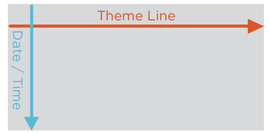
8th DIA China Annual Meeting

May 15–18 | China National Convention Center, Beijing

Quality & Transformation – New Era of Drug Development

QUICK GUIDE:



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SUNDAY, MAY 15, 2016 | PRE-CONFERENCE WORKSHOPS

	Workshop 1	Workshop 2	Workshop 3	Workshop 4
8:30 - 12:00		3rd Floor, 301B Medical Coding	3rd Floor, 302A Strategy and Key Considerations for Simultaneous Filing of Innovative Drugs in China and Abroad	3rd Floor, 302B CDISC Standards for Clinical Trial
13:30 - 17:30	3rd Floor, 301A Demystifying Regulatory Inspections in China			

MONDAY, MAY 16, 2016 | CONFERENCE DAY 1

13:30 - 17:30	Opening Plenary Session + Special Forum 4th Floor, Plenary Hall B (Refreshment Break | 15:00 - 15:30 | 1st Floor, Ballroom A+B
17:30 - 19:00	Welcome Reception 1st Floor, Ballroom A+B

TUESDAY, MAY 17, 2016 | CONFERENCE DAY 2

	Theme 1	Theme 2 / Theme 3	Theme 4	Theme 6
	Regulatory Science	Theme 2: CFDA Townhall Theme 3: Innovative Breakthrough in Therapy	Clinical Trial Sites in China	Quantitative Science
8:30 - 10:00	**Session 0101** 3rd Floor, 311A Enhancement for Post-Marketing Commitment Clinical Trials to Realize Accelerated Approvals	**Session 0301** 3rd Floor, 311B Advancement of NSCLC Management - Implication of Precision Medicine to Personalized Care	**Session 0401** 3rd Floor, 310 CFDA Inspection: Whether a Bright Sunny Sky Will Appear After Haze Swept Off?	**Session 0601** 3rd Floor, 303A Bridge the Real World to the Clinical Development - Part 1
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 0102** 3rd Floor, 311A eCTD: Implementation and Preparation	**Session 0302** 3rd Floor, 311B Breakthrough of Drug Development and Patient Management in Key Respiratory	**Session 0402** 3rd Floor, 310 Risk Based Quality Control: How to Have a Good Cooperation between CRA and CRC	**Session 0602** 3rd Floor, 303A Bridge the Real World to the Clinical Development - Part 2
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00	Main Meeting Room: 3rd Floor, 309A+B | Satellite Meeting Room: 311 A+B China Food and Drug Administration (CFDA) Town Hall - Part 1			
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30	Main Meeting Room: 3rd Floor, 309A+B | Satellite Meeting Room: 3311 A+B China Food and Drug Administration (CFDA) Town Hall - Part 2			

WEDNESDAY, MAY 18, 2016 | CONFERENCE DAY 3

	Theme 1	Theme 3	Theme 5	Theme 6
	Regulatory Science	Innovative Breakthrough in Therapy	Operational Excellence	Quantitative Science
8:30 - 10:00	**Session 0105** 3rd Floor, 311A Best Practice for Communication between Sponsors and Health Authorities	**Session 0305** 3rd Floor, 311B The Clinical Research of New Vaccines	**Session 0505** 3rd Floor, 310 To be Operational Excellence in Clinical Trial - Part 1	**Session 0605** 3rd Floor, 303A Data Quality and Integrity - Part 1 Clinical Trial Data Management and Collaborated Quality Control
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 0106** 3rd Floor, 311A Expedited Pathway to Facilitate Drug Development	**Session 0306** 3rd Floor, 311B Breakthrough of Hepatitis Treatment in China	**Session 0506** 3rd Floor, 310 To be Operational Excellence in Clinical Trial - Part 2	**Session 0606** 3rd Floor, 303A Data Quality and Integrity - Part 2 Global Data Integrity vs. CFDA Data Self-Assessment
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00	**Sessionm 0107** 3rd Floor, 311A How to Establish Proper IND Framework in China - Part 1: Filing and Review Process and Dossier Requirement	**Session 0307** 3rd Floor, 311B Innovative Medicines in Cardiovascular and Metabolic Field Made Huge Impact on Cardiovascular Treatment	**Session 0507** 3rd Floor, 310 To be Operational Excellence in Clinical Trial - Part 3	**Session 0607-1** 3rd Floor, 303A Global Requirements of Submission Data Standards: Past, Current and Future **Session 0607-2** 3rd Floor, 305 Pharmaceutical Biostatistics Group Operating Models in China - What the Multinational Pharma Companies Have Learned in the Last Seven Years
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30	**Session 0108** 3rd Floor, 311A How to Establish Proper IND Framework in China - Part 2: Supporting System			**Session 0608** 3rd Floor, 303A Nurturing Statistical Mindset in Data Management for Quality Improvement

