THE 14TH GLOBAL SUMMIT ON REGULATORY SCIENCE (GSRS24) IN-PERSON ANNUAL CONFERENCE

Little Rock Marriott, Little Rock, Arkansas, United States
September 17-19, 2024

Digital Transformation in Regulatory Science

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GSRS24 Program At A Glance

Theme: Digital Transformation in Regulatory Science

Venue: Little Rock Marriott, Little Rock, AR, USA

Sept 17, 2024 (Tuesday)	Sept 18, 2024 (Wednesday)	Sept 19, 2024 (Thursday)
	7:00 AM: Registration Open	**7:00 AM: Registration Open**
	8:30 AM – 9:00 AM: WELCOME REMARKS • GCRSR Chair • U.S. FDA/NCTR Director • U.S. FDA Commissioner	**9:00 AM – 10:40 AM: SESSION 4** ***Theme: Generative AI for Regulatory Applications*** • 20min/talk; 5 talks
12:00 PM: Registration Open	**9:00 AM – 12:00 PM: PLENARY SESSION** ***Theme: Global Landscape of Digital Technology in Regulatory Science*** • 30min/talk; 5 talks • Break: 10:30 AM – 11:00 AM	**10:40 AM – 11:00 AM: *BREAK*** **11:00 AM – 12:00 PM: SESSION 5** ***Theme: Expert Opinions - Is Regulatory Science Ready for AI?*** • Moderated discussion
12:00 PM – 1:30 PM: *LUNCH BREAK*		**12:00 PM – 1:30 PM: *LUNCH BREAK***
1:30 PM – 4:30 PM: **Pre-conference Workshop** ***A Dive into Digital Transformation: Navigating the FAIR Data Frontier of Regulatory Science – An Evidence-Based Toxicology Collaboration (EBTC) Workshop***	**1:30 PM – 3:10 PM: SESSION 2** ***Theme: Digital Technology for Regulated Products and Public Health*** • 20min/talk; 5 talks	**1:30 PM – 2:50 PM: SESSION 6** ***Theme: Use Cases and Demonstration*** • 20min/talk; 4 talks
	3:10 PM – 3:30 PM: *BREAK*	**2:50 PM – 3:10 PM: *BREAK***
	3:30 PM – 5:10 PM: SESSION 3 ***Theme: Challenges and Opportunities of AI/ML in Regulatory Science*** • 20min/talk; 5 talks	**3:10 PM – 4:50 PM: SESSION 7** ***Theme: Digital Technologies – Novel Applications*** • 20min/talk; 5 talks **4:50 PM – 5:10 PM: CLOSING REMARKS** • U.S. FDA Acting Chief Scientist
	5:10 PM – 5:30 PM: *GROUP PHOTO*	**5:10 PM – 5:30 PM: *BREAK***
	5:30 PM – 7:30 PM: POSTER SESSION **(Drinks and hors d'oeuvres)**	**5:30 PM – 7:30 PM: CLOSING RECEPTION** **(Drinks and hors d'oeuvres @ Museum of Discovery)**

CONFERENCE PROGRAM

All times are in U.S. Central Daylight Time (CDT)

Day 0 (Tuesday, September 17, 2024)	
1:30 – 4:30 PM	**PRE-CONFERENCE WORKSHOP:** **A Dive into Digital Transformation: Navigating the FAIR Data Frontier of Regulatory Science—An EBTC Workshop**

Moderator:

Dr. Paul Whaley, Evidence-based Toxicology Collaboration (EBTC) (www.EBTox.org)

Overview:

This interactive workshop is designed to elevate participants' understanding of FAIR (Findable, Accessible, Interoperable, and Reusable) data principles, with a focus on practical application in regulatory science. Through moderated discussions, attendees will gain in-depth understanding of the complexities of FAIR data, exploring its crucial role in research, risk assessment, and regulatory decision-making. By engaging participants from diverse backgrounds to share experiences and insights, the workshop aims to foster a collaborative environment that enhances engagement, encourages meaningful contributions, and strengthens professional networks at the GSRS Conference.

