International Conference on Drug Development (ICD2)

February 13 & 14, 2017 • Austin, Texas

ICD2 • Day I Afternoon • Monday February 13, 2017

12:00	**Lunch**	*Hill Country Dinning Room*
2:00	**Welcome and Opening Remarks**	*The Forum* **Salomon Stavchansky, Ph.D.** ICD2 Conference Scientific Chair Alcon Centennial Professor of Pharmaceutics University of Texas at Austin College of Pharmacy
3:00	**Round Table Presentations:** *Listening to Patients: Impact of Patient Centricity on Drug Development and the Drug Regulatory Process*	*Sessions Moderator:* **Arthur A. Ciociola, Ph.D., FACG** Vice President, Head of Global Regulatory Affairs Research and Development Alcon Laboratories
3:00	**FDA/CDER Update** A Panoramic View of the FDA – What are the Challenges, Where are We Going, and How are We Going to Get There *Introduction by Arthur A Ciocola, Ph.D., FACG, Alcon Research Ltd.*	**Robert M. Califf, M.D.** Professor of Medicine Duke University School of Medicine Former Commissioner of the FDA
3:30	Patient Centric Drug Development: A Key to Success *Introduction by Kay Holcomb, Senior VP for Science Policy, BIO*	**Jay P. Siegel, M.D.** Chief Biotechnology Officer Head of Scientific Strategy & Policy Johnson & Johnson
3:50	Patient Centricity: Global Operational Changes to Accelerate Drug Development *Introduction by Charles Hoiberg, Ph.D., Executive Director, Pfizer*	**Cathryn M. Clary, M.D.** Global Head Patient Affairs and Policy Novartis Pharmaceuticals Corporation
4:10	**Break**	*Outside Forum*
4:25	An Integrated Approach to Maximizing Patient Value: The Ionis Story *Introduction by Charles Hoiberg, Ph.D., Executive Director, Pfizer*	**Stanley T. Crooke, M.D., Ph.D.** Chairman of the Board & Chief Executive Officer Ionis Pharmaceuticals
4:45	Bold Changes in the Regulatory Process – Legal Perspectives on Responding to Challenging Times *Introduction by Charles Hoiberg, Ph.D., Executive Director, Pfizer*	**Peter Barton Hutt, J.D., LLB, LLM, Esq** Senior Counsel Covington & Burling LLP
5:05	**Round Table Discussion:** *Listening to the Patients: Impact of Patient Centricity on Drug Development and the Drug Regulatory Process* *Discussion Moderated by Kay Holcombe, Senior Vice President Science Policy at Biotechnology Innovation Organization (BIO)*	**Panel of Afternoon Speakers**, *joined by* **Janet Woodcock, M.D.** Director Center for Drug Evaluation and Research US Food and Drug Administration **Andrew C. von Eschenbach, M.D.** President of Samaritan Health Initiatives, Inc. Adjunct Professor at MD Anderson Cancer Center
6:15	**Reception and Dinner**	*Foothills Dinning Room*
7:30	**Keynote Presentation** The Promise Of Bioelectronic Medicine in Chronic Disease and Regulatory & Quality Considerations as We Bring that Promise to Patients *Introduction by Alice E. Loper, Ph.D., Head, Drug Product R&D, Global Vaccines Technical R&D, GlaxoSmithKline*	**Kristoffer Famm, Ph.D.** President at Galvani Bioelectronics Vice President Bioelectronics R&D at GlaxoSmithKline

