ACT EU workshop on ICH E6 (R3) Agenda

19-20 February 2025,
Hybrid meeting / EMA, Amsterdam, Room 1D

As part of the published Accelerating Clinical Trials in the EU (ACT EU) multi-annual workplan 2025-2026 and acknowledging the important role of the international Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Efficiency Guideline 6 (E6) as the global regulatory guideline for Good Clinical Practice, the ACT EU Priority Action – GCP Modernisation is conducting a Workshop on ICH E6 (R3) on **19 and 20 February 2025.**

The workshop aims to engage all stakeholders of ICH E6 R3, including but not limited to **patients, healthcare professionals, including investigators, regulators, service provider, ethics committee members, industry and academia.**

The objectives of this workshop are to:

- provide an overview of the major changes in the ICH E6(R3) guideline, including changes from the draft version of the ICH E6(R3) guideline that was published for public consultation;
- highlight key concepts for adaptation of Good Clinical Practice to recent developments in trial design, organisation and technology, and how these will help to future-proof the guideline;

- enable discussion with stakeholders on the implementation of ICH E6(R3).
- Provide a brief update on the draft ICH E6(R3) Annex II

This workshop is open to all stakeholders through the public broadcast link (no pre-registration required).

ACT EU workshop on ICH E6 (R3) Agenda

Day 1 – 19 February 2025, 09:30 – 18:00 (CET/CEST)

Chaired by Peter Twomey (EMA)

09:15 Joining and technical checks

09:30 Welcome and opening speeches

9:30–9:40	**Opening remarks from EMA Executive Director** *Emer Cooke (EMA)*	**10‘**
9:40-9:45	**Opening remarks from HMA representative** *Momir Radulović (JAZMP)*	**5’**
9:45–9:50	**ACT EU and the GCP modernization** *Peter Arlett (EMA)*	**5’**

09:50 Session 1: ICH E6 (R3) - Overview of Renovation and Key Concepts

9:50–10:00	**ICH guideline development and legal standing of ICH E6 in the EU** *Lenita Lindström (EC)*	**10’**
10:00–10:30	**Overview of ICH E6(R3) renovation** *Peter Twomey (EMA)*	**30’**
10:30-11:00	**Key concepts of ICH E6(R3)** *Gabriele Schwarz (BfArM)*	**30’**

11:00-11:30 Panel and audience discussion **30'**

Gabriele Schwarz (BfArM)
Lisbeth Bregnhøj (DKMA)
Peter Twomey (EMA)
Rebecca Stanbrook (EFPIA)
Susanne Nørskov (EFPIA)

11:30 Coffee break

12:00 Session 2: ICH E6(R3) main changes - Investigator oversight

12:00-12:30 Investigator: Main changes **30'**

Susanne Nørskov (EFPIA)

12:30-13:00 Panel and audience discussion **30'**

Denis Lacombe (EORTC)
François Houÿez (EURORDIS)
Gabriele Schwarz (BfArM)
Monique Al (CTCG/CCMO)
Pirkko Lepola (EnprEMA)
Susanne Nørskov (EFPIA)

13:00 Lunch break

14:00 Session 2 (continuation): ICH E6(R3) main changes - Informed consent

14:00-14:20 Setting the scene **20'**

Gabriele Schwarz (BfArM)

14:20-14:50 Informed consent **30'**

Denis Lacombe (EORTC) / François Houÿez (EURORDIS)

14:50-15:10 **Panel and audience discussion** **20'**

Denis Lacombe (EORTC)
François Houÿez (EURORDIS)
Gabriele Schwarz (BfArM)
Hilde de Keyser (CFE)
Monique Al (CCMO)
Petr Szturz (EORTC)
Sally Hofmeister (WDO CAB)

15:10 Session 3: ICH E6 (R3) - Overview of draft ICH E6(R3) Annex II

15:10-15:40 **Draft ICH E6(R3) Annex II update** **30'**

Andrew Thomson (EMA)

15:40 Session 4: ICH E6 (R3) - The role of Community Advisory Boards and patients

15:40-16:25 **Meaningful engagement of patients in clinical trials: Community Advisory Boards** **45'**

