Thursday | May 20, 2021 | ICH Day						
8:30–10:00	ICH Plenary Session					
10:00–10:15	Tea break					
10:15–15:00 *(Lunch & Tea Break in Between)*	How Data Standard Meets ICH Requirements	AM: **E17** PM: **E9(R1)** Estimands and Sensitivity Analysis in Clinical Trials	**E6** Quality Perspectives	Q Series	ICH Safety Guidelines: Regulatory Evolving Trend and China Implementation	

Thursday | May 20, 2021 | Pre-conference Short Courses						
15:30–18:00	Robust Pharmacovigilance Quality Management System from Regulator Perspective	New Drug IP & Data Protection	Data Management from the Inspection Perspective	Case Study from a Negative Clinical Trial Results - Oncology	Neuroscience Clinical Development Forum	Design, Data Management and Statistical Analysis of Observational Studies
13:30–17:00	Forward Looking Talent Development - Rooted Global Mindset					

Friday | May 21, 2021	
9:00–12:00	Opening Plenary
13:30–17:00	Global Modernization Regulatory Townhall

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	Regulatory Science		New Breakthroughs in Treatment	Clinical Operations and Quality Compliance		Site Management & Clinical Study	Data & Data Standards
8:30–10:00	0101 Applying Regulatory Flexibility in the Age of COVID-19		0201 Breakthrough of New Cardiovascular Drugs	0301 Patient Recruitment		0401 China's Clinical Diagnosis and Treatment Needs of Oncology	0501 Risk based Monitoring (RBM) Data Management
10:30–12:00	0102 IND Strategy under New Regulatory Environment		0202 Breakthrough of Rheumatism Immunotherapy	0302 Clinical Supply Chain Management		0402 The Present and The Future of China Clinical Site	0502 Cross Functional Cooperation of Data Quality in Clinical Trial
13:30–15:00	0103 Communication Strategy and Practice with Drug Agency in New Regulatory Environment		0203 Strategies of Tumor Immune Combination Therapy	0303 Decentralized Clinical Trials Operations & Talent Development		0403 Key Considerations of Hospital Ethics	0503 Medical Data Review in Clinical Trials
16:00–17:30	0104-1 Expedited Program and Experience Sharing in China	0104-2 EMA Session	0204 Monoclonal Antibody vs. Bispecific Antibody - a Debate Session	0304 Study Cost and Vendor Contract Management		0404 Effective Communication with Clinical Site	0504 Opportunities and Challenges of Connecting Central Database with Sponsor's EDC

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8:30–10:00	0105-1 Co-development of Therapeutic Drug and Companion Diagnostics for Precision Medicine	0105-2 PMDA Session	0205 Clinical Trial Design for Novel Targets and Modalities of Tumor	0305 Clinical Project Management		0405 IIT's Key Roles and Value Mining	0505 Data and Imaging Management in Oncology Clinical Trial
10:30–12:00	0106 Discussion on New Policy in Pilot Zone		0206 The Opportunity of New Drug in China from the Difference of Tumor Spectrum between East and West	0306-1 Science in the Clinical Quality Management Practice - How Far Are We from Our "North Star"?	0306-2 TranCelerate Special Session (Invited Only)	0406 Patient Centered Clinical Study Needs and Practice	0506 Data Automation in Lifecycle Clinical Trial Program

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Statistics	Gene/Cell Therapies	CMC & GMP	Medical Writing & Medical Affairs	Pharmacovigilance & Risk Management	Rare Diseases & Patient Engagement
0601 Complex Innovative Design	0701 Cell and Gene Therapy Development	0801 GMP Inspection and Case Study under New Regulations	0901 CSR Preparation under ICH E3: Content-centric and Process-regulated	1001 Patient Safety Monitoring during the Clinical Trials	-
0602 Benefit-risk Considerations of Drug Development under Pandemic	0702 Regulatory Science of Cell and Gene Therapy	0802 Continuous Manufacturing	0902 Clinical Documents beyond the Clinical Study Report	1002 An Evolving PV Work Model in the Changing Regulatory Environment	-
0603 Data Monitoring Committee(DMC)-Challenges and Opportunities under the New Guidance	0703 CMC Challenges in the New Trend of Cell and Gene Therapy	0803 The Regulatory Interpretation and Case Study of Clinical and Post-marketing Pharmaceutical Change Management - Chemical Drugs	0903 The Value of Medical Affairs in Launch of New Products Targeting Ignored Diseases	1003 Safety Dossier Development in NDA/BLA	1103 Patient-Centered Drug Development
0604 Patient Focused Design	0704 Clinical Development of Cell and Gene Therapy Products	0804 The Regulatory Interpretation and Case Study of Clinical and Post-marketing Pharmaceutical Change Management - Biological Drugs	0904 Talent Strategy and Development Opportunities under Different R&D Models in Biopharma Industry	1004 PV Forward Looking from New Tech Perspective	1104 Global Regulation and Development of Rare Diseases

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0605 Rare Disease Drug Development	0705 Risk Control for Cell Therapy Product Development and Hospital Risk Management		0905 The Challenges and Countermeasures of Compliance in Medical Affairs	1005 PV Inspection Readiness "Quality in Routine"	
0606 A Panel Discussion Among Statistician, Physician and CMO	0706 Cell and Gene Therapy Panel Discussion		0906 The Strategy of Post Market Studies and Implement	1006 Safety Surveillance and Risk Management in Innovative Oncology Drug	

Sunday | May 23, 2021 | ISPE Special Forum

8:30–12:00	Forum 1: Global Remote/Desktop Inspection Requirements & Technology Transformation	Forum 2 Industrialization of Biologicals and Process Development	Forum 3 Clinical Supply Chain Management

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- Discussion on the most cutting edged hot topics
- Interaction with KOLs around the world

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Engage & Exchange
- Led by DIA China Community Members
- Collaborative learning opportunities
- Peer-to-peer information exchange

Innovation Theater
- Activities in exhibition hall, lead and support by exhibitors
- Display the latest technology and achievements of innovative enterprises

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Emerging Technologies and Digital Health	CDx & Assay Testing	Early Phase Clinical Research	Hot Topics and Late Breakers	WPS
1201 Application of Image Recognition and Voice Intelligent Technologies in Clinical Study	1301 Diagnostics Help Science Win through Precision	1401 Early Phase Risk Control for New Modalities Development - 1	1501 The Past, Present and Future of FDA's New Drugs Regulatory Program Modernization	Session in Progress
1202 Application of Merging Technologies in Clinical Study	1302 Genomic Biomarkers Related to Oncology Drug Development	1402 Early Phase Risk Control for New Modalities Development - 2	1502 Hematopoietic Tumors	
1203 Digital Therapies: from Concept to Practice	1303 Development Strategy of CDx	1403 Registration Path VS. Development Path of Modified New Drugs	1503 Market Access	
1204 Medical Big Data in Clinical Study	1304 PK/PD Analysis in Clinical Research and Development of New Drugs	1404 Data Interpretation of Differentiated Targets	1504 Quality Control and Audit of Research Center Data	

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1205 Cutting-edge Progress of Decentralized Trials		1505-1 China Pharmaceutical R&D Leadership Forum	1505-2 A Broader View of Research and Application of Real-World Data in Drug Development – 1		-
1206 AI Applications in Drug and Medical Device Development		1506-1 New Drug Development Management and Key Decision-Making Process	1506-2 A Broader View of Research and Application of Real-World Data in Drug Development – 2	1506-3 R&D Head and CMO Forum	

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