

UNIVERSAL ACTIVITY NUMBERS

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
SC #20	Real World Evidence Studies to Evaluate the Safety and Effectiveness of Therapeutic Interventions – Is the Data Fit for Purpose and How Will You Know?	0286-0000-19-500-L04-P	Knowledge
SC #21	Basics of European Medical Device Regulation	0286-0000-19-501-L04-P	Application
SC #22	Protocol Co-Design with Patients and Advocates	0286-0000-19-502-L04-P	Application
SC #23	Preparing for a US FDA Advisory Committee Meeting	0286-0000-19-503-L04-P	Application
SC #24	Data Visualization in the Life Sciences	0286-0000-19-504-L04-P	Application
SC #27	eCOA 101: The What, Why, and How of eCOA to Reduce Barriers to Adoption in Clinical Studies	0286-0000-19-507-L04-P	Application
SC #28	R&D QA Comprehensive Quality Strategy: An Approach to Managing Quality Risks Throughout the Drug Development Lifecycle	0286-0000-19-508-L04-P	Application
SC #30	Machine Learning in Pharmacovigilance	0286-0000-19-509-L04-P	Knowledge
SC #33	European Regulatory Meetings: How Best to Prepare and Perform	0286-0000-19-512-L04-P	Knowledge
SC #34	Implementing a Risk-Based Monitoring Solution: Understanding the Basics of a Sustainable Model	0286-0000-19-513-L04-P	Knowledge
SC #35	Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Effecting Pharmaceutical Development	0286-0000-19-514-L04-P	Knowledge
SC #36	A Novel Interactive Safety Graphic to Evaluate Potential Drug-Induced Hepatotoxicity	0286-0000-19-515-L04-P	Application
SC #37	Patient Literacy 101: Practical Strategies for Improving Your Patient Materials	0286-0000-19-516-L04-P	Application
SC #40	Interdisciplinary Safety Evaluation During Product Development	0286-0000-19-517-L04-P	Knowledge
SC #41	Toolkit Approach to Best Practices in Root Cause Analysis and CAPA Management Workshop	0286-0000-19-518-L04-P	Application
SC #42	Patient Preferences: Using Conjoint Analysis and Stated Preferences in Drug Development and Regulatory Decision Making	0286-0000-19-519-L04-P	Application
SC #43	Back to the Future: Combination Products in the 21st Century	0286-0000-19-520-L04-P	Application

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
100	DIA 2019 Global Annual Meeting Keynote Address and Opening DIAlmond Session: Who Owns My Health Data: Patients, Data, and the Future of R&D	0286-0000-19-730-L04-P	Knowledge
105	Addressing Heterogeneity of Real World Evidence in Drug Safety	0286-0000-19-522-L04-P	Knowledge
106	Moving Forward in EU Pharmacovigilance	0286-0000-19-523-L04-P	Knowledge
107	Emerging Technologies in Clinical Research	0286-0000-19-534-L04-P	Knowledge
108	Innovation in Enrollment, Recruitment, and Retention	0286-0000-19-535-L04-P	Knowledge
109	When Disaster Strikes: Developing a Proactive Plan to Address Challenges Brought on by Large Scale Natural Disasters	0286-0000-19-536-L04-P	Knowledge
110	Automation with Intelligence: Transformation From Human Resource to Artificial Intelligence in Risk Management	0286-0000-19-524-L04-P	Knowledge
111	PhactMI Benchmarking Survey Highlights: How are the Twenty Seven Member Companies Executing on Medical Information Initiatives	0286-0000-19-525-L04-P	Knowledge
112	Collecting Better Patient Experience Data: Lessons Learned from Patient Organizations	0286-0000-19-526-L04-P	Knowledge
113	Artificial Intelligence in Drug Discovery and Development: Emerging Technologies and Applications	0286-0000-19-527-L04-P	Knowledge
