DIA 2021 Global Annual Meeting UAN and PMI Numbers

Session#	**Session Title**	**ACPE UAN**	**Type of Activity**	**PMI#**
100 SL	#100 DIA Global Annual Meeting - Opening DIAmond and Plenary Session	0286-0000-21-668-L04-P	Knowledge	
111 SL	COVID-19 Real-World Data Analysis and Vaccine Surveillance: Examples from FDA and The Danish Medicines Agency's Approaches	0286-0000-21-522-L04-P	Knowledge	
112 SL	Measuring Clinically Meaningful Change of Function: A Case Study of Patient-Centered Clinical Outcome Assessments in Early Parkinson's Disease	0286-0000-21-532-L04-P	Knowledge	
113 SL	Technology Changes Needed to Manage Drug Supply for Decentralized Trials	0286-0000-21-524-L04-P	Knowledge	
114 SL	Machine Learning Enabled Digital Data Flow and Advanced Real-World Evidence	0286-0000-21-525-L04-P	Knowledge	
115 SL	Patient-Centric Engagement Strategies	0286-0000-21-526-L04-P	Knowledge	
116 SL	Implicit Bias in Early Phase Clinical Trials: The Sociocultural Implications of Advancing the Science	0286-0000-21-527-L04-P	Knowledge	
117 SL	Leveraging Pharma Intelligence Data and Statistical Modeling to Inform Project Strategies	0286-0000-21-528-L04-P	Knowledge	21660EX90U
118 SL	Advanced Analytics, Cross-Industry Collaboration, and Data Sharing to Change the Paradigm in Clinical Quality	0286-0000-21-529-L04-P	Knowledge	
119 SL	FDA Perspectives on Modernization of Clinical Trials: Clinical Practice Data, Decentralized Trials, Digital Health Technologies	0286-0000-21-530-L04-P	Knowledge	
120 SL	Defining Quality for Cell and Gene Therapy Products	0286-0000-21-531-L04-P	Knowledge	
121 SL	Statistical Considerations with the Patient in Mind	0286-0000-21-523-L04-P	Knowledge	
122 SL	Market Access, Medical Affairs, and Regulatory Affairs Functions Working Together to Address Payor and Regulatory Requirements	0286-0000-21-533-L04-P	Knowledge	
127 SL	Are You Ready for a NISS? Industry and Regulatory Perspectives on the US FDA Newly Identified Safety Signal Process	0286-0000-21-534-L04-P	Knowledge	
128 SL	FDA Science Strategies: Purposeful Scientific Leadership to Advance Innovation and Improve Patient Outcomes	0286-0000-21-535-L04-P	Knowledge	
129 SL	Walking the Talk: What Happens When Clinical Trialists Join Clinical Trials?	0286-0000-21-536-L04-P	Knowledge	
130 SL	Real-World Response: Harnessing Electronic Health Records to Develop Robust Clinical Endpoints in Solid Tumors	0286-0000-21-537-L04-P	Knowledge	
131 SL	How are Medical and Health Economics Data Generated and Disseminated to Various Customer Segments?	0286-0000-21-538-L04-P	Knowledge	

132 SL	Ensuring Patient Engagement Methodologies Are 'Fit for Purpose' from the Beginning: A Key Factor for Meaningful Outcomes	0286-0000-21-539-L04-P	Knowledge	
133 SL	Role of Clinical Pharmacology Guidances and Policies in Enhancing Drug Development	0286-0000-21-540-L04-P	Knowledge	
134 L	Risky Business: How to Successfully Manage Project Risk	0286-0000-21-541-L04-P	Application	2166ZTRTIJ
135 SL	Risk-Based Remote Site Monitoring	0286-0000-21-542-L04-P	Knowledge	
136 SL	Parallel Scientific Advice: Increasing International Dialogue Early in the Product Lifecycle	0286-0000-21-543-L04-P	Knowledge	
137 SL	Health Canada Town Hall	0286-0000-21-544-L04-P	Knowledge	
138 SL	Advancing ICH Quality Standards to Support Continual Improvement and Innovation in Manufacturing Technologies and Approaches	0286-0000-21-545-L04-P	Knowledge	
139 SL	Hiding in Plain Sight: Quantifying Underdiagnosed Populations	0286-0000-21-546-L04-P	Knowledge	
143 SL	A Journey of Interdisciplinary Collaboration to Improve Safety Evaluation in Drug Development	0286-0000-21-547-L04-P	Knowledge	
