Session #	Session Title	UAN	Activity Type	PDU
100	Opening Plenary: Revolutionizing Life Sciences - How Diversity, Innovation, and Artificial Intelligence are Accelerating the Future of Health	0286-0000-23-669-L04-P	Knowledge	
101	Artificial Intelligence: Delivering on the Promise	0286-0000-23-510-L04-P	Knowledge	
102	Risk-Based Monitoring in Clinical Trials: A Four-Year Analysis	0286-0000-23-511-L04-P	Knowledge	
103	Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials	0286-0000-23-512-L04-P	Knowledge	
104	Inspired by Big-Tech and Humbled by Complexity of Clinical Research: Clinical Trial Digital Transformation	0286-0000-23-513-L04-P	Knowledge	
105	What's in the Future for Global Advancements in Patient Engagement and Patient-Focused Medical Product Development?	0286-0000-23-514-L04-P	Knowledge	
106	New Alternative Methods-Only IND/CTA Application: Distant Dream or Immediate Possibility?	0286-0000-23-515-L04-P	Knowledge	
107	Moving Into and Advancing In a Project Management Career	0286-0000-23-516-L04-P	Knowledge	
108	Data Analytics for Quality Assurance: Shifting the Paradigm from Issue Detection to Quality Evidence Generation	0286-0000-23-517-L04-P	Knowledge	
109	Cell and Gene Therapies Pulse Check	0286-0000-23-518-L04-P	Knowledge	
110	Disruptive Medicine Innovation: Combination Products	0286-0000-23-519-L04-P	Knowledge	
111	E9(R1) Implementation: Practical Applications of Using Estimands in Protocols, SAPs, Data Standards and Examples of use of Estimands	0286-0000-23-520-L04-P	Knowledge	
112	Applying Implementation Science Methods to Generate Evidence to Improve Access to New Therapeutics: What has Been Learned?	0286-0000-23-521-L04-P	Knowledge	
114	Navigating the Constellation of Efforts to Increase Representation in Clinical Research	0286-0000-23-522-L04-P	Knowledge	
125	Enhancing the Quality of Safety Data Collection	0286-0000-23-523-L04-P	Knowledge	
126	Can We Further Innovate Clinical Trial Designs? Lessons Learned and Future Opportunities	0286-0000-23-525-L04-P	Knowledge	
127	Patient-Reported Outcome Measures to Support Oncology Clinical Development and Labeling: Responding to FDA's Draft Guidance	0286-0000-23-524-L04-P	Knowledge	
128	Building Trust: Data Privacy in Decentralized Clinical Trials	0286-0000-23-527-L04-P	Knowledge	
129	Innovative Digital Health Technologies: Strategies for Successful Integrations, Quality, and Compliance	0286-0000-23-526-L04-P	Knowledge	
130	On the Path to Enlightened Conversations : Setting up Structured Content Authoring	0286-0000-23-672-L04-P	Knowledge	
131	Beyond the Why: How to Effectively Implement a Patient-Led Approach to Clinical Trial Design and Conduct	0286-0000-23-529-L04-P	Knowledge	
132	Contemporary Challenges in Personalized Medicine and Companion Diagnostics	0286-0000-23-530-L04-P	Knowledge	
133	Unleashing the Fearless Quality Professional	0286-0000-23-531-L04-P	Knowledge	
134	Accelerated Approval in Rare Diseases: The Role of Novel Biomarker, Surrogate Endpoints, and Other Innovative Approaches in Expediting Development	0286-0000-23-533-L04-P	Knowledge	
135	Combating Misinformation with Authoritative Medical Product Information	0286-0000-23-532-L04-P	Knowledge	
136	WHO Town Hall: The New Era of WHO Listed Authorities (WLAs), Reliance in Action, and Country and Regional Focus for Regulatory Systems Strengthening	0286-0000-23-534-L04-P	Knowledge	