114	Patient Perspective Diversity: Taking Cultural Differences in Patient Views Into Drug Development in US, EU, and Japan	0286-0000-19-528-L04-P	Knowledge

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
115	Quality Management Post-Quality Management System Implementation In The Wake of ICH E6 (R2)	0286-0000-19-529-L04-P	Knowledge
116	Harnessing Power of Advanced Technologies for Digital Transformation in Regulatory Affairs	0286-0000-19-530-L04-P	Knowledge
117	International Regulatory Convergence	0286-0000-19-537-L04-P	Knowledge
118	Statistical Considerations for Trials Using Surrogate Endpoints for Accelerated Approval	0286-0000-19-531-L04-P	Application
119	Making Value-Based Contracting Stick	0286-0000-19-532-L04-P	Knowledge
120	FDA Payer Communication Guidance, Twenty Years in the Making: Now What?	0286-0000-19-533-L04-P	Knowledge
131	On the Soapbox: Designing Babies - Medical, Ethical, and Social Questions	0286-0000-19-733-L04-P	Knowledge
135	Using Real World Data to Develop a Safety Monitoring Program and Ensure Pre- and Post-Market Continuity	0286-0000-19-538-L04-P	Knowledge
136	Interpretation of New Pharmacovigilance Regulations: Key Insights	0286-0000-19-539-L04-P	Knowledge
137	Emerging Technology to Improve Sponsor-Site Interactions	0286-0000-19-547-L04-P	Knowledge
138	Blockchain in Clinical Trials Demo: Truth or Dare	0286-0000-19-548-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
139	Developing Standard Core Clinical Outcome Assessments and Endpoints: FDA Perspective and Plans	0286-0000-19-549-L04-P	Knowledge
140	Use of Real World Data in Clinical Trials: Abstracting Endpoints from Encounters	0286-0000-19-540-L04-P	Knowledge
141	Knowledge Management and Information Sharing to Support Business Continuity	0286-0000-19-541-L04-P	Knowledge
142	Show Me the Money! Patient and Caregiver Roles and Compensation in Research, Development, and Innovation	0286-0000-19-542-L04-P	Knowledge
143	Opportunities and Challenges with First-In-Human Multiple Expansion Cohort Designs in Oncology	0286-0000-19-543-L04-P	Knowledge
144	Ready or Not: Business Continuity Planning	0286-0000-19-544-L04-P	Knowledge
145	Examining Essential Elements of Vendor Governance and Comparing Perspectives of Large and Emerging Biopharma	0286-0000-19-545-L04-P	Knowledge
146	Communications with Regulators Beyond Formal Meetings	0286-0000-19-546-L04-P	Knowledge
147	Update from Health Canada: The Health Protection Branch	0286-0000-19-552-L04-P	Knowledge
148	Hot Topics in Digital Health: How is FDA's Approach Evolving, and What Do Industry and Patients Need to Know?	0286-0000-19-553-L04-P	Knowledge
149	Hype Versus Reality: Artificial Intelligence and Drug Development	0286-0000-19-554-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
150	TFDA Town Hall: Focus on Regenerative Medicine	0286-0000-19-734-L04-P	Knowledge
151	Update on ICH Quality Topics	0286-0000-19-551-L04-P	Knowledge
152	Making Data Meaningful: Using Data Visualization to Drive Efficiency in Safety Analysis	0286-0000-19-550-L04-P	Knowledge
154	Current Initiatives on Patient Involvement in the Medicinal Product Lifecycle: CIOMS XI	0286-0000-19-555-L04-P	Knowledge
155	Incorporating Systems-Theory and Human Factors into the Investigations of Serious Harm in Clinical Research	0286-0000-19-570-L04-P	Knowledge
156	Clinical Research in Emerging Regions	0286-0000-19-566-L04-P	Knowledge
157	A Large Academic Medical Center's Perspective on Using Precision Medicine to Find Patient Disease Subgroups at Scale	0286-0000-19-567-L04-P	Knowledge
