

CAN Review Board Update

Freda Lewis-Hall, M.D.
Chair, CAN Review Board
Vice President, Chief Medical Officer, Pfizer

Cures Acceleration Network Review Board (CAN RB) Update

- Virtual CAN RB Meeting held December 9, 2016
- The agenda included:
 - NCATS Director's Update
 - Christopher P. Austin, M.D.
 - In-depth discussion of the first 5 years of the CAN
 - 3 Scientific Presentations
 - Panel Discussion
 - No concepts were presented

17th Meeting of the NCATS CAN Review Board

AGENDA

11:00-11:15 AM	Call to Order and Opening Remarks
	Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs)
	Confirmation of Dates for Future NCATS Advisory Council / CAN Review Board Meetings
	Anna Ramsey-Ewing, Ph.D. (CAN Executive Secretary)
11:15-11:30 AM	Update on NCATS
	Christopher P. Austin, M.D. (Director, NCATS)
11:30-1:30 PM	CAN: Five Years and Counting
	Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs) and NCATS Staff Members
1:30-2:30 PM	Discussion
	Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs)
2:30 PM	Adjourn

NCATS Director's Update

- NCATS Strategic Plan
 - Strategic Principles
 - Strategic Goals
- FY17 Budget
- 21st Century Cures Act
 - NCATS-related Provisions

21st Century Cures Act

- Key NCATS-related Provisions
 - Allows NCATS to support clinical trials through phase IIB (instead of IIA) and phase III (instead of IIB) for rare diseases
 - Changes NCATS' Annual Report to a biennial report
 - Report must include list of methods and tools developed, and whether they are being used by FDA

CAN: Five Years and Counting

Presentation Outline

- **Origins and Establishment of CAN**
- **Five Years of Projects and Thinking**
- **CAN Research Program Highlights**
- **Panel: Opportunities to Fulfill the Mandate to Innovate**
- **Discussion: Future Directions**

CAN

Budget Funding History

- FY 11 - \$0
- FY 12 - \$9.9 M
- FY 13 - \$9.4 M
- FY 14 - \$9.8 M
- FY 15 - \$9.8 M
- FY 16 - \$25.8 M
- *FY 17 - \$25.8 M (request)*

CAN

Funding Mechanisms

- **Grant Awards** - Awards up to \$15M per project for the first fiscal year; potential additional funding in subsequent years
- **Matching Funds** - As a condition for receiving an award under this provision, an eligible entity shall contribute to the project non-federal funds in the amount of \$1 for every \$3 awarded
- **Flexible Research Authority** - To use other transaction (OT) to fund projects in accordance with the terms and conditions of this section, awards made under OT for a fiscal year shall not exceed 20% of the total funds appropriated under CAN for such fiscal year

CAN Approved Concepts

- Via 2014 CAN RB project selection process
 - Increasing Access to Compounds and Tox Data
 - Proof of Principle (POP) Awards
 - Sensors and Devices to Detect Clinical Outcomes
- Via 2015 NCATS-generated concept clearances
 - Tissue Chip Testing Centers: Validating Microphysiological Systems
 - SaME Therapeutics: Targeting Shared Molecular Etiologies underlying multiple diseases to accelerate translation
 - 3-D Bioprinting of Human Tissues for Drug Screening
 - Proteomic Profiling for Clinical Applications

CAN RESEARCH PROGRAM HIGHLIGHTS

NCATS

Scientific Presentations

- Tissue Chips: *Human Microphysiological Systems: Organs-on-Chips for Drug Safety and Efficacy Testing* (Dan Tagle)
- Translator: *Biomedical Data Translator* (Christine Colvis)
- 3D BioPrinting: *Update on 3-D bioprinting of human tissues for drug screening* (Anton Simeonov)

PANEL: FULFILLING THE MANDATE TO INNOVATE

NCATS

Important Questions

- Administrative Synergy
 - *Can we achieve administrative and managerial synergy by utilizing currently available and new tools or combinations of tools to support innovative biomedical translation activities?*
- Amplifying CAN's Impact
 - *Can we amplify the impact of CAN projects by establishing collaborations with non-NIH entities and among NIH components?*

Panel Addressed Many Topics

- Funding Instruments at NIH
- Characteristics of Effective Instruments
- Additional Resources Available to Support Innovation and Collaboration
- Types of Participants on NCATS Programs
- Examples of NCATS Collaborations
- Other Models of Collaboration

Examples of NCATS Collaborations

- IQ Consortium
- New Therapeutic Uses (NTU)
- Therapeutics for Rare and Neglected Diseases (TRND) Program
- Tissue Chip Program
 - NIH-CASIS
 - Validation Centers



Future Directions

Preparing for post-CAN transitions



DISCUSSION

NCATS