WC12

Program

WC12
3Rs OVER THE EDGE

8 PLENARIES
6 PARALLEL TRACKS
400 PRESENTATIONS
400 POSTERS
SOCIAL EVENTS

Enclosed document contains >95% complete version of the program with session descriptions, chairs, and speakers.

Please continue to monitor our website for updates.

If you are a presenter and have not registered yet, please do so immediately.

Symposia/Workshops

Regulatory Acceptance and Global Harmonization

- S400- Adversity Reinvented: Non-Animal Frameworks for Predictive & Protective Decision-Making
- S401 - Phase-in of Non-Animal Methods by the Pharmaceutical Industry
- S402 - Unlocking a New NAM-Based Paradigm: Transforming the Evaluation of Agrochemicals
- S403 - Dedicated Acute Lethality Necessary with NAMs? Cross-Sector 3Rs Efforts in Acute Toxicity
- S404 - Is it Good Enough? Establishing Scientific Confidence in New Approach Methods
- S045 - Meeting at the Falls: ICATM Partner Updates
- S406 - Regulatory Acceptance of NAMs in EcoTox – How Do We Get there?
- S407 - The 3Cs: Curating & Cultivating Change for Faster Integration of NAMs in Animal-Free Policy Making
- S408 - NAMs in Developmental Neurotoxicity – Difficult Road Leading to Change
- S409 - Warp-Speed Replacement? Remaining Challenges in Vaccine and Biologics Batch Testing
- S410 - NAMs in Practice: Fit-for-Purpose NGRA Across Sectors
- S411 - A Decade of Progress: Lessons from Animal-Free Cosmetics Policy Worldwide
- S412 - Putting All the Chips on the Table! Doubling Down on Regulatory Acceptance of MPS

Next-Gen Education

- S413 - An Auspicious Outreach Plan for Adverse Outcome Pathways in Higher Education
- S414 - Comp-Tox in Education: Data Literacy for Next-Generation Risk Assessment
- S415 - Improving Competence and Trust: Implementing the 3Rs in Practice
- S416 - Replacement at the Forefront - Implementing Animal Free Science Education
- S417 - Bringing the 3Rs into the Classroom: It's Never Too Early
- S418 - It's How You Say It! Effective Science Communication to Promote Animal Replacement
- S419 - Implementing the 3Rs in Higher Education
- S420 - Early Career Researchers: Access to NAMs, Funding Opportunities, and Career Paths
- S421 - Waste Not! Training the Trainers for Better Experiments
- S422 - Of Mice and Not Men: Empowering Next-Gen Scientists for Careers in NAMs

Ethics, Welfare, Policies, and Regulations

- S423 - Show Me the Animal Data! Animal Methods Bias in Publishing and Funding
- S424 - Monkeys on the Edge: Ethical Research with Nonhuman Primates
- S425 - Contemporary Challenges for the Animal Care Committeess
- S426 - More Than the 3Rs – What Should Principles of Animal Ethics Look Like Today?
- S427 - Role of Roadmaps to Accelerate the Transition to Animal-Free Science
- S428 - Transparency and Openness as Tools to Push the 3Rs Over the Edge
- S429 - A World of 3R Centres: Unity in Diversity
- S430 - Science for Policy, Policy for Science: Engaging Policymakers to Advance Science & Ethics
- S431 - Industry, Regulators, and Human Health: Whose Onus is it to Defend Animal Data?

Human-Centred Biomedical Research

- S432 - Replacement in Action – Animal-Free Reagents, Methods, and Standards
- S433 - Disease-in-a-Dish? MPS for Disease Modelling
- S434 - In-a-Dish or On-a-Chip? Complex In Vitro Models
- S435 - Future of Multi-Scale Modelling and Simulation in Disease and Toxicology
- S436 - The Human Lung: Infection Biology and Inhalation Toxicology
- S437 - Challenging the Status Quo: Roadmap to Accelerate Transition to Animal-Free Research

Refinement and Impact on Science

- S438 - Refinement's Impact on Research – A Critical Review
- S439 - Refinement in Challenging and Constrained Situations
- S440 - Gegevens worden opgehaald. Wacht een paar seconden en knip of kopieer vervolgens opnieuw.
- S441 - Reducing Severe Suffering: Time for a Strategic Approach
- S442 - From Systematic Reviews to Pre-Registration: Streamlining for Better Research
- S443 - 21st Century Animal Welfare Assessment
- S444 - Smart Statistics to Reduce and Refine Animal Use
- S445 - Refined Mouse Handling: Evidence, Barriers, and Solutions to Practical Use

21st Century Predictive Toxicology

- S446 - Chems-on-Chips: MPS for Organ Tox & Chemical Risk Assessment
- S447 - What's in the Mix? New Approach Methods for Chemical Mixtures Risk Assessment
- S448 - Tipping Point in Omics: Transcriptomic Points of Departure (tPODs) and QIVIVE in Regulatory Decision-Making
- S449 - ASPIS: From Molecular Toxicology to Regulatory Acceptance, the Next Step for Animal-free Testing
- S450 - New Approach Methods for Developmental and Reproductive Toxicity Testing
- S451 - Physiologically-Based Pharmacokinetic Modelling for Chemical Risk Assessment
- S452 - On the Runway: Interactive Predictive Tox Models
- S453 - New Approaches to Genotoxicity Testing and Risk Assessment
- S454 - Predictive Toxicology: Data, Development, Delivery, and Application
- S455 - Progress in Quantifying Adverse Outcome Pathways to Support Next Generation Risk Assessment
- S456 - Advances in NAMs for EcoTox Testing & Risk Assessment, Part 1: Biological Models and Techniques
- S457 - Advances in NAMs for EcoTox Testing & Risk Assessment, Part 2: Computational Tools and Frameworks
- S458 - Artificial Intelligence (AI): Current Advancements and Applications in Advancing the 3Rs
- S459 - What's New in Skin Sensitization?

Posters

Regulatory Acceptance and Global Harmonization

TUESDAY

Next-Gen Edcation

TUESDAY

Ethics, Welfare, Policies, and Regulations

TUESDAY

Human-Centred Biomedical Research

MONDAY

Refinement and Impact on Science

MONDAY

21st Century Predictive Toxicology

WEDNESDAY

Regulatory Acceptance and Global Harmonization

- **S400- Adversity Reinvented: Non-Animal Frameworks for Predictive & Protective Decision-Making**
- **S401 - Phase-in of Non-Animal Methods by the Pharmaceutical Industry**
- **S402 - Unlocking a New NAM-Based Paradigm: Transforming the Evaluation of Agrochemicals**
- **S403 - Dedicated Acute Lethality Necessary with NAMs? Cross-Sector 3Rs Efforts in Acute Toxicity**
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- **S412 - Putting All the Chips on the Table! Doubling Down on Regulatory Acceptance of MPS**

Session S400 (Symposium)

Monday, August 28, 14:00 – 16:00

Adversity Reinvented: Non-Animal Frameworks for Predictive & Protective Decision-Making

Chairs: **Patience Browne**, OECD & **Donna Macmillan**, Humane Society International

Adversity has traditionally been assessed using in vivo toxicity tests, however, with the advent of sophisticated testing strategies using combinations of New Approach Methods (NAMs) and increasingly target-relevant test systems, adversity must be reinvented. Although NAMs face a number of challenges for demonstrating their suitability in making regulatory decisions, there are now many examples of their use within Integrated Approaches to Testing and Assessment or Next-Generation Risk Assessment frameworks designed to be both predictive and protective of human health and the environment. This session will discuss adversity, the integration of NAMs in regulations, and examples of NAM-based decision making.

#36 Introduction to the Traditional Concept of In Vivo Adversity
Kim Boekelheide; Brown University

#162 In the Room Where It Happens: Assessing Pesticide Hazard
Alison Harrill, U.S. Environmental Protection Agency

#150 Reducing the Burden on Animals and the Heart: An Evidence-Based Approach to Cardiotoxicity Assessment
Alexandra Schaffert, Institute of Medical Biochemistry, Medical University Innsbruck, Innsbruck, Austria

#347 Critical needs for non-animal regulatory hazard assessment: a REACH perspective
Tomasz Sobanski, European Chemicals Agency

#206 The process and importance of integrating NAMs in GHS
João Barroso, European Commission, Joint Research Centre

#315 AOP-based in vitro adversity to predict in vivo effects
Nicole Kleinstreuer, NIEHS/DTT/PTB/NICEATM

#183 Rethinking NAM Adversity
Patience Browne, OECD

#381 Tiered approaches for next generation risk assessment (NGRA) of chemicals: Two case studies
Maria Teresa Baltazar, Safety and Environmental Assurance Centre, Unilever

#359 Development of a non-animal Integrated Approach to Testing and Assessment for Acute Aquatic Toxicity for Classification and Labelling
Donna Macmillan, Humane Society International

Session S401 (Symposium)

Monday, August 28, 14:00 – 16:00

Phase-in of Non-Animal Methods by the Pharmaceutical Industry

Chairs: **Joanne Storey**, GSK & **Kirsty Reid**, EFPIA

The purpose of this session is to explore technological frontiers, ethical frameworks, and regulatory acceptance of new approach methodologies in the pharmaceutical industry. Methodologies utilized in the discovery and development of human medicines will be presented covering demonstrable application to date, innovative technologies, future concepts and remaining hurdles. Approaches will be covered by phase, from early discovery, then to development, including safety and toxicological testing of pharmaceuticals up to regulatory acceptance, followed by the quality control of vaccines manufacture. The session will end with a broad presentation on additional challenges facing the large-scale uptake of methodologies and the future vision.

#258 An integrated research and testing strategy to go beyond the 3Rs
Kevin Thibault-Duprey, Sanofi

#582 The progression of MPS utilization in drug Discovery
Jason Ekert, UCB Pharma

#680 Making NAMs the ethical solution to animal use in the pharmaceutical industry
Aurélie Thomas, AstraZeneca

#269 Collaborative initiatives supporting reduction of NHP use in drug development
Smitha PS Pillai, Pfizer

#303 Support of first-in-human clinical trials with human in vitro toxicity testing
Mario Beilmann, Boehringer Ingelheim Pharma GmbH & Co KG., Nonclinical Drug Safety, Biberach, Germany

#175 Non-Animal methods in quality control of vaccine testing batch release
Shahjahan Shaid, GSK Marburg

#791 Animal-free methods in life sciences and healthcare - successes and challenges
Kerstin Kleinschmidt-Dörr, Merck KGaA Darmstadt, Germany

#801 Advancing acceptance of NAMs for regulatory testing of medicinal products in the EU
Sonja Beken, European Medicines Agency

Session S402 (Workshop)

Wednesday, August 30, 9:00 – 10:30

Unlocking a New NAM-Based Paradigm: Transforming the Evaluation of Agrochemicals

Chairs: **Gina Hilton**, PETA Science Consortium International & **Marc Corvaro**, Corteva Agriscience

The rapidly growing human population, increasing climate-related pressures, and associated scientific advancements in agriculture and safety science are heightening the demands for sustainable, safe and effective crop protection solutions. Although the existing agrochemical safety evaluation paradigm, which relies on traditional toxicology methods, is well established, it is unlikely to meet the emerging challenges of a developing and ever-expanding sustainable agriculture. This session will foster a discussion on how to rethink agrochemical safety evaluation to make it fit-for-purpose, integrative of new science, and explore the applicability of new approaches for regulatory decisions in the face of changing global and local needs.

#365 Agrochemical evaluation for the 21st century: achieving the vision
Raechel Puglisi, Health and Environmental Sciences Institute

#704 A next-generation framework for agrochemical risk assessment
Gina Hilton, PETA Science Consortium International e.V.

#629 Achieving an Animal-Free Product Safety Assessment
Richard Currie, Syngenta Ltd

#93 Defined Approaches for GHS Categorization to Assess Eye Irritation Potential of Agrochemical Formulations
Amber Daniel, Inotiv

#300 A "question-box" approach: practical considerations for NAM-based agrochemical safety assessment
Marco Corvaro, Corteva Agriscience Italia, Rome, ITA

#566 Regulatory opportunities and challenges to reduce testing on animals in a next-generation risk assessment
Deborah Ramsingh, Health Canada

Session S403 (Symposium) - **Session sponsored by Reckitt**

Monday, August 28, 9:00 – 10:30

Advancements and Opportunities in the Replacement, Reduction and Refinement of Acute Toxicity Tests

Chairs: **Fiona Sewell**, NC3Rs & **Glenn Myatt**, Instem

Acute toxicity tests are currently conducted as part of global regulatory risk assessment and hazard classification packages for industrial chemicals and agrochemicals. These tests are generally carried out in rodents, fish and birds. Historically, the endpoint of acute toxicity studies (via varying exposure routes) has been mortality. These studies are therefore associated with severe suffering and present a great opportunity for the application of 3Rs principles. This session will highlight alternative models and approaches that are accepted, being evaluated or are currently in development to reduce the reliance on animals for provision of acute toxicity data across sectors.

#441 Refining and removing global mammalian acute toxicity testing requirements
Fiona Sewell, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)

#467 Replacing animal use in the acute toxicity 'six-pack' for industrial chemicals and pesticides – US perspective
Lindsay O'Dell, U.S. EPA

#166 A step-by-step approach for assessing acute oral toxicity without animal testing for cosmetic ingredients
Hajime Kojima, National Institute of Health Sciences (NIHS)

#21 Acute Toxicity In Silico Models and Expert Reviews
Glenn Myatt, Instem

#91 Development and Curation of an Acute Inhalation Toxicity Database
Emily Reinke, Inotiv-RTP

#387 Evaluation of an in silico model for predicting pesticide acute oral toxicity
Patricia Bishop, The Humane Society of the United States

#710 Applying the 3Rs to Fish Acute Toxicity Tests in an Industrial Chemical Company
Sarah Hughes, Shell Global Solutions (US) Inc.

Session S404 (Symposium)

Wednesday, August 30, 14:00 – 16:00

Is it Good Enough? Establishing Scientific Confidence in New Approach Methods

Chairs: **Anne Gourmelon**, OECD & **Anna van der Zalm**, PETA Science Consortium International e.V.

To reduce use of animals in toxicity testing, while more effectively protecting human health and the environment, there is a need to define criteria to establish scientific confidence in new approaches. While the principles of validation of new approaches, established by the Organisation for Economic Co-operation and Development, remain true today, the processes by which they are evaluated need to be revisited to improve the timeliness of their uptake. This session will explore collaborative projects led by international scientists from regulatory, industry and non-governmental organizations to update the processes for evaluating new approaches and ensuring their readiness for regulatory use.

#72 The current and future role of OECD in chemicals assessment
Anne Gourmelon, OECD

#313 Human Biological Relevance: Topical Toxicity Case Studies
Nicole Kleinstreuer, NIEHS/DTT/PTB/NICEATM

#205 The future of validation: It's not all about ring trials
João Barroso, European Commission, Joint Research Centre

#573 Increasing Scientific Confidence through Good Practice in the Application of Mechanistic Data
Bette Meek, University of Ottawa

#156 Inference Model Performance: A Key Component for Scientific Confidence Frameworks for NAMs
Richard Becker, American Chemistry Council

#240 Technical Framework for Enabling High Quality Measurements in New Approach Methodologies (NAMs)
Elijah Petersen, NIST

#52 Accelerating the transition to animal-free NGRA: a transformative governance approach
Merel Ritskes-Hoitinga, Utrecht University, Faculty of Veterinary Medicine, IRAS tox

#508 Evaluating New Approach Methodologies for use in Next Generation Risk Assessment
Alistair Middleton, Unilever

Session S405 (Symposium)

Thursday, August 31, 9:00 – 10:30

Meeting at the Falls: ICATM Partner Updates

Chairs: Nicole Kleinstreuer, NICEATM & **Michele Regimbald-Krnel**, Health Canada

The International Cooperation on Alternative Test Methods (ICATM) was created to foster dialog among national validation organizations. This dialog facilitates international cooperation in the critical areas of validation studies, independent peer review, and development of harmonized recommendations. Representatives from ICATM members and partner organizations will present updates on progress on NAMs, with particular emphasis on regulatory acceptance and implementation in their respective areas.

