TRANSFORMATION OF DRUG DEVELOPMENT – CHALLENGES AND OPPORTUNITIES
ADVANCING INNOVATIVE SOLUTIONS TO MEET PATIENT'S MEDICAL NEEDS OF SERIOUS CONDITIONS AND RARE DISEASES

MONDAY, 24TH OF FEBRUARY 2014

12:00 – 1:30 LUNCH
Hill Country Dining Room

2:15 - 3:00 Welcome and Opening Remarks
Salomon Stavchansky, Ph.D.
ICD2 Conference Scientific Chair
Alcon Centennial Professor of Pharmaceutics
The University of Texas at Austin College of Pharmacy

Janet Woodcock, M.D.
Director • Center for Drug Evaluation & Research
FDA

3:45 – 4:00 FDA Challenges Expediting Drug Development – Scientific, Clinical and Regulatory Considerations of Breakthrough Therapies and Accelerated Approvals
Janet Woodcock, M.D.
Director • Center for Drug Evaluation & Research
FDA

4:00 – 4:15 Market Access and Innovative Industry Therapies
Ray Sacchetti
Senior Vice President, US Virology & Transplant
Bristol-Myers Squibb

4:15 – 4:30 Break

4:30 – 4:45 Payers Perspective of Expediting Drug Development – Integrated Health Care Benefits to Accelerate Breakthrough Therapies to Patients. Innovative Partnerships for Better Clinical Outcomes and Care at a Lower Cost
Tracy J. Mayne, Ph.D.
Vice President, Global Health Economics and Outcomes Research
Covance

4:45 – 5:00 Patient Perspective of Expediting Drug Development – Patient Role in Knowledge Generation
J. Russell Teagarden, RPh., M.A.
Senior Vice President, Medical & Scientific Affairs
National Organization for Rare Disorders (NORD)

5:00 – 5:15 Oncologist Perspective – Towards Patient Drug Development Better Communication of Risk, Benefit and Medical Evidence
Ethan Basch, M.D.
Director, Cancer Outcomes Research
Associate Professor Medicine and Public Health
Lineberger Comprehensive Cancer Center
University of North Carolina-Chapel Hill

5:15 – 6:00 ROUND TABLE DISCUSSION WITH AFTERNOON SPEAKERS
joined by Isaam Zineh, PharmD of CDER, FDA

Moderator: Maria Rivas, M.D.
Vice President
Global Medical Affairs, R & D
Abbvie Pharmaceutical

Moderator: Joseph Lamendola, Ph.D.
Vice President Global Regulatory Sciences, US and Regulatory Policy
Bristol-Myers Squibb Company

All presentations located in the Forum

ROUND TABLE SESSIONS: Transforming and Expediting Drug Development

4:45 – 5:00 Patient Perspective of Expediting Drug Development – Patient Role in Knowledge Generation

5:00 – 5:15 Oncologist Perspective – Towards Patient Drug Development Better Communication of Risk, Benefit and Medical Evidence
### Monday, February 24th

**6:00 – 6:15**  Dean’s Welcome  
M. Lynn Crismon, Pharm.D., FCCP, BCCP  
Dean  
James T. Doluisio Regents Chair in Pharmacy Fellowship, Behrens Inc., Centennial Professor of Health Outcomes & Pharmacy Practice  
The University of Texas at Austin College of Pharmacy

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<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>6:15 – 7:00</td>
<td><strong>Welcome Reception</strong></td>
<td>Patio Outside Canyon Dining Room</td>
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<td>7:00 – 8:00</td>
<td><strong>DINNER</strong></td>
<td>Canyon Dining Room</td>
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**Tuesday, February 25th**

