



# ISSX

## International Society for the Study of Xenobiotics

Volume 45

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## ISSX President's Message

By Ann Daly,  
ISSX President

Welcome to the President's message for this second newsletter of 2021. 2021 continues to be a busy year for the Society. We held a well-attended workshop back in March, our regular webinars are reaching many of you, and we are now looking forward to the fast approaching virtual 24th North American ISSX Meeting (entitled *Broadening our Horizons*) from September 13 to 17. Please visit the meeting website on <https://www.issx2021.org/> to find out more. When we made the decision to go virtual for this meeting last April, we made some changes to the program, including running our short courses on a Monday and the rest of the meeting from Tuesday to Friday. We also cut out certain features of our regular in-person meetings such as the Annual Member Meeting and the Awards lectures to make each day slightly shorter and more focussed. The content we removed is being offered as separate webinars

instead. I think Raymond Evers and Joseph Balthazar, our meeting co-chairs, together with Zoë Fuller, our Executive Director, have done extraordinarily well in moving to a virtual program. I hope you will agree. I strongly encourage you to register if you have not already done so. Registrants will be able to access content after the meeting and will be able to view some content including posters beforehand!

Several other things are worth reporting. We now have 996 paid members in the current year. I warmly welcome all our new members. I hope to be able to meet some of you virtually during the upcoming North American meeting. We also have just announced our 2021 ISSX Awards. Rachel Tyndale is the recipient of North American Scientific Achievement Award in Honor of Ronald W. Estabrook and David Rodrigues has won the Award for Distinguished Accomplishments

in Drug Discovery and Development. It's a great pleasure to congratulate both Rachel and David. They have both been ISSX members for many years and are important leaders in the field with very distinguished careers to date. Finally, we recently completed electing some new officers. Aleksandra Galetin from University of Manchester will become President-Elect and Secretary beginning in 2022 and will move on to President in 2024. Mary Paine from Washington State University becomes our Treasurer-Elect. Both Alex and Mary will be joining Council in January when Scott Obach succeeds me as President. We also re-elected three Council members for a second term of office



Ann Daly  
ISSX President

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# Book Review

## ARTIFICIAL INTELLIGENCE IN DRUG DISCOVERY

Editor; Nathan Brown

Royal Society of Chemistry

406pp. ISBN: 978-1-78801-547-9 (2020).

The application and exploitation of artificial intelligence techniques are becoming more and more crucial in assisting the pharmaceutical industry in its ongoing quest for more reliable and effective drugs. Employing such aids to learn and extrapolate from previously inputted drug structure and biological response data facilitates the design of advantageously modified and novel biomolecules. Predicting theoretical properties of proposed structures and then directing the optimisation of synthetic routes to provide these compounds, in alignment with but before expensive laboratory work unfolds, is of untold help in this task. The ability to provide further simulation of scenarios in both pharmacodynamic and pharmacokinetics areas, leading to potential modifications in structure, could offset hitherto capricious complications that may be observed during the later stages of drug development and testing.

As mentioned in the brief for this book, the aim is, “to introduce the reader to *AI and machine learning tools and techniques*.” The editor provides three chapters, the “Introduction,” a chapter overviewing “The history of artificial intelligence and chemistry,” and the final chapter entitled, “Summary and outlook.” The remaining fourteen chapters have been assembled by thirty-six authors and included the below titles: “Chemical topic modeling - and unsupervised approach originating from text-mining to organise chemical data;” “Deep learning and chemical data;” “Concepts and application in conformal prediction in computational drug discovery;” “Non-applicability domain. The benefits of defining ‘I don’t know’ in artificial intelligence;” “Predicting protein-ligand binding affinities;” “Virtual screening with convolutional neural networks;”

“Machine learning in the area of molecular dynamics simulations;” “Compound design using generative neural networks;” “Junctional tree variational autoencoder for molecular graph generation;” “AI via matched molecular pair analysis;” “Molecular de novo design through deep generative models;” “Active learning for drug discovery and automated data curation;” “Data-driven prediction of organic reaction mechanisms;” “ChemOS: An orchestration software to democratize autonomous discovery.” The book is rounded off with an inclusive subject index.

To quote from the editor’s final chapter, his summary conclusion reads, “*It is unlikely that any one innovation will be the dominant method going forward, but it is likely however that novel combinations of both new and old methods, with appropriate enhancements will lead to significant advances in these methods in drug discovery efforts.*” This is a complex area and computer predictions must always be tested. However, they have been and will continue to be an enormous aid, an invaluable tool in the challenges that are faced, and our understanding and reliance upon them will increase, particularly in this age of “big data.” For anyone interested in this captivating area this book is a must.

### Notified by

Steve Mitchell

Imperial College London, UK

### Book Ordering Information

The Royal Society of Chemistry

Thomas Graham House

Cambridge, UK

+44(0)1223 420066

website: <https://www.rsc.org>

(sales) +44(0)1223 432360



# 2021 ISSX and IQ Consortium

## Workshop: Translation of *in vivo*: ADMET Science to *in vivo*: Current Perspectives and Challenges in Review

In March ISSX and the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) jointly presented a virtual workshop, Translation of *in vitro* ADMET Science to *in vivo*: Current Perspectives and Challenges. The four-day virtual workshop, co-chaired by Christopher Gibson of Merck Research Laboratories and Lei Zhang, was a great success in both registrations and attendee and speaker engagement and participation.

This workshop brought together scientists from academia, industry, and regulatory agencies in an interactive format to discuss contemporary topics in applied small molecule enzyme and transporter research. The daily sessions covered not only laboratory and analytical challenges associated with studying enzymes and transporters *in vitro*, but also challenges and potential solutions/best practices in translation of *in vitro* ADMET data to *in vivo* drug disposition and clinical drug-drug interactions (DDIs).

The workshop featured a mixture of presentations, including overview of the challenges in each research area, rapid-fire talks, followed by roundtable discussion sessions. In addition, interactive virtual poster sessions were presented throughout the course of the workshop. This format allowed for the exchange of perspectives and ideas across regulatory, academic and industrial spaces to help address ADMET challenges in the discovery and development of tomorrow's medicines.

In addition to the lectures and panel discussions, the workshop also featured interactive virtual poster sessions. ISSX congratulates Olena Anoshchenko, Kayla Frost, and Flavia Storelli for earning Best Poster Award certificates for their outstanding presentations.

ISSX thanks the Workshop Organizing Committee, speakers, and attendees for their active participation throughout the workshop. The workshop was supported by a grant from Genentech, a member of the Roche Group.