#356 Evolving regulatory frameworks require methods that are both innovative and scientifically valid
Valérie Zuang, European Commission - Joint Research Centre

#126 Update on recent activities at JaCVAM
Yoko Hirabayashi, The Center for Biological Safety and Research (CBSR), the National Institute of Health Sciences (NIHS)

#482 The Progress of Alternative Methods in Brazil: Activities of BraCVAM
Octavio Presgrave, Institute of Science and Technology in Biomodels (ICTB), Oswaldo Cruz Foundation (FIOCRUZ), Rio de Janeiro, RJ, Brazil, ;Brazilian Centre for Validation of Alternative Methods (BraCVAM), Oswaldo Cruz Foundation (FIOCRUZ), Rio de Janeiro, RJ, Brazil

#114 KoCVAM's accomplishments in development of the alternative methods listed in the OECD TGs and support for the introduction and utilization of non-animal alternative methods in Korea
Jae-ho OH, Toxicological Screening & Testing Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Cheongju, Chungbuk, Republic of Korea

#696 Update on Canada's efforts to reduce the reliance on animal toxicity testing,
Michèle Régimbald-Krnel, Director, Environmental Health Science and Research Bureau, Healthy Environments and Consumer Safety Branch, Health Canada

#337 Regulatory Acceptance and Implementation of New Approach Methodologies in Taiwan
Pinpin Lin, National Institute of Environmental Health Sciences, National Health Research Institutes, Taiwan

#185 The OECD and the Future of Risk Assessment
Patience Browne, OECD

#319 ICCVAM Activities 5 Years into the Strategic Roadmap: Successes and Opportunities
Nicole Kleinstreuer, NICEATM

Session S406 (Workshop)

Monday, August 28, 11:00 – 12:30

Regulatory Acceptance of NAMs in EcoTox – How Do We Get there?

Chairs: **Cristina Inglis**, Health Canada & **Kellie Fay**, US Environmental Protection Agency

Regulatory acceptance of new approach methods for ecotoxicology can face several barriers, including insufficient validation for different use contexts, a lack of standardization in data processing and uncertainties in interpretation or extrapolation to multiple species. This workshop will cover topics such as the OECD path to mutual acceptance of data, lessons learned during the development of the OECD 249 rainbow trout gill cell-based assay, using Interspecies Correlation Estimation models for extrapolation of acute toxicity in aquatic organisms, understanding the relationship between transcriptomic points of departure and traditional fish toxicity endpoints such as endocrine disruption. Join us for this interactive session, where we will cover these topics with Q&A, live surveys and more!

#184 OECD Path to Mutual Acceptance of NAM Data
Patience Browne, OECD

#569 Lessons learned on validation, acceptance and uptake of the rainbow trout gill cell-based assay (RTgill-W1)
Kristin Schirmer, ETH Zürich, Department of Environmental Systems Science, ;Swiss Federal Institute of Aquatic Science and Technology/Utox, ;EPF Lausanne, School of Architecture, Civil and Environmental Engineering

#120 Accepting the separation of toxicology and statistics in New Approach Methodologies in Ecological Risk Assessment
Sandy Raimondo, US Environmental Protection Agency

#659 Establishing Scientific Confidence of Cross-Species Extrapolations through Case Studies
Adriana C Bejarano, Shell Global Solutions Inc.

#780 Comparing transciptomic, metabolic and behavioural points of departure in zebrafish larvae exposed to a diverse suite of toxicants
Jason O'Brien, Environment and Climate Change Canada

Session S407 (Workshop)

Wednesday, August 30, 14:00 - 16:00

The 3Cs: Curating & Cultivating Change for Faster Integration of NAMs in Animal-Free Policy Making

Chairs: **Beta Montemayor**, Cosmetics Alliance Canada & **Tim Singer**, Health Canada

In their landmark paper "Toxicity Testing in the 21st Century – A Vision and a Strategy" from 2007, Krewski et al., 2007 reflects on how "pivotal events" can "set the stage for transformative change". In the case of moving the fields of toxicology and regulatory risk assessment into the 21st century, this paper speaks to "building confidence in new approaches" and "facilitating institutional change" – in this regard, enabling regulatory acceptance is a key pillar of this vision and strategy.

With the rapid proliferation of NAMs and with continued technical evolutions and innovations maturing at a furious pace, the need and time for direct integration and recognition of NAMs into regulatory policy frameworks is acutely becoming one of the most pressing hurdles for delivering on the full potential of the 3Rs. Although significant progress has been made in the development of NAMs over the past 15+ years; application, integration and/or uptake of these tools by regulatory authorities remains relatively slow and very selective to date. Authorities have sought to build confidence in NAMs through case studies and scientific dialogue, but as yet, there remains a strong dependence on animal-based approaches and/or data considerations as a familiar backstop to facilitate regulatory-decision making. While some jurisdictions have been "early adopters" of maturing NAMs (typically considered as additional lines of evidence alongside more traditional assessment approaches) some current global coordination policies, such as Mutual Acceptance of Data, have moved much more slowly. In short, regulatory toxicology has made progress in, but has not yet fully embraced or delivered on, achieving the "institutional change' required to realize the Tox 21 vision.

This interactive workshop will look to foster an emerging dialogue beyond WC-12 and bring focus to bridging NAMs with science policy making by identifying specific and achievable steps countries and key stakeholders could take over the next 3 years, to accelerate their widespread acceptance and thereby enable integration into domestic regulatory frameworks. This workshop will kick-off with presentations from an esteemed panel whom will present reflections from around the world and offer perspectives regarding key challenges and policy adoption challenges and/or priorities that need to be addressed over the short-, medium- and relatively long-term, including re-think validation needs to encourage the hastening of the pace of adoption of NAMs into regulatory policy. An audience-lead, Q&A session will follow which will shape an interactive dialogue to help identify 3 tangible principles and commitments for action (the 3 Cs) that together, the World Congress Community can collectively prioritize over the next 3 years, to help advance and accelerate the pace of regulatory adoption and integration of NAMs to support decision-making.

Workshop Panel:
Daniel Krewski, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa
Maurice Whelan, EURL-ECVAM
Olivia Osborne, Science Evidence and Research, UK Food Standards Agency
Patience Brown, Organisation for Economic Cooperation and Development (OECD)
Tala Henry, US EPA Office of Pollution Prevention and Toxics

Session S408 (Symposium)

Tuesday, August 29, 11:00 – 12:30

NAMs in Developmental Neurotoxicity – Difficult Road Leading to Change

Chairs: **Ellen Fritsche**, Leibniz Research Institute for Environmental Medicine & **Helena Hogberg**, NICEATM/NIEHS

It is well established that exposure to environmental chemicals is contributing to the significant increase in prevalence of neurodevelopmental disorders in children. However, there are limited developmental neurotoxicity (DNT) information on chemicals in use due to challenges and limitations with the current in vivo guidelines. Therefore, the regulatory bodies consider a battery of new approach methods (NAMs) to replace and reduce DNT animal experiments and close important data gaps on DNT potential of chemicals. This session will describe development of the OECD guidance document of NAMs for DNT testing, data analyses and interpretation, regulatory and industrial application, and future directions.

#489 The DNT IVB – a challenging road leading to change
Ellen Fritsche, IUF - Leibniz Research Institute for Environmental Medicine, DNTOX GmbH

#310 Generating Screening Level Developmental Neurotoxicity (DNT) Information of Chemicals in a New Approach Methods (NAMs) Battery
Helena Hogberg, NICEATM, PTB, DTT, NIEHS

#588 Comparison of dose-response modeling pipelines for developmental neurotoxicity (DNT) new approach methods (NAMs)
Kelly Carstens, US Environmental Protection Agency

#453 Mapping of DNT NAMs' signaling pathways in human physiology and disease
Eliska Kuchovska, IUF - Leibniz Research Institute for Environmental Medicine

#529 Prediction of developmental neurotoxicity using a read across approach
Yukuto Yasuhiko, Division of Pharmacology, National Institute of Health Sciences

#615 Early Screening Using Cheminformatics in an Integrated Assessment for Neurotoxicity/Developmental Neurotoxicity
Sue Marty, Dow, Inc.

Session S409 (Symposium)

Tuesday, August 29, 11:00 – 12:30

Warp-Speed Replacement? Remaining Challenges in Vaccine and Biologics Batch Testing

Chairs: **Laura Viviani**, SciEthiQ & **Elliot Lilley**, NC3Rs

Biologicals such as vaccines, cytokines, enzymes, and hormones are tested extensively post-licensure as part of routine quality control and batch release testing to ensure the safety and potency of products. It is estimated that more than 10 million animals a year are used worldwide in biologics development and that 80% of these animals are used for quality control and batch release testing. In recent years, there has been considerable progress towards adoption of 3Rs approaches in batch release testing. This symposium will highlight efforts to accelerate global harmonization of the regulatory acceptance and industry implementation of 3Rs approaches for batch release of human vaccines.

#140 Why are we at a turning point in implementing and accepting non animal testing for vaccines batch release testing? Successes and remaining global challenges in the field.
Laura Viviani, SciEthiQ, Consultant for Humane Society International

#122 Review of animal testing requirements in WHO Guidelines and Recommendations for biologicals: a proposal to implement 3Rs principles
Elliot Lilley, NC3Rs

#153 Alternative Methods for Potency And Safety Test for Batch Release In Human Vaccines
Pradip Das, Biological E Limited Hyderabad, India

#155 EDQM's work on implementing alternatives to animal testing
Catherine Milne, EDQM

#157 Regulatory Considerations for the Development, Licensure, and Use of Non-Animal-Based Quality Control Assays for Vaccines
Robin Levis, U. S. Food and Drug Administration

#373 Global harmonisation of acceptance and implementation of 3Rs approaches in Biologicals quality control and batch release testing– an industry perspective
Emmanuelle Coppens, Sanofi

#389 Insights from a contract testing laboratory; adoption of new approach methodologies for adventitious agent testing of biologics
Sarah Sheridan, Merck KGaA

#174 The consistency approach for the substitution of in vivo testing for the quality control of established vaccines: practical considerations and progressive vision
Shahjahan Shaid, GSK Marburg

#103 Europe enforces and supports in-vitro methods
Ingo Spreitzer, Paul-Ehrlich-Institut

#714 Development of non-animal methods for potency testing of diphtheria and tetanus vaccines
Laura Hassall, Medicines and Healthcare products Regulatory Agency

Session S410 (Symposium)

Wednesday, Aug 30., 11:00 – 12:30

NAMs in Practice: Fit-for-Purpose NGRA Across Sectors

Chairs: **Anne Gourmelon**, OECD & **Maria Baltazar**, Unilever

There is an ongoing need to provide robust scientific evidence that non-animal New Approach Methodologies (NAM) can be used in safety assessments in both regulatory and risk assessment contexts. In this session we will explore some of the different NGRA approaches that are currently being applied and adopted by different sectors, namely cosmetic, pharmaceutical and pesticide with a perspective from industry and regulatory bodies. Practical examples of approaches to assess general occupational risk assessment, carcinogenicity, acute inhalation toxicity, and skin sensitisation without the use of animal testing will be shared. In addition, recommendations for promoting the regulatory acceptance of NAMs will be discussed.

#361 EPAA Project: Use of New Approach Methodologies (NAMs) in regulatory decisions for chemical safety
Carl Westmoreland, Unilever, SEAC

#201 Building confidence in a new approach to agrochemical carcinogenicity assessment
Richard Currie, Syngenta Crop Protection LLC

#656 Assessing the Utility of In Vitro Assessment for Acute Inhalation Toxicity
Angela Hofstra, Syngenta Canada Inc

#515 Application of the GARDskin Medical Device assay for regulatory approval of medical devices according to MDR
Andy Forreryd, SenzaGen AB

#700 Development and Execution of an Occupational Next Generation Risk Assessment (NGRA) on an Exclusive Use Cosmetic Ingredient under EU REACH: A Case Study on C12-15 Alkyl Benzoate
James Dawick, Innospec Limited, Oil Sites Road, Ellesmere Port, Cheshire, CH65 4EY, UK

#660 Recommendations for Promoting the Regulatory Acceptance of Microphysiological Systems,
Yiguang Zhu, Johns Hopkins University, Bloomberg Schools of Public Health and Whiting School of Engineering, Department of Environmental Health and Engineering, Baltimore, MD, USA

#777 Regulatory Considerations on New Approach Methodologies for Developmental Immunotoxicity
Suzanne Fitzpatrick, US FDA

Session S411 (Symposium)

Tuesday, Aug 29, 9:00 – 10:30

A Decade of Progress: Lessons from Animal-Free Cosmetics Policy Worldwide

Chairs: **Aviva Vetter**, Humane Society International, & **Erin Hill**, Internatinal Collaboration on Cosmetics Safety

It has been a decade since the European Union made history by implementing a landmark ban on animal testing for cosmetics and the sale of newly animal tested cosmetics. The following decade has produced remarkable advancement in the identification of new approach methodologies and principles, which achieved the Herculean task of revolutionizing the field of toxicology, as demonstrated by the increasing acceptance and confidence in Next Generation Risk Assessment (NGRA). This session will offer an overview of scientific advancements in animal- free cosmetic safety assessment, the importance of the educational component, and the challenges for regulatory acceptance in different geographies.

#306 Challenges and prospects for Colombia and Latin America in the evaluation of the safety of ingredients and cosmetic products
Maria C. Lozano, Pharmacy Department Faculty of Science, National University of Colombia

#372 Challenges as well as global developments on science and perception of societies
Horst Wenck, Beiersdorf AG

#385 Building confidence in NGRA and milestones achieved in terms of acceptance, incl. dialogue with SCCS
Gladys Ouedraogo, L'Oréal Research & Innovation

#602 Dissemination of Science: Animal-Free Safety Assessment (AFSA) Education and Training modules
Gavin Maxwell, SEAC, Unilever

#755 The legislative and advocacy road to reform
Ms. Aviva Vetter, Humane Society International

#756 An overview of the evolution of cosmetics regulation in China
To be confirmed

Session S412 (Workshop) - **Session sponsored by Bayer Crop Protection**

Tuesday, August 29, 14:00 - 16:00

Putting All the Chips on the Table! Doubling Down on Regulatory Acceptance of MPS

Chairs: **Charu Chandrasekera**, Canadian Centre for Alternatives to Animal Methods & **Lena Smirnova**, Johns Hopkins Center for Alternatives to Animal Testing

Microphysiological systems (MPS), encompassing intricate 3D models such as organoids, organ-chips, and bioprinted tissues, have emerged as a prominent platform to emulate human biology in vitro. Despite their demonstrated ability to faithfully recapitulate normal and aberrant physiological functions, regulatory acceptance of MPS remains a significant hurdle. A panel of experts representing technology developers, industry stakeholders, and government regulators will discuss key challenges in the field, including technology capabilities/gaps, validation/confidence building, and regulatory considerations & context-of-use for diverse applications. The session aims to develop a draft strategic roadmap toward regulatory acceptance of MPS by examining critical issues and fostering collaboration among stakeholders.

Adrian Roth, Roche, **#658 Pharma Industry needs for faster adoption of MPS**

Jason Ekert, UCB Pharma

Sue Marty, Dow Chemicals

Harald Schlatter, Procter & Gamble

Lorna Ewart, Emulate

Itedale Namro Redwan, CellInk

Deborah Ramsingh, Health Canada/PMRA

Sonja Beken, EMA

Maurice Whelan, ECVAM

Patience Browne, OECD

Next-Gen Education

- **S413 - An Auspicious Outreach Plan for Adverse Outcome Pathways in Higher Education**
- **S414 - Comp-Tox in Education: Data Literacy for Next-Generation Risk Assessment**
- **S415 - Improving Competence and Trust: Implementing the 3Rs in Practice**
- **S416 - Replacement at the Forefront - Implementing Animal Free Science Education**
- **S417 - Bringing the 3Rs into the Classroom: It's Never Too Early**
- **S418 - It's How You Say It! Effective Science Communication to Promote Animal Replacement**
- **S419 - Implementing the 3Rs in Higher Education**
- **S420 - Early Career Researchers: Access to NAMs, Funding Opportunities, and Career Paths**
- **S421 - Waste Not! Training the Trainers for Better Experiments**
- **S422 - Of Mice and Not Men: Empowering Next-Gen Scientists for Careers in NAMs**

Session S413 (Workshop)

Monday, August 29, 11:00 – 12:30

An Auspicious Outreach Plan for Adverse Outcome Pathways in Higher Education

Chairs: **Jessica Ponder**, Physicians Committee for Responsible Medicine & **Dalma Martinovic**, University of St. Thomas, USA

The Adverse Outcome Pathway (AOP) framework is gaining momentum as a pragmatic tool in the fields of human health, environmental toxicology and next-generation risk assessment. For the same reasons that make AOPs successful at communicating the advantages and availability of NAMs across a wide variety of disciplines and applications, AOPs are an ideal format for introducing NAMs in toxicology education at the undergraduate and graduate level. This workshop will therefore focus on developing a practical strategy for improving the prevalence of lesson plans and course content for higher education to inform the next generation of toxicologists on the AOP framework.