144 SL	Launching Megatrials During a Pandemic: Lessons Learned from COVID-19 Vaccine Clinical Trials	0286-0000-21-548-L04-P	Knowledge	
145 SL	Realizing the Value of Digital Biomarkers Across the Product Lifecycle	0286-0000-21-549-L04-P	Knowledge	
146 SL	Driving Innovation in Data Standards and Regulatory Submissions at FDA	0286-0000-21-550-L04-P	Knowledge	
147 SL	Advancing the Science of Patient Input: How are WE doing? Multi-Stakeholder Perspective	0286-0000-21-551-L04-P	Knowledge	
148 SL	Challenges and Opportunities in Early Development of RNA Therapeutics	0286-0000-21-552-L04-P	Knowledge	
149 SL	Culture of Quality: A Competitive Advantage	0286-0000-21-553-L04-P	Knowledge	
150 SL	Continuity of Randomized Controlled Trials During the Trying Times of COVID-19 and What We've Learned	0286-0000-21-554-L04-P	Knowledge	
151 SL	Next Generation of Combination Products: Insights from the FDA Office of Combination Products and Industry Expert Application	0286-0000-21-555-L04-P	Knowledge	
152 SL	Implementation Progress of ICH Q12	0286-0000-21-556-L04-P	Knowledge	
153 SL	Regulatory, Industry, Patient and Academic Perspectives on Machine Learning in Clinical Trials	0286-0000-21-557-L04-P	Knowledge	
154 SL	How Can We Compliantly Exchange Pre-Approval Information with Payers	0286-0000-21-558-L04-P	Knowledge	
210 SL	Assuring Access to Safe Medicines in Pregnancy and Lactation: International Regulators Perspective	0286-0000-21-559-L04-P	Knowledge	
211 SL	Managing Global Trials in Latin America: Covid Impact Update	0286-0000-21-560-L04-P	Knowledge	
212 SL	Post COVID: Sites Evolving Role in the Clinical Trial Ecosystem	0286-0000-21-561-L04-P	Knowledge	

213 SL	Perspectives on Real-World Data/Evidence Collection Through Expanded Access During the Covid-19 Pandemic	0286-0000-21-562-L04-P	Knowledge	
214 SL	Developing a Best-in-Class Learning and Performance Program for the MSLs of Today and the Future	0286-0000-21-563-L04-P	Knowledge	
215 SL	Pediatric Engagement in Research: Young People Have a Voice	0286-0000-21-564-L04-P	Knowledge	
216 SL	Brave New World: Early Clinical Trials in a Pandemic	0286-0000-21-565-L04-P	Knowledge	
217 SL	Project Management in Times of Crisis: Perspectives from PMs Supporting COVID-19 Related Projects	0286-0000-21-566-L04-P	Knowledge	2166V1QD7Y
218 SL	Novel and Innovative Approaches to Inspections: Verification of Quality and Compliance Using Remote Methodologies and New Technology	0286-0000-21-567-L04-P	Knowledge	
219 SL	Advancing Medicines' Regulation in Europe: Key Strategies to 2025	0286-0000-21-568-L04-P	Knowledge	
220 L	Office of Generic Drugs and Office of Pharmaceutical Quality Generics Town Hall	0286-0000-21-569-L04-P	Knowledge	
221 SL	Global Harmonization of Complex and Innovative Trial Designs	0286-0000-21-596-L04-P	Knowledge	
225 SL	International Coalition of Medicines Regulatory Authorities (ICMRA): Harnessing Achievements During COVID-19 for the Future	0286-0000-21-571-L04-P	Knowledge	
236 L	Systems Thinking: A Better Way of Safety Management Planning	0286-0000-21-572-L04-P	Knowledge	
237 SL	Diversity in Clinical Research: Practical Strategies for Taking Personal Action	0286-0000-21-573-L04-P	Knowledge	
238 SL	Are External Control Arms Ready for Primetime?	0286-0000-21-574-L04-P	Knowledge	
239 L	Quality by Design for Clinical Trials: A Hands-On, Multi-Stakeholder Workshop	0286-0000-21-575-L04-P	Application	
240 SL	Driving Change Globally: Transforming the Regulators as Early Digital Adopters	0286-0000-21-576-L04-P	Knowledge	
241 SL	Opportunities for Harmonization of Clinical Trial Information in Regulatory Documents	0286-0000-21-577-L04-P	Knowledge	
