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?	0286-0000-18-500-L04-P	Application
SC #21	The IDMP Challenge: Points to Consider for Pharmacovigilance Departments	0286-0000-18-501-L04-P	Knowledge
SC #22	Protocol Co-Design with Patients and Advocates	0286-0000-18-502-L04-P	Application
SC #23	R&D QA Comprehensive Quality Strategy: An Approach to Managing Quality Risks Throughout the Drug Development Lifecycle	0286-0000-18-503-L04-P	Knowledge
SC #24	Preparing for a US FDA Advisory Committee Meeting	0286-0000-18-504-L04-P	Knowledge
SC #27	The Evolving Role of Payers in Drug Development: Pricing, Pharmacoeconomics, and Health Technology Assessment	0286-0000-18-506-L04-P	Knowledge
SC #28	Preparing Documents for Disclosure and Public Sharing	0286-0000-18-507-L04-P	Knowledge
SC #31	Machine Learning in Pharmacovigilance	0286-0000-18-508-L04-P	Knowledge
SC #33	Quality Tolerance Limits/Issue Management: Taming the Beast of Clinical Development Risk	0286-0000-18-509-L04-P	Application
SC #34	Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Effecting Pharmaceutical Development	0286-0000-18-510-L04-P	Knowledge
SC #35	FDA Advisory Committee Purpose and Noninferiority Case Study: Rivaroxaban	0286-0000-18-511-L04-P	Application

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
SC #36	Value Pricing Bootcamp: A Crash Course in How to Use Real World Evidence to Better Measure Outcomes and Evaluate New Innovative Therapies	0286-0000-18-512-L04-P	Knowledge
SC #37	Data Visualization in the Life Sciences	0286-0000-18-513-L04-P	Application
SC #42	Back to the Future: Combination Products in the 21st Century	0286-0000-18-516-L04-P	Application
100	Opening Plenary Session and Keynote Speaker	0286-0000-18-517-L04-P	Knowledge
105	Cardiac Safety in Drug Development and the Critical Role of Public-Private Partnerships: The Cardiac Safety Research Consortium Model	0286-0000-18-518-L04-P	Knowledge
106	Signal Management: Separating Needles From Haystacks	0286-0000-18-519-L04-P	Knowledge
107	The Metamorphosis of Clinical Trials: Evolving Roles of Stakeholders in Digital Trials	0286-0000-18-520-L04-P	Knowledge
108	From Patients and Advocacy Groups to Operations and Beyond: Obtaining and Incorporating Input from Stakeholders in Protocol Design	0286-0000-18-521-L04-P	Knowledge
109	The Who, What, How, When, and Why of Using Mobile Technology in Clinical Trials	0286-0000-18-522-L04-P	Knowledge
110	Using Fast Healthcare Interoperability Resources (FHIR®) for Clinical Research	0286-0000-18-523-L04-P	Knowledge
111	Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics Driven Approach to Monitor Data Integrity	0286-0000-18-524-L04-P	Knowledge

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
112	Scientific Communication Key Message Development, Management, and Dissemination	0286-0000-18-525-L04-P	Knowledge
113	Patient-Focused Medicines Development: Where it has Led Us to Today, What Challenges Remain, and What do We Still Need to do to Achieve Success?	0286-0000-18-526-L04-P	Knowledge
114	A Hot Debate: Perspectives on Benefit and Risk from Patients Across Diseases	0286-0000-18-527-L04-P	Knowledge
115	Regenerative Medicine Advanced Therapies: Facilitating Product Development and Approval	0286-0000-18-528-L04-P	Knowledge
117	Beyond Robotics Process Automation: Next Generation Integrated QMS for R&D	0286-0000-18-529-L04-P	knowledge
118	How Can We Optimally Incorporate Real World Evidence into Regulatory Decision Making?	0286-0000-18-530-L04-P	knowledge
119	'Target'ing Pediatric Oncology Development: New Global Pediatric Considerations Under FDARA 2017	0286-0000-18-531-L04-P	knowledge
120	FDA Innovation in Pharmaceutical Quality Assessment and Inspection	0286-0000-18-532-L04-P	knowledge
121	Use of Historical Information in Clinical Trial Design	0286-0000-18-533-L04-P	knowledge
122	Contracting for Value: from Outcomes- based Contracts to Bundled Payment Programs: What's Working and Why	0286-0000-18-534-L04-P	knowledge
123	Unmet Medical Need: Diversity of Definitions and Viewpoints – Detangling the Challenge	0286-0000-18-698-L04-P	Knowledge

