#ClinicalTrials

ACT EU PA04

Multi-stakeholder Workshop on ICH E6(R3) - Public Consultation

Thursday 13th July 2023 - 13:30-18:10 CEST
Friday 14th July 2023 – 10:00-15:40 CEST

Virtual Workshop – Webex

Background and objectives

The renovation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2) guideline on "Good Clinical Practice" (GCP) aims to address the application of GCP to the increasingly diverse range of clinical trial types and data sources.

As part of the published Accelerating Clinical Trials in the EU (ACT EU) multi-annual workplan 2022-2026 and acknowledging the important role of ICH E6 as the global regulatory guideline for GCP, a multi-stakeholder workshop on ICH E6(R3) public consultation is being organised by ACT EU Priority Action 4 (PA04). The workshop aims to engage all stakeholders of ICH E6(R3), including but not limited to, patients, healthcare professionals, assessors, inspectors, industry, and academia. It is envisaged that future discussion with stakeholders on the implementation of ICH E6(R3) could take place under the auspices of the ACT EU Multi-stakeholder platform once this is constituted.

Day 1, 13th July, will begin at 13:30 CEST until 18:10 CEST. The session will be a live broadcast. The session will include a welcome address by the Executive Director of the EMA, presentations by the Rapporteur and Regulatory Chair of the ICH E6(R3) Expert Working Group (EWG), in-depth presentations on both the principles of ICH E6(R3) and Annex I, panel discussions with relevant stakeholders and multiple Q&A sessions.

Day 2, 14th July, will begin at 10:00 CEST until 15:40 CEST, and will focus on discussions in a number of breakout sessions. This day will therefore not be publicly broadcast, and pre-registration will be required. The breakout sessions will run on multiple tracks held simultaneously, twice during the day, allowing relevant stakeholders to attend different breakout sessions if there are two topics of interest for them.

ACT EU PA04 – Multi-stakeholder Workshop on ICH E6(R3) – Public Consultation

Chaired by Marita Kailajärvi (FIMEA) & Peter Twomey (EMA)

Day 1 – 13 July 2023, 13:30-18:10 CEST

13:00 Joining and technical checks

13:30 Welcome and setting the scene

Welcoming Address **10'**
Emer Cooke (EMA)

Outline of the Day & Objectives **10'**
Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)
Kim Pietsch (DE-PEI/EMA)

13:50 Background to Renovation of GCP & Road to ICH E6(R3)

Chair: Momir Radulovic (JAZMP)

Perspective on the GCP renovation work in ICH **10'**
Lenita Lindström (EC/ICH Assembly Chair)

The Road to ICH E6(R3) Public Consultation **10'**
Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)

What is new? – An overview of ICH E6(R3) **20'**
M. Khair ElZarrad (US FDA/Rapporteur ICH E6(R3) EWG)

Question & Answer Session - Slido **10'**
Lenita Lindström, Peter Twomey & M. Khair ElZarrad

14:40 Principles of ICH E6(R3) & Annex I

Chair: Marita Kailajärvi (FIMEA/CTCG)

The Principles of ICH E6(R3) **30'**
Lisbeth Bregnhøj (DKMA/EC ICH E6(R3) EWG Member)
Susanne Nørskov (EFPIA ICH E6(R3) EWG Member)

Annex I **60'**
Gabriele Schwarz (DE-BfArM/EC ICH E6(R3) EWG Member)
Lisbeth Bregnhøj (DKMA/EC ICH E6(R3) EWG Member)
Rebecca Stanbrook (EFPIA ICH E6(R3) EWG Member)

16:10 Coffee Break

16:30 Panel Discussion, Q&A on Principles & Annex I

Chair: Spiros Vamvakas (EMA)

Panel Discussion: Exploring stakeholder's perspectives **30'**
Moderator: Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)

Panellists:
Pirkko Lepola (Enpr-EMA)
Piotr Szymański (Healthcare Professional Representative/ESC)
Gunilla Andrew-Nielson (MPA/CTCG)
Rob Camp (Patient Representative/EUPATI Spain)
Herman Goossens (Universiteit van Antwerpen)
Fergus Sweeney (Good Clinical Practice Expert)

Panel facilitated Q&A Session – Principles & Annex I **45'**

Additional Panellists:
Rebecca Stanbrook (EFPIA ICH E6(R3) EWG Member)
Gabriele Schwarz (DE-BfArM/EC ICH E6(R3) EWG Member)