242 L	Navigating Non-Trial Preapproval Access as a Patient	0286-0000-21-578-L04-P	Application	
243 SL	Epigenetic Drugs: Taking it to the Clinic- An Up and Coming Mode of Targeting Disease	0286-0000-21-579-L04-P	Knowledge	
244 SL	How to Stay Grounded in Project Management Best Practices While Moving at the Speed of Light Integrating a New Company	0286-0000-21-669-L04-P	Knowledge	216673TIJV
245 SL	GCP Quality and Compliance: The Regulator's Perspective	0286-0000-21-580-L04-P	Knowledge	
246 SL	Global Regulatory Harmonization for Increased Patient Access to Medicines Through the International Council for Harmonisation (ICH)	0286-0000-21-581-L04-P	Knowledge	
247 SL	Update on FDA's Real-World Evidence Program: Current FDA Demonstration Projects	0286-0000-21-582-L04-P	Knowledge	

248 SL	Supporting Quality/CMC Development in Early Access Approaches (PRIME/Breakthrough Designation)	0286-0000-21-583-L04-P	Knowledge	
249 SL	Innovative Statistical Strategies and Designs in Oncology Drug Development	0286-0000-21-584-L04-P	Knowledge	
250 SL	How Can Real-World Evidence be Communicated Compliantly to Payers or Healthcare Providers?	0286-0000-21-585-L04-P	Knowledge	
255 SL	Treating Covid-19 Patients with Unproven Interventions Outside Trials: EUAs, Expanded Access, Right to Try, and Off-Label Use	0286-0000-21-586-L04-P	Knowledge	
256 SL	Innovative and Efficient Trial Designs and Statistical Approaches in Small Patient Populations: Rare Diseases and Pediatrics	0286-0000-21-587-L04-P	Knowledge	
257 SL	Is There a Role for Federal Incentives to Stimulate Greater Diversity in Clinical Trials?	0286-0000-21-588-L04-P	Knowledge	
258 SL	Effective Medical and Scientific Stakeholder Engagement: Are Digital Solutions The Answer?	0286-0000-21-589-L04-P	Knowledge	
259 SL	Parents Just Don't Understand: Does This Apply to Healthcare Too?	0286-0000-21-590-L04-P	Knowledge	
260 SL	What Do We Do Now? Why You Need A Resource for Ethical Questions During Drug Development	0286-0000-21-591-L04-P	Knowledge	2166KDCGEN
261 SL	Innovative Approaches to Trial Execution, Quality, and Compliance	0286-0000-21-592-L04-P	Knowledge	
262 SL	Frameworks for Digital Endpoints via the IND Pathway	0286-0000-21-593-L04-P	Knowledge	
263 SL	Pandemic Preparedness: Accelerating Treatments to Overcome Antimicrobial Resistance	0286-0000-21-594-L04-P	Knowledge	
264 SL	Multinational Collaborative CMC Review for Efficient and Rapid Product Approval	0286-0000-21-595-L04-P	Knowledge	
265 SL	A Regulatory/Industry Panel on Estimands: Alignment of the Clinical Objective, Trial Design, Analysis, and Interpretation	0286-0000-21-597-L04-P	Knowledge	
309 L	From Opportunity to Strategy: Introducing Intelligent Automation Technologies within Pharmacovigilance for the ICSR Process	0286-0000-21-599-L04-P	Knowledge	
310 SL	Patient-Focused Benefit-Risk Assessment and Risk Management: Methodology for Engaging with Patients: What has been Learned?	0286-0000-21-600-L04-P	Knowledge	
311 SL	Leveraging Smartphones as Measurement Devices for Remotely Conducted Performance Outcome Tests: Notes from the Field	0286-0000-21-601-L04-P	Knowledge	
312 SL	Real Talk About Artificial Intelligence and Automation in Clinical Research Today	0286-0000-21-602-L04-P	Knowledge	
313 SL	Worldwide COVID-19 Pandemic Effects on Real-World Data: Research Can Go On	0286-0000-21-603-L04-P	Knowledge	
314 SL	Lean Writing: Making Regulatory and Clinical Documents Simple and Straightforward	0286-0000-21-604-L04-P	Knowledge	

315 SL	Towards a Patient-Focused Drug Development Ecosystem: Adoption of Core Outcome Sets	0286-0000-21-605-L04-P	Knowledge	
316 SL	It's Like Building the Airplane While Flying it: Biomarker Discovery and Development in Clinical Trials	0286-0000-21-606-L04-P	Knowledge	
