

# **Program Evaluation of the Centers of Excellence in Regulatory Science and Innovation (CERSIs)**

**Subcommittee Update to the FDA Science Board**

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# CERSIs and Time of Evaluation

- FDA's Centers of Excellence in Regulatory Science and Innovation (CERSIs) are:
  - joint efforts between FDA and academic institutions to work collaboratively on projects that promote regulatory science, including innovative research, education, and scientific exchange
  - cooperative agreement, 3 year grant (U01)
- Currently, there are four CERSIs in operation (2011, 2014):
  - University of Maryland (M-CERSI)
  - Georgetown University (GU-CERSI)
  - Johns Hopkins University (JHU)
  - UC-San Francisco (UCSF) & Stanford University
- Initial funding of two original CERSIs complete and two additional CERSIs recently established– ideal time for review

# Charge to the Subcommittee

The questions are organized under the following focus areas of CERSI operations: Overall Missions, Scientific Research Projects, Education and Training Projects, and Administration and Infrastructure.

## **Overall Missions of CERSI**

- Do the established roles and functions for CERSIs and for the CERSI network appropriately advance FDA's regulatory science needs and priorities? Could the roles and functions be modified or enhanced to further advance FDA's regulatory science needs and priorities?
- What criteria should be used to measure the overall success and impact of CERSIs and the CERSI network for FDA and the participating academic centers?

# Charge to the Subcommittee

## **CERSI Scientific Research Projects**

- The Scope, Goal, Objectives, Achievements and Impacts
  - Models, network, metrics

## **CERSI Education and Training Projects**

- The Scope of Work, Goal, Objectives, Outcomes and Impacts
  - Types of training programs

# Charge to the Subcommittee

## **CERSI Administration and Infrastructure**

- Building Effective Public-Private Partnerships
- Investment and Return on Investment
- Building Synergy among the CERSIs, FDA, and Stakeholders

# The CERSI Evaluation Subcommittee

- Memo officially established in January 2015, full membership on-board ~ April 2015. Goal to complete work by March 2016.
- Members:
  - Sherine E. Gabriel, MD
  - Rebecca Jackson, MD
  - Emma Meagher, MD
  - Robert J. Meyer, MD
  - Amy Patterson, MD
  - Robert Pinner, MD
  - Theodore F. Reiss, MD, MBE
  - Michael Rosenblatt, MD
  - Scott Steele, PhD, Chair
  - Laura L. Tosi, MD

# The CERSI Evaluation Process

- Meetings (kickoff monthly calls in April 2015)
- Resource table
- Review of background materials
  - Area leads identified for the four domains
- Site Visit on October 1-2, 2015
  - Meetings across FDA Centers and Offices and with each CERSI

# Initial Key Findings

## Overall mission

### FDA

- Diffuse and broad mission/goals for CERSIs
  - Lack of specific objectives from outset
- Insufficient engagement with FDA Centers

### CERSIs

- Leading research institutions
- Different views of approach and mission
- Value for CERSI as a “Network” unclear
- Challenges with sustainability

# Initial Key Findings

## Scientific Research

- Extensive research expertise and infrastructure
- Identification and focus on FDA priorities
  - Resources necessitate leveraging existing projects
- Challenges with CERSI access to FDA data
- Project & portfolio management issues

# Initial Key Findings

## Education and Training

- Potential misalignment between FDA training and workforce needs/gaps and CERSI programs
- Barriers to placing scholars at FDA
- Limitations on FDA staff time and incentives for training and professional development

# Initial Key Findings

## Administration and Infrastructure

- ORSI contribution to supporting CERSIs
- Duration of funding and ramifications for long-term FDA engagement with CERSIs
- Role and potential for CERSI Network and broader partnerships
  - Scope: Focus on FDA needs? National needs? Role for CTSA Consortium and other partners?

# Areas for Potential Recommendations

## Overarching Issues

- Clearer vision with well defined objectives for the CERSI Program
- Roadmap or needs assessment from FDA
- Broader Human Capital issues (workforce, training, data access)
- Scope of CERSIs

# Areas for Potential Recommendations

- **Strategic Planning, Mission and Goals**
- **Governance and Portfolio Management**
- **Coordination, Communication and Collaboration**
- **Metrics and Evaluation**
- **Resources and Sustainability**

# Next Steps

- Drafting Full Report
- Goal to present final report at March 2016 Science Board Meeting