WC11 VIRTUAL CONGRESS
Welcome

Dear colleagues,

Welcome to 11th edition of the World Congress on Alternatives and Animal Use in the Life Sciences! Originally, in a pre-COVID19 era (can you still remember?), foreseen to be held in the city of Maastricht in The Netherlands, but – since the virus is still raging on across the world – now presented to you via the World Wide Web. This, of course, is rather unfortunate because we cannot offer you the great hospitality our city is famous for, and having spontaneous conversations digitally is not that obvious either. But we, as the Local Organizing Committee, took these potential downsides as a challenge to bring to you an innovative platform which should go beyond a generic series of online PowerPoint presentations. I believe we managed to develop great graphics to create a virtual, but realistic congress environment. We have added a few features (such as 3 talk shows) where lively discussions can be initiated, and due to the advances of IT technology, allow interactions across the globe. We hope that you will appreciate it.

As an overarching theme for designing the scientific program we have chosen: “3Rs in transition: from development to application”. This has been inspired by the observation that in the last decade tremendous progress has been made in a wide range to technologies (stem cells, organ-on-a-chip, genomics, micro-engineering, ...) all supportive for realizing non-animal test models of the highest grade, and boosting scientific research in the 3Rs, and in particular Replacement, to a yet unmet level, whilst acceptance of such new generation models by the various application domains is still quite low. We aim to explore this seeming discrepancy, not only in the field of chemical safety testing, but also in vaccine development, and certainly also in creating relevant human disease models. We hope that you will find this inspiring for your own efforts in the 3Rs.

Again, a warm welcome to the virtual congress and we hope you enjoy, get inspired and connected!

Jos Kleinjans,  
Chair - Local Organizing Committee WC11

“Wherever possible, specialists should not be segregated in separate laboratories. The aim should rather be to assemble as many different kinds as possible under one roof.”


In line with this philosophy, the World Congress on Alternatives and Animal Use in the Life Sciences has been a triannual event that brings together specialists in the field of the 3Rs and closely related subjects. Despite the challenges we face in these times of COVID19, where videoconferencing is the norm and interacting on a personal level is reduced to a minimum, we have created congress surroundings that stimulate the exchange of scientific ideas and inspire you to connect to colleagues all over the globe.

In over 100 symposia, workshops and key note lectures, distinguished experts as well as young scientists share with us the fruit of their recent work on innovative non-animal methods, good research practice, harmonization, education, transition towards animal free research, ethics, etc. We have created networking areas where you can meet old friends and promising new contacts to exchange exciting ideas and forge bonds for future cooperation.

If you are an early career scientist, we want you to feel particularly welcome! We have collaborated with YOU-WC11 to organize several interactive sessions and events that promote dialogue amongst yourselves and with experienced peers. You are the future, we invite you to learn, share and challenge current views!

Organizing a world conference is no chick feed, but many hands make light work. We have much enjoyed putting together the scientific program and are very thankful for the help of the members of the international scientific committee, the local organizing committee, the many session organizers and of course our sponsors.

We hope that this virtual congress will bring you an experience you never to forget. Enjoy!

Pascalle Van Loo  
Chair - International Scientific Committee
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COMMITTEES

Local organizing committee

CONGRESS CHAIRS

- **Prof. Dr. Jos Kleinjans** (chair)
  Maastricht University, the Netherlands

- **Dr. Janny van den Eijnden-van Raaij** (co-chair)
  Institute for Human Organ and Disease Model Technologies, the Netherlands

COMMUNICATION COMMITTEE

- **Zvonimir Zvonar** (chair)
  European Partnership for Alternative Approaches to Animal Testing (EPAA), Belgium

- **Prof. Dr. Ellen Fritsche**
  Heinrich-Heine-Universität Düsseldorf, Germany

- **Prof. Dr. Mathieu Vinken**
  Vrije Universiteit Brussel, Belgium

- **Prof. Dr. Ellen Fritsche**
  Heinrich-Heine-Universität Düsseldorf, Germany

- **Marjolein van Boxel, BSc**
  Gemeente Westvoorne, the Netherlands
COMMITTEES
Local organizing committee

SPONSORSHIP COMMITTEE

Dr. Rob Taalman (chair)
Cosmetics Europe, Belgium

Prof. Dr. Jos Kleinjans
Maastricht University, the Netherlands

Dr. Jan van Bertham
Natl. Institute for Public Health and the Environment, the Netherlands

Dr. Hana Ketelbegeers
Concawe, Belgium

OTHER LOC MEMBERS

Prof. Dr. Aldert H. Piersma
Utrecht University, the Netherlands

Dr. Anne Kienhuis
Natl. Institute for Public Health and the Environment, the Netherlands

Prof. Dr. Johan W.M. van Heemskerk
Maastricht University, the Netherlands

Prof. Dr. Bas J. Blaauwboer
Utrecht University, the Netherlands

Prof. Dr. Coenraad Hendriksen
Utrecht University, the Netherlands

Dr. Cyrille A.M. Vouw
University of applied Sciences Utrecht, the Netherlands

Dr. Pascale L.P. van Loo
Utrecht University, the Netherlands

Dr. Irene Mansou
European Partnership for Alternative Approaches to animal testing, Brussels, Belgium

Dr. Gianni Dal Negro
RD Platform Technology & Science, GSK, Hertfordshire, United Kingdom

Dr. Ad Peijnenburg
Wageningen University & Research, Wageningen, the Netherlands

Dr. Nicolaus Rivron
Maastricht University, the Netherlands

Dr. Ad Peijnenburg
Wageningen University & Research, Wageningen, the Netherlands

Dr. Kirsty Reid
EFPIA – European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium

Saskia Aan, MSc
Dutch Society for the Replacement of Animal Testing, The Hague, the Netherlands

Dr. Thomas Heynisch
European Partnership for Alternative Approaches to animal testing, Brussels, Belgium

Bas de Waard, MSc
The Netherlands Organisation for Health Research and Development, the Netherlands

Prof. Dr. Robert Passier
University of Twente, the Netherlands

Dr. Pascalle L.P. van Loo
Utrecht University, the Netherlands

Dr. Kirsty Reid
EFPIA – European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium
COMMITTEES
Scientific committee

Dr. Pascale L.P. van Loo
Utrecht University, the Netherlands
Chair - International Scientific Committee

Janny van den Eijnden-van Raaij
Institute for human Organ and Disease Model Technologies (The Netherlands)

Laura Gribaldo
European Commission (Italy)

Adrian Ionescu
EPFL (Switzerland)

Yasu Kanda
NIHS Japan (Japan)

Paulin Jirkof
3R Koordinatorin UZH (Switzerland)

Nicole Kleinstreuer
NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) (USA)

Vijay Pal Singh
CSIR-Institute of Genomics & Integrative Biology (India)

Peter Loskill
Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB (Germany)

Kartheinz Peter
Monash University (Australia)

COMMITTEES
Scientific committee

Aldert Piersma
National Institute for Public Health and the Environment (The Netherlands)

Kate Willet
Humane Society International (USA)

Weida Tong
NCTR/FDA (USA/China)

Kirsty Reid
European Federation of Pharmaceutical Industries and Associations (Belgium)

ORGANISATION
Congress Secretariat

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QUESTIONS & SUPPORT
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+31(0)43-36 27 008

Klinkhamer Group wishes all participants an inspiring virtual experience.

connecting smart people.

professional congress organiser

Klinkhamer Group wishes all participants an inspiring virtual experience.

dedicated by all means.
klinkhamergroup.com
The ASPCA Animal Poison Control Center wishes to welcome all participants to the 11th World Congress on Alternatives and Animal Use in the Life Sciences.

Download the official WC11 app now in the app stores. It contains the most up-to-date program information and news. It also contains background information about the congress, speakers, parallel sessions, and posters. You can also use the app to put together your own program. Please note that the app contains the same information as the WC11 Virtual Event Platform, and it is therefore not necessary to download. However, it can be useful for times when you are away from the computer for a while.

HOW TO DOWNLOAD THE APP?
You can find the WC11 app in the App Store and Google Play under the search term WC11 Maastricht. Use the QR codes on this page to go directly to the download page of the app.

TWEET ABOUT WC11?
Use #wc11maastricht

**PROGRAM AT A GLANCE**

The program of the 11th World Congress on Alternatives and Animal Use in the Life Sciences (WC11) will be virtual due to continued COVID-19 imposed restrictions, and will be spread over a two-week period, from 23 August - 2 September 2021.

Times mentioned are in Amsterdam/Brussels time (AMS CEST UTC+2)

### Week 1

**MONDAY 23 AUGUST 2021 - DAY 1**

1.30 - 2.15 PM WC11 Virtual Opening Ceremony and Welcome Address
2.15 - 3.15 PM KEYNOTE: André Kuipers
3.15 - 3.30 PM WC11 TV live from the studio
3.30 - 5.30 PM Parallel Sessions + Q&A
5.30 - 5.45 PM WC11 TV live from the studio
5.45 - 6.45 PM KEYNOTE: Russel Thomas
6.45 - 7.00 PM WC11 TV live from the studio
7.00 - 9.00 PM Parallel Sessions + Q&A
9.00 - 11.00 PM WC11 Welcome Reception in WC11 Network Rooms

**TUESDAY 24 AUGUST 2021 - DAY 2**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM KEYNOTE: Donald Ingber
6.15 - 6.30 PM WC11 TV live from the studio
6.30 - 8.30 PM Parallel Sessions + Q&A
9.00 - 10.00 PM WC11 Talkshow 1 (Theme: Safety)

**WEDNESDAY 25 AUGUST 2021 - DAY 3**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM KEYNOTE: Jason Ekert
6.15 - 6.30 PM WC11 TV live from the studio
6.30 - 8.30 PM Parallel Sessions + Q&A
9.00 - 10.00 PM WC11 Talkshow 2 (Theme: Disease)

**THURSDAY 26 AUGUST 2021 - DAY 4**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM KEYNOTE: Malcolm McLeod
6.15 - 6.30 PM WC11 TV live from the studio
6.30 - 8.30 PM Parallel Sessions + Q&A

**FRIDAY 27 AUGUST 2021 - DAY 5**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 6.00 PM Pre-poster warm-up session
6.00 - 7.00 PM Poster sessions + Q&A with presenters
7.00 - 8.00 PM WC11 Talkshow 2 (Theme: Disease)

### Week 2

**MONDAY 30 AUGUST 2021 - DAY 6**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM KEYNOTE: Anne Deplazes
6.15 - 6.30 PM WC11 TV live from the studio
6.30 - 8.30 PM Parallel Sessions + Q&A

**TUESDAY 31 AUGUST 2021 - DAY 7**

1.00 - 1.30 PM WC11 TV live from the studio
1.30 - 2.30 PM KEYNOTE: Dr. Tharanga Thoradeniya
2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.15 - 6.15 PM Poster sessions + Q&A with presenters
6.30 - 8.30 PM Parallel Sessions + Q&A

**WEDNESDAY 1 SEPTEMBER 2021 - DAY 8**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.15 - 6.15 PM Poster sessions + Q&A with presenters
6.30 - 8.30 PM Parallel Sessions + Q&A
8.30 - 9.30 PM WC11 Talkshow 3 (Theme: Innovative Technologies)

**THURSDAY 2 SEPTEMBER 2021 - DAY 9**

2.30 - 3.00 PM WC11 TV live from the studio
3.00 - 5.00 PM Parallel Sessions + Q&A
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM KEYNOTE: Joseph Wu
6.15 - 6.30 PM WC11 TV live from the studio
6.30 - 7.30 PM Björn Ekwall Memorial Fund (BEMF) Award
6.30 - 8.00 PM WC11 Award Ceremony
8.00 - 8.45 PM Closing Ceremony

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The WC11 Magazine was created a few weeks before the congress and is therefore not fully up to date. The most up to date program can be found in the app and the WC11 Virtual Event Platform.
KIRSTEN PAULUS
Moderator

Nice to meet you! My name is Kirsten Paulus and I’m honoured to be your host during the 11th WC coming August and September. Wonderful that we’ll meet. Especially in these times it is important to get together, to share expertise and to invest in the development of alternatives for animal testing. Although it’s a virtual congress I’m sure that we’ll make it a successful exchange of knowledge.

Let’s take the opportunity to reconnect and start building relationships for the future. I’m going to do my very best and use my experience as a moderator and TV and Radio-presenter to make this all happen. With one shared goal: to make this congress inspiring, interesting and enjoyable.

I’m looking forward to see you all, work together with all of you from all around the world and make this congress unforgettable.

Take care. Stay safe,
Kirsten Paulus

TALKSHOW 1
Presence and Future of the Next-Generation Risk Assessment Approach.
© 24 August 2021, 9:00 PM CEST.

TALKSHOW 2
Human Diseases and Drug Development and will focus on neurodegenerative diseases.
© 27 August 2021, 7:30 PM CEST.

TALKSHOW 3
New technologies and the Use of human-derived material.
© 1 September 2021, 8:30 PM CEST.

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**PROGRAM**
Monday 23 August 2021 - Day 1

**PLENARY SESSIONS**
1.30 - 3.30 PM

**WC11 Virtual Opening Ceremony and Welcome Address**

The opening ceremony promises to be a one-of-a-kind unique experience. Live from the MECC in Maastricht, the Netherlands, where the congress was scheduled to take place in 2020.

During the opening ceremony we hear welcoming words from:

- Jos Kleinjans, Chair of the WC11 Local Organizing Committee
- Martin Paul, President of Maastricht University
- Kristin Schreiber, Director DG GROW at the European Commission
- Christian DeSaintes, Policy Officer, DG Research & Innovation at the European Commission

After the official welcoming remarks, the Harmonie St. Joseph Sittard from the Netherlands will provide the musical backdrop for the end of the opening ceremony.

Right after the opening ceremony we will switch to the WC11 Studio for the first keynote by WC11, Astronaut André Kuipers.

**KEYNOTE:**

**DR. ANDRÉ KUIPERS**

European Space Agency

Born on 5 October 1958 in Amsterdam, the Netherlands, André Kuipers is married with three daughters and a son. He enjoys flying, scuba diving, skiing, hiking, traveling, and history.

In December 2002, André was assigned as a Flight Engineer for a Soyuz flight to the International Space Station. The DELTA mission was sponsored by the Dutch government in an agreement between ESA and the Russian Federal Space Agency and took place from 19–30 April 2004. The flight had three objectives: to exchange the Soyuz spacecraft that serves as Space Station lifeboat, to exchange the Station crew and for André to perform 21 experiments in human physiology, biology, technology and education.

In August 2009, André was assigned to Expedition 30/31, a long-duration mission to the International Space Station called PromISSe. Together with Russian cosmonaut Oleg Kononenko and NASA astronaut Don Pettit, André was launched on 21 December 2011 from Baikonur Cosmodrome in Kazakhstan. During his mission, he took part in around 50 experiments covering a wide range of disciplines. He was the prime crewmember for the rendezvous and docking of ESA's third Automated Transfer Vehicle. He was also involved in berthing SpaceX's Dragon ferry. André and his crewmates returned to Earth on 1 July 2012.

Read more about André Kuipers on the website of the European Space Agency: https://www.esa.int/Science_Exploration/Human_and_Robotic_Exploration/Astronauts/Andre_Kuipers

**WC11 TV live from the studio**

3:15 - 3.30 PM

**PARALLEL SESSION MO-1**

**Parallel Session MO-1**

1.30 - 5.30 PM

**Remove ATT, TABST & LABST. How far away we are to global harmonization for those safety tests?**

Many institutions and organization have been working independently or jointly to remove those obsolete safety testing from the production and batch release testing for human (ATT) and veterinary vaccines (TABST, LABST).

Many regulatory agencies and international organizations have successfully removed or suggested the remove or the waiver of those tests. How far away are we from their global elimination?

Chair:
L. Viviani, Humane Society International

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<th>Speakers</th>
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<td>3.30 PM</td>
<td>REMOVE ATT, TABST &amp; LABST: HOW FAR AWAY ARE WE TO GLOBAL HARMONIZATION FOR THOSE SAFETY TESTS?</td>
<td>L. Viviani, Humane Society International</td>
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<td>3.45 PM</td>
<td>REMOVE ATT, TABST &amp; LABST: THE JOURNEY OF HOW THEY BECAME OBSOLETE</td>
<td>K. Schulte, EPA - European Partnership for Alternative Approaches to Animal Testing</td>
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<td>4.00 PM</td>
<td>WAIVING THE TARGET ANIMAL BATCH SAFETY TESTS OF VETERINARY VACCINES. AN INDUSTRY PERSPECTIVE.</td>
<td>C. Philippe, Boehringer Ingelheim</td>
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<td>4.15 PM</td>
<td>THE INTEREST TO ADOPT A CHANGE ON TABST &amp; LABST IN BRAZIL.</td>
<td>M. Vinicius de Santana Leandro, Ministry of Agriculture Brazil</td>
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<td>4.30 PM</td>
<td>REMOVAL OF ABNORMAL TOXICITY TEST FROM HUMAN VACCINES IN INDIA: A SUCCESSFUL APPROACH</td>
<td>S.K. Goel, Serum Institute of India</td>
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**PROGRAM**
Monday 23 August 2021 - Day 1
## PROGRAM
### Monday 23 August 2021 - Day 1

### 3.30 - 5.30 PM  MO-1 S200

**Establishing a European Network of 3Rs Centers and 3Rs-Societies**

Several 3Rs centers have recently been established around the world dealing with different aspects of replacement, reduction and refinement of animals used for scientific purposes. The session aims at providing an overview of the diversity and experiences the various centers may face within their countries. In addition, it will discuss possible synergies and collaborative activities that can help furthering the implementation of 3Rs at different levels such as research, education, and dissemination.

**Session chair and co-chair**
H. Spielmann, EUSAAT (European Society for Alternatives to Animal Testing) and C. Chandrasekera, Canadian Centre for Alternatives to Animal Methods (CCAAM)

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<td>3.30 PM</td>
<td>ID 76 THE EUSAAT INITIATIVE TO ESTABLISH A EUROPEAN NETWORK OF 3RS CENTERS</td>
<td>W. Neuhaus, AIT Austrian Institute of Technology</td>
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<td>3.45 PM</td>
<td>ID 24 NORECOPA: A HUB OF INTERNATIONAL 3R RESOURCES</td>
<td>A. Smith, Norecopia</td>
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<td>4.00 PM</td>
<td>ID 75 THE BERLIN-BRANDENBURG RESEARCH PLATFORM B3R - RESEARCH AND</td>
<td>M. Schäfer-Noring, Freie Universität Berlin</td>
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<td>GRADUATE EDUCATION SINCE 2014</td>
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<td>4.15 PM</td>
<td>ID 909 CANADIAN CENTRE FOR ALTERNATIVES TO ANIMAL METHODS</td>
<td>C. Chandrasekera, CCAAM</td>
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<td>4.30 PM</td>
<td>ID 80 ASIAN CONGRESS SUPPORTED BY THE JAPANESE SOCIETY FOR ALTERNATIVES</td>
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<td>TO ANIMAL EXPERIMENTS (USAAE)</td>
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<td>4.45 PM</td>
<td>ID 77 PROMOTION OF THE 3RS CONSENSUS FORMATION IN CHINA THROUGH</td>
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<td>TRANSFORMATION BETWEEN ACADEMIA AND INDUSTRY</td>
<td>S. Cheng, Shanghai Jiaotong</td>
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<td>5.00 PM</td>
<td>SESSION 200 Q&amp;A</td>
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### 3.30 - 5.30 PM  MO-1 S167

**Replacing Fetal Bovine Serum (FBS) – Innovative Alternatives and Transition Strategies**

Cell culture media are commonly supplemented with fetal bovine serum (FBS), obtained from the blood of unborn calves, to ensure cell proliferation and maintenance. Its unknown composition and high lot-to-lot variability can cause unintended outcomes and problems in experimental reproducibility. Furthermore, FBS production is subject to ethical and animal welfare concerns, as there are certain indications that fetuses are already capable of suffering. Alternatives are on the market, e.g., lysates of human blood platelets (hPL) or chemically defined media. The workshop aims to discuss the use and collection of FBS, performance of existing alternative media and demonstrates transition strategies.

**Session chair and co-chair**

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<td>3.30 PM</td>
<td>ID 284 DAM TRANSPORTATION, FETAL SUFFERING AND LEGAL OBJECTIONS - WHY</td>
<td>Tilo Weber, German Animal Welfare Federation / Animal Welfare Academy</td>
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<td>FETAL BOVINE SERUM SHOULD BE A THING OF THE PAST</td>
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<td>3.45 PM</td>
<td>ID 88 REPLACING FETAL BOVINE SERUM: A PIECE OF CAKE?</td>
<td>Jan Valk, 3Rs-Centre Utrecht Life Sciences, Utrecht University</td>
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<td>4.00 PM</td>
<td>ID 245 REPLACING FETAL BOVINE SERUM (FBS) - INNOVATIVE ALTERNATIVES AND</td>
<td>Karen Bieback, Institute of Transfusion Medicine and Immunology, Medical Faculty Mannheim,</td>
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<td></td>
<td>TRANSITION STRATEGIES</td>
<td>Heidelberg University; German Red Cross Blood Service Baden-Wurttemberg - Hessen</td>
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<td>ID 480 TOWARDS THE REPLACEMENT OF FETAL BOVINE SERUM IN CELL CULTURE</td>
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<td>APPLICATION: THE EXAMPLE OF A549 CELLS</td>
<td>Aline Chary, Luxembourg Institute of Science and Technology</td>
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<td>4.30 PM</td>
<td>ID 534 WHAT IS TRULY ANIMAL-FREE TESTING? MOVING TOWARDS ANIMAL-</td>
<td>Carol Treasure, XCellR8 Ltd, Techspace One, Neeckwith Lane, Daresbury, Cheshire WA4 4AB, UK</td>
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<td>PRODUCT-FREE IN VITRO SYSTEMS</td>
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<td>4.45 PM</td>
<td>ID 1032 A UNIQUE THREE DIMENSIONAL MULTIWELL PLATE FOR ANIMAL FREE</td>
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<td>EVALUATION OF TOXICITY</td>
<td>Stina Oredsson</td>
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<td>ID 92 SETTING THE SCENE FOR A NEW PARADIGM FOR RISK ASSESSMENT: EVOLUTION VERSUS REVOLUTION</td>
<td>Aldert Piersma, RIVM</td>
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<td>ID 668 VALIDATION IN A REGULATORY CONTEXT - A EUR-LAC PERSPECTIVE ON PRINCIPLES, PRACTICE AND PROGRESS</td>
<td>Maurice Whelan, European Commission, Joint Research Centre (JRC)</td>
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<td>4.00 PM</td>
<td>ID 144 RETHINKING VALIDATION: BUILDING CONFIDENCE IN HUMAN MODELS THROUGH BIOLOGICALLY BASED DESIGN</td>
<td>Rebecca Clewell, 21st Century Tox Consulting LLC</td>
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<td>ID 121 NEXT GENERATION RISK ASSESSMENT FOR CONSUMER SAFETY: WHAT DO WE NEED FROM VALIDATION?</td>
<td>Carl Westmoreland, Unilever SEAC</td>
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<td>4.30 PM</td>
<td>ID 429 TOWARDS AN ANIMAL-FREE HUMAN HEALTH ASSESSMENT: WHAT ARE THE REGULATORY NEEDS?</td>
<td>Peter Bos</td>
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<td>4.45 PM</td>
<td>ID 787 IMPROVEMENT OF IN SILICO MODELS FOR TOXICITY PREDICTION BY IDENTIFYING, CHARACTERISING AND REDUCING UNCERTAINTIES</td>
<td>Mark Cronin</td>
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<td>3.30 PM</td>
<td>ID 15 OPENNESS IN THE UK SINCE THE CONCORDAT</td>
<td>Wendy Jarrett, Understanding Animal Research</td>
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<tr>
<td>3.45 PM</td>
<td>ID 4 THE TRANSPARENCY AGREEMENT IN SPAIN: AN EXAMPLE OF SUCCESS</td>
<td>Javier Guillén, AAALAC International</td>
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<tr>
<td>4.00 PM</td>
<td>ID 544 IMPLEMENTING TRANSPARENCY IN PORTUGAL</td>
<td>Ana Santos, NOVA Medical School, NOVA University Lisboa, FELASAn</td>
</tr>
<tr>
<td>4.15 PM</td>
<td>ID 8 TALKING ABOUT HARMS</td>
<td>Barney Reed, RSPCA</td>
</tr>
<tr>
<td>4.30 PM</td>
<td>ID 458 PROMOTING TRANSPARENCY AROUND ANIMAL RESEARCH ACROSS REGIONS</td>
<td>Susanna Louhimies, European Commission</td>
</tr>
<tr>
<td>5.00 PM</td>
<td>SESSION 149 Q&amp;A</td>
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Methods to enhance biotransformation capability for in vitro high-throughput screening assays

In vitro high-throughput screening (HTS) assays have been developed over the past decade for generating toxicity profiles for thousands of data-poor environmental compounds. Although highly successful, the effort has been limited by a lack of effective biotransformation capability in the standard cell types used in these in vitro assays. Thus, results from these assays may not accurately reflect in vivo activity. To address this problem, several laboratories are developing methods to provide metabolic activation capability to these in vitro systems. This symposium will highlight novel, ongoing approaches for providing biotransformation capability to HTS assays, with an emphasis on human-relevant metabolism. In vitro high-throughput screening (HTS) assays have been developed over the past decade for generating toxicity profiles for thousands of data-poor environmental compounds. Although highly successful, the effort has been limited by a lack of effective biotransformation capability in the standard cell types used in these in vitro assays. Thus, results from these assays may not accurately reflect in vivo activity. To address this problem, several laboratories are developing methods to provide metabolic activation capability to these in vitro systems. This symposium will highlight novel, ongoing approaches for providing biotransformation capability to HTS assays, with an emphasis on human-relevant metabolism.