317 SL	Best Practices for Project Managers Working in Drug Development Collaborations	0286-0000-21-607-L04-P	Knowledge	2166II3IH9
318 SL	Digital by Design: Embedding Digital Across the Enterprise and the Product Lifecycle	0286-0000-21-608-L04-P	Knowledge	
319 L	The FDA's Clinical Trial Diversity Initiative in the Setting of the Ongoing COVID-19 Pandemic	0286-0000-21-609-L04-P	Knowledge	
320 SL	Model Informed Drug Development (MIDD) Pilot Program: Experience and Impact Over First Three Years	0286-0000-21-610-L04-P	Knowledge	
321 SL	Nitrosamines: What We Have Learned as Regulators and Industry Professionals for a New Path Forward	0286-0000-21-612-L04-P	Knowledge	
322 L	Clinically Meaningful: How is it Different from Statistical Significance?	0286-0000-21-613-L04-P	Knowledge	
327 SL	When Can You Trust Real-World Evidence for Decision-Making?	0286-0000-21-670-L04-P	Knowledge	
334 SL	Risk Minimization Program Evaluation: How Can we Advance the Science?	0286-0000-21-614-L04-P	Knowledge	
335 SL	Technology-Driven Endpoints for Patient Retention and Engagement for Clinical Trials	0286-0000-21-615-L04-P	Knowledge	
336 SL	Converge and Conquer: The Overlapping Roles of Data Management, Operations, Monitoring and More, and What it Means for Industry	0286-0000-21-616-L04-P	Knowledge	
337 L	Interpreting and Writing About Clinical Trial Data	0286-0000-21-617-L04-P	Knowledge	
338 SL	Patient Engagement and Quality by Design: Integrating the Patient Perspective in Clinical Trial Design	0286-0000-21-618-L04-P	Knowledge	
339 SL	Best Practices in Governance Meetings	0286-0000-21-619-L04-P	Knowledge	2166Z86NT1
340 SL	Assessing Risk in the Pharmacovigilance System for the Purpose of Audit and Inspection	0286-0000-21-620-L04-P	Knowledge	
341 SL	How Has FDARA Section 504 (RACE Act) Changed the Pediatric Oncology Landscape?	0286-0000-21-621-L04-P	Knowledge	
342 SL	Scientific Advances in Biosimilar Development	0286-0000-21-622-L04-P	Knowledge	
343 SL	COVID-19 Pandemic and Beyond: Challenges Performing Inspections, Current State of Manufacturing Facility Regulatory Oversight Tools, and Learnings	0286-0000-21-623-L04-P	Knowledge	
344 SL	Mixing Modes of Clinical Outcome Assessments in Response to COVID-19	0286-0000-21-624-L04-P	Knowledge	
345 SL	Beyond Cancer: Why Pharma is Moving to High Quality Real-World Data for Immunology and Other Chronic Diseases	0286-0000-21-625-L04-P	Knowledge	

351 SL	The Rare Disease Clinical Outcome Assessment Consortium: Collaboration Aimed at Accelerating Rare Disease Drug Development	0286-0000-21-626-L04-P	Knowledge	
352 SL	Breaking the Document Paradigm to Digitize Study Start Up: The Digital Data Flow Initiative	0286-0000-21-627-L04-P	Knowledge	
353 SL	The Covid -19 Digital Response of Countries and Companies: What is Here to Stay?	0286-0000-21-628-L04-P	Knowledge	
354 SL	Improving Efficiency and Quality of Regulatory Documents	0286-0000-21-629-L04-P	Knowledge	
355 SL	The Intersection of Health Equity and Personalized Medicine	0286-0000-21-630-L04-P	Knowledge	
356 SL	How to Streamline Project Management Methodology Across an Organization: End Reliance on Trackers and Emails	0286-0000-21-631-L04-P	Knowledge	21661VV0R6
357 SL	Risk-Based Quality Management Practical Approaches	0286-0000-21-642-L04-P	Knowledge	
358 L	COVID-19 Vaccines: Regulatory Strategies for Public Health Emergencies	0286-0000-21-632-L04-P	Knowledge	
359 SL	Companion Diagnostics: Could Co-Development be Expedited to Facilitate Access to Accelerated Novel Therapeutics?	0286-0000-21-633-L04-P	Knowledge	
360 SL	Who Should Pay for Expanded Access?	0286-0000-21-634-L04-P	Knowledge	
