58th International Conference on Drug Development (ICD²)

February 26 & 27, 2018 • Austin, Texas

ICD² • Day I • Monday February 26, 2018

12:00	**LUNCH**	*Hill Country Dining Room*
1:00	**Welcome and Opening Remarks** *Conference Theme: Challenges of Public Health and Scientific Advances in Biomedicine in the 21st Century – Affordability of Drugs by Leveraging Digital Technologies to Transform Drug Development and Regulatory Risk-Benefit Models – Innovation in Manufacturing Technologies*	*The Forum* **Salomon Stavchansky, Ph.D.** ICD2 Conference Scientific Chair Alcon Centennial Professor of Pharmaceutics Molecular Pharmaceutics and Drug Delivery University of Texas at Austin College of Pharmacy
1:30	**Round Table Presentations:** *Challenges of Digital Technology and Biomedical Sciences in the 21st Century. Implementation of the 21st Century Cures Act and PDUFA IV – Leveraging Digital Technologies – Part A*	
1:30	**CDER Perspective – 21st Century Cures Act and PDUFA VI – Implementation and Deliverables** *Introduction by **Arthur A. Ciociola, Ph.D., FACG**, Global Franchise Head, Regulatory Affairs, Novartis Pharmaceuticals Ophthamology*	**Janet Woodcock, M.D.** Director Center for Drug Evaluation and Research US Food and Drug Administration
2:10	**Strategic and Policy Reforms to Improve Clinical Outcomes and Access to Quality Drugs and Medical Digital Technologies in the 21st Century** *Introduction by **Arthur A. Ciociola, Ph.D., FACG**, Global Franchise Head, Regulatory Affairs, Novartis Pharmaceuticals Ophthamology*	**Mark B. McClellan, M.D., Ph.D.** Director & Margolis Professor of Business Medicine and Policy Margolis Center for Health Policy Duke University
2:50	**Round Table Discussion: Woodcock & McClellan** *Challenges of Digital Technology and Biomedical Sciences in the 21st Century. Implementation of the 21st Century Cures Act and PDUFA IV – Leveraging Digital Technologies – **Part A*** *Discussion Moderated by **Arthur A. Ciociola, Ph.D., FACG**, Global Franchise Head, Regulatory Affairs, Novartis Pharmaceuticals Ophthalmology*	
3:15	**BREAK**	*Outside Forum*
3:30	**Round Table Presentations:** *Challenges of Digital Technology and Biomedical Sciences in the 21st Century. Implementation of the 21st Century Cures Act and PDUFA IV – Leveraging Digital Technologies – **Part B***	
3:30	**CDRH Perspective – 21st Century Cures Act and MDUFA VI – Implementation and Deliverables** *Introduction by **Andrea Masciale**, VP, Regulatory Policy and Global Analytics, Johnson & Johnson Worldwide Government Affairs and Policy*	**Ed Margerrison, Ph.D.** Director Office of Science and Engineering US Food and Drug Administration
4:00	**CBER Perspective – 21st Century Cures Act and BSUFA VI – Implementation and Deliverables** *Introduction by **Andrea Masciale**, VP, Regulatory Policy and Global Analytics, Johnson & Johnson Worldwide Government Affairs and Policy*	**Celia Witten, M.D., Ph.D.** Deputy Director Center for Biologics Evaluation and Research US Food and Drug Administration
4:30	**PhRMA's Expectations – 21st Century Cures Act and PDUFA VI – Implementation and Deliverables** *Introduction by **Nicholas Pelliccione, Ph.D.**, VP, Regulatory Affairs, Turing Pharmaceuticals*	**Richard Moscicki, M.D.** Chief Medical Officer Executive Vice President Pharmaceutical Research and Manufacturers of America
5:00	**BIO's Expectations – 21st Century Cures Act and PDUFA VI – Precision Medicine - Implementation and Deliverables** *Introduction by **Kay Holcombe***	**Cartier Esham, Ph.D.** Executive Vice President for Emerging Companies Biotechnology Innovation Companies (BIO)
5:30	**Round Table Discussion: Panel of Afternoon Speakers** *Challenges of Digital Technology and Biomedical Sciences in the 21st Century. Implementation of the 21st Century Cures Act and PDUFA IV – Leveraging Digital Technologies – **Part B*** *Discussion Moderated by **Kay Holcombe***	
6:15	**WELCOME RECEPTION**	*Outside The Forum*
6:45	**DINNER**	*Canyons Dining Room*
7:30	**Keynote Presentation** **Communicating Uncertainty in Decision Analytics to Facilitate Drug Development and Regulatory Evaluation** *Introduction by **Mehul Mehta, Ph.D.**, Director, Division of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration*	**Baruch Fischhoff, Ph.D.** Howard Heinz University Professor Department of Engineering and Public Policy Institute for Politics and Strategy Carnegie Mellon University