Speakers:

1. Dr. Paul Whaley, Co-Chair Open Science Working Group, EBTC
2. Dr. Alexander Tropsha, K.H. Lee Distinguished Professor, University of North Carolina at Chapel Hill
3. Dr. Katya Tsaioun, Executive Director, EBTC
4. Dr. Thomas Hartung, Director of the Center for Alternatives to Animal Testing (CAAT), Johns Hopkins University

Day 1 (Wednesday, September 18, 2024)	
8:30 – 9:00 AM	**WELCOME REMARKS** • **Dr. Weida Tong, GCRSR Chair** • **Dr. Tucker Patterson, U.S. FDA/NCTR Director** • **Dr. Robert M. Califf, U.S. FDA Commissioner**
9:00 AM – Noon	**SESSION 1 (PLENARY SESSION): GLOBAL LANDSCAPE OF DIGITAL TECHNOLOGY IN REGULATORY SCIENCE** **Co-Chairs: Dr. David Strauss (U.S. FDA); Dr. Tucker Patterson (U.S. FDA)**
9:00 – 9:30 AM	***Transforming the Future of Regulatory Science*** **Mr. Ram Iyer,** Chief Data Officer, Office of Digital Transformation (ODT), U.S. Food and Drug Administration (FDA), United States
9:30 – 10:00 AM	***Advancing Risk Assessments through FAIR Knowledge Exchange: The RAKIP Initiative*** **Mr. Matthias Filter**, Head of Study Centre for Food Chain Modelling and Artificial Intelligence, German Federal Institute for Risk Assessment (BfR), Germany
10:00 – 10:30 AM	***BREAK***
10:30 – 11:00 AM	***Modernizing Regulatory Practices through Digital Tools and Technologies: Saudi Food and Drug Authority Experience*** **Dr. Adel Alrwisan**, Executive Director of Research and Studies Department, Saudi Food and Drug Authority (SFDA), Saudi Arabia
11:00 – 11:30 AM	***Digital Transformation and Use of AI Tools: ANVISA Experience*** **Mr. Anderson da Mota Ribeiro**, Chief Data & Analytics Officer (CDAO), Brazilian Health Regulatory Agency (ANVISA), Brazil
11:30 AM – Noon	***When Culture Devours Strategy: Navigating the Cultural Challenges of AI Implementation in the Public Sector*** **Mr. Michael Renaudin**, Lead Swissmedic 4.0, Swissmedic, Switzerland
12:00 – 1:30 PM	***LUNCH BREAK***
1:30 – 3:10 PM	**SESSION 2: DIGITAL TECHNOLOGY FOR REGULATED PRODUCTS AND PUBLIC HEALTH** **Co-Chairs: Dr. Bill Slikker (Former Director of U.S. FDA/NCTR); Dr. Yoko Hirabayashi (National Institute of Health Sciences, Japan)**
1:30 – 1:50 PM	***Digital Transformation of FDA Drug Labeling in the Era of AI*** **Dr. Hong Fang**, Health Information Scientist, Office of Scientific Coordination (OSC), National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), United States
1:50 – 2:10 PM	***Leveraging Reader Studies for Digital Pathology*** **Dr. Kim Blenman**, Assistant Professor, Department of Internal Medicine and Department of Computer Science, Yale University, United States
2:10 – 2:30 PM	***Harnessing the Value of Digital Health Technologies in Clinical Development***