17:45 Presentation on Annex II & Q&A

Annex II & Q&A **15'**
Andrew Thomson (EMA)
Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)

18:00 Closing Remarks

Wrap up: take-home messages & next steps
Marita Kailajärvi (FIMEA/CTCG)

18:10 End of Day 1

ACT EU PA04 – Multi-stakeholder Workshop on ICH E6(R3) – Public Consultation

Day 2 – 14 July 2023, 10:00-15:40 CEST

09:30 Joining and technical checks

10:00 Welcome and setting the scene

Welcome Address **5'**
Evdokia Korakianiti (EMA)

Perspective from the ACT EU Steering Group **5'**
Peter Arlett (EMA)

Explaining the Breakout Sessions **5'**
Kim Pietsch (DE-PEI/EMA)
Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)

10:15 Breakout Sessions – A

A1 - Principles	**A2 – Sponsors**	**A3 – Investigator**
Rapporteurs: *Piotr Szymański (Healthcare Professional Representative/ESC)* *Rob Camp (EUPATI)*	**Rapporteur:** *Rebecca Stanbrook (EFPIA ICH E6(R3) EWG Member)*	**Rapporteur:** *Gabriele Schwarz (DE-BfArM/EC ICH E6(R3) EWG Member)*
Co-Rapporteur: *Susanne Nørskov (EFPIA ICH E6(R3) EWG Member)* **Moderator:** Ivana Silva (EMA)	**Co-Rapporteur:** *Gunilla Andrew-Nielson (MPA/CTCG)* **Moderator:** Cécile Henrot (EMA)	**Co-Rapporteur:** *Marita Kailajärvi (CTCG/FIMEA)* **Moderator:** Tiina Holmberg (FIMEA/EMA)

11:45 Lunch Break

12:45 Breakout Sessions – B

B1 - Principles	**B2 – New document structure. Including a look into the re-written essential records appendix**	**B3 – Data Governance**	**B4 – Modernisation of GCP**
Rapporteur: *Susanne Nørskov (EFPIA ICH E6(R3) EWG Member)* **Co-Rapporteur:** *Fergus Sweeney (Good Clinical Practice Expert)* **Moderator:** Tiina Holmberg (FIMEA/EMA)	**Rapporteur:** *Rebecca Stanbrook (EFPIA ICH E6(R3) EWG Member)* **Co-Rapporteur:** *Kim Pietsch (DE-PEI/EMA)* **Moderator:** Cécile Henrot (EMA)	**Rapporteur:** *Lisbeth Bregnhøj (DKMA/EC ICH E6(R3) EWG Member)* **Co-Rapporteur:** *Gabriele Schwarz (DE-BfArM/EC ICH E6(R3) EWG Member)* **Moderator:** Ross Brennan (EMA)	**Rapporteur:** *Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)* *Andrew Thomson (EMA)* **Co-Rapporteur:** *François Houÿez (EURODIS)* **Moderator:** Camelia Mihaescu (EMA)

14:15 Coffee Break

14:30 Feedback from Breakout Sessions

All Rapporteurs & Co-Rapporteurs from Breakout Sessions A & B

15:30 Closing remarks

Wrap up: take-home messages & next steps
Peter Twomey (EMA/Regulatory Chair of the ICH E6(R3) EWG)

15:40 End of Workshop

List of Speakers

Name	Biography
Emer Cooke (EMA)	Emer Cooke is as of 16 November 2020 the new Executive Director of the European Medicines Agency, based in Amsterdam. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA). She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies. Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the pharmaceutical's unit of the European Commission.
Peter Twomey (EMA)	Peter Twomey is currently the Head of Inspections at EMA, with responsibility for the Office tasked with supervising compliance with GMDP, GCP, GLP, GVP and BE practices for human and veterinary medicines, market surveillance, quality defects and recalls and harmonisation and policy development in the inspections area. He is the current Regulatory Chair of the Expert Working Group drafting the revision of ICH GCP E6 (revision 3). He previously worked at the Irish Health Products Regulatory Authority, where he held the position of senior GCP/Pharmacovigilance inspector and GCP/PV Inspection manager, and representative at the GCP/Pharmacovigilance EMA inspector working groups (IWGs) and the CMDh GCP IWG working party. He also held the role of Pharmacovigilance inspector with the UK-MHRA, and positions in various areas of industry, including PV (QPPV and PV manager), medical affairs and wholesaling (responsible person). He holds a BSc and Master's degrees in pharmacy, and two Bachelor of Laws degrees.
Kim Pietsch (DE-PEI/EMA)	Kim is a Good Clinical Practice Inspector. He currently is Seconded National Expert from Paul-Ehrlich-Insitut, Germany. He is working within the Inspections Office, Quality and Safety of Medicines Department, European Medicines Agency. He is the Coordinator of ACT EU PA04 and the Chair of this workshop's Program Committee.