François Houÿez (EURORDIS) / Hilde de Keyser (CFE CAB) / Sally Hofmeister (WDO CAB)

16:25 Coffee break

16:55 Session 5: Interactive session on revised ICH E6 (R3)

16:55-17:40 **Interactive Q&A on all Sessions** **45'**

17:40 Closing remarks

17:40-18:00 **Wrap up** **20'**

Peter Twomey (EMA)

ACT EU Workshop on ICH E6 (R3) Agenda

Day 2 – 20 February 2025, 09:30 – 14:00 (CET/CEST)

Chaired by Peter Twomey (EMA)

09:15 Joining and technical checks

09:30 Opening remarks and overview of the day

09:30-09:35 Opening remarks and overview of the day **5'**

Kim Pietsch (EMA)

09:35 Session 1: ICH E6(R3) main changes - Sponsor oversight and Data Governance

09:35-10:05 Sponsor: main changes **30'**

Rebecca Stanbrook (EFPIA)

10:05-10:45 Data Governance **40'**

Lisbeth Bregnhøj (DKMA)

10:45-11:30 Panel and audience discussion **45'**

Gabriele Schwarz (BfArM)
Lisbeth Bregnhøj (DKMA)
Rebecca Stanbrook (EFPIA)
Denis Lacombe (EORTC)
Jan Geissler (Patvocates)

11:30 Coffee break

12:15 Session 2: ICH E6(R3) main changes - Essential Records and Safety Management

12:15-12:45 Essential records **30'**

Susanne Nørskov (EFPIA)

12:45-13:15 Safety management **30'**

Gabriele Schwarz (BfArM)

13:15-13:45 Panel and audience discussion **30'**

Elke Stahl (chair of the safety-CTCG subgroup)
Gabriele Schwarz (BfArM)
Rebecca Stanbrook (EFPIA)
Petr Szturz (EORTC)
Susanne Nørskov (EFPIA)

13:45 Closing remarks

13:45-14:00 Wrap up **15'**

Peter Twomey (EMA)

List of speakers and panellists

Andrew Thomson	Regulatory chair of the ICH E6(R3) Annex 2 Expert Working Group, European Medicines Agency (EMA)
Denis Lacombe	Chief Executive Officer, European Organisation for Research and Treatment of Cancer (EORTC), stakeholder co-chair of Multi-stakeholder Advisory Group
Elke Stahl	Chair of the safety-CTCG subgroup, Assessor Clinical Trials, Federal Institute for Drugs and Medicinal Devices (BfArM)
Emer Cooke	Executive Director, European Medicines Agency (EMA)
François Houÿez	Treatment Information and Access Director, European Organisation for Rare Diseases (EURORDIS)
Gabriele Schwarz	EC ICH E6(R3) Expert Working Group member, The Federal Institute for Drugs and Medical Devices (BfArM)
Hilde de Keyser	Chief Executive Officer at Cystic Fibrosis Europe (CFE)
Jan Geissler	Founder and the managing director of Patvocates
Kim Pietsch	ACT EU Priority Action coordinator, European Medicines Agency (EMA)
Lenita Lindström	Senior Expert at European Commission (EC) - DG Health and Food Safety, ICH assembly chair
Lisbeth Bregnhøj	EC ICH E6(R3) Expert Working Group member, Danish Medicines Agency (DKMA)
Momir Radulović	Executive Director at Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia (JAZMP)
Monique Al	Special advisor at Central Committee on Research Involving Human Subjects, (CCMO), Vice-chair CTCG, co-chair MedEthicsEU
Peter Arlett	Head of Data Analytics and Methods Task Force, European Medicines Agency (EMA)
Peter Twomey	Head of Inspections (EMA), Regulatory chair of the ICH E6(R3) Expert working group, European Medicines Agency (EMA)
Petr Szturz	Medical oncologist, member of European Organisation for Research and Treatment of Cancer (EORTC) Board.
Pirkko Leopola	Chair of the European Network of Paediatric Research at the EMA (Enpr-EMA)
Rebecca Stanbrook	ICH E6(R3) Expert Working Group member, European Federation of Pharmaceutical Industries and Associations (EFPIA)
Sally Hofmeister	World Duchenne Organization (WDO), Coordinator of the Duchenne Community Advisory Board (CAB)
Spiros Vamvakas	CHMP Scientific lead and Scientific Adviser on Human Medicines, European Medicines Agency (EMA)
Susanne Nørskov	ICH E6(R3) Expert Working Group member, European Federation of Pharmaceutical Industries and Associations (EFPIA)

