Session #	Session Title	ACPE UAN	Type of Activity	PMI#
100	Opening Plenary: The Future of Healthcare	0286-0000-22-660-L04-P	Knowledge	
108	Support of IND Safety Reporting by the Aggregate Safety Assessment Plan (ASAP)	0286-0000-22-511-L04-P	Knowledge	
109	Risk-Based Monitoring in Clinical Trials: An Evolution of Practices During the COVID Pandemic	0286-0000-22-512-L04-P	Knowledge	
110	Adaptive Designs Save Time and Money: Regulatory Agencies Accept Them - Why Aren't They Used More?	0286-0000-22-513-L04-P	Knowledge	
111	The Role of Sensors in Clinical Research: Integrating Sensor Generated Data into Data Platforms to Power Clinical Research and Patient Care	0286-0000-22-514-L04-P	Knowledge	
112	ICH Q2 (R2) and Q14: Can We Realize the Vision for Risk-Based Approvals of Analytical Procedures and Changes?	0286-0000-22-521-L04-P	Knowledge	
114	Data Integrity Across the Product Lifecycle	0286-0000-22-515-L04-P	Application	
115	Scientific Communication During a Pandemic: The Ethics of Ensuring Accuracy and Combatting Misinformation	0286-0000-22-516-L04-P	Knowledge	
116	Incorporating Patient Experience Data in Global R&D	0286-0000-22-517-L04-P	Knowledge	
117	The Translational Value of Animal Models in Rare Diseases	0286-0000-22-518-L04-P	Application	
118	Real-World Evidence Frameworks Across the World: Three International Perspectives	0286-0000-22-519-L04-P	Knowledge	
119	Is it Time to Change the Accelerated Approval Pathway?	0286-0000-22-520-L04-P	Knowledge	
120	Practical Applications of the Estimand Framework in Novel, Complex Settings	0286-0000-22-522-L04-P	Application	
121	Identifying Value and Driving Access to Drug-Based Products Evaluated Using Digital Endpoints	0286-0000-22-523-L04-P	Application	
131	Innovations for Implementing REMS	0286-0000-22-524-L04-P	Knowledge	
132	ICH E2D Update: Innovations in Collecting Safety Data from Disparate Sources	0286-0000-22-525-L04-P	Knowledge	
133	New Tools for Creating Flexible and Sustainable Master Protocols	0286-0000-22-526-L04-P	Knowledge	
134	FDA Update on the Upcoming PDUFA VII Data and Technology Commitment	0286-0000-22-527-L04-P	Knowledge	
135	Demystyfing the Delivery of Healthcare Economic Information (HCEI) by Medical Affairs and Market Access Personnel	0286-0000-22-528-L04-P	Knowledge	
136	Developing and Implementing a Strategic Framework to Guide Patient Engagement	0286-0000-22-529-L04-P	Knowledge	
137	Successful Virtual Partnering	0286-0000-22-530-L04-P	Knowledge	2166OXQND7
138	ICH E8(R1): Regulators' Perspectives on Quality-by-Design of Clinical Studies	0286-0000-22-531-L04-P	Knowledge	
139	FDA and EMA Benefit-Risk Assessments: Can We Optimize and Is There an Enhanced Role for Sponsors and Patient Preferences?	0286-0000-22-532-L04-P	Knowledge	
140	ICMRA: COVID-19 Response and International Collaboration	0286-0000-22-534-L04-P	Knowledge	
142	The Future of CMC Regulatory Submissions: Streamlining Activities Using Structured Content and Data Management	0286-0000-22-536-L04-P	Knowledge	
143	A Targeted Learning Framework for Causal Effect Estimation Using Real-World Data	0286-0000-22-537-L04-P	Knowledge	
144	Value of Patient Experience Data in Healthcare Decision-Making	0286-0000-22-538-L04-P	Knowledge	
201	Transforming PV at the MHRA	0286-0000-22-539-L04-P	Knowledge	

202	Innovations in Risk Minimization: Methods, Tools, and Design Approaches	0286-0000-22-540-L04-P	Knowledge	
203	The Site Landscape: Data and Discussion of the State of the Clinical Research Site	0286-0000-22-541-L04-P	Knowledge	
204	Diversity and Inclusion in Clinical Trials: Concrete Strategies for Enhancing Health Equity	0286-0000-22-542-L04-P	Knowledge	
