Monday, September 19
Continuing Education Course descriptions are available on-line.

AM Courses
08:00–12:00
AM1: Intermediate Cardiovascular
AM2: Study Design—Considerations for Balancing the Scientific, Economic, and Regulatory Equation
AM3: Supplemental Safety Pharmacology Studies
AM4: Microsampling Techniques and Novel Applications in Exposure Assessment

Lunchtime Mini Course: 12:30–13:30
PM9: Lunchtime Mini Course: Case Studies—The Journey from PreClinical to Clinical

PM Courses
14:00–18:00
PM5: Drug Abuse Liability Testing
PM6: ECG Interpretation
PM7: Principles of Best Practice: How Will You Know When You Get There?
PM8: Safety Pharmacology Endpoints: Integration into Toxicology Studies

18:00-19:00 Welcome Reception

Tuesday, September 20

8:30-9:30 Keynote Address: Assessment of Nephrotoxicity - What We Know and What We Still Need to Know!
Professor W. Pfaller, MD, Innsbruck Medical University, Innsbruck, Austria

9:30-10:00 Annual Business Meeting

10:00-10:30 Break

Morning Sessions
10:30-12:00

Track A: Bridging Safety Assessment between Academia, Regulators, and Industry
Co-chairs: Jason Gill, PhD, University of Bradford, Bradford, United Kingdom and Kathy Derakhchan, PhD, Amgen, Inc., Thousand Oaks, CA, United States
Safety Pharmacology and progression in this area is dependent upon good integration between the three corners of the drug development triangle: Industry, Academia and Regulators. This session will provide information regarding strategies and initiatives to bridge the gaps between these three areas. An objective of this session is to provide perspectives and viewpoints in order to encourage discussion as to how to overcome the three main obstacles to progress: the restrictions of economics, the clarity of regulatory guidance and the limits of scientific knowledge.

10:30-11:00  IMI: Academia-Industry Interface  
*Michel Goldman, MD, PhD, Innovative Medicines Initiative, Brussels, Belgium*

11:00-11:30  Safety Assessment: The Regulators Perspective  
*Andrea Laslop, MD, Austrian CHMP Representative, Vienna, Austria*

11:30-12:00  Safety Assessment in an Academic Setting  
*Kevin Park, PhD, University of Liverpool, Liverpool, United Kingdom*

**Track B: Applied Technology—In Silico: Science in the IT Age**  
*Co-Chairs: Herbert Barthlow, AstraZeneca Pharmaceuticals, Wilmington, DE, United States and Tomas Mow, DVM, PhD, H. Lundbeck A/S, Copenhagen, Denmark*

This session will focus on the use of computer based software tools to aid in the prediction of safety pharmacology results prior to testing *in vitro* or *in vivo*. Additionally, the utility of data warehousing and its applications in the pharmaceutical industry will be presented.

10:30-11:00  The Use of *In Silico* Technology to Predict Secondary Pharmacology Effects during High Throughput Screening of Compounds  
*Scott Boyer, PhD, AstraZeneca Global Safety Assessment, Molndal, Sweden*

11:00-11:30  The Use of *In Silico* Technology in Cardiovascular Safety: Modeling of Action Potentials  
*Pr. Jean-Yves Le Guennec, PhD, Physiopathologie Cardiovascular, Montpellier, France*

11:30-12:00  Company Data Warehouses—How Useful Are They for Predicting Safety?  
*Claus Stie Kallesoe, MSci Pharm, Diploma Software Development, E-MBA, Research Informatics, H. Lundbeck A/S, Copenhagen, Denmark*

**Track C: Translation—Impact of Early Screens in Safety Strategy: Biomarkers**  
*Co-Chairs: Lothar Meister, BASF Switzerland, Basel, Switzerland, and Brian Guth, PhD, Boehringer Ingelheim Pharma, Biberach an der Riss, Germany*
This session aims at defining the impact that biomarkers –their discovery, daily use, importance- have had on the development strategy for the small-, medium-sized, and large pharmaceutical companies. The first speaker will give a detailed presentation of the decision-making variants which differentiate the world’s most active pharmaceutical companies; how do they use biomarkers in early development? Are they used in safety pharmacology, or as tools in efficacy pharmacology? In pre-clinical research, or during early clinical phases? Subsequent speakers will examine how biomarkers remain of value across species, from rodents to humans. Forward translation will be examined, whereby a biomarker discovered in a preclinical species is followed through late-phase development animal species. The last talk of the session will discuss reverse translation: biomarkers first used in Man, and introduced into early development programs as a tool to quantify safety and efficacy of a lead compound.