#11 Goals for Integrating NAMs into Next Generation Education
Merel Ritskes-Hoitinga, Utrecht University, Faculty of Veterinary Medicine, IRAS tox, ;Aarhus University, Department of Clinical Medicine, AUGUST

#564 Advancing Higher Education on AOPs for the Integration of NAMs in Testing and Assessment
Bette Meek, University of Ottawa

#727 "Adverse Outcome Pathways:" a perfect framework on which to build a thesis
Catherine Willett, Humane Society International

#84 Professional Advantages of AOP Development for Graduate Students
Hao Zhu, Rowan University

Session S414 (Symposium)

Wednesday, August 30, 11:00 – 12:30

Comp-Tox in Education: Data Literacy for Next-Generation Risk Assessment

Chairs: **Marc Teunis**, University of Applied Sciences, Utrecht & **Thomas Hartung**, Johns Hopkins Center for Alternatives to Animal Testing

Multiple large scale research projects are currently under way to deliver so called New Approach Methodologies or NAMs. These NAMs can consist of in vitro or in silico approaches to classify hazard of compounds and to perform risk assessment. Artificial Intelligence and other data driven approaches are central to this development. In this session we will be focusing on how to develop and increase statistical literacy as this is the basis for understanding and working with these new technologies. We aim to show that this is relevant for the complete educational chain, from primary school to professionals.

#20 International computational collaborations for predictive toxicology
Kamel Mansouri, NICEATM/PTB/DTT/NIEHS

#34 Mechanistic computational modeling for chemical toxicity evaluations
Hao Zhu, Rowan University

#38 Artificial Intelligence for Regulatory Science Research
Weida Tong, FDA/NCTR

#104 Educating Risk Assessors in the Probabilistic Risk Assessment Approach
Alexandra Maertens, Johns Hopkins Bloomberg School of Public Health

#343 Bringing reproducible research and programming skills to large research consortia; think big act small
Marc Teunis, HU University of Applied Sciences, Utrecht

#411 Novel Approach Methodologies and Change Management: a need for a professional Master program
Rinske Drost, HU University of Applied Sciences Utrecht

Session S415 (Symposium)

Monday, August 28, 9:00 – 10:30

Improving Competence and Trust: Implementing the 3Rs in Practice

Chairs: **Susanna Louhimies**, European Commission & **Kathy Ryder**, Dept of Health Northern Ireland

Personnel working in laboratory animal science comes from varying educational backgrounds. However, adequate education, training, demonstration and maintenance of competence are all prerequisites to work with live animals irrespective of the geographical location. This session will discuss on how to address and change mindset, concepts of competence, mutual recognition of competence and CPD frameworks. It will present tools (including open access) that can be used in the development, achievement, assessment, recording and maintenance of competence. It will also discuss barriers and some potential solutions on how competence claims can be trusted to improve mutual acceptance and free movement of researchers.

#677 Education and Training in Laboratory Animal Science in the European Union: Benefits, Challenges, and Solutions for Mutual Recognition
Nuno Henrique Franco, i3S - Instituto de Investigação e Inovação em Saúde, Universidade do Porto

#683 ETPLAS - FELASA join forces to establish a CPD framework for the EU.
Jan-Bas Prins, The Francis Crick Institute, London, United Kingdom; Leiden University Medical Centre, Leiden, The Netherlands

#746 How to assess competence? Standards, transparency and objectivity in assessing practical skills
Lucy Whitfield, OWL Vets Ltd

#655 A competency-based approach to teaching animal Welfare & the 3Rs to research animal professionals
Carly O'Malley, Charles River

#721 Free, open access training and competence assessment tools - no excuses left!
Susanna Louhimies, European Commission

#642 Overcoming mindset as a barrier to implementing change
Nicola Osborne, Responsible Research in Practice Ltd

#32 Oversight to facilitate high quality training
Kathy Ryder, Department of Health, Northern Ireland, UK

Session S416 (Symposium)

Monday, August 28, 11:00 – 12:30

Replacement at the Forefront - Implementing Animal Free Science Education

Chairs: **Janneke Hogervorst**, PETA UK & **Daniela Salvatori**, Utrecht University

Education is a key but underestimated element in the transition to animal-free innovation. Technology is moving quickly, and a human-based approach – one that does not use animals - is the way forward for sustainable, personalized public health and chemical safety assessment. This session features speakers from academia, industry and non-governmental organisations to discuss what is necessary to establish human-based science as a strategic topic in education, in co-creation with all stakeholders. The session aims to highlight key ingredients for an animal-free education roadmap that is functional and flexible within and outside academia for skilling and reskilling students and professionals.

#70 Keeping toxicology education relevant in the 21st century
Gina Hilton, PETA Science Consortium International e.V.

#593 Animal-Free Science Education and Training in Brazil and LATAM
Marize Campos Valadares, Laboratory of Education and Research in Toxicology In Vitro - Tox In - Pharmacy Faculty, Federal University of Goiás

#604 Accelerating the Transition to Animal-Free Safety Assessment: what can we learn from the Cosmetics Animal Testing bans?
Gavin Maxwell, SEAC, Unilever

#770 A new documentary film series on humane innovations in veterinary education
Nick Jukes, InterNICHE

#687 Training the Next Generation of Researchers in the Organ-on-Chip Field
Silke Keller, 3R-Center for In Vitro Models and Alternatives to Animal Testing, Eberhard Karls University Tübingen, Germany

#766 Transforming students' minds and hearts through teaching innovative, humane science and bioethics
Kathrin Herrmann, Senate Department for Justice and Consumer Protection, Berlin, Germany; Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing (CAAT)

#425 Ambition statement on innovation in higher education using fewer laboratory animals in The Netherlands
Daniela Salvatori, Faculty of Veterinary medicine, Utrecht University

Session S417 (Symposium)

Tuesday, August 29, 11:00 – 12:30

Bringing the 3Rs into the Classroom: It's Never Too Early

Chairs: **Katrin Schütte**, European Commission & **Jan-Bas Prins**, The Leiden University Medical Centre

Let's catch the train when it's still at the station: Introducing the Three Rs at all education levels starting from primary school with age-appropriate teaching material and techniques all the way to university education. The session explores tools and methodologies developed and tested with teachers and experts in pedagogy, including use of Virtual Reality as an effective didactic tool. A number of educational resources have been delivered together with a report that informs education decision-makers on how to facilitate incorporation of the Three Rs into curricula. The session will also cover continued education of professionals already working in the field.

#405 Three Rs for school-goers – From Study to Virtual Reality.
Pierre Deceuninck, European Commission, Joint Research Centre (JRC), EURL ECVAM

#572 Introducing the Three Rs into primary and secondary schools in Europe
Agueda Gras Velazquez, European Schoolnet

#74 A Complete Curriculum: Introducing the 3Rs in Secondary School
Alicia Pate, International Foundation for Ethical Research

#832 Enhancing science education by ending high school dissection
Nick Jukes, InterNICHE

#606 Advancing Three Rs uptake in university education through a European network
Francesca Caloni, Università degli Studi di Milano

#500 ETPLAS for the benefit of free movement of researchers and harmonisation of quality standards across Europe
Jan-Bas Prins, The Francis Crick Institute, London, United Kingdom, Leiden University Medical Centre, Leiden, The Netherlands

#745 Survey Says: How Canadians View the Use of Animals in Post Secondary Education & Training
Liz White, Chief Executive Officer, Animal Alliance of Canada Fund

Session S418 (Symposium)

Wednesday, Aug 30, 9:00 – 10:30

It's How You Say It! Effective Science Communication to Promote Animal Replacement

Chairs: **Catharine E. Krebs**, Physicians Committee for Responsible Medicine & **Kathrin Herrmann**, Johns Hopkins Center for Alternatives to Animal Testing

Effective science communication is imperative in accelerating the important shift towards human-centered biomedical research and testing. It requires complex scientific concepts to be easily digestible; it requires the use of persuasive arguments that drive home the myriad costs of animal research; and it requires combating misinformation and hyperbole from high-powered pro-animal research interests that are firmly planted in the status quo. In this workshop, experts will present about effectively communicating the need to shift the research paradigm away from animals with a variety of stakeholders, including researchers, the media, and the public.

#262 Public awareness of human-relevant, animal-free science: gaining support through effective communication
Rebecca Ram and Rob Harrison, LUSH PRIZE

#449 Nonanimal Research in the News: Capturing Attention, Making Waves
Reina Pohl, Physicians Committee for Responsible Medicine

#567 We need to have a respectful conversation about animal use in research
Elin Törnqvist, Department of Animal Health and Antimicrobial Strategies, Swedish National Veterinary Institute (SVA), Uppsala, Sweden; Institute of Environmental Medicine, Karolinska Institutet, Solna, Sweden

#80 The Right Tool for the Job: Why and How to Adapt Your Science Communication for In-person and Virtual Events
Matteo Piumatti, Altertox Academy

#523 Misinformation, disinformation, hyperbole, and exaggeration: communicating the truth in the fake news era
Lindsay Marshall, The Humane Society of the United States

Session S419 (Symposium)

Tuesday, August 29, 9:00 – 10:30

Implementing the 3Rs in Higher Education

Chairs: **Mohammad Akbarsha**, National College/Society for Alternatives to Animal Experiments-India & **Thomas Hartung**, Johns Hopkins Center for Alternatives to Animal Testing

The Session aims at reviewing the extent to which 3Rs has percolated into higher education curricula in countries across the globe, and the role players. The session Chair is Mohammad Abdulkader Akbarsha, the India Doerenkamp Chair, whereas the Co-Chair is Thomas Hartung, Director, CAAT. Valentine Salamone (Altertox, Belgium), Christian Pellevoisin (Mattek, France), Mohammad Akbarsha (Society for Alternatives, India), Twyla Francois (Animal Alliance of Canada), Arti Ahluwalia (Centro 3R, Europe), Lena Smirnova (CAAT, Johns Hopkins, USA) and Miriam Zemanova (Muliple affiliations in Switzerland and Australia) shall share their Organizations/affiliates' experience/data regarding prescription/training of 3Rs until now and the miles to go.

#471 Training and courses offered at Johns Hopkins Center for Alternatives to Animal Testing
Lena Smirnova, Johns Hopkins University

#234 Formal Courses for College Students to Sensitize About NAMs: Catch Them Young
Mohammad Abdulkader Akbarsha, National College (Autonnomous), Tiruchirappalli, India (rc@nct.ac.in) & Society for Alternatives to Animal Experiments-India

#390 Centro 3R, Mainstreaming Replacement through Pervasive 3R Education
Arti Ahluwalia, Universita' di Pisa, ;Interuniversity Center for the Promotion of 3Rs Principles in Teaching and Research (Centro 3R)

#764 On the Wild Side: Strategies for Advancing the 3Rs Education of Wildlife Researchers
Miriam A. Zemanova, Environmental Sciences and Humanities Institute, University of Fribourg, Switzerland; Oxford Centre for Animal Ethics, UK; Animalfree Research, Switzerland

#132 New approach methodologies (NAMs) in higher education: involvement of industry players
Christian Pellevoisin, MatTek Life Sciences

#110 Fun with NAMs
François Busquet, Altertox

#273 Defenceless: Animal-Based Trauma Training in the Canadian Military
Twyla Francois, Animal Alliance of Canada

Session S420 (Symposium)

Tuesday, August 29, 9:00 – 10:30

Early Career Researchers: Access to NAMs, Funding Opportunities, and Career Paths

Chairs: Kathrin Herrmann, John Hopkins Center for Alternatives to Animal Testing (CAAT) & **Christian Desaintes**, European Commission

This session provides information on national and international initiatives from various organizations based in Europe, including the European Commission, or in the United States to support early-career researchers who aspire to work with animal-free New Approach Methodologies (NAMs). It highlights the role of private funding organizations, which can more easily prioritize a potential impact on reducing or replacing animals. The session details two recent initiatives in the Netherlands, intending to expand internationally, aiming at helping young researchers to take their research towards broader implementation and transition to animal-free innovations.

#459 Creating Community and Opportunity for Early-Career Researchers
Kathrin Herrmann, Senate Department for Justice and Consumer Protection, Berlin, Germany; Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing (CAAT)

#676 Private Funding and Support for Early Career Researchers in Non-Animal Methods: Strategies for Success
Sue Leary, Alternatives Research & Development Foundation

#620 Initiatives from the European Commission to promote animal-free research
Christian Desaintes, European Commission

#352 Helping animal-free innovation cross the Valley of Death. Empowering young researcher to take the leap from lab to business.
Saskia Aan, Stichting Proefdiervrij (Dutch Society for the Replacement of Animal Testing)

#323 Young TPI: empowering young people to go animal-testing-free
Victoria de Leeuw, Centre for Health Protection, National Institute for Public Health and the Environment (RIVM)

#170 The Path to Better Science: 3Rs and more
Adrian Smith, Norecopa

Session S421 (Workshop)

Thursday, August 31, 9:00 – 10:30

Waste Not! Training the Trainers for Better Experiments

Chairs: **Derek Fry**, University of Manchester UK; FELASA Working Group on Experimental design in education and training & **Nuno Franco**, i3S, Universidade do Porto; FELASA Working Group on Experimental design in education and training

Over the past decade, there has been an increasing recognition of the extent of poor practice in various types of experiments, including both animal and in vitro studies. It is widely acknowledged that low-quality animal experiments lack validity and result in the wastage of animals. Similarly, in vitro studies that produce misleading data can squander valuable resources, lead to animal experiments based on incorrect assumptions, and erode confidence in alternative methods. To prevent the persistence of poor practices, it is crucial for the next generation of researchers to be well-informed about conducting reliable and reproducible experiments. Tutors with diverse backgrounds in both country and biomedical fields have actively engaged in the development and testing of educational tools and new materials aimed at enhancing the understanding of key concepts, including the principles of the 3Rs in experimental design and practice. The primary objective of these efforts is to minimize wastage by enabling young scientists to conduct better experiments and guide others towards good practice. As part of this endeavor, a training-the-trainers program has been initiated. Tutors responsible for educating young researchers are trained in using the new educational material effectively. Subsequently, they take on the role of training others, with support from one of the core trainers during their initial courses. The workshop will consist of a series of 5 to 10-minute talks, each focused on one of the key concepts, the rationale behind the chosen educational approach, or personal experiences with its implementation. Following each talk, there will be a 10 to 15-minute interactive period, where participants can engage in quizzes and small group discussions facilitated by the session chairs. By sharing insights, experiences, and educational tools during this session, we aim to empower the next generation of researchers to conduct experiments responsibly and adhere to the principles of the 3Rs. Ultimately, this collective effort will contribute to reducing waste, improving research practices, and fostering a culture of ethical and effective experimentation in the scientific community.