ICD^2 • Day II • Tuesday February 27, 2018

7:40	**Continental Breakfast**	*Outside The Forum*
8:30	**Round Table Presentations:** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part A***	
9:00	**Challenges and Opportunities in Chemistry Manufacturing Controls in the Age of Personalized Medicine – FDA Perspective** *Introduction by* ***Sarah Pope Miksinski, Ph.D.,*** *Senior Director and Group Manager, GMD, Astra Zeneca*	**Wendy Wilson-Lee, Ph.D.** Branch Chief (Actg), Branch I Center for Drug Evaluation and Research US Federal Drug Administration
9:30	**Drug Development Acceleration Clinical Relevance and Harmonization – ICH Future** *Introduction by* ***Charles Hoiberg, Ph.D.,*** *Executive Director, Global Regulatory CMC Group, Pfizer*	**Peter Honig, M.D., M.P.H.** Senior Vice President and Head of Worldwide Safety and Regulation, Pfizer
10:00	**Round Table Discussion: Panel of Morning Speakers** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part A*** ***Joined by:*** **Paul Seo, Ph.D.** Lead (Acting), Biopharmaceutics Staff, Office of New Drug Quality Assessment Center for Drug Evaluation and Research US Food and Drug Administration *Discussion Moderated by* ***Sarah Pope Miksinski, Ph.D.,*** *Senior Director and Group Manager, GMD, Astra Zeneca*	
10:30	**BREAK**	*Outside The Forum*
10:50	**Round Table Presentations:** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part B***	
10:50	**Industry Perspective of Digital Technologies in Drug Development and Therapeutics – Digital Drugs?** *Introduction by* **Kenneth I. Kaitin, Ph.D.** Professor and Director, Tufts Center for the Study of Drug Development Tufts University	**Andrew Wright** Vice President of Digital Medicines Otuska Pharmaceutical
11:10	**Pharma's Perspective of Digital Technologies in Drug Development and Therapeutics** *Introduction by* **Gretchen Trout,** Head, North America Policy & FDA Liaison, Regulatory Affairs, Novartis Pharmaceuticals Corp.	**Jacob LaPorte, Ph.D.** Head of Digital Technology Novartis
11:30	**Otsuka's Regulatory Experience in the Journey of Digital Medicine Drug Development** *Introduction* ***Pravin Jadhav, Ph.D. M.P.H., M.Pharm,*** Senior Director, Corporate Projects, R&D Innovation, Otsuka Pharmaceutical Development and Commercialization	**Henrietta Ukwu, M.D., FACP, FRAPS** Senior Vice President Head, Global Quality & Global Regulatory Affairs Otsuka Pharmaceutical
11:40	**Round Table Discussion: Panel of Morning Speakers** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part B*** *Discussion Moderated by* ***Pravin Jadhav, Ph.D. M.P.H., M.Pharm,*** Senior Director, Corporate Projects, R&D Innovation, Otsuka Pharmaceutical Development and Commercialization	
12:10	**LUNCH**	*Hill Country Dining Room*
1:30	**Round Table Presentations:** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part C***	