Session Chair
Kristine Witt, National Toxicology Program/NIEHS and Menghang Xia, SOT/National Center for Advancing Translational Sciences

Time    Abstract Speakers
3.30 PM  INCORPORATION OF A METABOLIC COMPONENT INTO IN VITRO TOX21 HIGH THROUGHPUT SCREENING ASSAYS Menghang Xia, National Center for Advancing Translational Sciences, NIH
3.45 PM  RETROFITTING AN IN VITRO TOX21 HIGH THROUGHPUT SCREENING ASSAY FOR P53 ACTIVATION WITH METABOLIC CAPABILITY: COMPARING RESULTS FROM HUMAN AND RAT LIVER MICROSOMES PREPARATIONS Kristine Witt, U.S. National Toxicology Program/NIEHS/NIH
4.00 PM  A HUMAN XENOBIOTIC METABOLIC SYSTEM ADAPTED TO QUANTITATIVE HIGH-THROUGHPUT SCREENING PROCESSES Ludovic LE HEGARAT, ANSES, French Agency for Food, Environmental and Occupational Health & Safety
4.15 PM  DEVELOPMENT OF METABOLICALLY COMPETENT HUMAN AND RAT SPHEROID MODELS AND APPLICATION OF HIGH-THROUGHPUT TRANSCRIPTOMICS TOWARDS 3R'S STRATEGY Sreenivasa Ramasahajara, Biomolecular Screening Branch, Division of National Toxicology Program, National Ins
4.30 PM  USE OF HUMAN CELL LINES WITH DIFFERENT BIOACTIVATION CAPACITIES TO DETERMINE THE GENOTOXIC MECHANISM OF ACTION Marc Audebert, INRAE TOXALIM
4.45 PM  DECIDING ON AN ASSAY SETUP TO CONTROL TEST CHEMICAL CONCENTRATIONS IN VITRO Nynke Kramer
5.00 PM  SESSION 79 Q&A
**PARALLEL SESSION MO-2**

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<tr>
<th>Time</th>
<th>Abstract</th>
<th>Speakers</th>
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<tr>
<td>7.00 PM</td>
<td><strong>ID 19</strong> THE CURRENT TRANSLATIONAL GAP: PROBLEMS AND SOLUTIONS</td>
<td>Erwin L Roggen, ToxGenSolutions BV</td>
</tr>
<tr>
<td>7.30 PM</td>
<td><strong>ID 65</strong> LINCRNAS AS NOVEL SOURCE OF DIAGNOSTIC APPLICATIONS FOR EARLY ALZHEIMER’S DISEASE AND OTHER DEMENTIA TYPES - ADDIA CONSORTIUM AND ADNIT CONSORTIUM</td>
<td>Hüseyin Firat, Amoneta Diagnostics SAS</td>
</tr>
<tr>
<td>8.00 PM</td>
<td><strong>ID 251</strong> MAPPING POTENTIAL BIOMARKERS FOR EARLY SPORADIC ALZHEIMER’S: STATUS OF THE INTERREG VL-NL PROJECT <code>MEMORIES</code></td>
<td>Jacco Briedé, Maastricht University</td>
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<tr>
<td>8.30 PM</td>
<td><strong>SESSION 71 Q&amp;A</strong></td>
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**PARALLEL SESSION MO-2**

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<th>Time</th>
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<tr>
<td>7.00 PM</td>
<td><strong>ID 222</strong> UPDATE ON INNOVATIVE APPROACHES TO SHARE ORGANS AND TISSUES IN SCIENCE</td>
<td>Annemarie Lang, Department of Rheumatology and Clinical Immunology, Charité-Universitätsmedizin Berlin; AniMatch UG (haftungsbeschränkt)</td>
</tr>
<tr>
<td>7.15 PM</td>
<td><strong>ID 300</strong> SEARCHBREAST: A VIRTUAL BIORESOURCE TO FACILITATE THE SHARING OF SURPLUS ANIMAL MATERIALS DERIVED FROM BREAST CANCER STUDIES</td>
<td>Valerie Speirs, University of Aberdeen</td>
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<tr>
<td>7.30 PM</td>
<td><strong>ID 488</strong> BUILDING AN INTERNAL INFORMATION INFRASTRUCTURE TO DISSEMINATE SURPLUS ANIMALS</td>
<td>Claudia Abramjuk, FEM, Charité Universitätsmedizin Berlin</td>
</tr>
<tr>
<td>7.45 PM</td>
<td><strong>ID 1014</strong> HOW TO REDUCE REDUCTION TO PRACTICE - AN EXAMPLE</td>
<td>Beate Obermüller, University of Graz</td>
</tr>
<tr>
<td>8.00 PM</td>
<td><strong>ID 598</strong> VITAL TISSUE, AN INITIATIVE TO SUPPLY Viable HUMAN MATERIALS TO LABORATORIES IN THE NETHERLANDS</td>
<td>Evita van de Steeg</td>
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<tr>
<td>8.30 PM</td>
<td><strong>SESSION 76 Q&amp;A</strong></td>
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Innovative Technologies
Disease
Ethics, Welfare
and Regulation
Safety

PROGRAM
Monday 23 August 2021 - Day 1

7.00 - 9.00 PM MO-2 S235

Case studies of industrial adoption using Microphysiological Systems

The Pharmaceutical industry has implemented a broad array of in vitro systems to support preclinical evaluation of new drug candidates. Microphysiological Systems (MPS) are considered to further improve prediction of safety and efficacy of new drug candidates prior to their use in humans. MPS-based assays are increasingly becoming part of the internal decision-making processes within Pharma and this session aims to present case studies of industrial adoption while discussing their impact on the 3R’s.

Session chair and co-chair
A. Roth, Hoffman La Roche and L. Ewart, AstraZeneca

Time Abstract Speakers
7.00 PM INTRODUCTION TO THE SESSION: CASE STUDIES FROM INDUSTRY USING MICROPHYSIOLOGICAL SYSTEMS L. Ewart, Emulate Inc.
7.15 PM HUMAN IMMUNOCOMPETENT ORGAN ON CHIP PLATFORMS ALLOW SAFETY PROFILING OF TUMOR-TARGETED T-CELL BISPECIFIC ANTIBODIES G. A. Hamilton, Emulate Inc. and L. Cabon, Roche
7.30 PM A HIGH-THROUGHPUT, MICROFLUIDIC PLATFORM FOR DRUG SCREENING ON VASCULARIZED 3D TISSUES J. Joore, Mimetas
7.45 PM A HUMAN-DERIVED PROXIMAL TUBULE-ON-A-CHIP REPLICATES ASO-INDUCED KIDNEY INJURY BIOMARKERS T. Nieskens, AstraZeneca
8.00 PM ORGANOIDS: LESS ANIMAL STUDIES, MORE RELEVANT DATA R. Vries, Hubrecht Institute
8.30 PM SESSION 235 Q&A

New Approach Methodologies (NAM)-supported Read-Across Approaches for Regulatory Purposes

Read-across (RAx) is one of the most commonly used alternative approaches for data gap filling in registrations submitted under cosmetics safety assessment and REACH. New approach methodologies (NAM) have started to be deployed to reduce uncertainty and establish robust read-across. In this session, the use of NAM-supported RAx will be introduced and exemplary case studies from the Cosmetics Europe Long-Range Science Strategy and the EU-ToxRisk project will be presented. The EU-ToxRisk advisory document will be described. A strong focus will be given on its regulatory foundation and future impact. Finally, the available approaches and tools for RAx-supported risk assessment will be discussed.

Session chair and co-chair
S. Hougaard Bennekou, National Food Institute, Technical University of Denmark and D. Kroese, TNO, Netherlands Organisation for Applied Scientific Research

Time Abstract Speakers
7.00 PM SETTING THE SCENE: NEW APPROACH METHODOLOGIES (NAM)-SUPPORTED READ-ACROSS APPROACHES Hennicke Kamp, BASF SE
7.15 PM A CASE STUDY COMBINING READ-ACROSS AND NAM, THE EXAMPLE OF PROPYL-PARABEN IN SYSTEMIC TOXICITY, FROM A TO Z Gladys Ouedraogo, Cosmetics Europe
7.30 PM FROM CASE STUDIES TO A REGULATORY GUIDANCE: THE EU-TOXRISK NAM-ASSISTED RAx ADVISORY DOCUMENT Bob van de Water, Leiden University
7.45 PM REGULATORY FEEDBACK ON THE EU-TOXRISK (NAM)-SUPPORTED READ-ACROSS ADVISORY DOCUMENT Matthias Herzler, German Federal Institute for Risk Assessment (BfR)
8.00 PM NAVIGATING THE REGULATORY LANDSCAPE OF READ-ACROSS: A PERSPECTIVE OF APPROACHES, TOOLS WITHIN AN IATA FRAMEWORK Luciana Lizarraza, US EPA
8.30 PM SESSION 163 Q&A
PROGRAM
Monday 23 August 2021 - Day 1

7:00 - 9:00 PM MO-2 S1196 Barriers of Refinement Use in Practice

Refinement research has the potential to improve the lives of many animals. However, implementation of Refinement is often limited, even when refinements are based on scientifically sound discoveries. Barriers to implementation may include: economical constraints, apprehensions about changes to data, limitations in products marketed by animal research suppliers and people (their cultural backgrounds, attitudes and beliefs towards animals). This workshop explores what is perceived as the potential barriers to implementation of Refinement, with the aim of highlighting paths forward for successful application. Real case studies will be presented to reveal existing barriers and as examples on ways to achieve change.

Session chair and co-chair
K. Hermann, Johns Hopkins University Bloomberg School of Public & Center for Alternatives to Animal Testing

Time Abstract Speakers
7:00 PM ID 150 PERCEIVED BARRIERS TO IMPLEMENTING REFINEMENTS IN EUTHANASIA FOR RODENTS
L. Amendola, University of British Columbia
7:15 PM ID 819 PRACTICAL CHALLENGES AND CONSIDERATIONS IN REFINING EUTHANASIA METHODS IN LABORATORY ANIMAL RESEARCH IN RODENTS – A PHARMACEUTICAL INDUSTRY CASE STUDY
S. Robinson, AstraZeneca
7:45 PM LOW STRESS HANDLING OF MICE: CHALLENGES AND SOLUTIONS FOR IMPLEMENTATION
J. Hurst, University of Liverpool
8:00 PM ID 366 EDUCATION AND TRAINING TO FULLY IMPLEMENT REFINEMENT METHODS IN PRACTICE
K. Herrmann, Johns Hopkins Bloomberg School of Public Health & CAAT
8:30 PM SESSION 1196 Q&A

PROGRAM
Monday 23 August 2021 - Day 1

7:00 - 9:00 PM MO-2 S111 Modern, Mechanistic Approaches to Cancer Risk Assessment

For decades, risk assessors have relied on the rodent cancer bioassays to identify potential human carcinogens. The rodent bioassays are required by numerous regulatory authorities for carcinogenicity assessment. However, five decades of research have revealed more informative, human-relevant approaches to assess potential carcinogenic effects. Questions are being asked about how to modernize cancer risk assessment through the use of mechanistic approaches that reduce testing on animals and provide more health protective information to ensure chemical safety. During this session, experts will deliver presentations and a panel discussion providing insight into current challenges and opportunities in designing human-relevant chemical carcinogenicity assessment.

Session chair
Gina Hilton, PETA Science Consortium International e.V.

Time Abstract Speakers
7:00 PM ID 11 MODERNIZING THE NTP’S CARCINOGENICITY TESTING PROGRAM
Warren Casey, US National Toxicology Program
7:15 PM ID 72 TOWARDS REPLACING THE TWO-YEAR BIOASSAY WITH SHORT-TERM NAMS: GENOMIC AND NONGENOMIC ACTIVATION LEVELS CAN IDENTIFY RAT LIVER TUMORIGENS
Chris Ceron, Environmental Protection Agency; Center for Computational Toxicology and Exposure
7:30 PM ID 17 APPLICATION OF THE KEY CHARACTERISTICS IN CARCINOGEN HAZARD IDENTIFICATION
Kathryn Guyton, IARC
7:45 PM ID 44 RECAAP: CARCINOGENICITY WAIVERS FOR FOOD-USE PESTICIDE REGISTRATION
Gina Hilton, PETA Science Consortium International e.V
8:00 PM ID 170 DEVELOPING AN INTEGRATED APPROACH TO TESTING AND ASSESSMENT FOR NON-GENOTOXIC CARCINOGENS
Nathalie Derue, Organisation for Economic Co-operation and Development
8:15 PM ID 63 ADVANCING CARCINOGENICITY ASSESSMENT: A NOVEL METHODOLOGICAL APPROACH TO INTEGRATE INFORMATION AND FURTHER THE IMPACT ON THE 3RS
Federica Madia, European Commission, Joint Research Centre
8:30 PM SESSION 111 Q&A
### PROGRAM
Tuesday 24 August 2021 - Day 2

#### PLENIARY SESSIONS

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<td>2.30 - 3.00 PM</td>
<td>WC11 TV - Live from the studio</td>
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#### PARALLEL SESSION TUE-1

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<tr>
<th>Time</th>
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<tr>
<td>3.00 - 5.00 PM</td>
<td>S75</td>
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<td></td>
<td>Modeling the musculoskeletal system and related disorders in vitro – Cells, scaffolds and biomechanics</td>
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<td>The development of physiological relevant models to simulated parts of the musculoskeletal system such as bone or cartilage requires the combination of tissue engineering, cell biology and biomechanics. In the proposed symposium different aspects and approaches for this specific area will be presented including bone-, cartilage- or joint-on-a-chip technologies, macro- tissue and bioreactor approaches towards sophisticated tissue engineering and qualitative network models.</td>
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**Session chair**
Frank Schulze, German Centre for the Protection of Laboratory Animals (Bf3R) and Marcel Karperien, University of Twente, The Netherlands

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<tbody>
<tr>
<td>3.00 PM</td>
<td>ID 50</td>
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<tr>
<td></td>
<td>The Effect of Mechanical Loading in a Bone-on-a-Chip</td>
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<tr>
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<td>Frank Schulze, German Federal Institute for Risk Assessment; German Centre for the Protection of Laboratory Animals</td>
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<tr>
<td>3.15 PM</td>
<td>ID 896</td>
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<tr>
<td></td>
<td>Microfabrication Technologies for Engineering of a Moving Joint-on-Chip</td>
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<td>Marcel Karperien, University of Twente</td>
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<td>3.30 PM</td>
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<td>In Silico Modelling as a Way to Prioritize Experiments and Reduce Experimental Testing for Osteoarthritis Drug Target Discovery</td>
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<tr>
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<td>Raphaëlle Lesage, Prometheus, Division of Skeletal Tissue Engineering, KU Leuven; Belgium; Biomechanics Section, KU Leuven</td>
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<td>3.45 PM</td>
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<td>Developing an In Vitro Model of Glucocorticoid-Induced Osteoporosis</td>
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<td>Annemarie Lang, Department of Rheumatology and Clinical Immunology, Charité-Universitätsmedizin Berlin; German Rheumatism Research Center</td>
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<tr>
<td>4.00 PM</td>
<td>ID 167</td>
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<tr>
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<td>An In Vitro 3D Fracture Gap Model as a Tool for Preclinical Testing Procedures</td>
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<td>Mortiz Pfeiffenberger</td>
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<td>4.30 PM</td>
<td>ID 75 G6A</td>
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<td>Session 75 G6A</td>
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#### PROGRAM
Tuesday 24 August 2021 - Day 2

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<tr>
<th>Time</th>
<th>Speaker</th>
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<tr>
<td>3.00 PM</td>
<td>Rehoming Rodents, Views and Criteria</td>
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<td>M. Janssens, Netherlands National Committee for the Protection of Animals Used for Scientific Purposes (NCaC)</td>
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**Session chair**
M. Janssens, Netherlands National Committee for the Protection of Animals Used for Scientific Purposes (NCaC)

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<td>3.00 PM</td>
<td>ID 23</td>
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<tr>
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<td>Re-homing Rodents – What’s your Opinion?</td>
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<td>M. Janssens, Utrecht University</td>
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<td>3.15 PM</td>
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<td>Re-homing Rodents - Perspective and Experience of an Animal Welfare Organisation</td>
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<td>J. Fitzi, Swiss Animal Protection</td>
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<td>3.45 PM</td>
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<tr>
<td></td>
<td>Re-homing Rodents: Opportunities and Challenges</td>
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<td>P. Van Loo, Utrecht University</td>
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<tr>
<td>4.00 PM</td>
<td>ID 983</td>
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<tr>
<td></td>
<td>Holding Animal-Based Research to Our Highest Ethical Standards</td>
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<td>Andrew Fenton</td>
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<td>4.30 PM</td>
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**Please note:**
- The program is subject to change.
- Check the official conference website for the most up-to-date information.

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**Innovative Technologies**

**Disease**

**Ethics, Welfare and Regulation**

**Safety**
Tuesday 24 August 2021 - Day 2

**Emerging 3D organoid technology toward animal alternative testing**

The ability to generate 3D organoids or “mini-organs” that more closely mimic native tissue function has great potential for various applications, such as safety issues. Many strategies have been taken to build human relevant structures through developmental principles, self-guided assembly, and bioengineering. These efforts have resulted in the development of organ-specific, human relevant models. However, effective implementation of these advances requires an understanding of their advantages and limitations for practical application. Here we bring together top scientists from regulatory, academia and industry to discuss the exciting challenges for engineering complexity into organ-like systems, their implementation, and future perspectives.

**Chair**

Y. Kanda, National Institute of Health Sciences (NIHS) Japan

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**Time** | **Abstract** | **Speakers**
---|---|---
3.00 PM | ID 306 | HUMAN IPS CELL-BASED MODELS FOR PREDICTIVE TOXICOLOGY
Y. Kanda, National Institute of Health Sciences (NIHS) Japan

3.15 PM | ID 268 | HUMAN ENGINEERED HEART TISSUES AS A VERSATILE IN VITRO MODEL
N. Kojima, Yokohama City University

5.30 PM | ID 367 | SKIN SENSITIZATION TESTING STRATEGY FOR JAPAN AND ASIA
T. Shimizu, Tokyo Women’s Medical University

3.45 PM | ID 57 | CELL SHEET-BASED MYOCARDIAL TISSUE ENGINEERING FOR ANIMAL ALTERNATIVE
T. Shimizu, Tokyo Women’s Medical University

4.00 PM | ID 102 | EU-JETVAL THYROID VALIDATION STUDY: CHEMICAL SELECTION STRATEGY
Francesca Pistollato, European Commission, Joint Research Centre

4.15 PM | ID 108 | MODERATED PANEL DISCUSSION: IS IT TIME TO SAY “BYE BYE BUEHLER”?
Janine Ezendam, National Institute for Public Health and the Environment (RIVM)

4.30 PM | ID 126 | SESSION 215 Q&A

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**Modern Regulatory Methods for Skin Sensitization: Bye-Bye Buehler?**

New approach methods (NAMs) for skin sensitization are accepted in regulatory and industry settings. Combining NAMs in defined or integrated approaches, predicts human skin sensitization hazard often better than in vivo methods. Yet, animal tests are still used to fulfill skin sensitization-data requirements. The Buehler, in particular, not only impacts animal welfare but receives scientific criticism concerning sensitivity when compared to other methods. The goal of this workshop is to broach the controversial question: “Is the Buehler a redundant in vivo test?” and discuss how to build confidence in non-animal skin sensitization approaches for chemical hazard and safety decisions.

**Session chair**

J. Ezendam, National Institute for Public Health and the Environment

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**Time** | **Abstract** | **Speakers**
---|---|---
3.00 PM | ID 620 | WHERE ARE WE NOW: REPLACEMENT OF IN VIVO SKIN SENSITISATION ASSAYS
Emma Grange, Cruelty Free International

3.15 PM | ID 137 | EUROPEAN LESSONS LEARNED FROM REACH SUBMISSIONS USING NAM SKIN SENTISITIZATION DATA
Laura Rossi, Europea Chemicals Agency

5.30 PM | ID 48 | A NORTH AMERICAN REGULATORY PERSPECTIVE ON SKIN SENSITIZATION RISK ASSESSMENT
Nicole Kersttreuver, NISHS/NICEATM

3.45 PM | ID 367 | SKIN SENSITIZATION TESTING STRATEGY FOR JAPAN AND ASIA
Takao Ashikaga, National Institute of Health Sciences

4.00 PM | ID 108 | MODERATED PANEL DISCUSSION: IS IT TIME TO SAY “BYE BYE BUEHLER”?
Janine Ezendam, National Institute for Public Health and the Environment (RIVM)

4.15 PM | ID 102 | EU-JETVAL THYROID VALIDATION STUDY: CHEMICAL SELECTION STRATEGY
Francesca Pistollato, European Commission, Joint Research Centre

4.15 PM | ID 126 | SESSION 126 Q&A
**PROGRAM**

**Tuesday 24 August 2021 - Day 2**

**3.00 - 5.00 PM TUE-1 S114**

**Artificial Intelligence for Risk and Safety Assessment**

Artificial Intelligence (AI) consists of an array of methodologies that are capable of extracting complex patterns from big data. The session will discuss the basic concept and methodologies of AI applied in predictive toxicology. The 21st century toxicology has increasingly used new tools, particularly alternative methodologies which generates new data streams. With examples from risk assessment and drug development, the guiding principle and best practice of applying AI in toxicology will be discussed with a specific emphasis on application for the new data streams.

*Session chair and co-chair*  
W. Tong, NCTR/FDA and T. Hartung, Johns Hopkins University

**Time** | **Abstract** | **Speakers**
---|---|---
3.00 PM | ID 27 | ARTIFICIAL INTELLIGENCE FOR DRUG SAFETY AND BIOMARKER DEVELOPMENT  
Wenda Tong, NCTR/FDA

3.15 PM | ID 952 | ARTIFICIAL INTELLIGENCE FOR SAFETY IN DRUG DISCOVERY  
Stefan Platz, AstraZeneca

5.30 PM | ID 908 | DEEP LEARNING FOR PREDICTING MOLECULAR PROPERTIES  
Djork-Arné Clevert, Bayer AG, Machine Learning Research

3.45 PM | ID 902 | REFERENCE-FREE ANNOTATION FOR SINGLE-CELL TRANSCRIPTOMICS USING GRAPH NEURAL NETWORK MODEL  
Xiaohui Fan, College of Pharmaceutical Sciences, Zhejiang University

4.00 PM | ID 902 | INFERBERT: A BERT-BASED CAUSAL INFERENCE FRAMEWORK FOR IMPROVING AI INTERPRETABILITY  
Z. Liu, NCTR/FDA

4.15 PM | ID 114 | SESSION 114 Q&A

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**3.00 - 5.00 PM TUE-1 S116**

**Human relevance in both dose and effect for in vitro testing of respiratory toxicity**

Technical developments have resulted in systems that can be used to expose cells via the air to mimic inhalation exposure. Decisions on the exposure system and the cell model are dependent on the research question. However, results of the exposures need to be translated to human effects at some point. In this session, the translation of inhaled concentrations and effects in Air-Liquid-Interface (ALI) cultured cell models to human effects will be addressed.

*Session chair*  
R. Vandebriel, RIVM and H. Braakhuis

**Time** | **Abstract** | **Speakers**
---|---|---
3.00 PM | ID 134 | NEEDS FOR APPLICATION OF AIR-LIQUID-INTERFACE MODELS IN RISK ASSESSMENT OF INHALED COMPOUNDS  
Yvonne Staal, RIVM

3.15 PM | ID 492 | APPLIED AND DELIVERED DOSE DETERMINATION FOR ALI ACUTE INHALATION TOXICITY TESTING OF A PETROLEUM-DERAIVED SUBSTANCE  
Svetlana Fijnje, VITO NV (Flemish Institute for Technological Research)

5.30 PM | ID 213 | IN-VITRO INHALATION EXPERIMENTATION DESIGN AND DOSIMETRY CONSIDERATIONS FOR IN-VITRO TO IN-VIVO PREDICTION OF RESPIRATORY TOXICITY  
Detlef Ritter, Fraunhofer ITEM

3.45 PM | ID 96 | EXPOSURE OF LUNG CELL MODELS TO COMPLETE UNFILTERED AND FILTERED EXHAUST FROM GASOLINE / DIESEL CARS AND COMPARISON WITH FINDINGS IN HUMANS  
Barbara Rothen-Rutishauser, Adolphe Merkle Institute, University of Fribourg, Fribourg, Switzerland

4.00 PM | ID 320 | ORGANOID-BASED EXPANSION OF AIRWAY EPITHELIAL CELLS FROM CLINICAL SAMPLES WITH LOW CELL NUMBERS FOR MODELLING EFFECTS OF CIGARETTE SMOKE EXPOSURE  
Pieter Hiemstra, Department of Pulmonology, Leiden University Medical Center, Leiden, The Netherlands

4.15 PM | ID 1089 | USE OF CAUSE-AND-EFFECT ANALYSIS TO OPTIMIZE THE RELIABILITY OF IN-VITRO INHALATION TOXICITY MEASUREMENTS USING AN AIR-LIQUID INTERFACE  
Frank Stefan Bierkandt

4.30 PM | | SESSION 116 Q&A
Innovative Technologies
Disease Ethics, Welfare and Regulation
Safety

PROGRAM
Tuesday 24 August 2021 - Day 2

5.00 - 5.15 PM
WC11 TV live from the studio

5.15 - 6.15 PM
KEYNOTE:

DR. DONALD INGBER
Harvard University

Donald E. Ingber, M.D., Ph.D. is the Founding Director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, Judah Folkman Professor of Vascular Biology at Harvard Medical School and the Vascular Biology Program at Boston Children’s Hospital, and Professor of Bioengineering at the Harvard John A. Paulson School of Engineering and Applied Sciences. He received his B.A., M.A., M.Phil., M.D. and Ph.D. from Yale University.

Ingber is a pioneer in the field of biologically inspired engineering, and at the Wyss Institute, he currently leads a multifaceted effort to develop breakthrough biologically inspired technologies to advance healthcare and to improve sustainability. His work has led to major advances in mechanobiology, tumor angiogenesis, tissue engineering, systems biology, nanobiotechnology and translational medicine. Through his work, Ingber also has helped to break down boundaries between science, art and design.