### WORKSHOP ORGANIZING COMMITTEE

#### Workshop Organizing Committee Chairs:

Christopher Gibson, Merck Research Laboratories, West Point, PA, USA and Lei Zhang, Silver Spring, MD, USA

#### Workshop Organizing Committee Members:

Adrian Fretland, Repare Therapeutics, Cambridge, MA, USA  
Aleksandra Galetin, University of Manchester, United Kingdom  
Yurong Lai, Gilead Sciences, Foster City, CA, USA  
Laurent Salphati, Genentech Inc., South San Francisco, CA, USA  
Kimio Tohyama, Takeda Pharmaceuticals, Cambridge, MA, USA  
Jashvant Unadkat, University of Washington, Seattle, WA, USA



# The ISSX Webinar Series

## About the ISSX Webinar Series

The ISSX Webinar Series is an engaging and innovative way to hear from and interact with speakers from around the world on a range of topics related to the metabolism and disposition of xenobiotics. Members can participate for free. Participate in regularly scheduled live webinars with an exciting range of speakers, as well as watch previous webinars on your own schedule.

ISSX webinars are presented by internationally recognized scientists on a variety of subjects relevant to the field. The ISSX Continuing Education Committee is charged with the responsibility for reviewing these educational offerings and setting the webinar schedule.

## MARK YOUR CALENDAR FOR THESE UPCOMING ISSX WEBINARS

### SEPTEMBER 2021

**September 28 at 11:00 AM ET (15:00 UTC)**

#### **Prediction of Transporter-mediated PK and DDIs using Mechanistic PBPK Models: Challenges and Opportunities**

*Presented by Bridget L. Morse, Pharm.D., Ph.D.,  
Lilly Research Laboratories*

Use of physiologically-based pharmacokinetic (PBPK) modeling for predicting the clearance and drug-drug interactions (DDIs) for transporter substrates addresses many disadvantages in using allometry or static models. These include species differences in transporter expression, expression of transporters at more than one physiological site, prediction of plasma/tissue concentration profiles over time, and potential to incorporate effects of extrinsic factors on transporter function.

For predicting human renal clearance, allometry has been demonstrated to predict rather well, regardless of the role of transporters in renal clearance. There are a few examples for prediction of renal clearance using PBPK modeling directly using *in vitro* transporter data, and these demonstrate generally acceptable predictivity particularly for organic anion transporters (OATs) 1/3. Similarly for the prediction of OAT-mediated DDIs, both static and PBPK modeling have been generally predictive using *in vitro* inhibition constants. Recent work has shown that modeling renal secretion by OCT2/MATEs and other transporters to be less straightforward.

Alternatively, for hepatic transport mediated by organic anion transporting polypeptides (OATPs), multiple efforts have shown that clearance is underpredicted using *in vitro* uptake clearances from primary hepatocytes in PBPK models. As such, when predicting human CL using PBPK modeling, scaling factors often have to be incorporated. Similarly, DDIs mediated by the OATPs tend to be underpredicted by PBPK models when *in vitro* inhibition constants are used directly. Regarding hepatic clearance mediated by organic cation transporter (OCT)

1, there has been little investigation on the use of PBPK modeling for predicting clearance of these substrates.

This webinar will address the current state of the science in using PBPK modeling for prediction of human pharmacokinetics and DDIs for transporter substrates, including strategies for addressing discrepancies in *in vitro*-to-*in vivo* extrapolation.

### OCTOBER 2021

**October 26 at 11:00 AM ET (15:00 UTC)**

#### **Chemoinformatics and Machine Learning to Understand Drug Transporter Selectivity**

*Presented by Dr. Sanjay K. Nigam, M.D.,  
University of California San Diego*

Drug transporters interact with a wide range of pharmaceuticals, toxins, metabolites, signal molecules and gut microbiome-derived small molecules. This raises concerns not only about drug-drug interactions but also drug-metabolite and drug-nutrient interactions, among others. Chemoinformatics combined with machine learning methods are useful for identifying molecular properties of small molecules favored by a particular SLC or ABC transporter. This is one several computational strategies that can lead to a clearer understanding of potential interactions between drugs, toxins, metabolites, nutrients, and gut microbe products. It can also lead to a better understanding of transporter-mediated interorgan and interorganismal small molecule communication in normal and pathophysiological states, as proposed in the Remote Sensing and Signaling Theory. This theory focuses on the underlying biological pathways that make drug ADME possible and can serve as a basis for more efficient targeting of drugs to tissues in health and disease (Nigam SK. What Do Drug Transporters Really Do? Nature Rev. Drug Disc. 2015).

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and appointed some new members to the Nominations committee, as reported elsewhere in this newsletter.

I believe many of you mainly worked from home for the past 16 or more months but are now gradually returning to your labs, offices, and classrooms. However, I also realise we still have challenges with Covid-19 so I'm

happy to be keeping our main meeting for the year virtual. I hope you will agree with this decision and join us online. We remain optimistic that we will be able to meet in person next September in Seattle.

I end by thanking all the team at the ISSX office in Washington DC for their continuing excellent service!

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## The ISSX Webinar Series

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### **Additional webinars will be announced soon!**

Check the **ISSX webinar schedule** to stay in the know on upcoming scientific lectures and discussions.

### **Did you miss a recent webinar?**

Sign into your ISSX membership account and view all past webinars **here**.

### **Do you have an idea for a webinar? Submit a Proposal to Present for the ISSX Webinar Series**

We want to hear from you! Complete a brief form online to **submit your proposal today**. The information presented in the ISSX Webinar must be balanced and provide the attendee with an objective viewpoint. Proposals for the ISSX Webinar will be evaluated for the ability to provide educational content to ISSX members. The scientific content (merit) of the webinar is subject to review and prior approval by the ISSX Continuing Education Committee (CEC) is needed before proceeding.

# Join Us this September 13–17 for the virtual 24th North American ISSX Meeting: Broadening Our Horizons

24<sup>TH</sup> NORTH AMERICAN  
**ISSX**  
MEETING

## Meeting Organizing Committee

**Meeting Chair:** Raymond Evers, Janssen  
Pharmaceutica (J&J)

**Meeting Co-Chair:** Joseph Balthasar, State University  
of New York at Buffalo

## Committee Members:

Ann Daly, Newcastle University  
Xiaoyan Chu, Merck & Co.  
Christine Fandozzi, Merck & Co.  
Lucinda Hittle, Merck & Co.  
Marcel Hop, Genentech, Inc.  
Amit Kalgutkar, Pfizer Inc.  
Valerie Kramlinger, Novartis  
Kaushik Mitra, Janssen Pharmaceutica  
Bhagwat Prasad, Washington State University  
Erin Schuetz, St. Jude Children's Research Hospital  
Ping Zhao, Bill and Melinda Gates Foundation

## Meeting Program\*

### MONDAY, SEPTEMBER 13, 2021

#### Short Course 1: Drug Metabolism in Pharmaceutical Drug Discovery and Development

*Co-Chairs: Valerie Kramlinger, Novartis, Cambridge,  
Massachusetts, USA and Ana Vergara, Merck & Co.,  
West Point, Pennsylvania, USA*

The course is designed to include a number of topics that both cover and branch out from our traditional liver and small-molecule focused mindset. The unifying focus through each topic would be to discuss how biotransformation work directly influences drug discovery and development in industry.

