



Session#	Session Title	UAN	Activity Type	PDU#
104	Reporting of Pre-Market and Post-Market Safety Reports to FDA Adverse Event Reporting System (FAERS) Using ICH E2B R3 Standards	0286-0000-24-518-L04-P	Knowledge	
105	The Intersection of Science, Ethics, and Participant Collaboration in Pediatric Rare Disease Product Development	0286-0000-24-519-L04-P	Knowledge	
106	Machine Learning and Simulations to Facilitate Clinical Trials	0286-0000-24-520-L04-P	Knowledge	
107	Cloud-Driven Transformation: Empowering Pharma Industry and Regulators	0286-0000-24-521-L04-P	Knowledge	
108	Risk Management in Advanced Device Technology Development	0286-0000-24-522-L04-P	Knowledge	
109	GCP Renovation: How Will GCP Inspection Change in Europe, Japan, and the US?	0286-0000-24-523-L04-P	Knowledge	
110	Modernizing CDER's New Drugs Review Program (NDRP): A Progress Update	0286-0000-24-524-L04-P	Knowledge	
111	China Town Hall	0286-0000-24-525-L04-P	Knowledge	
112	Regulatory Convergence for CMC Requirements: The Challenges and Benefits of a Single Global Dossier	0286-0000-24-526-L04-P	Knowledge	
113	Master Protocols: Integrating and Debating Clinical Trial Designs	0286-0000-24-527-L04-P	Knowledge	
114	Breaking Boundaries: Overcoming Policy Crosstalk and Globalization Barriers to Foster Innovation	0286-0000-24-528-L04-P	Knowledge	
116	Navigating the Trusted, Responsible, and Ethical Horizon of Artificial Intelligence: Uniting Healthcare Perspectives	0286-0000-24-529-L04-P	Knowledge	
130	Interactive Safety Graphics in the Regulatory Decision-Making Process	0286-0000-24-530-L04-P	Knowledge	
131	Innovative Approaches to the Design of Pediatric Development Programs: What's New in the Use of Pediatric Extrapolation	0286-0000-24-531-L04-P	Knowledge	

132	The Cost of Moving the Needle on Clinical Trial Representation: Strategies for Diversity Budget Planning and Resourcing	0286-0000-24-532-L04-P	Knowledge	
133	ICH M11 Protocol Template: A Global Solution for Global Drug Development	0286-0000-24-533-L04-P	Knowledge	
134	Shifting Medical Writing Value Propositions with the Use of Technology Tools	0286-0000-24-534-L04-P	Knowledge	
135	Enhancing the Science of Patient Engagement and Patient Input: What's in the Future?	0286-0000-24-535-L04-P	Knowledge	
136	In Vitro Diagnostic/Companion Diagnostics Developments in the US and Impact on Global Programs	0286-0000-24-536-L04-P	Knowledge	
137	Options to Consider When Balancing Risk, Timelines, Cost, and Patient Centricity While Meeting Project Optimus Guidelines	0286-0000-24-537-L04-P	Knowledge	2166YE3LVS
138	Having the End in Mind When Building Quality into Clinical Trials: A Regulatory and Industry Perspective	0286-0000-24-538-L04-P	Knowledge	
139	Comparative Perspectives on Regulating AI in Drug Development: US Versus EU	0286-0000-24-539-L04-P	Knowledge	
140	The State of Real-World Evidence for Regulatory Decision-Making: Views from FDA, EMA, and PMDA	0286-0000-24-540-L04-P	Knowledge	
141	Innovation in Manufacturing Globally	0286-0000-24-541-L04-P	Knowledge	
142	Causal Inference Methodology in Drug Development	0286-0000-24-542-L04-P	Knowledge	
144	Paradigm Shift in Adverse Event Report Management and Sharing: The Case, The Need, and Possible Ways Forward	0286-0000-24-543-L04-P	Knowledge	
145	Selective Safety Data Collection: As a Tool to Advance Clinical Trial Designs	0286-0000-24-544-L04-P	Knowledge	
146	Past, Present, and Future: How Industry and FDA are Handling the Evolving Clinical Trial Diversity Regulatory Landscape	0286-0000-24-545-L04-P	Knowledge	
147	Data and Technology Influence on ICH Initiatives: M4Q(r2)/Q12 and Global Harmonization	0286-0000-24-546-L04-P	Knowledge	
148	Navigating the Regulatory Landscape: Real-World Data and Real-World Evidence in Regulatory Documents	0286-0000-24-547-L04-P	Application	
149	Effective Patient / Industry Collaboration: Valuing Patient Lived Experience To Inform Trial Design	0286-0000-24-548-L04-P	Knowledge	
150	Building Trust in New Alternative Methods in Investigational New Drug Applications	0286-0000-24-549-L04-P	Application	
151	Elevate Leadership: Harnessing the Five Superpowers	0286-0000-24-550-L04-P	Knowledge	2166LI6KQZ
152	Innovative Alternative Approaches to Evaluating GCP During the COVID-19 Public Health Emergency and Beyond	0286-0000-24-551-L04-P	Knowledge	