Name	Biography
Marita Kailajärvi (FIMEA)	Marita Kailajärvi is a medical doctor by background, and she specialised in clinical chemistry (hospital laboratories). She has been working full-time in clinical drug and medical devices trials since 2002, first as an investigator in phase I-IIa trials in a CRO. She then worked with PET imaging trials in a private company and at University of Turku, Finland. Since 2017, she has been clinical assessor in clinical trials unit of Finnish Medicines Agency (FIMEA). She is the FIMEA representative in HMA Clinical Trials Coordination Group (CTCG).
Spiros Vamvakas (EMA)	Spiros Vamvakas, MD, is the Scientific Lead/Scientific Adviser on Human Medicines at the European Medicines Agency and serves on the EMA core team for COVID-19 products and guidelines. He joined the EMA in 1999, where he was responsible for establishing the orphan drug designation and had roles in scientific advice/protocol assistance for the qualification of novel methodologies, and as an advisor to health technology assessment organizations and payers. Between 2003 and 2016 Dr Vamvakas represented EMA in ICH, serving as EMA Coordinator, as a member of the Management Committee, and as leader of the New Topics Subcommittee. Dr Vamvakas received his medical degree at the University of Würzburg, Germany, and is a board-certified specialist in pharmacology and toxicology from the Bavarian Chamber of Physicians. He has an active teaching appointment at the University Clinic of Würzburg in the Department of Pharmacology and Toxicology and formerly taught at the University of Rochester Medical Centre. Since 2019 he has been an associate editor of the journal Clinical Pharmacology and Therapeutics
M. Khair ElZarrad (US/FDA)	Khair, who is part of the Food & Drug Administration (FDA), is currently the Rapporteur of the ICH E6(R3) Expert Working Group.
Lenita Lindstrom (EC)	Senior expert, Unit A4/"Multilateral international relations" Directorate General for Health and Food Safety (DG SANTE) at the European Commission. Chair of the ICH Assembly Lenita Lindström-Gommers is a lawyer by education (University of Helsinki, Finland) and she has been working in the European Commission since 1995. She joined the pharmaceuticals unit in 2008 where she is responsible for international relations in the field of pharmaceuticals. She is the Chair of the Assembly of the ICH Association, a non-profit association under Swiss law of which the European Commission is a Founding Member. Prior to joining the pharmaceuticals unit, she worked in the Directorate General for Competition.
Andrew Thomson (EMA)	Andrew Thomson is a statistician with over 15 years' experience in the regulatory system. He started at the MHRA