Ingber has authored more than 450 publications and over 120 issued or pending patents, founded 5 companies, and been a guest speaker at more than 500 events internationally. He is a member of the National Academy of Medicine, National Academy of Inventors, American Institute for Medical and Biological Engineering, and the American Academy of Arts and Sciences. He was named one of the Top 20 Translational Researchers world-wide in 2012 (Nature Biotechnology), a Leading Global Thinker of 2015 (Foreign Policy magazine), and has received numerous other honors in a broad range of disciplines, including the Robert A. Pritzker Award and the Shu Chien Award (Biomedical Engineering Society), the Roux Whipple Award (American Society for Investigative Pathology), the Lifetime Achievement Award (Society of In Vitro Biology), the Leading Edge Award (Society of Toxicology), Founders Award (Biophysical Society) and the Department of Defense Breast Cancer Innovator Award.

One example of Ingber’s most recently developed technologies are Human Organs-on-Chips. These are microfluidic cell culture devices created with microchip manufacturing methods and lined by living human cells, which are being used to replace animal testing as a more accurate and affordable in vitro platform for drug development and personalized medicine. In 2013, Ingber’s work on Organs-on-Chips was honored by the NC3Rs Annual Award from the National Centre for the Replacement, Refinement, and Reduction of Animals in Research, London; in 2015, this technology was named Design of the Year by the London Design Museum and was also acquired by the Museum of Modern Art (MoMA) in New York City for its permanent design collection; and in 2016, they were named one of the Top 10 Emerging Technologies of 2016 by the World Economic Forum.

6.15 - 6.30 PM
WC11 TV live from the studio

PROGRAM
Tuesday 24 August 2021 - Day 2

6.30 - 8.30 PM TUE-2
PARALLEL SESSION TUE-2
Pharmaceutical Industry initiatives driving the 3Rs

There are a large number of initiatives underway within the pharma sector going beyond the legislative requirements for 3Rs. EFPIA recently published a brochure and would use a session to highlight some issues in the pharma sector.

Chair
Kirsty Reid, EFPIA and Thierry Decelle - Sanofi

Time
Abstract
Speakers
6.30 PM
ID 62
INTEGRATED RESEARCH AND TESTING STRATEGY TO GO BEYOND THE 3RS
Thierry Decelle, Chief Veterinary Officer - Sanofi
6.45 PM
ID 54
3R INITIATIVES OF THE PHARMACEUTICAL INDUSTRY
Kirsty Reid, EFPIA
7.00 PM
ID 422
REDUCING ANIMAL USE IN PHARMA BY INTEGRATING ELECTROCORTICALGRAM, BEHAVIOR & CARDIO-HEMODYNAMIC READOUTS IN FREELY MOVING RODENTS
Francesca Pibiri
7.15 PM
ID 279
RETROSPECTIVE EVALUATION OF ANIMAL AND NON-ANIMAL MODELLING: EFFICACY-RELATED EXAMPLES INFORMING ORGANISATIONAL PRACTICES AND DRIVING IMPROVEMENTS
Maria Beaumont
7.30 PM
ID 445
BUILDING TRUST IN STEM CELL MODELS FOR COMPOUND SELECTION IN PHARMA: A TASK WORTH THE EFFORT
And Teisman
7.45 PM
ID 1084
3D HUMAN AIRWAY EPITHELIAL MODELS TO STUDY SARS-COV-2 PATHOGENESIS
Samuel Constant
8.00 PM
SESSION 108 Q&A
PROGRAM
Tuesday 24 August 2021 - Day 2

6.30 - 8.30 PM TUE-2 S143
Open Science and Transparency in Animal-Based Research

Open Science is the umbrella term for efforts aimed at achieving more openness in science. In principle, results and data of publicly funded research should be made freely available at no cost. Especially in animal-based research, open science and transparency also have important ethical dimensions. What responsibilities do funders, journal editors, and reviewers have to make this possible? What responsibility do scientists have to create more openness in science? In this session, we will ask different stakeholders to present their view on Open Science and Transparency in animal-based research and invite the audience to discuss with the experts.

Sponsored by Laboratory Animals Limited

Session chair
J-B. Prins, The Francis Crick Institute & Laboratory Animals Limited (LAL)

Time Abstract Speakers
6.30 PM ID 110 COMMUNICATING ANIMAL RESEARCH: A PLOS ONE PERSPECTIVE
Alejandra Clark, Public Library of Science
7.00 PM ID 351 DORA DECLARATION, OPEN SCIENCE AND ITS IMPACT ON THE ASSESSMENT OF ANIMAL RESEARCH
Illes de Waard, ZonMw - The Netherlands Organisation for Health Research and Development
7.30 PM ID 1131 INCREASING TRANSPARENCY AND REPRODUCIBILITY OF ANIMAL RESEARCH: FOCUS ON OPEN SCIENCE
A. Olssen, University of Porto
7.45 PM ID 586 EDITORS' MORAL OBLIGATIONS - PROFIT, REGULATION AND VIRTUE
Gavin Jarvis, University of Cambridge
8.00 PM SESSION 143 Q&A

6.30 - 8.30 PM TUE-2 S115
Scientific highlights in emulating human biology on chips

Microfluidic Microphysiological Systems (MPS, also referred to as organ-on-chip, multi-organ-chip, human body-on-chip or patient-on-chip tools) are considered an enabling technology for the development of approaches to reliably emulate human biology in vitro. Therefore, the value of such systems for basic and applied research of human biology becomes more and more evident. From human lung oedema and four-organ homeostasis on chips towards nerve growth, beating mini-hearts and microbiome on chips: MPS tools represent amazing opportunities to reduce and replace laboratory animals in human life science. The session aims for introducing discovery highlights using MPS.

Session chair and co-chair
J. van den Eijnden-van Raaij, hDMT and P. Loskill, Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB & Eberhard Karls University Tübingen

Time Abstract Speakers
6.30 PM ID 947 SCIENCE, ETHICS AND ACCEPTANCE OF HUMAN MICROPHYSIOLOGICAL SYSTEMS - AN ULTIMATE ALTERNATIVE TO TESTING IN LABORATORY ANIMALS AND HUMAN VOLUNTEERS
Uwe Marx, TissUse GmbH; Technische Universität Berlin
7.00 PM ID 67 BLOOD VESSELS IN ORGANS-ON-CHIPS
Andries Van der Meer, Applied Stem Cell Technologies, University of Twente
7.15 PM ID 109 EYE-ON-CHIPS: NEXT-GENERATION MICROPHYSIOLOGICAL IN VITRO MODELS FOR OPHTHALMOLOGY RESEARCH AND OCULAR TOXICOLOGY
Peter Loskill, Faculty of Medicine, Eberhard Karls University Tübingen, Sickenstr. 7/1, 72076 Tübingen, Germany; Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB, Nobelstraße 12, 70569 Stuttgart, Germany
7.30 PM ID 178 OVERVIEW OF RESEARCH PROGRAM FOR USER-DRIVEN MPS DEVELOPMENT IN JAPAN
Hitoshi Narasaka, Stem Cell Evaluation Technology Research Association
7.45 PM QUANTITATIVE IN SILICO MODELLING OF A DIABETES MICRO-PHYSIOLOGICAL SYSTEM ALLOWS FOR TRANSLATION TO HUMANS
G. Cedersund, Linköping University
8.00 PM SESSION 115 Q&A
Flexible, efficient and performance-driven in-house method validation responding to current regulatory challenges for identifying human thyroid disruptors

The OECD has published the international guidance document on Good In Vitro Method Practices (GIVIMP) to support method developers and end-users working in academic, industry and government laboratories across all 36 OECD member countries and beyond in harmonisation efforts of the new generation of mechanistic in vitro methods responding to current regulatory challenges. Applying GIVIMP during the in vitro method development stage and in-house validation assessing the method's performance will help improve the quality and reliability of generated data needed to support safety decisions also in challenging fields like the thyroid disrupter field.

The European Commission is funding and coordinating a large scale efforts to obtain a set of mechanistically informative alternative methods to detect chemicals that disrupt normal thyroid hormone function, in collaboration with the European Union Network of Laboratories for the Validation of Alternative Methods (EU-NETVAL) and the method developers. An initial set of methods has been identified as candidates taking primarily into account the information reported in an OECD scoping document on in vitro and ex vivo methods for the identification of modulators of thyroid hormone signaling (OECD no. 207), but also an OECD Detailed Review Paper (OECD No. 129), and feedback received at various Expert Group meetings. Furthermore, research efforts are funded by the European and International funding programmes to support the necessary development of new methods and approaches in this particular field to complement the information gaps identified. The symposium will illustrate how global collaboration and approaches in this particular field to complement the information gaps identified. The symposium will illustrate how global collaboration and harmonisation and interdisciplinary efforts and increasing common awareness of common agreed regulatory information needs can deliver mechanistic and integrated approaches responding to current regulatory challenges for identifying human thyroid disruptors.

Session chair and co-chair: S. Coecke, EURL ECVAM, European Commission Joint Research Centre

Time Abstract Speakers
6.30 PM ID 473 GLOBAL COLLABORATION, HARMONISATION AND INTERDISCIPLINARY EFFORTS DELIVER MECHANISTIC METHODS AND INTEGRATED APPROACHES FOR IDENTIFYING HUMAN THYROID DISRUPTORS S. Coecke, EURL ECVAM, European Commission Joint Research Centre
6.45 PM ID 466 IN HOUSE GIVIMP METHOD VALIDATION AS A KEY PROCESS FOR ACCELERATING THYROID IN VITRO METHODS FROM BENCH TO REGULATORY USE K. Renlen, Le Charite, Bfr, Berlin
7.00 PM ID 496 EUROPEAN NETWORK OF HIGH QUALITY LABORATORIES ASSESSING EFFICIENTLY THE RELEVANCE OF FULLY ANIMAL-FREE THYROID MECHANISTIC METHODS B. Birk, BASF
7.15 PM ID 277 MECHANISTIC AND INTEGRATIVE STRATEGIES FOR IDENTIFYING THYROID-ACTIVE CHEMICALS IMPACTING ENVIRONMENTAL AND HUMAN HEALTH K. Hilšcherová, RECETOX Masaryk University
7.30 PM ID 508 BIOKINETICS AND DOSE-RESPONSE MODELS TO PREDICT THYROID DISRUPTION EFFECTS A. Lumen, The Food and Drug Administration (FDA)
7.45 PM ID 185 IDENTIFYING HUMAN THYROID DISRUPTORS IN THE 21ST CENTURY NEEDS A REAL PARADIGM SHIFT IN RISK ASSESSMENT APPROACHES A. Piersma, RIVM National Institute for Public Health and the Environment
8.00 PM SESSION 13 Q&A

Alternative approaches and predictive methods to fish toxicity testing

Fish, as representatives of one of the trophic levels, are key aquatic organisms for environmental risk assessment. However, they fall into the scope of several international regulations for the protection of animals used for scientific purposes. Replacing animal testing for the environmental safety assessment in various sectors therefore faces significant challenges when addressing issues such as short- and long-term toxicity to fish, endocrine modulation and bioaccumulation. This session will present the promising methodologies and progress made in these areas over the past decade, and highlight issues associated with fish testing and the potential of alternative approaches to predict relevant endpoints.

Session chair and co-chair: V. Rouxet, L’Oréal and M. Paparella, Medical University of Innsbruck

Time Abstract Speakers
6.30 PM ID 302 FISH CELL LINES OF RAINBOW TROUT AS ALTERNATIVES TO FISH IN ENVIRONMENTAL RISK ASSESSMENT: WHERE WE STAND AND WHERE WE NEED TO GO K. Schimmer, EWAG
6.45 PM ID 783 THE ZEBRAPHISH EMBRYO AS ALTERNATIVE MODEL FOR ACUTE AND CHRONIC FISH TOXICITY - INCLUSION OF ADDITIONAL ENDPOINTS TO REPLACE FISH TOXICITY TESTS IN THE COMPARATIVE ASSESSMENT WITH DAPHNIA AND ALGAE S. Scholz, UFZ
7.00 PM ID 409 CURRENT STATUS OF THE OECD PROJECT ON INTEGRATED APPROACHES TO TESTING AND ASSESSMENT FOR ACUTE FISH TOXICITY C. Fallbender, PETA International Science Consortium Ltd
7.15 PM ID 339 THE BIOTRANSFORMATION AND BIOACUMULATION OF IONIZABLE ORGANIC COMPOUNDS IN RAINBOW TROUT CELL LINES F. Balk, Eawag, Swiss Federal Institute of Aquatic Science and Technology
7.30 PM USE OF FISH EMBRYOS TO ASSESS ENDOCRINE DISRUPTION M. Leonard, L’Oréal
7.45 PM ID 166 LIMITATIONS AND UNCERTAINTIES OF ACUTE FISH TOXICITY ASSESSMENTS CAN BE REDUCED USING ALTERNATIVE METHODS Martin Paparella, Medical University Innsbruck
8.00 PM SESSION 183 Q&A
PROGRAM
Tuesday 24 August 2021 - Day 2

6.30 - 8.30 PM TUE-2 S205 A Virtual Human Platform for Safety Assessment

The Virtual Human Platform for Safety Assessment (VHP4Safety) is a new integrated approach for assessing safety, based on quantitative information of human biology, toxicology and exposure. The VHP4Safety will form an overarching platform integrating high quality data from existing databases and algorithms, as well as new data acquired within the project. During this session we dive into the topic of predictive modelling, data science, exposure assessment and advanced human in vitro models, to design a platform that reflects the Virtual Human and address the emerging societal challenge towards transition to animal-free safety assessment completely based on human data.

Session chair
T. Hartung, John Hopkins

Time Abstract Speakers
6.30 PM ID 1128 IN SILICO MEDICINE: BRINGING THE COMMUNITY TOGETHER AND THE FIELD FORWARD Liesbet Geris, University of Liege
7.15 PM ID 1109 TOXICOLOGICAL MECHANISTIC INFERENCE FROM GENE EXPRESSION ASSAYS WITH MECHSPY Ruchir Shah
7.30 PM ID 463 NETWORK INTEGRATION AND MODELLING OF DYNAMIC DRUG RESPONSES AT MULTI-OMICS LEVELS Ralf Herwig
7.45 PM ID 1000 COMPARING AND INTERPRETING TOX21 DATA ANALYSIS APPROACHES Agnes Karmas
8.00 PM SESSION 205 Q&A

6.30 - 8.00 PM YOU-WC11 - SPEED COLLABORATING

This is a unique opportunity for first-time attendees, but also other early career scientists to connect, ask questions, and exchange experiences. Sign up for the Speed Collaborating to get to know other early career scientists directly from the beginning, this is meant to further improve your personal congress experience, especially in this challenging time.

WC11 TALKSHOW LIVE FROM THE STUDIO IN MAASRICHT

9.00 - 10.00 PM WC11 TV - Talkshow

Talkshow 1 will address the topic of the Presence and Future of the Next-Generation Risk Assessment Approach. It has been 8 years since the EU ban on animal testing for cosmetic ingredients has been applied. In addition, the Scientific Committee on Consumer Safety (SCCS) has published a new evaluation and a 11th revision report.

PROGRAM
Wednesday 25 August 2021 - Day 3

PLENARY SESSIONS

2.30 - 3.00 PM WC11 TV - Live from the studio

PARALLEL SESSION WED-1

3.00 - 5.00 PM WED-1 S93 Reproducibility in preclinical studies

Reproducibility is an important topic of discussion at present, including a need for improved experimental design. A IMI project called EQIPD (https://quality-preclinical-data.eu/), could bring interesting input into the discussion for preclinical studies to improve implementation of 3Rs. Some info on EQIPD/What are the key drivers for decision making in drug development? The pharmaceutical industry and basic research depend on robust data and scientific rigor as key drivers for decision making. They determine the pace of knowledge gain and ultimately the time needed to make new drug treatments available to patients. What factors impact the transition from preclinical to clinical testing? Recent publications report challenges with regard to the robustness, rigor and validity of research data, which often impact the transition from preclinical to clinical testing. How can we improve innovation and data quality to speed up drug development? We seek to provide simple and sustainable solutions that facilitate data quality without impacting innovation and freedom of research. Our consortium will pool resources from both academia and industry to pilot this action in neuroscience and drug safety with applicability beyond these research areas

Sponsored by EFPIA.

Session chair
Kirsty Reid, EFPIA

Time Abstract Speakers
3.00 PM ID 648 IMPROVING REPRODUCIBILITY AND TRANSLATION OF ANIMAL RESEARCH - AN INDUSTRY PERSPECTIVE Thomas Steckler, Janssen Pharmaceutica NV
3.30 PM ID 353 ACHIEVING REPRODUCIBILITY THROUGH RESPONSIBLE ANIMAL RESEARCH Nicola Osborne, Responsible Research in Practice
3.45 PM ID 350 NC3RS RESOURCES TO IMPROVE THE REPRODUCIBILITY OF IN VIVO AND IN VITRO EXPERIMENTS Mark Prescott, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)
4.00 PM ID 1132 SR AND META-ANALYSIS OF ANIMAL STUDIES Malcolm Macleod, University of Edinburgh
4.15 PM ID 174 MORE THAN 3RS - THE 3VS AND THE ETHICS OF ANIMAL RESEARCH Hanno Wuerbel, University of Bern
4.30 PM SESSION 93 Q&A
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Wednesday 25 August 2021 - Day 3

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<tr>
<td>3.00 PM</td>
<td>ID 914</td>
<td>FINDING ALTERNATIVES USING TEXT BASED ARTICLE CLASSIFICATION Wyannd Alkema, TenWise BV, Hanze University of Applied Sciences</td>
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<td>3.30 PM</td>
<td>ID 976</td>
<td>DEVELOPMENT OF COMPLEX HUMAN ORGANOID TECHNOLOGY FOR VIRAL INFECTIONS, AN EUROPEAN APPROACH Adithya Sridhar, Amsterdam UMC</td>
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<td>3.45 PM</td>
<td>ID 629</td>
<td>TRANSLATING ANIMAL MODEL RESULTS TO HUMAN DISEASE Giulia Moreni, Amsterdam UMC</td>
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<td>4.00 PM</td>
<td>ID 821</td>
<td>HUMAN GUT ORGANOIDS FOR SARS-COV2 AND ENTEROVIRUS RESEARCH Ikrame Aknouch, Amsterdam UMC</td>
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<td>4.00 PM</td>
<td>ID 1051</td>
<td>BRAIN ORGANOIDS AS ANIMAL FREE MODELS FOR VIROLOGY Josse Depla, Amsterdam UMC</td>
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<td>3.00 PM</td>
<td>ID 58</td>
<td>Benefitts, Challenges and Emerging Technologies for Preclinical Systematic Reviews Nadia Soliman</td>
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<td>3.30 PM</td>
<td>ID 915</td>
<td>A Funder’s Role in Stimulating Transparency in 3Rs Research Erica van Oort, ZonMw - The Netherlands Organisation for Health Research and Development</td>
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<td>4.00 PM</td>
<td>ID 915</td>
<td>SESSION 34 Q&amp;A</td>
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<td>3.00 PM</td>
<td>ID 705</td>
<td>Katrin Schutte, European Commission</td>
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<td>3.30 PM</td>
<td>ID 51</td>
<td>Alie de Boer, Food Claims Centre Venlo, Campus Venlo, Maastricht University</td>
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<td>3.45 PM</td>
<td>ID 788</td>
<td>Robert Landsiedel, BASF SE</td>
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<td>4.00 PM</td>
<td>ID 1039</td>
<td>Alan Brough, National Heart &amp; Lung Institute, Imperial College London</td>
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<td>4.15 PM</td>
<td>ID 717</td>
<td>Brunhilde Blömeke, Trier University</td>
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<td>SESSION 70 Q&amp;A</td>
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Challenges of Non-Animal Approaches for Food Safety & Nutrition in the 21st Century: From Inception to Application

This session proposal aims to discuss: • Different applicable legislations for non-animal approaches in the food sector • The way food scientists approach animal and animal-free studies • Benchmarking of non-animal approaches in different industry sectors • Real life risk assessment application in food safety and nutrition

Session chair
Marcel Leist, Center for Alternatives to Animal Testing in Europe (CAAT) - University of Konstanz

APPlicable Legislation for Non-animal Approaches in the Food System
Katrin Schutte, European Commission

Animal-free Strategies in Food Safety & Nutrition
Alie de Boer, Food Claims Centre Venlo, Campus Venlo, Maastricht University

The Windy Road to the Use of Non-animal Approaches for Regulations of Chemicals
Robert Landsiedel, BASF SE

What are the Strategies that can be used Now in Food Safety Risk Assessment Avoiding Animal Testing?
Alan Brough, National Heart & Lung Institute, Imperial College London

In Vitro Coculture Model (H-CLAT/RHE) Composed of THP-1 Cells and 3D Reconstructed Human Epidermis to Assess Activation and Maturation of Dendritic Cells
Brunhilde Blömeke, Trier University

Decision making in non-animal cosmetic safety assessment

There has been significant progress globally over recent years in advancing the science that underpins non-animal cosmetic safety assessment that has facilitated the ability to perform cosmetic safety assessment while using no new animal data. The Animal-Free Safety Assessment (AFSA) Cosmetics collaboration between Humane Society International, industry partners and other interested groups was created to facilitate implementation of robust consumer safety decisions by government health authorities, manufacturers of cosmetic products and ingredients, CROs and service providers, and other stakeholders, with the objective of transitioning the global industry fully away from reliance on new animal data by 2023. Presentations in this session will introduce the project and cover several aspects of the risk assessment process, including established and developing science areas.

Chair
P. Russell, Unilever
Can non-animal models identify environmental endocrine disruptors?

Non-animal test systems are widely used in toxicology to characterize the biological properties of chemicals. In particular, in vitro assays allow identifying mechanisms of action, including endocrine activity, that are relevant for humans. The new European regulation on the identification of endocrine disruptors requires that potential endocrine properties of chemicals are investigated with regard to both human health and the environment. However, in vitro test systems are rarely available to investigate endocrine activity in non-mammalian environmental species (e.g., fish, amphibians, birds). As a consequence, the implementation of the new European regulation on endocrine disruptors results in the use of huge numbers of animal in testing. Recently, embryo assays have been developed as non-animal alternatives to chronic tests on fish and amphibians. The workshop will address various aspects of the use of non-animal tests for the identification of environmental endocrine disruptors including the latest technological developments, advantages and limitation of non-animal tests, regulatory acceptance of embryo assays, and the societal demand for reducing tests on animals.

Sponsored by Bayer

Time | Abstract | Speakers
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3.00 PM | ID 594 | ENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS IN FISH EMBRYOS
S. Scholz, Helmholtz Zentrum für Umweltforschung (UFZ)

3.15 PM | ID 607 | USE OF NON-ANIMAL MODELS FOR THE HAZARD IDENTIFICATION OF ENDOCRINE DISRUPTING PROPERTIES: A REGULATORY PERSPECTIVE
M. Arena, European Food Safety Authority (EFSA)

3.30 PM | ID 255 | REDUCING, REPLACING AND REFINING AQUATIC VERTEBRATE TESTING IN THE IDENTIFICATION OF ENDOCRINE DISRUPTORS
B. Labram, NCIRS

3.45 PM | ID 610 | THE USE OF NON-ANIMAL MODELS IN REGULATORY EVALUATION OF ENVIRONMENTAL ENDOCRINE DISRUPTORS - AN INDUSTRY PERSPECTIVE
L. Lagadic, Bayer AG, Crop Science Division

Session chair
L. Lagadic, Bayer AG
PROGRAM
Wednesday 25 August 2021 - Day 3

5.00 - 6.30 PM  PLENARY SESSIONS

5.00 - 5.15 PM  WC11 TV live from the studio

5.15 - 6.15 PM  KEYNOTE:

DR. JASON EKERT
GlaxoSmithKline

Dr. Jason Ekert has been head of the Complex In Vitro Models (CIVM) group for the last three years in the In Vitro In Vivo Translation department in the Research organization at GlaxoSmithKline. He leads an integrated enterprise strategy for sustained portfolio-driven growth in R&D applications of complex human-relevant and translatable complex in vitro models (eg Spheroids, Organoids, Microphysiological systems and bioprinting). The CIVM group drives the coordination and prioritization of development and integrated use of complex in vitro technologies for target identification/validation, efficacy, safety and DMPK studies. He has led a cross-functional matrix team for the last three years at GSK that is a multi-disciplinary team (Scientists that span from target ID/validation, screening, lead optimization, safety, DMPK and the research units) which coordinates activities, collaborates externally and identifies ready soon platforms that can positively impact the portfolio. He’s the vice-chair elect for the IQ-MPS affiliate. Dr Ekert received his PhD in Medical Science from Adelaide University in Australia. He performed post-doctoral training at the University of California, Davis and Coriell Institute for Medical Research.

Before coming to GlaxoSmithKline Dr Ekert worked for 11 years at Janssen BioTherapeutics in early biotherapeutic drug discovery in target discovery, drug validation and mechanism of action studies applying 3D cell cultures, induced pluripotent stem cells and primary cells in complex cell-based assays across multiple therapeutic areas.

6.15 - 6.30 PM  WC11 TV live from the studio
**Program**

**Wednesday 25 August 2021 - Day 3**

**6.30 - 8.30 PM WED-2 S16**

Focus on Severe Suffering

All laboratory animal suffering is a concern, but the RSPCA believes that reducing and avoiding severe suffering should be a top priority. There are a number of reasons to do this: (i) the ethical and animal welfare benefits of reducing suffering, (ii) the legal requirement to minimise suffering set out in legislation, and (iii) the scientific benefits – it is acknowledged that good science goes hand in hand with good welfare. This symposium will focus on the work of the RSPCA to reduce and ultimately end severe suffering, as well as showcasing practical examples from invited speakers.