137	International Collaboration for Pharmaceutical Quality and Manufacturing Agility	0286-0000-23-535-L04-P	Knowledge	
138	Advances in Real-World Evidence: Real-World Data Hybrid Randomized Clinical Trials, Publication Scandal, and China's Real-World Evidence Heaven	0286-0000-23-536-L04-P	Knowledge	
139	Do Surrogate Endpoints Expedite or Hinder Payer Coverage of Drugs?	0286-0000-23-537-L04-P	Knowledge	
149	Utilizing Wearable Biosensors to Better Manage Patient Safety During Immuno-Oncology Studies	0286-0000-23-538-L04-P	Knowledge	
150	Enabling the Use of Randomized Pragmatic Studies to Generate High Quality Real-World Evidence for Regulatory Decisions	0286-0000-23-540-L04-P	Knowledge	
151	What Patients and Care Partners are Saying about Hybrid and Decentralized Trials	0286-0000-23-539-L04-P	Knowledge	
152	Digital Endpoints in Clinical Trials: Qualifications, Collaborations, and Risk-Based Approaches	0286-0000-23-541-L04-P	Knowledge	
153	The True Decentralization of Clinical Trials: Benefits and Drawbacks of Blockchain Technology	0286-0000-23-542-L04-P	Knowledge	
154	Best Practices in Effective Gathering of Medical Information Industry Insights	0286-0000-23-543-L04-P	Knowledge	
156	What's Next in Precision Medicine? Translational Strategies for Dose Optimization in the Age of Project Optimus	0286-0000-23-545-L04-P	Knowledge	
157	IMPALA (IntercoMPany quALity Analytics) Industry Consortium: Quality Analytics Use Cases and Early Health Authority Feedback	0286-0000-23-546-L04-P	Knowledge	
158	Emerging Therapies and Technologies: Leveraging Opportunities for Engaging in Pre-Competitive Research and with Medicine Regulators to Support Innovation	0286-0000-23-548-L04-P	Knowledge	
159	The Promise of Vaccine Platforms to Advance Regulatory Science: Where are we Now, Where are we Going, and How do we get There?	0286-0000-23-547-L04-P	Knowledge	
160	Regulatory Cooperation, Coordination, and Reliance in Times of Crisis: The ICMRA Role	0286-0000-23-549-L04-P	Knowledge	
161	Challenges in Analytical Development of Cell and Gene Therapy Products, Regulatory Perspectives, and Convergence	0286-0000-23-550-L04-P	Knowledge	
162	Supporting Providers in Value-Based Contracts: Machine Learning and Recursive Neural Networks for Outcomes and Treatment Journey Optimization	0286-0000-23-551-L04-P	Application	
201	Completing the Risk Management Cycle: Review of Risk Management Effectiveness	0286-0000-23-552-L04-P	Knowledge	
202	Innovating Patient Recruitment Through Pharmacy Channels	0286-0000-23-553-L04-P	Knowledge	
203	Ethical Considerations for Conducting Research During Times of Disruption	0286-0000-23-554-L04-P	Knowledge	
204	ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP): Enabling Consistency and Information Exchange	0286-0000-23-555-L04-P	Knowledge	
205	The Case for Generating Synthetic Data as Real-World Data: Regulatory and Planning Perspectives	0286-0000-23-556-L04-P	Knowledge	
206	Innovation Across Medical Affairs Throughout the Global Pandemic	0286-0000-23-557-L04-P	Knowledge	
207	Utilizing Analytics, Visualizations, and Decision Science to Drive Strategic Decision Making	0286-0000-23-558-L04-P	Application	2166VKTHSS
208	NMPA Town Hall	0286-0000-23-604-L04-P	Knowledge	
209	International Regulatory Convergence and Collaboration	0286-0000-23-559-L04-P	Knowledge	
210	Pediatrics and the Paradox of Progress: What's New, What's Next, What's Needed?	0286-0000-23-560-L04-P	Knowledge	
