

Wednesday | July 29, 2020 | ICH GUIDELINE TRAINING

8:30-9:30 ICH 30 Years - What Will Come in the Next Decade

9:30-10:00 Tea Break

10:00-17:00 (Tea Break and Lunch) E6/E8 E14 E9(R1) E2B(R3) M8

Thursday | July 30, 2020 | PRE-CONFERENCE SESSIONS

8:30-12:00 RWE to Support Regulatory Decision Making Randomization and Supplier Management in Clinical Trials Lab Data Management Real-time Review Master Protocol Development Boot Camp for Startup Company Adaptive Design & Enrichment Design Biomarkers Development and use in Drug Development

14:00-20:00 Opening Plenary & Welcome Reception

Friday | July 31, 2020

14:00-17:00 Regulatory Special Sessions

July 31 - August 1, 2020

Regulatory Science	Innovative Breakthrough in Therapy	Clinical Trials, Operations and Quality Compliance	Data and Data Standard	Quantitative Science	Biologics Development	GMP & Value Access
Provisions for Drug Registration and Related Regulations - 1	-	Site Operation Excellence in China's New Clinical Research Environment	Risk-Based Cross Functional Data Management	Challenges and Opportunities for Statisticians in the Era of New Technology and Innovative Design	Biosimilar Development	Yeehong Special Session
Provisions for Drug Registration and Related Regulations - 2	-	Practice and Thinking of New Site Operation Model	Data Warehouse & Data Lake	RWE Design and Case Study	Innovative Biologics Process Development	Value & Access
Review Oriented Inspection and Audit	Negative Result of Oncology Drug Development - Case Study and Experience Sharing	Quality Management of Clinical Trials at Investigator Site	Data Management in QbD	Decision-making on Key Steps in Drug R&D	Technology of Gene/Cell Therapies	New Regulatory Approaches for New Manufacturing Technologies
Digital Technology to Advance Drug Development and Patient Access	New Technologies and Drug Targets for Immu-Onco	Ethical Review of Multi-Center Clinical Trials and Ethics Committee	eSource and Digital Data Management	Statistics Considerations in Rare Disease	Regulatory Considerations for Gene/Cell Products	Global Pharmacopeia Harmonization - Is it Achievable?
Overseas Regulatory Hot Topics	Cancer Patient Journey in Ecosystem - 1	Decentralized Trial	Real World Data Collection & Management	Benefit-risk Assessment in Drug R&D and Evaluation	Clinical Trial Design of Biologics	
	Cancer Patient Journey in Ecosystem - 2	CPM	Regulations and Practices of Clinical Data Submission	Early Phase Adaptive Designs		



July 31 - August 1, 2020						
Medical Writing & Medical Affairs	PV & Risk Management	Patient Engagement	Merging Technologies and Digital Healthcare	Preclinical Development and Early Phase Clinical Research	Professional Development	Hot Topics and Late Breakers
Regulatory Medical Writing Coming a Full Circle -from IND to NDA	Safety Considerations in Clinical Development Plan	Rare Diseases - Regulatory Perspectives	eSource	The Current Status and Pain Point of China Drug Development	Career Development of Clinical Research Professionals	Clinical Trial Quality in E-era: Business Enabler and Differentiator
Medical Writing Evolution in the New Era	Safety Challenge in New Onco Treatment	Rare Diseases - Clinical Development and Investment	Digital Health Technologies in Clinical Trials	"Small Study, Big Influence" - The Advantages and Disadvantages	Career Pathway for Healthcare Talents	FDAAA Special Session
Preparation for Launching New Drug	Case Study for ICH E2E & E2F	Patient-Centered Drug Development - 1	Virtual Trials and Patient Recruitment	Early Development Strategies for New Therapeutics Modalities - 1		Regulation and Innovation: Driving the Co-development of Therapeutic Drug and Companion Diagnostics for Precision Medicine and Optimizing the Clinical Trial Design
Post Market Lifecycle Management and Data Generation	Post Marketing Surveillance - Epidemiological Method & Case Study	Patient-Centered Drug Development - 2	5G and Blockchain Applications in Healthcare	Early Development Strategies for New Therapeutics Modalities - 2		Clinical Compliance Management & Data Protection
Innovative Medical Education	RSI Writing and Communication: from IB to Labeling			Health Person or Patient? - Participants Consideration of Phase I Study for Special Therapeutic Areas		Globe Collaboration to Protect Human Health - Lesson Learned from COVID-19 Pandemic
Career Development in Medical Affairs Professionals	Safety Considerations for MAH and GVP					Drug Development Strategy of Infection Diseases

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