Session chair
P. Hawkins, RSPCA Animals in Science Department

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<tr>
<td>6.30 PM</td>
<td>ID 71</td>
<td>INTRODUCTION - FOCUS ON SEVERE SUFFERING</td>
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<td>P. Hawkins, RSPCA</td>
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<td>6.45 PM</td>
<td>ID 849</td>
<td>COMBINING MATHEMATICS WITH MEDICINE TO MAKE BETTER USE OF ANIMAL DATA: SEPSIS CASE STUDY</td>
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<td>M. Nandi, King's College London</td>
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<td>7.00 PM</td>
<td>ID 22</td>
<td>POTENTIAL REFINEMENT OF ANIMAL MODELS OF NEUROPATHIC AND INFLAMMATORY PAIN</td>
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<tr>
<td>K. Abelsson, University of Copenhagen</td>
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<tr>
<td>7.15 PM</td>
<td>ID 29</td>
<td>MONITORING OF SEVERITY AND IMPLEMENTATION OF REFINEMENT MEASURES IN DSS INDUCED COLITIS IN MICE</td>
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<td>P. Jirkhof, University of Zurich</td>
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<tr>
<td>7.30 PM</td>
<td>ID 260</td>
<td>HUMANE ENDPOINTS, TAILOR MADE</td>
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<td>N. Verhave, Universiteit Leiden</td>
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<tr>
<td>7.45 PM</td>
<td>ID 39</td>
<td>AVOIDING MORTALITY DURING PROCEDURES</td>
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<tr>
<td>P. Hawkins, RSPCA</td>
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<tr>
<td>8.00 PM</td>
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<td>SESSION 16 Q&amp;A</td>
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</tbody>
</table>

**Program**

**Wednesday 25 August 2021 - Day 3**

**6.30 - 8.30 PM WED-2 S160**

Human Organs-on-Chips: Advancing Regulatory Science through Innovation

A growing number of assays based on microphysiological systems (MPS) are being adopted by the pharmaceutical industry to evaluate new drugs and therapies. Data generated by these types of systems are increasingly used in portfolio decision-making thus reducing the use of laboratory animals. Simultaneously, scientists working in regulatory authorities have been actively involved in MPS-based research. The session aims to provide a perspective of how regulatory bodies from US, Europe, China, Russia and South Korea towards the replacement of laboratory animal-based assays and guidelines by qualified MPS-based assays.

Session chair
S. Fitzpatrick, US Food and Drug Administration and S. Beken, Federal Agency for Medicines and Health Products (FAMHP)

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<thead>
<tr>
<th>Time</th>
<th>Abstract</th>
<th>Speakers</th>
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<tr>
<td>6.45 PM</td>
<td>ID 946</td>
<td>DEVELOPING PERFORMANCE BASED QUALIFICATION CRITERIA FOR ORGANS ON A CHIP - US FDA PERSPECTIVE</td>
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<tr>
<td>Suzanne Fitzpatrick, US Food and Drug Administration, Center for Food Safety and Applied Nutrition</td>
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<tr>
<td>7.00 PM</td>
<td>ID 892</td>
<td>DEVELOPING PERFORMANCE BASED QUALIFICATION CRITERIA FOR ORGANS ON A CHIP - EU PERSPECTIVE</td>
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<tr>
<td>Sonja Beken, Federal Agency for Medicines and Health Products (FAMHP)</td>
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<td>7.15 PM</td>
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<td>THE POTENTIAL OF MICROPHYSIOLOGICAL SYSTEMS TO ENTER THE CHANGING RUSSIAN DRUG APPROVAL REGULATION ENVIRONMENT</td>
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<td>A. Tonevitsky, Higher School of Economics</td>
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<td>7.30 PM</td>
<td>ID 943</td>
<td>CHINESE PERSPECTIVE OF THE IMPLEMENTATION OF ORGAN-ON-CHIP-BASED ASSAYS INTO THE REGULATORY LANDSCAPE</td>
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<td>Xiaobing Zhou, National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control</td>
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<td>7.45 PM</td>
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<td>3D TISSUE CHIPS AND MICROPHYSIOLOGICAL SYSTEMS: KOREAN EFFORTS FROM DEVELOPMENT TO REGULATORY ADAPTATION</td>
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<td>S. Kim, Seoul National University Hospital</td>
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<td>8.00 PM</td>
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<td>SESSION 160 Q&amp;A</td>
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New Approach Methods in AgroChemical Development and Regulatory Decisions

New approach methods are being designed and applied to answer risk assessment and risk management questions. They are also being developed to inform data needs for chemical safety evaluation. There is also the potential to eliminate redundant and unnecessary studies through waiving repeat dose studies when adequate information is available to assess human health risk. The symposium will present a framework for fit for purpose evaluation of new approach methods, the application of new approach methods for determining inhalation risk, a new approach method for predicting developmental toxicity, and the US EPA’s successful program to waive repeat dose studies which has saved several hundred thousands of animals.

Sponsored by Syngenta

Session chair
Douglas Wolf, Syngenta Crop Protection and Monique Perron, United States Environmental Protection Agency

Time Abstract Speakers
6.30 PM ID 855 AN EVALUATION FRAMEWORK FOR NEW APPROACH METHODOLOGIES (NAMS) FOR HUMAN HEALTH SAFETY ASSESSMENT Stanley Parish, Health and Environmental Sciences Institute
7.00 PM ID 887 APPLICATION OF NEW APPROACH METHOD FOR DETERMINING DEVELOPMENTAL TOXICITY Richard Currie, Syngenta
8.00 PM ID 68 WAIVING REPEAT Dose STUDIES WHILE CONFIDENTLY PROTECTING HUMAN HEALTH FROM EXPOSURE TO AGRICULTURAL CHEMICALS Douglas Wolf, Syngenta

Culture of Care - a culture driven, pro-active approach towards improving standards

The purpose of the workshop is to demonstrate that a culture driven approach will deliver more and better outcome in terms of continuously optimised animal welfare instead of a reactive approach of merely reacting to problems when they arise. Emphasis should be on examples of improved animal welfare because that initiative was driven by a Culture of Care.

Session chair and co-chair
S. Robinson, Astra Zeneca and T. Bertelsen - Novo Nordisk

Time Abstract Speakers
6.30 PM ID 155 A SIMPLE-TO-USE MODEL TO WORK PURPOSEFUL AND FOCUSED WITH CULTURE OF CARE T. Bertelsen - Novo Nordisk
6.45 PM ID 815 A FIVE CATEGORY FRAMEWORK FOR IMPLEMENTING CULTURE OF CARE S. Robinson, Astra Zeneca
7.00 PM ID 678 CULTURE OF CARE AND GOVERNANCE: TWO SIDES OF THE SAME COIN J. Prins, The Crick Institute
7.15 PM ID 138 CULTURE OF CARE AT NOVARTIS - THE PATH FOR BETTER SCIENCE B. Ledermann, Novartis
7.30 PM ID 846 THE ONGOING JOURNEY TO CHAMPION AND ENHANCE A CULTURE OF CARE A. White, GSK
7.45 PM ID 549 INCLUSIVE CULTURE OF CARE AT A GLOBAL CRO: A NECESSARY ADJUNCT TO GOVERNANCE Ghislaine Poirier

8.00 PM SESSION 173 Q&A
## PROGRAM
Wednesday 25 August 2021 - Day 3

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<tr>
<th>Time</th>
<th>Abstract</th>
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<tr>
<td>6.30 PM</td>
<td>ESTABLISHMENT OF A DEVELOPMENTAL NEUROTOXICANT SCREENING USING SOX1-GFP MOUSE EMBRYONIC STEM CELLS</td>
<td>Weida Tong, NCTR, FDA</td>
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<td>6.45 PM</td>
<td>AN INTEGRATED APPROACH ALTERNATIVE FOR SCREENING REPRODUCTIVE, DEVELOPMENTAL AND ENDOCRINE DISRUPTING ACTIVITY WITH EX VIVO WHOLE RAT EMBRYO CULTURE</td>
<td>Eui-Bae Jeung</td>
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<td>7.00 PM</td>
<td>AN ANALYSIS OF THE LIMITATIONS AND UNCERTAINTIES OF IN VIVO DEVELOPMENTAL NEUROTOXICITY TESTING AND ASSESSMENT TO IDENTIFY THE POTENTIAL FOR ALTERNATIVE APPROACHES</td>
<td>Martin Paparella</td>
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<td>7.15 PM</td>
<td>COLINEAR HOX GENE EXPRESSION IN THE NEURAL EMBRYONIC STEM CELL TEST (ESTN) DEFINES ITS BIOLOGICAL DOMAIN AND REVEALS EFFECTS OF COMPOUNDS</td>
<td>Victoria de Leeuw</td>
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<td>7.30 PM</td>
<td>IN VITRO SCREENING FOR DEVELOPMENTAL NEUROTOXICITY BY USING A HUMAN CELL-BASED TESTING BATTERY: A CASE STUDY OF FLAME RETARDANTS</td>
<td>Melanie Pahl</td>
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<td>7.45 PM</td>
<td>AN INTER-LABORATORY CASE STUDY TO HARMONIZE ZEBRAFISH LIGHT-DARK TRANSITION TEST TO PREDICT DEVELOPMENTAL NEUROTOXICITY</td>
<td>Celia Rodríguez</td>
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<td>8.00 PM</td>
<td>SESSION 309 Q&amp;A</td>
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Every product Unilever makes must be safe for people to use and safe for our planet. We believe that animal experiments should not be used to make sure that are products are safe.

Unilever started to develop non-animal approaches to assess the safety of its products and ingredients over 40 years ago and we are committed to using what we have learnt to help accelerate use of new science and technology in chemical and product safety assessment, to ultimately replace the need for animal test data.

Our ability to innovate using non-animal safety assessment approaches is underpinned by scientific partnerships with over 70 leading research teams globally to develop and apply new capability. We look to openly share the experience gained from these collaborations through publications, presentations and through our website (tt21c.org/resources/).

In the spirit of this goal, we would like to welcome you to the 11th World Congress on Alternatives to Animal Use in the Life Sciences and invite you to come and meet us at one of our events:
- Oral & poster presentations throughout the Congress
- Unilever - sponsored sessions - live panel discussions & presentations throughout the congress and YOU-WC11 welcome reception
- Congress booth for more information and any questions you may have

Everything Unilever shares during the WC11 is available for download here: https://tt21c.org/events/WC11/
Thursday 26 August 2021 - Day 4

PROGRAM

PLenary Sessions

2.30 - 3.00 PM

WC11 TV - Live from the studio

PARALLEL SESSION THU-1

3.00 - 5.00 PM

THU-1 S118 $ A global movement to improve science using animal-free antibodies

We are on the brink of a sea change on antibody production. In Europe, the ECVAM Scientific advisory committee has endorsed the scientific validity of replacement methods not requiring animal immunization and the U.S. NICEATM aims to improve research quality and reproducibility by accelerating their development and use. No longer must we accept the scientific shortcomings of animal-derived antibodies. Considering the $80 billion scale of the antibodies industry, importance to all scientific disciplines, vast animal use and commitment by government authorities to the implementation of Directive 2010/63/EU, the landmark movement to animal-free sequence-defined antibodies will have an enormous global influence. We are on the brink of a sea change on antibody production. In Europe, the ECVAM Scientific advisory committee has endorsed the scientific validity of replacement methods not requiring animal immunization and the U.S. NICEATM aims to improve research quality and reproducibility by accelerating their development and use. No longer must we accept the scientific shortcomings of animal-derived antibodies. Considering the $80 billion scale of the antibodies industry, importance to all scientific disciplines, vast animal use and commitment by government authorities to the implementation of Directive 2010/63/EU, the landmark movement to animal-free sequence-defined antibodies will have an enormous global influence.

Session chair and co-chair

A. Gray, AFABILITY & University of Nottingham and K. Groff, PETA International Science Consortium Ltd

Time Abstract Speakers

3.00 PM ID 118 BARRIERS AND CHALLENGES FACING THE REPLACEMENT OF ANIMAL- DERIVED ANTIBODIES (ADAS)

João Barroso, European Commission, Joint Research Centre, Ispra (VA), Italy

3.15 PM ID 766 SCIENTIFIC VALIDITY OF NON-ANIMAL-DERIVED ANTIBODIES

Alison Gray, AFABILITY

3.30 PM ID 1 ANIMAL-FREE MULTICLONAL ANTIBODY GENERATION AS A REPLACEMENT FOR POLYCLONAL ANTIBODIES

Stefan Dübel, Technische Universität Braunschweig

3.45 PM ID 907 RECOMBINANT ANTIBODIES: A COMPLETE TOOLBOX FOR ACADEMIA

Pierre Cosson, University of Geneva, Faculty of Medicine

4.00 PM ID 127 RECOMBINANT ANTIBODY TECHNOLOGY: TAKING ANTIBODIES FROM BENCH TO BEDSIDE

Lia Cardarelli, Toronto Recombinant Antibody Centre, University of Toronto

4.15 PM ID 101 STRATEGIZING TO OPTIMIZE THE DEVELOPMENT AND USE OF ANIMAL-FREE ANTIBODIES IN THE U.S.

Katherine Groff, PETA Science Consortium International e.V.

4.30 PM SESSION 118 Q&A

3.00 - 5.00 PM

THU-1 S102 $ Refinement of pain & stress assessment to enhance animal welfare in rodents

Evidence-based pain and stress assessment is essential for accurately identifying, predicting, and preventing animal suffering. It is also central for informing harm-benefit assessment of animal experimentation, thus furthering both animal welfare and regulatory compliance. Reliable and sensitive assessment is also essential for implementing refinement measures and evaluating their effect. To fulfill these goals, scientists, animal care and veterinary personnel need reliable assessment tools for providing species-relevant measurements of the animal’s physical and affective state. In this session, we aim to highlight recent scientific advances in rodent health, welfare, pain and stress assessment, such as automated grimace score, assessment or thermography with the potential to further both the 3Rs and scientific quality.

Session chair

Nuno Henrique Franco, I3S, University of Porto

Time Abstract Speakers

3.00 PM ID 84 TOWARDS AN AUTOMATED FACIAL EXPRESSION ANALYSIS IN MICE USING DEEP LEARNING

Katharina Hohlbaum, Institute of Animal Welfare, Animal Behavior, and Laboratory Animal Science, Department of Veterinary Medicine, Freie Universität Berlin

3.15 PM ID 690 ASSESSMENT OF ACUTE STRESS AND ANXIETY BY INFRARED THERMOGRAPHY

Charité-Universitätsmedizin Berlin; German Rheumatism Research Center

3.45 PM ID 28 INTER-LABORATORY VARIABILITY IN BEHAVIOR-BASED SEVERITY ASSESSMENT

Nuno Henrique Franco, I3S - Instituto de Investigação e Inovação em Saúde, Universidade do Porto

4.00 PM ID 599 PAIN ASSESSMENT AND MANAGEMENT IN BONE-LINKED MOUSE MODELS

Universidade do Porto

4.15 PM ID 310 IDENTIFICATION OF APPROPRIATE METHODS FOR SEVERITY ASSESSMENT IN A WIDELY USED MOUSE MODEL OF ACUTE COLITIS

Charité-Universitätsmedizin Berlin; German Rheumatism Research Center

4.30 PM SESSION 102 Q&A
Innovative approaches for CNS research - from brain organoids to new single cell culture methods

A functioning central nervous system (CNS) is key for living, and ageing is a major risk factor for dysfunction. With the increase in human lifespan the incidence of neurodegenerative diseases is rising. There is a demand for good models for neurodegenerative diseases, as current in vivo models have limitations and ethical concerns. Modelling the CNS in vitro is, however, challenging. Recent discoveries in neuroscience, such as the breakthroughs of induced pluripotent stem cell technology, 3D-organotypic cultures and organs-on-chip, move the field forward. This workshop will overview how scientists are embracing new cutting-edge technologies and provide a guidemap for future developments.

Session chair
J. Bajramovic, Biomedical Primate Research Centre

Time Abstract Speakers
3.00 PM ID 850 FROM MICROPHYSIOLOGICAL TO MICROPATHOPHYSIOLOGICAL SYSTEMS TO STUDY NEUROTOXICITY AND CNS DISEASES L. Smirnova, Johns Hopkins
3.30 PM ID 578 TRANSCRIPTOME GUIDED APPROACHES TO MIMIC HOMEOSTATIC ADULT MICROGLIA IN CULTURE R. Timmerman, Biomedical Primate Research Centre
4.00 PM ID 1022 NEW WAYS OF NEUROTOXICITY TESTING IN PRE-CLINICAL DRUG DEVELOPMENT S. Kustermann, Roche
4.30 PM SESSION 177 Q&A

Program:
Thursday 26 August 2021 - Day 4

3.00 - 5.00 PM THU-1 S177 Innovative approaches for CNS research - from brain organoids to new single cell culture methods

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4.00 PM ID 1022 NEW WAYS OF NEUROTOXICITY TESTING IN PRE-CLINICAL DRUG DEVELOPMENT S. Kustermann, Roche
4.30 PM SESSION 177 Q&A

Program:
Thursday 26 August 2021 - Day 4

3.00 - 5.00 PM THU-1 S195 Industry and public sector partnerships in education to foster the implementation of alternative methods

Newer alternative methods to animal tests in toxicology are increasingly using advanced techniques. These are sometimes more complex than historical animal tests and their appropriation by stakeholders, CROs, safety evaluators, regulatory bodies require new knowledge, equipment and also availability of the test systems. Their validation is a must but not always sufficient to be accepted everywhere. To be trusted and routinely used there is a need of communication and training at an international level for both current professionals and next generation of toxicologists. In this context a number of initiatives involving private companies in partnership with educational/research institutions, learned societies and nonprofit organizations have emerged to organize theoretical as well as hands-on-training of human-relevant alternative methods. This allows students, scientists and toxicologists, to quickly become familiar with newer methods and to better understand how to use the results for GHS (global harmonization system) classification or risk assessment. In these approaches the notion of partnership is crucial. On one hand, private companies, such as methods providers or end-users, have expertise and access to technologies and methods. On the other hand, public establishments, academic institutions or learned society are representative of the intended population and have legitimacy in education. After a short presentation of some examples involving private and public/nonprofit players conducted in Europe, South America, India or China this round table will discuss some of the barriers experienced (funding, mistrust...), definition of education and training good practices (mixing theory and practice, hosting laboratory...) and ways to improve the effectiveness and recognition of these courses (university partnership, certification, webinars...). Finally, the interest of coordination and generalization of this kind of partnerships to accelerate the spread of alternative methods to animal experimentation worldwide will be discussed.

Session chair and co-chair
Christian Pellevoisin from the Episkin Academy & Vijay Pal Singh from CSIR-Institute of Genomics & Integrative Biology (India/SAAE-I)

Time Abstract Speakers
3.00 PM ID 575 ROUND TABLE: INDUSTRY AND PUBLIC SECTOR PARTNERSHIPS IN EDUCATION TO FOSTER THE IMPLEMENTATION OF ALTERNATIVE METHODS: ALTERNATIVES TO ANIMALS IN EDUCATION AND RISK ASSESSMENT: AN OVERVIEW WITH SPECIAL REFERENCE TO INDIAN CONTEXT Abbarsah, Mohammad A., Society for Alternatives to Animal Experiments-India (SAAE-I)
3.15 PM ID 793 BRAZIL IS ON: ANIMAL TESTING BAN AND AVAILABLE OECD TG IN BRAZIL L. Balottin, National Institute of Metrology, Quality and Technology (INMETRO)
3.30 PM ID 496 WAYS TO IMPROVE THEIR EFFECTIVENESS AND RECOGNITION F. Busquet, Altertox Academy
3.45 PM ID 591 THE DEVELOPMENT OF ALTERNATIVE METHODS IN CHINA AND THE ROLE OF THE INDUSTRIES C. Shujun, Shanghai Jiao Tong University
4.00 PM ID 670 FEEDBACK FROM 8 YEARS OF TRAINING TO ALTERNATIVE METHODS IN INDUSTRIAL AND ACADEMIC CONTEXTS C. Pellevosin, EPISKIN Academy
4.30 PM SESSION 195 Q&A

Program:
Thursday 26 August 2021 - Day 4

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4.30 PM SESSION 195 Q&A
Use of New approach methodologies - NAMs- to derive Point(s) of departure, opportunities and limitations

Several initiatives have generated a wealth of non-animal data. “new approach methodologies” -NAMs-. In 2007, the American National Academy of Science called from moving away from measuring apical endpoints to considering upstream events. Regulatory changes like in the cosmetics sector in Europe incentivized such initiatives. NAMs have been used in different decision-making contexts. Biological effects at the molecular, cellular and/or tissue level compared to internal concentrations based on use scenarios yielded PoDs protective of human health and conservative. The session covers cases with PoDs from NAMs with a 30 min discussion highlighting opportunities and limitations of such approaches.
PROGRAM
Thursday 26 August 2021 - Day 4

5.00 - 6.30 PM
PLENARY SESSIONS

5.00 - 5.15 PM
WC11 TV live from the studio

5.15 - 6.15 PM
KEYNOTE:

PROF. DR. MALCOLM MCLEOD
University of Edinburgh

Malcolm Macleod is Professor of Neurology and Translational Neurosciences at the University of Edinburgh, member of the UK Commission for Human Medicines and the UK Reproducibility Network. He also leads the European Quality in Preclinical Data IMI project and the SE Scotland Stroke Research Network. He was co-CI of the EuroHYP trial of brain cooling for acute stroke and is UK coordinator for the PRECIOUS trial of preventing complications following stroke.

Since founding the Collaborative Approach to Meta-analysis and Review of Animal Data form Experimental Studies (CAMARADES) in 2004 his research has largely focussed on how best to increase the value of biomedical research. This has included work with funders, journals (including randomised studies of different approaches to improve quality, and the proposed MDAR Minimum Standards Framework) and most recently with institutions (recently appointed Research Improvement lead at the University of Edinburgh). He led the development and implementation of the SyRF platform (app.syrf.org.uk) which supports systematic reviews of in vivo research.

Since 2007 he has been clinical lead for Neurology at NHS Forth Valley. For more information visit: https://orcid.org/0000-0001-9187-9879 and for more information about his talks visit: https://osf.io/de6qh/


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Thursday 26 August 2021 - Day 4

6.30 - 8.30 PM THU-2 S219

Rigor, Relevance and Reproducibility in (animal) research: when "Science’s 3Rs" come into play

While one can think there is failure to improve experimental design and increase 3Rs principle uptake in the scientific community, this session aims at bridging science quality and the 3Rs: - providing concrete scientific perspectives on how rigor, relevance and reproducibility foster the best use of research models and deliver scientific results that ultimately benefit the 3Rs; - illustrating the continuity and complementarity in the use of non-animal and animal research models as the best approach to shift from animal to non-animal methods over time through knowledge sharing; - ultimately aligning researchers and regulators to the same ultimate 3Rs goal.

Sponsored by Sanofi R&D

Session chair and co-chair
S. Rao, SANOFI R&D and A. L Andreu, EATRIS

Time Abstract Speakers
6.30 PM ID 890 RIGOR, RELEVANCE AND REPRODUCIBILITY IN THE USE OF IN VIVO MODELS IN THE PHARMACEUTICAL INDUSTRY S. Rao, Sanofi R&D
7.00 PM ID 761 INCREASING THE RELIABILITY OF PRECLINICAL DATA: ENABLING APPROACHES I. Lefevere, Sanofi R&D
7.30 PM ID 112 REPRODUCIBILITY CRISIS IN PRECLINICAL RESEARCH A. Andreu, EATRIS
8.00 PM SESSION 219 Q&A
PROGRAM
Thursday 26 August 2021 - Day 4

6.30 - 8.30 PM THU-2 S231 Building confidence in Next Generation Risk Assessment

Next Generation Risk Assessment (NGRA) is an exposure-led, hypothesis-driven approach that uses new approach methodologies (NAMs) to ensure the chemical safety without the use of animal data. Whilst some NAMs have been validated and adopted by regulators (e.g. OECD test methods for skin sensitization) there is a need amongst both industry and regulatory risk assessors for more examples to demonstrate the utility of NAMs for decision-making on effects that are associated with systemic exposure to chemicals. This symposium will increase awareness and confidence in the use of NAMs for decision-making, by showcasing several of the components of an NGRA framework.

Session chair and co-chair
C. Westmorland, Unilever and M. Varçin, Cosmetics Europe

Time | Abstract | Speakers
--- | --- | ---
6.30 PM | PERSPECTIVES ON THE USE OF HIGH THROUGHPUT PROFILING ASSAYS IN NEXT GENERATION RISK ASSESSMENT | J. Harrill, US Environmental Protection Agency (EPA)
7.00 PM | PREDICTIVE VALUE OF PBK-MODEL PREDICTIONS BASED ON IN VITRO AND IN SILICO INPUT DATA AS ESSENTIAL TOOL IN NEXT GENERATION (ANIMAL-FREE) RISK EVALUATIONS | A. Punt, Wageningen Food Safety Research (WFSR)
7.15 PM | IN SILICO APPROACHES TO LINK ADVERSE OUTCOMES TO MOLECULAR INITIATING EVENTS THROUGH ADOPs | T. Allen, University of Cambridge
7.30 PM | AN INDUSTRY PERSPECTIVE ON STRATEGIES FOR INTEGRATING NEW APPROACH METHODOLOGIES FOR NEXGEN RISK ASSESSMENT: COUMARIN AS A CASE STUDY | M. Baltazar, Unilever
7.45 PM | INTEGRATING TOXICOGENETICS AND TOXICOLOGY IN DECISION-MAKING IN AN NGRA CONTEXT: 2 COSMETICS-EUROPE CASE STUDIES | G. Guadagnolo, L’Oreal
8.00 PM | SESSION 231 Q&A

PROGRAM
Thursday 26 August 2021 - Day 4

6.30 - 8.30 PM THU-2 S230 The in3 project: An integrated interdisciplinary approach to animal-free nanomaterial and chemical safety assessment

In3 is a EU’s Marie Skłodowska-Curie Action - Innovative Training Network project funded by the EU Horizon 2020 under grant no. 721975. In3 focuses on research and training of 15 PhD students in utilising integrated in silico and in vitro tools for animal-free toxicity assessment. There is a particular interest in the project on utilising human induced Pluripotent Stem Cells (hiPSC) differentiated to toxicologically relevant target tissues such as brain, lung, liver, vasculature and kidney, but also anchoring this information to mechanistic toxicology and utilising read across and adverse outcome pathways.

