

Aligning Regulatory and Industry Perspectives on the Revision of ICH S7A

ACE Events, Brussels, Belgium | 3-5 February 2026

<https://www.afsacollaboration.org/ICH-S7A>

Released over 20 years ago, the ICH S7A guideline established an important framework to protect clinical trial participants and patients; however, persistent safety-related attrition and post-approval withdrawals underscore the need to revisit and evolve the guidance in light of scientific, technological, and regulatory advances. This workshop aims to establish a shared vision and build consensus among regulatory and industry stakeholders on revising ICH S7A to inform and support a formal decision to reopen the guidance. Over three days, discussions will focus on identifying priorities, exploring practical and technical considerations, and outlining a coordinated path forward that will help shape the future of safety pharmacology and form the foundation for a revised ICH S7A guideline.

Table of Contents

Agenda.....	2
Participant Biosketches	6
List of Participants	35
About the Organizers	37

Agenda

Feb 3, Day 1- Scene Setting and Goals	
8:30-9:00	In-person Check-in
9:00-9:20	Welcome & Overview of Workshop Goals <i>Jan Turner (Humane World for Animals)</i>
9:20-9:50	ICH Overview Presentation <i>Par Tellner (EFPIA)</i> Presentation of ICH revision process, components of concept paper, and revision expectations.
9:50-10:20	Rationale for Reopening ICH S7A <i>Jean-Pierre Valentin (UCB)</i>
10:20-11:05	Clinical Perspectives and Expectations <i>Moderator: Jean-Pierre Valentin (UCB)</i> <i>Daniel Stiehl (UCB), Charles Benson (Lilly)</i> Clinical perspectives on the strengths, limitations, and gaps of the current safety pharmacology package, and what is needed to better support clinical trial design and execution.
11:05-11:20	<i>Coffee break</i>
11:20-12:50	Regulatory Perspectives and Expectations <i>Moderator: Jan Turner (Humane World for Animals)</i> <i>Britt Duijndam (MEB), Satoshi Tsunoda (PMDA), TBC (FDA)</i> Regulatory perspectives on current expectations, key priorities, and alignment across regions.
12:50-13:50	<i>Lunch provided</i>

<p>13:50-15:50</p>	<p>Industry Practices and Future Perspectives in Safety Pharmacology <i>Moderator: Jennifer Pierson (HESI)</i> <i>Brian Roche (CRL), Emile Desfosses and Thierry Jolas (Eurofins), Michael Rolf (AZ), Jill Nichols (Amgen), Matthew Abernathy (Lilly), Lyn Rosenbrier-Ribeiro (Grünenthal)</i></p> <p>Pharmaceutical and CRO perspectives on industry priorities, challenges, and common practices, informed by pre-survey results and case studies on derisking approaches, tools, and processes.</p>
<p>15:50-16:50</p>	<p>Stakeholder Feedback on Proposed Revision <i>Moderator: Jennifer Pierson (HESI)</i></p> <p>Presentation of pre-survey results followed by a facilitated discussion to gather participants' perspectives on reopening S7A, and address questions, perceived risks, barriers, and challenges.</p>
<p>16:50-17:00</p>	<p>Day 1 Closing Remarks <i>Jan Turner (Humane World for Animals)</i></p>
<p>17:00-18:30</p>	<p><i>Reception with light refreshments</i></p>

<p>Feb 4, Day 2 – Building the ICH S7A Concept Paper</p>	
<p>9:00-9:15</p>	<p>Day 1 Recap and Day 2 Objectives <i>Jennifer Pierson (HESI)</i></p>
<p>9:15-10:45</p>	<p>Concept Paper Content Part I: Breakout Groups <i>Moderators: Sonja Beken (FAMHP) and Derek Leishman (Lilly)</i></p> <p>Part I of this session will consist of breakout group discussions addressing the following:</p> <ul style="list-style-type: none"> • Considerations for secondary pharmacology test systems • Functional endpoint assessment integrated in in vivo repeat dose toxicity studies • Toward a WOE for specific functional endpoint assessments – integration of in vitro / in silico data