TUESDAY, MAY 17, 2017 | CONFERENCE DAY 2

	Theme 7	Theme 8	Theme 9 / Theme 18	Theme 10
	CMC & Generic Drug	Biologics & Biosimilar	Theme 9: Quality System Theme 18: Companion Diagnostics	Pharmacovigilance
8:30 - 10:00	**Session 0701** 3rd Floor, 302A Bundling Review and Approval of Packaging Components and Pharmaceutical Excipients	**Session 0801** 3rd Floor, 303B Recent Trends in the Regulation of Biopharmaceutical Products	**Session 0901** 3rd Floor, 306B How to Improve the Ethics Review Quality	**Session 1001** 3rd Floor, 301B Innovation and Initiatives of Pharmacovigilance Operation in China
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 0702** 3rd Floor, 302A International Registration of Generic Drug	**Session 0802** 3rd Floor, 303B Development of Biosimilars: Technical Aspects	**Session 0902** 3rd Floor, 306B Inspections on Quality and Compliance – What Are Inspectors' Expectations	**Session 1002** 3rd Floor, 301B Pharmacovigilance in a New Era – Hot Topics
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00	**Session 0703** 3rd Floor, 302A Life-Cycle Management of Biological Products		**Session 1803** 3rd Floor, 301A Molecular Information Towards New Era of Precision Medicine - Part 1	**Session 1003** 3rd Floor, 301B Data-Driven Decision Making
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30	**Session 0704** 3rd Floor, 302A Quality Consistency of Generic Drug		**Session 1804** 3rd Floor, 301A Molecular Information Towards New Era of Precision Medicine - Part 2	**Session 1004** 3rd Floor, 301B Effective and Timely Risk Communication

WEDNESDAY, MAY 18, 2016 | CONFERENCE DAY 3

	Theme 7	Theme 8	Theme 9 / Theme 15	Theme 11
	CMC & Generic Drug	Biologics & Biosimilar	Theme 9: Quality System Theme 15: Information Technology	Necessary Elements in Successful Drug Development Activities
8:30 - 10:00	**Session 0705** 3rd Floor, 302A Role of Public Standard in the Drug Registration - Part 1	**Session 0805** 3rd Floor, 303B Clinical Trial Design of Biosimilar - Part 1	**Session 0905** 3rd Floor, 306B Transform Quality Science from Reactive to Proactive	**Session 1105** 3rd Floor, 306A Inheriting and Innovation: How Medical Writers Working in Global Pharmaceutical Companies Support Regulatory Requirements from Different Authorities
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 0706** 3rd Floor, 302A Role of Public Standard in the Drug Registration - Part 2	**Session 0806** 3rd Floor, 303B Clinical Trial Design of Biosimilar - Part 2	**Session 1506** 3rd Floor, 306B Information Technology in Clinical Studies: Regulatory Requirement	**Session 1106** 3rd Floor, 306A How Does Medical Writing Support China Local Company on Drug Registration Abroad
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00	**Session 0707** 3rd Floor, 302A BE Study of Generic Drug	**Session 0807** 3rd Floor, 303B Naming and Pharmacovigilance for Biologics	**Session 1507** 3rd Floor, 306B The Application of Information Technology in Clinical Trials	**Session 1107** 3rd Floor, 306A Risk-Based Project Management
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30	**Session 0708** 3rd Floor, 302A Biowaiver: In-vitro Dissolution	**Session 0808** 3rd Floor, 303B Cutting Edge Technologies in Biologics Development	**Session 1508** 3rd Floor, 306B Information Technology in Clinical Studies	**Session 1108** 3rd Floor, 306A Project Risk Management: Dealing with the Certainty of the Uncertainty