#346 Decisions, decisions
Derek Fry, University of Manchester UK; FELASA Working Group on Experimental design in education and training

#465 What can possibly go wrong?
Nuno Henrique Franco, i3S, Universidade do Porto; FELASA Working Group on Experimental design in education and training

Session S422 (Workshop)

Thursday, August 31, 9:00 – 10:30

Of Mice and Not Men: Empowering Next-Gen Scientists for Careers in NAMs

Chairs:

In the third decade of the 21st century, it is paradoxical that animal data still serve as the gold, silver, and bronze standards while the ultimate goal of the scientific community is to advance knowledge and science for the benefit of humans. The main focus of this solution-room workshop is to address the pervasive “animal data bias” entrenched in the contemporary scientific culture—where animal studies are all too often requested to validate human biology-based studies. Through a moderated panel discussion with audience participation, the goal is to collate ideas for a bottom-up approach to support next-gen NAM scientists in navigating the treacherous waters of grant and journal reviews to obtain funding, publish, and build a successful career without having to generate new animal data. We hope to produce a workshop report to share the ideas widely among the 3Rs community and beyond.

Ethics, Welfare, Policies, and Regulations

- **S423 - Show Me the Animal Data! Animal Methods Bias in Publishing and Funding**
- **S424 - Monkeys on the Edge: Ethical Research with Nonhuman Primates**
- **S425 - Contemporary Challenges for the Animal Care Committeess**
- **S426 - More Than the 3Rs – What Should Principles of Animal Ethics Look Like Today?**
- **S427 - Role of Roadmaps to Accelerate the Transition to Animal-Free Science**
- **S428 - Transparency and Openness as Tools to Push the 3Rs Over the Edge**
- **S429 - A World of 3R Centres: Unity in Diversity**
- **S430 - Science for Policy, Policy for Science: Engaging Policymakers to Advance Science & Ethics**
- **S431 - Industry, Regulators, and Human Health: Whose Onus is it to Defend Animal Data?**

Session S423 (Symposium)

Wednesday, August 29, 11:00 – 12:30

Show Me the Animal Data! Animal Methods Bias in Publishing and Funding

Chairs: **Emily Trunnell**, PETA & **Catherine E. Krebs**, Physicians Committee for Responsible Medicine

Developing and increasing the use of non-animal research methods is needed to reduce the numbers of animals used in science. However, barriers to these efforts exist, including "animal methods bias," a preference for animal-based methods where nonanimal-based methods are suitable. Speakers in this symposium will describe animal methods bias and discuss the evidence for it, ways to address it when it occurs in manuscript peer review and research funding, how language and institutional lock-in contribute to it, and how transdisciplinary and meta-research can be used to mitigate it.

#571 Confronting Animal Methods Bias in Scientific Publishing
Catharine E. Krebs, Physicians Committee for Responsible Medicine

#610 PRIVAT: a peer review tool for appraising in vitro studies
Sebastian Hoffmann, seh consulting + services; Evidence-Based Toxicology Collaboration

#12 Animal Methods Bias in NIH Research Funding Review Committees
Emily Trunnell, People for the Ethical Treatment of Animals U.S.

#577 Challenging the old ways: a call to rethink behavioral methods
Jenny Berrio, Københavns Universitet

#28 Language and workflow in biomedical research indicate institutional bias and how translational medicine can help abolish non-human animal experimentation.
Melanie Ort, Institute of Chemistry and Biochemistry, Department of Biology, Chemistry and Pharmacy, Freie Universität Berlin, Germany; Charité – Universitätsmedizin Berlin, Julius Wolff Institute

#9 Animal-Reliance Bias Mitigation: Developing Evidence from Transdisciplinary Research
Merel Ritskes-Hoitinga, Utrecht University, Faculty of Veterinary Medicine, IRAS tox, ;Aarhus University, Department of Clinical Medicine, AUGUST

Session S424 (Symposium)

Wednesday, August 30, 14:00 - 16:00

Monkeys on the Edge: Ethical Research with Nonhuman Primates

Chairs: **Syd Johnson**, Upstate Medical University & **Lisa Jones-Engel**, PETA & **Susanna Louhimies**, European Commission

This session focuses on the shifting landscape of non-human primate (primate) experimentation. Recent events, including the uplisting of two species of primates to endangered, regulatory flexibility towards and expansion of non-animal alternatives, as well as increased public consciousness around the scientific, ethical and welfare consequences, are changing the way the historical reliance on primates is viewed. This session tackles each of these issues with experts in primate behaviour, biology, conservation, neuroscience, disease, welfare, non-animal alternatives and ethics providing insights into a path forward to a full replacement while providing practical examples of reduction and refinement for those primates still used.

#675 Macaques Over the Edge
Lisa Jones-Engel, People for the Ethical Treatment of Animals, ;Long-tailed Macaque Project

#14 Global Trends in Laboratory Primate Use: 1950 – Present
Andrew Rowan, WellBeing International

#349 Non-Animal Methods in Neuroscience – Focus on Alzheimer's and Parkinson's disease
Annalisa Gastaldello, European Commission

#664 Can we justify using nonhuman primates in neuroscience research? A costs versus benefits discussion.
Katherine Roe, PETA

#795 Pharma actions to push the boundaries of the Three Rs in non-human primate use
Kirsty Reid, European Federation of Pharmaceutical Industries and Associations

#716 Application of Refinement to Reduce the number of Primates used in biomedical research and improve their welfare
Melanie Graham, University of Minnesota

#726 Nonhuman primate research ethics beyond the 3Rs
Andrew Fenton, Department of Philosophy, Dalhousie University

#612 The Three Pillars of Ethical Research with Nonhuman Primates
L Syd Johnson, Upstate Medical University

Session S425 (Workshop)

Monday, August 28, 11:00 – 12:30

Contemporary Challenges for the Animal Care Committees

Chairs: **Ryan Merkley**, Physicians Committee for Responsible Medicine & **John Baumann**, Indiana University

Speakers will discuss new and longstanding challenges for animal care committee, including issues related to workload, regulatory loopholes, the development of nonanimal methods, and shifting public perceptions around the use of animals in experiments.

#382 Never Say "No": An Analysis of Corner-Cutting Measures by IACUCs at Major Public Universities in the United States
Ryan Merkley, Physicians Committee for Responsible Medicine

#663 Bringing IACUCs into the 21st century: ethical gaps and room for improvement
Angela Hvitved, Alternatives Research & Development Foundation

#76 New Korean Legal mandates on IACUC Qualification and Compliance Training Programs to Enhance the Three Rs Principles: 2022 Amendment of the Animal Protection Act
Byung In Choe, Nicholas Cardinal Cheong Graduate School for Life, The Catholic University of Korea

#16 Protocol Review and the Promotion of Alternatives
Andrew Rowan, WellBeing International

#619 Reagent Responsibility: IACUC Assessment of Research Tools
Katherine Groff, PETA Science Consortium International e.V.

#23 The Iron Fist and Velvet Glove: Expanding the Implementation of the 3Rs
John Baumann, Indiana University

Session S426 (Symposium)

Monday, August 28, 9:00 – 10:30

More Than the 3Rs – What Should Principles of Animal Ethics Look Like Today?

Chairs: **Marc Avey**, Canadian Council on Animal Care & **Nuno Franco**, i3S, Universidade do Porto

When UFAW published the now renowned Principles of Humane Experimental Technique by Russell and Burch, and though driven by an ethical dilemma which needed addressing, there was likely no intention to propose Replacement, Reduction and Refinement as the sole ethical principles for animal research. Indeed, the 3Rs are of an epistemological approach for ethically responsible research built on empirical evidence, rather than a set of ethical principles tout court. This session will explore key ethical principles to be considered before any animal is used for a research project.

#98 Marseille Declaration: Together we prioritize animal welfare
Jan Ottesen, Novo Nordisk

#154 Bird's Eye View: Strengthening Protections for Wild Animals in Research
Ron Baron, Physicians Committee for Responsible Medicine

#203 Building value and trust through scientific rigor and transparency
Hanno Wuerbel, University of Bern

#464 Beyond harm-benefit – demanding a life worth living for laboratory animals
Nuno Henrique Franco, i3S, Universidade do Porto

#403 How do we get to where we must go in Principles of Animal Ethics?
Margaret Landi, Scientists Center for Animal Welfare

#270 What key ethics principles should be: Setting National Standards for the 21st Century
Gilly Griffin, Canadian Council on Animal Care

#424 Unified Ethical Principles and Utilization of the Basel Declaration
Sally Thompson-Iritani, University of Washington

Session S427 (Symposium)

Tuesday, August 29, 14:00 - 16:00

Role of Roadmaps to Accelerate the Transition to Animal-Free Science

Chairs: **Kimberley Jayne**, PETA UK & **Luísa Ferreira Bastos**, Eurogroup for Animals

There is growing recognition that animal-based methods in research and testing do not adequately protect human health or the environment. A number of countries and agencies have produced roadmaps to accelerate innovation towards animal-free research and testing methods, some of which contain concrete steps to reduce and replace animal use. However, the number of animals used continues to be high. In this symposium, we will look at the progress already achieved, opportunities for the immediate to long-term reduction and replacement of animal use, and what can be learned from these roadmaps to inspire others to implement similar strategies.

#247 A six-step strategy for a roadmap towards animal free-science in the United Kingdom
Kimberley Jayne, People for the Ethical Treatment of Animals UK

#312 Progress towards reducing use of animals in chemical testing and adoption of new methods to evaluate the safety of chemicals and medical products in the United States
Nicole Kleinstreuer, NIEHS/DTT/PTB/NICEATM

#520 EU roadmap towards full replacement of animal-testing for industrial chemicals
Katrin Schutte, European Commission

#379 Towards a more efficient chemical safety assessment applying animal-free approaches
Elisabet Berggren, Joint Research Centre, European Commission

#363 Key elements for achieving a transition to non-animal science
Barney Reed, Royal Society for the Prevention of Cruelty to Animals

#543 The Need of Harmonization of Alternative Methods and Animal Use in Latin America
Octavio Presgrave, Institute of Science and Technology in Biomodels (ICTB), Oswaldo Cruz Foundation (FIOCRUZ), Rio de Janeiro, RJ, Brazil ;Brazilian Center for Validation of Alternative Methods (BraCVAM), Oswaldo Cruz Foundation (FIOCRUZ), Rio de Janeiro, RJ, Brazil

#599 Accelerating animal free-innovations: milestones and lessons learned in the Dutch transition program
Erica van Oort, Ministry of Agriculture, Nature and Food Auality, The Netherlands

#342 Target images and their role in facilitating the transition towards non-animal science
Jan-Bas Prins, member of the Netherlands National Committee for the protection of animals used for scientific purposes (NCad), Director of the Biological Research Facility at the Francis Crick Institute

Session S428 (Symposium)

Tuesday, August 29, 9:00 – 10:30

Transparency and Openness as Tools to Push the 3Rs Over the Edge

Chairs: **Susanna Louhimies**, European Commission & **Andrew Rowan**, WellBeing International

Transparency in animal research is a shared objective and a legitimate expectation by the public. It improves public's understanding on why animals are still being used whilst supporting efforts to transition to research and testing without animals. The talks present a corporate transparency commitment and national openness initiatives; beyond voluntary initiatives, EU laws mandate open access databases which can aid in directing funding for alternative approaches and, together with open data, tracking animal and non-animal research trends to develop indicators. Additionally, a benchmarking tool for animal-free innovation transition and the role of funders in promoting transparency compliance are discussed.

#708 20 Years of Learnings from a Corporate Animal Welfare and Reporting Program
Sarah Hughes, Shell Global Solutions (US) Inc.

#421 United States Animal Research Openness Initiative
Sally Thompson-Iritani, University of Washington

#542 "Initiative Transparente Tierversuche" – the German initiative to promote transparent communication on animal research
Valeska M. Stephan, Permanent Senate Commission on Animal Protection and Experimentation of the German Research Foundation, ;Rostock University Medical Center

#725 Non-Technical Project Summaries to direct funding decisions on research on alternatives
Susanna Louhimies, European Commission

#408 Monitoring Three Rs implementation – Open access data for indicator building.
Pierre Deceuninck, European Commission, Joint Research Centre (JRC), EURL ECVAM

#446 The Beyond Animal Testing Index (BATI): A benchmarking tool for a world beyond animal testing.
Cyrille Krul, University of Applied Sciences Utrecht

#283 How can funders improve transparency and quality of animal research? A case study
Bas de Waard, The Netherlands Organisation for Health Research and Development, the Hague, the Netherlands

Session S429 (Symposium)

Tuesday, August 29, 11:00 – 12:30

A World of 3R Centres: Unity in Diversity

Chairs: **Hajime Kojima**, National Institute of Health Sciences & **Adrian Smith**, Norecopa

This session will showcase the ways in which 3R activities are being coordinated at many levels: globally, nationally, regionally and institutionally. The session includes reports from 3R centres and associations in Europe, the US and Asia, illustrating the diversity of ways in which the 3Rs are being implemented, and how these interact to form effective networks for dissemination. A successful partnership between industrial stakeholders in Europe will also be described. In addition, the session highlights how a pharmaceutical company promotes the 3Rs within its own organisation, leading to improvements both in animal welfare and data quality in drug discovery.

#97 Norecopa: A one-stop-shop for global 3R resources
Adrian Smith, Norecopa

#688 The Rise of European 3R Centres and their Network EU3Rnet
Winfried Neuhaus, Faculty of Medicine and Dentistry, Danube Private University, 3500 Krems, Austria; AIT Austrian Institute of Technology GmbH, Competence Unit Molecular Diagnostics, 1210 Vienna, Austria; EUSAAT - European Society of Alternatives to Animal Testing

#679 The European Partnership for Alternative Approaches to Animal Testing (EPAA): Accelerating the Transition to Animal-Free, Sustainable Innovation
Gavin Maxwell, EPAA; SEAC, Unilever

#83 Development of an internal granting program for proactive 3Rs advancement
Brianna Gaskill, Novartis Institute for Biomedical Research

#265 The 3Rs Collaborative: Creating Evidence-Based, Practical, and Impactful 3Rs Change
Megan LaFollette, The 3Rs Collaborative

#127 Korea Information Center for the 3Rs: The First 12 years
Byung In Choe, Nicholas Cardinal Cheong Graduate School for Life, The Catholic University of Korea

#167 Latest activities and future directions of JSAAE for Asian cooperation toward 3Rs
Hajime Kojima, Center for Biological Safety and Research (CBSR), the National Institute of Health Sciences (NIHS)

Session S430 (Symposium)

Wednesday, August 30, 9:00 – 10:30

Science for Policy, Policy for Science: Engaging Policymakers to Advance Science & Ethics

Chairs: **Mikalah Singer**, Center for Contemporary Sciences & **Erin Hill**, International Collaboration on Cosmetics Safety

A panel of experts will analyze the policy framework underlying the most transformative innovations of the decade. Emphasis will be placed on applications like Organ-on-a-Chip, 3D-bioprinting, and related Microphysiological Systems (MPS), all poised the transform the healthcare industry. Presentations will include analyses of the recent legislative and regulatory victories and objective assessments of the existing policy barriers impeding progress in the US, EU, and Asia. The implementation of discerning policies towards improving the drug development process, reducing the cost of medicine, streamlining biomedical research, improving safety and toxicity testing, and promoting sustainability will be evaluated through the societal, technological, and economic lens.

