

# The 3Rs Collaborative's MPS Initiative: Advancing education & technology through collaboration



MPS World Summit, June 2024

Presented by: Megan R. LaFollette, 3RsC Executive Director

# Today's Agenda

- 1. Introduction to the 3Rs Collaborative**
- 2. Broad overview of 3RC-MPS Initiative**
- 3. Overview of Working Group Progress & Resources:**
  - Tech Hub
  - Workshops & Briefs
  - Regulatory Overview
- 4. Regulatory group & paper overview**
- 5. How to Join & Conclusion**

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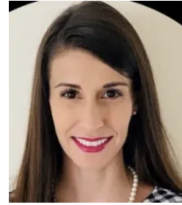
**The 3Rs Collaborative is a US-based non-profit  
whose mission is to advance better science –  
for both people & animals**



**Refine.  
Reduce.  
Replace.**



# 3RsC members span across the scientific field.



# The 3RsC's Strategy has 3 Goals:



**1. Promote the 3Rs Broadly** by creating a research landscape that is knowledgeable & supportive of the 3Rs



**2. Promote Specific 3Rs Strategies** by advancing implementation of high-impact, evidence-based, & practical 3Rs techniques.



**3. Promote Our Organization** by building collaborations & awareness of resources and programs from the 3Rs Collaborative.

# Our 3Rs efforts span across critical topics:



**Environmental  
Health  
Monitoring**



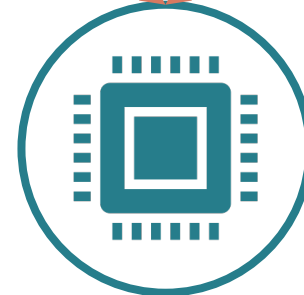
**Translational  
Digital  
Biomarkers**



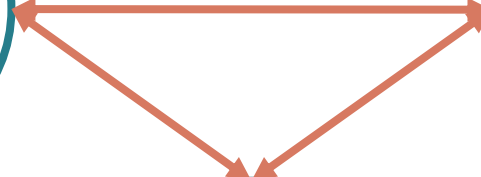
**Artificial  
Intelligence  
- Preclinical**



