

## Innovations in Regulatory Science Summit | Posters | January 11, 2026

#	Title	Presenting Author (Affiliation)
1	Scaling Medical Device Regulatory Science Using Large Language Models	Jean Feng (UCSF)
2	Assessing Temporal Trends in Editing Patterns of AI Scribe Drafts	Augusto Garcia-Agundez (UCSF)
3	Pediatric Use of Novel Drugs Approved by the US FDA from 2011 to 2023 According to Pediatric Labeling Status	Mahnum Shahzad (Harvard Medical School)
4	Manufacturer Perspectives on Predetermined Change Control Plans for AI/ML-Enabled Medical Devices: A Qualitative Study of Early Adoption	Stephan Buch (Dresden Univ of Technology)
5	Autonomy and Scope in AI-Enabled Medical Devices: Mapping the Terrain for Regulatory Adaptation	Oscar Freyer (Dresden Univ of Technology)
6	The Need for a Captain of the Ship: Europe's Medical Device Regulation Stakeholders are Calling for a Central MedTech EU Agency - How Should that Look?	Anett Schoenfelder (EKfZ for Digital Health, TU Dresden)
7	Hospitals as AI Factories - Comparison of In-house Medical Device Manufacturing in the US and Europe	Anett Schoenfelder (EKfZ for Digital Health, TU Dresden)
8	Regulatory Science Framework for Drug Development	Anna-Marika Bauer (Critical Path Institute)
9	Pitfalls and Solutions of Composite Endpoints: Simulated Performance of a Hierarchical Composite Outcome and Gated Endpoint Assessment of the I-SPY ARDS Phase 2 Platform Trial	Derek W. Russell (Univ of Alabama at Birmingham)
10	The Integrated Patient Journey: Leveraging Automation and Visualization to Create a Single Source of Truth in Oncology	Kylie Juan (UCSF)
11	Re-engineering Adverse Event Capture in Phase 2 Oncology Trials: A Structured, Point-of-Care Framework to Improve Data Quality and Reduce Documentation Burden	Adam Asare (UCSF / Quantum Leap Healthcare)
12	Gene Regulation Underlying Chemotherapy-Induced Peripheral Neuropathy	Thu Pham (UCSF)
13	An AI-enabled Analysis of the Influence of Regulatory Commenting on FDA's Real-World Data/Real-World Evidence Guidances	Susan Chong (Amgen)
14	AI-Powered, Age-Sensitive Engagement Elevates Recruitment & Retention of Older Adults in Alzheimer's Disease Trials	Tran Le (Grove AI)
15	Prediction of Solvent Penetration Rate-limited Release of Drug from Amorphous Solid Dispersion Discs of Various Geometries	James Polli (Univ of Maryland)
16	Impact of M-CERSI Workshops on Drug and Biologics Development and Assessment: Physiologically Based Biopharmaceutics Modeling Example	James Polli (Univ of Maryland)
17	Evidence-Based Dosing in Pregnancy: Leveraging Prescribing Patterns and PBPK Simulations to Prioritize Drugs for PK Evaluation	Brooke Langevin (Univ of Maryland School of Pharmacy)
18	Real-world Practice Patterns of IDH Inhibitors and Outcomes of On-label IDH Inhibitor Use for Acute Myeloid Leukemia in the US	Chenyu Lim (Duke Univ)
19	Patient-Reported Outcome Measure Recall Periods for Symptoms and Dysfunction in Temporomandibular Disorders: A Targeted Literature Review	Jennifer Cavender (Univ of North Carolina)
20	Patterns and Periodicity of Jaw Pain in Temporomandibular Disorders: A Patient Survey	Jennifer Cavender (Univ of North Carolina)
21	Variability of Real World Utilization in Buprenorphine Dosing	Jennifer Cavender (Triangle CERSI)
22	Prevalence of Dosage Modifications and Impact on Response Milestone Among Patients with CML Treated with Imatinib Using RWD	Benyam Muluneh (Univ of North Carolina - School of Pharmacy)
23	Implementing the Principal Stratum Strategy for Intercurrent Events with Survival Outcomes: A Tutorial	Susan Halabi (Duke Univ)
24	Integrating New Approach Methodologies into Regulatory Science: Evidence Generation through Virtual Imaging Trials	Ehsan Samei (Duke Univ)
25	Supporting Quality, Relevance, and Reliability Upon EHR-Sourced Data Accrual	Nora Emmott (Duke-Margolis Institute for Health Policy)
26	Proposed Areas of International Harmonization of RWE Relevance, Reliability, and Quality Standards Among Medical Product Regulators	Molly Shields (Duke-Margolis Institute for Health Policy)
27	Evolving Regulatory Paradigms: Streamlining Biosimilar Development Through Integrated Evidence	Mwango Kashoki (Parexel International)