211	Office of Generic Drugs/Office of Pharmaceutical Quality Town Hall	0286-0000-23-561-L04-P	Knowledge	
212	Full Exposure: Artificial Intelligence to Advance, Replace, and Add Efficiency for Patient Benefit	0286-0000-23-562-L04-P	Knowledge	
216	Benefit-Risk Balance for Medicinal Products: CIOMS Working Group XII Report	0286-0000-23-563-L04-P	Knowledge	
217	Good Recruitment Practice Under Regulation (EU) No 536/2014	0286-0000-23-564-L04-P	Knowledge	
218	The Future of Regulatory Submissions: Opportunities and Challenges	0286-0000-23-565-L04-P	Knowledge	
219	Medical Storytelling Inserted Into All Aspects of Medical Affairs	0286-0000-23-566-L04-P	Knowledge	
220	Disrupting the Status Quo: Best Practices for Bringing Together Patients and Medical Staff to Positively Impact Trial Diversity	0286-0000-23-567-L04-P	Knowledge	
221	The Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) Collaboratory: Facilitation of Medical Product Development for Rare Diseases	0286-0000-23-568-L04-P	Knowledge	
222	How to Make Good Decisions Quickly	0286-0000-23-569-L04-P	Knowledge	21662KBZUN

223	One Year On: How Quality Briefs are Transforming the Approach to Quality and Driving Innovation to Serve Patients	0286-0000-23-570-L04-P	Knowledge	
224	Time for Alignment? A Policy Landscape Update on the Use and Acceptance of Real-World Data/Real-World Evidence for Regulatory Purposes	0286-0000-23-573-L04-P	Knowledge	
225	Post-Pandemic Regulatory Innovation for Clinical Trials and Opportunities for Global Alignment	0286-0000-23-572-L04-P	Knowledge	
226	Patient Experience Data in the Label: Closing the Loop	0286-0000-23-571-L04-P	Knowledge	
227	ANVISA Townhall	0286-0000-23-574-L04-P	Knowledge	
228	A Regulatory Pharmaceutical Quality Knowledge Management System to Improve the Availability of Quality Medicines	0286-0000-23-575-L04-P	Knowledge	
229	The Full Picture: Innovative Software Tools for data Insight Generation and Exploration	0286-0000-23-576-L04-P	Knowledge	
230	Is Mark Cuban Really Solving the Drug Pricing Problem?	0286-0000-23-577-L04-P	Knowledge	
242	Novel Methods for Signal Identification for Medicines and Medical Devices	0286-0000-23-578-L04-P	Knowledge	
243	Hot off the Press: Site Challenges and Solutions in Workforce and Technology	0286-0000-23-580-L04-P	Knowledge	
244	Meta-Collaboration to Improve Decentralized Trial Excellence: Updates from the Collaboration Landscape	0286-0000-23-579-L04-P	Knowledge	
245	Global Regulatory Perspectives About Real-World Data: DARWIN EU®, FDA, and Other Current Initiatives	0286-0000-23-581-L04-P	Knowledge	
246	Tech-Enabled Narratives: Technology Meets Process FTW (For the Win!)	0286-0000-23-582-L04-P	Knowledge	
247	Measuring Impact of Patient Engagement Across Research and Development	0286-0000-23-583-L04-P	Knowledge	
248	Agile Project Management Practitioners Tackle Challenges Within the Life Sciences	0286-0000-23-584-L04-P	Application	2166F24D3A
249	Pharmacovigilance: Regulator's Perspectives on Quality Approaches to Additional Risk-Minimization Measures and Post-Pandemic Inspection Reflections	0286-0000-23-585-L04-P	Knowledge	
250	Implementing Digital Health Technologies in Clinical Trials: How to Apply New Resources to Address Key Questions	0286-0000-23-586-L04-P	Knowledge	
251	Asia Town Hall	0286-0000-23-587-L04-P	Knowledge	