Session chair
M. Culot, Université d’Artois

Time | Abstract | Speakers
--- | --- | ---
6.30 PM | THE IN3 PROJECT - AN INTEGRATED INTERDISCIPLINARY APPROACH TO ANIMAL-FREE NANOMATERIAL AND CHEMICAL SAFETY ASSESSMENT | P. Jennings, Vrije Universiteit Amsterdam
6.45 PM | STUDY THE EFFECT OF CYCLOSPORIN A ON FUNCTIONALITY OF ENDOTHELIAL CELLS DIFFERENTIATED FROM INDUCED PLURIPOTENT STEM CELLS AS AN IN VITRO TOXICITY MODEL | Z. Mazzol, Evrycote GmbH
7.00 PM | EXPLOITING THE USE OF IPSC DERIVED RENAL PROXIMAL TUBULAR LIKE CELLS TO INVESTIGATE MEGALIN MEDIATED AMINOGLYCOSIDES TOXICITY | V. Chandrasekaran, Vrije Universiteit Amsterdam
7.15 PM | IPSC-DERIVED HUMAN BRAINSPHERES: A MULTIFACETED AND POWERFUL 3D MODEL FOR NEUROTOXICITY TESTING | C. Nunes, Université de Lausanne
7.30 PM | PROBABILISTIC MODELLING OF AN ADVERSE OUTCOME PATHWAY NETWORK FOR DEVELOPMENTAL NEUROTOXICITY | N. Spinu, John Moores Liverpool University
7.45 PM | NEW READ ACROSS MODULES FOR SAFER CHEMICALS | A. Caballero, Istituto di Ricerche Farmacologiche Mario Negri
8.00 PM | SESSION 230 Q&A
### PROGRAM
**Thursday 26 August 2021 - Day 4**

**6.30 - 8.30 PM THU-2**
**S85**

A walk through 10 years of CAAT-Europe’s highlights

The Center for Alternative to Animal Testing in Europe (CAAT-Europe), housed at the University of Konstanz, coordinates transatlantic activities to promote the development of new and improved methods in toxicology, to provide a platform for different stakeholders for exchanging ideas, and to support the 3Rs principle of human science. CAAT-Europe is going to celebrate the 10th anniversary of its foundation, with a session focused on the most relevant CAAT articles that have been published in the last years. The presentations will cover several topics, as in vitro regulatory, systemic and investigative toxicology; including the application of omics, microphysiological systems and good practice guidance for supporting a human-centered toxicity testing paradigm change. Each speaker will introduce a single publication to tell the story behind its compilation and to discuss its implication and impact on the actual and future discussion in the 3Rs field.

**Speakers:**
- **(2010) CAAT-EUROPE’S BIRTH**
  - Thomas Hartung, CAAT/ Johns Hopkins University
- **(2011) ‘How are reproductive toxicity and developmental toxicity addressed in REACH dossiers?’**
  - Costanza Rovida, CAAT-Europe
- **(2013) ‘Metabolomics in toxicology and preclinical research’**
  - Bernard Van Ravenzwaay, BASF SE
  - Michael Schwarz, Johns Hopkins Bloomberg School of Public Health
  - Francois Busquet, Allentox
- **(2016) ‘Biology-inspired microphysiological system approaches to solve the prediction dilemma of substance testing’**
  - Thomas Steger Hartmann, Bater
- **(2017) ‘Good Cell Culture Practice for stem cells and stem-cell-derived models’**
  - Sandra Coecke, JRC EURL-ECVAM
  - Marco Beilmann, Boehringer Ingelheim

The impact of the CAAT publication series on ALTEX

Sonja von Aulock, ALTEX

**Session chair**

M. Leist, CAAT-Europe/ University of Konstanz and G. Paliocca, CAAT-Europe/ University of Konstanz

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### PROGRAM
**Friday 27 August 2021 - Day 5**

**PLENARY SESSIONS**

**2.30 - 3.00 PM WC11 TV - Live from the studio**

**PARALLEL SESSION FRI-1**

**3.00 - 5.00 PM FRI-1**

**S208**

Application of new-approach methodologies to assess the safety of medical devices

The safety assessment of medical devices traditionally relies heavily on animal testing, which represents a significant portion of global animal use. However, a paradigm shift to replace and complement these animal tests with new processes is taking place. These processes include improved and detailed analytical chemistry and new approach methodologies (NAMs). When an adverse biological effect is also of interest to other sectors (e.g., industrial chemicals), adaptation of established NAMs is very promising. However, when the adverse effect is medical device-specific, new NAMs need to be developed. The proposed workshop will introduce this emerging, but important field for application of NAMs to medical devices by presenting successes and promising ongoing projects. These include: (1) the validation and acceptance of in vitro irritation testing using reconstituted human epidermis (RHE) models, (2) an overview of in vitro methods for skin sensitization testing that use RHE and cell-based models, (3) an in vitro thrombogenicity assessment method where fresh human blood is used to replace in vivo models, and (4) the application of the monocye activation test as an alternative to current in vivo pyrogenicity assays.

**Session chair and co-chair**

S. Hoffmann, seh consulting + services and K. Coleman, Medtronic

**Time** |
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<td>S. Stoppelkamp, Universitätsklinikum Tübingen</td>
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Wildlife research is considered crucial for successful species conservation in the midst of current biodiversity loss, but often includes invasive research practices. Wildlife research can thus result in a fundamental conflict between individual animal welfare and the welfare of the population or ecosystem, which could be significantly minimized if the 3Rs principles were more broadly implemented. The purpose of this session is to invite the audience of the World Congress to share their experiences in integrating the 3Rs principles in wildlife research, present solutions that can promote broader implementation of these principles, and define priorities for the near future.

Session chair
M. Zemanova, Centre for Compassionate Conservation, University of Technology Sydney & Animalfree Research, Switzerland

**APPLYING THE 3RS PRINCIPLES IN WILDLIFE RESEARCH THROUGH NON-INVASIVE METHODS**
Miriam Zemanova, Centre for Compassionate Conservation, University of Technology Sydney

**IS WILDLIFE RESEARCH “SECOND-RATE SCIENCE”? WHAT CAN LAB ANIMAL AND FIELD SCIENTISTS LEARN FROM ONE ANOTHER?**
Adrian Smith, Norecopa

**FIELD VS LABORATORY 3R. IT’S NOT ABOUT WHAT WE DO WITH THE ANIMALS. IT’S ABOUT THE RESEARCH AND ITS SETTING!**
Adriaan de Jong

**EVALUATING THE WELFARE OF WILDLIFE: IDENTIFYING PRIORITIES**
Cathy M. Dwyer

**SESSION 113 Q&A**

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**Using the Semantic Web for Rapid Integration of Publicly Available Biological Information**
The diversity of publicly available biological data, and the variety of methods used to store online resources in different formats, provides a challenge for researchers in the integration and analyses of these data. This workshop will discuss novel methods of data conversion and integration used to capture and link biological data. Challenges and benefits will be explored by a panel of experts in relation to capturing information related to toxicological adverse health outcomes using computational methods.

Session chair
Holly Mortensen, US EPA

Session co-chair
Penny Nymark, Institute of Environmental Medicine, Karolinska Institute, Stockholm, Sweden

**US EPA ADVERSE OUTCOME PATHWAY DATABASE (AOP-DB) SEMANTIC INTEGRATION AND WORKSHOP OPENING REMARKS**
H. Mortensen, US EPA

**TOWARDS BUILDING HARMONIZED AND INTEROPERABLE E-INFRASTRUCTURES FOR REPRODUCIBLE NEW APPROACH TOXICOLOGY - THE OPENRISKNET CONCEPT**
Thomas Exner, Edelweiss Connect GmbH

**TOWARDS BIOLOGICAL PLAUSIBILITY USING LINKED OPEN DATA**
Egon Willighagen, University of Maastricht

**INTEROPERABILITY: IT’S IN THE SEMANTICS**
Jerven Tjalling Bolleman, Swiss Institute for Bioinformatics

**SEMANTIC MODELLING OF ADVERSE OUTCOME PATHWAYS AND THE IMPLEMENTATION IN REPRODUCIBLE WORKFLOWS**
Marvin Martens, University of Maastricht

**ADVERSE OUTCOME PATHWAYS AND DATA INTEGRATION**
Penny Nymark, Karolinska Institutet

**EPA ORD NAKNOWBASE (NKB): NANOMATERIAL DATABASE SEMANTIC WEB INTEGRATION FOR ACCESS AND COLLABORATION**
Weston Slaughter, US EPA

**SESSION 67 Q&A**

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**Session chair**
H. Mortensen, US EPA

**Session co-chair**
Penny Nymark, Institute of Environmental Medicine, Karolinska Institute, Stockholm, Sweden
Diving into the scientific knowledge big data looking for alternatives

The implementation of a new method or model by life science researchers is based on six phases: 1) access to scientific knowledge; 2) theoretical familiarisation; 3) experimental reproduction; 4) adaptation to their own specific research paradigm; 5) internal validation and 6) deployment. In this view, easy access to scientific knowledge is the gatekeeping phase towards final deployment (and enhanced uptake) of non-animal models and methods, because it empowers not only researchers, but also regulators, ethical approval boards and those responsible for project/animal licence approvals to discover already available alternatives, importantly reducing duplication of efforts, and boosting the horizontal use and cross-validation in different fields of application. Improving, or facilitating, informed access to scientific knowledge means that all these stakeholders know how to search for publications of interest and, on the other side, implies that key publications are easy findable. Our experience tells us that literature search skills in these communities often need improvement and additionally, increasing visibility of non-animal methods could improve familiarity with, and uptake of such methods and could therefore reduce animal use. It is also true that, for identifying key publications, the precise nature of the models and/or methods must be better highlighted in titles/abstracts when drafting scientific documents. The overall aim of this workshop is to improve literature search skills for the disparate groups of stakeholders who are required to maintain currency with developments in non-animal methodologies. We will provide tips for highlighting non-animal alternatives when drafting a document, consider how and where to search for reliable sources of information and also describe how automated, deep learning methods could be employed to create and update libraries.

Session chair: Laura Grimaldi, European Commission JRC and Adelaide Dura, European Commission JRC

Time Abstract Speakers
3.00 PM ID 20 HOW TO BETTER HIGHLIGHT YOUR RESEARCH BY USING THE RIGHT KEYWORDS IN TITLES AND ABSTRACTS Lindsay Marshall, The Humane Society of the United States/Humane Society International
3.15 PM ID 673 GOOD PRACTICE: KEY EXPERIMENTAL DETAILS TO HIGHLIGHT WHEN DRAFTING YOUR RESEARCH ARTICLE Fabrizio Rossi, FRESCI by Science&Strategy SL
3.30 PM ID 93 MIND THE GAP: IMPROVING LITERATURE SEARCH SKILLS TO ACCESS THE MOST RELEVANT SCIENTIFIC AND TECH KNOWLEDGE David Straccia, FRESCI by SCIENCE&STRATEGY SL
3.45 PM ID 258 DATA ACCESS AND EU INSTITUTIONS Francois Busquet, altertox
4.00 PM ID 637 ADVANCING MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE TECHNIQUES FOR USE IN (SEMI-)AUTOMATIC LITERATURE REVIEWS Krystof Dibusz, EcoMole
4.15 PM ID 1117 NAMMED: DEVELOPMENT OF AN ARTIFICIAL INTELLIGENCE DATABASE TO COLLECT AND STRUCTURE NON-ANIMAL METHODS IN USE FOR BIOMEDICAL RESEARCH Marco Straccia, FRESCI by SCIENCE&STRATEGY SL
4.30 PM SESSION 65 Q&A

The Animal Welfare Body - how are we doing?

Every establishment designated under Directive 2010/63/EU must have an Animal Welfare Body (AWB), which has important tasks, including advising on animal welfare and the Three Rs. This workshop reflects on the implementation of the AWB, including what works well, how to address any outstanding challenges; and the activities of AWB networks. It will focus on Replacement, including what it is realistic to expect from the AWB, and how the AWB can create a culture that encourages effective searches for alternatives. We will combine talks and discussion, share ideas, and identify areas where further support may be needed for the AWB.

Session chair and co-chair: P. Hawkins, RSPCA Animals in Science Department and N. Stockhofe-Zurwieden, Wageningen University and Research

Time Abstract Speakers
3.00 PM ID 459 ANIMAL WELFARE BODY - TASKS AND ROLE Susanna Louhimies, European Commission
3.15 PM ID 40 THE ANIMAL WELFARE BODY - HOW ARE WE DOING Norbert Stockhofe-Zurwieden, Wageningen UR
3.30 PM ID 38 INTERACTIVE DISCUSSION - HOW ARE WE DOING? Penny Hawkins, RSPCA
4.00 PM ID 898 CREATING A CULTURE THAT PROMOTES REPLACEMENT Reinoud Gosens, University of Groningen
4.15 PM FOLLOWED BY AN INTERACTIVE DISCUSSION IN 4 BREAKOUT ROOMS EACH WITH 15 PEOPLE Feedback and wrap-up Penny Hawkins, RSPCA
### PROGRAM

Friday 27 August 2021 - Day 5

#### 3.00 - 5.00 PM  S213

**Documentary Film and Alternatives Room**

The Documentary Film and Alternatives Room showcases a number of new and recent documentary films that address animal experimentation and the innovative, humane methods being implemented in education and training, research and testing. Each film’s producers will be available for questions and answers after the showings. The room will also feature demonstrations and footage of a range of education and training tools, from virtual reality models for comparative anatomy practical classes to advanced synthetic cadavers for medical and veterinary surgery training.

**Session chair**
Nick Jukes, InterNICHE

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<td>DVM: TRAINING THE ANIMAL DOCTOR</td>
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<td>GOLD DOESN'T RUST: THE FAILING STANDARD OF THE ANIMAL MODEL</td>
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#### 3.00 - 5.00 PM  S315

**Enabling Animal-Free Safety Assessment of Cosmetics Globally**

Sponsored by Humane Society International

**Session chair**
Nick Jukes, InterNICHE

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<td>PREDICTING GHS CLASSES FOR SKIN SENSITIZATION USING VALIDATED NON-ANIMAL TESTS: THE KINETIC DIRECT PEPTIDE REACTIVITY ASSAY COMBINED WITH THE 2 OUT OF 3 DEFINED APPROACH</td>
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<td>COSMETICS EUROPE NGRA DATA CASE STUDY</td>
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<td>LIVE Q&amp;A (MIX OF QS BASED ON THE CASE STUDIES PRESENTED AND WIDER QS - ALL PARTICIPANTS CAN SUBMIT QS VIA THE CHAT)</td>
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#### 3.00 - 5.00 PM  S316

**EPAA training session on Skin sensitisation**

Sponsored by EPAA

**Session chair**
Francois Busquet, Altertox

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#### 3.00 - 5.00 PM  S317

**CONTINUED EDUCATION - READ-ACROSS SUPPORTED BY NEW APPROACH METHODOLOGIES (NAM)**

Delivered by Cosmetics Europe and EU-ToxRisk

**Session chair**
Mustafa Varçin, Cosmetics Europe, Arianna Gausti

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<td>KEYNOTE INTRODUCTION - BASICS OF READ-ACROSS AND LEAD-IN TO CASE STUDIES</td>
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<td>3.25 PM</td>
<td>CASE STUDY I - PREDICTION OF MICROVESICULAR LIVER STEATOSIS – A READ-ACROSS CASE STUDY WITH SHORT BRANCHED CARBOXYLIC ACIDS</td>
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<td>CASE STUDY II – PREDICTION OF DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART): A READ-ACROSS CASE STUDY WITH SHORT BRANCHED CARBOXYLIC ACIDS (2-METHYLHEXANOIC ACID)</td>
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<td>CASE STUDY III – CASE STUDY ON THE USE OF INTEGRATED APPROACHES FOR TESTING AND ASSESSMENT FOR SYSTEMIC TOXICITY ARISING FROM COSMETIC EXPOSURE TO CAFFEINE</td>
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<td>4.40 PM</td>
<td>LIVE Q&amp;A AND CONCLUSION</td>
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PROGRAM
Friday 27 August 2021 - Day 5

3.00 - 5.00 PM
YOU-WC11 - WORKSHOP 2
“CAREER DEVELOPMENT - CREATING A CONVINCING PERSONAL PROFILE FOR DIFFERENT FIELDS OF ACTIVITY”

One major challenge throughout the scientific career is publishing. Therefore, this workshop will focus on the questions – How does publishing work? Why do we need peer reviewing and how do I review appropriately? What do I need for a high-quality publication? Three experts will present their perspectives, insights, and experiences which will be followed by an interactive discussion round in three separate virtual rooms each guided by one of the experts.

Session chair
Annemarie Lang, Charité-Universitätsmedizin Berlin

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<td>FROM PH.D. TO POSTDOC: JOURNEY TOWARDS SCIENTIFIC SELF-REALIZATION</td>
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<td>3.15 PM</td>
<td>HOW TO FIND THE BALANCE BETWEEN SCIENTIFIC MOTIVATION AND BEING FOCUSED? Vijay Pal Singh, CSIR-Institute of Genomics &amp; Integrative Biology (India)</td>
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<td>3.25 PM</td>
<td>FINALLY PROFESSOR - WHAT COMES NEXT? Thomas Hartung, CAAT / Johns Hopkins University</td>
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<td>INTRODUCTION 2</td>
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<td>3.40 PM</td>
<td>INDUSTRY: AS ALTERNATIVE PATH OR FIRST CHOICE?</td>
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<td>BRIDGING RESEARCH AND SCIENTIFIC EDITING: BEHIND THE SCENES OF A SCIENTIFIC JOURNAL Sonja von Aulock</td>
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<td>Q&amp;A AND BREAK OUT ROOMS (VIA ZOOM)</td>
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5.00 - 6.00 PM
PLENARY SESSIONS
Pre-poster warm up sessions live from the studio

Sponsored by Toxys

Session chair
Giel Hendriks

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<td>TOXTRACKER, A HIGHLY QUANTITATIVE NEW APPROACH METHOD FOR MECHANISTIC GENOTOXICITY ASSESSMENT Inger Brandsma, Toxys</td>
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<td>6.25 PM</td>
<td>APPLICATION OF IN VITRO TO IN VIVO EXTRAPOLATION TO TOXTRACKER DATA FOR POINT OF DEPARTURE DERIVATION Marc Beal, Health Canada</td>
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<td>GENERAL DISCUSSION AND CONCLUSIONS</td>
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PARALLEL SESSION FRI-2

5.00 - 7.00 PM
S314 Applications of New Approach Methods in Genotoxicity and Developmental toxicity testing

Every year, large numbers of new compounds are being developed for a wide range of purposes. Due to the large numbers of compounds that require safety assessment, there is an increasing demand for rapid and reliable in vitro assays that assess their toxicity in an early phase of drug or product development. At the same time, there is a strong demand to reduce animal testing. We have therefore developed various in vitro cell-based assays for chemical safety assessment, with the focus on understanding the mode-of-action (MoA) of toxic compounds. ToxTracker is a unique stem cell-based reporter assay for reliable genotoxicity and carcinogenicity hazard identification. The ToxTracker assay reliably identifies genotoxic compounds and provides insight into their mode-of-action. The assay is able to discriminate between direct DNA reactivity and indirect genotoxicity related to oxidative stress or protein damage and can differentiate between genotoxic compounds with a clastogenic or aneugenic MoA. Various extensions of ToxTracker to further investigate the MoA of genotoxic compounds are combined in the ToxTracker suite. ReproTracker is a human induced pluripotent stem cell (hiPSC)-based biomarker assay that follows the differentiation during early embryonic development. The hiPSCs are differentiated into the primordial endoderm, ectoderm and mesoderm germ layers and further matured into hepatocytes, cardiomyocytes, and neural rosettes. The differentiation process is followed by morphological profiling and expression pattern analysis of cell-specific biomarkers. In this system, decrease in the expression of the biomarker genes and morphology disruption of the differentiated cells following compound treatment indicated teratogenicity. In this session we will discuss how results from the in vitro assays can be extrapolated to in vivo exposures and how these assays help in replacing or reducing animal testing by providing reliable in vitro data.

Sponsored by Toxys

Session chair
Giel Hendriks

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### PROGRAM
Friday 27 August 2021 - Day 5

**5.00 - 6.00 PM**  
(Sponsored) **THE ROLE OF MANUFACTURERS TOWARDS THE 3RS**

More than 9 million animals are used for scientific purposes every year in the EU (European Union, 2020). In vivo testing has been the gold standard for preclinical and toxicology research, nevertheless the field is transitioning to new approach methodologies (NAMs). To make NAMs the new standard, the development of advanced physiologically relevant products is key. This aim is not trivial and requires the cooperation between developers and the industry. We want to raise awareness of the importance of the inclusion of manufacturers in the development of NAMs, both at the scientific and regulatory level. SABEU is the original manufacturer of microporous membranes and plastics for cell culture and life sciences. We are playing an active role to accelerate the transition towards the 3Rs. Our TRAKETCH® Membranes are an excellent support for Villus-Like Microstructured Hydrogels (Altay et al., 2020) and our TRAKETCH® Tissue Cultured Treated Membranes are integrated in innovative organ-on-a-chip supporting human mature adipose tissue (Rogal et al., 2020) and in an oviduct-on-a-chip (Ferraz et al., 2018). Furthermore, these membranes form the porous support incorporated in cellQART® Cell Culture Inserts. These NAMs improve the assessment of drugs, increase drug development success rate and advance human benefit while protecting animal welfare. At SABEU we are aware of the urge for inclusion of manufacturers in the process of developing new applications in line with the 3Rs principle. We believe in cooperative product development; with over six decades of experience, we have the infrastructure and we offer sustainable shelf life products. Our operations are in line with the highest quality standards and the applicable normative, legal and regulatory requirements, guaranteeing 100% parameter consistency for reproducible results. We are actively seeking ways to put our expertise on the production of microporous membranes and plastics to help make ethical and sustainable technologies available.

Sponsored by SABEU GmbH

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### PROGRAM
Friday 27 August 2021 - Day 5

**5.30 - 6.30 PM**  
(Sponsored) **HEPATIC AND INTESTINAL ORGANOIDS: IMPROVING IN VITRO MODELS FOR DRUG DEVELOPMENT AND DISCOVERY**

Organoid and organotypic cultures model human and animal tissues with greater physiological relevance than traditional cell culture platforms. The liver and the intestine represent two key organs involved with drug absorption and metabolism in the body, making them important target tissues for the evaluation of drug efficacy and toxicity. Using organoid-based technologies, we can now model tissue types more effectively in vitro, thereby enhancing the precision and speed of metabolic research and drug development, prior to entering animal and clinical trials. This session will provide an overview of cell culture reagents developed by STEMCELL Technologies for the establishment, maintenance and differentiation of hepatic and intestinal organoid cultures derived from human tissues. Furthermore, we will highlight new assays and protocols optimized to work with both 3D and 2D organoid-derived culture models and how they can be utilized as a cutting-edge tool for in vitro drug development. Our data demonstrate the improved utility of human hepatic and intestinal organoids for analyzing drug responses compared to the common intestinal and hepatic cell lines currently used in academic, industrial, and clinical settings.

Sponsored by STEMCELL Technologies Inc.

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**Motivating Speakers**

**Riya Sharma, STEMCELL Technologies Inc.**

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**Poster session and possibility to ask questions to poster presenters**

**6.00 - 8.30 PM**

**PLENARY SESSIONS**

**6.00 - 7.30 PM**

**Poster session and possibility to ask questions to poster presenters**

**7.30 - 8.30 PM**

**WC11 TV - Talk show**

Talkshow 2 will discuss Human Diseases and Drug Development and will focus on neurodegenerative diseases. The context is that investigations into the understanding of complex neurodegenerative diseases (such as Alzheimer and Parkinson) still strongly rely on animal use. The same applies to the testing of candidate drugs to treat these diseases. Whole-animal studies are suggested to be needed to understand the complex biological processes, but do we really need animal testing?
From the very beginning, P&G knew that committing to animal-free testing would be a significant and challenging undertaking that would take years. Undeterred, we have used our passion to achieve the right thing: an ethical safety approach, combining better safety science that is more accurate than ever before. Several decades of effort and innovation have led us to establish the safety of cosmetic products without the use of animals.

WE ARE PASSIONATE ABOUT ANIMAL WELFARE AND RESPONSIBLE SAFETY ASSESSMENT

PROGRAM
Monday 30 August 2021 - Day 6

2.30 - 3.00 PM PLENARY SESSIONS
WC11 TV - Live from the studio

2.30 - 3.00 PM PARALLEL SESSION MO-1

1.00 - 5.00 PM MO-1

Biomed 2.0 -Non-animal Models for Biomedical Research

Animal models have been traditionally used in biomedical research to recapitulate human disease features and develop new drugs, as they are generally supposed to resemble some of the major hallmarks of human diseases. However, these animals do not develop the disease as it occurs in humans, and their use has not paved the way to the development of drugs effective in human patients for many highly prevalent non-communicable diseases, such as Alzheimer disease. Indeed, despite conspicuous research and economical endeavours, the clinical failures rate in drug development still remains very high, with an overall likelihood of approval from Phase I of about 9.6%. On the other hand, enhanced human clinical trials utilizing micro-dosing, and more representative study populations and durations, as well as surrogate human tissues, advanced imaging modalities and human epidemiological, sociological and psycho-logical studies, may increase our understanding of illness aetiology and pathogenesis, and facilitate the development of safe and effective pharmacologic interventions. Particularly when human tissues are used, non-animal models may generate faster, cheaper results, more reliably predictive for humans, whilst yielding greater insights into human biochemical processes. A first effort to gather existing knowledge about non-animal models of highly prevalent human diseases has been made by the Joint Research Centre of the European Commission. The final goal is to disseminate and improve knowledge sharing on potentials and limitations of human based models at different levels: scientific communities, universities and secondary schools, national committees for animal welfare and the public at large. Additionally, project proposals in translational research based on the use of both animal and/or non-animal approaches have been extensively funded at European level. Notwithstanding, defining indicators to measure return on investment in research funding strategies is necessary to retrospectively assess public health trends, and readdress funding strategies when needed. The session aims to shed light on the concepts, challenges and perspectives for implementation of innovative alternative non-animal methods in biomedical research. Literature reviews and meta-analyses of non-animal approaches as key tools to advance this area of science will be discussed, as well as possible indicators that could be suitable to measure return on investment in biomedical research.