158	Enhancing Patient-Focused Outcome Assessment in Medical Product Development	0286-0000-19-568-L04-P	Knowledge
159	Understanding the Data Journey In Virtual Trials	0286-0000-19-556-L04-P	Knowledge
160	New Communication Channels for Medical Information	0286-0000-19-557-L04-P	Application
161	Making Trials Work for Special Populations	0286-0000-19-558-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
162	Precision Medicines in Clinical Trials: Understanding and Overcoming Barriers to Adoption	0286-0000-19-559-L04-P	Knowledge
163	Strategic Integration: Is Anyone Getting it Right?	0286-0000-19-560-L04-P	Knowledge
164	Compliance: The Importance of Periodic Screenings to Ensure Good Inspection Health	0286-0000-19-561-L04-P	Application
165	Drug Development Tools in a Digital Era	0286-0000-19-562-L04-P	Knowledge
166	Updates on China Regulatory Reform	0286-0000-19-563-L04-P	Knowledge
167	Strategic Priorities of the International Coalition of Medicines Regulatory Authorities in an Increasingly Globalized Industry	0286-0000-19-571-L04-P	Knowledge
168	Regulating Innovation in Chemistry, Manufacturing, and Controls: Challenges and Opportunities	0286-0000-19-569-L04-P	Knowledge
169	How Statistics Can Help Improve Data Quality: ICH E6 R2	0286-0000-19-564-L04-P	Knowledge
170	Making Early Access for Patients Happen	0286-0000-19-565-L04-P	Application
201	To Err is Human: Progress and Challenges in the Prevention of Medication Errors	0286-0000-19-572-L04-P	Knowledge
202	Updates and Lessons Learned from Novel Approaches to Pharmacovigilance Collaboration	0286-0000-19-573-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
203	eConsent Done Right	0286-0000-19-585-L04-P	Knowledge
204	Protocol Developments of the Future	0286-0000-19-586-L04-P	Knowledge
205	Driving Enrollment with a Patient-Centric Focus to Artificial Intelligence	0286-0000-19-587-L04-P	Knowledge
206	Single Source of Truth, Integrations, or IoT (Internet of Things): Exploring Ways to Improve Connectedness of Clinical Data	0286-0000-19-574-L04-P	Knowledge
207	Leveraging Artificial Intelligence and Natural Language Processing in Medical Writing	0286-0000-19-575-L04-P	Knowledge
208	Patient Focus as Part of the Regulatory Affairs DNA: Opportunities and Challenges	0286-0000-19-576-L04-P	Knowledge
209	Emerging Issues in CRISPR and Gene Editing Symposium	0286-0000-19-577-L04-P	Knowledge
210	Increasing Personal Resilience To Manage Change	0286-0000-19-578-L04-P	Application
211	Pharmacovigilance Reporting and Quality	0286-0000-19-579-L04-P	Knowledge
212	Translating Academic Research into Product Development: Integrating GxPs into the Process (Part 1 of 4)	0286-0000-19-580-L04-P	Knowledge
213	Facilitating Access: Patient Perspectives on a Streamlined Development Approach for Treatments for Severely-Debilitating or Life-Threatening Diseases	0286-0000-19-581-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
214	Global Pediatric Policy Update: Are You Ready to Implement FDARA Section 504?	0286-0000-19-582-L04-P	Knowledge
215	Conducting Clinical Trials with GMOs: Strategies to Overcome Regulatory, Operational, and Patient Enrollment Challenges	0286-0000-19-589-L04-P	Application
216	Identifying the Reference Listed Drug for ANDA Submission, Overview of FDA's Orange Book, and Exclusivities for NDAs and ANDAs	0286-0000-19-590-L04-P	Knowledge
217	Quality Considerations for Complex Generics	0286-0000-19-588-L04-P	Knowledge
218	Real World Data to Real World Evidence	0286-0000-19-583-L04-P	Knowledge
