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

Little Rock Marriott, Little Rock, AR, USA
September 18-19, 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)
	8:00 AM: Registration Open	8:00 AM: Registration Open
	8:30 AM – 9:00 AM: WELCOME REMARKS • GCRSR chair & U.S. FDA/NCTR Director • Arkansas Governor (TBC) • U.S. FDA Commissioner	9:00 AM – 10:40 AM: SESSION 4 Theme: Generative AI for Regulatory Applications • 20min/talk; 5 talks
10:00 AM: 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 – 11:00AM	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 – 4:50 PM: SESSION 3 Theme: Challenges and Opportunities of AI/ML in Regulatory Science • 20min/talk; 4 talks	3:10 PM – 4:50 PM: SESSION 7 Theme: Digital Technologies – Novel Applications • 20min/talk; 5 talks
	5:10 PM – 5:30 PM: Break	4:50 PM – 5:10 PM: CLOSING REMARKS 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 1 (Wednesday, September 18)	
8:30 – 9:00 AM	**Welcome Remarks by GCRSR Chair Dr. Weida Tong and U.S. FDA/NCTR Director Dr. Tucker Patterson** • **The Honorable Sarah Huckabee Sanders, Governor of Arkansas (TBC)** • **Dr. Robert M. Califf, U.S. FDA Commissioner**
9:00 – 12:00 PM	**SESSION 1 (PLENARY SESSION): GLOBAL LANDSCAPE OF DIGITAL TECHNOLOGY IN REGULATORY SCIENCE** **Co-Chairs: Dr. Tucker Patterson (U.S. FDA); Ms. Elaine Johanson (U.S. FDA)**
9:00 - 9:30 AM	***Transforming the Future of Regulatory Science*** **Ms. Elaine Johanson**, Director, Health Informatics Staff, Office of Data, Analytics, & Research (ODAR), U.S. Food and Drug Administration (FDA), USA
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 & 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 – 12:00 PM	***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	***Trustworthy AI for Public Health Decisions Making: Is There Consensus on Evaluating & Documenting AI Tools Used by Authorities*** **Dr. Claudius Griesinger**, Member of the Leadership Team of the JRC's project portfolio on "Innovation in Life and Health Sciences," European Commission Joint Research Centre (EC-JRC), EU
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, USA
2:10 – 2:30 PM	***Harnessing the Value of Digital Health Technologies in Clinical Development*** **Dr. Jie Shen**, Director of Digital Science, AbbVie, USA
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 – 4:50 PM	**SESSION 3: CHALLENGES AND OPPORTUNITIES OF AI/ML IN REGULATORY SCIENCE** **Co-Chairs: Dr. Maurice Whelan (European Commission-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 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, USA
5:30 – 7:30 PM	**Poster Presentations (Drinks and hors d'oeuvres)**

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Day 2 (Thursday, September 19)	
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	***Presentation Title (TBD)*** Speaker from Health Canada (TBD)
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, US FDA, USA
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 – 12:00 PM	**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, US FDA, USA **Panel:** **Dr. Thomas Hartung**, Director of the Center for Alternatives to Animal Testing (CAAT), Johns Hopkins University, USA **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	***Navigating Innovation in a Regulatory Agency – A Management Perspective*** **Dr. Philippe Girard**, Vice Director, Head of Medicinal product licences and surveillance, Swissmedic, Switzerland

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, USA
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	***Bridging Hybrid AI and Digital Measures: Innovating from Preclinical Research to Clinical Trials*** **Dr. Szczepan Baran**, Chief Scientific Officer, VeriSIM Life, USA
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**
5:30 – 7:30 PM	**Closing Reception (Drinks and hors d'oeuvres at Museum of Discovery)**