10:30-11:00  Decision-Making Process  
Philip Bentley, PhD, Novartis, East Hanover, NJ, United States

11:00-11:30  Predicting the Clinical Safety of the Sodium Channel Late Current Blocker Ranolazine from Preclinical Studies: No Loss in Translation  
John Shryock, PhD, Gilead Sciences, Palo Alto, CA, United States

11:30-12:00  Reverse Translation: Man to Preclinical Biomarkers (Renal and Hepatotoxicity)  
Stefan Sultana, MD, Pfizer Global Research & Development, Sandwich, Kent, United Kingdom

12:00-13:00  Lunch Break, Poster Viewing, and Networking

13:00-14:00  Networking and Poster Viewing  
Poster Judging

14:00-15:00  Invited Oral Communications 1-3

15:00-16:00  Networking and Poster Viewing

**Afternoon Sessions**

16:00-18:00

Track A: Integrating Safety Pharmacology in Toxicology  
Co-chairs: Eric Rieux, Data Sciences International, Les Angles, France, and Andrea Mitchell, DVM, PhD, Covance, Madison, WI, United States

This session will focus on integration of safety pharmacology endpoints into large and small animal toxicology studies. Integrating safety pharmacology into toxicology studies requires careful planning and additional considerations. Detailed focus will be on long term implications of implanted telemetry devices, when and how to integrate telemetry in primate and dog toxicology studies, and examples how to integrate respiratory and CNS evaluations in rodent toxicology studies.
16:00-16:30  To Implant or Not To Implant: What Are the Long-Term Implications of Implants
Klaus Weber, DVM, PhD, MS Biology, Harlan Laboratories, Inc., Basel, Switzerland

16:30-17:00  Long-term Implication of Implanted Telemetry Devices in Dogs
Ted Baird, PhD, MPI Research, Mattawan, MI, United States

17:00-17:30  When and How to Integrate Telemetry in Toxicology Studies
Wendy Halpern, DVM, PhD, DACVP, Genentech, South San Francisco, CA, United States

17:30-18:00  Integrating Safety Pharmacology End Points in Rodent Toxicology Studies – “The How”
Andrea Mitchell, DVM, PhD, Covance, Madison, WI

Track B: Applied Technology—Biomimetic Microsystems and Cellular Technologies: Potential Utility in Predicting Safety
Co-chairs: Anthony Bahinski, PhD, MBA, FAHA, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA, United States, and Khuram Chaudhary, PhD, GlaxoSmithKline, King of Prussia, PA, United States

This session will focus on recent technical advances in microsystem technologies and tissue engineering for the development of more predictive in vitro assays for drug screening and safety evaluation. The session will discuss the following topics: organs-on-chip technologies that reconstitute human organ functions (lung, gut, kidney), 3-D engineered tissues that model the lining of the airway and lungs, iPSC derived human cardiomyocytes for cardiotoxicity evaluation and engineered liver models.

16:00-16:25  Biomimetic Microsystems Technologies: Organs-on-Chips for Safety Evaluation
Don Ingber, MD, PhD, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA, United States

16:25-16:50  Screening for Cardiac Liabilities of Drug Candidates in Human iPSC-cardiomyocytes Using MEA and xCELLigence Cardio
Liang Guo, MD, Hoffmann-La Roche Inc., Nutley, NJ, United States