219	Personalized Healthcare and Clinical Outcomes: How Real World Endpoints Can Improve Approval and Access to Medicine?	0286-0000-19-584-L04-P	Knowledge
228	Emerging Safety Challenges in New Oncology Treatments	0286-0000-19-591-L04-P	Knowledge
229	An Industry Collaboration on Pharmacovigilance Analytics	0286-0000-19-592-L04-P	Knowledge
230	Assessing Opportunities to Improve Outsourcing Oversight and the Vendor Qualification Assessment Process	0286-0000-19-604-L04-P	Knowledge
231	Outcomes, Endpoints, and Methods Supporting Oncology and Alzheimer Therapies	0286-0000-19-605-L04-P	Knowledge
232	Retooling Risk Assessment to Align with ICH-E6(R2) and Connect to Centralized Monitoring and Risk-Based Monitoring	0286-0000-19-606-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
233	Creating Clarity: Changes at CDISC to Make Standards Implementation Easier for all Stakeholders	0286-0000-19-593-L04-P	Knowledge
234	Quality and Compliance Management in Medical Information/Medical Affairs	0286-0000-19-594-L04-P	Knowledge
235	Walking the Talk: Using Home Nursing as a Patient-Centric Service in Clinical Trials - From Multiple Perspectives	0286-0000-19-595-L04-P	Knowledge
236	Our Doors are Open! Pathways and Programs for Patient Stakeholders to Engage with FDA	0286-0000-19-608-L04-P	Knowledge
237	The Rare Disease Experience in Clinical Trials	0286-0000-19-596-L04-P	Knowledge
238	Build and Leverage Your Networks to Influence Stakeholders	0286-0000-19-597-L04-P	Application
239	Improving Clinical Trial Risk Management: How To Leverage the IRB's Designed Purpose	0286-0000-19-598-L04-P	Application
240	Harmonizing Regulatory Science Through the International Council for Harmonization (ICH)	0286-0000-19-599-L04-P	Knowledge
241	PMDA Town Hall	0286-0000-19-600-L04-P	Knowledge
242	Use of Real World Evidence to Support Regulatory Decision-Making: First-Year Findings From the RCT-DUPLICATE Project	0286-0000-19-601-L04-P	Knowledge
243	The Future of Combination Products in the EU	0286-0000-19-609-L04-P	Knowledge

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
244	Where Quality Meets Safety and Efficacy: A Conversation with CMC Experts	0286-0000-19-607-L04-P	Knowledge
245	Artificial Intelligence Enhanced Data Analytics for Clinical Trials	0286-0000-19-602-L04-P	Knowledge
246	How Employers are Reinventing Healthcare and What it Means for Research Participation and Evidence	0286-0000-19-603-L04-P	Knowledge
255	Pharma and Regulatory Perspectives on Machine Learning Applications in Pharmacovigilance	0286-0000-19-610-L04-P	Knowledge
256	Wearables and Patient Technologies Utilized in Clinical Trials	0286-0000-19-623-L04-P	Knowledge
257	Clinical Trial Diversity: Moving from Admiring the Problem to Solving it	0286-0000-19-624-L04-P	Knowledge
258	Build-a-Bot Workshop: Design and Build a Conversational Agent that Speaks for You	0286-0000-19-625-L04-P	Application
259	FDA Data Standards Update	0286-0000-19-611-L04-P	Knowledge
260	Clinical Trial Disclosure and Transparency: Intersection of Regulators, Industry, and Patients	0286-0000-19-612-L04-P	Knowledge
261	Patient Experience Data: How Could this Data Enhance Decision-Making at Different Stages of Medical Product Development?	0286-0000-19-613-L04-P	Knowledge
262	Measuring the Impact of Patient Engagement Activities in Medicines R&D: A Way to Sustain the Cultural Change?	0286-0000-19-731-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