	<ul style="list-style-type: none"> Regulatory acceptance of in vitro and in silico methods and of WOE approaches
10:45-11:00	<i>Coffee break</i>
11:00-12:30	<p>Concept Paper Content Part II: Discussion <i>Moderators: Sonja Beken (FAMHP) and Derek Leishman (Lilly)</i></p> <p>Part II will bring the groups back together for report-outs, followed by an overall discussion on issues to be resolved.</p>
12:30-13:30	<i>Lunch provided</i>
13:30-15:30	<p>Deep Dive 1: Core Technical Considerations <i>Moderators: Brian Roche (CRL), Derek Leishman (Lilly), Lyn Rosenbrier-Ribeiro (Grunenthal) and Jean-Pierre Valentin (UCB)</i></p> <p>Breakout groups and group discussion on integrating the following topics in S7A:</p> <ul style="list-style-type: none"> WoE/IATA approaches Secondary pharmacology Modality- and technology-agnostic approaches NAMs and validation/qualification
15:30-15:45	<i>Coffee break</i>
15:45-17:00	<p>Deep Dive 2: Operational & Regional Considerations <i>Moderator: Peter Theunissen (MEB)</i> <i>Sonja Beken (FAMHP), Satoshi Tsunoda (PMDA), TBC (FDA)</i></p> <p>Panel with Q&A, and facilitated discussion on topics including:</p> <ul style="list-style-type: none"> Timing of studies Regional differences Future-proofing
17:00-17:15	<p>Day 2 Closing Remarks and Adjourn <i>Jennifer Pierson (HESI)</i></p>

18:00	<i>Group dinner at Le Jardin du Sommelier</i>
--------------	---

Feb 5, Day 3 – Next Steps	
9:00-9:15	Day 2 Recap and Day 3 Objectives <i>Jean-Pierre Valentin (UCB)</i>
9:15-10:30	Topic Proposal Content <i>Moderators: Sonja Beken (FAMHP) and Jean-Pierre Valentin (UCB)</i> Session to discuss and agree on content for the topic proposal submission including description, strategic importance of topic and feasibility.
10:30-10:45	<i>Coffee break</i>
10:45-11:45	Implementation Considerations <i>Moderator: Jan Turner (Humane World for Animals)</i> Session focused on implementation considerations, covering stakeholder engagement, feedback mechanisms, outcome dissemination, regulatory collaboration, and a clear plan of activities and outreach strategy.
11:45-12:15	Workshop Wrap-Up & Next Steps <i>Moderator: Jennifer Pierson (HESI)</i> Summarize workshop outcomes and communication, review action items and next steps.
12:15-13:15	Day 3 Closing Remarks, Lunch and Adjourn <i>Jean-Pierre Valentin (UCB) & Jan Turner (Humane World for Animals)</i>

**All time in CET*

Participant Biosketches

Tessie Alapatt, PhD

Senior Toxicologist, Division of Pharmacology-Toxicology for Infectious Diseases, FDA CDER



Dr. Tessie P. Alapatt is a Senior Toxicologist in the Division of Pharmacology-Toxicology for Infectious Diseases at FDA CDER. In 2025, Dr. Alapatt served as Acting Supervisor in the Division of Rare Diseases & Medical Genetics, where she provided scientific leadership and regulatory oversight for nonclinical drug reviews. She brings over a decade of specialized expertise in pharmacology and toxicology, with particular focus on infectious diseases and rare disease drug development.

She is an active member of the FDA Emerging Technologies Interest Group that focuses on regulatory considerations for New Approach Methodologies (NAMs) and recently co-authored a publication in the International Journal of Toxicology on FDA/CDER/OND's experience with NAMs in drug development. She has also co-authored a publication about FDA's perspectives on non-adverse findings in toxicology. She serves on several internal working groups where she actively reviews consults, organizes educational courses for FDA reviewers, including an internal workshop on safety assessments of pediatric excipients. She has served as a subject matter expert for the translational science team and provided her expertise in the review of biomarkers as reasonably likely surrogate endpoints (RLSE) for therapeutic indications

in rare diseases. She has contributed significantly to FDA's mission through her review work and by teaching courses, earning her CDER a Regulatory Science Excellence Award and several Faculty Recognition Awards.

Her academic credentials include a PhD in Reproductive Toxicology from the University of Illinois at Urbana-Champaign, an MS in Pharmacology and Experimental Therapeutics from the University of Maryland, and a Bachelor of Pharmacy from Rajiv Gandhi University of Health Sciences in India. She completed a postdoctoral training at Tufts University School of Medicine, where she co-developed a computational analysis methodology for 3D microphysiological systems (MPS) for breast cancer research.

