Wednesday | July 29, 2020 | ICH GUIDELINE TRAINING

8:30–9:30	**ICH 30 Years – What Will Come in the Next Decade** | A108-110, 1ST FLOOR		
9:30–10:00	Tea Break		
10:00–12:30		A108-110, 1ST FLOOR E9(R1) Estimands and Sensitivity Analysis in Clinical Trials	A105-106, 1ST FLOOR M8 Regulatory Operations Management in CTD/ eCTD Submission
13:30–17:30	A108-110, 1ST FLOOR E6/E8 Central Monitoring		A105-106, 1ST FLOOR Data and Data Standard Management under ICH-GCP Guideline

Thursday | July 30, 2020 | PRE-CONFERENCE SESSIONS

8:30-12:00	A108-109, 1ST FLOOR RWE to Support Regulatory Decision Making	A101-102, 1ST FLOOR Randomization and Supplier Management in Clinical Trials	A103-104, 1ST FLOOR Clinical Trial External Lab Data Management	A105, 1ST FLOOR Boot Camp for Startup Company	A106-107, 1ST FLOOR Adaptive Design & Enrichment Design	A110, 1ST FLOOR Pharmaceutical Medicine	A202-203, 2ND FL. Ophthalmic Forum
14:00-17:00	**Opening Plenary** | 3RD Floor, B302						
17:30-19:00	**Welcome Reception** | Exhibition Area, 3RD Floor, C3						

Friday | July 31 , 2020

	Reguatory Science	Innovative Breakthrough in Therapy	Clinical Trials, Operations and Quality Compliance		Data and Data Standard	Quantitative Science	Biologics Development
8:30-10:00	0101 A109-110, 1ST FLOOR Digital Technology to Advance Drug Supervision and Patient Access	0201 A103, 1ST FLOOR Negative Result of Oncology Drug Development - Case Study and Experience Sharing	0301 A206-207, 2ND FLOOR Practice and Thinking of New Site Operation Model		0401 A204-205, 2ND FL. Risk-based Data Monitoring with Cross-functional Coordination	0501 A211-212, 2ND FL. RWE Design and Case Study	0601 A104, 1ST FLOOR Biosimilar Development
10:00-10:30	Tea Break | Exhibition Area, 3RD Floor, C3						
10:30-12:00	0102 A109-110, 1ST FLOOR Risk-based Pre-Approval Inspection	0202 A103, 1ST FLOOR New Technologies and Drug Targets for Immuno Oncology	0302 A206-207, 2ND FLOOR Site Operation Excellence in China New Clinical Research Environment		0402 A204-205, 2ND FL. Data Warehouse & Data Lake	0502 A211-212, 2ND FL. Benefit-risk Assessment in Drug R&D and Evaluation	0602 A104, 1ST FLOOR Innovative Biologics Process Development
12:00-13:30	Lunch | 3RD Floor, B301						
13:30-15:00	0103 A109-110, 1ST FLOOR Regulation and Innovation: Driving the Co-development of Therapeutic Drug and Companion Diagnostics for Precision Medicine and Optimizing the Clinical Trial Design	0203 A103, 1ST FLOOR Strategy for Combination of Immuno-therapy	0303 A206-207, 2ND FLOOR Decentralized Clinical Trials: from Nice-to-have to Must-have		0403 A204-205, 2ND FL. Data Management in QbD	0503 A211-212, 2ND FL. Overcoming Challenges in Orphan Drug Development	-
15:00-15:30	Tea Break | Exhibition Area, 3RD Floor, C3						
15:30-17:00	0104-1 A109-110, 1ST FLOOR Overseas Regulatory Hot Topics	0104-2 A103, 1ST FLOOR Global Pharmacopeia Harmonization – Is it Achievable?	-	0304 A206-207, 2ND FL. Patient Protection under a Public Health Emergency	A208, 2ND FLOOR TransCelerate Special Session (Invited Only)	0404 A204-205, 2ND FL. eSource and Digital Data Management	0504 A211-212, 2ND FL. Early Phase Adaptive Designs	-