Session/	Title	Universal Activity Number	Type of
Short Course #			Activity
124	Analyzing Innovations Progress in the Gottlieb Era	0286-0000-18-535-L04-P	Knowledge
139	Novel Approaches to Pharmacovigilance Collaboration	0286-0000-18-536-L04-P	Knowledge
140	How Inspection Ready is your Organization?	0286-0000-18-537-L04-P	Knowledge
141	eSource: The Road to Real World Evidence – Are We There Yet?	0286-0000-18-538-L04-P	Knowledge
142	Mobile Accelerometry in Clinical Trials: Potential Applications and Meaningful Outcomes	0286-0000-18-540-L04-P	Knowledge
143	Applying Artificial Intelligence, Machine Language, Natural Language Processing, and Predictive Models in Clinical Trials to Deliver Value to Stakeholders	0286-0000-18-541-L04-P	Knowledge
144	The Evolving Biosimilars Landscape: A Medical Affairs Perspective	0286-0000-18-542-L04-P	Knowledge
145	A New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors	0286-0000-18-543-L04-P	Knowledge
146	Development of Microbiome - Derived Therapeutics	0286-0000-18-544-L04-P	Knowledge
147	Facilitating Nonclinical Data Sharing and Access Across the Industry	0286-0000-18-545-L04-P	Knowledge
149	A Quality-by-Design Approach to Trial Design and Conduct: Case Studies from the Clinical Trials Transformation Initiative	0286-0000-18-546-L04-P	Application

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
150	TFDA Town Hall	0286-0000-18-547-L04-P	Knowledge
151	Using Real World Evidence for Regulatory Support: Time to Embrace the Future	0286-0000-18-548-L04-P	Knowledge
152	FDA Expectations for Demonstration of Interchangeability	0286-0000-18-549-L04-P	Knowledge
153	New Technologies in Pharmaceuticals and Biopharmaceuticals: Opportunities and Regulatory Challenges	0286-0000-18-550-L04-P	Knowledge
154	Bayesian Application in Small-Sized Clinical Trials	0286-0000-18-551-L04-P	Application
155	Real World Evidence for Value and Access	0286-0000-18-552-L04-P	Knowledge
156	International Regulatory Convergence	0286-0000-18-553-L04-P	Knowledge
201	Generic Drug Products: Comparison of Safety Profile with Branded Cousin	0286-0000-18-554-L04-P	Knowledge
202	Quantifying the Impact of Credentialed Clinical Research Site Professionals on Clinical Trial Conduct Quality	0286-0000-18-555-L04-P	Knowledge
203	Utilizing and Understanding Real World Evidence Solutions to Efficiently Recruit the Most Appropriate Patients and Sites for Clinical Trials	0286-0000-18-556-L04-P	Application
204	FDA Data Standards Update	0286-0000-18-557-L04-P	Knowledge

Session/ Short	Title	Universal Activity Number	Type of Activity
Course #			
205	Best Practices for Implementing Lay Summaries and Communicating Results to Patients	0286-0000-18-558-L04-P	Application
206	Incorporating Patient Input Into US Food and Drug Administration's Medical Product Development and Regulatory Decision-Making	0286-0000-18-559-L04-P	Knowledge
207	Novel Approaches for Accessing the CNS: Nonclinical and Clinical Challenges	0286-0000-18-560-L04-P	Knowledge
208	Effective Management of Internal Stakeholders and External Strategic Partners from Multiple Perspectives: Non- Profit, CRO, and Pharmaceutical Industry	0286-0000-18-561-L04-P	Application
209	Oversight in the Era of E6 (R2)	0286-0000-18-562-L04-P	Application
210	Artificial Intelligence: The Future of Regulatory Affairs	0286-0000-18-563-L04-P	Application
211	Update on Collaboration and Trends in Global Companion Diagnostics	0286-0000-18-564-L04-P	Knowledge
212	Global Regulatory Strategies for Biosimilars	0286-0000-18-565-L04-P	Application
213	2018 Policy Mash-Up: New Shifts in the Healthcare Market and What They May Mean for Patients and the Biopharma Industry	0286-0000-18-702-L04-P	Knowledge
214	CMC Challenges for Breakthrough Therapies and Other Worldwide Accelerated Approval Programs	0286-0000-18-567-L04-P	Knowledge
215	Pediatric and Rare Disease Drug Development	0286-0000-18-568-L04-P	Knowledge

