

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/E17 E14 E9(R1) E2B(R3) M8

Thursday | July 30, 2020 | PRE-CONFERENCE SESSIONS

8:30-12:00 RWE to Support Regulatory Decision Making Randomized Drug Management 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

13:30-20:00 Opening Plenary & Welcome Reception

Friday | July 31, 2020

Afternoon 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	What's New in Antibiotic Development-1	Optimization of Site Operations	Real World Data Collection & Management	Challenges and Opportunities for Statisticians in the Era of New Technology and Innovative Design	Biosimilar	Yeehong Special Session
Provisions for Drug Registration and Related Regulations - 2	What's New in Antibiotic Development-2	Site New Operations Methods	Data Warehouse & Data Lake	Early Stage of Adaptive Design	Innovative Biologics Process Development	Value & Access
Review Oriented Inspection and Audit	Negative Result of Oncology Drug Development - Case Study and Experience Sharing	Quality Compliance in Clinical Development	eSource and Digital Data Management	Key Milestones of Statistics Decision Making in Drug Development - 1	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	Data Management in QbD	Statistics Considerations in Rare Disease	Regulatory Considerations for Gene/Cell Products	ChP Townhall
Overseas Regulatory Hot Topics	Cancer Patient Journey in Ecosystem - 1	Decentralized Trial	Risk-Based Cross Functional Data Management	Risk Benefit Assessment	Clinical Trial Design of Biologics	
	Cancer Patient Journey in Ecosystem - 2	CPM	Data Standard for IND/NDA	RWE Design and Case Study		



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	5G in Clinical Development	"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 E2D & E2A	Patient-Centered Drug Development - 1	Virtual Trials	Early Development Strategies for New Therapeutics Modalities - 1		New Therapeutics Modalities
Post Marketing Lifecycle Management	Post Marketing Surveillance - Epidemiological Method & Case Study	Patient-Centered Drug Development - 2	Blockchain for Healthcare	Early Development Strategies for New Therapeutics Modalities - 2		Combination Products
RWE Study in Post Marketing	RSI Writing and Communication: from IB to Labeling			Health Person or Patient? - Participants Consideration of Phase I Study for Special Therapeutic Areas		Business Continuity Plan (BCP) of Clinical Trial under Coronavirus Disease 2019 - Review and Lesson Learned
Career Development in Medical Affairs Professionals	Safety Considerations for MAH and GVP					

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