#212 Policy for science: the role of policymakers in supporting innovative science
Francois Busquet, altertox

#235 History in the Making: the European Citizens' Initiative to End Animal Testing
Julia Baines, PETA UK

#289 Recent progress of alternatives to animal testing from regulatory science in Japan
Yasunari Kanda, National Institute of Health Sciences

#322 Critical Dialogue for Evolving NAM Support and Policy in South Korea
Borami Seo, Humane Society International

#320 Advancing science and ethics through legislation: the HEARTS Act
Monica Engebretson, Cruelty Free International

#480 Engagement of Scientists with the Public and Policymakers to Promote Alternative Methods
Thomas Hartung, Johns Hopkins CAAT

#329 Partnering with policymakers to advance NAMs: Strategies and best practices that achieve results
Elizabeth Baker, Physicians Committee for Responsible Medicine

#635 Public policy: a key to driving scientific innovation and protecting animals
Kathleen Conlee, The Humane Society of the United States

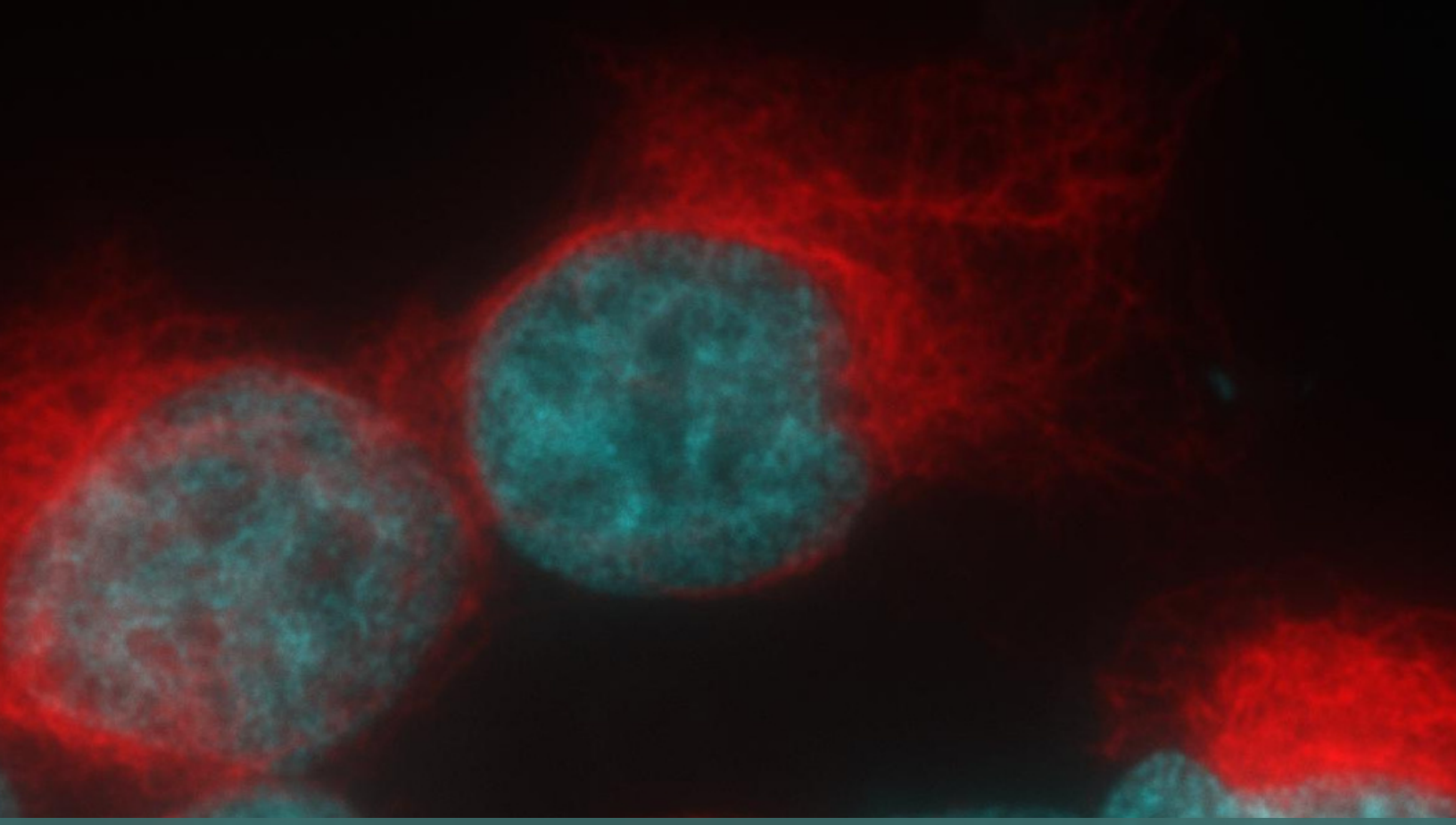
Session S431 (Workshop)

Wednesday, August 30, 11:00 – 12:30

Industry, Regulators, and Human Health: Whose Onus to Defend Animal Data?

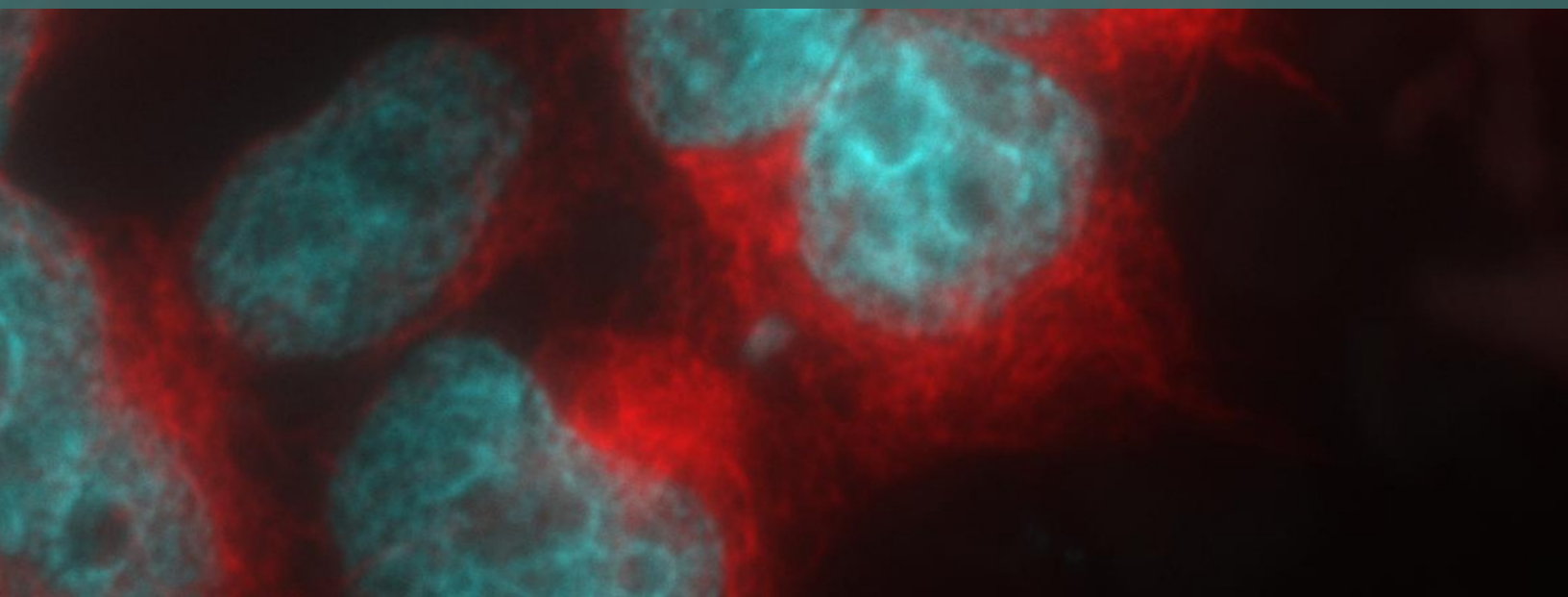
Chairs: **Harald Schlatter**, Procter & Gamble & **Mike Wade**, Health Canada

In toxicology and regulatory testing, the use of animal methods has been both a cornerstone and a subject of intense debate. This solution-room workshop is intended to be a thought-provoking exploration of the scientific and ethical considerations surrounding the necessity and responsibility of defending animal data in regulatory testing. The primary aim is to foster an open dialogue among participants, encouraging diverse perspectives through respectful discourse where attendees will explore the responsibilities and obligations of various stakeholders (including industry, regulatory bodies, technology developers, and animal welfare NGOs) in defending the utilization of animal data. This is an opportunity to engage in critical dialogue and collective introspection about the intersection of scientific progress and ethical responsibility as we seek to accelerate the pace of 21st century predictive toxicology for the protection of human health. We hope to craft a workshop report to continue this conversation beyond WC12.



Human-Centred Biomedical Research

- **S432 - Replacement in Action: Animal-Free Reagents, Methods, and Standards**
- **S433 - Disease-in-a-Dish? MPS for Disease Modelling**
- **S434 - In-a-Dish or On-a-Chip? Complex In Vitro Models**
- **S435 - Future of Multi-Scale Modelling and Simulation in Disease & Toxicology**
- **S436 - The Human Lung: Infection Biology and Inhalation Toxicology**
- **S437 - Challenging the Status Quo: Roadmap to Accelerate Transition to Animal-Free Research**



Session S432 (Symposium)

Wednesday, August 30, 9:00 – 10:30

Replacement in Action – Animal-Free Reagents, Methods, and Standards

Chairs: **Joao Barroso**, European Commission Joint Research Centre & **Charu Chandrasekera**, Canadian Centre for Alternatives to Animal Methods

#10 Animal free recombinant antibodies for research and diagnostics
Esther Wenzel, Abcalis

#318 An Animal Component-Free Human Neuroprogenitor Cell Culture Model for High-Throughput Chemical Hazard Screening
Megan Culbreth, US Environmental Protection Agency, Center for Computational Toxicology and Exposure (CCTE), Research Triangle Park, NC

#357 A Worldwide Survey on the Use of Animal-Derived Materials and Reagents in Scientific Experimentation
Tilo Weber, Animal Welfare Academy of the German Animal Welfare Federation, Neubiberg, Germany

#436 Beyond serum-free cell culture media design: a systematic approach towards long-term animal-origin free cultivation of RTgill-W1
Barbara Jozef, Eawag: Swiss Federal Institute of Aquatic Science and Technology, Dübendorf, Switzerland

#524 An integral approach to reduce the use of fetal calf serum
Jeffrey Bajramovic, 3Rs Centre Utrecht, Utrecht University, Utrecht, The Netherlands

#694 Development of a scale to classify the animal-free status of in vitro tests: a tool for transparent communication.
Carol Treasure, XCellR8 Ltd

#786 Spoiled Milk? Replacing Animal-Derived Blocking Buffers in Immunoassays
Justin Roberto, Canadian Centre for Alternatives to Animal Methods

Session S433 (Symposium)

Monday, August 28, 14:00 - 16:00

Disease-in-a-Dish? MPS for Disease Modelling

Chairs: **Lisa Levin**, Coridea & **Sandeep Raha**, McMaster University

Animal-based research is often attached to significant challenges with reproducibility and translatability to the human condition. In response, developers of microphysiological systems have aimed to create more human-relevant investigative methodologies by utilizing human cells to recapitulate normal and abnormal human physiology. This session will introduce some examples of how these technologies are being used to study liver disease, type 2 diabetes, IBD, degenerative and neoplastic neurological disorders, joint disease, cervical cancer, and cardiac ischemia.

#37 Patient Biomimetic Twins in Precision Medicine
D. Lansing Taylor, University of Pittsburgh, ;Drug Discovery Institute

#169 3D spheroids of the pancreatic beta cell line EndoC-βH5 for modelling diabetes-on-chip
Reyk Horland, TissUse GmbH, Berlin

#583 Early innate and adaptive immune responses in human intestinal tissue slices from IBD and non-IBD patients ex vivo
Valerie Beneke, Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Member of the German Center for Lung Research (DZL), Member of Fraunhofer Cluster Immune Mediated Diseases (CIMD), Hannover, Germany

#182 Human Neuron-on-a-chip platform to automate the screening of compounds targeting Alzheimer's Disease
Xue Ying Chua, PhD Physics: Ananda Devices, Laval, QC, Canada

#226 Automated Platform for Creating Patient-Derived Glioblastoma Organoids and High Throughput Drug Screening
Yuval Daskal, Grass Center of Bioengineering, The Hebrew University, Jerusalem, Israel

#771 An advanced in vitro model of human blood-brain barrier and its interaction with brain cancer neurospheres
Bhumika Singh, Kirkstall Limited

#559 Simulating mechanical forces during joint movement on cartilage in an animal-free bioreactor set-up
Alexandra Damerau, German Rheumatism Research Centre Berlin; Charité-Universitätsmedizin Berlin

#527 Modeling the Stages of Cervical Cancer Pathogenesis: Establishment of a Healthy Cervix-, a Pre-Cancerous CIN- and an Immunocompetent Carcinoma-on-Chip
Elena Kromidas, Department for Microphysiological Systems, Institute of Biomedical Engineering, Faculty of Medicine, Eberhard Karls University Tuebingen, Tuebingen, Germany

#782 High throughput cardiac ischemia model Human-on-a-Chip platform
Chase Miller, Hesperos, Inc.

Session S434 (Symposium)

Wednesday, August 30, 14:00 - 16:00

In-a-Dish or On-a-Chip? Complex In Vitro Models

Chairs: **Justin Roberto**, Canadian Centre for Alternatives to Animal Methods & **Nina Hobi**, AlveoliX

Changes to existing technologies are currently being made to improve and reduce the need for animal methods and revolutionize existing promising alternative methods. This session describes various complex in vitro models existing as microphysiological systems – whether in a dish or chip. These systems include various models of liver, heart, skin, neuromuscular junctions, tumors, and bone. These models aim to advance physiological relevancy by incorporation of vascularization, electrical stimulation, wound healing assays, perfusion, bioprinting, and immune response. Through these models and criteria to improve cell culture practices, this session serves complex in vitro models on-a-dish or on-a-chip.

#481 Good Cell Culture Practice (GCCP) 2.0 extending to Microphysiological Systems
Thomas Hartung, Johns Hopkins CAAT

#24 The Electro-Mitochondrial Coupling of a Microphysiological Human Heart
Mohammad Ghosheh, Alexander Grass Center for Bioengineering, The Hebrew University of Jerusalem, Jerusalem, Israel

#587 Human neuromuscular junction-on-a-chip platform as a drug development tool supporting development of therapies
Margaret Magdesian, Ananda Devices Inc.

#487 Unleashing the Potential of Bioprinted Tumors: A Step towards Personalized Cancer Therapy
Shreyas Gaikwad, Texas Tech University Health Science Center

#172 Development towards an Organ-on-the-Chip technology for complex in vitro testing of T cell products
Isabell Durieux, BIH-Center for Regenerative Medicine

#413 Development of an in vitro liver culture system for continuous bile recovery
Fumiya Tokito, University of Tokyo
#550 Development of a cartridge bioreactor for parallelized cultivation and stimulation of complex tissue models
Moritz Pfeiffenberger, Deutsches Rheumaforschungszentrum Berlin; Charité Universitätsmedizin Berlin

#717 Effects of Lactobacillus Plantarum on a Human Induced Pluripotent Stem Cell Derived Intestinal Epithelial Cell Model in Comparison with Human In Vivo Data and a Caco-2 Cell Based Model.
Meike van der Zande, Wageningen Food Safety Research - Wageningen University & Research

#78 Vascularization of multi-Organ-on-Chips with blood and lymphatic endothelial cells for the generation of immunocompetent skin models
Sue Gibbs, Amsterdam University Medical Center

Session S435 (Symposium)

Monday, August 28, 9:00 – 10:30

Future of Multi-Scale Modelling and Simulation in Disease and Toxicology

Chairs: **Catherine Mahony**, Procter & Gamble & **Tom Knudsen**, US EPA

Computational modelling to recapitulate human biology is at a turning point. Knowledge of molecular and cellular environments is now enabling computer predictions of differentiated states at the level of the cell, tissue, organ and even organism and computation has advanced sufficiently to be able to deal with human variability, disease states and life stages. In this session examples from across the globe of modelling and simulation initiatives will be presented, along with views on how such models and simulations might serve in lieu of animal testing. What is needed to develop beyond proof of concepts to build credible models will also be discussed and views from workshop attendees is encouraged to reach a point of clarity on action to be taken to overcome challenges.