Session chair and co-chair
L. Gribaldo, EUR-ECVAM, F3 Unit, JRC-EC and M. Straccia, FRESCI

Time Abstract Speakers
3.00 PM ID 662 AN INVENTORY OF NON-ANIMAL METHODS TO STUDY ALZHEIMER’S AND PARKINSON’S DISEASE Liesbeth Aerts, VIB Center for Brain & Disease Research, VIB, Belgium; IU Leuven - University of Leuven, Leuven, Belgium
3.15 PM ID 7 AVAILABLE AND EMERGING NON-ANIMAL MODELS FOR HUMAN RESPIRATORY TRACT DISEASES Lindsay Marshall, Humane Society International
3.30 PM ID 113 WHAT IS THE ANALYSIS OF BIOMEDICAL RESEARCH LITERATURE TEACHING US ABOUT THE USE OF NON-ANIMAL MODELS? Marco Straccia, FRESCI by SCIENCE&STRATEGY SL
3.45 PM ID 5 THE NEED TO ADDRESS HUMAN RELEVANCE AND MEASURE IMPACT AND INNOVATION OF BIOMEDICAL RESEARCH Francesca Pistoliato, European Commission, Joint Research Centre, Ispra, Italy
4.00 PM ID 140 INNOVATIVE STRATEGIES IN BIOMEDICAL RESEARCH: WHICH MODELS? Laura Gribaldo, JRC-EC
4.30 PM SESSION 122 Q&A
### PROGRAM
**Monday 30 August 2021 - Day 6**

**3.00 - 5.00 PM MO-1 S136**

**How to avoid polarization in dealing with uncertainties in public, scientific and regulatory debate**

Letting go of old habits and (false) certainties is a challenging process. Implementing animal-free innovations instead of, or alongside, animal-driven research is a complex transformation. Such a transformation process benefits from a fair, open-minded debate. There are many uncertainties, and a recurring pattern in transformation processes with different stakeholders is that uncertainties are used in the discussion to invalidate or ridicule arguments from other stakeholders. This leads to a destructive, increasingly polarizing discussion potentially paralyzing the transformation process. In this session we explore how to learn from previous experiences with complex transformation processes, and some successful drivers of transformation will speak.

**Session chair and co-chair**

Prof. Dr. J-B, Francis Crick Institute & Leiden University Medical Centre and Dr. W. de Leeuw, Head of Animal Welfare Body, University Utrecht, The Netherlands

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<tr>
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<tbody>
<tr>
<td>3.15 PM</td>
<td>ACCELERATING THE TRANSITION TO ANIMAL-FREE INNOVATION</td>
<td>Ingrid Visseren</td>
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<tr>
<td>3.30 PM</td>
<td>COMMUNICATING UNCERTAINTY ABOUT FACTS, NUMBERS, AND SCIENCE IN A POLARGED DEBATE</td>
<td>Anne Marthe van der Blies, University of Groningen</td>
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<tr>
<td>3.45 PM</td>
<td>MOVING BEYOND ANIMAL TESTING FROM A SCIENTIFIC POINT OF VIEW</td>
<td>D. Davatzopoulos, University Nijmegen</td>
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<tr>
<td>4.00 PM</td>
<td>MOVING BEYOND ANIMAL TESTING FROM A REGULATORY POINT OF VIEW</td>
<td>F. Musuamba, European Medicine Agency</td>
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<tr>
<td>4.30 PM</td>
<td>SESSION 136 Q&amp;A</td>
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**3.00 - 5.00 PM MO-1 S162**

**Novel cell-based technologies for predicting drug-induced liver injury**

Drug-induced liver injury remains the most common cause of the safety-related withdrawal of drugs from the market, and this despite extensive animal testing and in vitro testing. Therefore, there is a great need for better in vitro predictive models. During this session, the speakers will address progress made in different aspects of in vitro liver models that should enhance drug toxicity prediction. This includes different cells of origin (primary and pluripotent stem cell-derived liver cells), as well as advanced technologies to create tissue mimetics (laser-guided printing, fully defined hydrogel scaffold-based spheroids, organoid or spheroid formation) as well as multi-organ-on-a-chip systems.

**Session chair**

C. Verfaillie, Katholieke Universiteit Leuven

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<th>Time</th>
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<tr>
<td>3.00 PM</td>
<td>BIOLOGY-INSPIRED MICROPHYSIOLOGICAL SYSTEMS: THE ASSET OF MULTI-ORGAN CO-CULTURES</td>
<td>E. Dehe, TissUse GmbH</td>
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<tr>
<td>3.15 PM</td>
<td>A NEW IN VITRO MODEL FOR INTERROGATING DILI SUSCEPTIBILITY FOR PATIENTS WITH BENIGN FAITTY LIVER DISEASE</td>
<td>Katarzyna Sanchez, InSphero AG</td>
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<tr>
<td>3.30 PM</td>
<td>LIVER ORGANOIDS TO TOXICITY STUDIES</td>
<td>H. Clevers, Hubrecht Institute</td>
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<tr>
<td>3.45 PM</td>
<td>COMPLEX IN-VITRO MODELS: SYNTHETIC MATRICES FOR PLURIPOTENT STEM CELLS (PSC) DERIVED MULTI-CELLULAR 3D LIVER ORGANOID</td>
<td>Manoj Kumar, Stem Cell Institute, KU Leuven</td>
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<tr>
<td>4.00 PM</td>
<td>DEVELOPMENT OF A BIOPRINTED LIVER TISSUE MODEL AND ITS EVALUATION FOR DRUG TOXICITY TESTING</td>
<td>F. Guillemot, Poëtis</td>
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<tr>
<td>4.30 PM</td>
<td>SESSION 162 Q&amp;A</td>
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Adverse Outcome Pathways (AOPs) are frameworks for organizing and integrating diverse, and sometimes abundant, toxicological data. AOPs include identification of the initial chemical-biological interaction (the molecular initiating event), a complete sequence of biological events, key events, and relationships between events that lead to an adverse outcome of actionable concern. AOPs evolved from mode-of-action (MOA) and other preceding concepts and have expanded on this groundwork by more precisely defining the level of knowledge required to link a molecular interaction to an adverse effect. AOPs are not part of the toxicological evaluation beyond the proof of concept phase, yet to date, application of AOPs to chemical safety decision-making has been limited. This may be due in part to the substantial resources investment required to research, author, and review a complete AOP in the cases where all key events are known and there are non-animal methods to test these events. Testing strategies may be sufficiently predictive of the global responses to replace the need for in vivo data (e.g. skin sensitisation). However, for circumstances that do not achieve this level standard, a variety of these strategies that do not require as complete an understanding of the biological events between molecular interactions and adverse effects have been successfully deployed for chemical safety decision making. For example, evaluating the hazard of chemicals that may interact with vertebrate endocrine systems requires data on the chemical’s MOA and an adverse effect in an animal but to date, complete AOPs (MOA to special adverse outcome) are not available for most types of endocrine toxicity. This has not prevented regulatory agencies from using pathway-based models in chemical prioritization and hazard screening, and to replace the need for some in vivo testing. Another recent approach has been to interoperate, assemble and evaluate the relevant evidence on various cancer mechanisms according to defined key characteristics (KCs), chemical and biological properties of established carcinogens identified by the WHO’s International Agency for Research on Cancer (IARC). An approach based on the ICSs does not require an a priori hypothesis concerning the biological mechanisms or signaling that initiates the toxic effect or all eventual leading to carcinogenesis, but nonetheless can contribute to protecting human health; in some cases, in the absence of animal experiments. In other scenarios, AOP frameworks can be used to identify candidate assays to fill regulatory data gaps, even for circumstances where the intermediate events linking the molecular initiating event and adverse effect may not be well understood. For example, chemicals that interfere with retinoid pathway signaling are associated with some of the most common human birth defects. Rather than designing a new in vivo model to investigate retinoid signaling, in vitro and in silico mechanistic tests can help identify chemical safety hazard identification, and reduce the need for animal testing.

Session chair
Patience Browne, OECD

Time | Abstract | Speakers
--- | --- | ---
3.00 PM | ID 47 | Nicole Kleinstreuer, NIEHS/NICETAM
3.15 PM | ID 652 | Matthias Hezler, The German Federal Institute for Risk Assessment (BfR)
3.30 PM | ID 103 | Tom Knudsen, US Environmental Protection Agency
4.00 PM | ID 524 | Kathryn Guyton, IARC
4.15 PM | ID 644 | Anne Gourmelon, OECD and João Barroso, EURL ECVAM Joint Research Center
4.30 PM | SESSION 104 Q&A | Anne Kienhuis, RIVM
Innovative Technologies Disease Ethics, Welfare and Regulation Safety

PROGRAM
Monday 30 August 2021 - Day 6

5:00 - 6:30 PM PLENARY SESSIONS

5:00 - 5:15 PM WC11 TV live from the studio

5:15 - 6:15 PM KEYNOTE: 
DR. ANNA DEPLAZES ZEMP
UNIVERSITY OF ZURICH

Anna Deplazes Zemp is a Senior Researcher at the Ethics Research Institute at the Department of Philosophy of the University of Zurich. She has a multidisciplinary background with a first academic training in molecular biology at the University of Zurich and a PhD in biochemistry at the ETH Zurich. Since the beginning of her studies, she has been interested not only in the natural sciences but also in the social and especially moral-ethical aspects of research and application of the life sciences. Therefore, after her doctorate, she did a second study in philosophy and dedicated her further research to applied ethics. Based on her multidisciplinary background, her main research interests lie at the interface between ethics and the natural sciences. She published in peer reviewed journals particularly on the ethics of biotechnology, justice in the context of genetic resources and environmental ethics. Deplazes Zemp is currently leading a small research team in a project called 'People’s Place in Nature' at the University of Zurich, in which she combines philosophical and social science methods to study the human-nature relationship. Moreover, she teaches various lectures, seminars and courses on research ethics, environmental ethics and the ethics of biotechnology to students in different disciplines.

Anna Deplazes Zemp has been involved in various inter and transdisciplinary research projects involving natural scientists, social scientists, philosophers and other stakeholders. She is an active member of the Forum for Genetic Research of the Swiss Academies of Arts and Sciences, current member of the board of trustees of WWF Switzerland and of the Nuclear Waste Advisory Board for the Swiss Federal Administration.

6:15 - 6:30 PM WC11 TV live from the studio

PROGRAM
Monday 30 August 2021 - Day 6

6.30 - 8.30 PM PARALLEL SESSION MO-2

6.30 - 8.30 PM MO-2 S84 Beyond the 3Rs: Expanding the Use of Human-Relevant Replacement Methods in Biomedical Research

The current landscape of alternative methods calls for a strategic focus on (1) biomedical research (where many human disease processes remain unclear), (2) replacement methods (given the myriad types of models now available (e.g., organs-on-a-chip)), and (3) human relevance (given problems with the current translatability of models). This roundtable will reflect this strategic focus by addressing the use of human relevant models in several areas of biomedical research, including cardiovascular disease, Alzheimer disease, autism, and cancer.

Session chair and co-chair
Martin Stephens, Johns Hopkins Bloomberg School of Public Health and Kathrin Herrmann, Johns Hopkins Bloomberg School of Public Health

Time Abstract Speakers
6.30 PM ID 21 OVERVIEW OF NEW APPROACHES IN BIOMEDICAL RESEARCH - THE BIOMED21 COLLABORATION
Lindsay Marshall, The Humane Society of the United States/Humane Society International

6.45 PM ID 696 IN-SILICO TRIALS FOR DRUG SAFETY AND EFFICACY ASSESSMENT
Cristian Trovato, University of Oxford

7.00 PM ID 3 THE NEED TO PRIORITIZE ‘REPLACEMENT’ IN ALZHEIMER’S DISEASE RESEARCH
Francesca Pistolatto, European Commission, Joint Research Centre, Ispra, Italy

7.15 PM ID 689 APPLICATIONS OF BRAIN-MODEL TECHNOLOGY TO STUDY CHEMICAL INDUCED NEURODEVELOPMENTAL DISORDERS
Helena Hogberg, Center for Alternatives to Animal Testing (CAAT), Johns Hopkins Bloomberg School of Public Health

7.30 PM ID 513 MINI ME - TISSUE-ON-A-CHIP AS A MIMIC FOR PATIENT RESPONSE
John Greenman, University of Hull

8.00 PM SESSION 84 Q&A
## Program
### Monday 30 August 2021 - Day 6

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<td>6.30 PM</td>
<td>523</td>
<td>MENINGOCOCCAL GROUP B VACCINE: A JOURNEY TOWARDS A COMPLETE ANIMAL TEST FREE RELEASE PROCESS</td>
<td>Orazio Oliverio, GSK</td>
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<td>6.45 PM</td>
<td>695</td>
<td>REGULATORY CONSEQUENCES OF THE VALIDATION OF REPLACEMENT IN VITRO TOXICITY AND ANTIGENICITY ASSAYS FOR CLOSTRIDIUM SEPTICUM VACCINE ANTIGENS</td>
<td>Marie-Emmanuelle Behr-Gross, EDQM Council of Europe</td>
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<td>7.00 PM</td>
<td>860</td>
<td>NSH REPLACEMENT FOR HUMAN RABIES VACCINE. METHOD DEVELOPMENT AND STRATEGY FOR IMPLEMENTATION OF NEW ELISA FOR COMMERCIAL PRODUCT</td>
<td>Audrey Toinon, Sanofi Pasteur</td>
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<td>7.15 PM</td>
<td>373</td>
<td>ALTERNATIVES TO ANIMAL TESTING IN VACCINE MANUFACTURING AND RELEASE</td>
<td>Denison Chang, Virbac</td>
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<td>9.30 PM</td>
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<td>SESSION 120 GQA</td>
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### Session 120 GQA

This session will review how 3R can be used in Vaccines development, from early development strategy to launch. The presentation will focus on success stories of recent developed vaccines and future trends.

**Session Chair and Co-chair**

S. Shaid, GSK and C. Stirling, Zoetis

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<td>6.30 PM</td>
<td>456</td>
<td>GENETICALLY ALTERED ANIMALS (GAA) – WHY THE THREE RS ARE IMPORTANT</td>
<td>S. Louhimies, European Commission</td>
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<td>7.00 PM</td>
<td>437</td>
<td>EU EXPERT WORKING GROUP PROPOSALS FOR COMMON GUIDANCE ON THE CREATION AND BREEDING OF GENETICALLY ALTERED ANIMALS (GAAS)</td>
<td>D. Anderson, PMS</td>
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<td>7.15 PM</td>
<td>935</td>
<td>APPLICATION OF THE 3RS IN CREATION OF GAA MICE - THE CHALLENGES OF NEW TECHNOLOGIES</td>
<td>B. Jerchow, Novartis Institutes for BioMedical Research, Novartis Pharma AG, Basel, Switzerland</td>
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<tr>
<td>7.30 PM</td>
<td>659</td>
<td>THREE R CHALLENGES IN THE BREEDING OF GA RODENTS</td>
<td>A. Zintzsch, University of Basel</td>
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<td>7.45 PM</td>
<td>12</td>
<td>ANIMAL WELFARE ASSESSMENT OF GENETICALLY ALTERED GÖTTINGEN MENINGOCOCcal VACCINE</td>
<td>L. Mikkelsen, Ellegard</td>
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<td>8.00 PM</td>
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<td>SESSION 221 GQA</td>
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**PROGRAM**

Monday 30 August 2021 - Day 6

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<td>6.30 PM</td>
<td>ID 355 ADVANCING THREE Rs UNDER A EUROPEAN PARLIAMENT PILOT PROJECT</td>
<td>K. Schutte, European Commission</td>
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<tr>
<td>6.30 - 8.30 PM</td>
<td>MO-2  S135 Advancing Three Rs education and training under a European Parliament Pilot Project</td>
<td>European Parliament Pilot project promoting alternatives and the Three Rs in education and training facilitates the development of six interactive, open access e-learning modules on critical aspects of Directive 2010/63/EU and the development and uptake of non-animal alternatives to aid today’s users and method developers. Furthermore, the Education and Training Platform for Lab Animal Science (ETFLAS) is developing Learning Outcome assessment criteria and tools for competence assessment. Finally, targeting future generations, EURIL ECVAM is preparing learning resources and guidance for educators on how to include the Three Rs in a curriculum for high schools, universities and for early career scientists.</td>
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<tr>
<td>6.45 PM</td>
<td>ID 37 E-LEARNING RESOURCES TO SUPPORT TRAINING FOR PROJECT EVALUATION, PROJECT AND PROCEDURE DESIGN, AND SEVERITY ASSESSMENT FRAMEWORK</td>
<td>Paul Flecknell, Flaire Consultants Ltd</td>
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<td>7.15 PM</td>
<td>ID 407 A EUROPEAN COMMISSION FUNDED PROJECT TO DEVELOP LEARNING OUTCOMES AND ASSESSMENT TOOLS TO FACILITATE HARMONISATION OF LAS EDUCATION AND TRAINING IN EUROPE</td>
<td>Jan-Bas Prins, Leiden University Medical Centre; The Francis Crick Institute</td>
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<tr>
<td>7.30 PM</td>
<td>ID 603 ADVANCING THREE Rs EDUCATION AND TRAINING UNDER A EUROPEAN PARLIAMENT PILOT PROJECT AT EURL ECVAM</td>
<td>Marcelle Holloway, European Commission, Joint Research Centre (JRC)</td>
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<td>8.00 PM</td>
<td>SESSION 135 G6A</td>
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Evidence suggests that pain and suffering can alter an animal’s behavior, physiology, and immunology, which can lead to variation in experimental results that compromise the reliability and repeatability of animal studies. Refinement refers to methods that minimize the pain, suffering, distress, or lasting harm that may be experienced by animals in research to improve scientific results gained by animal experimentation. Furthermore, evidence is mounting that animals are poor models for human disease research, drug development, and safety assessment. Yet, they are still widely used in research and testing. In this debate, speakers will take a stance on whether the time is right to move beyond the principle of refinement and towards more reliable, human-relevant models for biomedical research and toxicology. Speakers will discuss the limitation of animal experiments, scientific advancements that can replace rather than refine the use of animals, if and how these replacement methods are being used and implemented by the scientific community, and if a paradigm shift is inevitable to improve scientific methodology to ensure improved human health and safety.

Session chair
Janine McCarthy, Frank Schulze

Time | Abstract | Speakers
--- | --- | ---
6.30 PM | INTRODUCTION OF DISCUSSION 1 |  
6.35 PM | DISCUSSION 1: DROPPING AN R: IS IT TIME TO RETIRE REFINEMENT? | Charu Chandrasekera
6.50 PM | DISCUSSION 1: DROPPING AN R: IS IT TIME TO RETIRE REFINEMENT? | Lars Lewejohann
7.05 PM | INTRODUCTION OF DISCUSSION 2 |  
7.10 PM | DISCUSSION 2: FUNDING AND REGULATION: DOES ONE POSE A GREATER THREAT TO ADVANCEMENT? | Elizabeth Baker
7.25 PM | DISCUSSION 2: FUNDING AND REGULATION: DOES ONE POSE A GREATER THREAT TO ADVANCEMENT? | Rebecca Ram
7.40 PM | Q&A AND BREAK OUT ROOMS (VIA ZOOM) |  

**THARANGA THORADENIYAP**
**UNIVERSITY OF COLOMBO**

Tharanga Thoradeniya is a Senior Lecturer at the Department of Biochemistry and Molecular Biology, Faculty of Medicine, University of Colombo, Sri Lanka. Dr. Thoradeniya has a multidisciplinary background and has broad research interests and experience in metabolism and functionality of micronutrients, nutrition modulation of chronic disease risk, food systems, animal welfare and alternatives. Dr. Thoradeniya obtained her Bachelor of Veterinary Science (B.V.Sc) degree from the Faculty of Veterinary Medicine and Animal Science, University of Peradeniya, Sri Lanka an her Ph.D. in Nutritional Biochemistry from the University of Colombo, Sri Lanka.

She is a Commonwealth Fellow and has received many awards including the President’s Awards for scientific research. Dr. Thoradeniya is a past president of the Sri Lanka Association for Laboratory Animal Sciences and Sri Lankan Academy of Young Scientists, and currently the Vice-president of the Sri Lanka College of Biochemists.

She has extensive experience in animal welfare and ethics and is playing a leading role in conducting training on animal welfare and ethics locally and in the region. She was awarded the 2020 Global Animal Welfare Award by the World Veterinary Association (WVA) and Ceva Sante Animale (Ceva) for her outstanding service and dedication in promoting animal welfare.
Innovative Technologies
Disease
Ethics, Welfare and Regulation
Safety

PROGRAM
Tuesday 31 August 2021 - Day 7

3.00 - 5.00 PM TUE-1 S121
3R in vaccines batch release: Progress and future strategies
This session will review what is the situation on the use of animal in vaccine batch release and how 3R could be integrated in the acceleration and simplification of vaccines batch release process. It will also to present cross industry initiative and success stories leading to animal reduction in Batch release.

Session chair and co-chair
S. Shaid, GSK and S. Uhlrich, Sanofi Pasteur

Time Abstract Speakers
3.00 PM ID 937 VACCINE BATCH TO VACCINE BATCH COMPARISON BY CONSISTENCY TESTING (VAC2VAC) Hilde Depraetere, European Vaccine Initiative

3.15 PM ID 533 3R APPROACH FOR POTENCY TESTING OF HUMAN COMBINED DTAP VACCINES: CURRENT STATUS AND NEXT STEPS Emmanuelle Coppens, Sanofi Pasteur

3.30 PM ID 441 TECHNOLOGY IS MOVING GSK TOWARDS THE SUBSTITUTION OF ANIMAL-TESTING Shahjahan SHAID, GSK Biologicals - Vaccines

3.45 PM ID 893 A VIEW FROM THE VETERINARY SECTOR ON 3R’S IN BATCH RELEASE Catrina Stirling, Zoetis Inc.

4.00 PM ID 912 REGULATORY ACCEPTANCE FOR THE SUBSTITUTION OF IN VITRO FOR IN VIVO VACCINE POTENCY AND SAFETY ASSAYS FOR BATCH RELEASE: SCIENCE VERSUS THE FEAR FACTOR Dean Smith, Health Canada

4.15 PM ID 421 IMPROVED PRODUCT CHARACTERIZATION USING NON-ANIMAL METHODS: DEVELOPMENT OF AN IMMUNOASSAY FOR DIPHTHERIA AND TETANUS VACCINES Paul Stickings

4.30 PM SESSION 121 Q&A

PROGRAM
Tuesday 31 August 2021 - Day 7

3.00 - 5.00 PM TUE-1 S118
Lessons Learned and Practical Considerations for the Use of In Vitro Exposure Systems to Assess Respiratory Toxicity

Session chair and co-chair
A. Clippinger, PETA Science Consortium International e.V. and Dr. L. Milchak - 3M Company

Time Abstract Speakers
3.00 PM ID 287 KEY LEARNINGS FROM IN VITRO VAPOR AND DIRECT LIQUID EXPOSURE STUDIES FOR ACUTE RESPIRATORY TOXICITY Lawrence Milchak, 3M Company

3.15 PM ID 66 AIR-LIQUID INTERFACE EXPOSURE FOR INHALATION TESTING: CASE STUDIES Sandra Verstraeten, VITO NV (Flemish Institute for Technological Research), Unit HEALTH

3.30 PM ID 1130 APPLYING NAMS IN BMD ANALYSIS AND CFD MODELING TO ADVANCE IN VITRO INHALATION TOXICITY TESTING M. Higuchi, US Environmental Protection Agency Office of Research and Development

3.45 PM ID 884 USING A DRY POWDER VITROCELL SYSTEM TO EXPOSE RESPIRATORY EPITHELIAL MODELS Vicki Stone, Heriot-Watt University

4.00 PM ID 882 ADVANCED HUMAN 3-DIMENSIONAL TEST SYSTEMS PAIRED WITH MODERN EXPOSURE SYSTEMS: PROGRESS TOWARD RECREATING PHYSIOLOGICAL-LIKE INHALATION EXPOSURES Holger Behrsing, IIVS, Inc.

4.15 PM SESSION 128 Q&A
PROGRAM
Tuesday 31 August 2021 - Day 7

3.00 - 5.00 PM TUE-1 S26
“Proof in animals”: Has journal editorial policy fallen behind advances in human-based approaches?
Biomedical scientists using the growing toolbox of human-derived, non-animal technologies have been questioned by peer reviewers or journal editors as to whether their findings have been corroborated in an animal model. Demands for an animal data to “validate” human-based approaches reinforce the dubious gold standard status of animal models for humans, and run contrary to the 3R principle that the scientific mainstream purports to embrace. This round table will bring together science leaders and journals’ editors to critically examine this topic, and to draw a path forward that embraces human-focused technologies as the new mainstream.

Session chair
Marcia Triunfol, Humane Society International

Time Abstract Speakers
3.15 PM ID 895 ROLE OF BIOMEDICAL JOURNALS’ POLICIES IN PROMOTING THE DISSEMINATION OF THE 3RS Laura Gribaldo, JRC, European Commission
3.30 PM ID 936 HUMAN ORGAN CHIPS: FROM EXPERIMENTAL MODELS TO CLINICAL MIMICRY Donald Ingber, Wyss Institute for Biologically Inspired Engineering at Harvard University
3.45 PM PUBLICATION BIAS: THE PROBLEM THAT NEEDS TO GO AWAY Marcia Triunfol, Humane Society International
4.00 PM TO BE PROVIDED Nicole Kleinstreuer, National Institutes of Health
4.15 PM ID 683 CONFRONTING PUBLISHING BIAS AGAINST IN VITRO APPROACHES Catharine Krebs, Physicians Committee for Responsible Medicine
4.30 PM SESSION 69 Q&A

PROGRAM
Tuesday 31 August 2021 - Day 7

3.00 - 5.00 PM TUE-1 S110
Beyond animal welfare policy – how other areas of policy can boost non-animal alternative
Transitions are long-term processes. What is the current state of the transition towards animal-free innovation? The phase TPI is in is characterized by dynamics of build-up. What are the different push and pull factors to build up a new practice with the use of human knowledge and data and without the use of animals?