TUESDAY, MAY 17, 2017 | CONFERENCE DAY 2

	Theme 12	Theme 13	Theme 16	Theme 19
	Medical Affairs	Rare Diseases Forum	Medical Devices	White Paper Showcase
8:30 - 10:00	**Session 1201** 3rd Floor, 301A Medical Affairs Strategic Transformation in the New Era	**Session 1301** 3rd Floor, 305 Rare Diseases Part 1:The Concept of Rare Diseases	**Session 1601** 3rd Floor, 302B Challenges and Opportunities in the New Regulatory and Innovation Environment - Part 1	**Session 1901** 3rd Floor, 308 Clinical Trial in Mobile Internet Era: Model Optimization and Efficiency Improvement
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 1202** 3rd Floor, 301A Post-Marketing Studies in the New Era of Precision Medicine	**Session 1302** 3rd Floor, 305 Rare Diseases Part 2: The Practice of Rare Diseases	**Session 1602** 3rd Floor, 302B Challenges and Opportunities in the New Regulatory and Innovation Environment - Part 2	**Session 1902** 3rd Floor, 308 The Path Forward of Future Clinical Trials
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00			**Session 1603** 3rd Floor, 302B Challenges and Opportunities in the New Regulatory and Innovation Environment - Part 3	
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30				

WEDNESDAY, MAY 18, 2016 | CONFERENCE DAY 3

	Theme 12	Theme 14	Theme 17	Theme 19
	Medical Affairs	CRO/SMO	Early Stage Drug Development	White Paper Showcase
8:30 - 10:00	**Session 1205** 3rd Floor, 301A The Roles and Working Models of Field Medical Science Liaisons in China	**Session 1405** 3rd Floor, 301B Ready for the Big World? – How Can Chinese Pharmaceutical Companies Leverage CRO to Grow Bigger and Faster?	**Session 1705** 3rd Floor, 302B Non-Clinical Safety Assessment in the New Drug Development	**Session 1905** 3rd Floor, 308 Value of Pharmacometric Analyses in Drug Development
10:00 - 10:30	Refreshment Break 1st Floor, Ballroom A+B			
10:30 - 12:00	**Session 1206** 3rd Floor, 301A The Working Model of Medical and Commercial Functions in the Patient-Centric Healthcare Environment	**Session 1406** 3rd Floor, 301B Time for an Upgrade – Evolving Cooperation Model between CROs and Pharmaceutical Companies	**Session 1706** 3rd Floor, 302B Pharmacometrics and Mechanism-Based PK/PD Modeling in Early Drug Development	**Session 1906-1** | 3rd Floor, 308 Drive Global Innovation with an Integrated Drug Development Strategy **Session 1906-2** | 3rd Floor, 305 Australia: A Premier Destination for Early Stage Clinical Trials
12:00 - 13:30	Luncheon 1st Floor, Ballroom C & South Lobby			
13:30 - 15:00	**Session 1207** 3rd Floor, 301A Medical Communication: Opportunities under the "New Normal"	**Session 1407** 3rd Floor, 301B A Journey without Detour – Data Quality Matters	**Session 1707** 3rd Floor, 302B Biomarkers and Translation Medicine	**Session 1907** 3rd Floor, 308 Pharmacovigilance – Customized Safety Database for Chinese Regulations
15:00 - 15:30	Refreshment Break 1st Floor, Ballroom A+B			
15:30 - 17:30	**Session 1208** 3rd Floor, 301A HEOR & Market Access	**Session 1408** 3rd Floor, 301B SMO/CRC – A Bridge over the Troubled Water	**Session 1708** 3rd Floor, 302B Early Clinical Development	