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
216	Early HTA Scientific Advice: Does it Improve Internal Company Decision-Making and Ensure Predictability of HTA Outcome?	0286-0000-18-569-L04-P	Knowledge
217	Triple-A RWE: Adequate Data, Appropriate Study Designs, and Actionable Evidence	0286-0000-18-570-L04-P	Knowledge
226	Regulators' Utilization of Real-World Data in Pharmacovigilance Activities	0286-0000-18-571-L04-P	Knowledge
228	Global Clinical Trials: Lessons in Effective Execution	0286-0000-18-572-L04-P	Knowledge
229	Mobile Reported Outcomes: A Forum on Patient and Caregiver Assessments	0286-0000-18-573-L04-P	Application
230	Common Data Model Harmonization for Evidence Generation	0286-0000-18-574-L04-P	Knowledge
231	Automation with Intelligence: From Standard- Based Solution to Metadata-Driven Automation	0286-0000-18-575-L04-P	Knowledge
232	Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications	0286-0000-18-576-L04-P	Knowledge
233	The Patient's Assessment of the Patient- Focused Drug Development Meeting Initiatives	0286-0000-18-577-L04-P	Knowledge
234	Personalized Medicine Approaches During Early-Phase Clinical Research	0286-0000-18-578-L04-P	Knowledge
235	The Adventures of Patient Experience in Drug Development	0286-0000-18-579-L04-P	Knowledge

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
236	Executives Respond to the State of the Industry Report on Risk-Based Approaches in Clinical Trials: Opportunity or Threat?	0286-0000-18-580-L04-P	Knowledge
237	Expanded Access: Where Are We Now?	0286-0000-18-581-L04-P	Knowledge
238	The European Medical Devices Regulation and MDUFA IV: One Year On - Is it Any Clearer?	0286-0000-18-582-L04-P	Knowledge
239	Generic Drug Town Hall	0286-0000-18-583-L04-P	Knowledge
240	Biosimilars: Demonstrating Structural and Functional Similarity	0286-0000-18-584-L04-P	Knowledge
241	Time-to-Event Analysis in Clinical Trials	0286-0000-18-585-L04-P	Knowledge
242	Unmet Medical Need: Can the Stakeholders Align? Progress to Date	0286-0000-18-700-L04-P	Knowledge
243	Global Perspectives on Patient Engagement	0286-0000-18-586-L04-P	Knowledge
251	Risk Management: New Directions	0286-0000-18-587-L04-P	Knowledge
252	Do the End(point)s Justify the Means? A Peak at Endpoints Accepted by FDA with an Eye Towards Mobile Technology Collection	0286-0000-18-588-L04-P	Knowledge
253	Digitizing a Patient-Focused Clinical Trial Experience	0286-0000-18-589-L04-P	Knowledge

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
254	Risk-Based Monitoring for Master Protocol Study: A Dilemma and Possible Ways to Go	0286-0000-18-590-L04-P	Knowledge
255	Use of Electronic Health Records (EHRs) as eSource in Clinical Investigations	0286-0000-18-591-L04-P	Knowledge
256	CTD Regulatory Defense Strategies: How Best to Prepare Your Response to Health Authority Queries	0286-0000-18-592-L04-P	Application
257	Globalizing and Regionalizing Medical Information Contact Centers	0286-0000-18-593-L04-P	Knowledge
258	Reaching the Underserved: Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels	0286-0000-18-594-L04-P	Knowledge
259	Measuring the Impact of Patient Engagement: What to Ask Depends on Who You Ask	0286-0000-18-704-L04-P	Knowledge
260	Optimizing Clinical Development With Adaptive Trial Designs	0286-0000-18-595-L04-P	Knowledge
261	Project Management Throwdown: How Not to Get Chopped	0286-0000-18-596-L04-P	Knowledge
262	The Risk Assessment Is Done: Now What? A Guide to Setting Up a Centralized Monitoring Plan	0286-0000-18-597-L04-P	Knowledge
263	Navigating the Regulatory Landscape of Drug-Device Combination Products	0286-0000-18-598-L04-P	Knowledge
264	Global Development Using Expedited Pathways in Established and Emerging Markets	0286-0000-18-599-L04-P	Knowledge