263	Drug Development for Ocular Disease, New Therapies, Regulations, and Patient Perspectives	0286-0000-19-614-L04-P	Knowledge
264	Immuno-Oncology Product Development: Overcoming Scientific and Regulatory Challenges	0286-0000-19-615-L04-P	Application
265	Decision Leadership: How Using a Structured Approach to Decision Making Can Help You Lead Teams Better	0286-0000-19-616-L04-P	Application
266	Electronic Systems: Are Yours Fit for Purpose?	0286-0000-19-617-L04-P	Knowledge
267	Translating Academic Research Into Product Development: The What and Why of cGMP in Translational Science (Part 2 of 4)	0286-0000-19-618-L04-P	Knowledge
268	Current Status of FDA Framework for the Evaluation of Real World Evidence	0286-0000-19-619-L04-P	Knowledge
269	Driving Complex Generics to Approval: What are the Keys to Success	0286-0000-19-620-L04-P	Knowledge
270	Where Quality Meets Safety and Efficacy: An Interactive Experience	0286-0000-19-626-L04-P	Knowledge
271	Master Protocols: Applications in Oncology	0286-0000-19-621-L04-P	Application
272	Aligning Facilitated Regulatory and Access Pathways: Observations from the North American Experience	0286-0000-19-622-L04-P	Knowledge
281	Structured Evidence Planning, Production, and Evaluation (SEPPE): A "Quality-Based" Framework for Drug Development	0286-0000-19-627-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
282	The Elephant in the Room: Meaningful Communication of Near Synonyms as Suspected Adverse Reactions	0286-0000-19-628-L04-P	Knowledge
283	Let's Talk Risk-Based Monitoring	0286-0000-19-639-L04-P	Knowledge
284	Virtual Clinical Trials	0286-0000-19-640-L04-P	Knowledge
285	Using Mobile Sensors in Clinical Trials and Evidentiary Considerations for Electronic Submissions	0286-0000-19-641-L04-P	Knowledge
286	The Machines are Here! Learn About Real Uses of Machine Learning and Artificial Intelligence in Pharma	0286-0000-19-629-L04-P	Knowledge
287	A Case Study in Structuring Clinical Content and Structured Content Management (SCM)	0286-0000-19-630-L04-P	Application
288	The Changing Landscape of Medical Affairs: Are We Prepared For 2020?	0286-0000-19-644-L04-P	Knowledge
289	Impact of Patient Engagement on the Biopharmaceutical Industry's Business and Organization	0286-0000-19-631-L04-P	Knowledge
290	The Responsibility Industry, Agencies, and Early Education own in Cure-Model Based Therapeutics	0286-0000-19-632-L04-P	Knowledge
291	Transgenic Products: A DNA Construct Goes Regulatory-A Coming of Age Story	0286-0000-19-633-L04-P	Knowledge
292	Conversations with the Participant: Layperson Summaries and Return of Results	0286-0000-19-634-L04-P	Knowledge

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
293	Real World Evidence: How Does its Use Challenge Quality and Compliance Programs?	0286-0000-19-635-L04-P	Knowledge
294	Update From the US FDA on Progress and Topics of Current Interest in US Biosimilar Policy, Regulation, and Outreach/Education	0286-0000-19-636-L04-P	Knowledge
295	Prescription Drug Labeling: New Guidances from the US FDA	0286-0000-19-643-L04-P	Knowledge
296	Informing Development and Authorizations Using Real World Evidence/Artificial Intelligence	0286-0000-19-645-L04-P	Knowledge
297	Integration of Manufacturing Quality Assessment and Pre-Approval Inspections	0286-0000-19-642-L04-P	Application
298	Clinical Safety Assessment: What's a Statistician Got to Do with It?	0286-0000-19-637-L04-P	Application
299	Public and Regulatory Response To Drug Pricing Concerns	0286-0000-19-638-L04-P	Knowledge