1:30	**Innovative Clinical Trail Design for Pediatric Therapeutics – Clinical Endpoints and Digital Therapeutics. Real World Evidence Data at the Basis for Pediatric Labeling** *Introduction by* **Gretchen Trout,** Head, North America Policy & FDA Liaison, Regulatory Affairs, Novartis Pharmaceuticals Corp.	**Gary Noel, M.D.** Pediatric Infectious Disease Chair, Janssen's Pediatric Advisory Committee Drug Development Center of Excellence at J&J
1:50	**Medicine and Translational Science – Real World Evidence - What is the Evidencing Basis for Regulatory Decision Making?** *Introduction by* **Kenneth I. Kaitin, Ph.D.** Professor and Director, Tufts Center for the Study of Drug Development Tufts University	**Justin T. Baker, M.D., Ph.D.** Assistant Professor & Director of Functional Neuroimaging & Bioinformatics Schizophrenia and Bipolar Disorder Program Scientific Director Institute for Technology in Psychiatry McLean Hospital, Harvard Medical School
2:10	**Application of Artificial Intelligence (AI) in Drug Discovery** *Introduction* ***John Engel, Esq****., Founder & Managing Member, Engel Novitt, PLLC*	**Henry Chen, MBA** Principal Offering Manager IBM Watson for Drug Discovery
2:30	**Round Table Discussion: Panel of Afternoon Speakers** *At the Intersection of Digital Technologies and Therapeutics. Incorporating Real World Evidence in Drug Development –* ***Part C*** *Discussion Moderated by* ***Pravin Jadhav, Ph.D. M.P.H., M.Pharm,*** Senior Director, Corporate Projects, R&D Innovation, Otsuka Pharmaceutical Development and Commercialization	
3:00	**BREAK**	*Outside The Forum*
3:15	**Round Table Presentations:** *Overcoming Regulatory Challenges in the Age of Personalized Therapy*	
3:20	**CBER Regulatory Perspective: Ethical, Legal and Regulatory Issues of Personalized Therapies** *Introduction by* **Paula Rinaldi,** North American Head of DRA, Novartis Pharmaceuticals	**Celia Witten, M.D., Ph.D.** Deputy Director Center for Biologics Evaluation and Research US Food and Drug Administration
3:40	**Pharma's Perspective: Overcoming Implementation and CMC Challenges of Personalized Therapy – Case Study I – CAR-T Technologies** *Introduction by* **Paula Rinaldi,** North American Head of DRA, Novartis Pharmaceuticals	**Shanthi Ganesham, Ph.D.** Head of Oncology North American Regulatory Affairs Novartis Pharmaceuticals
4:10	**Pharma's Perspective: Therapeutic Genome Editing: Prospects and Challenges- Precision of Zinc Finger Nucleases Technology – Case Study II** *Introduction by* **Lisa A. Shipley, Ph.D.,** Vice President & Global Head Pharmacokinetics, Pharmacodynamics & Drug Metabolism, Merck & Co., Inc.	**Michael Holmes, Ph.D.** Vice President, Research Sangamo Therapeutics
4:30	**Round Table Discussion: Panel of Morning Speakers** *Overcoming Regulatory Challenges in the Age of Personalized Therapy* *Discussion Moderated by* **Lisa A. Shipley, Ph.D.,** Vice President & Global Head Pharmacokinetics, Pharmacodynamics & Drug Metabolism, Merck & Co., Inc.	
5:00	**WELCOME RECEPTION**	*Outside The Forum*
6:00	**DINNER**	*Canyons Dining Room*
7:00	**FDA Panel Discussion** Discussion Focus: Digital Technologies & Theraputics, Emerging Manufacturing Technology and Regulation, Emerging Technologies in Gene Therapies, Regulatory Harmonization and ICH's Future. *Moderated by* ***Gerald J. Yakatan, Ph.D.,*** *Director, Founder and Chairman, IrisSys, Inc.*	**FDA Panel** FDA Representatives and Guests
	2018 ICD^2 • Concludes	
	Wednesday Morning Breakfast *(optional)* *Inform Check in Staff at Foothills Dining Room that you are with ICD^2*	*Hill Country Dining Room*