Interactive pdf to share:
Policy line of reasoning.
Policy and regulations on alternatives to animal testing | Publicatie | Transitie Proefdiervrije Innovatie

In this session we will:
1. Present an interview video with characterization of the current state of the transition towards animal-free innovation and with the Dutch TPI-partners and their coming promising actions.
2. Ask the participants in a real-time poll to share their motives for development and acceptance animal-free models and methods.
3. Have an online panel discussion on motivations for animal-free innovation.

Session chair and co-chair
Jasper Wegman

Time Abstract Speakers
3.00 PM ID 340 ANIMAL-FREE TESTING OF CELL-BASED MEDICINAL PRODUCTS Jan Willem van der Laan
3.15 PM ID 514 SCIENTIFIC WORKSHOP ON NON-ANIMAL APPROACHES FOR CHEMICAL SAFETY IN CHINA: CURRENT PROGRESS AND OUTLOOK Carl Westmoreland
3.30 PM ID 622 REACH AND THE 3RS – REINVIGORATING EFFORTS TOWARDS THE AVOIDANCE OF VIVO TESTING Emma Grange
3.45 PM ID 693 ANIMAL-FREE TESTING OF CELL-BASED MEDICINAL PRODUCTS Jan Willem van der Laan
4.00 PM ID 1008 IMPROVING ALTERNATIVE METHOD ADOPTION THROUGH TOOLS AND RESOURCES TO SUPPORT COMMUNITY KNOWLEDGE Shannon Bell
4.15 PM ID 1101 EXPERIMENTAL MODELS IN RESEARCH: A EU-WIDE SURVEY Lorenzo Del Pace
4.30 PM SESSION 313 Q&A

5.00 - 6.30 PM POSTERS SESSIONS
5.00 - 5.15 PM WC11 TV live from the studio
5.15 - 6.15 PM Poster session and possibility to ask questions to poster presenters
6.15 - 6.30 PM WC11 TV live from the studio
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Tuesday 31 August 2021 - Day 7

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<td>Promoting the use of 3Rs through partnership: EPAA</td>
<td>Rob Roggeband, EPAA and Vera Baumans, Utrecht University</td>
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<td>6.30 PM</td>
<td>203</td>
<td>A PUBLIC PRIVATE PARTNERSHIP FACILITATING DEVELOPMENT AND UPTAKE OF 3R APPROACHES</td>
<td>Giacomo Mattino (European Commission, DG GROW)</td>
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<td>6.45 PM</td>
<td>98</td>
<td>NEW IDEAS FOR SYSTEMIC TOXICITY: OUTCOME OF AN EPAA BLUE SKY WORKSHOP</td>
<td>George Daston, Procter &amp; Gamble</td>
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<td>7.00 PM</td>
<td>354</td>
<td>HARMONISATION OF THE THREE RS IN BIOLOGICALS</td>
<td>KATRIN SCHUTTE, EU Commission</td>
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<td>7.15 PM</td>
<td>363</td>
<td>OPTIMAL DURATION OF SAFETY STUDIES WITH MONOCLONAL ANTIBODIES</td>
<td>Peter van Meer, Medicines Evaluation Board</td>
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<td>183</td>
<td>TOOLS TO SUPPORT APPLICATION OF PHYSIOLOGICALLY-BASED KINETIC MODELLING IN SAFETY ASSESSMENT</td>
<td>Judith Madden, School of Pharmacy and Biomolecular Sciences, Liverpool</td>
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<td>7.45 PM</td>
<td>195</td>
<td>EPAA EFFORTS TO PROMOTE AND BUILD CONFIDENCE ON THE USE OF 3RS</td>
<td>Rob Roggeband, Procter &amp; Gamble</td>
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<td>8.00 PM</td>
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<td>SESSION 26 Q&amp;A</td>
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<tr>
<td>6.30 - 8.30 PM</td>
<td>S300</td>
<td>(Multi-)organ models-1 (Theme: Innovative Technologies)</td>
<td>Ilka Maschmeyer</td>
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<td>6.30 PM</td>
<td>135</td>
<td>MICROPHYSIOLOGICAL COCULTURE APPROACH FOR BRONCHIAL LUNG AND LIVER MODELS FOR SUBSTANCE EXPOSURE STUDIES</td>
<td>Katharina Schimek</td>
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<td>6.45 PM</td>
<td>347</td>
<td>DEVELOPMENT OF A HUMAN BONE-ON-A-CHIP TO MODEL INTRAMEMBRANOUS OSSIFICATION IN BASIC SCIENCE AND TOXICOLOGY</td>
<td>Julia Scheinpflug</td>
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<td>7.00 PM</td>
<td>728</td>
<td>A 3D-PRINTED MICROPLATE INSERT FOR HIGH-THROUGHPUT AND ULTRA-LONG TERM-HIGH RESOLUTION IMAGING OF LIVE HUMAN BRAIN ORGANOIDS: A NEW PLATFORM TO REPLACE ANIMAL MODELS IN BRAIN CANCER RESEARCH</td>
<td>Guillermo Alberto Gomez</td>
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<td>7.15 PM</td>
<td>842</td>
<td>HUMAN IMMUNOCOMPETENT CHOROID-ON-CHIP: A PROMISING TOOL FOR STUDYING OCULAR SIDE EFFECTS OF BIOLOGICAL DRUGS</td>
<td>Madalena Cipriano</td>
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<td>7.30 PM</td>
<td>931</td>
<td>A 3D AUTOLOGOUS iPSC-DERIVED HAIR BULB MODEL</td>
<td>Oussama El BARAKA</td>
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<td>7.45 PM</td>
<td>1107</td>
<td>MULTI-ORGAN-CHIP DEVELOPMENTS: TOWARDS A PARADIGM SHIFT IN DRUG DEVELOPMENT</td>
<td>Ilka Maschmeyer</td>
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<td>8.00 PM</td>
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<td>Maria Kiersgaard</td>
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<td>ROGENT FACILITY</td>
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<td>6.45 PM</td>
<td>AN INTERNATIONAL DATA CROWDSOURCING PROJECT TO UNDERSTAND AND</td>
<td>Mark Prescott</td>
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<td>MINIMISE AGGRESSION IN GROUP-HOUSED MALE LABORATORY MICE</td>
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<td>7.00 PM</td>
<td>A REFINEMENT WIKI</td>
<td>Adrian Smith</td>
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<tr>
<td>7.15 PM</td>
<td>CLICKER/TARGET TRAINING OF RESEARCH ANIMALS AS A REFINEMENT</td>
<td>Kathryn Bayne</td>
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<tr>
<td>7.30 PM</td>
<td>THE ANIMAL PROTECTION QUALITY CERTIFICATE, KEY FIGURES FOR THE</td>
<td>Roberto Plasenzotti</td>
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<td>IMPROVEMENT OF ANIMAL WELFARE</td>
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<td>7.45 PM</td>
<td>UPDATING PAIN RECOGNITION AND MANAGEMENT APPROACHES IN</td>
<td>Patricia Turner</td>
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<td>LABORATORY MICE AND RATS</td>
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<td>8.00 PM</td>
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<tr>
<td>6.30 PM</td>
<td>ENGINEERING A DYNAMIC MODEL OF THE ALVEOLAR INTERFACE FOR THE</td>
<td>Roberta Nossa</td>
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<td>STUDY OF AEROSOL DEPOSITION</td>
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<tr>
<td>6.45 PM</td>
<td>MODELING BLOOD-BRAIN BARRIER PERMEATION IN THE AUTOLOGOUS STEM</td>
<td>Leopold Koenig</td>
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<td>CELL-DERIVED CHIP4</td>
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<td>7.00 PM</td>
<td>OPTIMIZATION OF AN IN VITRO PLACENTAL TRANSFER ASSAY FOR SCREENING</td>
<td>Barbara Birk</td>
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<td>7.15 PM</td>
<td>TOWARDS A REGULATORY APPLICATION OF CACO-2 ADVANCED INTESTINAL</td>
<td>Isabella De Angelis</td>
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<td>BARRIER MODEL</td>
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<td>7.30 PM</td>
<td>SECRETOME CHARACTERIZATION OF 3D BRONCHIAL EPITHELIAL CULTURES</td>
<td>Daniel Sanchez-Guzman</td>
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<td>TO STUDY THE ROLE OF PROTEIN CORONA ON THE FATE AND LONG-TERM EFFECTS</td>
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<td>OF NANO Particles</td>
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<tr>
<td>7.45 PM</td>
<td>PARTICLE DEPOSITION AND EFFECTS IN AN AIR-LIQUID INTERFACE LUNG</td>
<td>Rob Vandebriel</td>
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<td>MODEL: AN INTERLABORATORY COMPARISON STUDY</td>
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**PROGRAM**

Tuesday 31 August 2021 - Day 7

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8.00 PM   | SESSION 302 Q&A                                                            |                                 |
you are not alone!

The importance of communication, active search for help, and formation of perspectives and experiences. The overall goal of this session is to highlight presentations will be followed by interactive discussion rounds to exchange will share their own experiences and potential solutions and strategies. The requirement support on how to properly face conflicts that can, for example, build up between a student and their peers or even for independent junior group leaders struggling between being a focused leader and an empathic mentor. In this workshop, speakers will provide insights on the causes and effects of imposter syndrome as well as areas of conflict potential. In addition, they will share their own experiences and potential solutions and strategies. The presentations will be followed by interactive discussion rounds to exchange perspectives and experiences. The overall goal of this session is to highlight the importance of communication, active search for help, and formation of talk rounds of early career scientists to foster exchange and mutual support - you are not alone!
**Application of an in vitro testing battery for developmental neurotoxicity (DNT) assessment in a regulatory context**

Recently, an increased prevalence of neurodevelopmental disorders, including autism, is observed. While these disorders result from a combination of multiple factors, exposure to environmental chemicals could contribute to developmental neurotoxicity (DNT). Currently, there is limited information on DNT effects and this data gap cannot be overcome with the current in vivo testing. The talks will present the recent international efforts led by EFSA, OECD, JRC and US EPA to develop a in vitro testing strategy to improve the current DNT regulatory assessment including the efforts to develop an OECD Guidance Document on the use of alternative methods for DNT evaluation.

**Time Abstract Speakers**

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<tr>
<td>3.00 PM</td>
<td>ID 164</td>
<td>THE INTERNATIONAL REGULATORY ROADMAP TO ENHANCE DEVELOPMENTAL NEUROTOXICITY TESTING</td>
<td>M. Sachana, Organisation for Economic Co-operation and Development (OECD)</td>
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<tr>
<td>3.15 PM</td>
<td>ID 894</td>
<td>EXAMPLES OF HOW DATA FROM IN VITRO DEVELOPMENTAL NEUROTOXICITY ASSAYS COULD BE USED TO MAKE DECISIONS ABOUT CHEMICALS</td>
<td>E. Fritsche, JUF - Leibniz Research Institute for Environmental Medicine</td>
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<tr>
<td>4.15 PM</td>
<td>ID 9</td>
<td>AN ADVERSE OUTCOME PATHWAY (AOP)-INFORMED INTEGRATED APPROACH TO TESTING AND ASSESSMENT (IATA) AS A TOOL TO CONDUCT A DEVELOPMENTAL NEUROTOXICITY (DNT) HAZARD CHARACTERIZATION</td>
<td>A. Bal-Price, European Commission Joint Research Centre</td>
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**Asia: A place ripe for the development of 21st century science**

This 90min round table will invite key regulators & government agencies from India, China, South Korea and Japan to present the strategies for investment into human biology-centric new approach methodologies in research & toxicology. Having made major progress in the regulatory aspect with respect to animal testing prohibition for cosmetics in some countries, reduction and replacement of animals for pesticide regulations in others, the stage is set for these countries to increase investment into non animal methodologies. The anticipated outcomes of the session would be to gain new insights on working towards increased investment into NAMs after regulatory acceptance of alternatives.

**Time Abstract Speakers**

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<tr>
<td>3.00 PM</td>
<td>ID 790</td>
<td>ASIA IS A RIPE PLACE FOR ALTERNATIVES TO ANIMAL TESTING: STATUS AND POTENTIAL IN INDIA</td>
<td>S. Parvatam, Centre for Predictive Human Model Systems (AIC - CCMB) India</td>
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<td>3.15 PM</td>
<td>ID 1110</td>
<td>PROMOTING ALTERNATIVES TO ANIMAL TESTING METHODS THROUGH STAKEHOLDER COLLABORATION</td>
<td>B. Seo, Humane Society International Korea</td>
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<td>3.45 PM</td>
<td>ID 484</td>
<td>SAFETY SCIENCES TOWARDS NON- ANIMAL TESTS IN CHINA: CURRENT STATUS AND PERSPECTIVES</td>
<td>X. Qu, The Society of Toxicity Testing and Alternative Methods, Chinese Environmental Mutagen Society China</td>
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<td>4.00 PM</td>
<td>ID 390</td>
<td>21ST-CENTURY TOXICOLOGY AND REGULATORY TESTING: AN UPDATE FROM JAPAN</td>
<td>H. Kojima, National Institute of Health Sciences Japan</td>
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**SESSION 23 Q&A**
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<td>3.00 PM</td>
<td>INTRODUCTION OF THE SUBJECT (TRAINING OF AWB MEMBERS)</td>
<td>Pieter Verbost and Ivo Tiebosch, session chairs</td>
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<td>3.15 PM</td>
<td>DISTANCE LEARNING RESOURCES TO SUPPORT TRAINING OF ANIMAL WELFARE BODY MEMBERS</td>
<td>P. Flecknell, Flaire Consultants</td>
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<tr>
<td>3.30 PM</td>
<td>CONTINUOUS TRAINING OF ANIMAL WELFARE BODY MEMBERS - AN EDUCATION PROGRAM FOR OVERSIGHT ON WELFARE AND CARE OF LABORATORY ANIMALS</td>
<td>C. Kunne, TNO</td>
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<td>3.45 PM</td>
<td>ANIMAL WELFARE BODIES: INITIAL TRAINING AND CONTINUING PROFESSIONAL DEVELOPMENT</td>
<td>N. Linklater, University of Marburg</td>
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<td>4.00 PM</td>
<td>IACUC FUNCTION AND MEMBERSHIP TRAINING IN KOREA: THE FIRST TWELVE YEARS</td>
<td>Gwi Hyang Lee</td>
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<td>4.15 PM</td>
<td>GENERAL DISCUSSION</td>
<td>Ivo Tiebosch, University of Utrecht</td>
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<td>4.30 PM</td>
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<td>3.00 PM</td>
<td>Corporate social responsibility</td>
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<td><strong>Session chair</strong></td>
<td>Judit van Luik</td>
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<td>3.00 PM</td>
<td>ID 86 CRITICAL INCIDENT REPORTING SYSTEM IN LABORATORY ANIMAL SCIENCE -</td>
<td>Sabine Juliane Bischoff</td>
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<td>CIRS-LAS</td>
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<td>3.15 PM</td>
<td>ID 131 CARING FOR THOSE CARING FOR RESEARCH ANIMALS: DEVELOPING A GLOBAL</td>
<td>Judy Murray</td>
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<td>CORPORATE RESILIENCE BUILDING PROGRAM</td>
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<td>3.30 PM</td>
<td>ID 630 IRON FIST &amp; VELVET GLOVE: EXPANDING THE IMPLEMENTATION OF THE 3RS</td>
<td>John R Baumann</td>
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<td>John R Baumann</td>
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<tr>
<td>3.45 PM</td>
<td>ID 746 PROMOTING TRANSPARENCY IN PRECLINICAL RESEARCH: PREREGISTRATION</td>
<td>Aina Cervera i Barea</td>
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<td>OF ANIMAL STUDIES ON AN ONLINE PLATFORM</td>
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<td>4.00 PM</td>
<td>ID 883 BEYOND PROGRAM REVIEW/POST APPROVAL MONITORING: DEVELOPING AND</td>
<td>John Baumann</td>
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<td>IMPLEMENTING A QUALITY IMPROVEMENT PROGRAM FOR LABORATORY ANIMAL</td>
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<td>RESEARCH PROGRAM</td>
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<td>4.15 PM</td>
<td>ID 972 THE BEYOND ANIMAL TESTING INDEX: HOW TO ASSESS YOUR INSTITUTES</td>
<td>Cyrille Irou</td>
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<td>CONTRIBUTION TO ANIMAL FREE INNOVATION AND THE 3R'S?</td>
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</table>
| 6.30 - 8.00 PM | **YOU-WC11 - WORKSHOP 5**  
**LET THE STARS SHINE - FIRE PRESENTATIONS GIVEN BY THE 3R EARLY CAREER SCIENTIST AWARD FINALISTS** |                                               |

### PLENARY SESSIONS
**Wednesday 1 September 2021 - Day 8**

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<td>5.00 - 5.15 PM</td>
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</table>
| 5.15 - 6.15 PM | **KEYNOTE:** DR. GER JANSSEN  
**Philips** |                                               |
|            |         | Ger Janssen has a PhD in Applied Physics from  |
|            |         | Eindhoven University of Technology in the     |
|            |         | Netherlands. He joined Philips in 2001 and in  |
|            |         | all his responsibilities in the company      |
|            |         | computational modelling is a recurring       |
|            |         | theme, in which he has now over 20 years of  |
|            |         | experience.                                  |
|            |         | He is currently head of the Digital Twin     |
|            |         | department in Philips Research and            |
|            |         | since 2018 also Program Manager Patient      |
|            |         | Digital Twin. In these roles he is shaping   |
|            |         | the digital twin activities of Philips from   |
|            |         | R&D to operational and clinical space. For   |
|            |         | these activities the guiding principle is     |
|            |         | that all Philips solutions should address     |
|            |         | the quadruple aim: better health outcome,     |
|            |         | better patient and staff satisfaction         |
|            |         | against lower costs.                          |
| 6.15 - 6.30 PM | WC11 TV live from the studio |                                               |

### DAY 8

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| 6.30 - 8.00 PM | **YOU-WC11 - WORKSHOP 5**  
**LET THE STARS SHINE - FIRE PRESENTATIONS GIVEN BY THE 3R EARLY CAREER SCIENTIST AWARD FINALISTS** |                                               |
**BREAKTHROUGHS TOWARDS ANIMAL FREE INNOVATIONS**

We are proud that the World congress is visiting our country again. The first time the World Congress was organized in The Netherlands we reached Nature and Science due to our Dutch lead in alternatives (teaching of the future generation of biomedical scientists, animal experimentation committees, training, activities in national policy and international legislation). I think we have something special again to show the world this time. Boosting better biomedical research by high technical innovations from adjacent disciplinary fields.

**SPEAKERS**

**Berend van Meer**, Leiden University Medical Center Health Sciences, Purdue University, West Lafayette, Indiana, USA

**Anke Tukker**, IRAS, Utrecht University, Utrecht, The Netherlands; School of BioEngineering Research, BioEngineering; University of Twente, Applied Microfluidics for medical applications. Sincerely yours, Prof.dr. Tjard de Cock Buning (Stichting Bouwstenen, societal organizations, scientific departments and government are able to join together in its pros and cons, e.g. price, exposure to laboratory science community, access of journalists and in center stage for out-of-the-box presentations. 2) a scheduled dynamic session of 90-120 minutes clips, followed by the announcement of the two winners, selected by an independent scientific jury (receiving some money and a piece of art with inscription). The goal for the initiatives is not the prize, this is the prize, but the exposure of these young talents to the world.

3) a satellite meeting at the day before the opening of the conference. Each option has its pros and cons, e.g. price, exposure to laboratory science community, access of journalists and media space. We support committee and research team are much motivated to join the nomination session. We hope that you feel sympathy for this typical Dutch presentation on the international World Congress. Typical in the way that The Netherlands show again that societal organizations, scientific departments and government are able to join together to boost high technical innovations in human based biomedical research. After two years of background research on the best way to stimulate such constructive animal friendly and biomedical boosting research, we decided to focus on the young talent, within 8 years after their master degree, who are currently under pressure to become scientific nomads due to poor governmental funding, inducing also a brain drain for The Netherlands, as well as in other countries. The World Congress will be the place where 6 nominated researchers in two categories (e.g. organoids and big data analysis of citizens and patients, or wider: in-silico and in-vitro) will present their outstanding results and their personal qualities by short 5 minutes clips, followed by the announcement of the two winners, selected by an independent scientific jury (receiving some money and a piece of art with inscription). The goal for the initiatives is not the prize, this is the prize, but the exposure of these young talents to the world.

4) all six movies will be connected to relevant media platforms, inspirin the public, high school students, the upcoming generation of biomedical students. And be supporting in the strong competition of Post-doc grants or short visiting grants worldwide, and thus intensifying and broadening the knowledge network of their research group. As it is well known, for the Dutch researchers, currently this initiative is in line with new governmental policy Transparant Proefdiervrij Innovatie, which is also an unique policy in the world. What we like to ask from the organizers of the World Congress, is to think in line with our initiative, which is rooted in the same values as your audience, i.e. for good and reliable alternative models for animals experiments, and provide us exposure of these 6 talented post-docs to the relevant audience. We were informed, that there are in principle several options available. 1) an option for in-vitro demonstrations, 2) a scheduled dynamic session of 90-120 minutes in which the nominated post-docs present their innovations and the prizes will be awarded. 3) a satellite meeting at the day before the opening of the conference. Each option has its pros and cons, e.g. price, exposure to laboratory science community, access of journalists and media space. We support committee and research team are much motivated to join the nomination session. We hope that you feel sympathy for this typical Dutch presentation on the international World Congress. Typical in the way that The Netherlands show again that societal organizations, scientific departments and government are able to join together to boost high technical innovations in human based biomedical research.
PROGRAM
Wednesday 1 September 2021 - Day 8

6.30 - 8.30 PM WED-2 S109
Computational Synthesis and Integration for Systems Toxicology in the Animal-free Zone

Human cell-based assays are providing vast in vitro data to profile chemical effects, but systems-based approaches are needed to tie these data to biological understanding (genetic signals & responses; tissue microphysiology; multiscale simulation; and computational prediction). Case studies will connect chemistry, toxicokinetics and toxicodynamics to animal-free prediction of developmental toxicity. Abstracts on in vitro data and in silico models are invited as well, especially AI-based methodologies for computational intelligence.

Session chair

Time Abstract Speakers
6.30 PM ID 852 COMPUTATIONAL INTELLIGENCE: OPENING DART’S 'BLACK-BOX’ WITH AGENT-BASED MODELS.
Thomas Knudsen, US EPA

6.45 PM ID 99 CHEMINFORMATICS AND GENE EXPRESSION DATA: LINKING CHEMICAL-BIOLOGICAL INTERACTION TO OUTCOME
George Daston, Procter & Gamble Co.