301	So Much Data, So Little Time: Hot Topics in Benefit-Risk Assessment	0286-0000-19-646-L04-P	Knowledge
302	Triple-s (3S) Smart Safety Surveillance	0286-0000-19-682-L04-P	Knowledge
303	Disruptive Technology Transforming Clinical Trials: The Case for Artificial Intelligence, Blockchain, and Mobile Tech/Wearables	0286-0000-19-659-L04-P	Knowledge
304	Operationalizing Master Protocols	0286-0000-19-660-L04-P	Knowledge

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
305	Demystifying Technology Selection in Mobile Clinical Trials	0286-0000-19-661-L04-P	Knowledge
306	Methods for Integrating EHR Data into EDC and eSource Databases	0286-0000-19-647-L04-P	Application
307	Can Topic-Based Approaches to Document Authoring Help Meet the Demands of Accelerated Marketing Application Timelines?	0286-0000-19-648-L04-P	Knowledge
308	Identifying High-Value Patient Engagement Opportunities: A Collaborative Three-Step Process for Sponsors and Patient Groups	0286-0000-19-649-L04-P	Application
309	Neoantigen-Based Cancer Therapies: Regulatory Challenges and Opportunities	0286-0000-19-650-L04-P	Knowledge
310	Project Planning 101: Turning Strategy into Execution	0286-0000-19-651-L04-P	Knowledge
311	Improving Trial Quality by Better Preparing Site Teams	0286-0000-19-652-L04-P	Knowledge
312	Translating Academic Research into Product Development: The Importance of Understanding GLPs at an Early Stage (Part 3 of 4)	0286-0000-19-653-L04-P	Knowledge
313	Model Integrated Evidence as Pivotal Information for Drug Regulatory Decision Making: When, Where, and Why	0286-0000-19-654-L04-P	Knowledge
314	Medical Devices: EU Medical Device Regulation, PMDA Updates, and US MDUFA IV – Where Are We Now?	0286-0000-19-655-L04-P	Knowledge
315	Measuring and Assessing Product Manufacturing Quality	0286-0000-19-662-L04-P	Knowledge

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Session/ Short Course #	Title	Universal Activity Number	Type of Activity
316	Implementation of Innovative and Adaptive Designs in Clinical Trials	0286-0000-19-656-L04-P	Knowledge
317	Designing Clinical Trials with the Right Endpoints: Applying ICH-E9(R1) - Getting the Questions Right (GTQR), Estimands and Handling Missing Data	0286-0000-19-657-L04-P	Knowledge
318	Opportunities and Challenges of Collecting Data in a Pre-Approval Access Setting: A Multi-Stakeholder Perspective	0286-0000-19-658-L04-P	Knowledge
319	How to Solve the Problem of Access for Rare Diseases	0286-0000-19-663-L04-P	Knowledge
327	Digital Risk Minimization: The "Next Generation" Risk Management Tools	0286-0000-19-664-L04-P	Knowledge
328	Risk-Based Monitoring: Best Practice Today and Technology for Tomorrow	0286-0000-19-673-L04-P	Knowledge
329	Global Clinical Trials: Make Them Really Global and Involve Africa	0286-0000-19-674-L04-P	Knowledge
330	The Analytics Revolution: Opportunities and Threats for Disrupting Clinical Development Operations	0286-0000-19-675-L04-P	Knowledge
331	A Pharma/CRO Partnership in the Design and Execution of Paperless Clinical Trials from eICF to Database Lock	0286-0000-19-680-L04-P	Knowledge
332	eSource Adoption: Where We Are - Our Experiences from eSource Implementation	0286-0000-19-665-L04-P	Knowledge
333	Pediatric Plans: The Challenges Between Regulations and Reality	0286-0000-19-666-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
334	Understanding and Exploring Elements of a Patient-Focused Product Launch	0286-0000-19-667-L04-P	Knowledge