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7:45	**Continental Breakfast**	*Outside The Forum*
8:30	**Round Table Presentations:** *Patient Centricity: Incorporating Real-World Evidence in Drug Development – Digital Technologies and Medicine*	*The Forum* *Opening Remarks:* **Kenneth I. Katin, Ph.D.** Professor and Director Study of Drug Development Center Tuffs University
8:40	Panoramic View of CDER. Ability of CDER to Regulate and Utilize Digital Technologies and Biomedicine to Accelerate Drug Development and Improve Patient Outcomes	**Janet Woodcock, M.D.** Director Center for Drug Evaluation and Research US Food and Drug Administration
9:40	**Break**	*Outside Forum*
10:00	Impact of Real World Evidence and New Partnership Initiatives that Accelerate and Improve Population Health. A Case Study Using Big Data and Technology to Enhance Medicine and Human Health *Introduction by Lisa Shipley, Ph.D., VP and Global Head of Pharmacokinetics, Pharmacodynamics & Drug Metabolism at Merck*	**Maria Rivas, M.D., FACP, FACE** Senior Vice President Global Medical Affairs, R & D Merck
10:20	Use of Observational and Real-World Evidence. A Case Study *Introduction by Lisa Shipley, Ph.D., VP and Global Head of Pharmacokinetics, Pharmacodynamics & Drug Metabolism at Merck*	**Donald Yin, Ph.D.** Associate Vice President Center for Observational and Real-World Evidence Merck
10:40	**Round Table Discussion:** *Linking Critical Product Quality Attributes and Critical Process Parameters to Clinical Product Performance of Single and Combination Drug-Device Products* *Discussion Moderated by Joanne Palmisano, M.D., FACP* Vice President • Drug Regulatory Affairs at Boehringer Ingelheim Pharmaceuticals	**Panel of Morning Speakers**
12:00	**Lunch**	*Hill Country Dinning Room*
1:10	**Round Table Presentations:** *The Future of Law and Digital Technologies*	*Moderator & Opening Remarks* **Rick Friedman, Ph.D.** Deputy Director Science & Regulatory Policy Center for Drug Evaluation and Research US Food and Drug Administration
1:15	Drug Development and Digital Technology: Hope, Chaos, and Reality *Introduction by Rick Friedman, Ph.D., Deputy Director Science & Regulatory Policy, CDER, FDA*	**William H. Carson, M.D.** President and Chief Executive Officer Otsuka Pharmaceutical Development & Commercialization, Inc.
1:40	Accelerated Global Drug Development of New Technologies and Simultaneous Conditional Regulatory Approval *Introduction by Terrance Ocheltree, Ph.D., R.Ph., Sr. Director, Regulatory Policy and Intelligence, AbbVie*	**Roger Nosal** Vice President of Global Chemistry Manufacturing and Controls Pfizer