	Dr. Jie Shen, Director of Digital Science, AbbVie, United States
2:30 – 2:50 PM	***AllerCatPro 3.0 – Protein Allergenicity Prediction with 3D Structure Features*** **Dr. Minh Nguyen**, Principal Scientist I at Bioinformatics Institute, A*STAR – Agency for Science, Technology and Research, Singapore
2:50 – 3:10 PM	***Current Status and Challenges for the Use of AI in the Pharmacovigilance Field in Japan*** **Dr. Noriaki Arakawa**, Section Chief of Division of Medicinal Safety Science, National Institute of Health Sciences (NIHS), Japan
3:10 – 3:30 PM	***BREAK***
3:30 – 5:10 PM	**SESSION 3: CHALLENGES AND OPPORTUNITIES OF AI/ML IN REGULATORY SCIENCE** **Co-Chairs: Dr. Maurice Whelan (EC-JRC); Dr. Suzanne Fitzpatrick (U.S. FDA)**
3:30 – 3:50 PM	***The Race for Regulation: Overview of Regulatory Efforts to Guide AI/ML Application and Acceleration*** **Mr. Cesare Furlanello**, Director of LIGHT (Lifescience Innovation & Good Healthcare Technologies) Center, Italy
3:50 – 4:10 PM	***AI at the European Food Safety Authority: Our Journey from Innovation to Implementation*** **Dr. Didier Verloo**, Head of Knowledge Innovation and Partnership Management Unit (KNOW), European Food Safety Authority (EFSA), Italy
4:10 – 4:30 PM	***Utilization of Machine Learning on the Classification of Silicone Oil Droplets and Protein Particles in Biopharmaceutical Products*** **Dr. Hiroko Shibata**, Section Chief of Division of Biological Chemistry and Biologicals, National Institute of Health Sciences (NIHS), Japan
4:30 – 4:50 PM	***Top 10 AI/ML Mistakes and Villains*** **Dr. Russ Wolfinger**, Director of Scientific Discovery and Genomics, JMP Statistical Discovery, SAS Institute, Inc., United States
4:50 – 5:10 PM	***ARPA-H and High-Risk/High-Reward R&D: Sparking Digital Transformations in Regulatory Science*** **Dr. Andrew Kilianski**, Program Manager of Health Science Futures, Advanced Research Projects Agency for Health (ARPA-H), Department of Health and Human Services, United States
5:10 – 5:30 PM	***GROUP PHOTO***
5:30 – 7:30 PM	**POSTER PRESENTATIONS (Drinks and hors d'oeuvres)**