153	Designing your Regulatory Intelligence Framework: Powered by Artificial Intelligence and Critical Thinking	0286-0000-24-552-L04-P	Knowledge
154	Impact of Accelerated Pathways on Patients in Five Countries/Regions	0286-0000-24-553-L04-P	Knowledge
155	Health Canada Town Hall	0286-0000-24-554-L04-P	Knowledge
156	Data Insight Generation: Leveraging Data Visualization in Study Planning, Monitoring, Exploration, Reporting, and Submission	0286-0000-24-555-L04-P	Knowledge
201	Considerations for Identification of Drug-Induced Liver Injury	0286-0000-24-556-L04-P	Knowledge
202	Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BE SAFE)	0286-0000-24-557-L04-P	Knowledge
203	Feasible Site Feasibility Assessments: Rethinking Business as Usual to Reduce Burden, Timelines, and Costs for Sustainability	0286-0000-24-558-L04-P	Knowledge
204	Wearable Sensors and Digital Health Technologies for Tracking Neurological and Neuromuscular Disorders	0286-0000-24-559-L04-P	Knowledge
205	Data Standards SOS: Reducing Burnout and Navigating Through Fatigue - Part 1	0286-0000-24-560-L04-P	Knowledge
206	Early Engagement to Enhance the Incorporation of Patient Experience Data in Drug Development Programs and Regulatory Decision-Making	0286-0000-24-561-L04-P	Knowledge
207	Early Experience with EU In Vitro Diagnostics Regulation: Performance Study Applications	0286-0000-24-562-L04-P	Knowledge
208	Good Data Governance Practices: Regulatory and Industry Perspectives	0286-0000-24-563-L04-P	Knowledge
209	Leveraging New Meeting Opportunities in PDUFA VII: Experiences with Type D and INTERACT	0286-0000-24-564-L04-P	Knowledge
210	Digital Biomarkers as Clinical Endpoints: The Road to Regulatory Acceptability	0286-0000-24-565-L04-P	Knowledge
211	PMDA Town Hall	0286-0000-24-566-L04-P	Knowledge
212	Supporting Regulatory Convergence and Reliance Through a Pharmaceutical Quality Knowledge Management Capability	0286-0000-24-567-L04-P	Knowledge
213	Beyond Traditional Trials: Real-World Data for External Controls, with Focus on Cancer Drug Applications	0286-0000-24-568-L04-P	Knowledge
218	Long-Term Safety of Approved Medicines: Approaches for Identifying, Characterizing, and Quantifying Delayed Adverse Events	0286-0000-24-569-L04-P	Knowledge
219	How to Compare FDA Medical Queries and Standardized MedDRA Queries with Interactive Graphics	0286-0000-24-570-L04-P	Knowledge
220	Targeting Shared Molecular Etiologies to Accelerate Drug Development for Rare Diseases	0286-0000-24-571-L04-P	Knowledge