Sonja Beken, PhD

Coordinator of the Unit of Non-clinical Evaluators, Belgian Federal Agency for Medicines and Health Products



Sonja Beken holds a Master in Biological Sciences and PhD in Pharmaceutical Sciences from the Vrije Universiteit Brussel (VUB), Belgium and a Master in Applied Toxicology from the University of Surrey, UK. She is a European Registered Toxicologist.

Sonja Beken is the Coordinator of the Unit of non-clinical evaluators at the Belgian Federal Agency for Medicines and Health Products. This Unit is responsible for the evaluation of non-clinical data submitted to support all phases of drug development (e.g. marketing authorizations, clinical trials, EU/national scientific advice, etc.).

Sonja Beken is the Chair of the 3Rs Working Party at the European Medicines Agency. She was ICH Rapporteur for the revision of the S5(R2) Guideline and is current member of the Implementation Working Group for ICH S7B/E14.

Over the years, Sonja Beken has contributed to the identification of opportunities for regulatory implementation of 3R testing paradigms through her active involvement in large-scale international initiatives.

Her main areas of expertise relate to regulatory science, non-clinical drug development, (in vitro) toxicology and metabolism as well as alternative models to animal experiments (3Rs, NAMs,).

Charles Benson, MD, PhD

Vice President of Medical, Exploratory Medicine and Pharmacology, Eli Lilly and Company



Dr. Benson earned his Bachelor of Science from the Massachusetts Institute of Technology (MIT) before pursuing both an M.D. and Ph.D. in Physiology and Biophysics at Indiana University. He completed his Internal Medicine residency at Scripps Clinic in La Jolla, California.

Dr. Benson currently serves as Vice President of Medical, Exploratory Medicine and Pharmacology at Eli Lilly and Company, where he has spent over 25 years advancing early phase clinical drug development and clinical pharmacology. He is internationally recognized for his leadership in applying quantitative approaches to early drug development, particularly his pioneering work in using concentration-response relationships for QT interval measurement.

Dr. Benson has been a member of the ICH E14 Working Group since 2007 and currently co-leads the IQ Integrated Cardiovascular Safety Working Group, where he continues to advance scientific understanding and regulatory application of QT interval assessment and other cardiovascular biomarkers. His current work focuses on developing integrated nonclinical-to-clinical risk assessment frameworks for cardiovascular biomarkers, utilizing weight-of-evidence approaches including pooled analyses and PK/PD methodologies. These efforts are supported by industry-wide evaluation of nonclinical and clinical data to establish best practices for cardiovascular safety assessment.

Annie Delaunois, DVM, PhD
Head of Safety & Secondary Pharmacology, UCB



Annie Delaunois is a veterinarian by training and holds a PhD in Pharmacology and Toxicology from the University of Liège, Belgium. She has been with UCB Biopharma (Braine-l'Alleud, Belgium) for over 19 years and currently serves as Head of Safety & Secondary Pharmacology within the Non-Clinical Safety Evaluation group. Prior to joining UCB, Annie spent seven years at the Lilly Development Center in Belgium.

Throughout her career, Dr. Delaunois has developed extensive expertise in in silico, in vitro, and in vivo models, with a particular focus on cardiovascular and CNS safety pharmacology. She is the current Vice President-Elect of the Safety Pharmacology Society (SPS). Dr. Delaunois has authored or co-authored approximately 80 publications and has participated in over 100 international conferences in the fields of safety pharmacology and toxicology.

Emile Desfosses, PhD

Preclinical Safety Director, Eurofins Discovery France



Neuropharmacologist by training, Dr. Emilie Desfosses has worked for six years in the pharmaceutical industry at Servier, initially focusing on *in vivo* studies and later as preclinical Safety representative in neurology and oncology projects. She has contributed to drug development from discovery to IND-enabling packages across various therapeutic modalities including small molecules, biologics and antisense oligonucleotides (ASOs).

This hands-on experience has shaped a deep awareness of animal welfare and the importance of ethical considerations in drug development

Since 2023, she has been working at Eurofins Discovery France as Preclinical Safety Director where she focuses on advancing *in vitro* safety pharmacology services integrating computational approaches to enable translational interpretation, improve predictivity, support early derisking and reduce reliance on animal testing in drug discovery.