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Short			Activity
Course #			
265	ICH M9 BCS-Based Biowaivers	0286-0000-18-600-L04-P	Knowledge
266	User-Friendly Tools for Study Planning and Analysis	0286-0000-18-601-L04-P	Knowledge
267	Developing and Partnering on Evidence for Outcomes and Value Assessment: Standardizing Measurement for Patient-Centered Care	0286-0000-18-602-L04-P	Knowledge
268	Future of PharmaTech	0286-0000-18-603-L04-P	Knowledge
276	Patient Engagement in Pharmacovigilance	0286-0000-18-604-L04-P	Knowledge
277	Pharmacovigilance: No Longer Going it Alone	0286-0000-18-605-L04-P	Knowledge
278	Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring	0286-0000-18-606-L04-P	Knowledge
279	Redefining the Site Investigator's Experience	0286-0000-18-607-L04-P	Knowledge
280	Debunking Decentralized Trials: Sharing Breakthroughs and Deal Breakers	0286-0000-18-608-L04-P	Knowledge
281	Future of Endpoints	0286-0000-18-609-L04-P	Knowledge
282	Building up Efficiencies, Breaking Down Barriers: Using Mobile Technology for Data Capture in Clinical Trials	0286-0000-18-610-L04-P	Knowledge

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283	Evolving Roles and Responsibilities for Medical Affairs Professionals	0286-0000-18-611-L04-P	Knowledge
284	Using Advocacy Partnerships to Improve Real World Evidence in Clinical Trials	0286-0000-18-612-L04-P	Knowledge
285	Gene Therapy: Advances in Translating Technology	0286-0000-18-613-L04-P	Knowledge
286	Which Regulatory Project Management Staff at FDA Should You Engage With? When and How?	0286-0000-18-614-L04-P	Knowledge
287	The Letter and Spirit of Risk-Based Monitoring: How to Creatively Implement Risk-Based Modeling and Unlock the Potential of the Team	0286-0000-18-615-L04-P	Knowledge
288	Is it Time to Change the Content and Format of Labeling?	0286-0000-18-616-L04-P	Knowledge
289	Electronic Submissions Demystified	0286-0000-18-617-L04-P	Knowledge
290	Priority Review Vouchers: Here to Stay and Worth the Effort?	0286-0000-18-566-L04-P	Knowledge
291	ICH Q12: A Paradigm Changing Guidance for Post-Approval Changes?	0286-0000-18-618-L04-P	Knowledge
292	Complex Innovative Designs and Model- Informed Drug Development Related: PDUFA VI Pilot Programs	0286-0000-18-619-L04-P	Knowledge
293	Medical Monitoring in Non-Interventional Studies: Need for Medical Leadership and Study Primary Care Management	0286-0000-18-620-L04-P	Knowledge

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294	Sustainable Healthcare Funding	0286-0000-18-621-L04-P	Knowledge
301	Automation in Pharmacovigilance: Doing More with Less	0286-0000-18-622-L04-P	Knowledge
302	Risk Communication and Patient Safety: Recent Learnings and New Approaches	0286-0000-18-623-L04-P	Knowledge
303	Regulatory and Ethical Considerations with Placebo Administration Using a Central Venous Access Device in a Pediatric Trial	0286-0000-18-624-L04-P	Knowledge
304	Data and Quality Approaches to Informing Global Investigative Site Selection	0286-0000-18-625-L04-P	Knowledge
305	Building a Roadmap to the Implementation of the Risk-Based Monitoring Process: Facilitating the Perspectives of All Stakeholders	0286-0000-18-626-L04-P	Knowledge
306	phactMI: A Collaborative Approach to Advancing the Practice of Medical Information and Enabling Innovative Customer Solutions	0286-0000-18-703-L04-P	Knowledge
307	Maintaining Patient Engagement in the Development of Patient-Reported Outcome (PRO) Measures	0286-0000-18-627-L04-P	Knowledge
308	How do Patients and Other Multi-Disciplinary Stakeholders Collaborate to Develop Patient Registries Which Accelerate Research?	0286-0000-18-628-L04-P	Knowledge
309	Evolution and Harmonization of First-in- Human Guidelines	0286-0000-18-629-L04-P	Knowledge
311	Harnessing the Power of Data and Analytics to Enhance Quality	0286-0000-18-630-L04-P	Knowledge