205	Optimizing Evidence Supporting Fit-for-Purpose Digital Clinical Measures Across the Drug Development Life Cycle	0286-0000-22-543-L04-P	Knowledge	
206	The Future of Content Authoring and Web Portal Technology, Publishing Stability Calculators: Challenges for Pushing Automation	0286-0000-22-545-L04-P	Knowledge	
207	Enhancing Interactions Among Stakeholders to Advance Patient-Focused Drug Development: Landscape of Current Activities	0286-0000-22-546-L04-P	Knowledge	
208	Keeping Passion for Project Management Alive	0286-0000-22-548-L04-P	Knowledge	2166ITBO85
209	New EU Clinical Trial Regulation: Experience So Far	0286-0000-22-544-L04-P	Knowledge	
210	Challenges of Translational and Early-Phase ASO Development	0286-0000-22-547-L04-P	Knowledge	
211	Shifting the Audit Paradigm for a More Effective Outcome	0286-0000-22-549-L04-P	Knowledge	
212	Where Are We With Antimicrobial Resistance (AMR) in the Regulatory Space?	0286-0000-22-550-L04-P	Knowledge	
213	Reflections on PDUFA: A Look Back at PDUFA VI and A Preview of PDUFA VII	0286-0000-22-551-L04-P	Knowledge	
214	New Policy Developments in Combination Products	0286-0000-22-552-L04-P	Knowledge	
215	Efforts Toward Global Convergence of CMC and GMP Expectations	0286-0000-22-553-L04-P	Knowledge	
219	Post-Approval Safety Studies: Approaches to Assessing Medication Exposure and Potential Safety Risks During Pregnancy	0286-0000-22-554-L04-P	Knowledge	
220	Collection of Quality Endpoint Data in a Decentralized Trial in Complex Indications: The Practical and Logistical Challenges	0286-0000-22-597-L04-P	Knowledge	
221	Complying with the EU-CTR Disclosure Standards in the Era of GDPR	0286-0000-22-557-L04-P	Knowledge	
222	Patient-Focused Drug Development: Reflecting on a Decade of Insights	0286-0000-22-558-L04-P	Application	
223	Meeting Regulatory Expectations: What Needs to be Considered When Using Digital Technologies to Generate Clinical Evidence?	0286-0000-22-533-L04-P	Knowledge	
224	ICMRA Update: Convergence and Collaboration on COVID-19 - Learning from the Present for the Future	0286-0000-22-661-L04-P	Knowledge	
225	Solving for ‘Shared Value’ of Cell and Gene Therapy with Real-World Evidence in the Post-Pandemic Healthcare Ecosystem	0286-0000-22-563-L04-P	Application	
226	Simulating Trial Activities with Patients: Our Experiences	0286-0000-22-555-L04-P	Knowledge	
227	Approaching the Assessment of Clinical Protocol Complexity	0286-0000-22-556-L04-P	Application	
228	Individualized Therapeutics: Walking the Line Between Research and Treatment	0286-0000-22-559-L04-P	Knowledge	
229	Accelerating Cell and Gene Therapy Development Through International Regulator Collaboration	0286-0000-22-560-L04-P	Knowledge	
230	Asia Town Hall	0286-0000-22-561-L04-P	Knowledge	
231	Leveraging Real-World Evidence for Regulatory Purposes	0286-0000-22-562-L04-P	Knowledge	

232	Preparing for the Future of Research and Development: 10-years of Multistakeholder Innovation, Collaboration and Transformation	0286-0000-22-659-L04-P	Knowledge	
241	Drug Safety In Africa: New PV Horizons	0286-0000-22-564-L04-P	Knowledge	
242	Risk Minimization for Health Products: What are we Learning for an Improved Path Forward	0286-0000-22-565-L04-P	Knowledge	
243	Technology-Enabled Clinical Trials Using Electronic Health Record (EHR)-Derived Real-World Data: Opportunities and Limitations	0286-0000-22-566-L04-P	Knowledge	
244	Planning and Conducting Efficient, High-Quality Decentralized Trials: A Multi-Stakeholder Initiative	0286-0000-22-567-L04-P	Knowledge	
