ACT EU multi-stakeholder platform kick off workshop

22-23 June 2023
Virtual meeting / EMA, Amsterdam, Room 1D

The success of clinical trials relies on a multitude of stakeholders and therefore regular dialogue between all parties can help to identify and advance clinical trial methods, technology and science, as well as remove roadblocks. To advance this, the EC-HMA-EMA initiative, Accelerating Clinical Trials in the EU (ACT EU), foresees the establishment of a multi-stakeholder platform (MSP) as one of its priority actions.

Through a series of workshops in 2023 and 2024, an EU multi-stakeholder platform on clinical trials will be established to advance discussions and joint action on priority topics.

The first workshop aims at:

- Understanding stakeholders' perspectives on how to transform the EU environment for clinical trials.
- Present and discuss the feedback obtained during the MSP public consultation.
- Initiate discussion on priority areas identified during the MSP public consultation.
- Present and discuss a proposed model for the establishment of the MSP on ACT EU.

This workshop is open to all stakeholders.

ACT EU multi-stakeholder platform kick off workshop

Day 1 – 22 June 2023, 13:00 – 18:30 (CEST)

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

12:30 Joining and technical checks

13:00 Welcome and opening speech

Opening remarks from EMA Executive Director **5'**
Emer Cooke (EMA)

Opening remarks from the European Commission **5'**
Sandra Gallina (EC)

Opening remarks from Heads of Medicines Agencies **5'**
Björn Eriksson (HMA)

13:15 Session 1: Setting the scene

Moderators: Peter Arlett (EMA) and Björn Eriksson (HMA)

ACT EU initiative **10'**
Monique Al (HMA/CCMO)

Outcome of public stakeholder consultation on ACT EU multi-stakeholder platform **10'**
Giacomo Capone (EMA)

Panel and audience discussion **45'**
Julian Isla (European Dravet Syndrome Federation)
Sara Badreh (European Hematology Association)
Lucia D'Apote (EFPIA)
Zubin Thacker (ACRO)
Stefan Gold (Charité Universitätsmedizin Berlin/GCTC)
Vaseeharan Sathiyamoorthy (WHO)

14:20 Coffee break

14:50 Session 2: Discussion on priority areas

Moderators: Stan van Belkum (HMA/CCMO) and Harald Mische (EC)

Clinical trial regulation (CTR) implementation update **10'**

Christophe Didion (EC)

Member States support to the CTR implementation **10'**
Marianne Lunzer (HMA/CTCG)

Panel and audience discussion **45'**
Claudio Lorck (EFPIA)
Derek Johnston (ACRO)
Julian Isla (European Dravet Syndrome Federation)
Amelie Michon (ECRIN)
Rosa Giuliani (ESMO)

The role of ethics committees in clinical trials **10'**
Helle Christiansen (DKETIK, Danish Centre for Ethics)

Panel and audience discussion **45'**
Wolfgang Berdel (AKEK, German ethics committee member, CTCG ethics advisory group)
Michel Zwaan (NVMETC, Dutch ethics committee member)
Marianne Carson (REK KULMU, Norwegian ethics committee)
Fiona Greenhalgh (EATG)
Donald Lo (EATRIS)
Rebecca Stanbrook (EFPIA)

16:50 Coffee break

17:20 Session 2: Discussion on priority areas

Moderators: Stan van Belkum (HMA/CCMO) and Harald Mische (EC)

Transparency of clinical trials **10'**
Laura Pioppo (EMA)

Panel and audience discussion **45'**
Julie Holtzople (EFPIA)
Zubin Thacker (ACRO)
Diana Navarro Llobet (Spanish Network for Clinical Research)
Rosa Giuliani (ESMO)
Rosa Castro (EPHA)

18:15 Conclusions and wrap up of day 1

Wrap up **15'**
Peter Arlett (EMA), Björn Eriksson (HMA) and Harald Mische (EC)

ACT EU multi-stakeholder platform kick off workshop

Day 2 – 23 June 2023, 08:30 – 13:30 (CEST)

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

08:30 Joining and technical checks

09:00 Welcome and opening speech

Outline of the day **5'**

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

09:05 Session 3: Discussion on priority areas

Moderators: Jane Moseley (EMA) and Gunilla Andrew-Nielsen (HMA/CTCG)

Supporting non-commercial clinical trials **10'**

Elke Stahl (HMA/CTCG)

