Assay Guidance Workshop on 3D Tissue Models for Antiviral Drug Development

June 7, 2022 – June 8, 2022
Virtual (All times are in ET)

AGENDA: Day 1

11:00 AM **Introductory Comments**

Catalyzing Translational Innovation
Joni L. Rutter, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)
Infectious Diseases and Global Preparedness
Robert Jordan, Bill & Melinda Gates Foundation
Overview of Pandemic Preparedness Initiatives and Prototype Pathogens
Emily Erbelding, National Institute of Allergy & Infectious Diseases (NIAID), NIH

11:30 AM **Overview of Workshop Objectives**
Sarine Markossian, NCATS, NIH

11:40 AM **Keynote: SARS-CoV-2, the Start of a New Scientific Renaissance in Biological Science**
Simon Funnell, UK Health Security Agency (UKHSA)

12:40 PM **Lunch**

1:20 PM **Session 1: 3D Tissue Models: Utility and Limitations**
Objective: Describe available tissue models and discuss challenges in building these models as well as their utility and limitations.
Chair: Marc Ferrer, NCATS, NIH
    1:20 PM **3D Cardiovascular Disease Models**
              Christine Mummery, Leiden University Medical Center
    1:40 PM **Human Tissue Stem Cell-Derived Organoids Model Viral Infection**
              Hans Clevers, F. Hoffmann-La Roche Ltd
    2:00 PM Linda Griffith, Massachusetts Institute of Technology (MIT)
    2:20 PM Anthony Atala, Wake Forest School of Medicine

2:40 PM **Break**

3:00 PM **Session 1:** *(continued)*
Chair: Marc Ferrer, NCATS, NIH
    3:00 PM **Vasculogenesis and Angiogenesis Engineering Models**
              Zhengpeng (Jason) Wan, MIT
    3:20 PM **Advances in Organ-on-Chip Platform Technologies Toward Higher Throughput, Multi-organ Interactions, and High Containment Operations**
              Jeffrey T. Borenstein, Draper
    3:40 PM Discussion and Q&A

4:15 PM **Summary of Day 1 and Adjourn**

AGENDA: Day 2

11:00 AM **Day 2 Welcome and Introduction**

11:10 AM **Session 2: Utility of the Existing 3D Tissue Models for Antiviral Drug Development**
Objective: Describe and discuss how these available 3D tissue models have been utilized in antiviral drug discovery/development and as tools for understanding and modeling infectious diseases.
Chair: Ann E. Eakin, NIAID, NIH

    11:10 PM **Modeling Respiratory Viral Infections in Human Lung Chips**
        Donald E. Ingber, Wyss Institute at Harvard University
    11:30 PM **Defining Viral Pathogenesis Mechanisms Using Human Cerebral Organoids**
        Lee Gehrke, MIT and Harvard Medical School
    11:50 PM **Human Intestinal Organoids as a Platform for Testing Antivirals to Human Norovirus**
        Sashi Ramani, Baylor College of Medicine
    12:10 PM **Antiviral Screening Pipeline and Lessons Learned**
        Sara Cherry, University of Pennsylvania

12:30 PM **Lunch**

1:10 PM **Session 2:** *(continued)*
Chair: Ann E. Eakin, NIAID, NIH
    1:10 PM Emily M. Lee, NCATS, NIH
    1:30 PM Calvin Kuo, Stanford
    1:50 PM Jia Zhu, Fred Hutchinson Cancer Research Center
    2:10 PM Discussion and Q&A

2:45 PM **Break**

3:00 PM **Session 3: Use of Robust and Reproducible 3D Tissue Models from Drug Discovery through Development**
Objective: Provide guidelines and considerations for developing robust and reproducible tissue models that can be used for testing therapeutics. Discuss challenges in affordability, accessibility, transferability, and reproducibility of these tissue models. Discuss their advantages vs disadvantages.
Chair: Robert Jordan, Bill and Melinda Gates Foundation
    3:00 PM **Connecting and Supporting the Tissue Modeling Community via the MPSCoRe Global Working Group**
        Nicole C. Kleinstreuer, National Institute of Environmental Health Sciences
    3:20 PM **Microphysiological Systems and Where Do They Fit in the Safety and Efficacy Evaluation of Antibody Therapies Targeting Viral Infections During Pregnancy**
        Evi Struble, U.S. Food and Drug Administration
    3:40 PM **Talk 3**
    4:00 PM **Talk 4**
    4:20 PM **Discussion and Q&A**

4:50 PM **Session 4 – Closing Session: Summary of Discussions and Perspectives on the Challenges Ahead**
Simon Funnell, UKHSA

5:10 PM **Closing Statement and Adjourn**