#### Short Course 2: Application of Regulatory Guidances for Transporter Related DDIs

*Co-chairs: Lei Zhang, Food and Drug Administration,  
Silver Spring, Maryland, USA and Xiaoyan Chu, Merck  
& Co., Inc., Rahway, New Jersey, USA*

In this short course, participants will learn: 1) the importance of transporters in modulating PK and PD of drugs and their clinical relevance; 2) the evolution of various decision criteria to predict tDDI from *in vitro* data including the underlying rationale and limitations; 3) how tDDIs of investigational drugs are evaluated during drug development from real cases; 4) advancements in several areas with active research such as the application of transporter endogenous biomarkers for DDI prediction, the design and implementation of clinical probe drug cocktail studies, and the *in vivo* assessment of transporter induction; 5) progress in global harmonization of DDI guideline in terms of tDDIs.

#### Short Course 3: Enabling Efficient Drug Discovery and Development via Physiologically-based Pharmacokinetic (PBPK) Modeling

*Co-chairs: Ping Zhao, Bill and Melinda Gates Foundation,  
Seattle, Washington, USA and Manthena Varma, Pfizer  
Inc., Groton, Connecticut, USA*

The focus of this course will include a review of what makes a PBPK model acceptable from a regulatory viewpoint, including best practices for qualifying and validating models.

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# Join us for the 24th North American ISSX Meeting

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## **Short Course 4: Training Course: From Active Molecules to Approved Therapeutics: Navigating Drug Development and Regulatory Challenges**

*Chair: Christine Fandozzi, Merck & Co., Inc., West Point, Pennsylvania, USA*

This course will cover the fundamentals in the translation from preclinical data to FIH dose selection and data needed in support of successful IND application and clinical studies.

**TUESDAY, SEPTEMBER 14, 2021**

## **Keynote Lecture: Janssen's Effort in the Development of a COVID-19 Vaccine**

*Hanneke Schuitemaker, Janssen Vaccines and Prevention of J&J, Leiden, The Netherlands*

In January 2020, when the genetic code of SARS-CoV-2 was published, Janssen started to work on a vaccine against COVID-19. A lead vaccine candidate, Ad26.COV2.S, was selected from 12 different spike protein designs, and leveraging the adenoviral vector platform. A single dose of this vaccine gave full protection in the lungs of challenge non-human primates and near complete protection in the nose. A first-in-human phase 1/2a study initiated in July 2020 and based on interim safety and immunogenicity results, a large (n~44,000 participants) phase 3 efficacy study (ENSEMBLE), testing the protective efficacy of a single dose vaccine against moderate to severe COVID-19, was initiated in September 2020, in 8 different countries on 3 continents. End of January 2021, the primary analysis revealed the vaccine was safe and well tolerated, with an overall efficacy of 66% against moderate to severe COVID-19. A vaccine efficacy of >80% was observed against severe/critical COVID-19, with full protection against COVID-19 related hospitalizations and death, also in South Africa and Brazil where new SARS-CoV-2 variants of concern (B.1.351 and P2 lineage, respectively) were highly prevalent in COVID-19 cases in the trial. Ad26.COV2.S received Emergency Use Authorization from FDA in February 2021, conditional Marketing Authorization in EU and Emergency Use Listing from the WHO in March 2021, and conditional emergency use authorizations in countries worldwide.

## **Symposium 1: Latest Developments for Assessing the ADME of Biologics**

*Co-chairs: Dhaval Shah, University at Buffalo, Buffalo, New York, USA and Vittal Shivva, Genentech Inc., South San Francisco, California, USA*

Disposition of Biologics is a very complex process, which depends on numerous drug and system related interactions. To facilitate the investigation of the key determinants responsible for the ADME of biologics, it is essential to develop novel analytical and experimental methods that can overcome the technical challenges associated with accurate and quantitative assessment of their disposition. Emerging techniques in this regard will not only help in establishing quantitative relationships between molecular properties and systemic exposure of biologics, but will also help in accurately characterizing and predicting the exposure of biologics at the site-of-action. In this session speakers will discuss novel state-of-the-art methods developed to assess the ADME of biologics.

## **Symposium 2: State of the Art Strategies to Enhance Brain Penetration of Small Molecules and Therapeutic Proteins**

*Co-chairs: Marilyn Morris, University at Buffalo, Buffalo, New York, USA and Xiaoyan Chu, Merck & Co., Inc., Rahway, New Jersey, USA*

The blood-brain barrier (BBB) and the blood-cerebrospinal fluid barrier (BCSFB) separate the brain and cerebrospinal fluid (CSF) from the systemic circulation, representing a barrier to the permeation of endogenous compounds and both small molecules and therapeutic proteins into the brain. Drug transporters at the BBB and BCSFB are involved in the brain uptake and efflux of many drugs. This symposium will 1) provide an overview of current knowledge and perspectives on roles of transporters at the BBB and BCSFB; 2) present novel *in vitro*, *in vivo* animal and clinical approaches applied in the elucidation and characterization of brain penetration, as well as clinical translation; and 3) provide an in-depth discussion of physiologically-based pharmacokinetic models to describe brain distribution and time course of therapeutic drugs and proteins, as well as the influence of dosing regimens and potential alterations with disease.

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## Symposium 3: Identifying Biotransformations of Next Generation Biologics

*Co-chairs: Mark Cancilla, Merck & Co., Inc., West Point, Pennsylvania, USA and Brooke Rock, Amgen, South San Francisco, California, USA*

The increased complexity of biologic drug modalities has changed our understanding of their pharmacokinetic and metabolic assessment. The overall stability of a chemically modified or engineered proteins upon administration has been demonstrated to be linked to its efficacy. This session will focus on identifying biotransformations of complex biologics to further understand their metabolic fate as well as to aid in their design for the assessment of their therapeutic potential.

## Symposium 4: Epigenetics in Drug Disposition and Drug Therapy

*Chair: Ann Daly, Newcastle University, Newcastle Upon Tyne, United Kingdom*

Epigenetics including DNA methylation, miRNA expression and histone modification contributes to the global gene expression including those relevant to xenobiotic metabolism and transport as well as disease processes including cancer. Though considerable progress has been made in this area, this is still a relatively poorly understood area with changes in epigenetic regulation due to disease and environmental factors of particular importance. Drugs that modulate epigenetic modification of gene expression are increasingly available and are especially relevant to oncology. This symposium will aim to cover both the drug disposition and drug discovery aspects of this area.

