



# 2015 ORSI Science Symposium

## Office of Regulatory Science & Innovation (ORSI)

Session 1	CERSI Presentations	08:35A – 11:30A
Session 2	Breakout	11:30A – 01:00P
Session 3	ORSI Initiatives Panel Discussion	01:00P – 01:40P
Session 4	Broad Agency Announcement (BAA)	01:45P – 02:45P
Session 5	Chief Scientist Grant Presentations	03:00P – 04:00P
Session 6	CORES Grant Presentations	04:00P – 05:00P

Monday, April 27, 2015

FDA Campus – Silver Spring, MD Bldg 31 – Great Room

Webcast Link: <https://collaboration.fda.gov/orsirs/>.

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

### Session 1 Centers for Excellence in Regulatory Science and Innovation (CERSI)

08:35AM – 09:15AM	University of Maryland CERSI Presentation- Speaker TBA
09:15AM – 09:55AM	Johns Hopkins University CERSI Presentation – Speaker TBA
09:55AM – 10:10AM	<b>Break</b>
10:10AM – 10:50AM	Georgetown University CERSI Presentation – Speaker TBA
10:50AM – 11:30AM	University of California at San Francisco/Stanford University CERSI Presentation – Speaker TBA

### Session 2 Breakout

11:30AM – 01:00PM **LUNCH, Poster Session, and Regulatory Science Student Talent Competition – Side-Session**

### Session 3 ORSI Initiatives Panel Discussion

01:00PM – 01:40PM	Center representatives and audience to discuss value and future of the ORSI Programs and Initiatives
01:40PM – 01:45PM	<b>Break</b>

### Session 4 Broad Agency Announcement (BAA) Extramural

01:45PM – 02:00PM	Epidemico: Social Media Listening for Adverse Event Surveillance – Dr. John Brownstein, Dr. Nabarun Dasgupta, Clark Freifeld, Chi Bahk, Carrie Pierce (Epidemico)
02:00PM – 02:15PM	Manila Consulting: The National Medical Device Curriculum: Supporting Innovation by Enhancing Academic Regulatory Knowledge – Drs. F. Kalush (FDA) and Gary Hill (Manila)
02:15PM – 02:30PM	NEMA Research: Nurse Pain Educator Pilot Program (NPE): A Method For Improving Communication About Pain Treatment – Speaker TBD, either Dr. Pergolizzi or Dr. Taylor (NEMA)
02:30PM – 02:45PM	Cross-Species Immune System Reference (Human Immune Atlas) by Stanford University. Speakers: Dr. Zachary Bjornson and Dr. Garry Nolan

### Session 5 Chief Scientist Intramural Grant Annual Presentations

03:00PM – 03:20PM	Rapid And Sensitive Detection Of Crutzfeldt-Jakob Disease Agents In Tissue And Blood Donations- Dr. Luisa Gregori, CBER
03:20PM – 03:40PM	Determination of Optimal Food Allergen Biomarkers for Effective Assays & Labeling- Dr. Lauren Jackson, CFSAN
03:40PM – 04:00PM	Using Cell Free MicroRNA (miRNA) as improved Clinical Biomarkers of Drug-Induced Liver Injury – Dr. Qiang Shi, NCTR

### Session 6 CORES Scientific Intramural Grant Presentations

04:00PM – 04:20PM	In vivo inhalation safety and characterization of nanomaterials in spray cosmetics and mineral-based powder cosmetics – Dr. Nakissa Sadrieh, CFSAN
04:20PM – 04:40PM	Physiologically-based pharmacokinetic (PBPK) modeling of nanomedicine: Building clinically relevant standards for FDA-regulated nanoparticulate drug products – Dr. Zou Peng, CDER
04:40PM – 05:00PM	Complement assays for detection of immune-sensitizing activity of nanomaterials – Dr. Julian Leakey, NCTR

**05:00PM CLOSING REMARKS & ADJOURN**