2022.12.8 | ICH Day

8:30–9:30	ICH Plenary				
10:00–15:00 *(Lunch & Tea Break in Between)*	E6R3	AM: E8R1 PM: Implementation and Consideration of ICH-E9(R1) Estimand Framework	Q12 Lifecycle Management & Q13 Continuous Manufacturing of Drug Substances and Drug Products	ICH Safety Guidelines: Nonclinical Safety Strategy Supporting FIH and Development of Modern Modalities	M4Q(R2)

2022.12.8 | Pre-conference Short Courses

15:30–18:00	Labeling Management	Regulatory Requirements of Medical Coding in Clinical Trials	RWD to Support Drug Application	Inspection Readiness via a Comprehensive PV QMS	Target Trial Emulation	DIA Global Forum Highlights	Ethics Forum	China Drug Regulatory Special Forum	When Medical Affairs Meet Clinical Development
13:30–17:00	PIC/S Forum								

2022.12.9

8:30–12:00	Opening Plenary
14:00–17:00	Global Modernization Regulatory Townhall | NMPA Townhall

2022.12.10

	Regulatory Science		Drug Clinical Development			
	China Regulatory Modernization	Global Regulatory New Trend	Non-oncology Drug Clinical Development	Oncology Drug Clinical Development	Novel Targets/New Modalities Drug Clinical Development	Clinical Pharmacology
8:30–10:00	Session 0101 Expedited Program under New Regulations - Considerations & Practices	-	Session 0201-A Drug Development in Cardiovascular Diseases – Challenges and Opportunities	Session 0201-B Collaboration and Acceleration for Cancer Cure - Hot Topics in Oncology Development	Session 0201-C Gene Therapy in Rare Diseases	-
10:30–12:00	Session 0102 Challenges and Considerations from Accelerated Approval to Full Approval	-	Sesion 0202-A Neurology & Psychiatry Drug Development	Session 0202-B Statistical Innovations and Practical Considerations for Oncology Drug Development	Session 0202-C CAR-T Therapies – Past, Current and Future	-
13:30–15:00	Session 0103 The Opportunity and Challenge Under the Concept of Clinical Value-Oriented Drug Innovation - Part 1	-	Session 0203-A Breakthrough of Rheumatism Immunotherapy	Session 0203-B Anti-PD1/L1 Bispecific Antibody	Session 0203-C RNAi Therapeutics: A New Class of Transformational Medicines	-
16:00–17:30	Session 0104 The Opportunity and Challenge Under the Concept of Clinical Value-Oriented Drug Innovation- Part 2	-	Session 0204-A Vaccine Development	Session 0204-B Development of Small Molecule Drugs & New Targets of ADC Drugs	Session 0204-C Development of Radioligand Therapies in Oncology	-

2022.12.11

8:30–10:00	Session 0105-A How to Further Promote the Convergence and Consistency of Global Supervision - Regulatory Innovation Trend in China, Japan, Europe and the United States	Session 0105-B FDA Session: Communicating with the FDA: Best Practices to Overcome Drug Approval Barriers and Regulatory Challenges	Session 0205-A Infection Disease Drug Development	Session 0205-B Application of New Technology in Oncology Drug R&D	Session 0205-C AI and Digital Tools in Drug Development - 1	Session 0205-D China Clinical Pharmacology's Today and Tomorrow
10:30–12:00	Session 0106-A Opportunities, Challenges and Suggestions for MAH Implementation in China	Session 0106-B PMDA & JPMA Joint Session: How Japanese Regulatory Authority and Industry Responded to Managing Clinical Trials under COVID-19 Pandemic	Session 0206-A Metabolic Endocrinology	-	Session 0206-C AI and Digital Tools in Drug Development - 2	Session 0206-D Make Clinical Pharmacology a "Symphony" of Medical & Drug Integration

