

EUCROF Presentation

**EMA Roundtable meeting with stakeholders
on the 10-year anniversary of the SME Office**

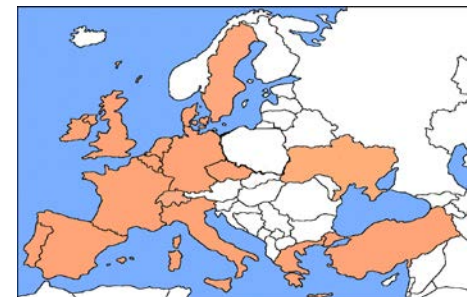
**27 November 2015
London**

Dr. Stefano Marini, MD
EUCROF President European Contract Research Organization Federation

EUCROF 2015

European CROs Federation

- 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

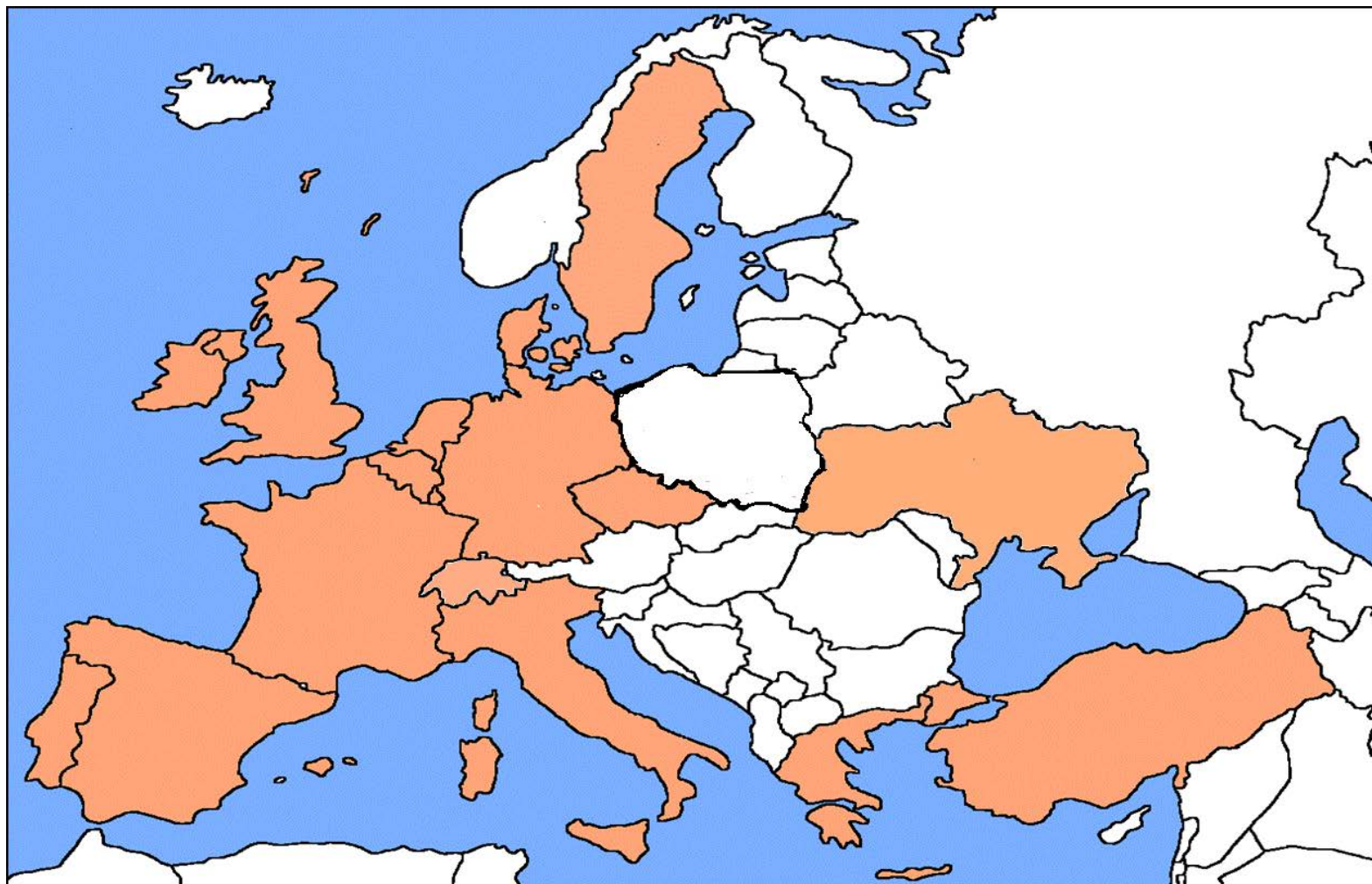


National Association	Country	N. CROs
1. ACRO-CZ	Czech Republic	18
2. ACRON	The Netherlands	40
3. AECIC	Spain	31
4. AFCROS	France	48
5. AICRO	Italy	19
6. ASCRO	Sweden	7
7. BeCRO	Belgium	29
8. BVMA	Germany	39
9. CCRA	United Kingdom	36
10. HACRO	Greece	10
11.SAKDER	Turkey	26

Local CROs

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

EUCROF Geographic Representativeness November 2015



EUCROF Mission

EUCROF is a legal no-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
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- EUCROF's goal is to promote Clinical Research by improving the knowledge, competence and skills of CROs in Europe