Britt Duijndam, Msc

Non-clinical assessor, Dutch Medicines Evaluation Board (MEB)



Britt Duijndam, Msc., is a non-clinical assessor at the Dutch Medicines Evaluation Board (MEB) since 2015, and she is involved in several research projects within the MEB aiming to evaluate the non-clinical development strategies of new modalities. She is a member of the ICH S7/E14 Implementation Working Group for the “Clinical and nonclinical evaluation of QT/QTc interval prolongation and proarrhythmic potential”, and a member of the internal drafting group supporting the EU regulatory experts in drafting the new ICH S13 Guideline on “Non-clinical safety studies for oligonucleotide-based therapeutics”.

Andrea Greiter-Wilke, DVM, PhD, DSP

**Subject matter expert for Safety pharmacology, Toxicology project leader,
F.Hoffman-La Roche**



Dr. [Andrea Greiter-Wilke](#) is a board-certified safety pharmacologist with two decades of experience at F. Hoffmann-La Roche in Basel. All in vivo safety pharmacology-related topics on study design, interpretation, regulatory interactions and assessment of due diligences are under her responsibility. Her main focus is on the cardiovascular area, but her expertise includes CNS, respiratory, and abuse liability assessment. She is an active member of the Safety Pharmacology Society and served as its president last year. Andrea has authored and co-authored many publications and acts as a reviewer for several journals. She is a veterinarian by training (Univ. of Vienna), practiced in private and university animal hospitals in Germany and the UK, and worked as postdoc at Cornell and Louisiana State University before joining Roche.

Stephen Jenkinson, PhD

Scientific Advisor for Cardiovascular Safety, Sanofi



Steve Jenkinson serves as a Scientific Advisor for Cardiovascular Safety within the Investigative Toxicology group at Sanofi. He is an in vitro pharmacologist with over 25 years of experience in drug discovery and safety pharmacology and earned his Ph.D. from the University of Leicester in the UK.

Throughout his career, Steve has contributed to assay development, target de-risking, and preclinical safety evaluation, with experience spanning receptor and ion channel pharmacology, cardiac safety, and neuroscience. He has collaborated with colleagues across the industry and participated in cross-pharma consortia, including IQ DruSafe and HESI, where he has supported efforts to advance in vitro safety pharmacology, secondary pharmacology, and clinically relevant in vitro safety models.

Steve has held scientific and leadership roles at Pfizer, Mitsubishi Tanabe, GlaxoSmithKline, and Metrion Biosciences, where he worked closely with project teams to help progress innovative therapeutics.

Thierry Jolas, PhD

Technical Director for *In Vitro* Pharmacology Services, Eurofins Cerep



Thierry holds a Doctorate Degree in Neurosciences from Pierre et Marie Curie University in Paris. He spent 5 years as a Post-Doctoral and Research Associate in GK Aghajanian Laboratory at Yale University. He then served as senior scientist for 5 five years at Schering-Plough Research Institute in Kenilworth before joining Eurofins Cerep in 2003.

At Eurofins Cerep, Thierry is currently Technical Director in charge of standard *in vitro* Pharmacology Studies, for a portfolio of more than 150 companies including 8 major pharma in the USA, Northern and Central Europe and also handles the assay transfer and maintenance team. He has a broad expertise in Neuroscience, Neuropharmacology, Safety Pharmacology, GPCRs, Ion Channels, Project Management, Study Protocol and Profile Design.

He presented several posters about comparison of binding and functional data at targets labelled as critical in Safety Pharmacology assessment.

Alessandra Lopes, PhD

Senior Manager for Non-clinical Safety, Johnson and Johnson



Past experiences: I worked for more than 10 years in the drug discovery field, from target validation till the IND submission, in both big pharma and small biotech, discussing safety and potential tox problems at each stage of the drug validation.

Shagun Krishna, PhD

Director of Toxicology, Physicians Committee for Responsible Medicine



Shagun Krishna, PhD, is the Director of Toxicology at the Physicians Committee for Responsible Medicine (PCRM). Her work focuses on advancing human-relevant, non-animal approaches for safety assessment, with particular expertise in cardiotoxicity. She specializes in integrating in vitro, in silico, and computational approaches, including IVIVE and PBPK modeling, to improve the prediction and regulatory assessment of cardiovascular risk.

Dr. Krishna has extensive experience working with international regulatory and scientific bodies, including the FDA, EPA, NIH, and OECD, contributing to the development of New Approach Methodologies (NAMs), IATA frameworks, and regulatory science initiatives related to systemic toxicity and cardiotoxicity. She brings a mechanistic, human-relevant perspective to discussions on the evolution of ICH safety guidelines.