335	Highlights of the Patient Engagement Preparedness, Capabilities, Experience, and Impact (PEPCEI) Study	0286-0000-19-736-L04-P	Knowledge
336	Exploring the Evolving Requirements for the Clinical Assessment of Abuse and Dependence Potential of CNS-Active Drugs	0286-0000-19-678-L04-P	Knowledge
337	Application of Project Management Methodologies and Tools in NonProfit Institutions	0286-0000-19-668-L04-P	Knowledge
338	Expanding Use of Interactive Response Technologies in Clinical Trials: Maintaining Data Quality and Reliability	0286-0000-19-669-L04-P	Knowledge
339	Hot Topics in Quality and Regulatory Affairs for Combination Products	0286-0000-19-670-L04-P	Application
340	Digital Technology Advances Labeling Management and Patient Access	0286-0000-19-671-L04-P	Knowledge
341	The Evolving Gene Therapy Regulatory Framework: A Brave New World	0286-0000-19-679-L04-P	Knowledge
342	When is Real World Evidence Ready for Prime Time?	0286-0000-19-681-L04-P	Knowledge
343	Efficient Preparation of Global CMC Dossiers	0286-0000-19-676-L04-P	Knowledge
344	Meaningful Patient-Focused Drug Development for Rare Disease and Personalized Medicine	0286-0000-19-672-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
355	History of Risk Evaluation and Mitigation Strategies (REMS): What Have We Learned?	0286-0000-19-683-L04-P	Application
356	Involving Patients in Medicinal Product Benefit-Risk Communication: How're We Doing?	0286-0000-19-732-L04-P	Knowledge
357	Accelerating Drug Development via Structured Content Reuse: Introducing the TransCelerate Clinical Template eSuite	0286-0000-19-696-L04-P	Knowledge
358	Improving the Trial Experience for Rare Disease Patients: Identifying and Overcoming Obstacles	0286-0000-19-697-L04-P	Application
359	Training for the Electronic Capture of PRO Data in Clinical Trials: Views from ePRO Vendors, Sponsors, Sites, and Patients	0286-0000-19-698-L04-P	Knowledge
360	Identification of Medicinal Products: FDA's Perspective and Approach	0286-0000-19-684-L04-P	Knowledge
361	Returning Plain Language Summaries to Research Participants: Best Practices and the Role of the IRB	0286-0000-19-685-L04-P	Application
362	Patient Engagement Quality Guidance: Results and Learnings from Global Multistakeholder Pilots	0286-0000-19-686-L04-P	Application
363	Neurodegenerative Diseases: Early-Stage Challenges and Optimal Models in Drug Development	0286-0000-19-687-L04-P	Knowledge
364	Effective Portfolio Management of Assets Across an Organization	0286-0000-19-688-L04-P	Application
365	Leveraging Data Analytics to Drive Compliance and Quality in a Risk-Based Monitoring Environment	0286-0000-19-689-L04-P	Knowledge

UNIVERSAL ACTIVITY NUMBERS

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
366	Translating Academic Research into Product Development: Integrating GCP Training into the Process (Part 4 of 4)	0286-0000-19-690-L04-P	Knowledge
367	Model-Informed Drug Development (MIDD) and Complex Innovative Designs (CID) Programs: Where are We and What Have We Learned?	0286-0000-19-691-L04-P	Knowledge
368	Global Rare Disease Town Hall	0286-0000-19-692-L04-P	Knowledge
369	User-Fee Programs Myth Busting: General Financial Principles Explained	0286-0000-19-693-L04-P	Knowledge
370	Challenges and Opportunities in Product Quality: Lifecycle Management	0286-0000-19-699-L04-P	Knowledge
371	Efficient Pediatric Drug Development: Incorporating Innovative Techniques Using Extrapolation and Historical Information	0286-0000-19-694-L04-P	Knowledge
372	Advancing Value and Access With Technology	0286-0000-19-695-L04-P	Application