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<thead>
<tr>
<th>Time</th>
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<th>Location</th>
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<tbody>
<tr>
<td>7:30 – 8:30</td>
<td><strong>Continental Breakfast</strong></td>
<td>Outside Forum</td>
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<tr>
<td>8:30 – 9:15</td>
<td><strong>Expedited FDA Programs Initiatives — Drugs and Biologics Building the Science (Clinical and Non Clinical) to Expedite Drug Development</strong></td>
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<td>9:15 – 9:30</td>
<td><strong>Clinical Perspective – Innovation in the Design of Clinical Studies</strong></td>
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<td>9:30 – 9:45</td>
<td><strong>Pharmaceutical Industry Perspective - Innovation in Clinical Drug Development</strong></td>
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<td>9:45 – 10:00</td>
<td><strong>Risks and Opportunities for Acceleration of Drug Development in Rare Diseases</strong></td>
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<td>10:00 – 10:30</td>
<td><strong>Break</strong></td>
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<td>10:30 – 10:45</td>
<td><strong>BIO Perspective - Innovation in Clinical Safety and Effectiveness</strong></td>
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<td>10:45 – 11:00</td>
<td><strong>Expediting Drug Development: Integrating Knowledge, Enabling Decisions and Submissions</strong></td>
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<tr>
<td>11:00 – 12:00</td>
<td><strong>Round Table Discussion with Morning Speakers</strong></td>
<td>joined by Janet Woodcock, MD, FDA/CDER</td>
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**Moderator:**
- Janet Woodcock, M.D.
  Director • Center for Drug Evaluation & Research  
  FDA

**Moderator:**
- Joanne Palmisano, M.D., FACP  
  Vice President  
  Drug Regulatory Affairs  
  Boehringer Ingelheim Pharmaceuticals

**Moderator:**
- Lisa A. Shipley, Ph.D.  
  Vice President & Global Head  
  Pharmacokinetics Pharmacodynamics & Drug Metabolism  
  Merck & Co., Inc.

**Moderator:**
- Jonathan Seltzer, M.D., MBA, MA, FACC  
  President  
  ACI Clinical  
  Director of Clinical Research  
  Lankenau Heart Institute
### TUESDAY 25TH OF FEBRUARY 2014 CONTINUED

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<tr>
<th>Time</th>
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<th>Location</th>
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<tbody>
<tr>
<td>12:00 – 1:30</td>
<td>LUNCH</td>
<td>Hill Country Dinning Room</td>
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**ROUND TABLE SESSIONS: Finding Solutions to Quality and Safety Challenges of Breakthrough Therapies, Building Data to Minimize Risk and Systems to Maximize Lifecycle Quality**

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Moderator/Keynote Speaker</th>
<th>Speakers/Panelists</th>
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<tbody>
<tr>
<td>1:30 – 1:45</td>
<td>FDA Challenges and Perspectives</td>
<td>Terrance Ocheltree, Ph.D., R.Ph.</td>
<td>Steven Lynn, M.S., Director, Office of Manufacturing and Product Quality (OMPQ) OC, CDER, FDA</td>
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<tr>
<td>1:45 – 2:00</td>
<td>Industry Challenges and Perspectives</td>
<td>Andrea Masciale</td>
<td>Roger Nosal, Vice President, Global CMC Pfizer, Inc.</td>
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<td>2:00 – 2:15</td>
<td>Clinical Safety Considerations for Expedited Approvals – FDA Perspective</td>
<td>Andrea Masciale</td>
<td>Mwango Kashoki, M.D., Medical Officer, Office of New Drugs CDER, FDA (VIA Videoconference)</td>
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<td>2:15 – 2:45</td>
<td>Break</td>
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<td>2:45 – 3:00</td>
<td>Companion Diagnostics and Breakthrough Therapies – Personalized Therapeutics</td>
<td>Andrea Masciale</td>
<td>Debra J Rasmussen, MBA, RAC Senior Director Global Regulatory Affairs Janssen Pharmaceuticals</td>
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<tr>
<td>3:00 – 4:00</td>
<td>ROUND TABLE DISCUSSION WITH AFTERNOON SPEAKERS</td>
<td>Charles Hoiberg, Ph.D.</td>
<td>Joined by Moheb M. Nasr, Ph.D. of GlaxoSmithKline</td>
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<td>5:30 – 6:00</td>
<td>RECEPTION</td>
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<td>Patio Outside Canyon Dinning Room</td>
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<td>6:00 – 7:30</td>
<td>DINNER</td>
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<td>Canyon Dinning Room</td>
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<tr>
<td>7:30 – 8:30</td>
<td>FDA PANEL</td>
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<td>Canyons Dinning Room</td>
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### WEDNESDAY 26TH OF FEBRUARY 2014

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<tbody>
<tr>
<td>7:30 – 8:30</td>
<td>BREAKFAST</td>
<td>Canyons Dinning Room</td>
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