#392 Developing an in silico Virtual Cornea for Predictive Toxicology
James Glazier, Indiana University

#435 Lab on a Laptop: Beyond the Experimental Model
Arti Ahluwalia, Universita' di Pisa, ;Centro di Ricerca E. Piaggio, Interuniversity Center for the Promotion of 3Rs Principles in Teaching and Research (Centro 3R)

#632 Engineering a Computable Epiblast for in silico Modeling of Developmental Toxicity
Thomas Knudsen, US EPA; Center for Computational Toxicology and Exposure

#638 A roadmap from single organ models to the integrated virtual human twin in disease and toxicology
Liesbet Geris, University of Liège & KU Leuven

#686 Establishing the credibility of computational models in biology and toxicology
Maurice Whelan, European Commission Joint Research Centre (JRC)

Session S436 (Symposium)

Tuesday, August 29, 14:00 - 16:00

The Human Lung: Infection Biology and Inhalation Toxicology

Chairs: **Brett Lidbury**, The Australian National University (NCEPH) & **Jorid Sørli**, The National research centre for the working environment

This session is devoted to New Approach Methodology (NAM) investigations of lung pathology post infection or as a result of inhalation toxicity. Currently there are no validated alternative methods to assess inhalation toxicity of airborne substances, leaving substantial gaps for animal-free research translation, drug/chemical manufacture, as well as safety regulation. In addition, modelling lung pathology is challenging due to organ complexity, thus requiring that NAMs be developed specifically for various lung tissues. How animal-free alternatives, developed for the study of lung disease due to infection or toxicity, can reinforce innovation in this context also will be discussed.

#46 Advanced immunocompetent in vitro primary human lung models for toxicity assessment and infectious disease research
Samuel Constant, Epithelix

#147 Human cell-based in vitro systems to assess respiratory toxicity of liquid and aerosolized surfactants
Andreas O Stucki, PETA Science Consortium International e.V., Stuttgart, DE

#214 Generation of an alveolus-on-chip model for personalized drug screening against viral-bacterial co-infections in viral pneumonia
Hristina Koceva, Institute of Biochemistry II, Jena University Hospital, Germany

#227 Efficacy and safety of metabolic interventions for the treatment of severe COVID-19: in vitro, observational, and non-randomized open label interventional study
Yuval Daskal, Grass Center of Bioengineering, The Hebrew University, Jerusalem, Israel

#290 Establishing scientific confidence in a cell-free method to predict decreased lung function
Jorid Sørli, The National Research Centre for the Working Environment

#452 High-throughput Preclinical Model of Breathing Human Alveoli
Kimia Asadi Jozani, School of Biomedical Engineering, McMaster University

#462 Using immortalised blood cells to study the long-term effects of common respiratory viruses
Claire Allan, La Trobe University Australia

#502 Targeting Respiratory Viruses: A Novel Alveolus-on-Chip Infection Model for Pre-Clinical Applications
Mirjam Kiener, Department of Urology, Inselspital, Bern University Hospital, Department for BioMedical Research (DBMR), University of Bern, Switzerland

#788 Alveoli-in-a-Dish: 3D-Bioprinted Human Lung Tissue Model for Inhalation Toxicity
Jessica Szawara, Canadian Centre for Alternatives to Animal Methods

Session S437 (Workshop)

Monday, August 28, 14:00 - 16:00

Challenging the Status Quo: Roadmap to Accelerate Transition to Animal-Free Research

Chairs: **Helder Constantino**, Humane Society International & **Jarrod Bailey**, Animal Free Research UK

Animal use worldwide in biomedical research has remained stable over the last two decades despite the emergence of new technologies grounded in human biology, which are increasingly regarded as game-changers in the field. Why are they so slow to catch on, and why are animal models still viewed by many as a cornerstone of biomedical research? This workshop aims to explore these questions with science and policy leaders whose ideas could act as a catalyst leading to greater changes. Audience participation will be encouraged in these thought-provoking debates. The discussions will be compiled into a flash report for distribution.

#729 Using a standardized tool to assess the translational (ir)relevance of animal models
Bianca Marigliani, Humane Society International

#451 Putting Patients First: A Human-Centered Approach to Translating In Vitro Virology Research into Clinical Practice
Avner Ehrlich, Grass Center for Bioengineering, Benin School of Computer Science and Engineering, Jerusalem, Israel

#186 Human Relevant Models in Biomedical Research – Progressing Science through Innovation
Annalisa Gastaldello, European Commission

#29 Helpathons to accelerate human relevant science
Sue Gibbs, Amsterdam University Medical Center, ;The Helpathon Hotel, Academic Center for Dentistry Amsterdam

#432 Developing and embedding education programmes for the transition towards Non-Animal Methods at Utrecht University
Daniela Salvatori, Veteterinary Faculty, TPI Utrecht, Utrecht University

#719 Advancing and enabling human-relevant research in India
Kasturi Mahadik, Centre for Predictive Human Model Systems, Atal Incubation Centre-CCMB

#707 What policy and science tools are needed to effectively transition away from animal models
Helder Constantino, Humane Society International

#418 Policy change underpinned by science: accelerating a shift towards human-focused research and testing by working with policy makers.
Jarrod Bailey, Animal Free Research UK

Refinement and Impact on Science

- **S438 - Refinement’s Impact on Research – A Critical Review**
- **S439 - Refinement in Challenging and Constrained Situations**
- **S440 - Gegevens worden opgehaald. Wacht een paar seconden en knip of kopieer vervolgens opnieuw.**
- **S441 - Reducing Severe Suffering: Time for a Strategic Approach**
- **S442 - From Systematic Reviews to Pre-Registration: Streamlining for Better Research**
- **S443 - 21st Century Animal Welfare Assessment**
- **S444 - Smart Statistics to Reduce and Refine Animal Use**
- **S445 - Refined Mouse Handling: Evidence, Barriers, and Solutions to Practical Use**

Session S438 (Symposium)

Thursday, August 31, 9:00 – 10:30

Refinement's Impact on Research – A Critical Review

Chairs: **Kathrin Herrmann**, Senate Department for Justice and Consumer Protection, Germany; Johns Hopkins Center for Alternatives to Animal Testing (CAAT) & **Joanna Makowska**, University of British Columbia; Animal Welfare Institute (AWI)

The development of refinement methods has flourished, but uptake into standard practice is slow. This symposium critically addresses the practical impact of refinement on scientific progress and animal use. We will hear from experts who have conducted refinement research or have reviewed its application in practice. We will also look into systematic reviews and meta-analyses of animal studies to assess what impact refinement methods have had on science, rigor and translatability to the human setting. Moreover, we will critically assess the extent to which refined animal models can reflect the biology and the pathobiology of humans.

#753 Better Animal Welfare and Better Science? – Observations by a Former Inspector
Kathrin Herrmann, Senate Department for Justice and Consumer Protection, Berlin, Germany; Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing (CAAT)

#776 How Far Should Refinement Go?
Joanna Makowska, University of British Columbia; Animal Welfare Institute (AWI)

#388 The RepRefRed Society (The Austrian 3R Center) and its impact on animal welfare and quality in science, caring for all. Part I

#440 The National 3R centers and their impact on animal welfare and quality in science part 2 - closing the gap of refinement

Birgit Reininger-Gutmann, The RepRefRed Society - The Austrian 3R Center; Medical University Graz
Roberto Plasenzotti, SAN Group, ;Austrian 3R Center

#779 Gaps and Considerations in Oversight and Research Limitations in use of Human Nonhuman Animal Chimeras
Ann Lam, Physicians Committee for Responsible Medicine

#1 Why I moved from working on Refinement to Replacement
Merel Ritskes-Hoitinga, Utrecht University, Faculty of Veterinary Medicine, IRAS tox; Aarhus University, Department of Clinical Medicine, AUGUST

#521 A fourth R – Reframing research to redefine refinement
Lindsay Marshall, The Humane Society of the United States

Session S439 (Symposium)

Monday, August 28, 11:00 – 12:30

Refinement in Challenging and Constrained Situations

Chairs: Amy Shurtleff, Group Lead Animal Models & Sally Thompson-Iritani, University of Washington

This session is focused on discussing the incorporation of refinements and efforts to minimize negative impact on the animals and the studies performed in constrained situations, such as high biocontainment or surgical environments. Multiple species will be discussed including mice, rats, hamsters, sheep, and non-human primates. Topics range from housing and socialization effects on animal health and physiology to innovative ways to administer analgesics for maximal efficacy. Particular attention will be paid to how these factors might impact future work and support for programs that require special attention to potentially infectious pathogens and efforts to track data for comparisons with historical data.

#609 Enhanced Caging Standards for Rats: effects on welfare and historical data
Lucia Amendola, Charles River Laboratories

#667 Pain management via the drinking water: a watertight affair?
Marion Bankstahl, Institute of Laboratory Animal Science and Central Animal Facility, Hannover Medical School, Germany

#366 Real-time lung function measurements of Syrian hamsters for SARS-CoV-2 research
Nadia Oreshkova, Wageningen Bioveterinary Research, Wageningen University

#367 Monitoring animal behaviour in infectious disease studies with accelerometers and video
Rineke de Jong, Wageningen University and Research

#455 Refinement in fracture management of the hindlimb post tibial fracture: establishment of a walking cast for sheep (SWC)
Prof. Rene H. Tolba, Institute for Laboratory Animal Science and Experimental Surgery- Faculty of Medicine - RWTH Aachen University, Aachen, Germany

#119 Restricted space does not have to mean restricted choice – keeping monkeys happy!
Michelle Nelson, Defence Science & Technology Laboratory, UK

Session S440 (Symposium) - **Session sponsored by Charles River**

Wednesday, August 30, 11:00 – 12:30

Caring for All: Behavioural Management to Improve Animal and Worker Welfare

Chairs: **Patricia Turner**, Charles River & **Susanna Louhimies**, European Commission

Animals, scientific outcomes and those caring for animals are all interlinked. Failures to adequately care for one often result in problems with the other two. Addressing promptly issues in an appropriate manner will help developing an environment that allows for a robust science to be carried out without unnecessary suffering and with a staff that can feel professional pride in the work that they carry out. The session explores various ways in which we can better care animals, science and those working with animals, and to take proactive action when issues arise.

#422 Compassion Resilience for working with Research Animals
Sally Thompson Iritani, University of Washington

#244 Caring for Our People Caring for Our Animals: Promoting Compassion Fatigue Resiliency
Megan LaFollette, The 3Rs Collaborative

#330 Aggression in group-housed male mice: a dual approach to increased understanding
Elin Törnqvist, The Swedish National Committe/The National veterinary institute

#699 An Outside the Box Approach for Housing Rats to Enhance Their Behavioural Repertoires
Patricia Turner, University of Guelph; Charles River

#331 Every Day With Every Interaction: Developing a Common Culture Across Disciplines
Kelly Morrisroe, Washington National Primate Research Center; University of Washington

#772 Caring for Science: CIRS-LAS for a Constructive Error Culture in Lab Animal Science
Sabine Bischoff, University Hospital Jena - Animal Welfare Office

#30 Raising Concerns for Good Animal Welfare and Reproducible Science
Kathy Ryder, Department of Health, Northern Ireland, UK

Session S441 (Symposium)

Tuesday, August 29, 11:00 – 12:30

Reducing Severe Suffering: Time for a Strategic Approach

Chairs: Penny Hawkins, RSPCA & **Gilly Griffin**, Canadian Council on Animal Care

Any level of laboratory animal suffering is concerning for the scientific community and public, but reducing and avoiding 'severe' suffering (Category D/E in Canada; USA Category E) should be a top priority. This symposium will promote a strategic approach, with case studies including disease models and toxicology protocols. There will also be examples of effective review bodies and processes, and internal communications, that have successfully driven reductions in severe suffering. These different perspectives will provide participants with new ideas, and information, to help inform a strategic, team approach to reducing suffering within their own establishment, company, or research field.

#51 A 'Roadmap' approach to help end 'severe' suffering
Penny Hawkins, RSPCA

#43 Applying the RSPCA Roadmap to reducing severe suffering in practice – case studies from a pharmaceutical company
Thomas Bertelsen, Novo Nordisk

#136 A Novel Scoring System for Humane Endpoints in Mouse Cecal Ligation and Puncture-Induced Sepsis
Lindsey Ferguson, Division of Animal Resources, Emory University, Atlanta, Georgia.

#144 Refining the Endpoint for Diphtheria and Tetanus Toxoid Potency Assays
Juthika Menon, Sanofi Vaccines

#239 Rethinking endpoints - setting national standards for the 21st Century
Marc Avey, CCAC

#236 Pain in Experimental Animal Studies and the Non-Affiliated Member?
Rabbi Art Vernon, Feinstein Institute for Medical Research, Northwell Health

Session S442 (Symposium)

Tuesday, Aug 29, 14:00 - 16:00

From Systematic Reviews to Pre-Registration: Streamlining for Better Research

Chairs: **Bettina Bert**, German Centre for the Protection of Laboratory Animals (BfR), German Federal Institute for Risk Assessment (BfR) & **Julia Menon**, Preclinicaltrials.eu, Netherlands Heart Institute

Before performing an animal experiment, systematic reviews can help to identify urgent research questions and to pinpoint scientific outcomes in need for confirmation. Systematic reviews can also detect quality issues animal research is facing that impede the reproducibility of corresponding results and their translation into clinics. Preregistration could be an effective tool to support researchers in better designing their studies and preventing questionable research practices. If NAMs should replace animal research in future, it is crucial to address quality issues already today. Learning from the mistakes from animal research can improve translation from NAMs into clinics.

#223 Recent Developments in Preclinical Systematic Review Methodology
André Bleich, Hannover Medical School

#611 The effect of environmental enrichment on anxiety-like responses of mice: a systematic review
Lucia Amendola, University of British Columbia

#540 Team science: support structures for robust evidence generation and meta-research
Natascha Drude, Berlin Institute of Health at Charité; QUEST Center for Responsible Research

#176 Replicability of preclinical cancer biology
Timothy Errington, Center for Open Science

#45 Preregistration in animal research – Critical evaluation of the current state
Céline Heinl, Federal Institute for Risk Assessment (BfR), German Centre for the Protection of Laboratory Animals (Bf3R)

#291 Does Preregistration of Animal Studies Work?: A Plan to Find Out
Julia M.L. Menon, The Netherlands Organisation for Health Research and Development, the Hague, the Netherlands; Netherlands Heart Institute, Utrecht, the Netherlands

#691 Building trust and increasing utility of NAMs through preregistration and open protocols
Ulf Toelch, BIH QUEST Center @ Charité Universitätsmedizin

#101 Working towards the 'essential 10'
Nikki Osborne, Responsible Research in Practice

Session S443 (Symposium)

Tuesday, August 29, 9:00 – 10:30

21st Century Animal Welfare Assessment

Chairs: **Michael Walker**, Canadian Council on Animal Care & **René Tolba**, Uniklinik RWTH Aachen – Institute for Laboratory Animal Science

Promoting good welfare and limiting negative outcomes of experiments are the fundamental steps to refinement, and the explicit goal of institutions housing and working with laboratory animals. However, how can we measure the welfare of, and impact of procedures on, animals? This session will provide guidance for assessing animal welfare, and in particular, will cover practical considerations emphasizing animal-based measures of well-being. Specific applied examples of welfare assessment approaches for rodents, sheep and primates are included.

#238 The Next Evolution in Animal Welfare Assessment Standards
Michael Walker, CCAC

#513 Leveraging Data Science for Better Severity Assessment in Laboratory Animal Science
Steven R. Talbot, Hannover Medical School, Institute for Laboratory Animal Science

#624 Insights from the home cage: Data science-driven activity analysis enables sensitive welfare assessment in colitis models
Andre Bleich, Hannover Medical School, Institute for Laboratory Animal Science

#501 Multimodal welfare assessment in laboratory mice after surgery
Christine Häger, Hannover Medical School, Institute for Laboratory Animal Science, Carl-Neuberg-Straße 1, 30625 Hannover, Germany

#256 Development of composite measure schemes for evidence-based severity assessment and refinement in neuroscientific research
Heidrun Potschka, Ludwig-Maximilians-University, Institute of Pharmacology, Toxicology and Pharmacy, Munich

#743 Animal welfare and 3Rs advantages of home-cage monitoring systems
Nuno Henrique Franco, i3S, Universidade do Porto

#654 A novel welfare primate welfare assessment tool for research primates
Carly O'Malley, Charles River

Session S444 (Symposium)

Wednesday, August 30, 9:00 – 10:30

Smart Statistics to Reduce and Refine Animal Use

Chairs: **André Bleich**, Institute for Laboratory Animal Science and Central Animal Facility / Hannover Medical School & **Dan Weary**, University of British Columbia

This session will describe new and known statistical methods which can aid reduction and refinement of animal use throughout the field of laboratory animal experimentation, in a manner that is accessible and comprehensible to all attending scientists. It will showcase, amongst others, optimisation of sample size calculations, examples of planning and prioritising test sequences to decrease animal use, replacing animals by meta-analyses, and the current status of education in statistical analyses and experimental design.