Session/ Short Course #	Title	Universal Activity Number	Type of Activity
312	Harmonizing Regulatory Science Through the International Council for Harmonisation (ICH)	0286-0000-18-631-L04-P	Knowledge
313	Global Rare Disease Town Hall	0286-0000-18-632-L04-P	Knowledge
314	What can We say About Combination Products? Labeling, Advertising, and Promotion of Combination Products	0286-0000-18-633-L04-P	Knowledge
315	Can I Implement That Now? Efficiently Managing Post-Approval CMC Changes	0286-0000-18-634-L04-P	Knowledge
316	Opportunities for Efficient and Innovative Study Designs	0286-0000-18-635-L04-P	Knowledge
317	Operationalizing Real World Evidence and Value	0286-0000-18-636-L04-P	Knowledge
318	Value-Based Assessment and Contracting: What Needs to be Done to Make it a Best Practice?	0286-0000-18-637-L04-P	Knowledge
329	Reducing the Burden of Drug Safety Risk Minimization Programs on the Healthcare System: How do We do so and What has Been Learned to-Date?	0286-0000-18-638-L04-P	Knowledge
330	Artificial Intelligence: Robots Taking Over Clinical Research	0286-0000-18-639-L04-P	Knowledge
331	Rebuilding or Building a Research Site in the Year 2020	0286-0000-18-640-L04-P	Knowledge
332	Clinical Data: Let's get to the Source and Streamline it to the End	0286-0000-18-641-L04-P	Application

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333	Streamlining Vendor Reconciliation	0286-0000-18-642-L04-P	Knowledge
334	Clinical Trial Results Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Pilot Program	0286-0000-18-643-L04-P	Knowledge
335	Collaboration Across the Medical Affairs Ecosystem to Advance Patient Care	0286-0000-18-644-L04-P	Knowledge
336	Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement	0286-0000-18-645-L04-P	Knowledge
337	Balancing Regulatory, Medical, and Operational Pillars to Get Pediatric Trials Done Globally	0286-0000-18-646-L04-P	Knowledge
338	You've Got Data #now What?	0286-0000-18-647-L04-P	Knowledge
339	Determining Data Integrity: Decoding the Impact of Inspectional Observations	0286-0000-18-648-L04-P	Knowledge
340	Harmonization Beyond ICH	0286-0000-18-649-L04-P	Knowledge
341	New FDA Draft Guidance on Part 11 in Clinical Investigations	0286-0000-18-650-L04-P	Knowledge
342	Sex Considerations in the FDA Drug Review Pipeline: The Where, When, and How	0286-0000-18-651-L04-P	Knowledge
343	Innovative Visualization Approaches	0286-0000-18-652-L04-P	Knowledge

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344	Biosimilar Interchangeability: A Global Perspective	0286-0000-18-653-L04-P	Knowledge
345	Unmet Medical Need: Path Forward – Creating a Commonly Agreed Criteria Globally	0286-0000-18-699-L04-P	Knowledge
346	Precision Medicine, Gene Editing, and Gene Therapy: Current Status and Regulatory Challenges of Integrating Genetic Medicine into Clinical Care	0286-0000-18-654-L04-P	Knowledge
358	Expedited E2B Safety Reporting in Interventional Clinical Trials: Convergence of Global Expectations?	0286-0000-18-655-L04-P	Knowledge
359	IMEDS: A Collaboration Based on the FDA's Sentinel Initiative	0286-0000-18-656-L04-P	Knowledge
360	Implementation of eConsent and Other Digital Clinical Trial Innovations	0286-0000-18-657-L04-P	Knowledge
361	A New Way of Authoring and Reviewing Documents for Clinical Development	0286-0000-18-658-L04-P	Knowledge
362	Do the Evolution: The Future Role of Clinical Data Management	0286-0000-18-659-L04-P	Knowledge
363	Innovative and Effective Authoring Strategies to Facilitate Accelerated Regulatory Submissions	0286-0000-18-660-L04-P	Knowledge
364	Achieving Customer Centricity to Advance Patient Care Through Innovative Communication Channels	0286-0000-18-661-L04-P	Knowledge
365	Engaging the Rare Disease Community to Design Clinical Trials	0286-0000-18-662-L04-P	Knowledge

