



**2015
ORSI Science
Symposium**

Office of Regulatory Science & Innovation (ORSI)

Session 1	CERSI Presentations	08:35AM – 11:30AM
Session 2	Breakout	11:30AM – 01:00PM
Session 3	ORSI Initiatives Panel Discussion	01:00PM – 01:40PM
Session 4	Broad Agency Announcement (BAA)	01:45PM – 03:00PM
Session 5	Chief Scientist Grant Presentations	03:10PM – 04:10PM
Session 6	CORES Grant Presentations	04:10PM – 04:50PM

Monday, April 27, 2015

FDA White Oak Campus – Silver Spring, MD - The Great Room (Bldg. 31)

Click [HERE](#) for in-person registration or [HERE](#) for webinar registration

07:30AM – 08:00AM	Registration - Breakfast available for purchase
08:00AM – 08:10AM	Dr. Stephen Ostroff – FDA Acting Commissioner: Opening Remarks
08:10AM – 08:15AM	Dr. Carol Linden – Director, Office of Regulatory Science & Innovation: Opening Remarks
08:15AM – 08:20AM	Dr. Frank Weichold – Director, Critical Path and Regulatory Science Initiatives: Opening Remarks
08:20AM – 08:35AM	Dr. Taha Kass-Hout – Chief Health Informatics Officer: Update on ‘openFDA’

Session 1 Centers of Excellence in Regulatory Science and Innovation (CERSI) Presentations

08:35AM – 09:15AM	University of Maryland CERSI Presentations <ul style="list-style-type: none"> • Science That Speeds Health Innovation – William E. Bentley, PhD • 3D Printed Biomimetic Phantoms for Assessment of Biophotonics Imaging Systems – Yu Chen, PhD • Noninvasive Detection of Protein Aggregation using Water Proton NMR – Bruce Yu, PhD
09:15AM – 09:55AM	Johns Hopkins University CERSI Presentations <ul style="list-style-type: none"> • Regulatory Science and Innovation: Optimizing the Evidentiary Basis for Decision-Making at the FDA – G. Caleb Alexander • Partnership to Advance Stated-Preferences Methods in Regulatory Science – John F. P. Bridges, PhD
09:55AM – 10:10AM	Break
10:10AM – 10:50AM	Georgetown University CERSI Presentation <ul style="list-style-type: none"> • Overcoming Challenges to Medical Product Innovation – Ira Shoulson, MD • Genetics of Vaccine Safety Signal Detection: Supporting FDA’s Data Mission Through Informatics – Peter McGarvey, PhD
10:50AM – 11:30AM	University of California at San Francisco/Stanford University CERSI Presentations <ul style="list-style-type: none"> • Innovative Regulatory Science on the West Coast – Russ B. Altman, MD, PhD • Renal Impairment in New Drug Development – Kathy M. Giacomini, PhD • Improving ADR Signal Detection by Combining Signals from Spontaneous Reports and Electronic Health Records – Nigam H. Shah, MBBS, PhD

Session 2 Breakout

11:30AM – 01:00PM	Lunch, Poster Session, and Regulatory Science Student Competition Winner Presentations
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Session 3 ORSI Initiatives Panel Discussion

- 01:00PM – 01:40PM Center representatives and audience discuss value and future of ORSI Programs and Initiatives
- 01:40PM – 01:45PM **Break**

Session 4 Broad Agency Announcement (BAA) Research Contract Program Presentations

- 01:45PM – 02:00PM MDIC: Patient-Centered Benefit/Risk Assessment: Developing a Useful Methodology for Integrating Patient-Centered Perspectives into Regulatory Decisions – William Murray, CEO
- 02:00PM – 02:15PM Epidemico: Social Media Listening for Adverse Event Surveillance – Dr. John Brownstein, Dr. Nabarun Dasgupta, Clark Freifeld, Chi Bahk, Carrie Pierce
- 02:15PM – 02:30PM Manila Consulting: The National Medical Device Curriculum: Supporting Innovation by Enhancing Academic Regulatory Knowledge – Dr. F. Kalush (FDA) and Dr. Gary Hill
- 02:30PM – 02:45PM NEMA Research Inc: Nurse Pain Educator Pilot Program (NPE): A Method For Improving Communication About Pain Treatment – Dr. Joseph Pergolizzi Jr., COO
- 02:45PM – 03:00PM Stanford University: Cross-Species Immune System Reference (Human Immune Atlas) – Dr. Zachary Bjornson and Dr. Garry Nolan
- 03:00PM – 3:10 PM **Break**

Session 5 Chief Scientist Intramural Grant Annual Presentations

- 03:10PM – 03:30PM Rapid & Sensitive Detection Of Crutzfeldt-Jakob Disease Agents In Tissue And Blood Donations – Luisa Gregori, PhD, CBER
- 03:30PM – 03:50PM Optimal Allergen Biomarkers for Effective Assays and Labeling: A Collaborative Project between FDA, IFSH and General Mills – Lauren Jackson, PhD, CFSAN
- 03:50PM – 04:10PM Urine microRNAs as novel biomarkers for acute liver failure patients – Qiang Shi, PhD, NCTR

Session 6 CORES Scientific Intramural Grant Presentations

- 04:10PM – 04:30PM Physiologically-Based Pharmacokinetic (PBPK) Modeling of Nanomedicine: Building Clinically Relevant Standards for FDA-Regulated Nanoparticulate Drug Products – Peng Zou, PhD, CDER
- 04:30PM – 04:50PM Complement Assays for Detection of Immune-Sensitizing Activity of Nanomaterials – Julian Leakey, PhD, NCTR
- 04:50PM – 05:00PM CLOSING REMARKS & ADJOURN**

America's Got Regulatory Science Talent Competition Winners

12:00-1:00 p.m. (in Press Room, Room 1504, Building 31)

Very Limited Seating Available – First Come, First Serve

12:00 pm **Introduction, Welcome Remarks, Overview of Competition**

12:05 pm **University of Rochester Talent Competition**, Introduction by Dr. Scott Steele and Dr. Joan Adamo – University of Rochester Medical Center
Winning Team: "Gene-ius"- Genome Database in Clinical Trials to Innovate Personalized Medicine- **Corey M. Hoffman**

12:20 pm **University of Maryland Talent Competition**, Introductions by Dr. William Bentley – University of Maryland CERSI

3rd Place Team "New Generation Regulation": Linkage of Instructional Videos to Medical Devices - **Benjamin Wu**, Sophia Ma, Kenneth Doan

2nd Place Team "One Correction": Making Drug Information More Accessible -**Emmanuel Ventura**, Kumaran Ramakrishnan, Kevin Lei, Pragya Shrestha, Bob Pang, Joyce Yu

1st Place Team "PHSRegulators": Mobile Application Conveying Safety Information to Communicate Risks of Medications and Devices -**Bilal Khokhar**, Priyanka Gaitonde, Elisabeth Oehrlein, Jan Sieluk, Maya Hanna

12:55 pm **Closing Remarks**