About the speakers and panellists

Andrew Thomson

EMA

Andrew Thomson is a statistician with nearly 18 years experience in the regulatory system. He is currently at the EMA, in the Taskforce dedicated to Data, Analytics and Methodology. Here his tasks include being part of the Scientific Secretariat for the Methodology Working Party, as well as being the Regulatory Chair for ICH E6 Annex 2 (GCP for trials incorporating decentralised and pragmatic elements and using Real World Data). Prior to joining the EMA in 2014, he spent 7 years at the UK Regulator, the MHRA, initially as a Statistical Assessor and subsequently Head of Epidemiology.

Denis Lacombe

EORTC

Denis Lacombe, MD. MSc, has a long-standing career in clinical research. As Chief Executive Officer of the EORTC, the largest European non-governmental multidisciplinary cancer clinical research infrastructure, DL has a unique grasp on EU matters related to research in health. Author of more than 150 publications, in cancer research and related matters, he has also developed a specific expertise in European policy affairs. He is a Member of the EMA Management Board, co-chair of the EMA Cancer Medicines Forum and co-chair of the ACT EU Advisory Group.

Elke Stahl

BfArM

Dr. Elke Stahl is a senior expert in clinical trials at the Federal Institute for Drugs and Medical Devices (BfArM), Germany, where she has worked since 2005. She has been serving as BfArM's representative in the European Commission Expert Group on Clinical Trials (CTEG) since 2009 and co-chairing the Clinical Trials Facilitation Group (CTFG) from 2014 to 2022. Dr. Stahl is also a member of the Clinical Trial Coordination and Advisory Group (CTAG) and has been involved with the EU Clinical Trials Information System (CTIS) working groups from the start. Prior to her work at BfArM, she gained experience as a pharmacokineticist in the pharmaceutical industry and conducted postdoctoral research at Hoffmann-La Roche Inc. (NJ) and the University of North Carolina (UNC, NC), USA. Dr. Stahl holds a Ph.D. in pharmacology and is a licensed pharmacist.

Emer Cooke

EMA

Ms Cooke is Executive Director of the EMA and Chair of ICMRA. Starting her mandate as ED in June 2020 amid a public health crisis of unprecedented scale she announced "My number one priority will be to drive forward EMA's response to the pandemic and the work already ongoing to support the development and approval of safe and effective COVID-19 vaccines and treatments." Doing precisely that has since earned her various accolades including an Honorary Doctorate for outstanding contribution to healthcare (RCSI - 2023) and the 'European of the Year 2022' title by European Movement Ireland. Ms Cooke obtained a degree in pharmacy and master's degrees in both Science and Business Administration from Trinity College in Dublin, Ireland.

François Houÿez

EURORDIS

François Houÿez has worked as a patient advocate since the early 1990s (HIV/AIDS, Act Up -Paris and EATG) and joined EURORDIS in May 2003. He now works as Information & Access to Therapies Director & Health Policy Advisor. He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA). François supervises EURORDIS's programme for Community Advisory Boards (EuroCAB) and the European Network of Rare Diseases Help Lines.

Gabriele Schwarz

BfArM

Gabriele Schwarz, a graduate pharmacist, joined the German Federal Institute for Drugs and Medical Devices (BfArM) in 2001. She is currently BfArM's GCP Strategy Expert and represents the EU in the ICH E6(R3) Expert Working Group. Until the end of 2022, she was head of the GCP Inspection Unit at the Federal Institute for Drugs and Medical Devices (BfArM) for more than a decade and a half. Over the years, she has contributed to the development of a considerable number of European guidelines, e.g. on Risk-Based Quality Management, eSource, (e)TMF and clinical trials with decentralised elements, as well as to international guidelines such as the OECD Recommendation on Clinical Trial Governance, the ICH E6(R2) and ICH E19 guidelines.