Jill Nichols, PhD

Senior Director of Safety Pharmacology Sciences, Amgen



Jill Nichols is Senior Director of Safety Pharmacology Sciences at Amgen, where she oversees exploratory and regulatory safety pharmacology studies for new drug candidates. Previously, she served as Executive Director and Global Lead of Pharmacology at Labcorp for seven years, managing Discovery and Safety Pharmacology, Inhalation Sciences, and Antibody Reagents and Vaccines operations. Before joining Labcorp, Jill spent 15 years at Pfizer in Safety Pharmacology in leadership roles spanning in vitro ion channel pharmacology and in vivo cardiovascular disciplines. Her research interests include the development of novel cardiovascular models, advanced data analysis methods, and translational pharmacology. Jill is actively engaged in several industry working groups advancing best practices and has previously served on the Safety Pharmacology Society Board of Directors.

Elisa Passini, PhD

Programme Manager for Drug Development, NC3Rs



Elisa joined the UK National Centre for the Replacement Refinement & Reduction of Animals in Research (NC3Rs) in July 2022 as Programme Manager for Drug Development. She is leading various NC3Rs projects to promote and support the application of the 3Rs within toxicology and safety pharmacology studies for pharmaceuticals.

She obtained her PhD in Bioengineering at the University of Bologna (Italy) in 2015, and – before joining the NC3Rs – she was a postdoctoral researcher in the Department of Computer Science at the University of Oxford, working on computer modelling and simulations of the human heart for prediction of drug cardiac safety.

The expertise/perspective I can bring to the workshop is mainly related to NAMs and 3Rs.

Jennifer Pierson, MPH

**Associate Director for Program Development and Resourcing and Director of the
Center for Translation Sciences, HESI**



Jennifer Pierson is the Associate Director for Program Development and Resourcing and Director of the Center for Translation Sciences at the Health and Environmental Sciences Institute, HESI Global. Jennifer has spent the past 20 years in scientific program management, 14 of those with HESI Global. In her current role, Jennifer manages the Cardiac Safety Committee, focused on improving understanding of cardiovascular risk from drugs and advancing implementation science. She was involved in the CiPA efforts and research supporting ICH S7B/E14. Jennifer received her BS in Biology in 2005 from Villanova University and her Master of Public Health in 2007 from Drexel University. She has also co-authored numerous papers related to toxicology, 3Rs and drug development research as well as participated in continuing education on toxicology and meeting facilitation.

Sebastian Prill, PhD

Associate Director in Clinical Pharmacology and Safety Sciences, AstraZeneca



Sebastian is an Associate Director in Clinical Pharmacology and Safety Sciences at AstraZeneca in Gothenburg, Sweden. With a background in cell biology, molecular biology, and bioengineering, he has extensive experience in developing and working with advanced human cell models (3D, Microphysiological Systems (MPS), in vitro disease models) in the pharmaceutical industry. Furthermore, Sebastian serves as the oligonucleotide hepatic safety lead at AstraZeneca and oversees the cross-organ oligonucleotide off-target assessment work stream.

Eva Rached, PhD, ERT

Nonclinical Assessor and GLP Inspector, Swissmedic



I joined Swissmedic (the Swiss Agency for Therapeutic Products) in 2016 as a nonclinical assessor and GLP inspector. Before this, I worked in CROs as a study director for in vivo toxicity studies and as a project manager. During my biology studies and doctorate, I conducted research in the field of toxicology, focusing on mechanistic toxicology, biomarkers, and alternative methods. Since 2015, I have been registered as a European Toxicologist (ERT).

As part of my work at Swissmedic, I have been a member of the ICH E14/S7B Working Group since 2018.

Kirsty Reid, PhD

Director of Science Policy, EFPIA



Dr Kirsty Reid is Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations (EFPIA). She holds a PhD in Ethnopharmacognosy (2003) from the University of KwaZulu-Natal, South Africa. For the past 20 years she has worked extensively on research and on EU public and regulatory affairs. She leads work on alternatives to animal testing, environment, health, safety and sustainability issues. She sits on the advisory boards of the European Horizon Europe Project Transpharm and the PharGTrans project, funded through the Research Council of Finland. She is the EFPIA representative in the European Partnership for Alternative Approaches to animal testing (EPAA), EFPIA representative as the accredited stakeholder to the ECHA and the EFPIA liaison on environment and chemical dossiers to the EMA. She has a number of published papers across these topics.