378.1	On the Soapbox: Good for People and Good for Research - Individuals as Research Partners	0286-0000-19-737-L04-P	Knowledge
379	From Trials to Real World: How Safety Protocols Impact REMS	0286-0000-19-700-L04-P	Application
380	Incorporating Patient Input into the Design and Conduct of Clinical Trials	0286-0000-19-712-L04-P	Knowledge
381	A New Path Forward for Using Decentralized Clinical Trials	0286-0000-19-713-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
382	Real World Data Quality for Regulatory Decision-Making	0286-0000-19-701-L04-P	Knowledge
383	Next-Generation Approaches for Developing Narratives	0286-0000-19-702-L04-P	Knowledge
384	Patient Preferences in Decision Making and the PREFER Project: Past, Present, and Future	0286-0000-19-703-L04-P	Knowledge
385	The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety	0286-0000-19-704-L04-P	Knowledge
386	Setting the Stage for Effective Stakeholder Collaboration	0286-0000-19-705-L04-P	Application
387	Global Perspective on ICH E8(R1): General Considerations for Clinical Trials	0286-0000-19-677-L04-P	Knowledge
388	Convergence of the Regulatory Pathways for Advanced Therapy Medicinal Products	0286-0000-19-707-L04-P	Application
389	Transparency, Expanded Access Navigator, Right to Try: Helping Patients Get Access to Investigational Medicines?	0286-0000-19-708-L04-P	Knowledge
390	Clinical Trial Innovation: Pathways for Selecting and Developing Novel, Fit-for-Purpose, Technology-Derived Study Endpoints	0286-0000-19-709-L04-P	Knowledge
391	Real World Evidence and Artificial Intelligence to Inform Post-Authorization Studies	0286-0000-19-717-L04-P	Knowledge
392	Breakthrough Therapy and PRIME Expedited Regulatory Pathways: Experience, Analysis, and Reflections from EMA, FDA, and Industry	0286-0000-19-735-L04-P	Knowledge

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
393	Case Studies in Resolving Quality Issues	0286-0000-19-715-L04-P	Application
394	Demystifying Basic Statistical Concepts for Anyone Involved with Clinical Trials	0286-0000-19-710-L04-P	Application
395	Utilization and Evaluation of Innovative Approaches for Efficient Drug Development	0286-0000-19-716-L04-P	Knowledge
396	Challenges to Access: Bringing Payers to the Table	0286-0000-19-711-L04-P	Knowledge
403	Successes and Challenges in Pharmacovigilance for Biologics and Biosimilars	0286-0000-19-718-L04-P	Knowledge
404	Investigational Medicinal Products: eLabeling Initiative, Supply Forecasting Strategies, and Patient-Centric Technology for Medicine Adherence	0286-0000-19-725-L04-P	Knowledge
405	eSource and the Sites: Have They Bonded?	0286-0000-19-726-L04-P	Knowledge
406	Electronic Submissions Update	0286-0000-19-719-L04-P	Knowledge
407	A Patient Engagement Wrap Up: Lessons Learned from DIA 2019 and Where Do We Go from Here	0286-0000-19-721-L04-P	Knowledge
408	FDA Botanicals	0286-0000-19-722-L04-P	Knowledge
409	Case Studies From FDA and MHRA: Good Clinical Practices	0286-0000-19-723-L04-P	Application

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

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
410	Advancing Benefit-Risk Assessment to Support FDA's Regulatory Review of Human Drugs and Biologics	0286-0000-19-724-L04-P	Knowledge
411	Recent CMC Changes in Emerging Regulatory Agencies	0286-0000-19-727-L04-P	Knowledge
412	Keeping Up with FDA and EMA Collaborations: Question Time	0286-0000-19-728-L04-P	Knowledge
413	FDA Town Hall	0286-0000-19-729-L04-P	Knowledge