#195 The "Stats" on Statistics Courses: Requirements in Select Canadian U15 Graduate Programs
Melanie C. H. Gibbons, College of Pharmacy and Nutrition, University of Saskatchewan

#221 Different Types of Meta-Analysis to Replace Animal Experiments Using Literature Data
Cathalijn Leenaars, Hannover Medical School

#514 The RELSA Score: An Evidence-Based Tool for Better Severity Assessment in Animal Research
Steven R. Talbot, Hannover Medical School, Institute for Laboratory Animal Science

#769 Cleaning house – doing away with outdated practices in sample size estimation
Otto Kalliokoski, University of Copenhagen

#785 Prioritising comparisons can decrease animal use
Steven Teerenstra, Radboud university medical centre

Session S445 (Symposium)

Monday, August 28, 9:00 - 10:30

Refined Mouse Handling: Evidence, Barriers, and Solutions to Practical Use

Chairs: **Megan LaFollette**, The 3Rs Collaborative & **Khia Dobbinson**, NC3Rs

Traditionally, research mice and rats are picked up by the tail to move them for standard procedures. However, evidence indicates that it is better for animal welfare, scientific quality, and ease of handling to refine rodent handling such as by picking animals up with tunnels or cupped hands. The scientific community is slowly but increasingly switching to these methods. In this session, participants will learn about the practical evidence, barriers, and solutions to widescale refinement of rodent handling in multiple settings. Additionally, one presentation will provide evidence for conducting translational immune research in conventional caging as superior to IVCs.

#131 Evidence for refined mouse handling: Better for animals, people, & science
Khia Dobbinson, NC3Rs

#187 Increasing Understanding & Implementation of Refined Mouse Handling: A longitudinal, cross-sectional benchmarking survey
Megan LaFollette, The 3Rs Collaborative

#216 Changing handling practices to improve animal welfare and scientific outcomes
Judy Murray, Charles River Laboratories

#628 Academic transition lessons: involving stakeholders, time trials, and breeding results
Elizabeth Nunamaker, Charles River Laboratories, ;North American 3Rs Collaborative

#630 Industry Implementation of Refined Mouse Handling: A roadmap, challenges, & solutions
Erin Straley, AstraZeneca

#576 Milestone based handling reduces stress and facilitates animal-experimenter interaction
Michael Marcotte, Campbell Family Mental Health Research Institute of CAMH, Toronto, ON, Canada

#225 Housing matters – Realistic human model systems depend on realistic exposure to pathogens
Agnes Ellinghaus, Julius Wolff Institute, Berlin Institute of Health at Charité – Universitätsmedizin Berlin, Germany

21st Century Predictive Toxicology

- S446 - Chems-on-Chips: MPS for Organ Tox & Chemical Risk Assessment
- S447 - What’s in the Mix? New Approach Methods for Chemical Mixtures Risk Assessment
- S448 - Tipping Point in Omics: Transcriptomic Points of Departure (tPODs) and QIVIVE in Regulatory Decision-Making
- S449 - ASPIS: From Molecular Toxicology to Regulatory Acceptance, the Next Step for Animal-free Testing
- S450 - New Approach Methods for Developmental and Reproductive Toxicity Testing
- S451 - Physiologically-Based Pharmacokinetic Modelling for Chemical Risk Assessment
- S452 - On the Runway: Interactive Predictive Tox Models
- S453 - New Approaches to Genotoxicity Testing and Risk Assessment
- S454 - Predictive Toxicology: Data, Development, Delivery, and Application
- S455 - Progress in Quantifying Adverse Outcome Pathways to Support Next Generation Risk Assessment
- S456 - Advances in NAMs for EcoTox Testing & Risk Assessment, Part 1: Biological Models and Techniques
- S457 - Advances in NAMs for EcoTox Testing & Risk Assessment, Part 2: Computational Tools and Frameworks
- S458 - Artificial Intelligence (AI): Current Advancements and Applications in Advancing the 3Rs
- S459 - What's New in Skin Sensitization?

Session S446 (Symposium)
Monday, August 28, 14:00 - 16:00

Chems-on-Chips: MPS for Organ Tox & Chemical Risk Assessment

Chairs: **Nicole Kleinstreuer**, NICEATM/NIEHS & **Suzanne Fitzpatrick**, US FDA

Organoid and microphysiological system (MPS) are two emerging new approach techniques that both recapitulate key organ features and human physiological complexity at scale. There are many efforts worldwide to evaluate MPS for their utility and predictive capacity for human safety and efficacy, but thus far, potential regulatory use of MPS has focused on the drug industry. However, there also several important contexts of use for MPS in the chemical risk assessment arena. Presentations in this session will highlight work ongoing globally to use these new approach methods for chemical risk assessment, both in terms of industrial implementation and regulatory acceptance.

#58 Japan's approach for applying MPS as a wet-simulator in chemical risk assessment
Seiichi Ishida, Sojo University; National Institute of Health Sciences

#85 Development of a microphysiological skin-liver-thyroid Chip3 and its application to evaluate the effects on thyroid hormones of topically applied cosmetic ingredients under consumer-relevant conditions
Leopold Koenig, TissUse GmbH

#242 Technical evaluation of an oral irritation assay using 3D constructs
Elijah Petersen, NIST

#261 A Human Integrated Organ System (MPS) for Developing Pharmacokinetic and Organ Toxicity Data In Vitro.
James M. McKim, LifeNet Health-IONTOX

#673 Novel in vitro tri-culture hepatic model to evaluate human relevance of chemical-induced thyroid toxicity
Shadia M. I. Catalano, Corteva Agriscience, Newark, DE, USA

#712 3D Placental Trophoblast Fusion and Invasion Model for Drug Toxicity Studies
Sonya Kouthouridis, Department of Chemical Engineering, McMaster University

#778 Advanced In Vitro Models for Nephrotoxicity Risk Assessment
Adam Pearson, NIEHS

#787 Hepatotoxicity-in-a-Dish: Microphysiological System to Model Drug Induced Liver Injury
Lucas Vajko Siddall, Canadian Centre for Alternatives to Animal Methods

#793 In vitro cell models for identifying potential metabolic disrupting chemicals
Ella Atlas, Health Canada

Session S447 (Symposium)

Tuesday, August 29, 14:00 - 16:00

What's in the Mix? New Approach Methods for Chemical Mixtures Risk Assessment

Chairs: **Suzanne Fitzpatrick**, US FDA & **Jean-Lou Dorne**, European Food Safety Authority

#228 Roadmap for NAMs-mixtures Assessment: Environmental pollutants
Jose V. Tarazona, Spanish National Environmental Health Center. Instituto de Salud Carlos III

#229 Chemical mixture risk assessment in Europe
Philip Marx-Stoelting, German Federal Institute for Risk Assessment

#324 Using Zebra Fish for Chemical Mixtures Risk Assessment
Robyn Tanguay, Sinnhuber Aquatic Research Laboratory; Oregon State University

#709 Preliminary metabolomic and toxicological studies of environmental contaminants – organophosphates (OPs), brominated flame retardants (BFRs) and poly-fluoroalkyl substances (PFASs) - detectable in waste of electrical and electronic equipment (WEEE) plants – the VAISAL project
Stefano Lorenzetti, ISS - Istituto Superiore di Sanità

#736 New approaches to comparing potencies and hazards of emerging BPA alternative chemicals
Geronimo Matteo, Department of Biology, University of Ottawa; Environmental Health Science and Research Bureau, Health CanadaKu

#762 High-Throughput BMC Analysis of Global Gene Expression in Human Liver Spheroids Suggests PFAS have Additive Effects in Mixtures
Gregory C. Addicks, Environmental Health Science and Research Bureau, Healthy Environments and Consumer Safety Branch, Health Canada

#479 A Call for a Human Exposome Project
Thomas Hartung, Johns Hopkins CAAT

#828 Application of Multi-Organ-Chips in risk assessment
Reyk Horland, TissUse

Session S448 (Symposium)

Wednesday, August 30, 14:00 - 16:00

Tipping Point in Omics: Transcriptomic Points of Departure (tPODs) and QIVIVE in Regulatory Decision-Making

Chairs: **Anthony Reardon**, Health Canada & **Carole Yauk**, University of Ottawa

Transcriptomics is recognized as a key tool in 21st-century toxicology testing. International efforts have advanced methods that harness transcriptomics to identify points of concerted molecular change (i.e., transcriptomic points of departure, tPODs). Such tPODs are converted into species-relevant administered equivalent doses through in vitro to in vivo extrapolation (IVIVE) for use in risk assessment applications. This symposium will review the latest advances in this field, providing updates from efforts to establish best practices in different contexts of use, summarize approaches being used by international regulatory agencies, and describe the outcomes of the most recent case studies applying these methodologies.

#305 Leveraging in vitro transcriptomic points of departure in chemical safety evaluation
Logan J. Everett, U.S. Environmental Protection Agency, ORD, Research Triangle Park, NC

#458 Quantitative in vitro-in vivo extrapolation (QIVIVE) in chemical risk assessment
Stephan Schaller, esqLABS GmbH

#442 Application of in vitro transcriptomics point of departure and IVIVE in early agrochemical discovery programs.
Enrica Bianchi, Corteva Agriscience

#631 Transcriptomic points of departure for fertilized Japanese quail embryos exposed to seven pesticides using the EcoToxChip Test Method
Niladri Basu, McGill University

#698 Characterizing the cytotoxic and molecular effects of environmentally relevant pesticides on human Caco-2 and HepG2 cell lines
Ke Xu, McGill University

#774 Integrating transcriptomics, quantitative adverse outcome pathways, in vitro and in vivo kinetics to predict amiodarone toxicity
Nynke Kramer, Wageningen University, Wageningen, The Netherlands

#151 Towards a mechanistic characterization of metabolic disruption using proteomics
Alexandra Schaffert, Institute of Medical Biochemistry, Medical University of Innsbruck, Innsbruck, Austria

#377 Advancing data interpretation approaches to support the use of transcriptomic points of departure for prioritization and assessment of chemical substances
Anthony Reardon, Existing Substances Risk Assessment Bureau, Health Canada, Canada

Session S449 (Symposium)

Thursday, August 31, 9:00 – 10:30

ASPIS: From Molecular Toxicology to Regulatory Acceptance, the Next Step for Animal-free Testing

Chairs: **Bob van de Water**, Leiden University & **Mathieu Vinken**, Vrije Universiteit Brussel

The safety of hundreds of thousands of chemicals in market products remains untested due to the high cost and slow pace of traditional animal testing. ASPIS - Animal-free Safety assessment of chemicals: Project cluster for Implementation of novel Strategies - is an EU-funded science for societal change initiative. Three consortia have been assembled (RISK-HUNT3R, ONTOX, and PrecisionTox) to develop better methodologies for assessing the effects of chemical exposure on human and environmental health without animal testing and to promote their regulatory acceptance. In this session, an overview of the research and technologies developed by the cluster will be given, including aspects of sustainability and synergies with related initiatives.

#220 ASPIS Strategy Towards Animal-Free Safety Assessment of Chemicals
Jonathan Freedman, University of North Carolina - Chapel Hill

#585 Toxicity by descent: Using phylogenetic relationships to predict interspecies differences in toxicity pathways
Joseph R. Shaw, O'Neill School of Public and Environmental Affairs, Indiana University, ;PrecisionTox Consortium

#526 TXG-MAPr tools: gene co-expression network analysis of toxicogenomic data to provide quantitative mode-of-action assessment and prediction of drug-induced toxicity
Bob van de Water, Leiden Academic Centre for Drug Research (LACDR), Leiden University

#614 Linking Exposure to Effect: The role of Toxicokinetics in ASPIS
Sylvia Escher, Fraunhofer ITEM

#457 Towards regulatory acceptance of qAOP-based NGRA through integration with a qualified open-source PBK framework
Stephan Schaller, esqLABS GmbH

#328 From academia to the shopping cart: how to use new methods in real life chemical risk assessment
Costanza Rovida, CAAT-Europe

#601 Virtual Human Platform for Safety Assessment (VHP4Safety)
Anne Kienhuis, Utrecht University; National Institute for Public Health and the Environment (RIVM)

Session S450 (Symposium)

Monday, August 28, 14:00 - 16:00

New Approach Methods for Developmental and Reproductive Toxicity Testing

Chairs: **Lena Smirnova**, Johns Hopkins Center for Alternatives to Animal Testing & **Jessica Palmer**, Stemina Biomarker Discovery

Developmental and Reproductive Toxicology (DART) is one of the most complex fields of toxicology. The complexity of effects caused by chemical exposure during the entire reproductive cycle and pre- and postnatal development requires repeated exposures and cannot be fully evaluated with just one test. This session brings together researchers working in different DART fields, from the male and female reproductive system to fetal development and quantitative in vitro/in vivo extrapolation. Assay developers, industry users, and regulators will come together to discuss the current situation for applying NAMs in DART testing and identify the current gaps and shortcomings in this field.

#565 Evaluation of Local Tolerance of Vaginal Formulations and Medical Devices with a 3D Human Vaginal Model
Seyoum Ayehunie, MatTek Corporation

#249 A liver and testis multi-organ-chip: towards a systemic male reprotoxicity model
Michelle Jäschke, TissUse GmbH

#137 Developmental toxicity Test using human iPS cells based on signal disruptions induced by chemical substances
Yusuke Okubo, National Institute of Health Sciences

#734 Qualification of the devTOX quickPredict Assay for Regulatory Use Under the ICH S5(R3) Guidelines
Jessica Palmer, Stemina Biomarker Discovery

#355 Robotic device for fully automated high-content screening on C. elegans as a novel NAMs platform for chemical toxicity assessment
Laurent Mouchiroud, Nagi Bioscience SA

#468 Brain organoids for developmental neurotoxicity testing and gene-environment interactions
Lena Smirnova, Johns Hopkins University

#402 Development of a Quantitative In Vitro to In Vivo Extrapolation (QIVIVE Workflow for Assessing Potential Developmental Toxicity
Harvey Clewell, Ramboll US Consulting, Inc.

#740 A Path Forward for New Approach Methodologies for Developmental Immunotoxicity Testing.
Fenna C.M. Sillé, Department of Environmental Health & Engineering; Center for Alternatives to Animal Testing, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD.

#517 Practical Application of New Approach Methods in Developmental and Reproductive Toxicity (DART) Testing
Iris Muller, Unilever, Safety and Environmental Assurance Centre

Session S451 (Symposium)

Monday, August 28, 11:00 – 12:30

Physiologically-Based Pharmacokinetic Modelling for Chemical Risk Assessment

Chairs: **Andreas Schepky**, Beiersdorf AG & **Lynea Murphy**, Corteva Agriscience

New approach methodologies (NAMs) in chemical risk assessment facilitate animal use reduction and in vitro assay readouts for quantitative hazard characterization. Next Generation Risk Assessments (NGRA) leverage NAMs to assure human safety without performing animal testing and extrapolate in vitro points of departure to external bioequivalent exposure regimes. Physiologically based kinetic (PBK) models describe the fate and integrate the knowledge on the absorption, distribution, metabolism, and excretion (ADME) of a chemical in the human body and provides a means for this extrapolation. This session will discuss the use of PBK modelling and NAMs and applicability in chemical risk assessment.

