viale Parioli 12, 00197 Rome, ITALY
www.eucrof.eu | info@eucrof.eu

EUCROF
European CRO Federation

The European CRO Federation, one voice towards clinical research

Our mission is to promote Clinical Research by improving knowledge, competence, expertise and skills of Contract Research Organisations (CROs) in Europe.

Highlights

- Consists of members and associated members from 17 European countries.
- Stands for 300 member CROs and over 15,000 employees.
- Represents and supports their interest towards the healthcare-related industry within the field of Clinical Research, as well as the medical and affiliated research community.
- Recognized by Regulatory Authorities as the representative for European based CROs, regularly approached to contribute to the continuous debate on the improvement of rules and regulations.

Benefits of EUCROF

- We strive to improve the collaboration and interaction amongst all stakeholders in the field of Clinical Research in Europe.
- We seek to support participation to international congresses and meetings to further underline the significant role of CROs in Clinical Research in Europe.
- We disseminate pertinent information to members.
- We organise and support training and educational programs.

How?

EUCROF's actions are carried out by Working Groups formed at the initiative of its members to develop domain-specific programmes and address corresponding issues.

- Clinical Research in Europe
- Clinical Trials Legislation
- Communication
- Early Phase Clinical Study
- Education and Training
- How to start a study in Europe
- Late Phase
- Medical Devices
- Paediatric

Member Associations

Belgium
Belgian Association of CROs (BeCRO)
29 members

Czech Republic
Association of CROs Czech Republic (ACRO-Cz)
15 members

France
Association Française des CROs (AFCROs)
60 members

Germany
Bundesverband Medizinischer Auftragsinstitute e.V. (BVMA)
40 members

Italy
Italian Association of CROs (AICRO)
13 members

Spain
Asociación Española de Compañías de Investigación Clínica (AECIC)
32 members

Sweden
Association of CROs active in Sweden (ASCRO)
7 members

The Netherlands
Associatie van Clinical Research Organisations in Nederland (ACRON)
40 members

Turkey
Sözlesmeli Arastirma Kuruluslari Dernegi (SAKDER)
25 members

United Kingdom
Clinical Contract Research Association (CCRA)
36 members

Associated members in Denmark, Greece, Ireland, Poland, Portugal, Switzerland and Ukraine

EUCROF aims to enforce its structuring role in the EU by encouraging and favouring the creation of national associations wherever they do not already exist.

Working Groups

1. Clinical Research in Europe - *Amparo Alemany*
2. CROs Associations in Europe - *Stefano Marini*
3. How to start a Clinical Trial in Europe - *Dagmar Chase*
4. Clinical Research in Paediatrics - *Martine Dehlinger-Kremer*
5. Clinical Trials Legislation - *Dagmar Chase*
6. Late Phase Research - *Giovanni Fiori*
7. Education and Training – *Antoinette Van Dijk*
8. Early Phase Research - *Philippe Van der Hofstadt*
9. *Medical Devices – Susanne Gerbl-Rieger*
7. *Communication - Christophe Golenvaux*
8. *New Technologies – Yoani Matsakis*

