

**Tuesday, May 22, 2018 | ICH Day**

8:30-10:00	2nd Floor, Hall 2-1   ICH Plenary Session				
10:00-10:30	Tea Break				
10:30-17:00 <i>(Lunch &amp; Tea Break in Between)</i>	2nd Floor 201AB E2 & M1 Pharmacovigilance and MedDRA	2nd Floor 201CD E6(R2) GCP	2nd Floor, Hall 2-II E9 (R1) Estimands and Sensitivity Analysis in Clinical Trials	2nd Floor, 203AB E14 The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	2nd Floor, 203CD M4 & M8 Requirements and Significance of eCTD Implementation
			2nd Floor, Hall 2-II E17 General Principles for Planning and Design of Multi-Regional Clinical Trials		

**Wednesday, May 23, 2018**

14:00-16:30	2nd Floor, Hall 1   Opening Plenary				
16:30-18:00	1st Floor, Exhibition Area   Welcome Reception				
18:00-20:00	2nd Floor, Hall 1   DIA China 10th Anniversary & Award Ceremony (Invitation Only)				

**Thursday, May 24, 2018**

	Regulatory Science	Innovative Breakthrough in Therapy	Clinical Development	Quantitative Science	Biologics and Biosimilars	
8:30-10:00	0101 2nd Floor, Hall 2-C Real-world Evidence Defined and Re-defined: Regulatory and Practical Considerations for Drug Development Part 1	0301 2nd Floor, Hall 2-A MDR Bacteria - What's New in Antibiotic Development Part 1: Regulatory Issues	0401 2nd Floor, Hall 3 Hospital Presidents Forum - Part 1	0501-1 2nd Floor, 203AB Informetric Technology to Enhance the Quality and Integrity of Clinical Data	0501-2 2nd Floor, 203CD Statistics Topics in Rare Disease Drug Development	0601 3rd Floor, 307 Recent Trends in the Regulation of Biosimilar
10:00-10:30	Tea Break					
10:30-12:00	0102 2nd Floor, Hall 2-C Real-world Evidence Defined and Re-defined: Regulatory and Practical Considerations for Drug Development Part 2	0302 2nd Floor, Hall 2-A MDR Bacteria - What's New in Antibiotic Development Part 2: Clinical Development	0402 2nd Floor, Hall 3 Hospital Presidents Forum - Part 2	0502-1 2nd Floor, 203AB Information Technology to Enhance the Efficiency and Quality of Drug Development	0502-2 2nd Floor, 203CD Innovative Statistics Methods in Dose Finding - Method, Status and Implementation	0602 3rd Floor, 307 Clinical Trial Design of Biologics
12:00-13:30	Lunch					
13:30-17:00	0203 & 0204   2nd Floor, Hall 1   China NDA Townhall					

**Friday, May 25, 2018**

8:30-10:00	0105 2nd Floor, Hall 3 Foreign Data to Support Registration E5, E17 - Part 1	0305-1 2nd Floor, Hall 2-A Checkpoint Inhibitors: Monotherapy vs. Combination Therapy	0305-2 2nd Floor, Hall 2-B Unmet Needs in Current Therapies for Liver Disease	0405 2nd Floor, Hall 2-C English Only How Collaboration is Driving Innovation in Research & Development	0505-1 2nd Floor, 203AB Quality Specification of Clinical Data in Clinical Trials	0505-2 2nd Floor, 203CD Bridge the Gap Between RWE vs. RCT Part 1	0605 3rd Floor, 307 Pharmacometrics in Early Stage of Clinical Development
10:00-10:30	Tea Break						
10:30-12:00	0106 2nd Floor, Hall 3 Foreign Data to Support Registration E5, E17 - Part 2	0306-1 2nd Floor, Hall 2-A New Approach for Oncotherapy Development	0306-2 2nd Floor, Hall 2-B Clinical Endpoints for Viral Hepatitis Therapy: Perspectives from Regulatory Professionals	0406 2nd Floor, Hall 2-C Clinical Trial AE Reporting—from Collection, to Processing, Analysis and Summary, to Authority Review	0506-1 2nd Floor, 203AB Cross Functional Cooperation to Ensure Data Quality	0506-2 2nd Floor, 203CD Bridge the Gap Between RWE vs. RCT Part 2	0606 3rd Floor, 307 Biosimilar Assessment based on Analytical and Pharmacokinetics Studies
12:00-13:30	Lunch						
13:30-15:00	0107 2nd Floor, Hall 3 Priority Review and Conditional Approval	0307-1 2nd Floor, Hall 2-A Development of Innovative CAR-T Therapy	0307-2 2nd Floor, Hall 2-B Immunotherapy for HBV Functional Cure	0407 2nd Floor, Hall 2-C New Technology to Support Clinical Trial Activity	0507-1 2nd Floor, 203AB Clinical Data Management for Domestic Pharmaceutical Globalization	0507-2 2nd Floor, 203CD Statistical Topics in Drug Development of Immuno-Oncology	0607 3rd Floor, 307 Innovative Biologics Process Development
15:00-15:30	Tea Break						
15:30-17:00	0108 2nd Floor, Hall 3 MAH Pilot Program in China, Experience and Reflection	0308-1 2nd Floor, Hall 2-A Next-generation Sequencing and Predictive Biomarkers in Cancer Therapies	0308-2 2nd Floor, Hall 2-B Breakthrough of Therapeutic Development in Liver Disease	0408 2nd Floor, Hall 2-C The Critical Strategy and Practice of Efficient Collaborative Clinical Operation in New Environment	0508-1 2nd Floor, 203AB Clinical Data Management in Oncological Trials		0608 3rd Floor, 307 Development of Cell Therapy and Regulatory Considerations