2022.12.10

	Patient Centered Clinical Operations and Quality Management			Clinical Needs and Trial Platform		Data Science	Biostatistics
	Clinical Operations	Investigational Drug Management & Supply Chain	Clinical Quality Management				
8:30–10:00	Session 0301-A Patient Education & Recruitment	Session 0301-B Internal Management of Investigational Drug - from the Sponsor Perspective: Part 1	-	Session 0401-A Overseas Clinical Trial Experience Sharing	Session 0401-B The Implementation and Difficulties in Establishment and Development of Research Hospital	Session 0501 Regulatory Requirements and Practice of Direct Data Capture (DDC)	Session 0601 On Rare Disease Drug Development Pathway and Clinical Study Designs – Case Studies
10:30–12:00	Session 0302-A Win-win Collaboration of Clinical Operations	Session 0302-B Internal Management of Investigational Drug - from the Sponsor Perspective: Part 2		Session 0402-A Standardization of IIT Study	Session 0402-B "Not" Clinical Value Driven Clinical Study	Session 0502 Source Data Management in Clinical Trials	Session 0602 Practicing ICH E17 for Simultaneous Global New Drug Development & Registration
13:30–15:00	Session 0303-A The Practice and Explore for DCT in Early Clinical Phase Studies	Session 0303-B Traceable Transportation of Investigational Drug from Sponsor to Clinical Site	Session 0303-C Jointly Build a Quality Management System for Clinical Trials - Part 1	Session 0403-A Ethics Regulation	Session 0403-B Discussion on the Difficulties and Challenges of Drug R&D Model Innovation - Part I	Session 0503 Data Anonymization and Data Privacy	Session 0603 Design and Considerations in Vaccine Trials
16:00–17:30	-	Session 0304-B Centralized Management of Investigational Drug in Clinical Site	Session 0304-C Jointly Build a Quality Management System for Clinical Trials - Part 2	Session 0404-A Ethics New Technology	Session 0404-B Discussion on the Difficulties and Challenges of Drug R&D Model Innovation - Part 2	Session 0504 Real World Data Quality Evaluation	Session 0604 Trial Design, Data Collection and Statistical Analysis for Decentralized Clinical Trials (DCTs)

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	Session 0305-A Emerging Technologies Empowering Clinical Operations – 1: Novel Digital Endpoints	-	Session 0305-C Quality by Design: Exploring the Opportunities and Challenges of GCP Quality from the Perspective of GCP Site Inspection	-	-	Session 0505 Clinical Data Talent Development	Session 0605 Application and Challenge of Artificial Intelligence in the Whole Lifecycle of Drug Development
	Session 0306-A Emerging Technologies Empowering Clinical Operations – 2: Experience and Technical Support of Digital Clinical Trials		Session 0306-C Quality by Design: Reflection from Inspection Findings and Possible Solutions	-	-	Session 0506 How to Ensure Data Quality through Cross Functional Collaboration: Case Sharing	Session 0606 Guidance on Risk Management: From Theory to Practical Implementation

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2022.12.10

Drug Safety & PV	CMC	Translational Medicines	Non-clinical & Animal Test	Medical Writing and Publication	Pediatric Drug Development Forum	Hot Topics	
Session 0701 Safety Considerations in Clinical Development	Session 0801 Regulatory Science in Gene and Cell Therapy - Part I	-	Session 1001 Nonclinical Data to Support Clinical Development	Session 1101 Value of Medical Writing in the Pharmaceutical Industry	Session 1201 Pediatric Drug Development –P 1: Pediatric Clinical Trials and Regulatory Consideration	Session 1301-A Market Access in Drug Development	Session 1301-B Market Access in Drug Development
Session 0702 Post Approval PV	Session 0802 Regulatory Science in Gene and Cell Therapy - Part 2		Session 1002 Nonclinical Assessment of New Modalities	Session 1102 The Value of Medical Writing in Clinical Document Preparation for NDA/BLA Submissions	Session 1202 Pediatric Drug Development –P2: The Use of Extrapolation in Pediatric Drug Development	Session 1302 eSource Data: Opportunities and Challenges for Improving Data Acquisition Efficiency	-
Session 0703 Regulatory Compliance in Drug Safety	Session 0803 CMC Development for Advanced Therapies & Technologies of Biologics	Session 0903 What Does Translational Medicine Really Mean?	-	-	Session 1203 Pediatric Drug Development –P 3: RWD & Panel Discussion	-	-
Session 0704 Drug Safety in Therapeutic Areas	Session 0804 CMC Regulation and Challenges of mRNA and Cell Therapy	Session 0904 Application of Translational Medicine: Innovations			-	Session 1304-A China Pharmaceutical R&D Talent Development	Session 1304-B Building a Portfolio for Global: Where We Are & Where to Focus

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Session 0705 COVID-19 Drug Safety	Session 0805 CMC Regulatory Requirements - Small Molecules Drug	Session 0905 Regulation Update on Translational Medicine	-	-	-	Session 1305-A Agility in Clinical Project Management	Session 1305-B Pharmaceutical Physicians and Pharmaceutical Medicine
Session 0706 PV Meets Information Technology and Methodology	Session 0806 CMC Regulatory Requirements - Biologic Drug	Session 0906 Exploring Collaboration Models in Translational Medicine				Session 1306 Innovation & GMP Compliance - Yeehong Joint Session	

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