From Research to Readiness: Advancing Research and Regulatory Acceptance of Microphysiological Systems for Infectious Disease Applications

Wednesday, May 31, 2023 – 8:30 am - 12:30 pm EDT
Thursday, June 1, 2023 – 8:30 am - 12:30 pm EDT

Virtual Workshop

Agenda and Program

While animal models can be useful in the study of infectious diseases, their susceptibility and manifestation of symptoms can differ substantially from humans. The emergence and global spread of COVID-19 underscores the need for human-based models of infection. The Microphysiological Systems for COVID Research (MPSCoRe) working group was organized to coordinate the use of microphysiological systems (MPS) to reduce animal use in studies of COVID-19 and other infectious diseases. MPSCoRe has six objectives:

- Provide a neutral forum to facilitate interaction and engagement among international research efforts.
- Raise awareness of MPS technologies and support their application in assessing the safety and efficacy of potential novel therapeutics.
- Work with global authorities to understand how MPS models can be considered in a regulatory context.
- Provide cross-discipline and cross-sector expertise in discussing and characterizing model performance and readiness criteria.
- Support the assessment of MPS against in vivo preclinical and clinical data.
- Ensure the 3Rs-opportunities that these model platforms offer are recognized.

In line with these objectives, MPSCoRe will hold a virtual workshop to facilitate discussion and collaboration about current regulatory approaches and to raise awareness of opportunities for accelerating the integration of MPS models in the regulatory framework. The workshop will feature presentations on MPS models for infectious disease research and where they are in terms of readiness as well as presentations from international regulators. There will be opportunities for registered participants to ask clarifying questions about the presentations during the event, as well as opportunities for group discussion.
The workshop is being organized by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), the UK National Centre for the Replacement Refinement & Reduction of Animals in Research (NC3Rs), the National Institute of Allergy and Infectious Diseases (NIAID), the National Center for Advancing Translational Sciences (NCATS), and the US Army DEVCOM Chemical Biological Center. A recording of the workshop will be made available at https://www.niehs.nih.gov/news/video/index.cfm.

Time (EDT)	Agenda – Wednesday, May 31
8:30 am – 8:40 am	**Welcome / Housekeeping** *Nicole Kleinstreuer, NICEATM*
8:40 am – 9:00 am	**Initiatives of AMED MPS project in Japan towards regulatory acceptance of MPS data** *Seiichi Ishida, Sojo University*
9:00 am – 9:20 am	**Organ-on-a-chip systems development at the NBACC** *Jeremy Boydston, National Biodefense Analysis and Countermeasures Center (NBACC)*
9:20 am – 9:40 am	**Soldier-on-a-chip: interrogating the effects of biological threat agent exposure using a multi-organ microphysiological system** *Tyler Goralski, US Army DEVCOM*
9:40 am – 10:00 am	**Evaluation of testicular organoids as a model for Zika virus infection** *Dayton Petibone, Food and Drug Administration (FDA)*
10:00 am – 10:20 am	**Moving beyond SARS-CoV-2: NIAID efforts for pandemic preparedness and prototype pathogens** *Mark Williams, NIAID*
10:20 am – 10:35 am	**Break**
10:35 am – 10:55 am	**Microphysiological systems to model and evaluate immune-endothelial cell interactions in inflammation** *Gwen Fewell, Synvivo*
10:55 am – 11:15 am	**Human organ chip models of infectious disease** *Don Ingber, Harvard Wyss Institute*
11:15 am – 12:15 pm	**Panel discussion** *Seiichi Ishida, Sojo University* *Jeremy Boydston, NBACC* *Tyler Goralski, US Army DEVCOM* *Dayton Petibone, FDA* *Mark Williams, NIAID* *Gwen Fewell, Synvivo* *Don Ingber, Harvard Wyss Institute*
12:15 pm – 12:30 pm	**Wrap-up / Adjournment** *Nicole Kleinstreuer, NICEATM*

Time (EDT)	Agenda – Thursday, June 1
8:30 am – 8:40 am	**Welcome / Housekeeping** *Anthony Holmes, NC3Rs*
8:40 am – 9:00 am	**Communication is key: deciphering acute and systemic inflammatory responses to SARS-CoV-2 infection using single- and multi-organ lung, liver and immune axis microphysiological systems** *Emily Richardson, CN Bio*
9:00 am – 9:20 am	**MPS in biosafety level 4 containment** *Gabriella Worwa, NIAID Integrated Research Facility (IRF) at Fort Detrick*
9:20 am – 9:40 am	**Opportunities for MPS to advance research in HIV and related comorbidities** *Dwight Yin, NIAID*
9:40 am – 10:00 am	**Modeling SARS-CoV-2 infections and therapeutic screening for COVID-19 with a high throughput microphysiological system for the human airway** *Landys Lopez Quezada, Draper Labs*
10:00 am – 10:20 am	**Utility of primary human cell based respiratory and intestinal tissue models for infection with SARS CoV-2 variants and drug toxicity and efficacy studies** *Seyoum Ayehunie, MatTek*
10:20 am – 10:35 am	**Break**
10:35 am – 10:55 am	**Steps and challenges of organ-on-a-chip technology for infectious disease applications in a containment level 3 laboratory** *Tanja Suligoj, Quadram Institute Bioscience*
10:55 am – 11:15 am	**UKHSA's state of readiness and perceived needs in the context of accelerating integration of MPS into infectious disease research** *Simon Funnell, UK Health Security Agency (UKHSA)*
11:15 am – 12:15 pm	**Panel discussion** *Emily Richardson, CN Bio* *Gabriella Worwa, NIAID IRF at Fort Detrick* *Dwight Yin, NIAID* *Landys Lopez Quezada, Draper Labs* *Seyoum Ayehunie, MatTek* *Tanja Suligoj, Quadram Institute Bioscience* *Simon Funnell, UKHSA*
12:15 pm – 12:30 pm	**Wrap-up / Adjournment** *Anthony Holmes, NC3Rs*