Hilde de Keyser

CFE

Hilde is a master in Sociology by training. She has over 20 years of experience working in the NGO-sector of which 13 years at CF Europe. With CF Europe she worked a lot on patient representation and multi-stakeholder collaboration in research and (access to) care for people with CF. She helped to develop the CF Community Advisory Board and the CF Round Table of Companies. Hilde is a Member of the European Lung Foundation Patient Advisory Committee, the European Lung Health Group and is involved in the European Reference Network on Rare Lung diseases.

Jan Geissler

Patvocates

Jan Geissler is a cancer survivor, long-standing patient advocate. Jan co-founded a number of patient organisations including the CML Advocates Network, WECAN and the Acute Leukemia Advocates Network. Jan represents patients on a number of advisory boards and committees, serves on the strategy board of the German National Decade Against Cancer and the Ethics Committee of the Bavarian Chamber of Physicians. He is founder and CEO of Patvocates, a think tank in patient advocacy and patient involvement, and founder and managing director the non-profit European Patient Advocacy Institute. He was the Director of EUPATI. He is engaged in the HARMONY Foundation and the EU project SafePolyMed.

Kim Pietsch

EMA

Kim Pietsch is currently seconded as National Expert to the Inspections office within the European Medicines Agency (EMA). Kim joined the Paul-Ehrlich-Institut (PEI) in 2012 as a GCP inspector and has conducted over 100 GCP inspections in relation to marketing authorization applications all around the globe and contributed to various guidelines and publications in relation to GCP as part and outside of this membership of the EU GCP Inspectors Working Group.

Lenita Lindström

EC – DG SANTE

Lenita Lindström-Gommers is a Senior Expert in the Directorate General for Health and Food Safety (DG SANTE) in the European Commission where she is responsible for international relations in the field of pharmaceuticals. Her main work relates to ICH where she was closely involved in the reform. She is the Chair of the ICH Assembly. Prior to joining DG SANTE, she was working in the Directorate General for Competition in the European Commission. She holds a Master of Laws degree from the University of Helsinki

Lisbeth Bregnhøj

DKMA

Lisbeth has been a GCP and pharmacovigilance inspector at DKMA since 2006. Prior to that, she has experience from an authority perspective on regulatory affairs and authorisation of clinical trial protocols, from a research and hospital perspective (Clinical pharmacology at a University Hospital in Denmark) and from working in the medicinal industry as a GCP auditor. Lisbeth has performed numerous GCP (and PhV) inspections, both national inspections on behalf of the DKMA and international inspections on behalf of the EMA in various settings such as sponsor sites, CRO sites and investigator sites. Lisbeth is part of the EU GCP Inspectors' Working Group and of the sub group who drafted the EU Guideline on computerised systems and electronic data in clinical trials. She represents EU as the topic lead in the ICH E6 R3 revision.

Momir Radulović

JAZMP

Momir Radulović leads the JAZMP since December 2018. He is a member EMA Management Board, a member of the EC Pharmaceutical Committee, HMA (Heads of Medicines) Management Group and Chair of EURIPID Board of Participants. His previous work experience includes Hospital and Community Pharmacy and Pharma industry, where his work focused on oncology medicines, HIV and vaccines.

Monique Al

CCMO

Monique Al obtained her degree in Human Nutrition at Wageningen University & Research, The Netherlands. Subsequently, she received a PhD in Human Biology in September 1994 at Maastricht University. After that, she worked for several nutritional and pharmaceutical companies in the field of clinical research. In 2001 she started as a scientific staff member at the Central Committee on Research Involving Human Subjects (CCMO) in The Netherlands. She is a coordinating advisor specialised in clinical trials and investigations at the CCMO.