245	Understanding the Consumer's Journey for Information From Searching for Information to Using Information	0286-0000-22-570-L04-P	Knowledge	
246	Project Management Across the Healthcare Continuum	0286-0000-22-572-L04-P	Knowledge	2166M0HPR0
247	Paying for Digital Health: What Evidence is Needed?	0286-0000-22-578-L04-P	Knowledge	
248	Healthcare Datasets as Assets: Secure and Compliant Valuation and Transaction Methods	0286-0000-22-568-L04-P	Knowledge	
249	Regulatory-Grade Real-World Evidence: Distilling to Practice	0286-0000-22-569-L04-P	Knowledge	
250	Patients as Central Partners in COA Design	0286-0000-22-571-L04-P	Knowledge	
251	Data Science, Text Analytics, and Machine Learning to Derive Insights from Clinical Quality, Compliance, and Real-World Data	0286-0000-22-573-L04-P	Knowledge	
252	International Collaborations: What’s New in Oncology?	0286-0000-22-574-L04-P	Knowledge	
253	Efforts to Improve Diversity of Clinical Trial Participants	0286-0000-22-575-L04-P	Knowledge	
254	Overcoming Challenges in Pediatric Product Development	0286-0000-22-576-L04-P	Knowledge	
255	Demystifying Statistical Concepts for Non-Statisticians Involved with Clinical Trials	0286-0000-22-577-L04-P	Application	
266	FDA's Updates on Ensuring Post Market Safety and Surveillance for Generic Drugs	0286-0000-22-579-L04-P	Knowledge	
267	Improving Safety Data Through Innovative Use of Technology	0286-0000-22-580-L04-P	Application	
268	Life Science Research Innovation Powered by Real-World Data	0286-0000-22-581-L04-P	Application	
269	Strategic Planning in Selecting the Right Countries and Sites for Clinical Trials	0286-0000-22-582-L04-P	Knowledge	
270	Recommendations for Conducting Bring Your Own “Device” (BYOD) Clinical Studies	0286-0000-22-583-L04-P	Knowledge	
271	Building the First Cloud-Based Submission Review Collaboration Platform	0286-0000-22-584-L04-P	Knowledge	
272	Fit-for-Purpose Patient Preference Studies: Emerging Recommendations from IMI PREFER	0286-0000-22-585-L04-P	Knowledge	
273	IMPALA (IntercoMPany quALity Analytics) Industry Group: Data Science Development and Other Collaboration Updates	0286-0000-22-586-L04-P	Knowledge	
274	Regulatory Convergence Successes and Opportunities	0286-0000-22-587-L04-P	Knowledge	
275	How to Interact with Regulators to Qualify a Digital Mobility Outcome?	0286-0000-22-588-L04-P	Knowledge	
275.1	PMDA Town Hall	0286-0000-22-535-L04-P	Knowledge	
276	Rethinking Fundamental ICH CMC Guidelines: Analytical Procedures, Stability, Specifications, and Risk Assessment	0286-0000-22-589-L04-P	Knowledge	

277	Quantitative Benefit-Risk Approaches in Drug Development and Approval: Examples from FDA and Industry	0286-0000-22-590-L04-P	Knowledge	
278	FDA Real-World Evidence Guidance for Regulatory Approval: Implications for Evidence Needs for Payers and Population-Based Decision Makers and Healthcare Providers	0286-0000-22-591-L04-P	Knowledge	
301	Uses of Artificial Intelligence for PV in the Context of COVID 19	0286-0000-22-593-L04-P	Knowledge	
302	Mission-Driven Research Partners: How Patient Advocacy Organizations Can Help Advance Your Therapeutic R&D Programs	0286-0000-22-594-L04-P	Application	
303	Grappling with Uncertainty: Pediatric Gene Therapy Trials and Ethics	0286-0000-22-595-L04-P	Application	
304	Transformation of the Data Manager to the Data Scientist	0286-0000-22-596-L04-P	Knowledge	
305	What's New at ICH? From the E11A Pediatric Extrapolation Guideline to Model Informed Drug Development (MIDD)	0286-0000-22-599-L04-P	Knowledge	
306	Leveraging Best Practices & Tools from the Discipline of PM to Uphold Quality, Protect Patient Safety, & Optimize Financial Budgets in a World of Complexities	0286-0000-22-600-L04-P	Knowledge	216632V6LJ