16:50-17:00  Break/Transition Time

17:00-17:30  Advances in the Assessment of Acute/Long-Term and Repeated Dose Inhalation Toxicity in Vitro
Samuel Constant, PhD, Epithelix Sarl, Geneva, Switzerland
17:30-18:00 Primary Hepatocytes in Hanging Droplets: Towards a Functional 3-D Microtissue Amenable to Toxicity Assays  
François Pognan, PhD, Novartis, Basel, Switzerland

Track C: Translation—Non-CV Adverse Effects  
Co-chairs: Dr. rer. nat. Franz J. Hock, Cordynamics, Dieburg, Germany, and Hai Ming Tang, Hoffmann-La Roche Inc., Nutley, NJ, United States

This session will focus on non-cardiovascular effects. It will deal with pre-clinical tools available for the assessment of pro-convulsive activity of new drugs, and their ability to predict safety issues across species. Both the industry and the regulatory agencies must deal with the meaning and potential translatability of these findings and both perspectives will be discussed. The second part of the session will continue exploring non-cardiovascular safety issues: the impact of endocrinological changes associated with stress of the safety assessment of compounds in development will be examined. Finally, the relatively low incidence of clinical respiratory safety issues is causing some to question whether preclinical respiratory safety issues are adequately detected across species; are our current models adequate, or are there really very few respiratory findings in the clinic?

16:00-16:30 Preclinical Assessment of Proconvulsive Drug Activity and Its Relevance for Predicting Adverse Events in Humans  
Marion Bankstahl, PhD, Department of Pharmacology, Toxicology, and Pharmacy, University of Veterinary Medicine Hannover, Hannover, Germany

16:30-17:00 Use of EEG in the Preclinical Assessment of Seizure Risk: A Regulatory Perspective  
Joseph C. Arezzo, PhD, Albert Einstein College of Medicine, Bronx, NY, United States

17:00-17:30 Stress Endocrinology  
Juergen Sandow, PhD, Centre of Pharmacology, Johann-Wolfgang-Goethe University, Frankfurt, Germany

17:30-18:00 Respiratory Safety Concerns  
Jürgen Pauluhn, PhD, DABT, Bayer Healthcare Research Center, Wuppertal, Germany

Wednesday, September 21

Morning Sessions  
8:30-10:00

Track A: Bridging Safety Assessment between Academia, Regulators, and Industry  
Co-chairs: Jason Gill, PhD, University of Bradford, Bradford, United Kingdom, and Niels-Christian Ganderup, MSc, Ellegaard Göttingen Minipigs, Dalmose, Denmark
Safety pharmacology has its roots in the field of pharmacology and still has strong ties to academic research. This session explores three areas under the headline of “new molecular and translational approaches” bridging these to safety pharmacology and animals studies. Being new and exploratory fields the presentations offer insights on emerging methods and approaches and, to some extent, challenges current views.

**8:30-9:00**

**Systems Pharmacology: As Important Dimension for Future Safety Assessment**
*Harrie Boonen, PhD, Faculty of Pharmaceutical Sciences, Copenhagen University, Copenhagen, Denmark*

**9:00-9:30**

**Human Tissue Approaches for Studying Drug Safety—Challenges and Opportunities**
*Mark O’Connor, PhD, Asterand, Herts, United Kingdom*

**9:30-10:00**

**miRNA and Cardiotoxicity**
*Daniele Catalucci, PhD, Institute for Biomedical Technologies, Milan, Italy*

**Track B: Other Perspectives of Arrhythmia Detection**
*Co-chairs: Rolf Beckmann, Bayer Schering Pharma AG, Berlin, Germany, Jean-Michel Guillon, Sanofi–Aventis, Vitry-sur Seine, France, and Kathy Derakhchian, PhD, Amgen, Inc., Thousand Oaks, CA, United States*

During the last decade U.S. FDA and pharmaceutical companies were focused on QT interval as a surrogate and have lost the importance of pre-clinical proarrhythmia models to move towards better predictors of drug-induced torsades de pointes arrhythmia. U.S. FDA and pharmaceutical companies’ perspectives on in-vitro and in-vivo pre-clinical models and how well these models will predict proarrhythmia effect in humans will be discussed.