Mike Rolf, PhD

Senior Director, Safety Pharmacology, AstraZeneca



Mike Rolf holds a PhD in physiology from the University of Cambridge and has spent over 20 years working in Secondary and Safety Pharmacology at AstraZeneca. He is currently Senior Director, Safety Pharmacology, with responsibility for Safety Pharmacology support across AstraZeneca's pipeline of innovative medicines in discovery and development. DSP certified, he is an active member of the Safety Pharmacology community with particular interests in integrated risk assessment, the application of modelling approaches in nonclinical safety and the use of nonclinical safety data to inform drug development beyond First in Human trials.

Lyn Rosenbrier Ribeiro, PhD
Discovery Safety Lead, Grunenthal



Lyn received her BSc (Hons) in Biomedical Sciences from the University of Bradford, followed by a PhD in Biochemistry from the University of Manchester. She has 20 years experience within drug discovery spanning medium to large pharma (Grunenthal, UCB, AstraZeneca), biotech (Medicines Discovery Catapult) and consultancy (R2 Pharmacology Ltd). Lyn started her career at AstraZeneca initially as a Lead Pharmacologist then transitioned to Safety Pharmacology in 2009, where she progressed to Associate Director of Mechanistic Pharmacology. Leading a team of Secondary pharmacologists, she drove strategic direction and operational delivery of in vitro pharmacological profiling data across all therapy areas. In 2019, Lyn joined Medicines Discovery Catapult and broadened her remit as an External Drug Discovery Project Manager, providing drug discovery expertise to progress academic and biotech companies' innovative projects. In parallel, she also established her own consultancy company, R2 Pharmacology Ltd, providing secondary pharmacology and mechanistic toxicology advice. In 2021, Lyn joined UCB as a Non-clinical Project Safety Lead and more recently joined Grunenthal as Director, Discovery Safety Lead, where she holds the remit for early safety and toxicology support to all projects as well as developing the discovery safety strategy to support successful pain medication development. Overall, her expertise spans pharmacology, safety & secondary pharmacology, assay development and preclinical toxicology and she has a strong passion for patient-centric in vitro/in vivo translation.

Daniel Stiehl, MD

Head of Benefit-Risk and Medical Safety, Early Development, UCB



Daniel P Stiehl, Dr. med., Habil. is the Head of Benefit-Risk and Medical Safety – Early Development at UCB, where he oversees a team dedicated to benefit-risk assessment across early-stage portfolios with a focus on neurology and immunology. Prior to this role, he served as Global Program Safety Lead at Novartis, managing safety teams across Phase 1–4 programs, including first-in-class therapeutics and an ocular gene therapy. Earlier at the Novartis Institutes for BioMedical Research, he led a Data Exploration & Analysis group in Discovery and investigative Safety, integrating clinical and non-clinical safety datasets and leading investigative genomics to elucidate mechanistic toxicology questions throughout drug development. He received his medical degree and doctorate from the University of Lübeck, Germany and completed his habilitation in Physiology at the University of Zürich, Switzerland.

Pär Tellner

Director Regulatory Affairs, EFPIA



Pär Tellner is Director, Team Leader and ICH MC at EFPIA since 2017. He is also in charge of the EFPIA support to different regulatory and quality working groups.

Pär has previously been working as Compliance officer (marketing ethics) and Director of Veterinary Medicine, LIF Sweden and as Head of regulatory affairs for several pharmaceutical companies, e.g Octapharma, Biovitrum, Pharmacia Plasma Products and Novartis. Pär has also been working as Senior Pharmaceutical Officer for the Swedish Medical Products Agency.

Pär graduated as a pharmacist at Uppsala University in 1986.

Konstantinos Tsarouchas, MD, MSc, PhD, ERT

Senior Consultant of Cardiology, University Hospital of Larissa, Greece

Dr. Konstantinos Tsarouchas is an experienced cardiologist combining hospital-based clinical practice of more than 20 years with academic teaching and research, particularly in heart failure and exercise cardiology. He is currently working as a Senior Consultant at the University Hospital of Larissa, Greece. He has (co-)authored more than 90 peer-reviewed scientific publications in international cardiology journals with nearly 6000 citations. His MSc in Exercise and Health focused on recovery of cardiac function after exercise in heart failure patients, while in his PhD research studied molecular and genetic mechanisms related to ascending aortic aneurysms. He is additionally a certified expert in echocardiography, heart failure and recently in cardiac electrophysiology and pacemaker implantation . He is the elected treasurer of the Management Board of the Hellenic Society of Toxicology and a European Registered Toxicologist for the past 10 years. Since 2024 he is a member of the OECD WPHA Expert Group on Cardiotoxicity of Chemicals.