Peter Arlett

EMA

Peter Arlett is Head of the Data Analytics and Methods Taskforce at the European Medicines Agency. In this role he leads on operations and transformation on clinical evidence at the EMA including clinical trials, real world evidence, safety reporting and data science including AI. He is Chair of the EMA Data Board, Co-Chair of the HMA-EMA Network Data Steering Group, Co-chair of the EMA AI Coordination Group, Co-chair of the Vaccine Monitoring Platform Steering Group, and Member of the ACT EU Steering Group. Prior to taking up this role in 2020, he held leadership roles within the EMA in the areas of pharmacovigilance, epidemiology, and risk management.

Prior to starting at EMA in 2008, Peter worked on new legislation and international collaboration for the European Commission, was the UK delegate to the European Committee for Human Medicinal Products, and was an assessor and manager at the UK's MHRA. He has a medical degree from University College London,and began his career as a hospital physician in Oxford and London.

In addition to his role at EMA, Peter is Honorary Professor at the London School of Hygiene and Tropical Medicine. He is also a Fellow of the Royal College of Physicians of Edinburgh and of the Faculty of Pharmaceutical Medicines of London.

Peter Twomey

EMA

Peter Twomey is the Regulatory Chair for ICH E6 R3 Expert Working Group, Chair of the GCP Inspectors' Working Group and Head of Inspections at the EMA. He previously held the position of GCP/PV Inspection Manager and GCP Inspector at the Irish Health Products Regulatory Authority, PV Inspector at the UK-MHRA, and various positions in industry. He holds a BSc and Masters degrees in pharmacy, and two Bachelor of Laws degrees.

Petr Szturz

EORTC

Petr Szturz is a medical oncologist at Lausanne University Hospital in Switzerland, where he oversees an outpatient immuno-oncology Phase I unit and leads the medical oncology program for head and neck cancer. He is also a member of the EORTC Board. Dr. Szturz has served as a principal investigator in clinical trials ranging from early to late stages of development. He has contributed to over 150 scientific publications and has been actively involved in editorial work.

Pirkko Leopola

FINPEDMED

Pirkko Leopola, MS.c., B.S.c. is a Development Manager in HUS Helsinki University Hospital and New Children's Hospital, and Executive Secretary of Finnish Investigators Network for Pediatric Medicines (FINPEDMED), Helsinki, Finland. Pirkko Lepola has almost 30 years working background in clinical research management, of which last 20 years specifically in paediatric clinical trials, research ethics, EU projects and research network collaboration. Since 2019 she has been a Chair of the European Network of Paediatric Research at the European Medicines Agency, Enpr-EMA.

Rebecca Stanbrook

EFPIA

Rebecca Stanbrook has worked in the pharmaceutical industry, as a regulator at the 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. Currently Rebecca works as GCP Strategic Lead in Process & Risk Surveillance, in the Strategy, Portfolio and Programme Operations Group of Development in Novartis Pharma AG. She is based in Basel.

Sally Hofmeister

World Duchenne Organization

Sally Hofmeister was born in the UK but has lived in Germany for most of her life where she worked as a translator and teacher. Her journey with Duchenne Muscular Dystrophy began in 1993 with the diagnosis of her then four-year-old son, the youngest of four children. He passed away in 2024. Sally was a founding member of the German Duchenne parent organization and served on it's board for 10 years. She was also a founding member of the World Duchenne Organization (formerly UPPMD) and has been a board member since 2007. Since 2018 her main focus has been setting up and running the Duchenne Community Advisory Board.

Spiros Vamvakas

EMA

Spiros Vamvakas is a board-certified medical doctor specializing in pharmacology and toxicology. He joined EMA in 1999, playing a key role in establishing Orphan Drug designation, Scientific Advice, and the Qualification of Novel Methodologies. From 2003 to 2016, he represented EMA in the International Council for Harmonisation (ICH), serving as EMA Coordinator, Management Committee member, and lead of the New Topics Subcommittee. After nearly 15 years as Head of Scientific Advice, he assumed his current role in 2020 as CHMP Scientific Lead and Scientific Adviser on Human Medicines, providing expertise across therapeutic areas. Additionally, he is an associate professor at the University of Würzburg and has been an associate editor of *Clinical Pharmacology and Therapeutics* since 2019.

Susanne Nørskov

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.