International Conference on Drug Development (ICD2) • Day I

Monday, February 23, 2015

12:00	**Lunch**	*Hill Country Dinning Room*
2:20	**Welcome**	*The Forum* **M. Lynn Crismon, Pharm.D., FCCP, BCCP** Dean & Professor The University of Texas College of Pharmacy
2:30	**Opening Remarks**	**Salomon Stavchansky, Ph.D.** ICD2 Conference Scientific Chair Alcon Centennial Professor of Pharmaceutics The University of Texas at Austin College of Pharmacy
3:00	**FDA/CDER Update** The Safety Risks of Biomedical Innovation? How to Define Clinical Value	**Richard A. Moscicki, M.D..** Deputy Center Director for Clinical Science FDA/CDER Speaking on behalf of Janet Woodcock, M.D. *Introduced by Robert Meyer, M.D., UVA Sch of Med.*
3:40	**Round Table Presentations:** *Risk Reduction in Drug Development and Biomedical Innovation in the XXI Century A Path to New Cures*	*Moderator:* **Robert Meyer, M.D.** Director of the Virginia Center for Translational and Regulatory Sciences University of Virginia School of Medicine
3:45	Bio Update and Perspectives	**The Honorable James C. Greenwood** President and CEO Biotechnology Industry Association (BIO) *Introduced by Kay Holcombe, BIO*
4:05	PhRMA Update and Perspectives	**John J. Castellani** President and CEO Pharmaceutical Research and Manufacturers of America (PhRMA) *Introduced by Andrea Masciale, Janssen, J&J*
4:25	**Break**	*Outside Forum*
4:40	Integration of CMS Perspectives in Biomedical Innovation and Market Access – Risk-Benefit Assessment	**Joel Brill, M.D.** Medical Director FAIR Health, Inc. *Introduced by Lisa Shipley, Ph.D., Merck & Co., Inc*
5:00	Legal Perspectives – A Path to 21st Cures Initiative	**John M. Engel, Esq.** Founding Partner & Manager Engel & Novitt, LLP *Intro by Nicholas Pelliccione, Ph.D., Turing Pharmaceuticals*
5:20	**Round Table Discussion:** *Risk Reduction in Drug Development and Biomedical Innovation in the XXI Century A Path to New Cures*	*Panel of Afternoon Speakers joined by **Paul Huckle**, Chief Regulatory Officer, GlaxoSmithKline.* *Moderated by **Robert Meyer, M.D.***
6:15	**Reception**	*Foothills Dinning Room*
7:00	**Dinner**	*Foothills Dinning Room*
8:00	**Transparency of Clinical Trial Data** The Right of the Clinical Scientist and the Patient to Know	**Joanne Wadestricher, M.D.** Chief Medical Officer Johnson and Johnson *Introduced by Volker Fisher, Ph.D., AbbVie*

International Conference on Drug Development (ICD2) • Day II

Tuesday February 24, 2015

7:30	**Continental Breakfast**	*Outside The Forum*
8:30	**Round Table Presentations:** *A Vision for Clinical Development in the XXI Century – The Right Targets for the Next Generation of Drug Development and Effective Therapeutics- Use of Real World Data*	*The Forum* *Moderator:* **Jonathan Seltzer, M.D., MBA, M.A., F.A.C.C.** President, ACI Clinical Director, Clinical Research Lankenau Heart Institute
8:35	Challenges and Opportunities of Fewer Patients Outcome Clinical Studies in the XXI Century	**Richard A. Moscicki, M.D..** Deputy Center Director for Clinical Science FDA/CDER Speaking on behalf of Robert Temple, M.D. *Introduced by Jonathan Seltzer, M.D., MBA, M.A., FACC*
9:15	Approach to the Acquisition and Use of Real World Clinical Data – Challenges and Predictive Tools	**Marc Berger** VP Real World Data and Analytics GH&V Real World Data Lead Pfizer, Inc. *Introduced by Jonathan Seltzer, M.D., MBA, M.A., FACC*
9:35	Big Data Analysis to Accelerate Biomedical Innovation and Product Development	**Jesse Berlin, Sc.D.** Vice-President, Pharmacoepidimiology Pharmaceutical Research and Development Johnson &Johnson *Introduced by Terrance Ocheltree, Ph.D., R.Ph., AbbVie*
9:55	Patient-Focused Drug Development - The Time is Now	**Paula E. Rinaldi, RPh, MPH** US Head DRA Novartis Pharmaceuticals *Introduced by Terrance Ocheltree, Ph.D., R.Ph., AbbVie*
10:15	Personalized Medicine and Novel Trial Design in Drug Development and Biomedical Innovation – Patient's Role	**Jane Perlmutter, Ph.D., M.B.A.** President and Founder of Gemini Group *Introduced by Samuel Maldonaldo, M.D., MPH, FAAP, J&J*
10:35	**Break**	*Outside Forum*
10:50	Expanded Access Programs for Drugs and Biologics: Concepts, Controversies, and Clinical Implications	**Martha B. Donoghue, M.D.** Medical Officer FDA/CDER/OND/OHOP *Introduced by Samuel Maldonaldo, M.D., MPH, FAAP, J&J*
11:10	Impact of Social Media on Drug, Biologics and Biomedical Innovation - Managing life changing illness	**Ben Heywood** Co-Founder, President PatientsLikeMe *Introduced by Joanne Palmisano, M.D., FACP, Boehringer Ingelheim*
11:45	Doing More with Less in Clinical Development in the XXI Century – How to?	**Lynn Marks, M.D.** Senior VP of Projects Clinical Platform and Science GlaxoSmithKliine *Introduced by Joanne Palmisano, M.D., FACP, Boehringer Ingelheim*
11:45	**Round Table Discussion:** *A Vision for Clinical Development in the XXI Century – The Right Targets for the Next Generation of Drug Development and Effective Therapeutics- Use of Real World Data*	*Panel of Morning Speakers, joined by Issam Zineh, Pharm.D., M.P.H., F.C.C.P, Clinical Pharmacology at CDER/FDA.* *Moderated by **Jonathan Seltzer, MD, MBA, FACC***
12:30	**Lunch**	*Hill Country Dinning Room*