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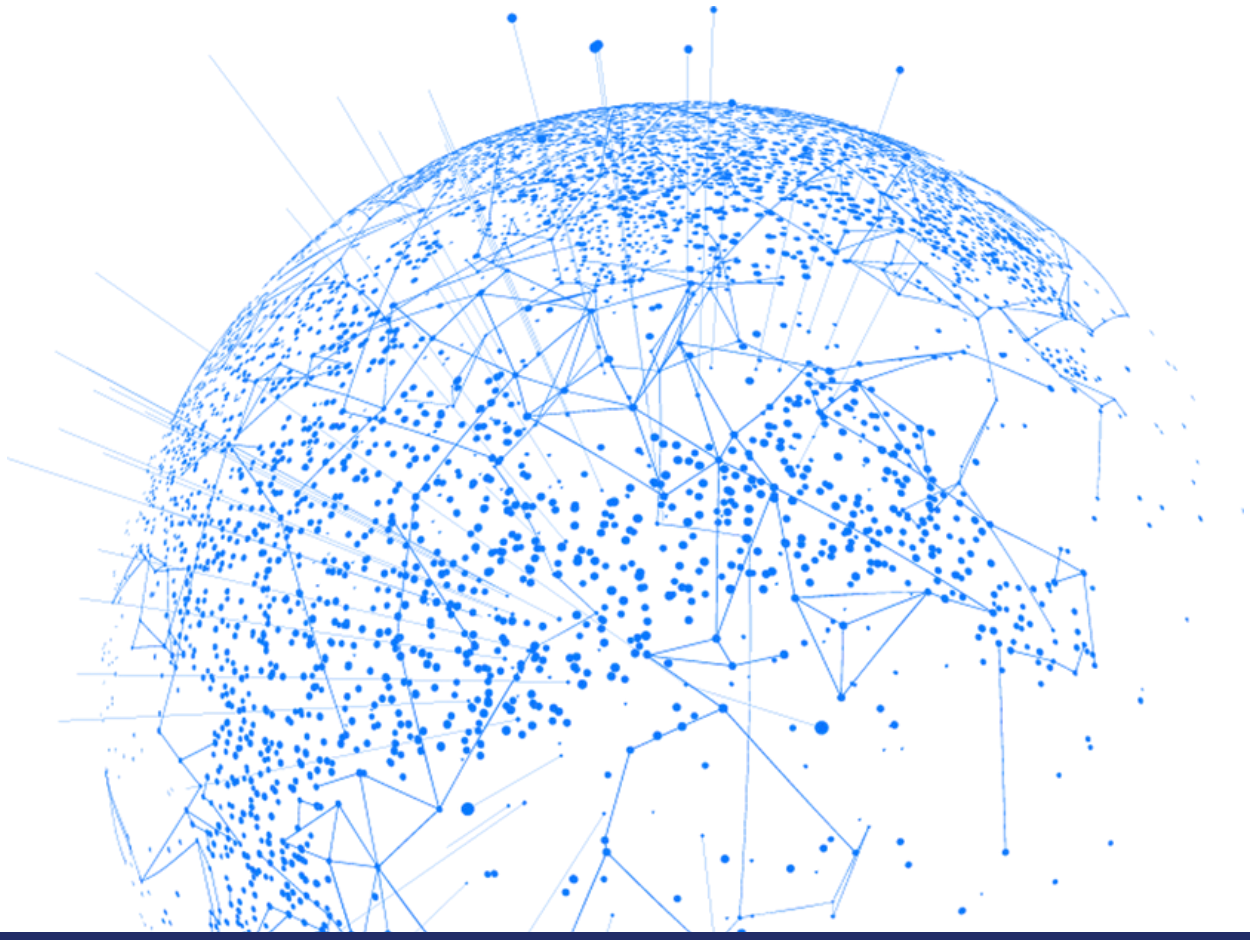
Day 2 (Thursday, September 19, 2024)	
9:00 – 10:40 AM	**SESSION 4: GENERATIVE AI FOR REGULATORY APPLICATIONS** **Co-Chairs: Dr. Kern Rei Chng (Singapore Food Agency); Dr. Dongying Li (U.S. FDA)**
9:00 – 9:20 AM	***LLMs Task Force Review: Lessons Learned and Future Challenges*** **Mr. Alexander Horst,** Data Scientist, Swissmedic 4.0, Swissmedic, Switzerland; **Mr. Michael Renaudin**, Lead Swissmedic 4.0, Swissmedic, Switzerland
9:20 – 9:40 AM	***Harnessing Generative AI for Sense-Making of Foodborne Outbreak Investigation Reports*** **Mr. Benjamin Er**, Team Lead of Food Safety Analytics & Epidemiology, Singapore Food Agency (SFA), Singapore
9:40 – 10:00 AM	***Revolutionizing Pharmaceutical Regulatory Policy Reporting: A Case Study on Harnessing Digitalization and Regenerative AI for Maximizing Efficiency*** **Dr. Anna Litsiou**, Director of International Regulatory Policy & Intelligence, International Regulatory Affairs, AstraZeneca, United Kingdom
10:00 – 10:20 AM	***AskFDALabel: Enhancing Drug Reviewers' Experience with Large Language Model in Daily Missions*** **Dr. Leihong Wu**, Research Scientist, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), United States
10:20 – 10:40 AM	***Collaborative Innovation: Unveiling a Use Case from Our Collabathon*** **Dr. Nicolas Perez**, Data Scientist, Swissmedic, Switzerland
10:40 – 11:00 AM	***BREAK***
11:00 AM – Noon	**SESSION 5: EXPERT OPINIONS - IS REGULATORY SCIENCE READY FOR AI?**
	Moderator: **Dr. Weida Tong**, Director of Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration (FDA), United States **Panel:** **Dr. Thomas Hartung**, Director of the Center for Alternatives to Animal Testing (CAAT), Johns Hopkins University, United States **Dr. Maurice Whelan**, Deputy Director for Health and Food, Head of the Systems Toxicology Unit, European Commission Joint Research Centre (EC-JRC), EU
12:00 – 1:30 PM	***LUNCH BREAK***
1:30 – 2:50 PM	**SESSION 6: USE CASES AND DEMONSTRATION** **Co-Chairs: Ms. Laila Sofia Mouawad (Brazilian Health Regulatory Agency); Mr. Michael Renaudin (Swissmedic)**
1:30 – 1:50 PM	***SafetAI Initiative: Harnessing AI for Enhanced Drug Safety Assessment for Liver Injury*** **Dr. Shraddha Thakkar,** Senior Research Scientist, Project Manager, Principal Investigator, Office of Translational Sciences (OTS), Office of Computational Sciences (OCS), Division of

