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
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<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>11:00-11:15 AM</td>
<td>Call to Order and Opening Remarks</td>
<td>Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs)</td>
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<td>Confirmation of Dates for Future NCATS Advisory Council / CAN Review Board Meetings</td>
<td>Anna Ramsey-Ewing, Ph.D. (CAN Executive Secretary)</td>
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<td>11:15-11:30 AM</td>
<td>Update on NCATS</td>
<td>Christopher P. Austin, M.D. (Director, NCATS)</td>
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<td>11:30-1:30 PM</td>
<td>CAN: Five Years and Counting</td>
<td>Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs) and NCATS Staff Members</td>
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<td>1:30-2:30 PM</td>
<td>Discussion</td>
<td>Freda Lewis-Hall, M.D.; Geoff Ginsburg, M.D., Ph.D. (CAN Review Board Co-Chairs)</td>
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<td>2:30 PM</td>
<td>Adjourn</td>
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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 - $9.9M
- FY 13 - $9.4M
- FY 14 - $9.8M
- FY 15 - $9.8M
- FY 16 - $25.8M
- **FY 17 - $25.8M (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

*~$5 million for FY 2016*
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
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
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