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366	Gene Therapy Clinical Trials: Current Challenges	0286-0000-18-663-L04-P	Knowledge
367	Real Life Strategies for Collaborative Stakeholder Management	0286-0000-18-664-L04-P	Knowledge
368	Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling	0286-0000-18-665-L04-P	Knowledge
369	Virtual Audits: Do They Achieve the Objective?	0286-0000-18-666-L04-P	Application
370	Clinical Outcomes Assessments (COA) Endpoints for Use in Rare and Ultra-Rare Disease Clinical Trials	0286-0000-18-667-L04-P	Application
371	What's New in Health Canada: Updates and New Endeavors	0286-0000-18-668-L04-P	Knowledge
372	AdPromo:Assessing Risk in the Current Regulatory Environment	0286-0000-18-669-L04-P	Knowledge
373	PMDA Town Hall	0286-0000-18-670-L04-P	Knowledge
374	Modernization and Harmonization of Inspectional Approaches	0286-0000-18-671-L04-P	Knowledge
375	Statistical Challenges in Assessing Drugs' Efficacy by Utilizing Biomarker Endpoints	0286-0000-18-672-L04-P	Knowledge
382	Artificial Intelligence: A Disruptive Journey for Pharmacovigilance	0286-0000-18-673-L04-P	Knowledge

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383	Safe Use and Prescribing of Opioid Medications: An In-Depth Look at the Strategies and Their Evaluation	0286-0000-18-674-L04-P	Knowledge
384	Innovations in Managing Global Clinical Supplies	0286-0000-18-675-L04-P	Knowledge
385	Does Sourcing Strategy Matter? Executives Debate the Influence of Outsourcing Model on Clinical Trial Execution	0286-0000-18-676-L04-P	Knowledge
386	Bring Your Own Device ePRO: Hold the Relish, or No Holds Barred?	0286-0000-18-677-L04-P	Knowledge
387	Evolving CDISC Standards and Technologies	0286-0000-18-678-L04-P	Knowledge
388	Using Patient-Centric Outcomes to Engage Patients in Shared Treatment Decision- Making	0286-0000-18-679-L04-P	Knowledge
389	Patient Observation Versus Patient Engagement: Optimizing Development	0286-0000-18-680-L04-P	Knowledge
390	Special Population Study Challenges	0286-0000-18-681-L04-P	Knowledge
392	FUNdamentals of Project Management	0286-0000-18-682-L04-P	Application
393	Think Like a Regulator: Evaluating Trial Integrity	0286-0000-18-683-L04-P	Knowledge
394	Update on BREXIT	0286-0000-18-705-L04-P	Knowledge

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395	PDUFA VI: Improving Transparency and Accountability of Electronic Submission and Data Standards Activities	0286-0000-18-684-L04-P	Knowledge
396	Current and Future Perspective on Mutual Recognition, Work Sharing, and Global Regulatory Convergence	0286-0000-18-685-L04-P	Application
397	Design and Statistical Considerations for Real World Evidence to Support Regulatory Decision-Making	0286-0000-18-686-L04-P	Knowledge
398	The Impact of Cell and Gene Therapy on the Payer System	0286-0000-18-687-L04-P	Knowledge
404	Payers, Industry, and Academia Collaborating on Post-Marketing Surveillance	0286-0000-18-688-L04-P	Knowledge
405	Putting Patient Experience First	0286-0000-18-689-L04-P	Knowledge
406	Improving Efficiency and Effectiveness in Data Management of Pediatric, Rare Disease, and Oncology Trials	0286-0000-18-690-L04-P	Application
407	Beyond Adult Patients, Untapped Advisors in Clinical Development: Adolescents, Parents, Siblings, and Spouses	0286-0000-18-691-L04-P	Knowledge
409	Emerging Best Practices and Challenges in Strategic Drug Development and Design Decision-Making	0286-0000-18-692-L04-P	Knowledge
411	Regulatory and Industry Perspectives on the Common Protocol Template	0286-0000-18-693-L04-P	Knowledge
412	Metrics and Meaning: Evolving Metrics in Generic Drug Application Review and Communications to Improve ANDA Submission Planning and Approvability	0286-0000-18-694-L04-P	Knowledge

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413	The Correlation Between Patient-Reported Outcomes and Clinician-Reported Outcomes	0286-0000-18-695-L04-P	Knowledge
414	Unmet Medical Need: What did We Create Together and Where to Take It?	0286-0000-18-701-L04-P	Knowledge
415	EMA/FDA Question Time	0286-0000-18-696-L04-P	Knowledge
416	FDA Town Hall	0286-0000-18-697-L04-P	Knowledge