307	Improve the Speed and Cost of Clinical Trials With Bayesian Approaches: Unpacked for Non-Statisticians	0286-0000-22-606-L04-P	Application	
308	Community and Patient Engagement: Putting Research into Context	0286-0000-22-598-L04-P	Knowledge	
309	Pharmacovigilance Quality: Key Considerations	0286-0000-22-602-L04-P	Knowledge	
310	BsUFA III and GDUFA III: Increasing FDA's Authority to Enhance Competition	0286-0000-22-603-L04-P	Knowledge	
311	Ahead of Analyses: Planning, Designing, and Pre-Specifying Observational Studies	0286-0000-22-604-L04-P	Knowledge	
312	COVID-19 360°: Embedding Global Best Practices in Routine Regulatory Action and Preparing for the Next Pandemic	0286-0000-22-605-L04-P	Knowledge	
313	China Town Hall	0286-0000-22-662-L04-P	Knowledge	
317	Let's Make a PV Agreement: Four Solutions You Can Use to Enhance Your Entire PVA Process	0286-0000-22-607-L04-P	Knowledge	
318	Rare Disease Data Sharing: A Value Proposition	0286-0000-22-608-L04-P	Knowledge	
319	Ensuring Diversity in Clinical Trials	0286-0000-22-609-L04-P	Knowledge	
320	De-Risking Decentralized: Understanding the Dimensions of Risk and Maximizing Data Quality in Decentralized Trials	0286-0000-22-610-L04-P	Knowledge	
321	FHIR in Clinical Research	0286-0000-22-611-L04-P	Knowledge	
322	Risky Business – The Sequel: Successfully Manage Program-Level Risk	0286-0000-22-614-L04-P	Application	2166KZRVD6
323	Remote GMP Assessments, Inspections and Audits: Here to Stay?	0286-0000-22-617-L04-P	Knowledge	
324	The Value of Medical Writing: The Regulator's Perspective, Development of Professional Medical Writers as Successful Leaders	0286-0000-22-612-L04-P	Knowledge	
325	Assessing and Integrating Patient Preferences into Treatment and Clinical Trial Design	0286-0000-22-613-L04-P	Knowledge	
326	China's Biopharma Innovation Landscape and Trends	0286-0000-22-601-L04-P	Knowledge	
327	New Approaches to Inspections	0286-0000-22-615-L04-P	Knowledge	

328	Approaches to Health Authority Collaboration: Are They Fit-for-Purpose and How Should They Evolve Post-Pandemic?	0286-0000-22-616-L04-P	Knowledge	
329	Complex Innovative Design: What's in Name? A Global Perspective on the Changing Design Landscape	0286-0000-22-618-L04-P	Knowledge	
330	Leveraging Real-World Evidence to Address Diversity Gaps in Randomized Clinical Trials: Regulatory, Clinical, and Other Considerations	0286-0000-22-619-L04-P	Knowledge	
340	Monitoring COVID-19 Vaccine Safety	0286-0000-22-620-L04-P	Knowledge	
341	New Approaches to Site Selection in Clinical Trials	0286-0000-22-621-L04-P	Knowledge	
342	Democratizing Data for Cancer Research and Real-World Evidence Generation	0286-0000-22-622-L04-P	Knowledge	
343	Redefining the Value Proposition for Innovation: Connecting Data, Technology, and Quality to Improve Outcomes	0286-0000-22-623-L04-P	Application	
344	Managing Up and Managing Down: Developing and Advocating for Your Medical Writing Team	0286-0000-22-624-L04-P	Application	
345	Statistical Issues in Master Protocols: Beyond Type I Error and Concurrent Controls	0286-0000-22-631-L04-P	Knowledge	
347	Enabling Digital Transformation in Health Care and Clinical Trials	0286-0000-22-592-L04-P	Knowledge	
348	Research and Innovation to Enhance Patient Access to Topical Dermatological Products in the US	0286-0000-22-625-L04-P	Knowledge	
349	The Power and Uncertainty of Data: How it Can be Used to Drive Efficiency While Recognizing its Limitations	0286-0000-22-626-L04-P	Knowledge	2166J2Y14T
350	The Transformation of Quality Assurance: The Roadmap	0286-0000-22-627-L04-P	Knowledge	