Working Groups

1. Clinical Research in Paediatrics

Martine Dehlinger-Kremer

2. Clinical Trials Legislation -

Dagmar Chase

3. Early Phase Research

Keith Berelowitz

4. Late Phase Research

Giovanni Fiori

5. Education and Training

Antoinette Van Dijk

6. Medical Devices –

Susanne Gerbl-Rieger

7. Communication

Christophe Golenvaux

8. New Technologies

Yoanni Matsakis

9. Outsourcing Management

Philippe Van der Hofstadt

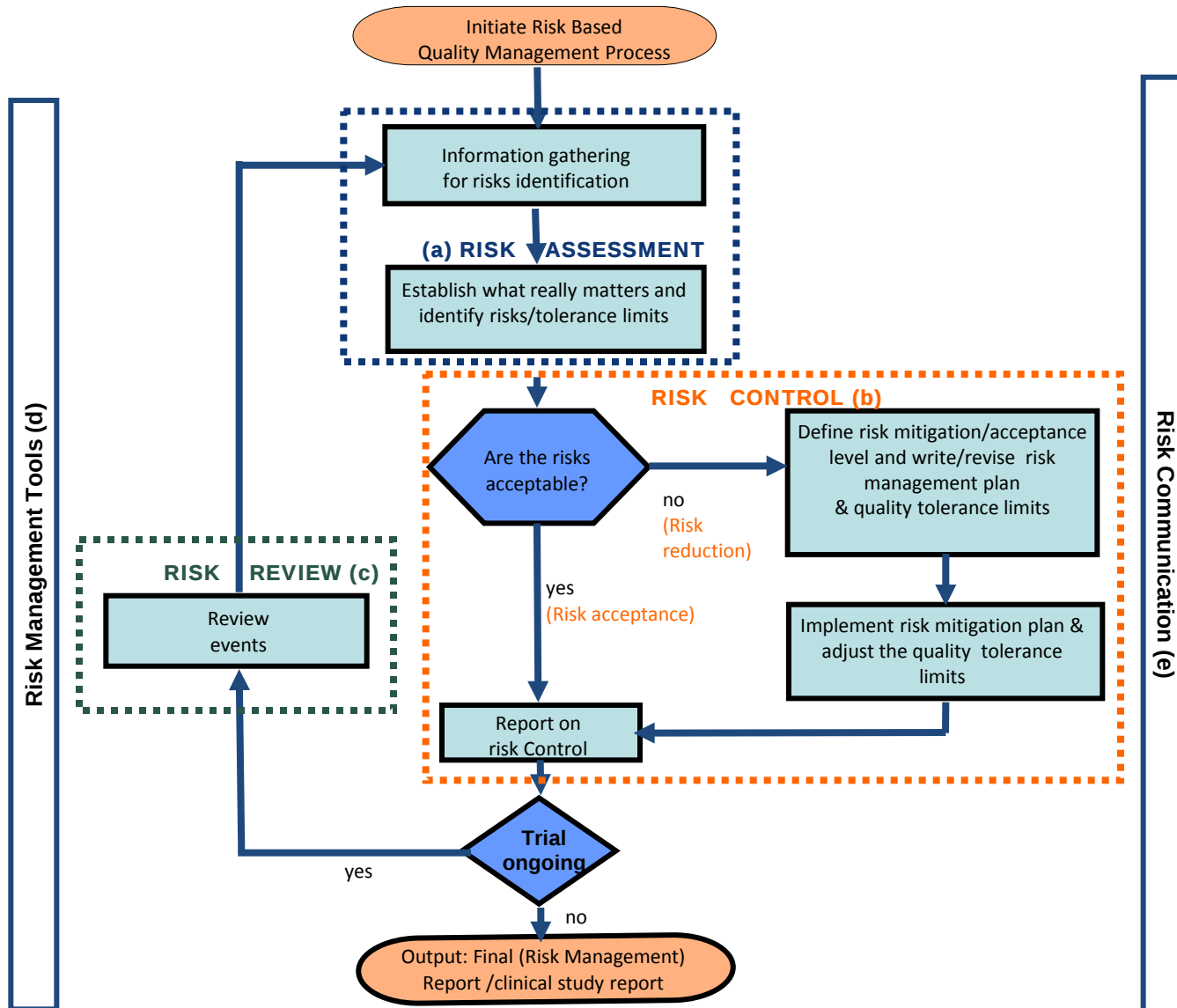
10. Pharmacovigilance

Nicolas Tsiakkas

EUCROF contribution to EMA initiatives 2015

Date	Event	EUCROF Attendees	City
08/12/2015	EU clinical trials portal and Union database stakeholders' meeting (EMA)	Michele Garot, Simon Lee	London
30/11/2015	GCP Inspectors WG and Interested Parties Joint Meeting - EDCS & RBM (Title: Electronic Data Capture systems and Risk Based Monitoring in	Michèle Garot, Dagmar Chase, Yoanni Matsakis	London
27/11/2015	Roundtable SME Initiative (EMA)	Stefano Marini	London
13/11/2015	UIA Associations Round Table	Christophe Golenvau	Brussels
12/11/2015	Advancement and Status of the EU CT Portal (AICRO conference)	Stefano Marini	Milano
15/10/2015	Workshop on Generics (EMA)	Stefano Marini, Ulrike Lorch, Simon Lee	London
1-2/10/2015	Annual joint DIA/EFGCP/EMA Better Medicines for Children Conference	Martine Dehlinger-Kremer	New York
30/09/2015	EFCGP Children's Medicines Working Party Meeting	Martine Dehlinger-Kremer	London
