Science at FDA: Update for the Science Board

Office of the Chief Scientist, FDA
March 4, 2015
Overview

• Science Board Update
• Travel and Conference Update
• OCS Updates
  – Regulatory Science & Innovation (ORSI)
  – Medical Countermeasures initiative (MCMi)
  – National Center for Toxicological Research (NCTR)
  – Women’s Health (OWH)
  – Minority Health (OMH)
  – Scientific Professional Development (OSPD)
  – Scientific Integrity (OSI)
Science Board Updates

• Welcome new members: Cindy Afshari, Tony Bahinski, AnnaLisa Jenkins, Minnie Sarwal, Connie Weaver, Sean Xie
• Maria Freire – Chair for 2015
• Bruce Psaty – Co-Chair for 2015
• FR Notice Calling for new members published January 23, 2015, closes March 24, 2015
Travel and Conference Update

Leslie Wheelock, RN, MS
Director, OSPD
Travel and Conference Update

• FDA conducted an assessment earlier this year to determine the impact of the 2012 travel restriction policy on the FDA scientific staff.

• Assessed importance of attending conferences, negative impact of not attending conferences and denial of requests.

• Surveyed 10416 scientists with 33.4% response
Travel and Conference Update

• Results
  – Important for: *collaboration* (91%), *learning current trend in the professional field* (96%), *informing others about FDA policies* (70%), *recruiting new scientists* (37%), and *to obtain continuing education credits* (43%)
  – Negative impacts for not attending scientific conferences are on: *promotion* (57%), *retention of top FDA scientific staff* (83%), *research or review responsibility* (78%), and *recruiting top scientists for FDA* (76%).
  – According to the travel records from all Centers, only 7 Center conference requests were denied travel during 2014; however, from the survey results requests were not approved at the local level. There were workload issues with the decisions made.
• FDA is participating with HHS HQ and other OpDivs to develop flexibilities so that HHS may support scientists attending conferences.
Office of Regulatory Science and Innovation (ORSI) Update

Carol D. Linden, PhD
Director, ORSI
# Intramural Grant Programs 2015

## Submission and review
- Five programs using harmonized system and timeline
- Automatic and web-based submission and review system built on SharePoint
- In addition to FDA internal reviewers, external reviewers were recruited.

## FY2015 Awards
- Nanotechnology- CORES
  - 6 awards ($776K)
- MCMi Challenge
  - 9 awards ($2.4K)
- Chief Scientist Challenge
  - 11 awards ($1.4M)
- OMH Challenge
  - 3 awards ($297K)
- OWH Intramural Research program
  - 16 awards ($1.6M)
FDA Broad Agency Announcement (BAA)

- Solicitation encourages science- and tech-based participants & academia to meet FDA goals for regulatory science
- Focus on FDA Scientific Priority Areas in *Advancing Regulatory Science*
- FY 15-16 renewal posted on Feb 23, 2015

FY2014:
- ~80 white papers received
- ~45 full proposal reviewed
- 30 awards made (Includes new contracts, modifications and options)

[https://www.fbo.gov/index?s=opportunity&mode=form&id=80ccadceb97c7ee8941b383ed6791fb1&tab=core&cview=0](https://www.fbo.gov/index?s=opportunity&mode=form&id=80ccadceb97c7ee8941b383ed6791fb1&tab=core&cview=0)
Established CERSIs in 4th Year

University of Maryland CERSI

Research Projects:
• Collaborations with CDER (Office of Clinical Pharmacology and Safe Use Initiative) and CDRH (Office of Science and Engineering Laboratories, OSEL)
  o provide scientific evidence for guidances and standards
• Conducting multi-tier collaboration with FDA Office of Minority Health
  o research related to health care disparities, health literacy, and cultural competency

Educational and Training Activities ongoing:
• Masters Degree Programs
  o MEng in Regulatory Science and Engineering (College Park)
  o MS in Regulatory Science (Baltimore)
• Monthly Lectures and Science Exchange Workshops
• Regulatory Science Innovation Awards
• America’s Got Regulatory Science Talent Competition
Established CERSIs in 4th Year

Georgetown University CERSI

Research Projects finishing:
• Georgetown Vaccine Information and Safety Resource (GVISR)
• Triple Negative Breast Cancer among Latina and African American Women

