

Below are the pharmacy designated Universal Activity Numbers (UANs) and type of activity that is applicable for each of the following program offerings

Session #	Title	Universal Activity Number	Type of Activity
104	Impact of Biologics, Vaccines, Oncology, and Breakthrough Therapy Designation on Traditional Global Drug Development Strategy	0286-0000-16-523-L01-P	Knowledge
107	Fatal Drug Trials in Phase 1: Understanding Risk, Subject Safety, Timelines, and Cost	0286-0000-16-615-L04-P	Knowledge
108	Drug/In Vitro Diagnostic Device Advertising and Promotion: Unapproved Combination Product or Awareness?	0286-0000-16-526-L01-P	Knowledge
110	Updates and Pending Issues in the US Biosimilar Environment	0286-0000-16-544-L01-P	Knowledge
111	Global Regulatory Harmonization in Asia: Is a New Trend Occurring?	0286-0000-16-551-L04-P	Knowledge
113	Clinical Developments in Immuno-Oncology, Part 1 of 2: Science, Current Methodologies, and Achievements	0286-0000-16-554-L01-P	Knowledge
114	Bringing the Trial to the Patient: Making the Patient Voice Central from Trial Design Onward	0286-0000-16-604-L04-P	Knowledge
115	Clinically Relevant Specifications: Translating Voice of the Patient Into Quality Attributes of the Product	0286-0000-16-605-L04-P	Knowledge
119	Narrative Medicine: Innovative Techniques for Including the Voice of the Patient in Clinical Trials	0286-0000-16-589-L04-P	Application
121	Rare Disease Clinical Trials: Coping with Unique Challenges	0286-0000-16-602-L01-P	Knowledge
124	Risk-Based Monitoring in Clinical Trials	0286-0000-16-518-L05-P	Knowledge
125	Patient Recruitment in Rare Diseases: Ideas and Framework for Out-of-the-Box Exploration	0286-0000-16-520-L01-P	Knowledge
126	Hope Is Not a Strategy: Quantifying Knowledge for Better Decision Making in Clinical Development	0286-0000-16-596-L04-P	Knowledge

129	Delivering Value Through Medical Information Metrics	0286-0000-16-530-L04-P	Knowledge
130	Take Two Aspirin and Text Me in the Morning: Technology Suited for 20,000 Virtual Patients on the PCORI Aspirin Trial	0286-0000-16-535-L04-P	Application
132	Electronic Implementation of New PRO Measures to Assess Treatment Benefit in Irritable Bowel Syndrome Trials: Lessons Learned	0286-0000-16-540-L01-P	Knowledge
133	Take Advantage of Global Expedited Pathways: Breakthrough, Sakigake, Prime!	0286-0000-16-543-L04-P	Knowledge
134	How Can We Utilize Mobile Health for Better Quality of Life and Medical Economy?	0286-0000-16-561-L04-P	Knowledge
135	Clinical Developments in Immuno-Oncology, Part 2 of 2: Clinical Implementation of Biomarkers	0286-0000-16-562-L01-P	Knowledge
138	Risk Communication and Management: The Art of Communicating Risk - Challenges and Best Practices	0286-0000-16-599-L04-P	Knowledge
139	Measuring the Impact and Influence of Patient Input on Regulatory and Health Technology Assessment Decision Making: What Are the Key Considerations?	0286-0000-16-568-L04-P	Knowledge
140	Understanding, Developing, and Implementing an Anticipated Events Review Process: Adoption of the FDA IND Rule on Safety Reporting Requirements	0286-0000-16-576-L05-P	Knowledge
202	Changing Cultures to Advance Patient Engagement	0286-0000-16-614-L04-P	Knowledge
203	Next Generation Collaborations: Transforming the Industry	0286-0000-16-609-L04-P	Knowledge
207	Advancing the Appropriate Use of Mobile Clinical Trials: The Clinical Trials Transformation Initiative	0286-0000-16-513-L04-P	Knowledge
212	Special Populations in Clinical Pharmacology Studies	0286-0000-16-524-L05-P	Knowledge
213	FDA Enforcement Update: Advertising and Promotion	0286-0000-16-527-L04-P	Knowledge
215	Exploring the Use of Virtual Technologies Within Medical Affairs Organizations	0286-0000-16-603-L04-P	Knowledge
218	Lessons Learned from Eight Years of Drug Development Tool/Novel Methodology Qualification	0286-0000-16-548-L04-P	Knowledge
219	Regulatory Science Considerations Applying to Novel Biologics and Bifunctional Biologics Development	0286-0000-16-552-L01-P	Knowledge