Name	Biography
	initially as a statistical assessor rising to senior assessor, and then moved to become Head of Epidemiology. For the last 9 years, he has been a statistician at the EMA, working in a variety of divisions across the Agency. He is currently in the Taskforce dedicated to Data, Analytics and Methodology. He is the Regulatory Chair for Annex 2 of the current revision of ICH E6
Lisbeth Bregnhøj (DKMA)	Lisbeth has been a GCP inspector at the Danish Medicines Agency (DKMA) since 2006, performing numerous national and international GCP and GVP inspections, on behalf of the DKMA and EMA in various settings such as sponsor sites, CRO/vendor sites and investigator sites. She has previously worked as a clinical trial assessor and as a regulatory affairs project lead. She has experience from a research and clinical practice perspective from working in a clinical pharmacology unit at a University Hospital in Copenhagen and has also worked as an auditor in the medical industry. Lisbeth is part of the GCP Inspectors Working Group and of the e-sub group and has chaired the drafting of the EU guideline on computerised systems and electronic data in clinical trials and is EC topic lead on the ICH E6 (R3).
Gabriele Schwarz (DE-BfArM)	Gabriele Schwarz, licensed pharmacist, has been employed at the Federal Institute for Drugs and Medical Devices (BfArM) since 2001. Until the end of 2022, she was Head of the GCP Inspectorate at BfArM and her responsibilities entailed the planning, coordination, and implementation of BfArM's GCP inspection activities, mainly in the context of the European marketing authorisation procedures for medicinal products. Since 2002 she has also been an appointed member of the GCP Inspectors Working Group (GCP IWG) hosted and chaired by the European Medicines Agency (EMA) and has been actively involved in a high number of sub-groups and regulatory document development. In 2012/2013 she contributed to the development of the OECD Recommendation on the Governance of Clinical Trials. Between 2014 and 2016 she represented the EU Member States in the ICH E6 Expert Working Group (EWG) which supplemented the ICH E6 Guideline on Good Clinical Practice (GCP) and from 2018 to 2022 she was a member of the ICH E19 EWG which developed a guideline on a selective approach to collecting safety data from clinical trials. Since the beginning of 2023, she has dedicated her expertise and resources to regulatory activities at European and international level. She currently represents the EU member states in the ICH E6(R3) EWG, which is working on a revision of the GCP guideline. In parallel, she contributes to several

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	Priority Actions of the Accelerating Clinical Trials in the EU (ACT EU) Initiative, a joint effort of the Commission, the EMA and the Head of Medicines Agencies, aiming to modernise the European clinical trials landscape and better address patient needs.
Rebecca Stanbrook (EFPIA)	Rebecca Stanbrook has worked in the pharmaceutical industry, as a regulator at MHRA and at various pharmaceutical companies for over 30 years. Her main areas of interest are clinical trials and pharmacovigilance. She is a pharmacist by profession and holds a Diploma in Research Quality Assurance. Rebecca is thrilled to be a member of the ICH E6 (R3) Expert Working Group as the EFPIA Topic Lead. Currently Rebecca works as Executive Director, Regulatory and Development Policy in the Regulatory Affairs Group of Novartis Pharma AG. She is based in Basel.
Susanne Norskov (EFPIA)	Susanne Nørskov has worked in the pharmaceutical industry at more pharmaceutical companies for more than 30 years. Her main areas include drug development focused on clinical research specifically within quality and compliance. She is a pharmacist by education and holds an executive education diploma in Leading Pharmaceutical Product Innovation. Since 2019, Susanne has been the deputy EFPIA topic lead on the ICH E6(R3) update. Currently Susanne is working as VP Global Clinical Compliance in the R&D Quality area at Novo Nordisk A/S, working out of Copenhagen, Denmark.
Momir Radulovic (JAZMP)	Momir Radulović leads the Slovenian Medicines and Medical Devices Agency since Dec 2018. He is a member European Medicines Agency Management Board, a member of EC Pharmaceutical Committee, a member of Heads of Medicines Management Group and EURIPID Board of Participants Chair. His previous work experience includes Hospital, Community Pharmacy and Pharma industry, where his work focused on oncology medicines, HIV, vaccines, and in vitro diagnostics. By living in 6 and working in 10 different countries with diverse health systems and cultural environments and through different work areas, projects, and assignments he has learned to adapt swiftly to changes and to seize the opportunities that those can offer.
Rob Camp (EUPATI)	Rob is part of EUPATI Spain, heading International Patient Collaboration. He was part of EURORDIS as consultant in patient group growth from 2008 - 2016. He spearheaded the Community Advisory Board (CAB) programme from 2018 to help patient networks collaborate with the research industry on clinical studies. This programme is now at EUPATI Spain, and more can be seen at www.globalcabs.org.