**Refinement  
(Mouse Handling & NHP PRT)**



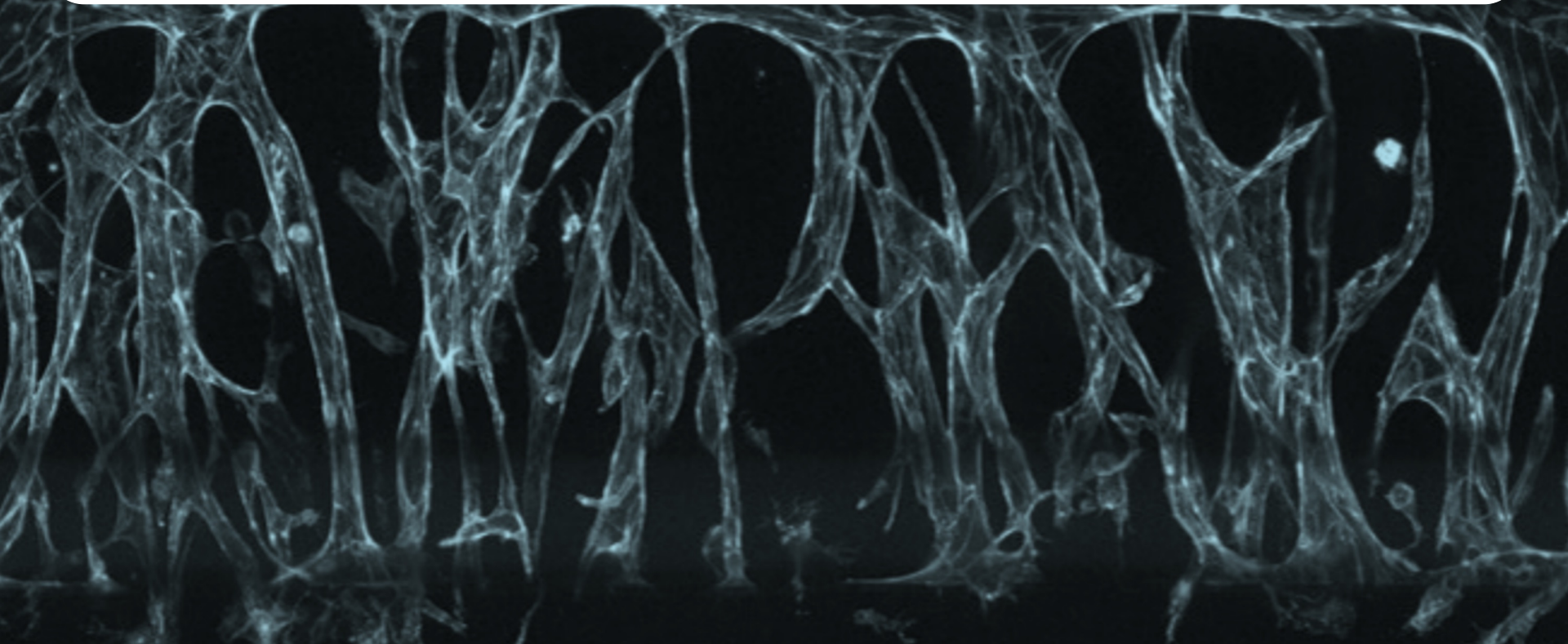
**Microphysiological  
Systems**



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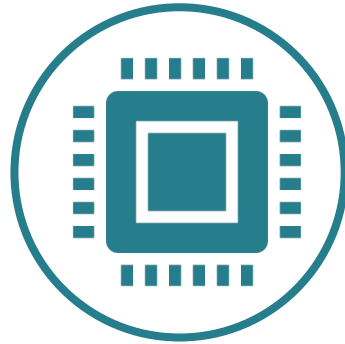
Our **microphysiological systems initiative** seeks to increase adoption & regulatory use of MPS where scientifically justified.



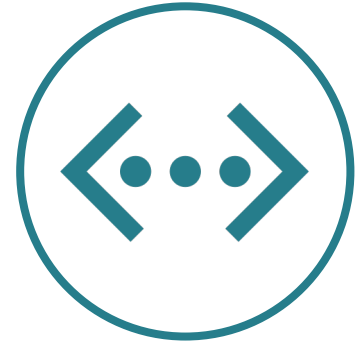
**3RsC-MPS members includes the 3 key stakeholders for MPS.**



**Regulators**



**Developers**

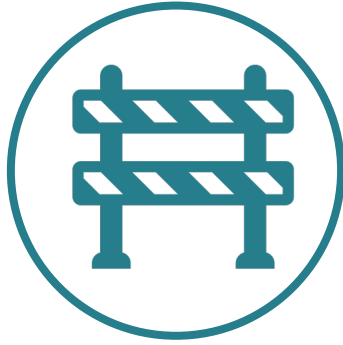


**End-Users**

Developers are in a **key position** to guide & assist MPS use & acceptance.



**Promise**



**Limitations**



**Tailored R&D**

**Our MPS group is unique because it's situated in an organization that recognizes the current necessity of animal research.**

**We are committed to advancing all three "Rs."**

**We have strong, positive relationships with current animal researchers.**

# 42 institutions (30 developers) are members of 3RsC-MPS.



# The 3RsC-MPS Initiative aims to:

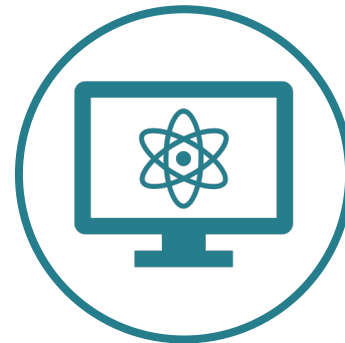
1. Provide **thought leadership and expert consensus** from developers combined with other stakeholders on implementation of MPS.
2. Facilitate appropriate **discussion, collaboration, and sharing** between commercial developers of MPS.
3. Create direct **engagement between developers, end-users and regulatory agencies** on the use of MPS.
4. Develop **external partnerships and collaborations**
5. Create **resources to facilitate increased engagement with MPS.**

# The 3RsC-MPS accomplishes these goals via 3 working groups:



## Regulatory

Forward the use of MPS in regulatory applications



## Technology Expo

Create, maintain, promote, & improve a central technology hub of providers.