**8:30-9:00**

**U.S. FDA Perspective: Case Study—Ranolazine**
*John Koerner, PhD, U.S. FDA, Silver Spring, MD, United States*

**9:00-9:30**

**Pharma Perspective: In Vitro/Vivo Proarrhythmia Models Used by the Industry**
*Gary Gintant, PhD, Abbott, Abbott Park, IL, United States*

**9:30-10:00**

**Other Parameters of Proarrhythmia Risk**
*Michael J. Curtis, PhD, FBPharmS, The Rayne Institute, St Thomas’ Hospital, King’s College, London, United Kingdom*

**Track C: Translation—Practical Implications of Chronopharmacology**
*Co-chairs: Maxim Soloviev, MD, PhD, Incyte Corporation, Wilmington, DE, United States, and Prof.Dr. med. Dr. h.c. Björn Lemmer, Management Board European Medicines Agency, Ruprecht-Karls-Universität Heidelberg, Institut fur Exp. & Klin. Pharmakologie & Toxikologie, Mannheim, Germany*
This session will discuss the following topics: circadian pattern of the cardiovascular system and its pathophysiological events; drug effects as a function of biologic timing; relations between chronotolerance and chronoefficacy of anticancer drugs; importance of circadian rhythm monitoring for providing early warnings of circadian disruption and subsequent systemic toxicities; drug delivery schedule adjustments according to the dynamic changes in biological functions in individual patients; age-related changes in circadian rhythm and its influence on pharmacodynamics and pharmacokinetics.

8:30-9:00  **Cardiovascular Clinical Chronopharmacology: The Ticking of the Biological Clock**  
Prof. Dr. med. Dr. h.c. Björn Lemmer, Management Board European Medicines Agency, Ruprecht-Karls-Universität Heidelberg, Institut fur Exp. & Klin. Pharmakologie & Toxikologie, Mannheim, Germany

9:00-9:30  **Implications of Chronopharmacology in the Elderly Patients**  
Bernard Bruguerolle, MD, PhD, Universite de la Mediterranee, Marseille, France

9:30-10:00  **Safe Cancer Chronotherapy: A Critical Determinant of Antitumor Efficacy**  
Francis Lévi, MD, PhD, INSERM, Villejuif, France

10:00-10:30  **Break**

**Track A: Applied Technology—Additional Safety Information to Be Gained from Safety Pharmacology Studies**  
Co-chairs: Jeffrey W. Richig, DVM, Anilab, LLC, Princeton, NJ, United States, and Bruce Morimoto, PhD, Allon Therapeutics, Vancouver, BC, Canada

This session provides additional information to aid researchers in cardiovascular safety concerning issues concerning cardiac contractility via the use of PV loops, as well as the use of biomarkers to predict acute drug-induced kidney injury. The usefulness of video technology in safety pharmacology studies will also be addressed.

10:30-11:00  **The Benefits of Synchronized EEG and Video Recording**  
Mario Sgro, MS, Covance Laboratories, In., Greenfield, IN, United States

11:00-11:30  **Acute Drug-induced Kidney Injury: Use of Biomarkers in a Safety Pharmacology Setting**  
Sabine Pestel, Boehringer Ingelheim Pharma GmbH & Co KG, Biberach an der Riss, Germany

11:30-12:00  **The Use of PV Loops as a Measure of Contractility**  
Robert L. Hamlin, DVM, PhD, The Ohio State University, Columbus, OH, United States
Track B: Applied Technology—The Early Detection of Impending Sudden Death
Co-chairs: Tomas Mow, DVM, PhD, H. Lundbeck A/S, Copenhagen, Denmark, and Eric Martel, PhD, CERB, Baugy, France

This session will discuss mechanisms and strategies for assessing drug-induced sudden death. A methodology for evaluating acute drug-induced organ failure and a strategy for determining whether death is associated with cardiovascular collapse, sudden cardiac death due to arrhythmia or cardiac arrest, respiratory failure or CNS convulsions/seizures will be presented. Detailed focus will be on in vitro and in vivo surrogate markers for predicting drug-induced torsades de pointes as well as an evaluation of species differences (dog versus minipig) in models of drug-induced arrhythmias.