221	Improving Patient Access to Clinical Trials Through Decentralization and Flexible Design: Lessons from Oncology	0286-0000-24-572-L04-P	Knowledge
222	External Control Arms at Scale: Multicenter, Multisource Infrastructure for External Control Arms	0286-0000-24-573-L04-P	Knowledge
223	Challenges in Exceeding the Quality of Existing Endpoints and Approaches Using Digital Tools	0286-0000-24-574-L04-P	Knowledge
224	Data Standards SOS: Reducing Burnout and Navigating through Fatigue - Part 2	0286-0000-24-575-L04-P	Knowledge
225	Regulatory Guidance and Papers on Technology Innovations	0286-0000-24-576-L04-P	Knowledge
226	Effective Patient Engagement in Patient Experience Data: Practical Insights from Case Studies in Hard-to-Reach Populations	0286-0000-24-577-L04-P	Application
227	How to Ensure Compliance in a Changing Regulatory Environment: A Regulators Perspective	0286-0000-24-578-L04-P	Knowledge
228	Access Consortium and Project Orbis: Experiences from Industry and Regulatory Authorities and Recommendations for Improvement	0286-0000-24-579-L04-P	Knowledge
229	Clinical Trial Enrollment Diversity: Why and How to Engage Community Health Centers	0286-0000-24-580-L04-P	Knowledge
230	International Regulatory Convergence: Regulatory Science to Address Challenges Brought by Pharmaceutical Innovation	0286-0000-24-581-L04-P	Knowledge
244	Evidence Generation to Support Regulatory Decision-Making: Shift of the Trend over Time	0286-0000-24-582-L04-P	Knowledge
245	The European Clinical Trials Environment Under the Accelerating Clinical Trials (ACT EU) Initiative: Two Years On	0286-0000-24-583-L04-P	Knowledge
246	The State of Clinical Trials in 2024: Are We Making the Grade?	0286-0000-24-584-L04-P	Knowledge
247	Bridging Randomized Clinical Trials and Real-World Data Utilizing Data Linkage and Tokenization	0286-0000-24-585-L04-P	Knowledge
248	The Evolving Role of Artificial Intelligence in the Medicinal Product Lifecycle	0286-0000-24-586-L04-P	Knowledge
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251	Enabling Patient Access Worldwide Including Japan or Other Countries to Innovative Drugs Through Global Development Strategy	0286-0000-24-589-L04-P	Knowledge

252	Ensuring Inspection Readiness for Clinical Trials Using Decentralized Clinical Trial Design Features	0286-0000-24-590-L04-P	Knowledge	
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265	Practical Approaches and Resources to Optimize Advocacy Group - Industry Collaborations: An Update on the PALADIN Consortium	0286-0000-24-597-L04-P	Knowledge	
266	Exploiting Real-World Data From Social Media in Patient-Focused Drug Development	0286-0000-24-692-L04-P	Knowledge	
267	Evolution of Electronic Product Information in LATAM: Challenges and Opportunities to Improve the Value of Healthcare	0286-0000-24-599-L04-P	Knowledge	
268	Strategies to Make your Clinical Trials More Inclusive for Patients with Disabilities	0286-0000-24-600-L04-P	Knowledge	
269	For Whom the Cell Tolls: Ethics in the Era of Precision Medicine	0286-0000-24-601-L04-P	Knowledge	
270	Something Borrowed Something New for Effective Project Management: Adopting Different Thinking Approaches and New Technologies in Life Science Project Management	0286-0000-24-602-L04-P	Application	2166XALVLX
271	How Will the Increasing use of Real-World Evidence for Regulatory Decision-Making Impact QA Strategies and GCP	0286-0000-24-603-L04-P	Knowledge	
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273	How to Provide Necessary Medicinal Products to Children?	0286-0000-24-605-L04-P	Knowledge	
274	Regulatory Policy Roundtable: Pharmaceutical Quality, Generics, Innovative Medicines	0286-0000-24-606-L04-P	Knowledge	
275	Securing the Chain: US and EU Legislative Reforms and Regulatory Actions for Drug Shortage Mitigation	0286-0000-24-607-L04-P	Knowledge	
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277	FDA's Approach in Harmonize Surveillance for Drugs and Biologics Safety and Quality Data	0286-0000-24-609-L04-P	Knowledge	

