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<th>Time</th>
<th>Session</th>
<th>Location</th>
<th>Speaker/Details</th>
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<tbody>
<tr>
<td>12:00</td>
<td>Lunch</td>
<td>Hill Country Dining Room</td>
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| 2:15  | 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  | FDA/CDER Update: Principles for Regulation and Oversight of Precision Medicine and Emerging Technologies - FDA Initiatives and Accessibility of Precision Medicine |                                    | Jonathan P. Jarow, M.D.  
Senior Medical Advisor to the Director  
Center for Drug Evaluation and Research  
US Food and Drug Administration |
| 3:40  | Round Table Presentations: **Precision Medicine, Emerging Technologies and Breakthrough Therapies** |                                    | Introductions and Sessions Moderator:  
Robert Meyer, M.D.  
Director of the Virginia Center for Translational and Regulatory Sciences  
University of Virginia School of Medicine |
| 3:40  | A Panoramic View of Precision Medicine, Emerging Technologies and Breakthrough Therapies |                                    | Kenneth I. Kaitin, Ph.D.  
Director  
Tuft's Center for the Study of Drug Development  
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.  
Founder and CEO  
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.  
Research Leader, Health and Analytics  
Battelle Memorial Institute |
| 4:50  | Payers Perspective on Precision Medicine – Clinical Assessment of Risk - Provider Behavior and Accountability |                                    | Matthew C. Fontana, M.D.  
Vice President and Chief Medical Officer, Pharmacy Health Care Service Corporation |
| 5:10  | Advancing Precision Medicine and Extension of Life                    |                                  | Ellen V. Sigal, Ph.D.  
Chairperson and Founder  
Friends of Cancer Research |
| 5:30  | Round Table Discussion: **Precision Medicine, Emerging Technologies and Breakthrough Therapies** | Foothills Dinning Room           | Panel of Afternoon Speakers, joined by  
John M. Engel, Esq  
Founding Partner & Manager  
Engel & Novitt, LLP  
Kay Holcombe  
Senior Vice President of Science Policy  
Biotechnology Industry Organization (BIO) |
| 6:30  | Reception and Dinner                                                   | Foothills Dinning Room           |                                                                                |
| 8:00  | Keynote                                                                 |                                  | Brian Otis, Ph.D.  
Director  
Google Life Sciences  
Research Associate Professor  
University of Washington |

*The University of Texas at Austin College of Pharmacy*
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<td>7:30</td>
<td>Continental Breakfast</td>
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<tr>
<td>8:15</td>
<td><strong>Round Table Presentations:</strong> Linking Critical Product Quality Attributes and Critical Process Parameters to Clinical Product Performance of Single and Combination Drug-Device Products</td>
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<td>Speaker Introductions by Charles Hoiberg, Ph.D.; Pfizer &amp; Andrea Masciale; Janssen</td>
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<td>9:55</td>
<td>Break</td>
<td>Outside Forum</td>
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<tr>
<td>10:35</td>
<td>Industry Perspective – Risk-based Approaches to Drug-Device Combination Product Development</td>
<td>Outside Forum</td>
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<td>10:55</td>
<td>FDA Perspective - Assuring Lifecycle Quality Performance for Traditional Drugs and Combination Products. Lessons Learned</td>
<td>Outside Forum</td>
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<td>11:20</td>
<td><strong>Round Table Discussion:</strong> Linking Critical Product Quality Attributes and Critical Process Parameters to Clinical Product Performance of Single and Combination Drug-Device Products</td>
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*Discussion Moderated by Sarah Pope Miksinski, Ph.D.; FDA*
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<tr>
<td>1:15</td>
<td>Round Table Presentations: Advancing Regulatory Clinical Pharmacology and Clinical Research in Assessing Safety and Efficacy of Medicines and Emerging Technologies. Lessons Learned and Disruptive Innovation</td>
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<td>Speaker Introductions by Mehul Mehta, Ph.D., FDA &amp; Lisa Shipley, Ph.D.; Merck</td>
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| 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 | MUST EDIT | Robert Temple, M.D.  
Deputy Center Director for Clinical Science  
Acting Deputy Director of the Office of Drug Evaluation  
Center for Drug Evaluation and Research  
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.  
Professor, Executive Director  
Center for Translational Medicine  
Schools of Pharmacy & Medicine  
University of Maryland |
| 2:30  | Clinical Pharmacology: De-Risking the Critical Path to Informed Decisions |                        | Isaam Zineh, PharmD, MPH, FCP, FCCP  
Director, Office of Clinical Pharmacology  
Office of Translational Sciences  
Center for Drug Evaluation and Research  
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.  
Director  
Office of Biostatistics Organization  
Center for Drug Evaluation and Research  
US Food and Drug Administration |
Director  
Global Preclinical ADME  
Merck |
Senior Director  
Clinical Pharmacology  
Pfizer |
<p>| 4:10  | Round Table Discussion Advancing Regulatory Clinical Pharmacology and Clinical Research in Assessing Safety and Efficacy of Medicines and Emerging Technologies. Lessons Learned and Disruptive Innovation |                        | Panel of Afternoon Speakers |
| 5:15  | Reception                                                             | Foothills Dinning Room |</p>
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<td>6:00</td>
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| 7:00  | **FDA Panel Discussion and Q&A with Attendees**

**FDA Panel Proposed Topics:**
- Product Quality Attributes and Clinical Outcomes
- Emerging Technologies – e.g., CRISPR, Synthetic Biology, Stem Cell Therapies, gene therapy, and others.

**Moderator:**
Gerald J. Yakatan, Ph.D.
Founder & Chairman
IriSys, Inc

**FDA Panelist:**
- **Rick Friedman, Ph.D.**
  Deputy Director
  Science & Regulatory Policy
  Center for Drug Evaluation and Research
  US Food and Drug Administration
- **Lisa Lavange, Ph.D.** *(pending)*
  Director
  Office of Biostatistics Organization
  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.**
  Lead (Acting), Biopharmaceutics Staff
  Office of New Drug Quality Assessment
  Center for Drug Evaluation and Research
  US Food and Drug Administration
- **Robert Temple, M.D.**
  Deputy Center Director for Clinical Science
  Acting Deputy Director of the Office of Drug Evaluation I
  Center for Drug Evaluation and Research
  US Food and Drug Administration
- **Issam Zineh, PharmD, MPH, FCP, FCCP**
  Director, Office of Clinical Pharmacology
  Office of Translational Sciences
  Center for Drug Evaluation and Research
  US Food and Drug Administration

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