221	Envision the Future: How Big Data and Artificial Intelligence Change Our Regulatory Environment	0286-0000-16-555-L04-P	Knowledge
222	Valuing the Clinical Trial Patient	0286-0000-16-566-L01-P	Knowledge
223	Global Harmonization: Current ICH Quality Initiatives	0286-0000-16-567-L04-P	Knowledge
224	Identifying Patient-Centered Outcomes for Use in Observational Research: Why and How	0286-0000-16-569-L01-P	Knowledge
225	One Size Does Not Fit All: Best Practices for Right-Sized Signal Management Systems	0286-0000-16-600-L04-P	Knowledge
227	Unique Global Regulatory Considerations and Drug Development Incentives in Rare Disease and Orphan Drug Development	0286-0000-16-590-L01-P	Knowledge
236	Expanded Access: Ethical, Regulatory, and Policy Challenges and Considerations	0286-0000-16-522-L04-P	Knowledge
238	Prescription Drug Marketing Regulatory Primer	0286-0000-16-528-L04-P	Application
241	Disease Interception: Shifting the Paradigm from Treatment to Prevention of Disease	0286-0000-16-547-L01-P	Knowledge
242	Regulatory Challenges in the Development of Combination Products Involving Digital Technology	0286-0000-16-556-L04-P	Knowledge
243	Patient Involvement Today and Tomorrow: What's in It for Patients?	0286-0000-16-563-L04-P	Knowledge
246	Valuing the Signal and the Noise in Health Care Horizon Scanning	0286-0000-16-574-L04-P	Knowledge
247	Fit for Purpose and Modern Validity Theory in PROs	0286-0000-16-575-L01-P	Knowledge
248	Mind the Gaps: The Science of Designing, Implementing, and Evaluating Benefit-Risk Communication for Medicinal Products	0286-0000-16-580-L04-P	Knowledge
250	Open-Label, Long-Term Extension Studies: Study Designs and Ethics	0286-0000-16-583-L04-P	Knowledge
252	Capturing Real-World Data in Rare Diseases	0286-0000-16-591-L01-P	Knowledge
253	Update from Health Canada	0286-0000-16-613-L04-P	Knowledge

254	CBER Town Hall: State of the Center and Plans for the Future	0286-0000-16-595-L04-P	Knowledge
257	Mobile Apps for Clinical Trials: DIY or AMAZON Strategy? When to Build, When to Buy	0286-0000-16-514-L04-P	Knowledge
260	A Risk-Benefit Approach to Planning Early Clinical Development	0286-0000-16-598-L04-P	Knowledge
261	Marketing After Amarin and Pacira	0286-0000-16-529-L04-P	Knowledge
262	Solving Challenges and Employing Best Practices in Medical Information Contact Centers	0286-0000-16-531-L04-P	Knowledge
263	Patient Centricity in Clinical Trials	0286-0000-16-536-L04-P	Knowledge
264	FDA Update on Data Standards	0286-0000-16-538-L04-P	Knowledge
265	Enabling Innovative New Endpoint Measurement Using Mobile Technology	0286-0000-16-541-L04-P	Knowledge
266	Perspectives on Expanded Access to Investigational New Drugs	0286-0000-16-545-L01-P	Knowledge
271	The Things Kids Say: Clinical Outcome Assessments in Pediatric Clinical Trials	0286-0000-16-570-L01-P	Knowledge
272	How Can We Build Reliability and Quality When Outsourcing Pharmacovigilance?	0286-0000-16-577-L04-P	Knowledge
273	Improving Adverse Drug Reaction Information in Product Labels	0286-0000-16-587-L04-P	Knowledge
274	Statistical Issues in the Evaluation of Biosimilars	0286-0000-16-588-L04-P	Knowledge
276	Using Input from Patient Communities to Develop PRO Instruments	0286-0000-16-592-L04-P	Knowledge
302	Europe and the US: Making Outcomes-Based Health Care Possible	0286-0000-16-610-L04-P	Knowledge
308	Patient Recruitment Workshop: Survey Results and Practical Application	0286-0000-16-519-L01-P	Application
314	Transforming Clinical Protocols into a Digital Platform: Driving Quality and Efficiency End-to-End	0286-0000-16-539-L04-P	Knowledge