## NEW INVESTIGATORS CAREER NETWORKING SESSION

This session is organized in coordination with the **ISSX New Investigators Group** and will feature opportunities for student and early-career scientists to connect and network with peers and senior scientists representing the sectors of academia, industry, and government. All attendees are welcome to join us for this engaging networking session.

## WEDNESDAY, SEPTEMBER 15, 2021

### Plenary Lecture 1: The Economics of the Pharmaceutical Industry

*Joseph DiMasi, Tufts Center for the Study of Drug Development, Boston, Massachusetts, USA*

The new drug development process is highly costly, very lengthy, and fraught with risk. This presentation will show data on the trends in drug development and regulatory approval cycle times, transition probabilities for clinical phases, approval success rates for clinical development, and pharmaceutical R&D costs. Drug development metrics vary by therapeutic area and for classes within therapeutic areas, and this will be demonstrated through a number of analyses, including for drugs to treat infectious diseases and cancer. The extent to which firms compete in development of therapies within therapeutic classes will also be examined through empirical analysis.

## Symposium 5: Driving Innovation in Qualitative and Quantitative Bioanalysis

*Co-chairs: Lucinda Hittle, Merck & Co., Inc., Rahway, New Jersey, USA and Valerie Kramlinger, Novartis, Cambridge, Massachusetts, USA*

As a partnership between the ISSX **Bioanalysis in ADME Science and Biotransformation Mechanisms and Pathways** Focus Groups, this session will present various aspects of quantitative and qualitative analysis. Topics include novel informatics, instrumentation and imaging; approaches will be presented with an emphasis on application to both small and large molecules. The objective of this session is to highlight state-of-the-art methodologies that are being applied to continuously improve bioanalytical and biotransformation capabilities for xenobiotics.

## Symposium 6: Beyond Rule of 5

*Co-chairs: Per Artursson, Uppsala University, Uppsala, Sweden and Dehua Pei, The Ohio State University, Columbus, Ohio, USA*

The drug space beyond rule of five (bRo5) is populated with drug molecules that are substantially larger than traditional drugs. These include macrocycles, cyclic and stapled peptides as well as PROTACs (degraders). bRo5 drugs can interact with promising intracellular targets that are “difficult-to-drug” using traditional membrane permeable molecules. For instance, bRo5, but not traditionally sized molecules can target protein-protein interactions, which typically have large, featureless, flat, or groove-shaped interfaces. While bRo5 drugs offers the opportunity to expand the number of “druggable” intracellular targets, they have well known drawbacks, including poor membrane permeability and oral bioavailability. This has stimulated the search for solutions that improve intracellular uptake and transcellular permeability, respectively. In this session,

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factors that influence the uptake and permeability of bRo5 compounds will be presented. Innovative approaches that increase intracellular target access will be covered and case stories from ADME and DMPK optimization of cyclic peptides and degraders in the pharmaceutical industry will be reviewed.

## PREDOCTORAL POSTER AWARD FINALIST PRESENTATIONS

*Co-chairs: Valerie Kramlinger, Novartis, Cambridge, Massachusetts, USA and Bhagwat Prasad, Washington State University, Spokane, Washington, USA*

Five predoctoral finalists for the ISSX Poster Awards Competition will be selected to present.

## ATTENDEE NETWORKING SESSION

Meet and connect with attendees, speakers, and exhibitors. All attendees are welcome to join us for this fast-paced networking session.

## THURSDAY, SEPTEMBER 16, 2021

### Plenary Lecture 3: The Projection of Drug Interactions Caused by Time-Dependent Inhibition of CYP3A

*Scott Obach, Pfizer, Inc., Groton, Connecticut, USA*

### Symposium 7: ADME Success Stories

*Co-chairs: Marcel Hop, Genentech Inc., South San Francisco, California, USA and Dermot McGinnity, AstraZeneca, Cambridge, United Kingdom*

Scientists from a range of companies will present both preclinical and clinical ADME data that have not been presented in detail before. They will describe the process of identification of a clinical candidate with optimal ADME properties and the struggles encountered and necessary compromises throughout the process. Human PK predictions and the corresponding clinical PK, metabolism and DDI data will be included as well.

### Symposium 8: New Strategies for Overcoming ADME Hurdles for Nucleic Acid

*Co-chairs: Jessica Hawes, Food and Drug Administration, Silver Spring, Maryland, USA and Donglu Zhang, Genentech Inc., South San Francisco, California, USA*

This symposium will cover the most recent advances in the development of new nucleic acid therapeutics, including ASO, siRNA, mRNA, and miRNA drugs. Areas of discussion include the principles, promise, and

challenges of developing nucleic acid-based therapeutics, with special focus on new strategies for improving ADME, pharmacokinetic and pharmacodynamic (PK/PD) properties of nucleic acid drugs. Four leading investigators in the fields will present the most recent findings and lead the discussion of new nucleic acid medications. Attendees are expected to learn the fundamental principles and new strategies in discovery and development of nucleic acid therapeutics.

## POSTDOCTORAL POSTER AWARD FINALIST PRESENTATIONS

*Co-chairs: Valerie Kramlinger, Novartis, Cambridge, Massachusetts, USA and Bhagwat Prasad, Washington State University, Spokane, Washington, USA*

Five postdoctoral finalists for the ISSX Poster Awards Competition will be selected to present.

## ATTENDEE NETWORKING SESSION

Meet and connect with attendees, speakers, and exhibitors. All attendees are welcome to join us for this fast-paced networking session.

## FRIDAY, SEPTEMBER 17, 2021

### 2020 and 2021 ISSX Awards Presentation

### ISSX 2021 Poster Awards Presentation

### Symposium 9: New Approaches to Improve the ADME Kinetics of Biologics

*Co-chairs: Joseph Balthasar, University at Buffalo, Buffalo, New York, USA and Greg Thurber, University of Michigan, Ann Arbor, Michigan, USA*

Biological agents such as siRNA, mRNA, peptides, and proteins often exhibit poor *in vivo* absorption, distribution, and elimination kinetics. This symposium highlights recent advances in the development of optimization strategies for the ADME of biologics, including approaches to enable improved oral and subcutaneous bioavailability, new methods to extend persistence / half-life, and strategies to improve tissue selectivity / targeting and within-tissue distribution. Speakers will review ADME challenges and discuss optimization methods, with an in-depth discussion of solutions that have been recently advanced within their laboratory.