## End-User Engagement

Create educational resource hub, webinar & posts to advance MPS and engage with end-users

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# Most of our resources are quickly and easily available via our MPS resource hub



[3Rs Resources](#) ▾

[Learn More](#) ▾

[Our Initiatives](#) ▾

[Events](#) ▾

[Subscribe](#)

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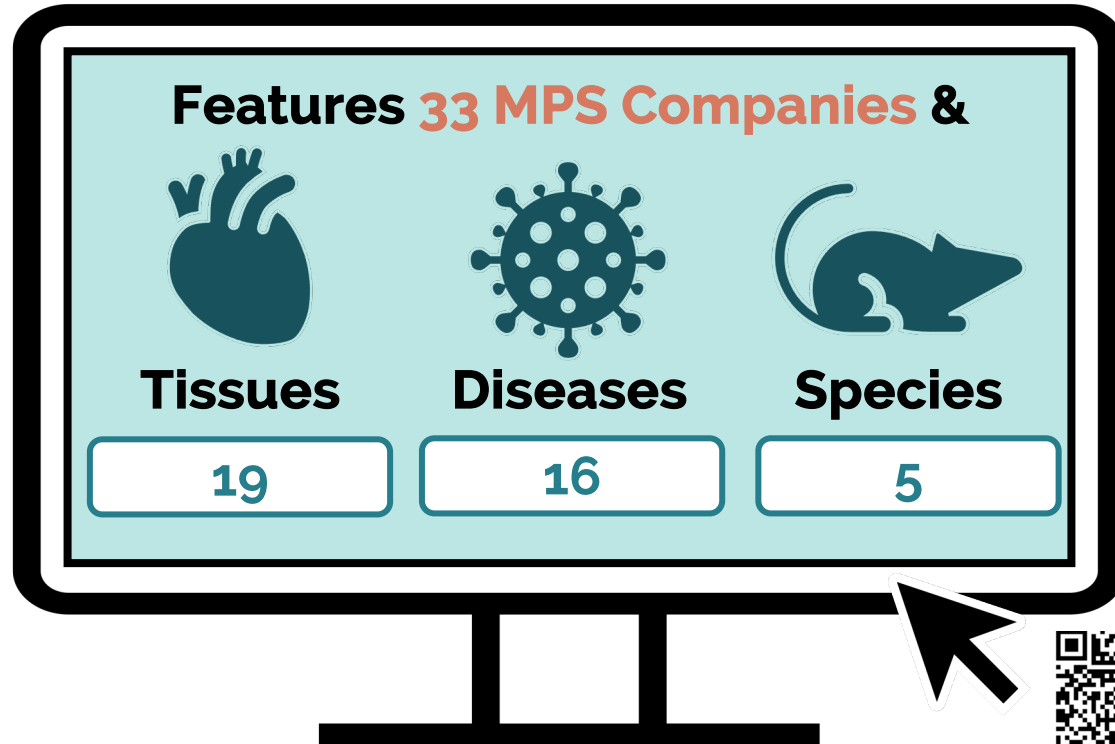
Donate

## Advancing better science - for both people & animals.

We collaborate to refine, reduce, & replace animals in research.