7.00 PM ID 866 QUANTITATIVE PREDICTION OF DEVELOPMENTAL TOXICITY BY MODELLING THE DARTABLE GENOME.
Richard Currie, Syngenta

7.15 PM ID 73 VIRTUAL MODELS FOR HUMAN DEVELOPMENTAL TOXICOLOGY Driven by NEW APPROACH METHODOLOGIES
Aldert Piersma, RIVM

7.30 PM ID 13 ACCELERATING REGULATORY USE OF ALTERNATIVES IN DART TESTING: HOW TO BUILD CONFIDENCE
Manon Beekhuijzen, Charles River

7.45 PM ID 881 MULTI-SCALE, VIRTUAL-TISSUE SIMULATIONS OF DEVELOPMENTAL TOXICITY AND TOXICOLOGY AS AN APPROACH TO MINIMIZE THE REQUIRED NUMBER OF ANIMAL EXPERIMENTS
James Glazer, Indiana University

8.00 PM SESSION 109 Q&A

PROGRAM
Wednesday 1 September 2021 - Day 8

6.30 - 8.30 PM WED-2 S305 (Multi-)organ models-3
Session chair
Janny van den Eijnden-van Raaij, hDMT

Time Abstract Speakers
6.30 PM ID 151 BIOENGINEERED 3-DIMENSIONAL LUNG ORGANOIDS AS AN ALTERNATIVE TO PATIENT-DERIVED XENOGRAFT MODELS OF SMALL CELL LUNG CANCER
Chandani Sen

6.45 PM ID 588 HUMAN LIVER-PANCREAS-HEART MICROPHYSIOLOGICAL SYSTEM FOR STUDYING CARDIO-METABOLIC DISORDERS
Lisa Vilen

7.00 PM ID 636 ESTABLISHMENT OF A HUMAN MULTI-ORGAN-CHIP PLATFORM TO REPLACE ANIMAL TRANSPLANT MODELS FOR PRECLINICAL EVALUATION OF TREG CELL THERAPIES
Isabell Dureux

7.15 PM ID 684 EXPLORING 3D BIOPRINTING TECHNOLOGY FOR THE DEVELOPMENT OF COMPLEX RECONSTRUCTED SKIN MODEL WITH HAIR FOLLICLE STRUCTURE AND AUTOMATION OF THE FABRICATION OF HAIR FOLLICLE SPHEROIDS
Carolina Motter Catarino

7.30 PM ID 797 ENHANCING PRECLINICAL PREDICTIONS FOR NEURODEGENERATIVE DISEASES USING BRAIN-ON-CHIP MODELS
Alex Bastiaens

7.45 PM ID 869 CRACK IT: 3D HIPSC-DERIVED LAMINATED RETINAL MODEL AS A TOOL FOR TOXICOLOGY AND DRUG DISCOVERY STUDIES
Cathy Vickers

8.00 PM SESSION 305 Q&A
### PROGRAM
Wednesday 1 September 2021 - Day 8

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<thead>
<tr>
<th>Time</th>
<th>Abstract</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>6.30 PM</td>
<td>SERUM MICRORNA SIGNATURES AS &quot;LIQUID BIOPSY&quot; FOR INTERROGATING HEpatotoxic MECHANISMS AND LIVER PATHOGENESIS</td>
<td>Julian Krauskopf</td>
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<tr>
<td>6.45 PM</td>
<td>THE HUMAN-BASED IN VITRO 3D ARTHRITIC JOINT MODEL FOR PRECLINICAL DRUG TESTING</td>
<td>Alexandra Damerau</td>
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<tr>
<td>7.00 PM</td>
<td>REPLACING THE NEED FOR BOVINE BLOOD PRODUCTS IN EARLY STAGE OPTIMISATION OF CARDIAC ASSIST DEVICES: IMPROVING THE INTERNATIONAL STANDARD</td>
<td>Antony P McNamee</td>
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<tr>
<td>7.15 PM</td>
<td>UNDERSTANDING NANOMATERIAL RISKS IN PULMONARY INFECTION: EFFECTS OF GRAPHENE RELATED MATERIALS ON HEALTHY AND STREPTOCOCCUS PNEUMONIAE INFECTED 3D RECONSTITUTED HUMAN LUNG CELLS</td>
<td>Savvina Chortarea</td>
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<tr>
<td>7.30 PM</td>
<td>A HUMAN iPSC-BASED MICROPHYSIOLOGICAL MODEL OF THE LIVER TO STUDY THE IMPACT OF HEPATIC STELLATE CELLS ON NAsh DEVELOPMENT</td>
<td>Martin Baasch</td>
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<tr>
<td>7.45 PM</td>
<td>TISSUE ENGINEERED MODELS OF FIBROTIC CARDIAC TISSUE FOR PRECLINICAL VALIDATION OF THERAPIES</td>
<td>Valeria Chiono</td>
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<tr>
<td>8.00 PM</td>
<td>SESSION 307 Q&amp;A</td>
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### PROGRAM
Wednesday 1 September 2021 - Day 8

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<tr>
<th>Time</th>
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<tr>
<td>6.30 PM</td>
<td>THE INTEGRATION OF IN VITRO CHEMICAL TRANSPLACENTAL PASSAGE INTO A GENERIC FBA MODEL FOR PREGNANCY</td>
<td>Styliani Fragki</td>
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<tr>
<td>6.45 PM</td>
<td>IN VITRO TO IN VIVO EXTRAPOLATION FOR DEVELOPMENTAL TOXICITY POTENCY OF VALPROIC ACID ANALOGUES</td>
<td>Xiaoqing Chang</td>
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<tr>
<td>7.00 PM</td>
<td>IN VITRO-IN SILICO BASED ASSESSMENT OF SPECIES DIFFERENCES IN KINETICS: TOWARDS HARMONIZATION OF IN VITRO CLEARANCE STUDIES</td>
<td>Jochem Louisse</td>
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<tr>
<td>7.15 PM</td>
<td>BOTTOM-UP PHYSIOLOGICALLY-BASED TOXICOLOGICAL MODELLING OF PERFLUOROOCCTANOIC ACID</td>
<td>James Chun Yip Chan</td>
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<td>7.30 PM</td>
<td>VALIDATION OF A BOTTOM-UP PBPK MODEL PREDICTION OF HEPATIC CONCENTRATIONS OF ROSUVASTATIN</td>
<td>Shawn Tan</td>
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<tr>
<td>7.45 PM</td>
<td>COMPARING MODEL PREDICTIONS AND ANALYTICALLY DETERMINED TEST CHEMICAL DISTRIBUTIONS IN VITRO</td>
<td>Nynke Kramer</td>
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<tr>
<td>8.00 PM</td>
<td>SESSION 307 Q&amp;A</td>
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**WC11 TV - Talk show**
Talk show 3 will focus on New technologies and the Use of human-derived material. The background here is that many biomedical laboratories are developing their own organ-on-a-chip system. There may be a need for separating the good from the bad, for standardization, and for thorough evaluation of the advantages and limitations of such approaches. Furthermore, such methods are based on human derived materials which have ethical implications.
**PROGRAM**

**Thursday 2 September 2021 - Day 9**

**PLENARY SESSIONS**

2.30 - 3.00 PM
WC11 TV - Live from the studio

**PARALLEL SESSION THU-1**

3.00 - 5.00 PM
Reverse Translation: Maximizing clinical relevance while reducing the need for preclinical data

The concept of reverse translation brings patient derived knowledge in the center and has a potential to revolutionize drug discovery and/or risk assessment of industrial and environmental chemicals. The symposium will discuss new biomarker based approaches to study drug induced organ injuries and inflammatory bowel disease. The goal of the symposium is to spark interest in application of novel biomarkers and discuss progress in their regulatory acceptance.

Session chair
J. Aubrecht, Takeda

**Time Abstract Speakers**

3.00 PM
REVERSE TRANSLATION: A PATIENT CENTRIC APPROACH TO DRUG DEVELOPMENT
J. Wagner, ForsiteCapital

3.15 PM
ABSTRACT ID - DEVELOPMENT OF NOVEL BIOMARKERS TO ACCELERATE DRUG DEVELOPMENT
J. Sauer, Critical Path Institute

3.30 PM
ABSTRACT ID - CALPROTECTIN IN IBD: “NEW TRICKS OF AN OLD DOG”
J. Aubrecht, Takeda

3.45 PM
ABSTRACT ID - METABOLOMIMIC SIGNATURES REVEAL COMPLEX INTERACTIONS OF MICROBIOME AND HOST IN HEALTH AND DISEASE
H. Li, Georgetown University

4.00 PM
SESSION 234 Q&A

**Animal Experimentation: Working Towards a Paradigm Change**

New human biology-based tools should facilitate a strong shift away from animal experimentation. However, in research, animals are still widely seen as the default option, even though interspecies differences compromise translation to the humans. In this workshop we discuss some of the obstacles and driving forces of change. We address the vague public policy provisions regarding animal replacement; the limited education and training possibilities on human-relevant approaches; insufficient funding for the development of non-animal models; psychological lock-in and entrenchment in science; and public misinformation about animal experimentation, as well as how education, funding redeployment, and political action can drive change.

Session chair and co-chair
M. Stephens, Johns Hopkins Bloomberg School of Public Health And K. Herrmann, Johns Hopkins Bloomberg School of Public Health

**Time Abstract Speakers**

3.00 PM
ID 738 BARRIERS TO THE IMPLEMENTATION OF ANIMAL-FREE ALTERNATIVES AND HOW TO OVERCOME THEM
K. Taylor, Cruelty Free International

3.15 PM
ID 832 EDUCATING FUTURE SCIENTISTS AND RAISING PUBLIC AWARENESS ON ANIMAL-FREE EXPERIMENTATION
K. Herrmann, Johns Hopkins Bloomberg School of Public Health

3.30 PM
ID 721 POLITICAL CAMPAIGNING: WHERE SCIENTIFIC AND ETHICAL ARGUMENTS MEET PUBLIC POLICY
E. McIvor, People for the Ethical Treatment of Animals (PETA)

3.45 PM
ID 810 STAKEHOLDER COLLABORATION TO IMPLEMENT REGULATORY AND POLICY CHANGE FOR DRUG DEVELOPMENT
E. Baker, Physicians Committee for Responsible Medicine (PCRM)

4.00 PM
ID 518 BREAKING THE LOCK-IN TO ANIMAL RESEARCH WITHIN ACADEMIA
P. Pound, Safer Medicines Trust

4.15 PM
RESEARCH AND TESTING WITHOUT ANIMALS: WHERE ARE WE NOW AND WHERE ARE WE HEADING?
T. Hartung, Johns Hopkins Bloomberg School of Public Health

4.30 PM
SESSION 216 Q&A
Harnassing the power of data to improve systemic toxicity prediction: multisectoral perspectives

Over the last decade, triggered by the fast development of IT technologies, especially through the explosion of calculation power and data generation/ storage capacity, a data revolution has been happening. Today outcomes of this ongoing revolution can be seen in almost all industrial sectors: health, car, beauty, fashion, game & entertainment. While little by little, big data, algorithms, artificial intelligence do reveal the power lying in data capture and exploitation.

At the same time, in the toxicology field (whatever the industrial sector or the geographical region) the need for better toxicity prediction has never been so high. In the Pharma industry, a low drug development success rate of 1/10 raises questions about factors (including low toxicity prediction) at the origins of such innovation crisis. In the Cosmetics industry, the animal testing ban which took place in 2013 in Europe, for its final phase left the safety disciplines with a bad gap and the uncapacity in specific circumstances to predict systemic toxicity and develop new ingredients. In the chemical sector, much attention has been placed recently on data-poor chemicals that are already in commerce and may have potential contributions to human diseases. Hence there is a high need to better substantiate toxicity profiles of new or already marketed chemicals.

In several industrial and public sectors, various initiatives have been fostering the development of information systems providing access to databases, computational tools and workflows for better toxicity prediction. Some initiatives have explored open innovation paths combining resources from industrial and public sectors. For, under the auspices of Innovation Medicines Initiative, paved the way to Pharma industry proprietary non-clinical data sharing on a large scale supporting the development of toxicity prediction algorithms. Research initiatives are integrating IT tools like Cosmos from SEURAT1, CE-ToxGPS from Cosmetics’ Europe Long Range Science Strategy, SEURAT1 gathered data from cosmetics and led to the establishment of cosmetics ingredients safety database. In the chemical sector, sectoral considerations are made in different initiatives like CERIC’s cheminformatics platform and the US EPA’s chemistry dashboard. The AMBiT system was built and includes data from the EU REACH and the Chemosphere databases from the European food safety agency. Learning on those 1st steps, some 2nd generation initiatives have been designed in order to harness even more the power of data, leading to better & smarter use of (non-)animal data and some 2nd generation initiatives have been designed in order to harness even more the power of data, leading to better & smarter use of (non-)animal data and improved toxicity prediction. This session will open windows on those cutting-edge initiatives, share their progress and explore how they could be beneficial across sectors.

Session chair
S. Dhalluin, L’Oreal

Non-animal Models in disease research

EXPLOITING SAFETY DATA SHARED BY PHARMACEUTICAL INDUSTRY: THE ETRANSAFE PROJECT
M. Pastor, University Pompeu Fabra

TOWARDS VIRTUAL CONTROL GROUPS FOR ANIMAL TOXICITY STUDIES – AN ETRANSAFE INITIATIVE
T. Steger-Hartmann, Bayer AG

ENABLING CHEMICAL SUBSTANCE DATA INTEGRATIVE ANALYSIS AND APPLICATIONS
N. Jeliazkova, Ideacorrect Ltd

DATA DRIVEN COMPUTATIONAL MODELLING TO SUPPORT SAFETY ASSESSMENT OF COSMETICS INGREDIENTS
M. Cronin, Liverpool John Moore University

SYSTEMIC TOXICITY PREDICTIONS USING IN VIVO AND IN SILICO APPROACHES
R. Judson, NCI/US

EVALUATION OF A NEW APPROACH METHODOLOGY TOOLBOX FOR THE NEXT GENERATION RISK ASSESSMENT OF SYSTEMIC TOXICITY
Sophie Cable

SESSION 185 Q&A
PROGRAM
Thursday 2 September 2021 - Day 9

3.00 - 5.00 PM THU-1 S310Q Education & Training: Global view

Session chair
Paulin Jirkof, University of Zurich

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<tr>
<th>Time</th>
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<th>Speakers</th>
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<tbody>
<tr>
<td>3.00 PM</td>
<td>&quot;MY ANIMAL RESEARCH: EXPERIMENTAL DESIGN&quot;: A PERSONALIZED, PRACTICE-</td>
<td>Ivo Tiebosch</td>
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<td>BASED LEARNING TRACK FOR PHD STUDENTS</td>
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<tr>
<td>3.15 PM</td>
<td>IMPLEMENTATION OF THE 5R’S (REPLACEMENT, REDUCTION, REFINEMENT, RESPONSIBILITY AND RESPECT) IN LABORATORY ANIMAL SCIENCE EDUCATION &amp; TRAINING COURSES IN THE UNIVERSITY OF CAPE TOWN, SOUTH AFRICA</td>
<td>Janet McCullum</td>
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<tr>
<td>3.30 PM</td>
<td>A COMPARISON OF TRAINING STANDARDS AMONGST INTERNATIONAL COLLEGES OF LABORATORY ANIMAL MEDICINE</td>
<td>Patricia Turner</td>
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<td>3.45 PM</td>
<td>HIGHLIGHTING MODERN APPROACHES THROUGH EDUCATION AND TRAINING</td>
<td>Tingting Lue</td>
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<td>4.00 PM</td>
<td>PROMOTE THE CONSENSUS OF 3RS IN CHINA THROUGH TRANSLATIONAL OF THE ACADEMIC AND INDUSTRIES</td>
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<td>4.15 PM</td>
<td>THE EDUCATION &amp; TRAINING PLATFORM FOR LABORATORY ANIMAL SCIENCE (ETPLAS) – A REFERENCE FOR LABORATORY ANIMAL SCIENCE AND 3R TRAINING</td>
<td>Nuno Henrique Franco</td>
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<tr>
<td>4.30 PM</td>
<td>SESSION 310 Q&amp;A</td>
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5.00 - 8.00 PM PLENARY SESSIONS

5.00 - 5.15 PM WC11 TV live from the studio

5.15 - 6.15 PM KEYNOTE:

PROF. JOSEPH WU
Stanford Cardiovascular Institute

Joseph C. Wu, MD, PhD is Director of the Stanford Cardiovascular Institute and Simon H. Stertzer, MD, Professor of Medicine and Radiology at the Stanford School of Medicine. Dr. Wu received his MD from Yale University School of Medicine. He trained in internal medicine and cardiology at UCLA followed by a PhD in the Dept of Molecular Pharmacology.

His lab works on biological mechanisms of patient-specific and disease-specific induced pluripotent stem cells (iPSCs). The main goals are to (i) understand basic cardiovascular disease mechanisms, (ii) accelerate drug discovery and screening, (iii) develop “clinical trial in a dish” concept, and (iv) implement precision cardiovascular medicine for prevention and treatment of patients.

Dr. Wu has received numerous awards, including National Institutes of Health (NIH) Director’s New Innovator Award, NIH Roadmap Transformative Award, American Heart Association (AHA) Innovative Research Award, Presidential Early Career Award for Scientists and Engineers given out by President Obama, AHA Established Investigator Award, Burroughs Wellcome Foundation Innovation in Regulatory Science Award, AHA Merit Award, and AHA Distinguished Scientist Award. Dr. Wu serves on the Scientific Advisory Board for the Keystone Symposia, FDA Cellular, Tissue, and Gene Therapies Advisory Committee, AHA National Board of Directors, Chair of the AHA Basic Cardiovascular Science Council, and Chair of the AHA National Research Committee.

Dr. Wu is an elected member of American Society of Clinical Investigators (ASCI), Association of University Cardiologists (AUC), American Institute for Medical and Biological Engineering (AIMBE), American Association for the Advancement of Science (AAAS), American Association of Physicians (AAP), and National Academy of Medicine (NAM).

6.15 - 6.30 PM WC11 TV live from the studio

6.30 - 7.30 PM Björn Ekwall Memorial Fund (BEMF) Award
## PROGRAM
### Thursday 2 September 2021 - Day 9

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<tr>
<th>Time</th>
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<td>6.30 PM</td>
<td><strong>WC11 - Award ceremony</strong></td>
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<tr>
<td>6.30 PM</td>
<td>The 2021 Russell and Burch Award</td>
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<td>Presented by The Humane Society of the United States</td>
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<td></td>
<td>Katie Conlee</td>
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<td>6.40 PM</td>
<td>ESTIV Best poster award</td>
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<td>Presented by the European Society of Toxicology In Vitro</td>
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<td>Helena Kandarova</td>
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<td>6.50 PM</td>
<td>ECOPA Award</td>
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<td>Presented by the European Consensus platform for Alternatives</td>
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<td>Costanza Rovida</td>
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<tr>
<td>7:00 PM</td>
<td>ALTEX Prize</td>
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<td></td>
<td>Presented by ALTEX – Alternatives to Animal Experimentation</td>
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<td></td>
<td>Sonja von Aulock</td>
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<td>7:10 PM</td>
<td>CATAT / Charles-River Animal Welfare Award</td>
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<td>Presented by the Center for Alternatives to Animal Testing</td>
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<td>Kathrin Herrmann</td>
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<tr>
<td>7:25 PM</td>
<td>JSAAE Award</td>
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<td></td>
<td>Presented by The Japanese Society for Alternatives to Animal Experiments</td>
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<td></td>
<td>Yasunari Kanda</td>
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<td>7:30 PM</td>
<td>You-WC11 Awards</td>
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<td></td>
<td>Annemarie Lang</td>
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<td>8.00 - 8.45 PM</td>
<td>WC11 TV - Closing ceremony live from the studio</td>
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Dear early career scientists, young investigators, and those young at heart,

We look forward to welcoming you during our YOU-WC11 events, which will accompany the upcoming virtual WC11! During the last months, we drafted and finalized a sophisticated program for YOU intending to boost and shape your career path within the field of 3Rs. From experience, we all know that networking and collaborating is one of the most powerful tools within research and also one of the most fun parts! Although we are not able to meet in person and go for a pub crawl as initially intended - we came up with a variety of events and workshops which will allow you to get in contact with other early career scientists and also experienced peers in the field to establish and build your professional network. Thus - don’t miss to join our Mentorship Journey, Speed Collaborating Session and Quiz Night! It will be a blast!

In addition to this, we will provide you with insights on publishing and different career paths - presented for YOU by experts in the field. Moreover, a pre-recorded, structured debate will tackle the most urgent topics that are challenging the expansion of the 3Rs - these concerns are our responsibility as Next Generation 3R Scientists! And finally, not to forget - although we all love being researchers, the job also comes with stressful responsibilities, frequent rejection, and continuous competition and comparison with others. Terms like “imposter syndrome” are not unknown and conflict management skills restore our survival. Thus, join our workshop on these topics - let’s learn from others and join forces - because YOU are not alone!

All workshops are open to all early career scientists and those young at heart. Most of the workshops consist of a pre-recorded presentation, followed by an interactive session on Zoom allowing for discussion and interactions in breakout rooms. And last but not least, we are happy to provide 3R Early Career Scientist Awards sponsored by AniMatch UG (haftungsbeschränkt; topics: Refine/Reduce) and the Physicians Committee for Responsible Medicine (topic: Replace). Our pre-selected finalists will have the opportunity to perform a live pitch of their poster or oral presentation during our “Let the Stars Shine” workshop.

Watch out for e-mails before the Congress - maybe YOU are one of the finalists!

Stay safe and see YOU soon!

Your YOU-WC11 Organizing Team
(Annemarie, Alexandra, Janine, Julia, Moritz & Frank)

DO YOU REMEMBER? IMPRESSIONS FROM OUR YOU-WC10 EVENTS IN SEATTLE 2017?
Find the full report here (PDF).

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DO YOU REMEMBER? IMPRESSIONS FROM OUR YOU-WC10 EVENTS IN SEATTLE 2017?
Find the full report here (PDF).
• P96 DISRUPTION OF CELLULAR MIGRATION/ADHESION AS COMMON KEY EVENT IN DRUG-INDUCED LIVER INJURY: OPTIONS FOR NEW IN VITRO TESTING STRATEGIES
Raymond Peters, Hogeschool Utrecht and Utrecht University (ABSTRACT ID: 254)

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- P575 CONTACTLESS BODY TEMPERATURE ASSESSMENT FOR DETERMINING HUMANE ENDPOINTS IN THE DECIDE PROJECT
  Roman Adamczyk, (ABSTRACT ID: 1092)
L’Oreal has devoted itself to beauty for over 100 years. With its unique international portfolio of diverse and complementary brands, the Group generated sales amounting to 26.9 billion euros in 2018 and employs 82,000 people worldwide.

Research & Innovation, and a dedicated research team of 3,993 people, are at the core of L’Oreal’s strategy, working to meet beauty aspirations all over the world. L’Oreal’s sustainability commitment for 2020 “Sharing Beauty With All” sets out ambitious sustainable development objectives across the Group’s value chain.

Consumer health and safety is and has always been an absolute priority of the L’Oreal Group. Defending animals’ welfare as well. To achieve these two objectives, L’Oreal conducts a very strict safety evaluation policy for its products. Starting by the development of the first models of reconstructed skins in 2019, L’Oreal has been a pioneer in the development and use of new alternative in vitro and in silico methods.

Thanks to this long term investment and conviction, L’Oreal stopped testing its products on animals in 1989, 14 years before required to do so by law. L’Oreal no longer tests its ingredients on animals neither tolerates any exceptions to this rule.

L’Oreal’s commitment to ending animal testing is supported by the provision of reconstructed skin models thanks to 3 production Units through its subsidiary EPISKIN SA (based in France, China, Brazil), the development and validation of new alternative methods and the sharing of its scientific advances.

In 2017, the OECD adopted two new alternatives methods developed by the L’Oreal Research Laboratories, to evaluate skin allergy and eye irritation. Today, L’Oreal is committed to develop next generation of new safety assessment approaches alternative to animal testing to ensure product safety for consumers and environment and support innovation.

Our brands are trusted everyday in millions of living rooms, kitchens, laundry rooms, and bathrooms – and have been family favorites from generation to generation for over 180 years. We know that to continue to be the brands people choose, we must continue to innovate high quality and safe ingredients. We also recognize that we must continue to evolve our approach to demonstrating safety.

We are committed to making animal testing obsolete. For more than 40 years, P&G has engaged in non-animal approaches and solutions. We have sponsored and contributed to all World Congresses on Animal Alternatives, including the first held in 1993 in Baltimore, Maryland. Over that time, P&G has invested more than $420 million in developing non-animal alternatives, yielding more than 25 alternative test assays invented or co-invented by our experts. Many of these approaches have been accepted as the new standard in non-animal safety assessment used by academia, industry or regulatory authorities around the world. Some of them, like the Direct Peptide Reactivity Assay (DPRA), have been recognized with prestigious awards by animal welfare groups.

Yet there is more to be done. Therefore, we are a proud sponsor of #BeCrueltyFree, calling for an end to all animal testing of cosmetic products globally.

And we are pleased to sponsor the 11th World Congress to enable the sharing and reapplication of the latest progress in non-animal alternatives. Let’s work together, because only together can we make our shared goal a reality: Making animal testing obsolete.
UNILEVER

On any given day, 2.5 billion people use Unilever products. Our range of more than 400 brands gives us a unique place in the lives of people all over the world. Seven out of every ten households around the world contain at least one Unilever product, and our range of world-leading, household-name brands includes Dove, Knorr, Axe, Hellmann’s and Omo. Unilever’s purpose and business strategy are to make sustainable living commonplace.

We use a wide range of non-animal approaches to assess the safety of our products for consumers. We are committed to ending animal testing. Our leading-edge research has one clear purpose: to continue to develop new non-animal approaches that can guarantee that our products are safe, without any need for animal testing. As part of our commitment to ending animal testing, we have a growing number of brands that ensure that neither their products – nor the ingredients they use – are subject to animal testing by suppliers or by regulatory authorities. These brands’ commitment to no animal testing is certified by animal welfare groups.

Our commitment to ending animal testing is underpinned by our work since the 1980s in developing and using alternatives to animal tests for assessing safety, e.g. computer-based modelling and cell-based ‘in vitro’ methods. Unilever’s framework for safety assessment is risk-based rather than hazard-based. This enables us to use a wide range of non-animal approaches to assess the safety of our products for consumers. We are making good progress in developing next generation (non-animal) risk assessment approaches for assessing new ingredients and share our scientific research on a dedicated Safety Science in the 21st Century website.

HUMANE SOCIETY INTERNATIONAL

Humane Society International works to create a kinder, more humane world for all animals through science, education, advocacy and policy change. Our Research & Toxicology team includes scientists, regulatory and government affairs professionals who are active on the ground in the world’s leading innovation economies. We work with industry and lawmakers to enact legislation that reduces reliance on animal testing in favor of best scientific practice and to implement bans on animal testing of cosmetics (hsi.org/becrueltyfree). We work with regulatory authorities and stakeholders to accelerate regulatory acceptance of animal-free safety assessment practices across multiple industry sectors (animalfreesafety.org). Our team also leads the BioMed21 Collaboration (biomed21.org) to move medical research to embrace 21st century science.
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ALTERNATIVES RESEARCH & DEVELOPMENT FOUNDATION
Established in 1993, ARDF promotes alternatives to the use of animals in biomedical research, testing and education. The foundation has awarded over $3.5M through its Annual Open Research Grant program. It also sponsors scientific meetings and presents the Cave Award for outstanding achievements in advancing alternative methods. ARDF recently launched the Alternatives in Research Challenge, a program to focus science funding and prize money exclusively in the area of alternative methods for biomedical research.

BEIERSDORF
Beiersdorf is a leading provider of innovative, high-quality skin care products and has over 135 years of experience in this market segment. The Hamburg-based company has about 20,000 employees worldwide and is listed on the DAX, the German benchmark equities index. Beiersdorf generated sales of €7.2 billion in financial year 2018. Its product portfolio comprises strong, international leading skin and body care brands including NIVEA, Eucerin, Hansaplast/Elastoplast, and La Prairie.

EPAA
The European Partnership for Alternative Approaches to Animal Testing (EPAA) is an unprecedented voluntary collaboration between the European Commission, European trade associations, and companies from 7 industry sectors. The partners are committed to pooling knowledge and resources to accelerate the development, validation and acceptance of alternative approaches to animal use in regulatory testing. The overall aim is the replacement, reduction and refinement (3Rs) of animal use in regulatory testing.

IFRA
The International Fragrance Association (IFRA) is the representative body of the fragrance industry worldwide. Comprised of eight multinational companies, hundreds of small and medium-sized companies in 21 National Associations, and eight supporting members, IFRA’s membership covers about 90% of the industry by production volume. We seek to promote the safe use of fragrance for everyone’s enjoyment, working with regulators and promoting our flagship self-regulatory program, the IFRA Code of Practice and the IFRA Standards.

THE HUMANE SOCIETY OF THE UNITED STATES
The Humane Society of the United States is working tirelessly to decrease and eventually end the use of animals for harmful research and testing. We work toward this goal by focusing on key areas such as eliminating cosmetics testing on animals through our Be Cruelty Free campaign, ending the use of dogs for testing, expanding the development and use of non-animal methods, and ensuring retirement of chimpanzees from laboratories to sanctuaries as soon as possible.

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