Saturday | August 1, 2020

8:30-10:00	0105 A109-110, 1ST FLOOR Lifecycle Registration Change Management	0205 A103, 1ST FLOOR Cancer Patient Journey in New Ecosystem - 1	0305-1 A206-207, 2ND FL. Quality Management of Clinical Trials at Investigator Site	0305-2 A208, 2ND FLOOR Clinical Compliance Management & Data Protection	0405 A204-205, 2ND FL. Real World Data (RWD) Management and Application in Clinical Research	0505 A211-212, 2ND FL. Decision-making on Key Steps in Drug R&D	0605 A104, 1ST FLOOR New Technologies of Gene/Cell Therapies
10:00-10:30	Tea Break | Exhibition Area, 3RD Floor, C3						
10:30-12:00	0106 A109-110, 1ST FLOOR Registration Strategy	0206 A103, 1ST FLOOR Cancer Patient Journey in New Ecosystem - 2	0306-1 A206-207, 2ND FL. New Technologies Enable Quality Management of Clinical Studies	0306-2 A208, 2ND FLOOR CPM	0406 A204-205, 2ND FL. Regulations and Practices of Clinical Data Submission	0506 A211-212, 2ND FL. Challenges and Opportunities for Statisticians in the Era of New Technology and Innovative Design	0606 A104, 1ST FLOOR Regulatory Considerations for Gene/Cell Products
12:00-13:30	Lunch | 3RD Floor, B301						
14:00–17:00	**Regulatory Special Sessions** | 3RD Floor, B302						

2020 DIA Regional Annual Meeting

DIA药物信息年会暨展览会

7月29日–8月1日 | 苏州 | Jul 29-Aug 1 | Suzhou, China

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GMP & Value Access	Medical Writing & Medical Affairs	PV & Risk Management	Patient Engagement	Merging Technologies and Digital Healthcare	Preclinical Development and Early Phase Clinical Research	Hot Topics and Late Breakers	WPS		
0701 A102, 1ST FLOOR Biologics GMP Inspection - Global Practice on Regulation and Implementation: Part 1	0801 A213-214, 2ND FL. Regulatory Medical Writing Coming a Full Circle –from IND to NDA	0901 A209-210, 2ND FL. Safety Considerations in Clinical Development Plan	1001 A101, 1ST FLOOR Rare Diseases - Regulatory Perspectives	-	1201 A202-203, 2ND FL. The Current Status and Pain Point of China Drug Development	-	1401-1 A105, 1ST FLOOR SDL Plc.	1401-2 A108, 1ST FLOOR CR Medicon	-
Tea Break | Exhibition Area, 3RD Floor, C3									
0702 A102, 1ST FLOOR Biologics GMP Inspection - Global Practice on Regulation and Implementation: Part 2	0802 A213-214, 2ND FL. Medical Writing Evolution in the New Era	0902 A209-210, 2ND FL. Safety Challenges for Immu-Oncology	1002 A101, 1ST FLOOR Rare Diseases - Clinical Development and Investment	-	1202 A202-203, 2ND FL. "Small Study, Big Influence" - The Advantages and Disadvantages	-	1402-1 A105, 1ST FLOOR WuXi AppTec	1402-2 A108, 1ST FLOOR 北京斯丹姆赛尔技术有限责任公司	1402-3 A301-302, 3RD FL. Shanghai Bestudy Medical Technology Co., Ltd.
Lunch | 3RD Floor, B301									
-	0803 A213-214, 2ND FL. Preparation for Launching New Drug	0903 A209-210, 2ND FL. Post Marketing Surveillance - Epidemiological Method & Case Study	-	1103 A102, 1ST FLOOR eSource	1203 A202-203, 2ND FL. Early Development Strategies for siRNA & ADCs Products - Part 1	1303 A208, 2ND FLOOR Career Pathway for Healthcare Talents	-	-	-
Tea Break | Exhibition Area, 3RD Floor, C3									
-	0804 A213-214, 2ND FL. Post Market Lifecycle Management and Data Generation	0904 A209-210, 2ND FL. RSI Writing and Communication: from IB to Labeling	-	1104 A102, 1ST FLOOR Digital Health Technologies in Clinical Trials	1204 A202-203, 2ND FL. Early Development Strategies for siRNA & ADCs Products - Part 2	-	-	-	-

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-	0805 A213-214, 2ND FL. Innovative Medical Education	0905 Safety Considerations for MAH and GVP	-	1105 A102, 1ST FLOOR Virtual Trials and Patient Recruitment	-	1305 A208, 2ND FLOOR Review on Clinical Development for Drugs/Treatment for COVID19 Pandemic in Globe	-	-	-
Tea Break | Exhibition Area, 3RD Floor, C3									
-	-	0906 A209-210, 2ND FL. ICH E2E & E2F Case Study	-	1106 A102, 1ST FLOOR 5G and Blockchain Applications in Healthcare	-	1306 A208, 2ND FLOOR Strategies of COVID-19 Vaccines and Antibodies Development and Early Clinical Trials Design	1406-1 A105, 1ST FLOOR Preswell Medical Company	1406-2 A108, 1ST FLOOR 普瑞盛（北京）医药科技开发有限公司	-
Lunch | 3RD Floor, B301									

Regulatory Special Sessions | 3RD Floor, B302