# The 10th DIA China Annual Meeting

May 22 ICH Day | May 23-25 Conference, Exhibition and Posters  
Beijing International Convention Center

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**DIAMOND Sessions**

- Live Steam
- Live Steam Member Only
- Simultaneous Translation

## Thursday, May 24, 2018

Generic Drug, CMC & GMP Inspection	Medical Writing & Medical Affairs	Safety	Patient Engagement	Artificial Intelligence	Medical Devices	Hot Topics and Late Breakers	White Paper Showcase	
Tea Break								
<b>0701</b> 2nd Floor, 201CD English Only GMP - FDA Special Session	<b>0801</b> 3rd Floor, 305AB Introduction and Experience Sharing for Clinical Submission Documents after the CFDA Joins the ICH	<b>0901</b> 3rd Floor, 305CD How to Improve Safety Reporting in Clinical Trial	-	<b>1101</b> 2nd Floor, 201AB Artificial Intelligence and Big Data in the Field of Medical Reform and Drug Development	<b>1201</b> 3rd Floor, 308 New Medical Device Regulations on Market Permission Set to Accelerate Innovation Industry - Part 1	-	<b>1401-1</b> 3rd Floor, 302 The Evolved Solution to the Constant Problem: Patient Recruitment and Patient Outcome	<b>1401-2</b> 3rd Floor, 303 RBM of Risk Management in Clinical Trials
<b>0702</b> 2nd Floor, 201CD ICH M9 Guideline: Biopharmaceuticals Classification System (BCS) - Based Biowaivers	<b>0802</b> 3rd Floor, 305AB Toward a Collaborative and Efficient Clinical Document Preparation	<b>0902</b> 3rd Floor, 305CD Post-Marketing Risk Management	-	<b>1102</b> 2nd Floor, 201AB AI in Clinical Trial Application - Challenge and Solution Part 1	<b>1202</b> 3rd Floor, 308 New Medical Device Regulations on Market Permission Set to Accelerate Innovation Industry - Part 2	<b>1302</b> 3rd Floor, 305 E Clinical QMS Evolution and Effectiveness Check	<b>1402-1</b> 3rd Floor, 302 Innovative Drug Clinical Research & Development in the New Era	<b>1402-2</b> 3rd Floor, 303 Covance White Paper Showcase Session: Driving Global Innovation with an Integrated Drug Development Strategy
Lunch								

0203 & 0204 | 2nd Floor, Hall 1 | China NDA Townhall

## Friday, May 25, 2018

<b>0705</b> 2nd Floor, 201CD Quality and Innovation - Key to Success in Global Generic Drug Market Part 1	<b>0805</b> 3rd Floor, 305AB Multi-Channels Medical Communication	<b>0905</b> 3rd Floor, 305CD Labeling Across Product Life Cycle	<b>1005</b> 3rd Floor, 308 Patient Initiatives Program - the Global Perspectives	<b>1105</b> 2nd Floor, 201AB AI in Clinical Trial Application - Challenge and Solution Part 2	-	<b>1305</b> 3rd Floor, 305E DIA - BayHelix Joint Investment Forum	<b>1405-1</b> 3rd Floor, 302 How can 3AUDIT Help Drug Safety Management	<b>1405-2</b> 3rd Floor, 303 Strategies and Technologies in Early Clinical Drug Development to Maximize Program Outcomes
Tea Break								
<b>0706</b> 2nd Floor, 201CD Quality and Innovation - Key to Success in Global Generic Drug Market Part 2	<b>0806</b> 3rd Floor, 305AB Phase IV Study and Management of Investigator Initiated Trial	<b>0906</b> 3rd Floor, 305CD PV Information System	<b>1006</b> 3rd Floor, 308 China's Progress in Rare Diseases	<b>1106</b> 2nd Floor, 201AB Big Data & AI in Clinical Trial Application - Challenge and Solution Part 3 Panel Discussion	-	-	<b>1406-1</b> 3rd Floor, 302 Network breaking-The Way to Explore the "New Service" in Clinical Research	<b>1406-2</b> 3rd Floor, 303 Trending of innovative medicine development China vs. Global
Lunch						<b>3rd Floor, 305E</b> The Talent Development in Responding to the Booming Life Science Future	<b>1407-1</b> 3rd Floor, 302 Practice and Application of Medical Language Intelligence Technology	<b>1407-2</b> 3rd Floor, 303 The NEXT Generation of Clinical Development
-	<b>0807</b> 3rd Floor, 305AB Life Cycle Medical Strategy	<b>0907</b> 3rd Floor, 305CD Cardiovascular Safety of Anticancer Drugs in Development	<b>1007</b> 3rd Floor, 308 Rare Diseases Forum Part 1: Cases Sharing	-	-	<b>1307</b> 3rd Floor, 305E Clinical Operation Personnel Career Development Forum	-	-
Tea Break								
-	<b>0808</b> 3rd Floor, 305AB Career Development of Medical Affairs Personnel	<b>0908</b> 3rd Floor, 305CD ICH E2 Guideline Update	<b>1008</b> 3rd Floor, 308 Rare Diseases Forum Part 2: Panel Discussion	-	-	<b>1308</b> 3rd Floor, 305E Regulatory Agency vs. Regulated Industry - Keys to A Successful Regulatory Career Path	-	-