252	One Dossier and One Timeline for a Post Approval Change: The Story of a Regulatory Reliance Pilot!	0286-0000-23-588-L04-P	Knowledge	
253	Quality in the Real World: Identifying and Addressing Inaccuracies and Gaps in Routinely Collected Patient Data	0286-0000-23-589-L04-P	Knowledge	
254	The Inflation Reduction Act Price Setting: What are the Impacts on Biopharmaceutical Innovation from Different Perspectives?	0286-0000-23-590-L04-P	Knowledge	
267	Negotiating your Way Through the Vigilance Agreement Maze: Is There a Better Way?	0286-0000-23-591-L04-P	Application	
268	Smarter Approaches to Pharmacovigilance Challenges	0286-0000-23-592-L04-P	Knowledge	
269	The Many Faces of In-Trial Interviews: Navigating Operational and Scientific Waters to Optimize Value for Clinical Trials	0286-0000-23-593-L04-P	Knowledge	
270	SMART-on-FHIR: Integrating Electronic Health Records as Real-World Data	0286-0000-23-595-L04-P	Knowledge	
271	IDMP Standards, Structured Submissions, and Data Harmonization Methods: How Will Your Company be Impacted?	0286-0000-23-594-L04-P	Knowledge	
272	On the Path to Enlightened Conversations: Implementing Structured Content Authoring (Part 2)	0286-0000-23-596-L04-P	Knowledge	
273	An Assessment of the Challenges Associated with Cell and Gene Therapies: Are Digital Health Technologies the Way Forward?	0286-0000-23-597-L04-P	Knowledge	
274	Modernizing Clinical Trials: A Regulatory Perspective	0286-0000-23-598-L04-P	Knowledge	
275	PMDA Town Hall	0286-0000-23-600-L04-P	Knowledge	
276	Globally Accelerating the Drive to eLabeling for All	0286-0000-23-599-L04-P	Knowledge	
277	Quality and CMC Aspects of Recent US Legislation: Challenges and Opportunities	0286-0000-23-601-L04-P	Knowledge	
278	Patient-Preferences and Multistate Models to Enhance Patient-Focus of Traditional Endpoints in Oncology	0286-0000-23-602-L04-P	Knowledge	
279	Improving Patient Access with Real-World Evidence: A Framework for Coverage and Formulary Decisions	0286-0000-23-603-L04-P	Knowledge	
301	Using Real-World Data to Evaluate Safety Signals	0286-0000-23-606-L04-P	Knowledge	
302	Pharmacovigilance in Africa: Nigeria and Ghana Health Authorities Share their Perspectives	0286-0000-23-605-L04-P	Knowledge	
303	Returning Individual Participant Data: A Cultural and Operational Shift Towards Personalized Clinical Trial Options	0286-0000-23-607-L04-P	Knowledge	
304	The Rapidly Changing Landscape of Data Collection and its Implications for Clinical Data Management	0286-0000-23-609-L04-P	Knowledge	
305	Real-World Data Quality: Components and Considerations of Data Sources Used for Regulatory Decision-Making	0286-0000-23-608-L04-P	Knowledge	
306	Writing Summary Documents for Rare Disease Submissions: Unique Challenges	0286-0000-23-610-L04-P	Knowledge	
307	Leveraging Project Management Skills for Significant Drug Development Deliverables	0286-0000-23-611-L04-P	Application	21662LVCDU
308	Strategies for Benefit-Risk Analysis in Regulatory Submissions	0286-0000-23-612-L04-P	Application	
310	A Case Study for Illumined Therapeutic Development: Shining the Light on ALS	0286-0000-23-613-L04-P	Knowledge	
314	Registries Aren’t Always the Answer: Novel Designs for Executing Post-Market Pregnancy Requirements	0286-0000-23-614-L04-P	Knowledge	
315	Opportunities to Improve Risk Minimization Outcomes with Behavioral Science	0286-0000-23-615-L04-P	Knowledge	
316	Best Practices for Managing Rare Disease Trials in Latin America as an Emerging Region	0286-0000-23-616-L04-P	Knowledge	