Panel and audience discussion **65'**

Mira Zuidgeest (UMCU)
Diana Navarro Llobet (Spanish Network for Clinical Research)
Donald Lo (EATRIS)
Amelie Michon (ECRIN)
Martin Landray (Oxford university/GCTC)
Denis Lacombe (EORTC)
Mencía de Lemus (SMA Europe)

Reinforcing coordination between scientific advice and CT approval **20'**

Jane Moseley (EMA)
Laurence O'Dwyer (HMA/EU-IN)
Sandra Petraglia (HMA/CTCG)

Panel and audience discussion **45'**

Elizabeth Vroom (World Duchenne Organization)
Mireille Muller (EFPIA)
Donald Lo (EATRIS)
Denis Lacombe (EORTC)
Roisin Adams (NCPE)
Marika Mokou (Mosaiques diagnostics)

Optimising the EU infrastructure for methodology guidance **15'**

Florian Lasch (EMA) and Ditte Zerlang Andersen (HMA)

Clinical trials in situations of public health emergency **15'**

Marco Cavaleri (EMA)

11:55 Coffee break

12:25 Session 4: Building a multi-stakeholder platform for Europe

Moderators: Melanie Carr (EMA), Maria Lamas (HMA)

Opportunities from a European CT multi-stakeholder platform **10'**

Gunilla Andrew-Nielsen (HMA)

Panel and audience discussion **45'**

Michal Rataj (EPF)
Rosa Giuliani (ESMO)
Roisin Adams (NCPE)
Derek Johnston (ACRO)
Lada Leyens (EFPIA)
Stefan Gold (Charité Universitätsmedizin Berlin/GCTC)
Herman Goossens (Antwerp University Hospital)

13:20 Closing remarks

Wrap up **10'**

Björn Eriksson (HMA), Sylvain Giraud (EC) and Peter Arlett (EMA)

13:30 Networking lunch

List of speakers

Amelie Michon	Head of Clinical Operations, European Clinical Research Infrastructure Network (ECRIN)
Björn Eriksson	Director General, Swedish Medical Products Agency (MPA), Heads of Medicines Agencies (HMA)
Christophe Didion	Policy Officer, DG Health and Food Safety (Sante), European Commission (EC)
Claudio Lorck	Associate Director Regulatory Policy and Intelligence at Abbvie, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Denis Lacombe	Chief Executive Officer, European Organisation for Research and Treatment of Cancer (EORTC)
Derek Johnston	Director, Regulatory Intelligence at Fortrea/Labcorp Drug development, representative of Association of Clinical Research Organizations (ACRO)
Diana Navarro Llobet	Head of Research and Innovation, University Hospital General de Granollers, Spain and Spanish Network for Clinical Research
Ditte Zerlang Andersen	EU Project Manager, Special Adviser Danish Medicines Agency (DKMA)
Donald Lo	Director of Medicines Development, European Infrastructure for Translational Medicine (EATRIS) and Scientific Lead, European Platform for Medicines Repurposing (REMEDi4ALL)
Elizabeth Vroom	Chair and co-founder of the World Duchenne Organization (UPPMD), founder and President of the Duchenne Parent Project Netherlands
Elke Stahl	Senior expert in Clinical Trials, German Federal Institute for Drugs and Medicinal Devices (BfArM), Clinical Trials Coordination Group (CTCG), Expert Group on CTs (CTEG), CT Advisory Group (CTAG)
Emer Cooke	Executive Director, European Medicines Agency (EMA)
Fiona Greenhalgh	Programme Officer and Project Coordinator, European AIDS Treatment Group (EATG)
Florian Lasch	Biostatistics Specialist, European Medicines Agency (EMA)
Giacomo Capone	Scientific Specialist and qualified Good Clinical Practice inspector on secondment, European Medicines Agency (EMA)
Gunilla Andrew-Nielsen	Head of Clinical Trials, Swedish Medical Products Agency (MPA), Clinical Trials Coordination Group (CTCG)
Harald Mische	Deputy-Head of Unit Medical Products, DG Health and Food Safety (Sante), European Commission (EC)
Helle Christiansen	Head of European Affairs, Danish National Center for Ethics (DKETIK)

