# International Conference on Drug Development (ICD2)

**February 22 & 23, 2016 • Austin, Texas**

## ICD2 • Day I Afternoon • Monday February 22, 2016

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| 12:00 | **Lunch** | *Hill Country Dinning Room* |
| 2:15 | **Welcome and Opening Remarks** | *The Forum*<br>**Salomon Stavchansky, Ph.D.**<br>ICD2 Conference Scientific Chair<br>Alcon Centennial Professor of Pharmaceutics<br>University of Texas at Austin College of Pharmacy |
| 3:00 | **FDA/CDER Update**<br>Principles for Regulation and Oversight of Precision Medicine and Emerging Technologies - FDA Initiatives and Accessibility of Precision Medicine<br>*Introduction by Arthur A. Ciociola, Ph.D., FACG; Alcon Research Ltd.* | **Jonathan P. Jarow, M.D..**<br>Senior Medical Advisor to the Director<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 3:40 | **Round Table Presentations:**<br>*Precision Medicine, Emerging Technologies and Breakthrough Therapies* | *Introductions and Sessions Moderator:*<br>**Robert Meyer, M.D.**<br>Director of the Virginia Center for Translational and Regulatory Sciences<br>University of Virginia School of Medicine |
| 3:40 | A Panoramic View of Precision Medicine, Emerging Technologies and Breakthrough Therapies | **Kenneth I. Kaitin, Ph.D.**<br>Director<br>Tuft's Center for the Study of Drug Development<br>Professor, Tufts University School of Medicine |
| 4:00 | Why Highly Effective Drugs are Not Enough: An Affordable Solution to Eliminating HCV | **Ann D. Kwong, Ph.D.**<br>Founder and CEO<br>TREK Therapeutics, PBC |
| 4:20 | **Break** | *Outside Forum* |
| 4:30 | Payers Perspective on Precision Medicine – Assessment of Risk - Provider Behavior and Accountability | **Kara M. Morgan, Ph.D.**<br>Research Leader, Health and Analytics<br>Battelle Memorial Institute |
| 4:50 | Payers Perspective on Precision Medicine – Clinical Assessment of Risk - Provider Behavior and Accountability | **Matthew C. Fontana, M.D.**<br>Vice President and Chief Medical Officer, Pharmacy<br>Health Care Service Corporation |
| 5:10 | Advancing Precision Medicine and Extension of Life | **Ellen V. Sigal, Ph.D.**<br>Chairperson and Founder<br>Friends of Cancer Research |
| 5:30 | **Round Table Discussion:**<br>*Precision Medicine, Emerging Technologies and Breakthrough Therapies*<br>*Discussion Moderated by Robert Meyer, M.D.; U Virginia School of Medicine* | **Panel of Afternoon Speakers**, *joined by*<br>**John M. Engel, Esq**<br>Founding Partner & Manager<br>Engel & Novitt, LLP<br>**Kay Holcombe**<br>Senior Vice President of Science Policy<br>Biotechnology Industry Organization (BIO) |
| 6:30 | **Reception and Dinner** | *Foothills Dinning Room* |
| 8:00 | **Keynote**<br>Proactive Initiatives in the Life Sciences - Robotics - “Smart Lens” technology for ocular medical uses and new approaches for cancer and Alzheimer’s disease<br>*Introduction by Volker Fischer, Ph.D., AbbVie Pharmaceuticals* | **Brian Otis, Ph.D.**<br>Director<br>Google Life Sciences<br>Research Associate Professor<br>University of Washington |

## ICD2 • Day II Morning • Tuesday February 22, 2016

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| 7:30 | **Continental Breakfast** | *Outside The Forum* |
| 8:15 | **Round Table Presentations:**<br>*Linking Critical Product Quality Attributes and Critical Process Parameters to Clinical Product Performance of Single and Combination Drug-Device Products*<br><br>*Speaker Introductions by Charles Hoiberg, Ph.D.; Pfizer & Andrea Masciale; Janssen* | *The Forum*<br>*Moderator and Opening Remarks:*<br>**Sarah Pope Miksinski, Ph.D.**<br>Acting Director<br>Office of New Drug Products<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br>**Paul Seo, Ph.D.**<br>Lead (Acting), Biopharmaceutics Staff<br>Office of New Drug Quality Assessment<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 8:50 | Biosimilars, Regulatory Innovation and Evolution - Linking Quality Product Attributes and Critical Process Parameters to Product Clinical Performance – Global Lessons Learned | **Mark McCamish, M.D., Ph.D.**<br>Head Global Biopharmaceutical Development<br>Sandoz |
| 9:15 | Disruptive Innovation - Quality Product Attributes and Manufacturing Changes of Macromolecules and Vaccines – Molecular Structure & Function | **John Baldoni, Ph.D.**<br>Senior Vice President<br>Platform Technology & Science<br>GlaxoSmithKline |
| 9:35 | Defining Meaningful Critical Quality Product Attributes and Critical Process Parameters to Clinical Product Performance of Small Molecules | **Roger Nosal**<br>Vice President of Global Chemistry<br>Manufacturing and Controls<br>Pfizer |
| 9:55 | **Break** | *Outside Forum* |
| 10:10 | Industry Perspective - Linking Drug-Device Critical to Quality Product Attributes and Process Parameters to Product Performance. A hypothetical Scenario | **Manfred Maeder, Ph.D.**<br>Head of Group Compliance & Audit for Devices and Combination Products<br>Novartis |
| 10:35 | Industry Perspective – Risk-based Approaches to Drug-Device Combination Product Development | **Karen Weiss, M.D.**<br>Vice President<br>Global Regulatory Policy and Intelligence<br>Janssen Pharmaceutical / Johnson & Johnson |
| 10:55 | FDA Perspective - Assuring Lifecycle Quality Performance for Traditional Drugs and Combination Products. Lessons Learned | **Rick Friedman, Ph.D.**<br>Deputy Director<br>Science & Regulatory Policy<br>Director Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 11:20 | **Round Table Discussion:**<br>*Linking Critical Product Quality Attributes and Critical Process Parameters to Clinical Product Performance of Single and Combination Drug-Device Products*<br><br>*Discussion Moderated by Sarah Pope Miksinski, Ph.D.; FDA* | **Panel of Morning Speakers**, *joined by*<br>**Jonathan P. Jarow, M.D..**<br>Senior Medical Officer to the Director<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br>**Issam Zineh, PharmD, MPH, FCP, FCCP**<br>Director, Office of Clinical Pharmacology<br>Office of Translational Sciences<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |

## ICD2 • Day II Afternoon • Tuesday February 23, 2016

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|---|---|---|
| 12:15 | **Lunch** | *Hill Country Dinning Room* |
| 1:15 | **Round Table Presentations:**<br>*Advancing Regulatory Clinical Pharmacology and Clinical Research in Assessing Safety and Efficacy of Medicines and Emerging Technologies. Lessons Learned and Disruptive Innovation*<br>*Speaker Introductions by Mehul Mehta, Ph.D., FDA & Lisa Shipley, Ph.D.; Merck* | *The Forum*<br>*Moderator:*<br>**Mehul Mehta, Ph.D.**<br>Director, Division of Clinical Pharmacology I<br>Office of Clinical Pharmacology<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 1:30 | Regulatory Perspective: Disruptive Innovation and Proactive Initiatives in Clinical Pharmacology and Clinical Research to Advance the Assessment of Safety and Efficacy of Emerging Technologies and Medicines. Case Studies | **Robert Temple, M.D.**<br>Deputy Center Director for Clinical Science<br>Acting Deputy Director of the Office of Drug Evaluation I<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 2:10 | Academic Perspective: Effectiveness of Quantitative Disease Models to Advance Precision Medicine and the Safety and Efficacy of Emerging Technologies – Case Studies | **Jogarao Gobburu, Ph.D.**<br>Professor, Executive Director<br>Center for Translational Medicine<br>Schools of Pharmacy & Medicine<br>University of Maryland |
| 2:30 | Clinical Pharmacology: De-Risking the Critical Path to Informed Decisions | **Isaam Zineh, PharmD, MPH, FCP, FCCP**<br>Director, Office of Clinical Pharmacology<br>Office of Translational Sciences<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 2:50 | **Break** | *Outside Forum* |
| 3:10 | The Role of Statistics in Advancing Clinical Pharmacology and Translational Tools – Predictable Uncertainties? | **Lisa Lavange, Ph.D.**<br>Director<br>Office of Biostatistics Organization<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| 3:30 | Industry Perspective: What Role Can Clinical Pharmacology Play in Leveraging Disruptive Technologies in Drug Development? | **Prajakti Kothare, Ph.D.**<br>Director<br>Global Preclinical ADME<br>Merck |
| 3:50 | Disruptive Innovation in the Industry –Expanding role of Clinical Pharmacology in Drug Development Decision making and Optimal Synthesis of Efficacy and Safety to Support Registration and Reimbursement. Case Studies | **Sriram Krishnaswami, Ph.D.**<br>Senior Director<br>Clinical Pharmacology<br>Pfizer |
| 4:10 | **Round Table Discussion**<br>*Advancing Regulatory Clinical Pharmacology and Clinical Research in Assessing Safety and Efficacy of Medicines and Emerging Technologies. Lessons Learned and Disruptive Innovation*<br>*Discussion Moderated by Mehul Mehta, Ph.D.; FDA* | **Panel of Afternoon Speakers** |
| 5:15 | **Reception** | *Foothills Dinning Room* |

## ICD2 • Day II Evening • Tuesday February 23, 2016

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|---|---|---|
| 6:00 | **Dinner** | *Foothills Dinning Room* |
| 7:00 | **FDA Panel Discussion and Q&A with Attendees**<br>FDA Panel Proposed Topics:<br>• Product Quality Attributes and Clinical Outcomes<br>• Emerging Technologies – e.g., CRISPR, Synthetic Biology, Stem Cell Therapies, gene therapy, and others.<br><br>*Moderator:*<br>**Gerald J. Yakatan, Ph.D.**<br>Founder & Chairman<br>IriSys, Inc | ***FDA Panelist:***<br><br>**Rick Friedman, Ph.D.**<br>Deputy Director<br>Science & Regulatory Policy<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Lisa Lavange, Ph.D.** *(pending)*<br>Director<br>Office of Biostatistics Organization<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Sarah Pope Miksinski**<br>Acting Director<br>Office of New Drug Products<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Mehul Mehta, Ph.D.**<br>Director, Division of Clinical Pharmacology I<br>Office of Clinical Pharmacology<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Paul Seo, Ph.D.**<br>Lead (Acting), Biopharmaceutics Staff<br>Office of New Drug Quality Assessment<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Robert Temple, M.D.**<br>Deputy Center Director for Clinical Science<br>Acting Deputy Director of the Office of Drug Evaluation I<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration<br><br>**Issam Zineh, PharmD, MPH, FCP, FCCP**<br>Director, Office of Clinical Pharmacology<br>Office of Translational Sciences<br>Center for Drug Evaluation and Research<br>US Food and Drug Administration |
| Morning | **Breakfast on Wednesday** | *Hill Country Dinning Room* |

## ICD2 • 2017 • February 13 & 14 • Austin, Texas