317	Leveraging Data Scientists and Data Managers in Clinical Data Management	0286-0000-23-618-L04-P	Knowledge	
318	Operationalizing Real-World Data: Methods, Acceptance, and Future Hopes	0286-0000-23-617-L04-P	Knowledge	
319	Is the Hype Real? Real-Life User Experience of Medical Writing Artifcial Intelligence Tools for Clinical Study Reports Production	0286-0000-23-619-L04-P	Knowledge	
320	Combining Qualitative and Quantitative Research to Generate Within-Patient Meaningful Changes in Clinical Outcome Assessments	0286-0000-23-620-L04-P	Knowledge	
321	What Can ICH Bring to the Future of Model-Informed Drug Development (MIDD)?	0286-0000-23-621-L04-P	Knowledge	
322	PI 1572 Responsibility and Oversight in Decentralized Clinical Trials	0286-0000-23-622-L04-P	Knowledge	
323	25-Years After FDAMA: How is FDA Applying the Confirmatory Evidence Standard for Substantial Evidence of Effectiveness?	0286-0000-23-624-L04-P	Knowledge	
324	Dose Optimization in Oncology: How Do we Tackle the Tricky Topic of Combinations?	0286-0000-23-623-L04-P	Knowledge	
325	Health Canada Town Hall	0286-0000-23-625-L04-P	Knowledge	
326	Reliance in Action: How to Ensure Product Sameness When Using Global Supply Chains	0286-0000-23-626-L04-P	Knowledge	
327	Patient-Focused Drug Development in Rare Disease Endpoint Selections	0286-0000-23-627-L04-P	Knowledge	
328	How Real-World Data from Wearable Biosensors and Artificial Intelligence (A)I-Based Analytics Is Enabling the Shift from Efficacy to Effectiveness	0286-0000-23-628-L04-P	Knowledge	
339	Operationalizing FDA Medical Queries	0286-0000-23-629-L04-P	Knowledge	
340	Regulatory Insights into Decentralized Clinical Trials	0286-0000-23-630-L04-P	Knowledge	
341	Managing BYOD and Wearables in Clinical Trials: Sustainable Data Collection	0286-0000-23-632-L04-P	Knowledge	
342	Real-World Data Standards and Protocol Designs for Information Exchange and Data Flow	0286-0000-23-631-L04-P	Knowledge	

343	Introduction to Estimands and Incorporation of the Estimand Framework in Protocols	0286-0000-23-633-L04-P	Knowledge	
344	Capturing the Patient Voice Using Longitudinal Qualitative Research Methods in Medical Product Development	0286-0000-23-634-L04-P	Knowledge	
345	Fostering Cross-Functional Team Success by Leveraging Project Management and Alliance Management Best Practices	0286-0000-23-635-L04-P	Application	2166M07XQD
346	Industry and Regulators' Experience with the Implementation and Use of Remote and Electronic Consent	0286-0000-23-636-L04-P	Knowledge	
347	FDA Rare Disease Town Hall	0286-0000-23-638-L04-P	Knowledge	
348	The Future of Biosimilar and Interchangeable Biologics: Global Development, Harmonization, and the Inflation Reduction Act	0286-0000-23-637-L04-P	Knowledge	
349	Evolving Global Landscape for Addressing Drug Shortages: Innovative Technology and Regulatory Strategies	0286-0000-23-639-L04-P	Knowledge	
350	Opportunities and Issues with Existing Analytical Technologies for Safety Monitoring of Ongoing Clinical Studies	0286-0000-23-640-L04-P	Knowledge	
351	Real-World Data: Maximizing Value and Quality Through End-to-End Patient Centricity	0286-0000-23-641-L04-P	Knowledge	
362	Assessing Safety in Rare Disease and Gene Therapy	0286-0000-23-642-L04-P	Knowledge	
363	Modernizing the Clinical Trials Environment in Europe: ACT EU and the New EU Clinical Trial Regulation	0286-0000-23-644-L04-P	Knowledge	
