6th Annual CERSI Innovations in Regulatory Science Summit

Poster List

Poster #	Poster Title	Presenting Author (Institution)
1	Mixed methods study to inform the development of a data-driven relapse risk detection tool for opioid use disorder	Jennifer Goldsack (Digital Medicine Society)
2*	Determinants of Opioid Use Disorder Relapse from the Biopsychosocial Perspective: A Systematic Review	Lauren Lederer (Duke)
3*	Developing A Digitally Derived Tool To Support The Prevention Of Relapse In Opioid Use Disorder: Pilot Study Protocol	Lauren Lederer (Duke)
4*	Sex-differences in respiratory and locomotor effects in response to xylazine.	Madigan Bedard (UNC Chapel Hill)
5	Safe AI-Enabled Digital Health Technologies Need Built-In Open Feedback	Stephen Gilbert (TUD Dresden University of Technology)
6*	Balancing Innovation and Safety: A Pathway to Regulating LLM-based Health Applications	Oscar Freyer (TUD Dresden University of Technology)
7*	Evaluating Over a Decade of FDA Breakthrough Therapy Designations: Approval Timelines and Evidence	Maximilian Siebert (Harvard-MIT Center for Regulatory Science)
8*	Comparison of Pediatric Labels Among New Drugs Approved in the United States and South Korea	Ahhyung Choi (Harvard-MIT Center for Regulatory Science)
9*	GenAI-Assisted GMP Quality Documentation Generation and Review	Jay Chen (UIUC /HVL)
10*	FDA Authorization of Therapeutic Devices Under the Breakthrough Devices Program, 2016-2024	Kushal Kadaki (Harvard Medical School)
11	In vitro-in vivo correlation of amorphous solid dispersion-enabled itraconazole tablets	James Polli (University of Maryland)
12	Applying Real-World Data and Real-World Evidence for Accelerated Approvals and Coverage Decisions	Nora Emmott (Duke-Margolis Institute for Health Policy)
13	Pilot Testing a Knowledge, Attitudes, and Practices Survey to Evaluate Community Pharmacists' Perspectives on Opioid Overdose Prevention and Treatment	Tamera Hughes (UNC Eshelman School of Pharmacy and Fred Wilson School of Pharmacy)
14	Understanding ABC transporters to navigate human diseases	Ruchika Bajaj (UCSF)
15*	An Ideal Design for Augmenting Randomized Controlled Trial with External Data	Sky Qiu (UC Berkeley)
16*	Constructing adverse event timelines for patients receiving CAR-T therapy using large language models	Jordan Guillot (UCSF)
17*	Associations between Laboratory Results and Mortality in Patients with Metabolic Dysfunction-Associated Steatohepatitis (MASH) by Diabetes and Antihypertensive Drug Status.	Jordan Guillot (UCSF)
18*	Real-world outcomes of patients with metabolic dysfunction-associated steatohepatitis (MASH) compensated cirrhosis at a large academic referral center	Jordan Guillot (UCSF)
19	Accelerating 510(k) Predicate Device Selection Using Large Language Models and Data Visualization	Xiao He (RegHero AI)
20*	Inclusion of Diverse Study Populations Across the Life Cycle of High-Risk Cardiovascular Devices	Claudia See (UCSF)

* denotes trainee poster

Poster #	Poster Title	Presenting Author (Institution)
21*	Disparities associated with CAR-T Therapy Access for Multiple Myeloma Patients	Jaysón Davidson (UCSF)
22*	Causal Inference and Adaptive Design for Evaluating Effectiveness of Medical Tests and Devices	Wenxin Zhang (UC Berkeley)
23*	The relationship between county-level racial economic segregation and low birthweight in California: an ecologic study	Hyelee Kim (UCSF)
24*	“Why Did the AUC Drop?” A Hierarchical Framework to Explain Performance Changes of Machine Learning Models across Hospital Sites	Harvineet Singh (UCSF)
25*	Portable Eye Examinations in the Oncology Clinic: An Innovative Pilot for Clinical Trial Screening	Renee Landzberg (UCSF)
26*	Assessing the Quality and Timeliness of Results Reporting for Clinical Trials on Antimicrobial Agents	Megan Curtin (UC Berkeley)
27	Factors Considered in the Causality Assessment of Adverse Drug Events: An Analysis of US FDA Regulatory Documents	Sarah Tanveer (Stanford University)
28*	How do individuals choose medicated eye drops for Eye Allergies?: A discrete choice experiment	Laura Formosa (UCSF)
29	Harmonizing Safety and Speed: A Human-Algorithm Approach to Enhance the FDA's Medical Device Clearance Policy	Omar Robles (Emerging Health LLC)
30	Streamlining the Consent and Enrollment Process for Clinical Trials: The I-SPY 2 Trial Screening Prototype	Samantha Wakerlin (UCSF)
32	OneSource AI: I-SPY2 TRIAL Whole Image Scan (WIS), Biomarker and Clinical Data Repository supporting Machine Learning and High Compute Analyses	Fred Howard (University of Chicago, Department of Medicine)
33*	The Impact Of Structured Pathology Reporting On Clinical Care And Research	Millicent Warner (UCSF)
34	OneSource Breast Care Center HL7 Vulcan Interoperability Bridge (VIB) Pilot: Integrating Clinical Care and Research using FHIR Schedule of Activities (SoA)	Adam Asare (UCSF/Quantum Leap Healthcare Collaborative)
35*	Implementation of a Complex Biomarker for Assessing Response to Treatment and Enabling Treatment De-escalation in the I SPY 2 TRIAL	Marcello Pajoh Casco (UCSF)
36*	Optimizing Data Collection To Enhance Clinic Workflows	Millicent Warner (UCSF)
37*	USCDI+ for research ready data	Ali Abbasi (UCSF)
38*	Degree and Certainty of Response to Treatment – A Framework for Aligning Patient, Clinician, and Regulatory Decision-Making Around Accelerated Approval in the Neoadjuvant Setting for High-Risk Breast Cancer	Keli Santos-Parker (UCSF)

* denotes trainee poster