Herman Goossens	Emeritus Professor of Microbiology at the University of Antwerp, founder of the European Surveillance of Antimicrobial Consumption (ESAC-Net) and the annual European Antibiotic Awareness Day
Jane Moseley	Senior Scientific Officer, European Medicines Agency (EMA)
Julian Isla	Founder of the European Dravet Syndrome Federation and member of the Therapeutic Advisory Group in the European Organisation for Rare Diseases (Eurordis)
Julie Holtzople	Senior Director Clinical Transparency and Data Sharing at AstraZeneca, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Lada Leyens	Senior Director Regulatory, and Clinical Trial Innovation and Digital Health at Roche, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Laura Pioppo	Clinical Trials Information System (CTIS) Business Expert at the European Medicines Agency (EMA)
Laurence O'Dwyer	Co-chair of the EU-Innovation Network and Scientific Affairs Manager at the Irish Health Products Regulatory Authority (HPRA)
Lucia D'Apote	Executive Director ELMAC & JAPAC, Global Regulatory and R&D Policy at Amgen, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Marco Cavaleri	Head of Biological Health Threats and Vaccines Strategy, European Medicines Agency (EMA)
Maria Jesús Lamas Díaz	Executive Director, Spanish Agency of Medicines and Medical Products (AEMPS), Heads of Medicines Agencies (HMA)
Marianne Carson	Senior Adviser, Norwegian Ethics Committees for Clinical Trials on Medicinal Products and Medical Devices (REK KULMU)
Marianne Lunzer	Austrian Medicines and Medical Devices Agency (AGES MEA) and Chair of Clinical Trials Coordination Group (CTCG)
Marika Mokou	Senior Scientist, Mosaiques Diagnostics
Martin Landray	Professor of Medicine and Epidemiology at the University of Oxford, Chief Executive Officer of Protas and Senior Lead for the Good Clinical Trials Collaborative (GCTC)
Melanie Carr	Head of Stakeholders and Communication Division, European Medicines Agency (EMA)
Mencía de Lemus	SMArt Horizon Project Leader, Spinal Muscular Atrophy (SMA) Europe
Michal Rataj	Vice President Polish Neuromuscular Diseases Association and ethics committee member European Patients' Forum (EPF)
Michel Zwaan	Professor of Medicine and Chair of Dutch Association of Ethics Committees (NVMETC)
Mira Zuidgeest	Associate Professor, University Medical Center Utrecht (UMCU), the Netherlands
Mireille Muller	Regulatory Policy Executive Director at Novartis, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)

Monique Al	Expert Advisor, Dutch Central Committee on Research Involving Human Subjects (CCMO), vice-chair Clinical Trials Coordination Group (CTCG), CTCG ethics advisory group
Peter Arlett	Head of Data Analytics and Methods Task Force, European Medicines Agency (EMA)
Rebecca Stanbrook	Executive Director, Development and Regulatory Policy at Novartis, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Roisin Adams	Head of HTA Strategy, Irish National centre for Pharmacoeconomics (NCPE)
Rosa Castro	Senior Policy Manager, European Public Health Alliance (EPHA)
Rosa Giuliani	Representative of European Society for Medical Oncology (ESMO) and Co-Chair of EMA's Healthcare Professional Working Party (HCPWP)
Sandra Gallina	Director-General, Directorate-General Health and Food Safety (Sante) at the European Commission (EC)
Sandra Petraglia	Head of Pre-Authorisation Department, Italian Medicines Agency (AIFA), Clinical Trials Coordination Group (CTCG), Expert Group on Clinical Trials (CTEG)
Sara Badreh	Project Manager in European Affairs, European Hematology Association (EHA)
Stan van Belkum	Director of the Central Committee on Research Involving Human Subjects (CCMO), the Netherlands
Stefan Gold	Professor of Clinical Neuroscience and Immunology at Charité Universitätsmedizin Berlin and Scientific Advisor to the Good Clinical Trials Collaborative (GCTC)
Sylvain Giraud	Head of Unit Medical Products, DG Health and Food Safety (Sante), European Commission (EC)
Vaseeharan Sathiyamoorthy	Senior Advisor, R&D, World Health Organisation (WHO)
Wolfgang Berdel	Senior Professor of Medicine at University of Munster, Chairperson Ethics Committee Westfalen-Lippe, Board Member Association of Medical Ethics Committees in Germany (AKEK)
Zubin Thacker	Director, Regulatory Affairs at IQVIA, representative of Association of Clinical Research Organizations (ACRO)