364	Can Pragmatic Trials Simultaneously Meet the Needs of Regulators, Payers, and Clinical Care?	0286-0000-23-643-L04-P	Knowledge	
365	Ethics-by-Design: Embedding Ethics into Uses of Data and Artificial Intelligence in the Pharmaceutical Industry	0286-0000-23-645-L04-P	Knowledge	
366	Patient-Generated Health Data and Real-World Evidence: How Can They Be Used to Accelerate Patient Engagement and Diversity?	0286-0000-23-646-L04-P	Knowledge	
367	Leading Cross-Functional Teams Through Mergers, Divestments, and Acquisitions	0286-0000-23-647-L04-P	Knowledge	2166X466JM
368	Quality by Design for Real-World Evidence Studies	0286-0000-23-648-L04-P	Knowledge	
369	Mobilizing Cooperation with the African Medicines Agency	0286-0000-23-650-L04-P	Knowledge	
370	Regulatory Reliance: Addressing Gaps to Harmonize and Enhance Uptake Globally	0286-0000-23-649-L04-P	Knowledge	
371	ICH Work to Harmonize Requirements for Safe and Effective Medicines: What's in It for Patients?	0286-0000-23-651-L04-P	Knowledge	
372	Patient and Quality Impacts of Restrictions on the Use of Titanium Dioxide (TiO2) in Medicines	0286-0000-23-652-L04-P	Knowledge	
373	From 1000's of Tables to Summarizing and Interactively Exploring Clinical Trials Data	0286-0000-23-653-L04-P	Knowledge	
401	Implementing the Program Safety Analysis Plan and Enhancing Ongoing Aggregate Review with an Interactive Open-Sourced Tool	0286-0000-23-654-L04-P	Knowledge	
402	Reverse-Engineering Digital Endpoints to Improve Trial Design and Expand Diversity and Access	0286-0000-23-655-L04-P	Knowledge	
403	Effective Use of Intelligent Automation in Clinical and Regulatory	0286-0000-23-656-L04-P	Knowledge	
404	Implementation of the New EU Clinical Trials Regulation	0286-0000-23-657-L04-P	Knowledge	
405	CIOMS: What it Does and the Guideline on Patient Involvement in the Development, Regulation, and Safe Use of Medicines	0286-0000-23-659-L04-P	Knowledge	
406	The Value of Patient-Centric Communication Strategies	0286-0000-23-658-L04-P	Knowledge	
407	Crafting the Message: Driving Drug Development Through Compelling Governance Interactions	0286-0000-23-660-L04-P	Knowledge	2166T5FW06
408	FDA Sponsor Interaction: Best Practices and New PDUFA Formal Meetings	0286-0000-23-662-L04-P	Knowledge	
409	ACCESS Consortium: What's Next?	0286-0000-23-663-L04-P	Knowledge	
410	International Medical Device Regulators Forum (IMDRF) and Technological Innovation: How International Medical Device Harmonization is Impacting Drug Strategy	0286-0000-23-661-L04-P	Knowledge	
411	Demystifying Statistical Concepts for ANYONE Involved with Clinical Trials	0286-0000-23-664-L04-P	Application	
412	Reporting of Pre- and Postmarket Safety Reports to FDA Adverse Event Reporting System (FAERS) Using ICH E2B Standards	0286-0000-23-665-L04-P	Knowledge	
413	The Other Side of the Table: Drug Development Professionals Share Their Experiences Participating as Patients in Trials	0286-0000-23-666-L04-P	Knowledge	
414	Process Automation and Artificial Intelligence in the Field: Practical Applications	0286-0000-23-667-L04-P	Knowledge	
415	Statistical Applications of Machine Learning (ML) and Artificial Intelligence (AI) in Drug Development and Success Stories of Application	0286-0000-23-668-L04-P	Knowledge	
416	EMA-FDA Question Time	0286-0000-23-670-L04-P	Knowledge	
417	FDA Town Hall	0286-0000-23-671-L04-P	Knowledge	