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## Symposium 10: Non-invasive Approaches for Drug Disposition Prediction: Biomarkers, Liquid Biopsies and PBPK Modeling

Co-chairs: Bhagwat Prasad, Washington State University, Spokane, Washington, USA and A. David Rodrigues, Pfizer Inc., Groton, Connecticut, USA

Characterization of variability in drug disposition is important for clinical study design and for individualized drug treatment. Because variability in drug disposition cannot be completely described by genetics, characterization of phenotypic variability is ideal. The use of non-invasive exosomes (i.e., isolated from biofluids) and endogenous biomarkers are emerging tools for prediction of drug metabolism and transport. Integration of metabolomics and proteomics data from tissue, blood, urine or exosomes into PBPK modeling provides a translational tool for better prediction of drug disposition. This symposium will provide an update on various non-invasive and *in silico* approaches of *in vivo* drug disposition prediction.

## Plenary Session: Predicting the Unpredictable—Idiosyncratic Drug Toxicity

Co-chairs: Amit S. Kalgutkar, Pfizer Inc., Cambridge, Massachusetts, USA and Kaushik Mitra, Janssen Pharmaceutica

Cumulative research over several decades has implicated the involvement of bioactivation (formation of electrophilic reactive species) in idiosyncratic drug toxicity. Consequently, “avoidance” strategies have been inserted into drug discovery paradigms, which include the exclusion of structural alerts and possible termination of reactive metabolite-positive compounds. The symposium will focus on the recent progress on the limitations of the structural alert avoidance strategy and novel strategies to assess idiosyncratic toxicity in preclinical/clinical drug discovery paradigm.

\*Program subject to change.

### REGISTRATION

Registration remains open through September 17! Review additional details about the meeting online at [www.issx2021.org](http://www.issx2021.org) and register to attend today.

ISSX THANKS THESE SPONSORS FOR THEIR GENEROUS SUPPORT OF THE 24TH NORTH AMERICAN ISSX MEETING:



# Welcome New Members

The International Society for the Study of Xenobiotics proudly welcomes the following new members. We greatly appreciate their support and hope that each remains aligned and affiliated with ISSX for many years to come.

## **Kenza Abouir**

**Omozojie Aigbogun**, Saskatoon, Saskatchewan, Canada

**Krishna Aluri**, AstraZeneca, Malden, Massachusetts, United States

**Benny Amore**, Esperion Therapeutics, Ann Arbor, Michigan, United States

**Rashi Asthana**, University of Toronto, Toronto, Ontario, Canada

**Justine Badee**, Novartis, Basel, Switzerland

**Amanda Balesano**, Pfizer, Groton, Connecticut, United States

**Pravita Balijepalli**, Washington State University, Spokane, Washington, United States

**Jeanine Ballard**, Merck & Co., West Point, Pennsylvania, United States

## **Sumit Bansal**

## **Keti Bardhi**

**Daniel Barratt**, University of Adelaide, Adelaide, Australia

**Marc-Olivier Boily**, Ventus Therapeutics, Montreal, Quebec, Canada

**Virag Bujdosó-Szekely**, SOLVO Biotechnology, Budapest, Hungary

**Jennifer Byerley**, Boehringer Ingelheim, Ridgefield, Connecticut, United States

**Jason Causon**, Sciex, Richmond Hill, Ontario, Canada

**Jennifer Cecile**, Appalachian State University, Boone, North Carolina, United States

**Merve Ceylan**, Uppsala University, Uppsala, Sweden

**Hobin Chen**, Graduate School of Pharmaceutical Sciences, Kyushu University, Fukuoka, Japan

## **Ping Chen**

**Shu Chen**, Genentech, Inc., South San Francisco, California, United States

**Yuping Chen**, Zai Lab US, Menlo Park, California, United States

**Shen Cheng**, University of Minnesota, Saint Paul, Minnesota, United States

**Yaofeng Cheng**, PTC Therapeutics, South Plainfield, New Jersey, United States

## **Christi Cho**

**Yoon Jeong Choi**, Boehringer Ingelheim, Ridgefield, Connecticut, United States

**Haithem Chtioui**, Chuv–University Hospital Lausanne, Lausanne, Switzerland

**Se-Eun Chun**, LG Chem, Seoul, Korea, South

**Gabriel Dalio Bernardes Da Silva**, University of Saskatchewan, Saskatoon, Saskatchewan, Canada

**Tom De Bruyn**, Genentech, Inc., San Francisco, California, United States

**Kevin Dement**, Takeda Development Center Americas, Inc., San Diego, California, United States

**Anup Deshpande**, BBRC-SYNGENE, Bangalore, India

**David Dickens**, University of Liverpool, Liverpool, United Kingdom

**Agata Dudek**, Ryvu Therapeutics S.A., Krakow, Poland

**Sadaf Ejaz**, Johnson and Johnson, Clifton, New Jersey, United States

**Katherine Fenner**, AstraZeneca, Cambridge, United Kingdom

**Uma Fogueri**, Loxo Oncology at Lilly, Durham, North Carolina, United States

## **Joanna Frąckowiak**

**Jolien Freriksen**, Radboud UMC, Nijmegen, Netherlands

**Chunying Gao**, Baltimore, Maryland, United States

**Raeanne Geffert**, Boehringer Ingelheim, Ridgefield, Connecticut, United States

**Avijit Ghosh**, Amgen, Doylestown, Pennsylvania, United States

**Janice Goh**, University of California San Francisco, San Francisco, California, United States

**Joe Gong**, Suny-Buffalo, Buffalo, New York, United States

**Yifan Gong**, Philadelphia, Pennsylvania, United States

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# Welcome New Members

Continued from previous page

**Tomoka Gose**, St. Jude Children's Research Hospital, Memphis, Tennessee, United States

**Sue Grepper**, Insphero, Brunswick, Maine, United States

**Jian Guo**, Blueprint Medicines, Cambridge, Massachusetts, United States

**Chunyan Han**, Pharmaron, Beijing, China

**Hirotaka Hatakeyama**, Chiba University, Chiba, Japan

**Meagan Hayashi**, University of Alberta, Edmonton, Alberta, Canada

**Lance Heinle**, Abbvie Inc, North Chicago, Illinois, United States

**David Hernandez-Toledano**, Center For Research and Advanced Studies of the National Polytechnic Institute, Mexico City, Mexico