406 SL	Development of Shared System and Shared REMS: Best Practices and Lessons Learned	0286-0000-21-635-L04-P	Knowledge	
407 SL	Reliability of Data Results in Clinical Trials (ICH E6 (R2)): What Does it Mean and How Can it be Accomplished?	0286-0000-21-636-L04-P	Knowledge	
408 SL	The Data Scientist's Handbook: 'Good Science' Principles in Non-Interventional Studies	0286-0000-21-637-L04-P	Knowledge	
409 SL	Recent Developments and Strategies in Pediatric Drug Development Documentation	0286-0000-21-638-L04-P	Knowledge	
410 SL	Patient-Focused Drug Development in Rare Diseases: Applying Guidances and Case Studies from the Field	0286-0000-21-639-L04-P	Knowledge	
411 SL	Virtual Project Management: A Way Forward!	0286-0000-21-641-L04-P	Knowledge	2166U8V7DJ
412 SL	Integrated Assessment of US Marketing Applications: A View into FDA Internal Operations	0286-0000-21-643-L04-P	Knowledge	
413 SL	Using Cloud-Based Platforms to Transform Global Regulatory Data Exchange	0286-0000-21-671-L04-P	Knowledge	
414 SL	How to Avoid Shortages? Insights from the EU Executive Steering Group on Shortages – Learnings from the COVID-19 Pandemic	0286-0000-21-644-L04-P	Knowledge	
415 SL	Fairness and Bias Detection and Mitigation in Machine Learning Algorithms: Real-World Evidence Applications and Examples	0286-0000-21-645-L04-P	Knowledge	
416 L	Remaining Challenges to the COVID-19 Response	0286-0000-21-570-L04-P	Knowledge	
420 SL	The Spirit of the IND Safety Reporting Final Rule	0286-0000-21-646-L04-P	Knowledge	

421 SL	Remote Implementation of Clinical Outcome Assessments During the COVID-19 Pandemic and Beyond	0286-0000-21-647-L04-P	Knowledge	
422 SL	EHR Interoperability Supporting COVID-19 Critical Care and Research	0286-0000-21-648-L04-P	Knowledge	
423 SL	The Pain and the Pleasure: Lessons from Going Live with a Structured Content Management (SCM) System	0286-0000-21-649-L04-P	Knowledge	
424 SL	Meaningful Patient Engagement Highlighted Through Patient Preference Studies and Core Outcome Sets	0286-0000-21-650-L04-P	Knowledge	
425 SL	Regulator Perspective: Maintaining GCP During Covid-19 and Beyond the Pandemic	0286-0000-21-652-L04-P	Knowledge	
426 SL	Emergency Use Pathways: What Leanings from COVID-19 Can be Generalized to Address Unmet Medical Needs?	0286-0000-21-653-L04-P	Knowledge	
427 SL	Real-World Evidence: A Global Regulatory Perspective and Discussion	0286-0000-21-654-L04-P	Knowledge	
428 SL	Mobilizing Manufacturing: Portable and Point of Care Manufacture of Medicines	0286-0000-21-655-L04-P	Knowledge	
429 SL	The Journey to a Modernization of Analytics	0286-0000-21-656-L04-P	Knowledge	
430 SL	Needs Assessment: Key Factor in Value-Based Funding for Medical Device Innovation	0286-0000-21-657-L04-P	Knowledge	
436 SL	What is the Breakthrough Risk Communication and Assessing Safety after Early Access to Pharmaceuticals?	0286-0000-21-658-L04-P	Knowledge	
438 SL	The Relationship Between Data, AI, and Bias	0286-0000-21-660-L04-P	Knowledge	
439 SL	Preparing Medical Information for Emergency Use Authorization (EUA) to a Full Launch During the COVID-19 Pandemic	0286-0000-21-661-L04-P	Knowledge	
440 SL	Predictive Compliance, Risk, and Quality Management Transformation: Will your Data Hold up to a Data Integrity Inspection?	0286-0000-21-662-L04-P	Knowledge	
441 SL	Managing in Complexity: Emergency Use Authorizations Process and COVID-19 Lessons Learned	0286-0000-21-663-L04-P	Knowledge	
442 SL	Population Diversity Considerations in Clinical Trials	0286-0000-21-664-L04-P	Knowledge	
446 L	EMA-FDA Question Time	0286-0000-21-666-L04-P	Knowledge	
447 SL	FDA Town Hall	0286-0000-21-667-L04-P	Knowledge	