	Regulatory Review & Research (DRRR), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, United States
1:50 – 2:10 PM	***Introducing TKPlate – Food Safety Without Animal Testing?*** **Dr. Didier Verloo**, Head of Knowledge Innovation and Partnership Management Unit (KNOW), European Food Safety Authority (EFSA), Italy
2:10 – 2:30 PM	***Automating the Surveillance of Products on the Internet: EPINET Tool*** **Mrs. Mariana Adelheit Von Collani**, Enforcement Advisor, Brazilian Health Regulatory Agency (ANVISA), Brazil
2:30 – 2:50 PM	***Streamline Clinical Review of Drug Application with a Widely Used Tool by Global Regulatory Agencies*** **Dr. Wenjun Bao**, Chief Scientist and Director of Advanced Analytics R&D, JMP Statistical Discovery, SAS Institute, Inc., United States
2:50 – 3:10 PM	***BREAK***
3:10 – 4:50 PM	**SESSION 7: DIGITAL TECHNOLOGIES – NOVEL APPLICATIONS** **Co-Chairs: Dr. Tammy Collins (Burroughs Wellcome Fund); Dr. Catherine Carrillo (Canadian Food Inspection Agency)**
3:10 – 3:30 PM	***Digital Innovations for Drug Review at the U.S. Food and Drug Administration*** **Dr. Lilliam Rosario**, Director of the Office of Computational Science (OCS), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA), United States
3:30 – 3:50 PM	***Data Science and Machine Learning in Microbial Omics: Standardization, Applications, and Challenges*** **Dr. Julie Chih-yu Chen**, Head of Data Sciences, Bioinformatics Section, National Microbiology Laboratory Branch, Public Health Agency of Canada (PHAC), Canada
3:50 – 4:10 PM	***Working Better Together – From Data Harmonization to Data Integration*** **Dr. William Hsiao**, Associate Professor, Simon Fraser University (SFU), Canada
4:10 – 4:30 PM	***ML/AL Based Allergenicity Prediction of Novel Food*** **Dr. Norimasa Tamehiro**, Section Chief of Division of Biochemistry, National Institute of Health Sciences (NIHS), Japan
4:30 – 4:50 PM	***Application of Deep Learning Convolutional Neural Networks to Identify Gastric Squamous Cell Carcinoma in Mice*** **Dr. Zhi Lin**, Deputy Director of Pathology Department of National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control (NIFDC), China
4:50 – 5:10 PM	**ANNOUNCEMENT OF GSRS25 AND CLOSING REMARKS** • **Mr. Michael Renaudin, Swissmedic, Switzerland** • **Dr. David Strauss, U.S. FDA Acting Chief Scientist**
5:30 – 7:30 PM	**CLOSING RECEPTION (Drinks and hors d'oeuvres at Museum of Discovery)**



Thank You

Thanks to all attendees and those who made GSRS24 a success!

https://gcrsr.net/2024-gsrs/

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