23/09/2015	EU clinical trials portal and Union database stakeholders' meeting (EMA)	Stefano Marini, Dagmar Chase, Ulricke Lorch, Simon Lee	London
18/09/2015	Draft appendix on disclosure rules to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 - EUCROF submission of expert opinion on publication of Phase 1 summary results in relation to patent protection	Ulrike Lorch, Simon Lee, Stefano Marini	London
15/09/2015	9 th EMA Pharmacovigilance stakeholder meeting (EMA)	Nicolas Tsiakkas, Xavier Fournie, Marco Anelli	London
4 -5/06/2015	Final Avicenna Event	Michèle Garot	Barcelona
28-29/05/2015	Annual Workshop of the European Network of Paediatric Research (EMA)	Martine Dehlinger-Kremer	London
26/05/2015	Access to Employment for People with Multiple Sclerosis	Michèle Garot	Brussels
07/05/2015	EU clinical trials portal and Union database stakeholders' meeting (EMA)	Michèle Garot, Ulrike Lorch, Stefano Marini	London
10/04/2015	EUPATI Conference	Stefano Marini	Rome
24/03/2015	Breaking down the barriers: Access to employment and the economics of brain health	Michèle Garot	Brussels
17/03/2015	Ricerca Clinica e Interazioni tra Industria Farmaceutica, Operatori Sanitari e Pubbliche Amministrazioni	Stefano Marini	Rome
25/02/2015	EU clinical trials portal and Union database stakeholders' meeting (EMA)	Stefano Marini, Dagmar Chase, Ulrike Lorch, Si	London

GCP IWG Reflection Paper On RBQM



**Thank you
for you attention**