10:30-11:00  Strategy for Assessing the Role of Acute Organ Failure in Drug-Induced Sudden Death
Dennis J. Murphy, PhD, DABT, GlaxoSmithKline, King of Prussia, PA, United States

11:00-11:30  The Electro-Mechanical Window as a TdP Risk-Marker following I_{ks}-Blockade in Different Species
Henk van der Linde, Janssen Pharmaceutica NV, Beerse, Belgium

11:30-12:00  Ex Vivo Pro-Arrhythmic Investigations in Göttingen Minipig Hearts—Comparison to Other Models
Morten Laursen, PhD, Exploratory Toxicology, Drug Safety, H. Lundbeck, Copenhagen, Denmark

Track C: Translation—Consortia Updates
Co-chairs: Pierre Lainée, DVM, PhD, AstraZeneca, Cheshire, United Kingdom, and Guillaume Froget, PhD, Porsolt and Partners Pharmacology, Boulogne-Billancourt, France

Modern scientific consortia accelerate the pace of research, and provide a framework within which the industry’s brightest scientists can cooperate in a non-competitive environment. Consortia have been influential in defining current best practices in safety pharmacology, and have been instrumental in assembling the present international safety guidelines. In this session, three major industry-academia consortia present the results of ongoing research projects in animal research and arrhythmia detection, as well as other preclinical safety issues of interest to both drug developers and regulators.

10:30-11:00  Conscious Dog Cardiovascular Telemetry Predictive Value to Man as Defined by the Animal Model Framework
Lorna Ewart, PhD, AstraZeneca, Macclesfield, United Kingdom
11:00-11:30  Translation of Drug-induced QTc Interval Prolongation from Early Discovery to Clinical Development  
Vincent Dubois, The Leiden University, Leiden, Netherlands

11:30-12:00  HESI Pro-Arrhythmia Project  
John Koerner, PhD, U.S. FDA, Silver Spring, MD, United States

12:00-13:00  Lunch Break, Poster Viewing, and Networking

13:00-14:00  Networking and Poster Viewing

Special Session: Environmental Pharmacology  
Moderator: Brian Guth, PhD, Boehringer Ingelheim Pharma, Biberach an der Riss, Germany

Safety pharmacology and toxicology concerns itself with target-related and off-target effects that attempt to predict side-effects associated with the clinical use of new drugs. Such effects may be related to plasma or tissue levels of the drug and we assume that as the drugs are eliminated from the body or metabolized, the effects disappear and our worries are over. But are they? Drugs entering the environment may present additional challenges and problems and this special session will include two fascinating cases related to medical products appearing in the environment where most of us would not expect them. The consequences of such environmental contamination with our potent new and old drugs can be enormous, as these two presentations will show.

13:00-13:30  Safety Assessment of Residues of Veterinary Medicinal Products in Foodstuffs of Animal Origin  
Ivo Schmerold, Institute of Pharmacology and Toxicology, University of Veterinary Medicine, Vienna, Austria

13:30-14:00  Diclofenac Related Decline in Southasian Vulture Populations—Facts and Options  
Jürgen Dämmgen, DVM, Boehringer Ingelheim Pharma, Ochsenhausen, Germany

14:00-15:00  Invited Oral Communications 4-6

15:00-16:00  Networking and Poster Viewing

Afternoon Sessions
16:00-18:00

Track A: Best Practices in Safety Pharmacology
Co-chairs: Eric Rieux, Data Sciences International, Les Angles, France, and Andrea Mitchell, DVM, PhD, Covance, Madison, WI, United States

This session will focus on current best practices in Safety Pharmacology studies from a broad perspective of viewpoints, industry, regulation and business development, covering the implication and benefits of carrying Best Practices. The session will provide an update from the Best Practice industry consortium. A view from the regulatory side will demonstrate how best practices in Safety Pharmacology compare to actual best practices to get to FIH. A business case will be made to carry best practices studies when doing due diligence and in-licensing.