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28	Feasibility of using Real World Data to Evaluate the Efficacy of Infliximab in Rheumatoid Arthritis Patients that Switch from Originator to Biosimilar	Eric Roberts (Division of Rheumatology, UCSF)
29	Feasibility of using Real World Data to Monitor Biosimilar Use: Patterns of Infliximab Biosimilar Uptake for Medicare, Medicaid, and Private Insurance from 2016 to 2022	Eric Roberts (Division of Rheumatology, UCSF)
30	Provider Counseling on Disposal and Patient Disposal Practices for Dental Opioid Prescriptions: Findings from the Acute Pain Pathways Study	Erfan Taherifard (Yale Univ)
31	The FDA Sentinel Initiative and Postmarket Drug Safety Surveillance: Challenges and Opportunities	Erfan Taherifard (Yale Univ)
32	Drug and Country Characteristics Associated with Global Access to FDA-Approved Novel Drugs between 2008 and 2019	Mengyuan Fu (Yale Univ)
33	Real-World Effectiveness of a Prescription Digital Therapeutic for Chronic Insomnia: Results from the Multicenter SLEEP-I Randomized Trial	Rohini Ghosh (Yale Univ)
34	Developing an AI-Based Model Using Noninvasive Biomarkers to Classify Liver Fibrosis Stages in Patients with Metabolic Associated Steatohepatitis (MASH)	Jordan Guillot (UCSF/Gilead)
35	Impact of Consumer Chemicals on Neuron Health Using hPSC-based Models	Kalyan Sankar (UCSF, Fattahi Lab)
36	Toward Automated Regulatory Decision-Making: AI-assisted Medical Device Risk Classification with Multimodal Transformers and Self-Training	Yu(Angie) Han (Univ of Oxford)
37	Standard Applicability Judgment and Cross-jurisdictional Reasoning: A RAG-based Framework for Medical Device Compliance	Yu(Angie) Han (Univ of Oxford)
38	AI-Driven Optimization of ECM and Stiffness for Donor-Specific Manufacturing of Mesenchymal Stromal Cells (MSCs)	Gaoxian Chen (Stanford CVI)
39	Orthogonal Contributions of Genetic, Clinical, and Environmental Risk Factors on Alzheimer's Disease Pathogenesis	Meri Okorie (UCSF)
40	Characterization of GABA Transporters in the Human Blood-Brain Barrier	Eric Ding (UCSF)
41	Adverse Event Reporting and Inappropriate Shocks Associated with the Subcutaneous Implantable Cardioverter Defibrillator Device	Denzel McCray (UCSF)
42	Post-Market Surveillance for AI-Driven Medical Devices: A Robust Framework for Detecting Algorithmic Drift in Complex Clinical Data	Siyu Zhou (UCSF)
43	Not All Clinical AI Monitoring Systems Are Created Equal: Review and Recommendations	Fan Xia (UCSF)
44	Association Between Expedited Regulatory Programs, Clinical Benefit, and Commercial Demand in Oncology	Benjamin Strauss (Patient Square Capital)
45	Global Clinical Trends of Microneedle Array Patches (MAPs): Focusing on Therapeutic Applications and Drug-Device Combination	Seunghyuk Shin (Dongguk Univ)
46	Real-world Predictors of Adverse Clinical Outcomes in Pancreatic Cancer Using a Machine-learning Framework	Akanksha Dua (UCSF)
47	Pre-Announced vs. Unannounced FDA Drug Inspections: How Surprise Visits Change Enforcement Outcomes	Yelena Ionova (Redica Systems)
48	Reasons for Lack of Complete Reprogramming One Year Following Medtronic Recall	Yimeng Li (Univ of California, San Francisco School of Medicine)
49	The Commissioner's National Priority Voucher Program (CNPV) at the FDA: Early Experience in Program Design and Implementation	Sree Vidya Manur (KLA Breakthrough Consultancy)
50	Regulatory and Regenerative Medicine Pathways: A Comparative Analysis of the US, Japan, and South Korea	Soobin Moon (Dongguk Univ)
51	Schema-Constrained AI for Automated Pharmacovigilance: From Unstructured Narratives to Regulatory-Ready ICH E2B(R3) Cases	Tara Pande (UCSF)
52	Graph Edit Distance Travelled in Hit-to-Candidate Trajectories	Amit Elia (UCSF)