351	Health Canada Town Hall	0286-0000-22-628-L04-P	Knowledge	
352	FDA Rare Disease Town Hall	0286-0000-22-629-L04-P	Knowledge	
353	Planning for the Worst: Approaches for Drug Shortage Avoidance	0286-0000-22-630-L04-P	Knowledge	
354	How Can Population Decisions Makers and Pharmaceutical Companies Engage Collaborative Research?	0286-0000-22-632-L04-P	Knowledge	
365	Field of Dreams: If We Build it, Will they Come? Using Implementation Science to Improve Digital Risk-Minimization Tools	0286-0000-22-633-L04-P	Knowledge	
366	Development of Standard Core Sets of Clinical Outcome Assessments and Related Endpoints	0286-0000-22-634-L04-P	Knowledge	
367	Local Conduct for Global Clinical Trials: Focus on Japan, Latin America, and Africa	0286-0000-22-635-L04-P	Knowledge	
368	Sneak Peak: First Share from Initiatives of a Global Collaboration to Address Barriers to Decentralized Trial Scale and Adoption	0286-0000-22-636-L04-P	Knowledge	
369	Approaches to Addressing Diversity and Inclusion in Clinical Research	0286-0000-22-637-L04-P	Application	
370	Where Are we Really on Data Interoperability?	0286-0000-22-638-L04-P	Knowledge	
371	Reimbursement, Compensation, and Incentives: Best Practices for Payments to Research Participants	0286-0000-22-639-L04-P	Knowledge	
372	Accelerating Innovation Through Investing	0286-0000-22-640-L04-P	Knowledge	
373	Effective Oversight Strategies of CROs and Digital Technology Vendors: How to Comply with Health Authority Expectations	0286-0000-22-641-L04-P	Knowledge	
374	Around the World: Regulator Perspectives on Decentralized Clinical Trials	0286-0000-22-642-L04-P	Knowledge	

375	The Global Impact of ORBIS: Case Studies and Perspectives	0286-0000-22-643-L04-P	Application	
376	How to Manage Device Design Changes Under EU MDR	0286-0000-22-644-L04-P	Knowledge	
377	Choosing the Most Convincing Clinical Endpoints in Cancer Clinical Trials: How to Balance Different Perspectives?	0286-0000-22-645-L04-P	Knowledge	
378	US Health Care System Adoption of a Class of New Technologies for the Treatment of Alzheimer's Disease: Access Challenges and Opportunities	0286-0000-22-646-L04-P	Knowledge	
404	Combination Product Safety: A Journey of Organizational Transformation	0286-0000-22-647-L04-P	Knowledge	
405	How the Heck do I Get this Digital Endpoint to Work in my Clinical Trial? Nuts and Bolts for Trials Teams	0286-0000-22-648-L04-P	Knowledge	
406	The PCORnet Response to COVID-19: The Importance of Partnerships, Data, and Digital Innovations to Provide Fast Answers	0286-0000-22-649-L04-P	Knowledge	
407	Methodologies Used to Aggregate Real-World Data and Clinical Trial Data	0286-0000-22-650-L04-P	Knowledge	
408	Writing at Lightspeed: Optimizing Submission Dossiers in Today's Environment Through Better Processes, Planning, and Technology	0286-0000-22-651-L04-P	Knowledge	
409	How to Build and Support a Culture that Values Critical Thinking and Open, Proactive Dialogue About Quality	0286-0000-22-652-L04-P	Knowledge	
410	Addressing Gaps in the Use of Real-World Evidence for Regulatory Decision-Making	0286-0000-22-653-L04-P	Knowledge	
411	FDA Oncology Center of Excellence's Real-Time Oncology Review Program: 2022 Update	0286-0000-22-654-L04-P	Knowledge	
412	Novel Visualization Tools for Safety Assessment: An Initiative Based on Multidisciplinary Collaboration	0286-0000-22-655-L04-P	Knowledge	
413	Where Next? Targeting Value Assessment and Contracting Optimizing Adoption, Use, and Payment for Technologies and Therapies in Care	0286-0000-22-656-L04-P	Application	
415	EMA-FDA Question Time	0286-0000-22-657-L04-P	Knowledge	
416	FDA Town Hall	0286-0000-22-658-L04-P	Knowledge	