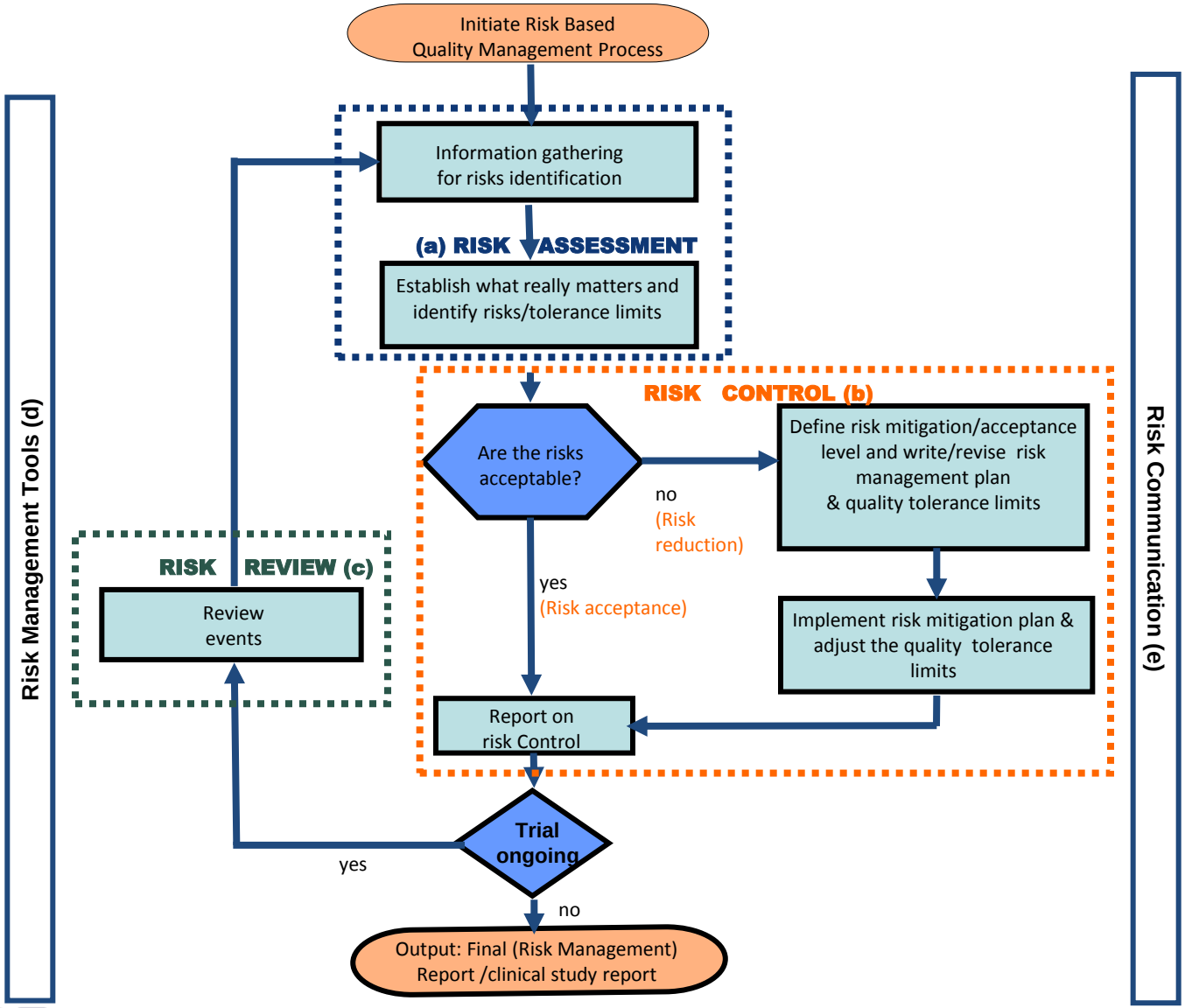
Outlook 2014 / 2015

- Various Webinars to be organised during 2014, open to the public? Paying fees?
- Meeting in San Diego with ACRO and JCROA
- Face-to-Face Meeting EB in Rome
- EUCROF Annual Meeting in Istanbul
- January 2015: 2nd EUCROF Conference in Paris celebrating EUCROF's 10th Anniversary

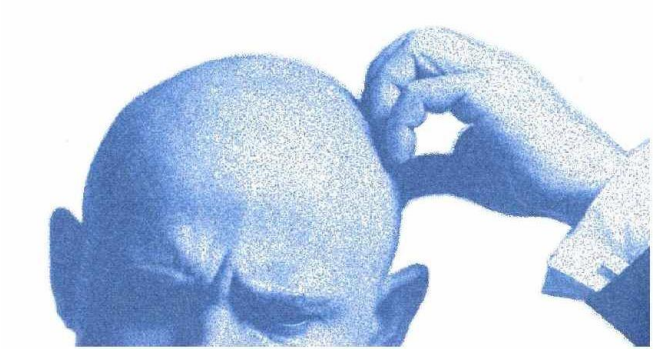
WG: Clinical Trials Legislation

- Detailed Guidance CT-1 (Submission to Competent Authorities, 2009)
- Detailed Guidance CT-3 (Collection, verification and presentation of Adverse Events/Adverse Reactions 2010)
- Technical Guidance - List of fields for result-related information to be submitted to the 'EudraCT' clinical trials database (2010)
- Harmonised requirements for non-investigational medicinal products in CTA submissions (2010)
- Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA (2010)
- Revision of the EU Clinical Trials Directive (2009, 2011)
- FDA Guidance: A Risk-based Approach to Monitoring (2011)
- Reflection Paper: Risk-based Quality Management (2012)
- Reflection Paper: Use of IVR/IWR Systems in Clinical Trials (2012)
- Delegated Act on Post-Authorisation Efficacy Studies (2013)
- Reflection paper on GCP compliance in relation to trial master files (paper and/or electronic) (2013)
- Declaration of Helsinki (2013)

GCP IWG Reflection Paper On RBQM



Permanent Services



- How to start a clinical trial in the EU/EEA → *Dagmar Chase*
- Support to new Associations/Members/ Associate members for their Start up → *Stefano Marini & Darina Hrdlickova*
- Regulatory Bodies Representation → *Whoever has Competence in EUCROF*

Thank you

Very Much

for your attention

Dziękuję bardzo za uwagę

Stefano Marini