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Our tech hub connects **end-users with relevant commercial tech providers.**



**COMING SOON**

**Publication Hub:**  
explore  
publications from  
commercially  
available  
companies using  
the same filters!



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## Tissues Offered

- BBB (7)  Bone (1)  Bone Marrow (4)  Cartilage (2)  CNS & Neuro (16)  Fat (3)  Gut (13)  Heart (7)  Kidney (10)  
 Liver (14)  Lung (15)  Multi-Organ (8)  Ocular (2)  Pancreas (5)  Reproductive (2)  Skeletal Muscle (7)  Skin (6)  
 Tumor (14)  Vasculature (9)
- 
- 

## Disease Area Offered

- Cardiovascular Disease (8)  COVID-19 (4)  Diabetes (5)  Fibrosis (9)  Hepatitis (5)  ImmunoOncology (11)  
 Inflammation (9)  Metabolic Disease (14)  Microbiome (3)  Neurodegenerative Disease (10)  Neurological Disease (11)  
 Neuromuscular Disease (6)  Osteoarthritis (4)  Retinopathies (1)  Sepsis (2)  Toxicology (24)
- 
- 

## Non-Human Species

- Dog (2)  Mouse (2)  Non-Human Primate (2)  Pig (2)  Rat (2)
- 
-

**We feature presentations including a broad intro to MPS & topic specific webinars**

# Microphysiological Systems Initiative

**We collaborate to increase industry adoption & regulatory acceptance of microphysiological systems.**

JOIN OUR INITIATIVE

VISIT OUR TECH HUB

[Overview](#)

[Tech Hub](#)

[Presentations](#)

[MPS & the FDA Modernization Act](#)

[Conferences](#)

[Initiative FAQ & How to Join](#)



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Through our partnership with the IQ-MPS Affiliate, we have organized **9 workshops** (+2 upcoming this year).

2022



Kidney



Liver



Neuro

2023



Vasculature



Gastro-intestinal



Blood brain barrier



Lung

2024



Immune/  
lymph



Neuromuscular/  
fibrosis



Cell  
Sourcing\*



Oncology\*

**\*Upcoming  
on Sep 17  
& Nov 12**

Each workshop features 15 min data driven presentations from developers.

# All workshops are recorded & hosted on our website & YouTube for easy reference.

Playlist

8 Videos

▶ Liver MPS Webinar



▶ Neurological MPS Webinar

▶ Kidney MPS Webinar

▶ BBB MPS Webinar

▶ Vascular MPS Webinar

▶ GI MPS Webinar

▶ Lung MPS Webinar

▶ Immune competent & Lymph node Webinar

## Organ-Specific Microphysiological Systems Workshops

The 3Rs Collaborative and International Consortium for Innovation & Quality (IQ) Microphysiological Systems (MPS) groups work together to put on a series of MPS presentations to facilitate communication between MPS technology providers and end-users.

Below are recordings of 3RsC hosted workshops on various organ-specific models. In these workshops, MPS companies with commercially available models will present data-driven highlights on their models. To connect with commercial technology providers, [check out our MPS Technology Hub](#).

**We created a brief related to the FDA Modernization Act 2.0 (with an update coming soon related to 3.0)**

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# Key facts about the FDA Modernization Act 2.0 & MPS

1. Does not “allow” the FDA to consider non-animal research data in a way they couldn’t before. MPS data had already been included & reviewed by FDA prior to it’s passage
2. Brings current FDA practice into legislation & indicates strong support for NAMs
3. MPS are currently most promising for efficacy, gaps in current tox models, early discovery studies prior to animal research, & in conjunction with animal or human models.

# Our regulatory group has engaged in strategic partnerships & educational aspects.



Strategic relationships with FDA Alternative Methods Working Group & **FDA-CDER**, C-Path, NIST, CAAT, Standards Coordinating Body & More



Contributed to **4 presentations or discussions** related to MPS use in regulatory applications



**Upcoming publication** on Using MPS for 3Rs & Regulatory Applications: Nuances, Stakeholder Responsibility, & Developer Perspectives

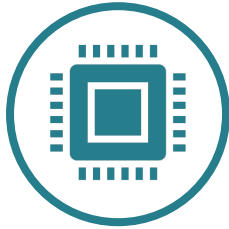
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**Using MPS for 3Rs & Regulatory Applications:  
Nuances, Stakeholder Responsibility, &  
Developer Perspectives**

# MPS can contribute to all 3Rs of animal research.



## Replacement

Avoiding the use of animals where they otherwise would have been used.