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2:05	Legal Perspectives on Digital Technologies in Medicine and Drug Development. Point Counter Point *Introduction by Terrance Ocheltree, Ph.D., R.Ph., Sr. Director, Regulatory Policy and Intelligence, AbbVie*	**John M. Engel, Esq** Founder and Managing Member EngelNovitt, PLLC
2:30	**Round Table Discussion** *The Future of Law and Digital Technologies* *Discussion Moderated by Paul Seo, Ph.D.,* Lead, Biopharmaceutics Staff, Office of New Drug Quality Assessment, Center for Drug Evaluation and Research, US Food and Drug Administration	**Panel of Afternoon Speakers**, *joined by* **Sarah Pope Miksinski, Ph.D.** Acting Director Office of New Drug Products Center for Drug Evaluation and Research US Food and Drug Administration
3:15	**Break**	*Outside Forum*
3:30	**Round Table Presentations:** Development of a Novel Comprehensive in Vitro and in Silico Regulatory Paradigm to Predict Clinical Pro-Arrhythmic Risk of New Drugs	*Moderator and Opening Remarks:* **Mehul Mehta, Ph.D.** Director, Division of Clinical Pharmacology I Office of Clinical Pharmacology Center for Drug Evaluation and Research US Food and Drug Administration
3:35	Regulatory Perspective – The History and Impact of the Existing Regulatory Paradigm and Need for a New Mechanistic Proarrhythmia Assessment *Introduction by Andrea Masciale, VP, Regulatory Policy and Global Analytic, J&J*	**Norman Stockbridge, M.D., Ph.D.** Director Division of Cardiovascular and Renal Products Office of Drug Evaluation I, Office of New Drug Center for Drug Evaluation and Research US Food and Drug Administration
3:55	Industry Perspective – The Need for CiPA in Drug Discovery and Focus on *in Vitro* Multi-ion Channel Assessment *Introduction by Andrea Masciale, VP, Regulatory Policy and Global Analytic, J&J*	**Bernard Fermini, Ph.D.** Vice President of Safety and Toxicology Assessment Chief Scientific Officer Coyne Scientific, LLC
4:15	Industry Perspective – Integrated Nonclinical Proarrhythmia Assessment under CiPA and Focus on Induced Pluripotent Stem Cell Derived Cardiomyocytes *Introduction by Paula Rinaldi, North American Head of DRA, Novatis*	**Gary Gintant, Ph.D.** CiPA Cardiomyocyte Working Group Lead Research Fellow, Integrative Pharmacology Integrated Sciences and Technology AbbVie
4:35	Regulatory Perspective – Integrated Cipa Risk Assessment with Focus on i*n Silico* Predictions of Pro-Arrhythmic Risk and Role of Ecgs in Phase 1 Clinical Trials *Introduction by Paula Rinaldi, North American Head of DRA, Novatis*	**David Strauss, M.D., Ph.D.** Director, Division of Applied Regulatory Science (Acting) Senior Advisor for Translational & Experimental Medicine, Office of Clinical Pharmacology, Office of Translational Sciences Center for Drug Evaluation and Research US Food and Drug Administration
4:55	**Round Table Discussion** Development of a Novel Comprehensive in Vitro and in Silico Regulatory Paradigm to Predict Clinical Pro-Arrhythmic Risk of New Drugs *Discussion Moderated by Mehul Mehta, Ph.D.,* *Director, Division of Clinical Pharmacology I, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration*	**Panel of Afternoon Speakers**

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6:00	**Reception and Dinner**	*Foothills Dinning Room*
7:30	**FDA Panel Discussion and Q&A with Attendees** FDA Panel Proposed Topics: • Digital technologies – Ability of the FDA to assess effectiveness and safety of emerging technologies. • Emerging manufacturing technology regulation to support new clinical development programs. • Emerging Technologies – e.g., Bioelectronics and implants. • Role of FDA in the "moonshot" initiative. *Moderator:* **Gerald J. Yakatan, Ph.D.** Founder & Chairman IriSys, Inc	***FDA Panelist:*** **Robert M. Califf, M.D.** Professor of Medicine Duke University School of Medicine *Former Commissioner* *US Food and Drug Administration* **Rick Friedman, Ph.D.** Deputy Director Science & Regulatory Policy Center for Drug Evaluation and Research US Food and Drug Administration **Sarah Pope Miksinski** Acting Director Office of New Drug Products Center for Drug Evaluation and Research US Food and Drug Administration **Mehul Mehta, Ph.D.** Director, Division of Clinical Pharmacology I Office of Clinical Pharmacology Center for Drug Evaluation and Research US Food and Drug Administration **Paul Seo, Ph.D.** Director (Acting) Division of Biopharmaceutics Office of New Drug Products Center for Drug Evaluation and Research US Food and Drug Administration **Norman Stockbridge, M.D., Ph.D.** Director Division of Cardiovascular and Renal Products Office of Drug Evaluation I, Office of New Drug Center for Drug Evaluation and Research US Food and Drug Administration **David Strauss, M.D., Ph.D.** Director, Division of Applied Regulatory Science (Acting) Senior Advisor for Translational & Experimental Medicine, Office of Clinical Pharmacology, Office of Translational Sciences Center for Drug Evaluation and Research US Food and Drug Administration
Morning	**Breakfast on Wednesday**	*Hill Country Dinning Room*

Agenda as of 2/6/17