Satoshi Tsunoda, PhD
Specialist (Toxicology), PMDA

For over 10 years, I have been reviewing and advising on the safety pharmacology of new pharmaceuticals at the regulatory authority (PMDA) and expert for the assaying of in vivo study. I have served as the ICH E14/S7B PMDA/MHLW topic leader for 8 years.

Janette Turner, PhD

Principal, Medicines, Humane World for Animals



Jan's PhD was in genetic toxicology but she has spent a large part of her career in the Life Science industry, as both an R&D scientist and in global product management, providing tools and reagents to pharma in high throughput screening and safety assessment functions. Latterly, Jan has worked in the cell therapy area, providing equipment and support for production of these new therapies. She has worked extensively with iPSCs for cardiotoxicology and neuro degenerative diseases and participated in the FDA CiPA initiative from 2013. As Principal, Medicines at Humane World for Animals, Jan has initiated the medicines workstream to change the way medicines are tested from animal based methods to new approach methodologies (NAMs), globally and with harmonization across regions.

Jean-Pierre Valentin, PhD, HDR, DSP, ERT, FRCPath, FRSB
Fellow and Strategic Advisor, UCB Pharma



Dr Valentin is a pharmaceutical scientist with over 30 years of experience in the biopharmaceutical industry, spanning both scientific and senior leadership roles across several companies. He has contributed to the discovery of numerous drug candidates and has overseen the safety and secondary pharmacology assessment of approximately 200 compounds across multiple therapeutic areas.

Dr Valentin is a former President of the Safety Pharmacology Society and currently holds leadership roles within HESI, IQ-DruSafe, and EFPIA-PDEG. Over the past decade, he has represented EFPIA on the ICH E14/S7B Implementation Working Group and has been actively involved in global regulatory science initiatives.

He has a longstanding commitment to training and mentoring through scientific societies, universities, and trade associations, and is the author of several patents and more than 250 scientific publications.

Hugo Vargas, PhD, DSP

Executive Director in Translational Safety & Risk Sciences, Amgen



Hugo Vargas, PhD, DSP is a nonclinical drug safety scientist with deep experience in the field of safety pharmacology. Hugo joined the pharmaceutical industry in 1991 and has first-hand experience with the implementation of safety pharmacology frameworks to support FIH and clinical development for conventional (small molecule) and novel drug modalities. Hugo joined Amgen Inc (2006) to create the Safety Pharmacology Sciences group and is currently an Executive Director in Translational Safety & Risk Sciences (TSRS) organization. TSRS is the core group responsible for nonclinical safety evaluation of all pipeline molecules at Amgen.

- Hugo leads the Translational Safety Research function, which is a diverse group of scientists with deep experience in safety pharmacology, immunology, drug safety, toxicology and nonclinical-clinical translation.
- Hugo is involved with several industry-wide activities and consortia related to safety pharmacology evaluation, as well as new alternative methodologies. In particular, he was appointed by the Pharmaceutical Research Manufacturers Association (PhRMA) to serve as the Deputy Technical Lead to the ICH E4/S7B Implementation Working Group.

Jufeng Wang, PhD

- (1) Senior Vice President, Safety Assessment, Pharmaron, Beijing, China**
- (2) President of Chinese Safety Pharmacology Society**
- (3) Acting leader of ICH S7B Work Group of China**



Dr. Jufeng Wang is a Senior Vice President, Safety Assessment in Pharmaron, Beijing, China. Before joining Pharmaron, Dr. Wang held a position of Director of National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control, NMPA, in China. He has over 25 years' experience in drug safety evaluation. He played important roles in preclinical drug safety assessment, especially in safety pharmacology. Most significantly, he played an important role in the review of technical guideline for drug research/development and GLP guideline in China. He worked at several pharmaceutical companies in USA as safety pharmacologist and toxicologist. He is Editor in Chief of the book "Principle of Safety Pharmacology" that was published in China.

Takashi Yoshinaga, PhD
JPMA rep, Eisai Col., Ltd.



Takashi Yoshinaga, PhD is the ICH E14/S7B IWG topic leader of JPMA, Japanese Safety Pharmacology Society (JSPS, Board/Director 2025-, former president 2020-2024, Executive Committee Member -2019), Head of Safety Pharmacology at Eisai.