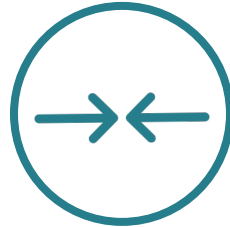
*Example: Using MPS for a study instead of an early animal study to determine efficacy or toxicity*



## Refinement

Minimizing pain, suffering, distress & improving animal welfare

*Example: Using MPS to determine a tighter dose range that causes less distress in an animal study*

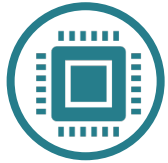


## Reduction

Ensuring that animal studies that occur use minimal animals that are required to obtain reliable & useful info.

*Example: Using MPS to define a dose range contributing to an experimental design that requires fewer animals*

# Each stakeholder has a unique role in advancing the use of MPS in regulatory applications



## Developers

- Provide **data driven expectations** of MPS & technical expertise
- Present & **promote their platforms** to regulators & end-users



## End-Users

- Come to developers with **clear research questions** & early findings
- **Involve developers** in regulatory submissions
- **Share case studies** of using MPS in general research & regulatory acceptance



## Regulators

- Help **identify unmet regulatory gaps** that MPS could fill
- **Encourage supplemental MPS** results in submission

**Developers & End-Users should work together to use MPS  
in areas **outside of regulatory purview.****

**Early Discovery**

**Target Identification**

**Helps to build confidence**

# End-Users, Regulators, & Developers Should Work Together On...

1

**Develop & validate  
MPS for specific  
contexts of use**

2

**Considerations for  
standards and  
outcome measures  
for specific contexts  
of use**

3

**Showing the  
advantages of MPS  
in regulatory  
submissions**



# Current Focus: **Cross-Platform Project** with FDA-CDER on MPS for Drug-Induced Liver Injury (DILI)

## **Overarching Goal = To build confidence in using MPS for DILI**

- To create the **first universal protocol** & experimental design for evaluating DILI with MPS, regardless of platform
  - Including determining cells, endpoints, and core reference compounds
  - Focus will be on acute liver toxicity with small molecules
- To run the **first simultaneous & coordinated cross-platform MPS study** across commercial platforms for a specific context of use
- To set-up multiple providers for **qualification**
- To set up FDA-CDER for developing **best practices/guidance** that can provide direction to sponsors about key criteria, validation, & reporting metrics

\*Project done under the PPP between 3Rsc & FDA-CDER

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# How to Join

1. Complete our membership application
2. It will be reviewed & approved
  - Must have clear focus on MPS
3. Pay your invoice
4. Get on-boarded

## Microphysiological Systems Initiative FAQ & How To Join

[Overview](#) [Tech Hub](#) [Presentations](#) [MPS & the FDA Modernization Act](#) [Conferences](#)

[Initiative FAQ & How to Join](#)



The 3Rs Collaborative's MPS Initiative is the premier expert working group for stakeholders across the industry, especially commercial developers – working to advance the adoption and acceptance of MPS. Below are asked questions about our initiative as well as information about how to join.

- ▶ [What is the 3RsC-MPS Initiative?](#)
- ▶ [What makes the 3RsC-MPS Initiative unique?](#)
- ▶ [What are the benefits of joining?](#)
- ▶ [Who can be a member?](#)
- ▶ [What is the monetary cost of participating? What does it cover?](#)
- ▶ [What is the time contribution expected of members?](#)
- ▶ [How do I become a member?](#)
- ▶ [What is involved in on-boarding?](#)

**The 3RsC-MPS Initiative has made significant progress in the 4 years since its inception.**



# Thank you to our members



**Sign-up for our newsletter to connect with me & for a copy of these slides.**



**Check out the tech hub & website: [3rc.org/mps](https://3rc.org/mps)**

**Email me to connect:  
[meglafollette@3rc.org](mailto:meglafollette@3rc.org)**