Educational and Training Activities ongoing:
• Continuing Education & Professional Development
  o Partners include various Georgetown schools, MedStar Health, others
• Fellowship in Regulatory Science
  o Post-doctoral training opportunity involving mentors from industry, academia, and government, and partners such as PhRMA, Georgetown faculty, and FDA
• MS in Clinical & Translational Research, Regulatory Science concentration
  o Concentration in regulatory science added onto an existing curriculum in Clinical and Translational Medicine, available online, and involved as partners: Georgetown and Howard Universities, CTSA, and FDA
New CERSI Established in 2014

UCSF-Stanford CERSI

First Year Research Projects:

• Improving efficiency and rigor of pharmacovigilance (CDER & CBER)
• Improving diagnostic accuracy of ADR signal detection (CDER & CDRH)
• Renal impairment in new drug development (CDER)
• Systematic review related to spinal orthopaedic device mechanics (CDRH)
• e-Source Checklist: integration of tools for clinicians to track data elements in EHRs (FDA-CDER, EMA, CDISC, IHE, UCSF, UCD, etc.)

Education-Exchange Unit:

• CERSI Monthly Lectures
• CERSI Young Entrepreneurs Roundtables
• CERSI Academic Programs

Infrastructure Unit

• Facilitating the CERSI Network (Allows for collaboration, sharing and leveraging resources among the 4 CERSIs)
New CERSI Established in 2014
Johns Hopkins University CERSI

First Year Research Projects:

• Application of Common Data Elements to Improve Regulatory Science (CDRH & CDER)
  o Systematically identifying, developing, and disseminating Common Data Elements with a focus on outcomes for use by sponsors & investigators engaged in eye and vision research

• Eliciting Patient Preferences to Enhance Regulatory Science (CDRH & CDER)
  o Focuses on building capacity to measure and incorporate patient and caregiver preferences within the context of regulatory benefit-risk assessments

Selected Educational and Training Activities:

• Certificates Related to Regulatory Science
  o Pharmacoepidemiology and Drug Safety Certificate
  o Risk Sciences and Public Policy Certificate Program

• Regulatory Science-Related Degree Programs
  o JHU Academic Programs – MS in Regulatory Science and Food Safety Regulation
FDA’s Technology Transfer Program

<table>
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<tr>
<th>FY14 Activities</th>
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<tr>
<td>19 new technologies</td>
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<tr>
<td>29 issued patents</td>
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<tr>
<td>8 new technology licenses</td>
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<tr>
<td>58 new collaborations</td>
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<td>&gt;300 intellectual property and collaboration concerns resolved</td>
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<td>&gt;$550,000 in royalties from licensed FDA technologies back into FDA labs</td>
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Consolidation and Expansion of FDATT

- Integrate patenting and licensing activities previously carried out by NIH
- Invest in FDATT with addition of personnel and increase in budget
- Increase program efficiency through FDA’s direct coordination and management of ALL technology transfer activities
Office of Counterterrorism and Emerging Threats (OCET) Update

Robert Fisher, PhD
Director, MCMi Regulatory Science
Medical Countermeasures Initiative (MCMi)
Recent Accomplishments

• Ebola Epidemic Response:
  – Providing scientific and regulatory advice to commercial developers and US government agencies that support Ebola product development
  – Worked with product sponsors, international regulators, and NIH to launch Ebola vaccine trials in record time
  – Collaborated with NIH to design an innovative and robust common clinical trial protocol to evaluate investigational treatments for Ebola
  – Collaborating with international regulatory counterparts in support of international response efforts
  – Facilitating access to investigational medical products for patients with Ebola when requested by clinicians
  – Authorized the use of seven diagnostic tests for Ebola virus under Emergency Use Authorization authority
Medical Countermeasures Initiative (MCMi)
Recent Accomplishments

• Approvals:
  – Granted first CLIA waiver for nucleic acid-based flu diagnostic test
  – Rapivab (peramivir) to treat influenza infection in adults

• Guidances:
  – Radiation Biodosimetry Devices (Draft Guidance)

• Averting Product Shortages:
  – Further extended expiration dating of DuoDote auto-injector lots based on scientific data while manufacturing issues are being resolved
National Center for Toxicological Research (NCTR) Update

Daniel Acosta, PhD
Deputy Director for Research
NCTR Update

NCTR/CTP

- 18 CTP-funded projects on inhalation toxicology, genotoxicity and cytotoxicity, biomarkers, carcinogenicity, and behavioral pharmacology (addiction) are activated.