2:15	**Round Table Presentations:** *Finding Solutions to Quality and Safety Challenges in Drug and Biologics Innovation and Development in the XXI Century*	*The Forum*
2:15	Moderator Introductory Remarks	**Sarah Pope Miksinski, Ph.D.** Director (Acting) Office of New Drug Quality Assessment FDA, CDER, OPS *Introduced by Alice E. Loper, Ph.D., GlaxoSmithKline*
2:35	Breakthrough Therapies and Manufacturing Challenges	**Sarah Pope Miksinski, Ph.D.**
2:55	Innovation of Manufacturing and Emerging Technology Integration of Review, Inspections and Monitoring	**Lawrence Yu, Ph.D.** Deputy Director (Acting) Office of Pharmaceutical Science FDA, CDER *Introduced by Alice E. Loper, Ph.D., GlaxoSmithKline*
3:15	**Break**	*Outside Forum*
3:30	Emerging Technologies and Manufacturing Efficiencies Noncell-based production technologies	**Joseph Tarnowski, Ph.D.** Senior Vice President of Chemistry, Manufacturing and Controls Biopharm R&D GlaxoSmithKline *Introduced by Alice E. Loper, Ph.D., GlaxoSmithKline*
3:55	Integrating Biomedical Innovations in The Transformation of Pharmaceutical Manufacturing in the XXI Century Challenges and Opportunities	**Charles Hoiberg, Ph.D.** Executive Director Pfizer, Inc *Introduced by Alice E. Loper, Ph.D., GlaxoSmithKline*
4:15	**Round Table Discussion:** *Finding Solutions to Quality and Safety Challenges in Drug and Biologics Innovation and Development in the XXI Century*	*Panel of Afternoon Speakers.* *Moderated by* ***Sarah Pope Miksinski, Ph.D.***
5:30	**Reception**	*Foothills Dinning Room*
6:00	**Dinner**	*Foothills Dinning Room*
7:00	**FDA Panel Discussion and Q&A with Attendees** FDA Panel Proposed Topics: • Biosimilars Risk Assessment – Harmonization initiatives: EU-Japan and USA • Changes in Import and Export Requirements – Why now? • User Fees and GDUFA challenges • Lessons Learned from FDA Compliance Initiatives - Data Integrity • Product Quality Attributes and Clinical Outcomes • Open questions from attendees _____ FDA Panelist: **Martha B. Donoghue, M.D.** Medical Officer, Neuro-Oncology, Pediatric Oncology, and Rare Tumors Group FDA, CDER, OND, OHOP **Sarah Pope Miksinski** Director (Acting) Office of New Drug Quality Assessment FDA, CDER, OPS	**Mehul Mehta, Ph.D.** Director, Division of Clinical Pharmacology I Office of Clinical Pharmacology OTS, CDER, FDA **Paul Seo, Ph.D.** Lead (Acting), Biopharmaceutics Staff Office of New Drug Quality Assessment FDA, OMPT, CDER, OPS **Lawrence Yu, Ph.D.** Deputy Director (Acting) Office of Pharmaceutical Science FDA, CDER **Issam Zineh, PharmD, MPH, FCP, FCCP** Director, Office of Clinical Pharmacology Office of Translational Sciences CDER, FDA *Moderator:* **Gerald J. Yakatan, Ph.D.** Founder & Chairman IriSys, Inc
Morning	**Breakfast on Wednesday**	*Hill Country Dinning Room*