16:00-16:30  Best Practice Consortia Update  
Derek Leishman, PhD, Eli Lilly & Co., Indianapolis, IN, United States

16:30-17:00  Best Regulatory Practice in Safety Pharmacology  
Walter Janssens, Federal Agency for Medicines and Health Products, FAGG, Beerse, Belgium

17:00-17:30  Raising the Bar of Best Practices – Due Diligence and the Implications of Poor Safety Pharmacology Data  
Rob Towart, PhD, Johnson & Johnson, Beerse, Belgium

17:30-18:00  Pharmacological Mechanism-Based Safety Prediction  
Darrell R. Abernethy, MD, PhD, U.S. FDA, Silver Spring, MD, United States

Track B: Applied Technology—Sleep Disorders: From Technological Advances to Market
Co-chairs: Ard Teisman, PhD, Janssen Pharmaceutica NV, Beerse, Belgium, and Tomas Mow, DVM, PhD, H. Lundbeck A/S, Copenhagen, Denmark

The objective of this session is to discuss the technical advances involved in the evaluation of the sleep/wake cycle and data analysis, the importance of using the right technology for the right species when evaluating the sleep/wake cycle and discuss sleep wake EEG from a clinical/translational point of view. The session may bring new aspects that have a potential impact on assessing drug safety.

16:00-16:30  Technical Advances Involved in the Evaluation of Sleep/Walk Cycle and Data Analysis  
Pim Drinkenburg, PhD, Janssen R&D, Pharmaceutical Companies of Johnson & Johnson, Beerse, Belgium

16:30-17:00  The Importance of Using the Right Technology for the Right Species When Evaluating the Sleep/Wake Cycle  
Pascal Champeroux, PhD, CERB, Baugy, France
17:00-17:30  **Sleep Wake EEG—A Clinical/Transitional Point of View**  
Gé Ruigt, Merck, Sharp and Dohme, Oss, The Netherlands

17:30-18:00  **Developing a Compound for Sleep Disorders—A Case Study**  
Bjarke Ebert, PhD, DSc, Medical Affairs-Mood & Anxiety Disorders, H. Lundbeck, Copenhagen, Denmark

**Track C: Translation—In Vitro Safety Profiling Strategies**  
Co-chairs: Gül Erdemli, MD, PhD, Novartis Institutes for BioMedical Research, Inc., Cambridge, MA, United States, and Lothar Meister, BASF Switzerland, Basel, Switzerland

Angled toward strategic consideration of Discovery-phase findings, this session will examine the importance of screening results on the go-no go decision process in the pharmaceutical industry. What value is given to high-throughput pharmacology? Are the findings sufficient to alter the development of a group of compounds, or do we use in vitro data to design in vivo studies, and then consider the in vivo safety findings in our decision-making process? Early discovery experiments are often mechanism-driven; are those mechanisms used to predict potential safety issues, and interrogate these issues specifically using high-resolution assays? Do we keep our usual models and assays, but look for potential safety issues a posteriori? Two detailed case studies will illustrate how discovery-phase information can be used to mitigate risk and avoid late-development failure.

16:00-16:30  **Identification of Risk, and Mitigation of Risk: From In Vitro Results to In Vivo**  
Gül Erdemli, MD, PhD, Novartis Institutes for BioMedical Research, Inc., Cambridge, MA, United States

16:30-17:00  **Case Study: Just How Much In Vitro Information Do We Consider?**  
Martin Traebert, PhD, Novartis Pharma AG, Basel, Switzerland

17:00-17:30  **In Vitro, In Vivo Relationships for Drug Induced Phospholipidosis: Mechanistic Insights and Case Studies**  
Holger Fischer, PhD, F. Hoffmann-La Roche Ltd, Basel, Switzerland

17:30-18:00  **Translating in vitro Mitochondrial Toxicity to Predict Cardiovascular Safety**  
Kendall B. Wallace, PhD, DABT, FATS, University of Minnesota Medical School, Duluth, MN, United States

**Thursday, September 22**

**Morning Sessions: “Hot Topics”**  
8:15-10:15

**Track A: Advanced Therapeutic Medicinal Products—Safety of Cell Therapeutics**
Co-chairs: Rolf Beckmann, PhD, Bayer Schering Pharma AG, Berlin, Germany, and Kathy Derakhchan, PhD, Amgen, Inc., Thousand Oaks, CA, United States

This session will focus on stem cells as therapeutics. Issues include early development of stem cells as medicinal products, regulatory aspects, an industry case study, and imaging of cell therapies in safety pharmacology assessment.