Global Coalition for Regulatory Science Research


Quantitative Assessment of Genotoxicity Data

- NCTR member of Quantitative Analysis Workgroup of HESI/ILSI Genetic Toxicology Technical Committee, which found that Benchmark Dose (BMD) that produces 10% > over background response (BMD), has greatest utility as Point of Departure (PoD) for establishing risk calculations

Advancing Regulatory Science

- The 43rd Toxicology Study Selection and Review Committee (TSSRC) meeting discussed progress on studies with bisphenol A, retinyl palmitate, triclosan, melamine, aloe vera, arsenic, and nanosilver studies conducted under the FDA-NCTR/NIEHS IAG (Nov 14).
- Sequence Quality Control (SEQC or MAQC IV) consortium of scientists from 12 countries led by NCTR completed and published studies in Nature Collections for the use of NexGen sequencing technologies in the regulatory applications.
Office of Women’s Health (OWH) Update

Pamela E. Scott, PhD, MA
Director, Research & Development Program
OWH Update

- **Research Roadmap** (in development)
- **Intramural Research Program**
  - *16 New Awards: $1.6M*
    - Leverage ongoing center-level projects to address sex and gender *(n=14)*
    - Women’s health-related research to support the implementation of FDASIA Section 907 Action Plan for *(n=2)*
      - Current research funding to CDER, CDRH, CBER, NCTR, ORA
- **Implementation of FDASIA Section 907 Action Plan**
  - Women’s Health Research Roadmap Development
  - Clinical Trials Initiative Collaboration (FDA/OWH and NIH/ORWH)
- **Other Research Activities (OWH ORISE Fellows)**
  - Systematic review of pregnancy exposure registries (OWH-funded fellow for CDER)
  - Assessment of inclusion of women in clinical trials and sex analysis (NDAs and BLAs approved in 2013-2014 by CDER)
  - Assessment of the regulatory impact of the OWH Research Program
• **Pregnancy Initiative** (w/ CDER)
  – Redesigning system for acquisition of reports (SOPs in development)
  – New Pregnancy Exposure Registry Site (in development)
  – Digital and Print information dissemination

• **Take Time to Care Program** (national consumer outreach program)
  – Publication Promotions and Collaborations (10 million annually)
    o New Safe Med Use materials for women with disabilities
    o Partnerships with USA.gov, text4baby, National Institute on Aging, OTIS, Everyday Health, and HHS Office on Women’s Health

• **College Women’s Health Campaign** (offering FDA information)
  – New Webpage [www.fda.gov/collegewomen](http://www.fda.gov/collegewomen)
  – Outreach to college health centers, health programs, sororities

• **Social Media Outreach**
  – eBlasts to disseminate FDA risk communications
  – Twitter and Pinterest Outreach
Office Of Minority Health (OMH) Update

Martin Mendoza, PhD
Health Programs Coordinator
Research and Collaborations Program
OMH Update

FDA Safety and Innovation Act  Section 907 Action Plan

• April 2015: Institute of Medicine / FDA OMH Roundtable Meeting: “Participation in Clinical Trials”

• OMH - NIH Inclusion Governance Board Collaboration

Research and Collaborations Program

• 2015 Intramural Program: 3 funded projects
  ➢ CDER, CBER, and NCTR

• CERSIs:
  ➢ Georgetown & University of Maryland
  ➢ Projects under development with UCSF/Stanford and Johns Hopkins

• FDA OMH - Morehouse Satcher Institute Partnership
  ➢ Health Policy Fellows in Regulatory Science and Minority Health

• Closing on 4/24: FR Notice for public input on OMH Research Agenda
OMH Update (cont.)

Communication and Outreach Program

• HHS – FDA OMH Collaborative Efforts
  ➢ HHS Heckler Report 30th Anniversary
  ➢ Million Hearts Initiative
  ➢ March: Colorectal Cancer Awareness Month

• March 2015 Webinar: “Working with FDA – How to Find and Comment to FDA Dockets”

• Coordination of FDA Language Access Activities - new public health advisor hire

• April 2015: Minority Health Month
  ➢ 2nd annual OMH Scientific Research Program Poster Display
  ➢ OMH - CDER CASE Scientific Seminar with Joseph Wright MD, MPH, Howard University College of Medicine
Office of Scientific Professional Development (OSPD) Update

Leslie Wheelock, RN, MS
Director
OSPD Update

• Graduated 18 Commissioner’s Fellows with 14 remaining at FDA.
• Recruiting 8th Class of Commissioner’s Fellows to begin October 2015
• Launched FDA Fellows Association
• Presented 5 Agency-wide training events on Genomics and MCM
• Co-sponsored with UMD CERSI a Pediatrics Drug Development Workshop
• Hosted Academic Visits for USF and Duke Universities
• Participated in the Emerging Researchers National Conference to advance STEM education