Name	Biography
	At EUPATI Spain in the last 18 months, he has worked on CABs in 7 disease areas and has helped patient groups meet with 16 sponsors of more than 22 studies related to rare diseases. In the next months, there are more meetings planned on adjusting clinical trials to the needs of people living with rare diseases. He worked as EUPATI Communications Coordinator at the European Patients' Academy (EUPATI) from 2014 - 2017. EUPATI's mission is three-fold: to train patients, to offer a toolkit to patient advocates as the go-to information source on medicines research and development, and to provide easy-to-read general research information a broad swathe of the general public. EUPATI Spain has made important inroads into allying with the Spanish national drugs agency, AEMPS, the pharmaceutical industry, FARMAINDUSTRIA, and with patients through our ongoing research education courses set up in 2017 which are now going stronger than ever.
Piotr Szymanski (ESC)	Piotr Szymanski, MD, FESC, received his medical degree from Warsaw Medical University and took his cardiology residency at the Center of Postgraduate Medical Education in Warsaw. He is Consultant Cardiologist and Head of the Clinical Cardiology Department at CSK MSWiA Hospital in Warsaw. His research and clinical interests focus on adult congenital heart disease and cardio-obstetrics. He serves as Deputy Chair of the Advisory Board of the Polish Health Technology Assessment Agency. He chairs the Regulatory Affairs Committee of the European Society of Cardiology as well as the Regulatory Committee of the Polish Cardiac Society. He is a past president of the Working Group on Echocardiography of the Polish Cardiac Society. Piotr Szymanski represents European Society of Cardiology at the Healthcare Professionals' Working Party (HCPWP) of the European Medicines Agency.
Pirkko Lepola (Enpr-EMA)	Mrs. Pirkko Lepola, Development Manager, HUS Helsinki University Hospital, Department of Children and Adolescents and HUS Research Management, Executive Secretary of FINPEDMED*, General Secretary of NORDICPEDMED**, Chair of the Enpr-EMA*** Coordinating Group. M.Sc. (Biotech. Drug Discovery), B.Sc. (Health Care), Teacher (Pedagogics). Specialized in administrative development of clinical research infrastructures, focusing on legal and quality aspects. Enhances stakeholder´s research collaboration by networking, education, and conference creation. Professional Background: Pharma Industry, CRO companies and University Hospital´s Research Units in Finland. Consortium partner in 3 EU Projects; 2013-2017 GRiP -project (Global Research in Paediatrics), 2017-2021 PedCRIN (The Paediatric Clinical Research Infrastructure Network), 2018-> c4c (Conect4Children-PanEuropean Pediatric Clinical Research Infrastructure), Expert work: Member of EFGCP MCWP (European Forum for Good Clinical Practice, Medicines for

Name	Biography
	Children Working Party), Member of the Advisory Board SwissPedNet (The Swiss Research Network of Clinical Pediatric Hubs), Member of the Board, Clinical Research Institute HUCH Ltd., Helsinki, Finland. Connection to ICH E6 (R3) work: Representation of pediatric clinical trials as a Chair of Enpr-EMA***
Gunilla Andrew Nelson (MPA/CTCG)	Since 2011, Gunilla Andrew-Nielsen has held her current position as Head of Clinical Trials and Special permissions at the Swedish Medical Products Agency (MPA). Since the launch of the Sweden government's Life Science Strategy (2019), she has been responsible for life science related issues within the agency and participated in one of the government's working groups within the framework of the national Health and Life Sciences Collaboration Programme. She represents the Swedish Medical Products Agency in various national innovation projects funded by Vinnova (Sweden's innovation agency) such as ATMP2030 and Testbed for Clinical Trials in Oncology. Since 2022, she has also been responsible for the Swedish Medical Products Agency's Innovation Office. Internationally, she is the MPAs representative in the CTCG (Clinical Trial Coordination Group) under the Heads of Medicines Agency (HMA) which is responsible for implementing the EU regulation for clinical trials. She also represents MPA in the EU-Innovation Network (EU-IN), which is a network for the Member States' pharmaceutical authorities' Innovation Offices. Prior to that, since the beginning of the 1990s, she has held various positions nationally and internationally in the pharmaceutical industry with focus on clinical trials and regulatory compliance.
Fergus Sweeney	Fergus has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Fergus worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance. Prior to his retirement, in May 2022, Fergus was Head of the Clinical Studies and Manufacturing Taskforce at the European Medicines Agency. He joined the Agency Inspection Sector in 1999, was Head of Sector, Compliance, and Inspections from 2009, Head of Division Inspections and Human Medicines Pharmacovigilance in 2013 (and Scientific Committee Services from 2016). Whilst at EMA he served as chair or delegate in various working groups with experts from regulators, the pharmaceutical industry, academia, and civil society, including patients. Among these he has been the regulatory chair of three ICH Expert Working Groups involving the revision of ICH E8 - General Considerations on Clinical Trials and both revision 2 and revision 3 of ICH E6 Good Clinical Practice