8:15-8:45 Preclinical Considerations in the Development of Stem Cells as Medicinal Products
Jens Reinhardt, PhD, Paul Ehrlich Institute, Langen, Germany

8:45-9:15 Regulator's View
David Jones, MHRA, London, United Kingdom

9:15-9:45 Industry Case Story: Stem Cell-Based Therapies for the Treatment of Cardiovascular Diseases
Rainer Marksteiner, PhD, Innovacell, Biotechnology AG, Innsbruck, Austria

9:45-10:15 Stem Cell Imaging
Ludwig Aigner, PhD, Paracelsus Medical University, Head of the Institute of Molecular Regenerative Medicine, Salzburg, Austria

Track C: Translation—Better Clinical Predictions Using Better Preclinical Models
Co-chairs: Pierre Lainée, PhD, DVM, AstraZeneca, Cheshire, United Kingdom, and Dany Salvail, PhD, IPS Therapeutique, Inc., Quebéc, Canada

Preclinical safety pharmacologists and clinicians view the concept of “patient” in different ways: To a preclinical safety pharmacist, a patient may appear as a slightly compromised evolution of a healthy preclinical safety model. On the other hand, to a clinician, a patient is likely the sum of concomitant pathophysiologicals, complementary impairments, and disjointed co-morbidities. Do we grasp the entirety of our end target—the patient to be treated? Is it possible that the preclinical safety toolbox is based on a wrong definition of “a patient?” And if the preclinical toolbox must be adjusted to account for the fullness of “a patient,” should the safety pharmacology community refine its use of the current healthy models, or discard cell-based and animal models completely, and replace these healthy systems with clinically-relevant, compromised animals models of disease? Following an examination of the definition of a diabetic patient by a clinician, the pros and cons of the “refinement approach” will be weighed against the possibility of using compromised animal models to increase the translatability of safety information from pre-clinical development to late-phase clinical trials. A panel discussion will follow to reveal industry trends and regulatory preferences.

8:15-8:45 The Fantasies and Realities of Diabetes and Diabetologists
John Cleland, University of Hull, Cottingham, United Kingdom
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:45-9:15</td>
<td><strong>Cardiovascular Safety Assessment for Diabetic Therapeutics</strong>&lt;br&gt;James Hennan, PhD, Bristol-Myers Squibb, Pennington, NJ, United States</td>
</tr>
<tr>
<td>9:15-9:45</td>
<td><strong>Safety Pharmacology Support of Paediatric Clinical Development</strong>&lt;br&gt;Nick McMahon, PhD, GlaxoSmithKline R&amp;D, Ware, United Kingdom</td>
</tr>
<tr>
<td>9:45-10:15</td>
<td><strong>New Drug Therapies for Geriatrics: Safety and Efficacy Challenges in a Complex Patient Population</strong>&lt;br&gt;William Evans, PhD, GlaxoSmithKline, Research Triangle Park, NC, United States</td>
</tr>
<tr>
<td>10:15-10:30</td>
<td><strong>Break</strong></td>
</tr>
<tr>
<td>10:30-11:00</td>
<td><strong>Junior &amp; Student Travel Awards, and Distinguished Service Award Presentation</strong></td>
</tr>
<tr>
<td>11:00-12:00</td>
<td><strong>Plenary: Value of Safety Pharmacology/What the Future Holds</strong>&lt;br&gt;Colin Dollery, BSc, MB, ChB, FRCP, GlaxoSmithKline, London, United Kingdom</td>
</tr>
<tr>
<td>12:00-13:30</td>
<td><strong>Lunch Break (Lunch on your own)</strong></td>
</tr>
</tbody>
</table>