**Harshad Jadhav**

**Tanguy Jamier**, AstraZeneca, Cambridge, United Kingdom

**Rohit Jindal**, Thermo Fisher Scientific, Frederick, Maryland, United States

**Mitch Johnson**, BioMed Valley, Kansas City, Missouri, United States

**Haleigh Jones**

**Jinhong Kang**, Köln, Germany

**Nandini Katti**, Washington State University, University Place, Washington, United States

**Michal Kosno**, Gdańsk, Polska

**Thomas Kralj**, Ringwood, Australia

**Deanna Kroetz**, University of California San Francisco, San Francisco, California, United States

**David Kukla**, Abbvie Inc, North Chicago, Illinois, United States

**Charles Larson**, Janssen, San Diego, California, United States

**Bethany Latham**, UNC Chapel Hill, Chapel Hill, North Carolina, United States

**Lawrence Lesko**, University of Florida, Orlando, Florida, United States

**Yong Li**, Inflarx Pharmaceuticals, Ann Arbor, Michigan, United States

**Jeonghyeon Lim**, Chungnam National University, Daejeon, Korea, South

**Karine Litherland**, Basilea Pharmaceutica International Ltd., Basel, Switzerland

**Jialin Liu**

**Charles Locuson**, Agios Pharmaceuticals, Wenham, Massachusetts, United States

**Dongping Ma**, Promega Corporation, Madison, Wisconsin, United States

**Gaëlle Magliocco**

**Melinda Manuel**, Takeda, San Diego, California, United States

**Eliza Mccoll**, University of Toronto, Toronto, Ontario, Canada

**Claire McDonald**

**Robyn Meech**, Flinders University, Bedford Park, Australia

**Nicola Melillo**, The University of Manchester, Manchester, United Kingdom

**Mira Merdas**, Servier, Orleans, France

**Vijaya Saradhi Mettu**, Washington State University, Spokane, Washington, United States

**Nicolo Milani**, F. Hoffman La Roche, Ltd., Basel, Switzerland

**Mikiko Nakamura**, Chugai Pharmaceutical Co., Ltd., Tokyo, Japan

**Katie Newgard**, Thermo Fisher Scientific, Carlsbad, California, United States

**Toan Nguyen**

**Advaith Nila Narayanan**

**Chen Ning**, China Pharmaceutical University, Nanjing, China

**Miaoran Ning**, Genentech, Inc., South San Francisco, California, United States

**Miaoran Ning**, Genentech, Inc., Highland Park, Illinois, United States

**Agustos Ozbey**, F. Hoffman La Roche, Ltd., Basel, Switzerland

**Gopinath Palanisamy**, Olema Oncology, Walnut Creek, California, United States

**Vijender Panduga**, AstraZeneca, Mölndal, Sweden

**Kishore Pasikanti**, Grunenthal Therapeutics, Cambridge, Massachusetts, United States

**Avinash Persaud**, J&J, East Norriton, Pennsylvania, United States

**Andy Pike**, AstraZeneca, Cambridge, United Kingdom

**Kelly Rathbun**, Office of the Texas State Chemist, College Station, Texas, United States

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# Welcome New Members

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**Paul Rearden**, Recursion Pharmaceuticals, Salt Lake City, Utah, United States

**Janielle Richards**, University of Toronto, Toronto, Ontario, Canada

**Drake Russell**, University of Washington, Seattle, Washington, United States

**Dora Santos**, Vertex Pharmaceuticals, San Diego, California, United States

**Chitra Saran**, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, United States

**Samantha Sernoskie**, University of Toronto, Toronto, Ontario, Canada

**Priya Sharma**, Amity University, Noida, India

**Danielle Sharpnack**, Genentech, Inc., San Francisco, California, United States

**Christina Shen**, Amgen, South San Francisco, California, United States

**Raku Shinkyo**, Eisai Inc., Cambridge, Massachusetts, United States

**Olha Shuklinova**, Jagiellonian University Medical College, Krakow, Poland

**Caroline Sychterz**, Bristol Myers Squibb, Downingtown, Pennsylvania, United States

**Ryan Takahashi**, Denali Therapeutics, South San Francisco, California, United States

**Yuta Tamemoto**

**Shawn Tan**, University of Manchester, Manchester, United Kingdom

**Andrea Treyer**, Janssen Pharmaceutica, Beerse, Belgium

**Anqi Tu**, Merck & Co., West Point, Pennsylvania, United States

**Steven Van Cruchten**, University of Antwerp, Wilrijk, Belgium

**Sumalatha Veeramachineni**, Waters Corporation, Milford, Massachusetts, United States

**Raman Venkataramanan**, University of Pittsburgh, Pittsburgh, Pennsylvania, United States

**Satoshi Wakabayashi**, Taisho Pharmaceutical Co., Ltd., Saitama, Japan

**Fan Wang**, Beigene, Naperville, Illinois, United States

**Wei Wang**, Genentech, Inc., South San Francisco, California, United States

**Xiangling Wang**, WuXi Apptec, Shanghai, China

**Ya-Feng Wen**, University of Minnesota, Minnesota, United States

**Lydia Woelflingseder**, Boehringer Ingelheim, Vienna, Austria

**Chunyun Xu**, WuXi Apptec, Shanghai, China

**Ryo Yoshinaga**, Senju Usa, Inc., Woodland Hills, California, United States

**Aoi Yoshitomo**

**Josh Yu**, Gilead Sciences, Foster City, California, United States

**Jeanelle Zamora**, Cytokinetics, Inc., South San Francisco, California, United States

**Guangnong Zhang**, Dicerna Pharmaceuticals Inc, Lexington, Massachusetts, United States

**Wenjuan Zhang**

**Wenqiu Zhang**, University of Minnesota, Minneapolis, Minnesota, United States

# ISSX Focus Groups

ISSX Focus Groups provide ISSX members with a great opportunity to network with your colleagues while discussing topics relevant to the day. Your participation in the ISSX Focus Groups help us to enhance the exchange of the most current scientific research information and open doors to endless opportunities for collaboration and career advancement. View the latest from the ISSX Focus Groups and join today!

## BIOANALYSIS IN ADME SCIENCE

The aims of this group include: (a) to promote state-of-the-art analytical technologies to solve challenging issues faced in ADME studies and bioanalysis, (b) to enable industrial scientists to actively contribute to and participate at ISSX meetings and associated activities, and (d) to enhance synergy between industrial scientists and academic researchers.

## BIOTRANSFORMATION, MECHANISMS, AND PATHWAYS

Points for discussion include: (a) metabolism-directed drug design (e.g., incorporation of D to reduce metabolic liability), (b) mechanisms underlying biotransformations that yield “unusual” metabolites and characterization of the metabolizing enzymes responsible for their formation, and (c) idiosyncratic immune-mediated toxicity via metabolism (e.g., reactive metabolites).

## MODELING AND SIMULATION

This group focuses on the role of modeling and simulation in drug development in all stages, including topics such as (a) translational extrapolations from preclinical data to clinical expectations, (b) drug-drug interactions, (c) extrapolations of PK/PD data to special populations, (d) early dose optimization, and (e) selection of doses for clinical testing.

## TRANSPORTERS

The goals of this focus group are to disseminate and promote state-of-the-art research and foster collaborations among ISSX members on the role of transporters in drug disposition, drug interactions, efficacy, and toxicity, and their impact on drug discovery, development, and regulatory decision making.