#22 Introduction to PBPK modeling for chemical risk assessment
Marjory Moreau, ScitoVation

#33 Physiologically-Based Kinetic Modelling as Fundamental for Next Generation Risk Assessment
Abdulkarim Najjar, Beiersdorf AG, Hamburg, Germany

#59 Spinosad: A Physiologically-based Pharmacokinetic (PBPK) Model in the Rat and Human including the Pregnancy Life-stage
Jeanne Domoradzki, Corteva Agriscience

#198 Integrating Enzyme Variability Into PB-K Models of Chemicals and Metabolites
Victoria Hull, Inotiv

#592 Modeling Life Stage Toxicokinetic Variability for Effective Chemical Prioritization
Barbara Wetmore, US Environmental Protection Agency

#768 Accounting for In Vitro and In Vivo Kinetics in Quantitative In Vitro to In Vivo Extrapolations of Organophosphate Pesticide Toxicity
Nynke Kramer, Wageningen University, Wageningen, The Netherlands

#474 Toward probabilistic risk assessment – the ONTOX project
Thomas Hartung, Johns Hopkins CAAT

Session S452 (Workshop)

Tuesday, August 29, 09:00 – 10:30

On the Runway: Interactive Predictive Tox Models

Chairs: David Reif, NIEHS & **Sunil Kulkarni**, Health Canada

This session will highlight developments in interactive predictive toxicology models for translational use. The five presentations include: (1) Orbitox as an interactive tool that revolutionizes toxicology predictions and facilitates the translation of results into real-world applications. (2) The role of ICE Data and Tools in advancing Next-Generation Alternative Methods (NAMs). (3) Introduction of ChemDIS-ZF as a computational system specifically designed for inferring chemical-disease relationships in zebrafish. (4) Regulatory safety assessments facilitated by the OECD QSAR Toolbox for hazard assessment and risk management. (5) The OECD's vision for a Global Chemical Knowledge Base, focusing on the integration of various tools and databases to enhance chemical research and understanding.

#152 OrbiTox: An interactive predictive toxicology and translational discovery tool
Vijar Gombar, Sciome, LLC

#179 ICE Data and Tools to Advance NAMs
Aswani Unnikrishnan, Inotiv, RTP, NC, United States

#278 ChemDIS-ZF: a computational chemical–disease inference system for zebrafish
Hung-Lin Kan, Institute of Biotechnology and Pharmaceutical Research, National Health Research Institutes, Miaoli County, 350, Taiwan

#358 Using OECD QSAR Toolbox to support regulatory safety assessments
Donna Macmillan, Humane Society International

#718 The OECD vision of a Global Chemical Knowledge Base: towards integration of tools and databases
Ester Carregal Romero, Organisation for Economic Co-operation and Development (OECD)

Session S453 (Symposium)

Wednesday, August 30, 9:00 – 10:30

New Approaches to Genotoxicity Testing and Risk Assessment

Chairs: **Gilly Stoddart**, PETA Science Consortium International e.V. & **Giel Hendriks**, Toxys

This session introduces innovative methods that have the potential to modernise regulatory genotoxicity testing and enhance human health protection without using animals. Presentations will feature a platform designed for multi-endpoint evaluation of genotoxicity (GeneTox21) followed by discussions regarding cutting-edge transcriptomic (TGxDDI) and mechanism-based (ToxTracker) approaches, along with their current regulatory status. Recent developments on metabolically competent three-dimensional cell culture models used for assessing cosmetics or chemicals and advancements in incorporating in silico techniques into genotoxicity risk assessment will also be presented. Finally, an outlook on innovative future methods will be given using the example of alternative RNA splicing mechanisms.

#591 GeneTox21 – An Integrated Platform for in vitro Genetic Toxicity Assessment of New and Existing Substances
Paul White, Environmental Health Science and Research Bureau, Health Canada

#56 Transcriptomic biomarker validation efforts: lessons learned from a decade of research on the TGx-DDI biomarker for detecting DNA damaging agents
Carole Yauk, University of Ottawa

#613 OECD Validation of the ToxTracker Assay for Genotoxic Mode of Action Assessment
Giel Hendriks, Toxys

#307 Rat liver S9 incorporation into the Reconstructed Skin Micronucleus assay to address scenarios of systemic metabolism
Stefan Pfuhler, Procter & Gamble

#650 Development of a 3d genotoxicity model for assessment of cosmetic formulations
Fiona Jacobs, XCellR8

#282 Incorporating in silico methods into genotoxicity risk assessment: moving beyond mutagenicity
Robert Foster, Lhasa Limited

#192 Charting the Pervasive Changes in Alternative Splicing Networks to Study Novel Modes-of-Action in Toxicogenomics
Rasim Barutcu, ScitoVation, 6 Davis Drive, Suite 146, Durham, NC, 27709

Session S454 (Symposium)

Wednesday, August 30, 14:00 - 16:00

Predictive Toxicology: Data, Development, Delivery, and Application

Chairs: **Ruchir Shar**, Sciome LLC & **Aswani Unnikrishnan**, Inotivco

The field of predictive toxicology has grown rapidly over the past decade. Improved methods of data reporting, identification, and integration along with expansion of computational capabilities to assemble, analyze and disseminate this information has been supporting applications aimed at replacing, reducing, and refining the use of animals in human and environmental health assessments. This Session will focus on the current and future advancements in predictive toxicology, with topics ranging from data curation and annotation efforts to predictive modeling applications, to applications aiding in implementation and establishment of scientific confidence in New Approach Methodologies.

#314 Developing Open-Access Datasets and Predictive Toxicology Tools
Nicole Kleinstreuer, NIEHS/DTT/PTB/NICEATM

#476 Annotating High-Throughput Screening Assays: Facilitating Interpretation and Data Use
Aswani Unnikrishnan, Inotiv

#739 Chronic drug-induced cardiotoxicity assessment using in vitro human iPSC-cardiomyocytes and human heart slices: a multi-platform study conducted by the HESI Stem Cell Working Group
Jessica Palmer, Stemina Biomarker Discovery

#285 Long-Read Transcriptome Sequencing as a Novel Tool for Toxicogenomics
Ralf Herwig, Max-Planck-Institute for Molecular Genetics, Dep. Computational Molecular Biology, Berlin

#634 Unbroken Physioxic Conditions for Reproducible, Predictive in vitro Human Models
Alicia Henn, BioSpherix

#391 Update on the use of New Approach Methodologies (NAMs) from the US Environmental Protection Agency's Office of Pollution Prevention and Toxics.
Kellie Fay, Environmental Protection Agency

#123 Curating chemical use and exposure predictions to contextualize chemical hazard
Victoria Hull, Inotiv

#380 Building confidence in the use of new approach methodologies for decision-making: the homosalate case study
Gladys Ouédraogo, L'Oréal R&I

Session S455 (Symposium)

Monday, August 28, 9:00 – 10:30

Progress in Quantifying Adverse Outcome Pathways to Support Next Generation Risk Assessment

Chairs: **Mark Cronin**, Liverpool John Moores University & **Huan Yang**, esqLABS GmbH

Quantitative Adverse Outcome Pathways (qAOPs) apply data relating to molecular initiating and key events (MIEs / KEs) using a variety of modelling techniques. Computation of qAOPs allows for outputs from New Approach Methodologies to be applied in Next Generation Risk Assessment. The aim of this session is to report on progress in the development of qAOPs from initiatives such as the European Union ASPIS Cluster. This session will outline the main methods and challenges faced by qAOPs, as well as describing modelling approaches for in systems toxicology for human health endpoints and the inclusion of toxicokinetics and exposure.

#416 Status of Quantifying Adverse Outcome Pathways to Support Next Generation Risk Assessment
Mark Cronin, Liverpool John Moores University

#338 Overcoming Challenges in the Development of quantitative AOPs
Richard Currie, Syngenta

#473 Methods2AOP: An International Collaboration Advancing AOP Key Event Descriptions
Agnes Karmaus, Inotiv

#553 Systems-Biology Modelling of Steatosis and Uncertainty Quantification Towards NGRA
Huan Yang, esqLABS GmbH

#448 Secondary pharmacology: strategies, deployment, and impact on the safety of new medicines
Jean-Pierre Valentin, UCB Biopharma

#63 Critical role of Toxicokinetics and ADME methods in Quantifying Exposure for Next generation Risk Assessment
Andreas Schepky, Beiersdorf AG, Global toxicology

#512 The Role of qAOPs in Exposure-Led NGRA: Benefits and Limitations
Alistair Middleton, Unilever

Session S456 (Symposium)

Tuesday, August 29, 11:00 – 12:30

Advances in NAMs for EcoTox Testing & Risk Assessment, Part 1: Biological Models and Techniques

Chairs: **Gina Hilton**, PETA Science Consortium International e.V. & **Ksenia Groh**, Eawag, Swiss Federal Institute of Aquatic Science and Technology

Environmental risk assessment of chemicals traditionally relies on extensive testing with vertebrate animals. Animal tests are, however, ethically controversial and resource-intensive. Therefore, similarly to human toxicology, a shift toward New Approach Methodologies (NAMs) is sought in ecological toxicity testing as well. The twin sessions covering this area aim to highlight recent developments in the NAMs-based approaches that help ensure adequate protection of the environment and are 6R-compliant, i.e., embrace the Relevance, Reproducibility, and Regulatory acceptance, in addition to the original 3Rs. This session—Part 1—focuses on empirical research, including omics, cell-based models and refined testing in fish and amphibians.

#113 EcoToxChip Test System: A Toxicogenomic New Approach Method (NAM) for Chemical Prioritization and Environmental Management
Niladri Basu, McGill University

#532 Strategies to build a modular, cell culture-based approach toward the replacement of fish in environmental risk assessment
Kristin Schirmer, EPF Lausanne, School of Architecture, Civil and Environmental Engineering; ETH Zürich: Department of Environmental Systems Science, Swiss Federal Institute of Aquatic Science and Technology/Utox

#775 Cytotoxic and molecular effects of soil extracts from the Agbogbloshie electronic waste site on the rainbow trout RTgill-W1 and human Caco-2 cell lines
Krittika Mittal, McGill University

#558 In vitro Screening of Three UV Stabilizers and a UV filter: Cytotoxicity, CYP1A Activity, and mRNA Expression in An Immortalized Embryonic Double-Crested Cormorant Cell Line
Tasnia Sharin, McGill University; Environment and Climate Change Canada

#536 Novel assay to monitor phosphorylation-based signaling in cultured fish cells
Ksenia Groh, Eawag, Swiss Federal Institute of Aquatic Science and Technology

#295 Fish and amphibian eleutheroembryo assays as alternatives to animal tests for regulatory assessment of endocrine activity of chemicals
Laurent Lagadic, Bayer AG Crop Science R&D, Germany

#340 Reducing the number of controls in fish early–life stage toxicity tests when solvents are required
Christopher Fassbender, PETA Science Consortium International e.V.

Session S457 (Symposium)

Wednesday, Aug, 30, 11:00 – 12:30

Advances in NAMs for EcoTox Testing & Risk Assessment, Part 2: Computational Tools and Frameworks

Chairs: **Fiona Sewell**, NC3Rs & **Kristin Schirmer**, EPF Lausanne, School of Architecture, Civil and Environmental Engineering; ETH Zürich: Department of Environmental Systems Science, Swiss Federal Institute of Aquatic Science and Technology/Utox

Environmental risk assessment of chemicals traditionally relies on extensive testing with vertebrate animals. Animal tests are, however, ethically controversial and resource-intensive. Therefore, similarly to human toxicology, a shift toward New Approach Methodologies (NAMs) is sought in ecological toxicity testing as well. The twin sessions covering this area aim to highlight recent developments in the NAMs-based approaches that help ensure adequate protection of the environment and are 6R-compliant, i.e., embrace the Relevance, Reproducibility, and Regulatory acceptance, in addition to the original 3Rs. This session—Part 2—focuses on decision frameworks and computational approaches that facilitate integration and interpretation of ecotoxicological data.

#685 A platform for identification of chemicals for which fish have high sensitivity
Christer Hogstrand, King's College London

#511 Cross-taxa Predictive Ecotoxicology: Data, Splitting, Performance
Kristin Schirmer, EPF Lausanne, School of Architecture, Civil and Environmental Engineering; ETH Zürich: Department of Environmental Systems Science, Swiss Federal Institute of Aquatic Science and Technology/Utox

#107 Strengthening the weight of evidence for Fish Embryo Toxicity (FET) data to replace Acute Fish Toxicity (SWiFT)
Adam Lillicrap, NIVA

#215 Data-driven Decision-making Using Advanced High-throughput Environmental Risk Assessment of Fragrance Materials
Aurelia Lapczynski, Research Institute for Fragarance Materials

#117 The Ecological Risk Classification Approach for Prioritizing Organic Substances in Canada: One Giant Leap for NAM-kind
Mark Bonnell, Environment & Climate Change Canada

#69 Leveraging big data & distribution approaches for environmental risk assessment
Kristin Connors, The Procter & Gamble Company

#749 EAS-E Suite: an integrated platform for New Approach Methodologies to facilitate hazard, exposure, and risk assessment.
Alessandro Sangion, University of Toronto; ARC Arnot Research and Consulting Inc.

Session S458 (Symposium)

Tuesday, August 29, 11:00 – 12:30

Artificial Intelligence (AI): Current Advancements and Applications in Advancing the 3Rs

Chairs: **Weida Tong**, NCTR & **Nicole Kleinstreuer**, NIEHS/DTT/PTB/NICEATM

In the 21st century, toxicology and risk assessment heavily rely on new data streams from New Approaches Methodologies (NAMs) to advance refinement, reduction and replacement (3Rs) of animal studies. Artificial Intelligence (AI) plays a crucial role in synthesizing and interpreting these complex and multi-dimensional data streams to align with the risk assessment framework. The symposium will discuss AI applications in toxicology and risk assessment, focusing on real-world examples in environmental chemical and drug safety. Its aim is to foster collaboration among the risk assessment, environmental chemistry, and simulation and modeling communities.

#478 Is it time for Tox-21c 2.0 thanks to AI?
Thomas Hartung, Johns Hopkins CAAT

#316 AI on the CompTox Continuum: Applications in Environmental Chemical Assessment
Nicole Kleinstreuer, NIEHS/DTT/PTB/NICEATM

#181 Deep Learning Profile QSAR Modeling to Impute In Vitro Assay Results and Predict Chemical Carcinogenesis Mechanisms
Alexandre Borrel, Inotiv, United States

#301 Next Generation Artificial Intelligence-Assisted Tools for Excelling Regulatory Acceptance, Global Harmonization and Research Evaluation in the Life Sciences
Giulia Panzarella, Dipartimento di Scienze della Salute, Università Magna Græcia di Catanzaro, Italy

#317 A SafetAI Initiative: AI based prediction initiative to assist reviewers with predicting toxicity end point
Shraddha Thakkar, Center for Drug Evaluation and Research, FDA

#477 Addressing the yearly $53B problem for pharma companies, using 'Patient-on-a-chip' technology and innovative AI.
Isaac Bentwich, Quris AI

#589 Organoid Intelligence (OI): the new frontier in biocomputing and intelligence-in-a-dish
Lena Smirnova, Johns Hopkins University

Session S459 (Symposium)

Thursday, August 31, 9:00 – 10:30

What's New in Skin Sensitization?

Chairs: **Petra Kern**, Procter & Gamble & **Sebastian Hoffmann**, seh consulting + services

Defined approaches outlined in the OECD Test Guideline 497 have ushered in a new era as the first standardized NAM-based assessment to fully replace an animal Test Guideline for hazard assessment. Skin sensitization is a fundamental hazard requirement for chemical safety evaluation as one of the "6 pack" of assays required for assessment of a very broad array of substance categories. This session will showcase recent developments in the methods of next gen skin sensitization testing and case studies of their use in hazard and risk assessment.

#90 Evaluating Skin Sensitization Hazard of Diverse Chemicals Using GARDskin
Emily N Reinke, Inotiv-RTP

#208 In vitro determination of a point of departure for Next Generation Risk Assessment (NGRA) of skin sensitizers: Reproducibility and precision of the GARDskin Dose-Response assay.
Andy Forreryd, SenzaGen AB

#259 Experience with gravimetric testing in the DPRA data: comparison to in vivo reference data
Susanne Kolle, BASF SE

#274 Defined Approaches for Skin Sensitization for Diverse Chemical Sets
Judy Strickland, Inotiv, Inc.

#600 The SARA-ICE Model for Predicting Skin Sensitizer Potency
Gavin Maxwell, SEAC, Unilever

#690 Towards NGRA: Skin Sensitization blazes a trail
Nathalie Alepee, L'Oreal

#763 Hazard and risk assessment of a new cosmetic ingredient using validated methodologies and New Approach Methodologies (NAMs): a case study
Carolina Motter Catarino, Safety Assessment Management - Grupo Boticário