

Joint Meeting of the National Center for Advancing
Translational Sciences Advisory Council (12th)
and
Cures Acceleration Network Review Board (15th)

JUNE 13, 2016

NCATS

Open Session Agenda

- Call to Order
- Approval of Minutes
- Confirmation of Future Meeting Dates
- **NCATS Director's Report**
 - Presentation
 - Discussion
- Clearance of Concepts
 - Presentations
 - Discussion and Consideration

Future Meeting Dates

Future Joint Meetings NCATS Advisory Council/CAN Review Board

2016

September 15

2017

January 12

May 4

September 7

2018

January 11

May 10

TBD

Future CAN Review Board (only) Meetings (by phone)

2016

December 9

2017

December 15

2018

December 14

SEE NCATS DIRECTOR'S UPDATE

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DISCUSSION

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CLEARANCE OF CONCEPTS

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Joint NCATS Advisory Council and Cures
Acceleration Network Review Board
June 13, 2016

Concept Clearance

NIH/NCATS Registry Program

Petra Kaufmann, M.D.

Director, Office of Rare Diseases Research

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NIH/NCATS Registry Program

- Background
 - Registry definition: A collection of standardized information about a group of patients who share a condition or experience.
 - Source: Data can come from patients, clinicians, electronic health records, etc.
 - Registries can support the translational research process by
 - Connecting potential participants to research studies (Contact Registry)
 - Providing datasets for research on disease progression and for clinical trials (Natural history registry)
 - The Office of Rare Diseases Research has supported registries through
 - Developing common data elements (CDEs)
 - Mapping data into a i2b2/tranSMART data repository, working with investigators at Harvard University

NIH/NCATS Registry Program

Goals:

To promote high quality, standardized registries that are:

- patient centered
- feasible
- sustainable
- focused on therapeutics development
- consistent across the therapeutics development lifecycle
 - data content, quality, format and transport standards



NIH/NCATS Registry Program

- Description
 - Developing data content and quality standards for registries
 - Aligning with FDA data submission framework
 - Implementing demonstration projects
 - Disseminating tools, templates and standard processes for registries

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Concept Clearance

SBIR Contract Topic: Development of Drone Labware

Lili M. Portilla, M.P.A.

Director, Office of Strategic Alliances

Sam Michael

Director, Automation and Compound Management

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Development of Drone Labware

- Background

- There is a market opportunity for a small business to develop and eventually commercialize a lab drone for High Throughput Screening (HTS) applications.
 - Drones have a much greater range of motion than stationary robotic arms and they are cheaper to maintain.
 - The open source community is constantly developing new tools to make drones more efficient and cheaper.
 - In an HTS setting, it is difficult to have robotic arms in shared work spaces due to synchronization concerns and the possibility of collision. Lab drones can occupy the same air space, allowing for the coordination of multiple drones in the same work area.
 - Use of lab drones can be transferable to other lab tasks, such as handling of hazardous materials.

Development of Drone Labware

- Goal
 - To develop an autonomous drone capable of taking a laboratory consumable (e.g. well-plate) from one station to another in a consistent and reproducible manner.
- Potential impact (including relevance to NCATS' mission)
 - There is impact for a small business to develop a lab drone system using open source/crowd sourcing software, thereby creating a new market niche to make fully automated HTS laboratory operations more accessible to labs not currently equipped or funded to do so.
- Criteria for evaluating success
 - SBIR contract mechanism will support and monitor milestones and deliverables delineated in the contract Statement of Work.

Joint NCATS Advisory Council and Cures
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Concept Clearance

**NIH-CASIS Coordinated Program in Tissue Chip
Systems for Translational Research in Space**

Danilo A. Tagle, Ph.D.
Associate Director for Special Initiatives

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NIH-CASIS Coordinated Program in Tissue Chip Systems for Translational Research in Space

- Goal
 - NCATS has established a MOU with the Center for the Advancement of Science in Space (CASIS) to deploy and further develop tissue chip technology platforms for biomedical research at the International Space Station (ISS) that will lead to a better understanding of the molecular basis of human disease and/or the effectiveness of diagnostic markers and therapeutic interventions.
- Brief description of outcome
 - Among the areas of research encouraged in this initiative is translational research examining the mechanisms that underlie the effects of diseases or conditions associated with bone and cartilage, skeletal muscle, brain, gastrointestinal tract, lung, liver, skin, microvasculature, or other tissues, as well as research designed to improve the translation of existing knowledge of strategies for the prevention and treatment of such diseases or conditions.

NIH-CASIS Coordinated Program in Tissue Chip Systems for Translational Research in Space

- Potential impact
 - Better understanding of microgravity, reduced-gravity environments at the ISS and radiation exposure and its effects on many of the human body's systems. It is now widely known that accelerated aging takes place in space due to muscle wasting, osteoporosis, reduced cardiopulmonary function, immune response, etc, but that these conditions are reversible when astronauts return to Earth.
- Criteria for evaluating success
 - Better insight into the molecular basis, including epigenome changes, for many human conditions in space and new information for novel targets for drug development for use on Earth

NIH-CASIS Coordinated Program in Tissue Chip Systems for Translational Research in Space

- What is the major obstacle to address?
 - Pushing the limits of tissue chip technology for use in space, including microfluidics, bioreactors, remote sensing, and ground control capabilities through successful collaborations between NIH-supported tissue chip developers and CASIS implementation partners
- Brief summary of ongoing research/activity in this area?
 - Prior investment by NIH (NCATS through CAN, NIH Common Fund, NIBIB, NIEHS, NIDCD, NIDDK, NCI, ORWH) in developing tissue chip technology for drug safety and efficacy testing

DISCUSSION AND CONSIDERATION

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OPEN SESSION ADJOURNMENT

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