315	Enhancing Pediatric Product Development in a Global Regulatory Environment: Extrapolation and Modeling and Simulation, Oh My!	0286-0000-16-549-L01-P	Knowledge
316	What's Your Preference? The Emerging Importance of Patient Preference Elicitation	0286-0000-16-553-L01-P	Knowledge
317	Global Medical Device Development: Regulatory Concordance or Discordance?	0286-0000-16-558-L04-P	Knowledge
321	Office of Pharmaceutical Quality Update	0286-0000-16-606-L04-P	Knowledge
322	Real-World Evidence in Drug Development: Creating the Right Environment for Enhanced Pre-Launch Evidence	0286-0000-16-571-L01-P	Knowledge
323	Social Listening for Pharmacovigilance: Practical Considerations and Challenges for Implementation	0286-0000-16-578-L04-P	Knowledge
324	Implementing Adaptive Designs Involves Greater Teamwork	0286-0000-16-584-L05-P	Knowledge
326	FDA Rare Disease Town Hall	0286-0000-16-608-L01-P	Knowledge
333	Hearing the Patient Voice in Pharma and What Patients Want You to Know	0286-0000-16-517-L04-P	Knowledge
335	Multi-Ethnic, Special Populations, and Patient Diversity in Clinical Trials	0286-0000-16-521-L04-P	Knowledge
336	Effect of International Reference Pricing on Planning for Global New Product Launches	0286-0000-16-597-L04-P	Knowledge
338	Evolving Methods in Pain Trials: Evaluating Abuse Deterrence, Drug Interactions, and Appropriate Patient Selection	0286-0000-16-525-L01-P	Knowledge
339	Evolution of Patient Safety Reporting: PSURs to RMPs, Challenges, and How to Face Them	0286-0000-16-532-L05-P	Knowledge
342	Big Data in Health Care and Life Sciences	0286-0000-16-542-L04-P	Knowledge
343	Strategies, Enablers, and Barriers to Medicine Development in the Emerging Markets: The 2025 Global Regulatory Landscape	0286-0000-16-546-L04-P	Knowledge
345	Are State Consumer Fraud Lawsuits Encroaching on FDA's Regulatory Authority?	0286-0000-16-564-L03-P	Knowledge
348	Interpreting Meaningful Change on PROs: When to Talk, When to Use Cumulative Distribution Functions, and When to ROC	0286-0000-16-572-L01-P	Knowledge

349	Measuring the Effectiveness of Risk Minimization: Principles and Regional Requirements	0286-0000-16-601-L04-P	Knowledge
350	Evaluating the Impact of Adverse Event Information from Solicited Programs on Benefit-Risk Profiles: Is It Worth the Effort?	0286-0000-16-582-L05-P	Knowledge
351	Emergent Study Designs and Analysis Methods Addressing Issues Associated with Pediatric Clinical Studies	0286-0000-16-585-L01-P	Knowledge
357	The Internet of Things and Clinical Research: Privacy, Security, and Ethical Aspects	0286-0000-16-515-L04-P	Knowledge
361	Protocol Endpoints: A Clear Map to Navigate The Yellow Brick Road and the End of Endpoint Creep	0286-0000-16-533-L04-P	Knowledge
362	Risk-Based Monitoring: Best Practices in Implementation for the Data Manager and Key Stakeholders	0286-0000-16-534-L04-P	Knowledge
363	Expedited Reviews and Other Pathways to Speed Up Access to Medicines	0286-0000-16-550-L01-P	Knowledge
365	Cross-Labeling of Drugs and Devices: How Can It Be Done?	0286-0000-16-559-L04-P	Knowledge
366	Infectious Disease Containment and Lessons Learned	0286-0000-16-565-L01-P	Knowledge
369	Innovative and Emerging Technologies	0286-0000-16-607-L04-P	Knowledge
370	Pricing, Patient Access, and What's Next for Today's Biopharma and Devices	0286-0000-16-573-L04-P	Knowledge
371	FDA and PatientsLikeMe: Exploring the Use of Patient-Generated Data in Drug Safety	0286-0000-16-581-L05-P	Knowledge
377	Pediatric Rare Disease Drug Development	0286-0000-16-593-L01-P	Knowledge
401	EMA/FDA Question Time	0286-0000-16-611-L04-P	Knowledge
402	Protocol Development Is a Team Sport	0286-0000-16-612-L04-P	Knowledge
403	Running Personalized Medicine Trials: Facts and Figures	0286-0000-16-516-L01-P	Knowledge
407	Successful Application of Wearables and Remote Monitoring in Clinical Trials: Lessons Learned and Future Progress	0286-0000-16-537-L04-P	Knowledge

409	Current Status of Genetic Testing in Medical Therapies: What Regulations We May Need in a Convergent Regulatory Environment	0286-0000-16-560-L04-P	Knowledge
410	The Role of Big Data in Transforming the Detection of Adverse Drug Reactions	0286-0000-16-579-L04-P	Knowledge
411	Nonclinical Statistics for Chemistry, Manufacturing, and Control: Case Studies and Regulatory Perspective	0286-0000-16-586-L04-P	Knowledge
412	CDER Town Hall	0286-0000-16-594-L04-P	Knowledge