NCATS Cures Acceleration Network Review Board

UPDATE

JANUARY 14, 2016

NCATS

National Center for Advancing Translational Sciences

Cures Acceleration Network Review Board (CAN RB) Update

- Virtual CAN RB Meeting held December 11, 2015
- The agenda included:
  - NCATS Director's Update
    - Pamela McInnes, D.D.S., M.Sc. (Dent.), Deputy Director, NCATS, delivered this update for Christopher P. Austin, M.D., NCATS director
    - The primary update concerned the fiscal year (FY) 2016 budget request
  - Concept Clearances
    - Dan Tagle, Ph.D., Associate Director for Special Initiatives, NCATS presented seven concepts; 3 previously considered and 4 new
- Robust discussion followed presentation of each concept
- All concepts were approved with suggestions and comments noted

CAN RB Update
Concepts

- **Previously Approved**
  - Increasing Access to Compounds and Toxicity Data
  - Proof of Principle (POP) Awards
  - Sensors and Devices to Detect Clinical Outcomes

- **New**
  - 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
  - Tissue Chip Testing Centers: Validating Microphysiological Systems

CAN RB Update
Previously Approved Concepts

- **Increasing Access to Compounds and Toxicity Data**
  - To access compounds that did not have a safety signal in pre-clinical studies but later were shown to have toxicity in humans, to investigate underlying mechanisms for human toxicity and why pre-clinical tools failed, and to incorporate this information into predictive modeling to benefit drug development.
- **Proof of Principle (POP) Awards**
  - To support promising pre-clinical research projects that were not previously funded due to the lack of a specific piece of translational data.
- **Sensors and Devices to Detect Clinical Outcomes**
  - To advance the integration of real-time data from multiple devices and sensors to meaningfully inform the assessment of clinical outcomes.

CAN RB Update
New Concepts

- **SaME Therapeutics: Targeting Shared Molecular Etiologies Underlying Multiple Diseases to Accelerate Translation**
  - To develop a matrix of diseases and molecular etiologies to identify shared molecular etiologies (SMEs) underlying multiple diseases and to stimulate the identification of SME-targeted drugs and conduct clinical trials of these agents.
- **3-D Bioprinting of Human Tissues for Drug**
  - To establish a multidisciplinary NIH-based Center that uses 3-D bioprinting to generate high- throughput screenable assay models of human tissues for drug discovery.
  - To enable extramural investigators to access the NIH 3-D bioprinting core group to establish human tissue models and protocols for the generation and differentiation of human induced pluripotent stem cells (iPSCs) for the tissue cells of interest

CAN RB Update
New Concepts *cont.*

- **Tissue Chip Testing Centers: ValidatingProteomic Profiling for Clinical Applications**
  - To establish new clinical tests and protein biomarkers based on quantitative proteomics, phosphoproteomics and validated antibodies;
  - To optimize technical and analytical tools and easy-to-use resources and databases for physicians and other clinical staff;
  - To integrate analysis of genetic and proteomic data for decision making in personalized health care; and
  - To achieve better understanding and longitudinal monitoring of pathophysiology and drug effects by quantitative proteomic readouts.
- **Tissue Chip Testing Centers: Validating Microphysiological Systems**
  - To create tissue chip testing center(s) that will be responsible for testing a select group of compounds using predefined assays according to FDA and pharmaceutical industry standards