### SAVE THE DATES FOR THESE UPCOMING ISSX MEETINGS AND EVENTS

#### 2021

##### **24th North American ISSX Meeting, Broadening Our Horizons**

*Meeting Chairs: Raymond Evers, Ph.D.  
and Joseph Balthasar, Ph.D.*

Join us for this virtual event! [www.issx2021.org](http://www.issx2021.org)  
September 13–17, 2021

#### 2022

##### **AAPS and ISSX Joint Transporters Workshop**

April 2022

##### **13th International ISSX and MDO Meeting**

*Meeting Chairs: Michael Zientek,  
Ph.D. and Xiaobo Zhong, Ph.D.*  
Seattle, Washington, USA  
September 11–14, 2022

#### 2023

##### **7th Asia Pacific ISSX Meeting**

*Meeting Chair: Thanga Mariappan, Ph.D.*  
Bangalore, India  
Spring 2023

##### **16th European ISSX and DMDG Joint Meeting**

*Meeting Chairs: Barry Jones, Ph.D.  
and Ana Alfrevic, Ph.D.*  
Summer 2023

##### **25th North American ISSX Meeting**

*Meeting Chairs: Amit Kalgutkar, Ph.D.  
and Fatemeh Akhlaghi, Ph.D.*  
Boston, Massachusetts, USA  
September 10–13, 2023



# Results of ISSX 2021 Election and Bylaws Vote

Thank you to all members who participated in the recent Society election and vote. Voting is an important right of membership in ISSX and it is your opportunity to help determine the future leadership of our Society. In this year's election, members of ISSX voted to elect a President-Elect/Secretary, a Treasurer-Elect, three members of Council, and three members of the Nomination Committee. Additionally, ISSX members voted on an update to the ISSX Bylaws.



*Aleksandra Galetin*



*Mary Paine*



*Kiyomi Ito*



*Uwe Fuhr*



*Nina Isoherranen*



*Deepak Dalvie*



*Elizabeth Gillam*



*Amin Rostami-Hodjegan*

## ISSX ELECTION FOR OFFICERS-ELECT, COUNCIL, AND NOMINATION COMMITTEE MEMBERS

### ISSX Officers-Elect:

**President-Elect/Secretary:** Aleksandra Galetin, University of Manchester, United Kingdom

**Treasurer-Elect:** Mary Paine, Washington State University, USA

### Council Members:

Asia Pacific: Kiyomi Ito, Musashino University, Japan (second term)

Europe: Uwe Fuhr, University Hospital of Cologne, Germany (second term)

North America: Nina Isoherranen, University of Washington, USA (second term)

### Nomination Committee Members:

Deepak Dalvie, Bristol Myers Squibb, USA

Elizabeth Gillam, The University of Queensland, Australia

Amin Rostami-Hodjegan, University of Manchester, United Kingdom

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# Results of ISSX 2021 Election and Bylaws Vote

Continued from previous page

On January 1, 2022 when these newly-elected officials join the slate of officers, Council and Nomination Committee members will be:

## OFFICERS:

**President:** Scott Obach, Pfizer Inc., USA

**President-Elect/Secretary:** Aleksandra Galetin, University of Manchester, United Kingdom

**Treasurer:** K. Sandy Pang, University of Toronto, Canada

**Treasurer-Elect:** Mary Paine, Washington State University, USA

## COUNCIL MEMBERS:

Uwe Fuhr, University Hospital of Cologne, Germany

Kiyomi Ito, Musashino University, Japan

Nina Isoherranen, University of Washington, USA

Simone Schadt, F. Hoffmann-La Roche Ltd, Switzerland

Jashvant Unadkat, University of Washington, USA

Kouichi Yoshinari, University of Shizuoka, Japan

Ylva Terelius, Scientific Affairs Committee (SAC) Chair, Ex Officio to Council, ADMEYT AB, Sweden

## NOMINATION COMMITTEE:

Ann Daly, Newcastle University, United Kingdom

Deepak Dalvie, Bristol Myers Squibb, USA

Elizabeth Gillam, The University of Queensland, Australia

Amit Kalgutkar, Pfizer Inc., USA

Peter Mackenzie, Flinders University, Australia

Amin Rostami-Hodjegan, University of Manchester, United Kingdom

Michael Zientek, Takeda, USA

The Society is grateful to all candidates who agreed to serve in the election as well as to the following members of the Nomination Committee who were responsible for assembling the slate of candidates:

Thomas Baillie, Chair and Immediate Past President, University of Washington, USA

Constanze Hilgendorf, AstraZeneca R&D, Sweden

Amit Kalgutkar, Pfizer Inc., USA

Peter Mackenzie, Flinders University, Australia

Miki Nakajima, Kanazawa University, Japan

K. Sandy Pang, University of Toronto, Canada

Michael Zientek, Takeda, USA

## BYLAWS VOTE

Bylaws are the rules that govern the internal management of an organization. They are written by the organization's founders or directors and cover, at a minimum, topics such as how directors are elected, how meetings of directors are conducted, and what officers the organization will have, and what their duties may include.

In April 2021, the ISSX Council met to review and discuss changes to the ISSX Bylaws which will increase the flexibility with which ISSX can appoint members to the Scientific Affairs Committee.

In the 2021 Election, members voted to pass the changes to the ISSX Bylaws as outlined below:

**Article and Section:** Article V, Section 3

## PREVIOUS LANGUAGE:

Scientific Affairs Committee:

The Scientific Affairs Committee will consist of thirteen (13) members: four (4) from the Americas region, four (4) from the Asia/Pacific region, four (4) from the European region, and the

President-elect as an ex-officio member, with half the members rotating off every two years. The President may consider appointing organizers of recent Society meetings as committee members. Its function is to oversee the planning, development and content of the scientific programs of meetings of the Society.

## NEW LANGUAGE

Scientific Affairs Committee:

The Scientific Affairs Committee will consist of thirteen (13) members: three (3) from the Americas region, three (3) from the Asia/Pacific region, three (3) from the European region, three (3) members representing any region and the President-elect as an ex-officio member, with half the members rotating off every two years. The President may consider appointing organizers of recent Society meetings as committee members. Its function is to oversee the planning, development and content of the scientific programs of meetings of the Society.

## ONCE ADOPTED:

Removes restrictions on filling the committee roster.

Increases flexibility of President to appoint members to the committee.

# ISSX Names 2021 North American Award Winners

## **North American Scientific Achievement Award in Honor of Ronald Estabrook**

The North American Scientific Achievement Award is named in honor of Ronald W. Estabrook and is presented to an ISSX member who has made major scientific contributions to the field. The focus of the award is the individual's scientific accomplishments and it is intended to recognize the best in the field within North America.