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279	Accelerating Innovation Through Design: Integrating Real-World Data into Clinical Trials	0286-0000-24-611-L04-P	Knowledge	
280	Innovation, Agility, and Accessibility in Trial Execution: Exploring the Roles, Pathways, and Potential for Integration of Embedded Clinics, Retail Pharmacies, and Diagnostic Providers in Clinical Research at Scale	0286-0000-24-693-L04-P	Knowledge	
281	Harnessing Real-World Evidence in Regulatory Decision-Making: Update on DARWIN EU, Use of Real-World Evidence in New Applications in the EU	0286-0000-24-613-L04-P	Knowledge	
282	Shame and Blame: Our Words are a Barrier to Clinical Research are a Care Option	0286-0000-24-614-L04-P	Knowledge	
283	The Value of Project Management in Driving Drug Discovery Success: A Comparison Between Small Versus Large Pharmaceutical Companies	0286-0000-24-615-L04-P	Knowledge	2166M3MMI2
284	Collaboration in an Expanding Regulatory Landscape for Pharmacovigilance	0286-0000-24-616-L04-P	Knowledge	
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286	Recent Evolution of Accelerated Approval Pathways: Impacts on the Pathways Use and Implementation	0286-0000-24-618-L04-P	Knowledge	
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289	Post-COVID cGMP Inspections by Global Regulatory Authorities	0286-0000-24-620-L04-P	Knowledge	
290	Charting the Biosimilars Beat Drop: The Latest Updates in the Biosimilars Landscape, Coverage, and Adoption in the US	0286-0000-24-621-L04-P	Knowledge	
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302	Have a Safe Trip: Clinical and Patient Alignment in Clinical Trials with Psychedelics	0286-0000-24-623-L04-P	Knowledge	
303	How Common Data Models Can Address the Challenges in the Use of Clinical Trial and Real-World Data for Evidence Generation	0286-0000-24-624-L04-P	Knowledge	
304	Synergizing Large Language Models and Digital Health Technology for Healthcare Transformation	0286-0000-24-625-L04-P	Knowledge	
305	All the Ways Medical Affairs Supports Product Development: From Clinical Trials to Product Launch	0286-0000-24-626-L04-P	Knowledge	
306	Which Clinical Outcome Assessment to Choose: Questionnaire or Sensor? Time to Align an Endpoint Selection Framework	0286-0000-24-627-L04-P	Knowledge	

307	Partnering with Regulatory Authorities to Unlock the Value in Digital Health Products	0286-0000-24-628-L04-P	Knowledge	
308	Unlocking Innovation: Implementing Future-Focused Risk-Based Quality Management Quality Briefs - A Cross-	0286-0000-24-629-L04-P	Application	
309	FDA Oncology Center of Excellence: Are Sponsors Taking Full Advantage of OCE Regulatory Policy “Projects?”	0286-0000-24-630-L04-P	Knowledge	
310	WHO Town Hall: Safeguarding Public Health - WHO's Vision for Global Regulatory Excellence	0286-0000-24-631-L04-P	Knowledge	
311	Australia, Canada, Singapore, Switzerland, and United Kingdom Consortium (Access): Re-Imagining Regulatory Collaboration	0286-0000-24-632-L04-P	Knowledge	
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313	The Future of Women’s Health: Do We Really Want Innovation? Policy Ideas To Advance Innovation, Access, and Novel Approaches	0286-0000-24-634-L04-P	Knowledge	
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325	A Paradigm Shift in Global Regulatory Reviews: Has the New Normal Arrived?	0286-0000-24-643-L04-P	Knowledge	
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346	A Clinical Research Workforce in Crisis: Imperatives for a Sustainable Staffing Model	0286-0000-24-649-L04-P	Knowledge
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348	Challenges and Solutions to Building the Right Patient-Centered Evidence to Support Fit-For-Purpose Sensor-Based Outcomes	0286-0000-24-651-L04-P	Knowledge
349	Study Design for Cell and Gene Therapy Trials: Regulatory Overview, Challenges, and Updates	0286-0000-24-652-L04-P	Knowledge
350	ICH Efforts to Incorporate Patient's Perspective to Enhance Quality, Relevance, Safety and Efficacy of Drug Development	0286-0000-24-653-L04-P	Knowledge
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352	Applying Machine Learning and Artificial intelligence for Predicting Product Profile Approvability (PoPPA)	0286-0000-24-655-L04-P	Application
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354	ICMRA Post-Pandemic: Regulators Looking into the Future	0286-0000-24-657-L04-P	Knowledge
355	Unlocking the Puzzle of Borrowing Adult Data for Designing Innovative Hybrid Pediatric Trials	0286-0000-24-658-L04-P	Knowledge
359	A Safety Surveillance Plan for Serious Anticipated Events	0286-0000-24-659-L04-P	Knowledge
360	More than Meets the Eye: AI's Potential to Identify Skin Manifestations of Internal Disease in Patients of Color	0286-0000-24-660-L04-P	Knowledge
361	Recruitment Optimization in Clinical Trials: Looking Towards an Adaptive Future	0286-0000-24-661-L04-P	Knowledge
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365	Embedding Diversity and Inclusion into Global Clinical Research: Where Have we Been and Where are we Going?	0286-0000-24-665-L04-P	Knowledge	
366	The Intersection of Patient-Experience Data and Benefit-Risk Analysis	0286-0000-24-666-L04-P	Knowledge	
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412	Unleashing Biopharma Potential: Maximizing Consortia Engagement with Strategic Change Management	0286-0000-24-687-L04-P	Knowledge	21664WZFGG
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