List of Participants

First name	Last name	Company/ Organization	Sector	Region
Matt	Abernathy	Lilly	Industry	US
Tessie	Alapatt	FDA	Regulator	US
Sonja	Beken	FAMHP / EMA	Regulator	EU
Charles	Benson	Lilly	Clinical	US
Ksenia	Blinova	FDA	Regulator	US
Annie	Delaunois	UCB	Industry	EU
Emile	Desfosses	Eurofins	CRO	EU
Britt	Duijndam	Medicines Evaluation Board	Regulator	EU
Chris	Ellis	FDA	Regulator	US
Andrea	Greiter-Wilke	Roche	Industry	EU
Stephen	Jenkinson	Sanofi	Industry	US
Thierry	Jolas	Eurofins	CRO	EU
Yasunari	Kanda	NIHS	Regulator	Japan
Mohamed	Kreir	J&J	Industry	EU
Shagun	Krishna	PCRM	NGO	US
Derek	Leishman	Lilly / PhRMA	Industry	US
Alessandra	Lopes	J&J	Industry	US
Jill	Nichols	Amgen	Industry	US
Claire	O'Brien	HESI	NGO	US
Ines	Pagan	FDA	Regulator	US

Elisa	Passini	NC3R	NGO	UK
Jennifer	Pierson	HESI	NGO	US
Colleen	Pike	Humane World for Animals	NGO	US
Sebastian	Prill	AstraZeneca	Industry	US
Eva	Rached	Swissmedic	Regulator	Switzerland
Kirsty	Reid	EFPIA	Industry	EU
Brian	Roche	Charles River Laboratories	CRO	US
Mike	Rolf	AstraZeneca	Industry	EU
Lyn	Rosenbrier-Ribeiro	Grunenthal / EFPIA	Industry	EU
Daniel	Stiehl	UCB	Clinical	EU
Alexandra	Taraboletti	HESI	NGO	US
Par	Tellner	EFPIA	Industry	EU
Peter	Theunissen	Medicines Evaluation Board	Regulator	EU
Martin	Traebert	Novartis	Industry	EU
Kostas	Tsarouhas	University Hospital of Larisa	Clinical	EU
Satoshi	Tsunoda	PMDA	Regulator	Japan
Janette	Turner	Humane World for Animals	NGO	UK
Jean-Pierre	Valentin	UCB / EFPIA	Industry	EU
Hugo	Vargas	Amgen	Industry	US
Jufeng	Wang	Pharmaron	CRO	China
Takashi	Yoshinaga	Eisai / JPMA	Industry	Japan

About the Organizers



**Humane
World for
Animals™**

Humane World for Animals —formerly called Humane Society International— works around the globe to replace animal experiments with innovative methods that don't use animals. Our teams in Australia, Brazil, Canada, the European Union, India, South Africa, South Korea, the United States and other key economies help change laws, regulations and scientific practices to end testing and research on animals and promote the development, acceptance and use of advanced non-animal methods. We lead the Animal-Free Safety Assessment Collaboration as well as the Biomedical Research for the 21st Century Collaboration, multi-sector, multi-country partnerships advancing animal-free science as the gold standard.



The Animal-Free Safety Assessment Collaboration (AFSA) is a unique multi-sector partnership between non-profit, corporate, and philanthropic leaders working to advance acceptance and use of animal-free safety science as a gold standard across regulatory frameworks worldwide – online at

AFSAcollaboration.org.



The Health and Environmental Sciences Institute (HESI Global) is a 501(c)(3) nonprofit organization operating to build science for a safer, more sustainable world through cross-sector global collaborative initiatives. With more than 30 years of experience bringing together thousands of scientists, HESI Global builds confidence and consensus in advancing technologies that impacts public health. Scientists from industry, academia and government agencies come together to share knowledge, data, and tools in a setting that allows for transparency and neutrality. This type of collaboration brings solutions that are greater than the sum of the individual parts. Collective use of resources finds efficiencies as well as consensus. Not only does this allow for sharing of resources but also sharing of expertise and building project ownership helping to ensure implementation in real-world settings. Work completed by HESI Global teams has a history of getting results including conducting studies that lead to FDA approved biomarkers and internationally accepted methodologies. HESI Global provides a bridge so that technological advances can be accepted into practice and make an impact public health.