The 2021 recipient is Rachel F. Tyndale, Ph.D., Professor, Pharmacology & Toxicology; Psychiatry, Endowed Chair in Addictions, Head Pharmacogenetics, Centre for Addiction and Mental Health at the University of Toronto.

Dr. Tyndale is recognized for this award because of her distinguished scientific career and especially her multiple contributions to our understanding of the important role of drug metabolizing enzymes in the brain—as well their genetic variation.

Dr. Tyndale's career has been spent almost entirely at the University of Toronto where she was initially a graduate student, receiving both M.Sc. and Ph.D. degrees, followed Post-Doctoral work at UCLA, and then a return to the University of Toronto for the remainder of her career. Throughout her career at the University of Toronto, her goal has been to better understand the mechanisms involved with drug abuse and optimize treatment approaches. Dr. Tyndale has studied the important role of cytochromes P-450, especially CYP2D6, CYP2A6 and CYP2B6, in the brain—and particularly their role in the biotransformation and effects of addictive substances such as nicotine.

Dr. Tyndale's scientific research is well-recognized in the realm of pharmacogenomics and in particular, the genetics of nicotine addiction. Her published research is highly cited with over 1,200 citations in 2020 and an H-index of 64. Notably, nine of her manuscripts have been cited over 200 times. Dr. Tyndale has produced 344 peer-reviewed publications and 95 book chapters and reviews. Dr. Tyndale's work has had a significant impact in merging pharmacogenomics with addiction science and the influence of her work on the health of patients suffering from nicotine addiction.

Dr. Tyndale has served as a regular member on a number of funding agencies and scientific journals. She

has made outstanding contributions in her professional services, including those toward ISSX by consistently providing leadership on the Council, Membership and Scientific Affairs Committees, on the Meeting Organizing Committee for the 2013 International Meeting, and as a symposium chair and speaker at several other ISSX meetings. Her scientific honors and recognition are extensive. She has received over 50 awards spanning clinical and basic pharmacology, neuroscience and genetics, including the following recent honors: elected a fellow of the AAAS (2020), was the Wiersma Visiting Professor of Neurobiology at CalTech (2018), received the Faculty of Medicine Graduate teaching award (2017), the Canada Research Chair in Pharmacogenomics (2016–2023) and was the Endowed Chair in Addictions (2013–2016). Dr. Tyndale was also previously awarded the 2005 ISSX North American New Investigator Award.

Her seminal contributions to the field of nicotine metabolism and addiction include work to understand enzymes involved in the metabolism of nicotine, research into the genetics of addiction, and her studies into nicotine metabolic ratios as biomarkers of CYP2A6 activity.

Dr. Tyndale also has an extraordinary record of accomplishment as a teacher. She has trained more than 40 doctoral students and 40 postdoctoral fellows and visiting scientists, and numerous undergraduate students. In recognition of her teaching, Dr. Tyndale was recently awarded the 2017 Faculty of Medicine Graduate Teaching Award for Sustained Excellence in Graduate Teaching and Mentorship at the University of Toronto.

Collectively, Dr. Tyndale's research accomplishments over several decades represent an enormous achievement and an outstanding contributions to the field of drug metabolism and the genetics of addiction. She is clearly a world leader in drug metabolism and the study of xenobiotics. She brings a unique aspect to the field of pharmacogenetics and pharmacology, and drug metabolism at the interface of behavior.

**Learn more about Dr. Tyndale's accomplishments on the ISSX website.** Dr. Tyndale will present an award lecture webinar in early 2022. Details will be announced once available.

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# ISSX Names 2021 North American Award Winners

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## Distinguished Accomplishments in Drug Discovery and Development Award

The Distinguished Accomplishments in Drug Discovery and Development Award was created in 2018 to honor an individual or a team employed in an organization involved in drug discovery and/or drug development. The award is bestowed on the basis of a single high impact scientific accomplishment that dramatically changed practices in the ADME characterization of drugs or drug candidates or a sustained body of scientific work that shows high impact on the ADME characterization of drugs.

The 2021 recipient is A. David Rodrigues, Ph.D., Senior Scientific Director and Head of the Transporter Sciences Group at Pfizer Global Research and Development. Dr. Rodrigues continues to drive innovation in the study of xenobiotic metabolism and clearance. During his 30-year career in the pharmaceutical industry he has had significant influence on the scientific direction in several areas of DMPK science and since joining Pfizer he has continued to expand his scope of influence into the areas of drug transporter sciences and ADME biomarkers.

Dr. Rodrigues's notable contributions to the field include pioneering studies of in vitro drug metabolism applied to drug discovery and development, PK/DDI predictions, and contributions to the evaluation and establishment of robust bioanalytical methods and research activities to identify endogenous biomarkers.

Dr. Rodrigues's sustained impactful contribution as a leading industry researcher is clearly demonstrated through his strong links with the broader scientific

community. Dr. Rodrigues has authored more than a dozen book chapters and >170 peer-reviewed manuscripts, and through presentations at more than 80 scientific meetings.

Dr. Rodrigues holds positions on editorial boards for multiple Q1 international DMPK-related journals including *Current Drug Metabolism*, *Drug Metabolism Letters*, and *Drug Metabolism & Disposition*. In 2009, Dr. Rodrigues's outstanding contributions to the pharmaceutical sector were acknowledged through his induction as a Fellow of The American Association of Pharmaceutical Scientists (AAPS). Dr. Rodrigues also has a long standing affiliation with the International Society for the Study of Xenobiotics as a member and through his service to the society on the Scientific Affairs Committee from 2006 to 2011. The quality and impact of the work that Dr. Rodrigues has lead and the clarity of his vision is exemplified through his leadership of two publications in Clinical Pharmacology and Therapeutics and role as a senior author on a 2019 British Journal of Clinical Pharmacology Best Manuscript award.

In addition to his many scientific accomplishments, he actively works across diverse scientific disciplines and as such has developed a wide network of active collaborators.

**Learn more about Dr. Rodrigues's accomplishments on the ISSX website.** Dr. Rodrigues will present an award lecture webinar in early 2022. Details will be announced once available.

**ISSX**International Society for the  
Study of Xenobiotics

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### Change of Address

If your mailing address, telephone, fax number, or e-mail has changed or will change, please let us know as soon as possible. You may update your contact information at any time using the online membership directory, which you can access in the Member Only section of the website. If you have forgotten your username and/or password, please contact [information@issx.org](mailto:information@issx.org).

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The quarterly *ISSX Newsletter* is an online publication featuring Society updates, scientific articles of interest, book reviews, summaries of ISSX meeting proceedings, and more. This publication is designed to update the ISSX membership on the activities and events of the organization and to provide an information forum.

Not only is the *ISSX Newsletter* promoted directly to all ISSX members, it is also available to anyone who visits the ISSX website.

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