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

Subcommittee Report 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)
  - UC-San Francisco (UCSF) & Stanford University
  - Johns Hopkins University (JHU)

- 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:

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?*

CERSI Scientific Research Projects

CERSI Education and Training Projects

CERSI Administration and Infrastructure

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)
- Review of background materials
  - Area leads identified for the four domains
- Site Visit on October 1-2, 2015
  - Separate meetings with FDA senior leadership, involved Center and Office leadership, ORSI leadership and staff, and with each separate CERSI
  - SWOT analyses in advance

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
- Divergent views of approach and mission
- Value for CERSI as a "Network" unclear
- Challenges with sustainability

Key Findings

Scientific Research

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

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

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?

Recommendations

Preamble and Context

- Recognize the very limited funding for CERSI Program and one of a broader suite of Regulatory Science initiatives
- Limited funding requires even greater prioritization and strategic needs assessment/plan
- Overall, clearly articulated vision with specific and aligned objectives, deliverables and metrics for success needed for proper evaluation

Recommendations

Cross-cutting Areas

- **Develop an FDA Regulatory Science Research and Education Roadmap**
  - Coordinated, comprehensive assessment to provide detailed agenda for regulatory science research and education
- **Define the Scope of the CERSI Program**
  - Based on roadmap and given other existing FDA CoEs

Recommendations

Cross-cutting Areas

- **Consider CERSI Selection Based on Broad Capabilities**
  - CERSIs as platforms with distinct expertise/resources to address a range of research questions
  - Complementary capabilities across the CERSI Network
- **Address Broader Human Capital Considerations**
  - Staff participating in training, placing trainees at FDA, broader workforce issues

Recommendations

- **Identify Strategic Needs and Establish Mission and Goals**
  - Roadmap/need assessment to inform needs and guide priorities
  - Establish mission and goals based on broad capabilities
    - Specific projects defined post award
    - Rationale for using CERSIs vs. other existing partnerships or mechanisms (BAA, etc.)
- **Provide Active Governance and Portfolio Management**
  - Project management that actively engages Centers
  - Portfolio management to review research/education programs across all CERSIs, FDA CoEs and relevant NIH and other programs

Recommendations

- **Improve Coordination, Communication, and Collaboration at All Levels**
  - FDA Coordination and Communication
    - Shared vision and coordination among leadership
    - Integrate four CERSI Steering Committees, with active planning/oversight
  - Address Barriers to Access FDA
    - Actual and perceived barriers to placing trainees at FDA and data sharing
    - Implement flexible approaches to address both issues (raised previously)
- **Improve Coordination and Sharing of Educational Resources**

Recommendations

- **Develop Metrics and Deliverables Based on CERSI Program Objectives and Re-evaluate CERSI Program**

- **Create an Effective CERSI Network and Collaborations among CERSIs, FDA, Industry, and Academic Partners**
  - Establish a Small Targeted Network that Leverages Partners
    - 4-8 CERSIs to pilot:
      - Development of novel methods, models and research tools
      - Designing new training approaches and programs
    - Focus on unique role and utilize other networks, CTSAs, PPPs, RUF to disseminate and expand (informing and leveraging other efforts)
    - Build critical PPPs while maintaining targeted FDA collaborations

Recommendations

- **Create an Effective CERSI Network and Collaborations among CERSIs, FDA, Industry, and Academic Partners *(continued)***

  - Balance the Network Size and Broader Regulatory Science Funding Requirements
    - 5 years initial funding, continued baseline funding to focus on FDA priorities
    - Prioritize small network with baseline funding vs. expanded network
    - Balance any growth with broader issues of staff time and support

Thank you

- The CERSI Evaluation Subcommittee
- FDA leadership and staff
  - ORSI support
- CERSIs