NCATS

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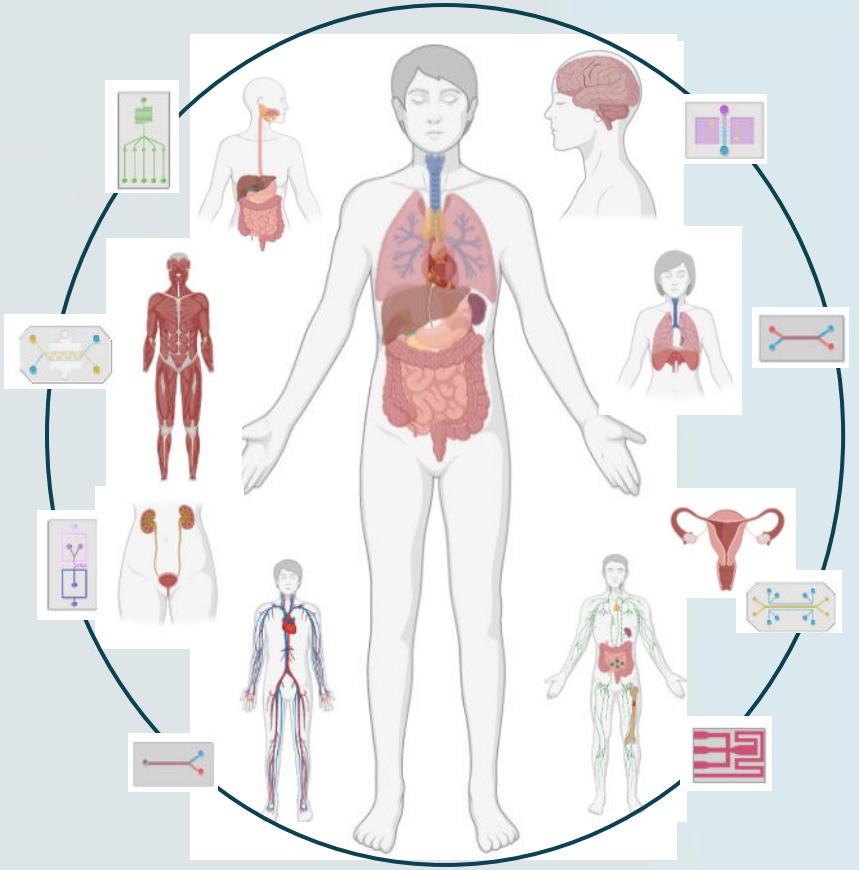
The NIH Tissue Chip for Drug Screening Program



Passley Hargrove-Grimes, PhD – Program Officer

March 5, 2026

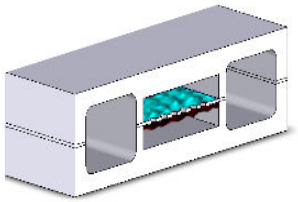
27th NIH TC Consortium Meeting and CIVM Qualification Public Workshop

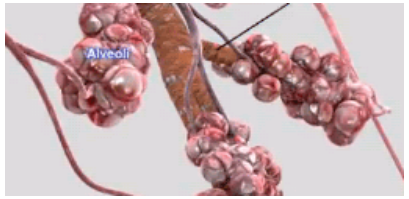
National Center for Advancing Translational Sciences

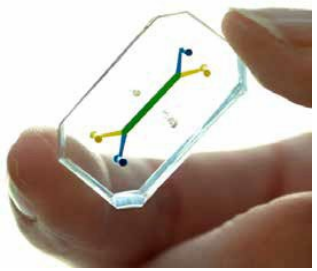
NCATS Tissue Chips for Drug Screening Program (2012-Current)

Program Goal:

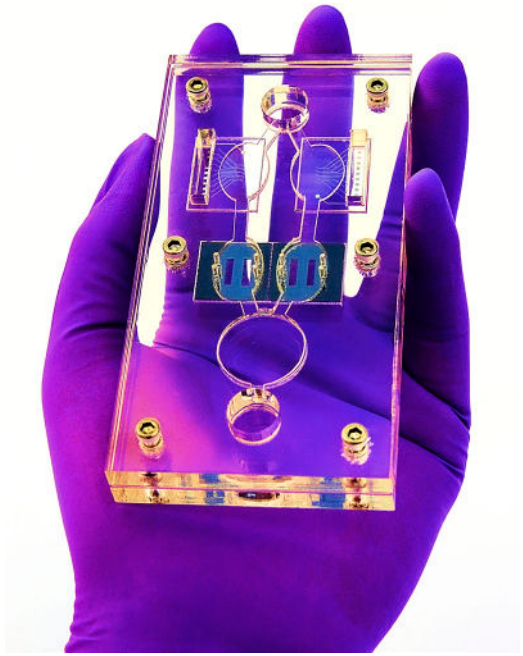
- Develop an *in vitro* human *3-D* culture systems (**tissue chips/microphysiological systems**) that emulate organ physiology and function
- Bring in advances in stem cell biology, microfluidics and bioengineering for risk assessment to accurately evaluate the efficacy, safety and toxicity of promising therapies



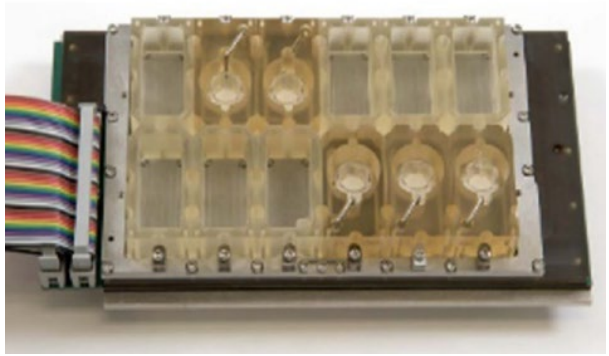




Emulate
Single organ chip
Science (2010)
328:1662-1668



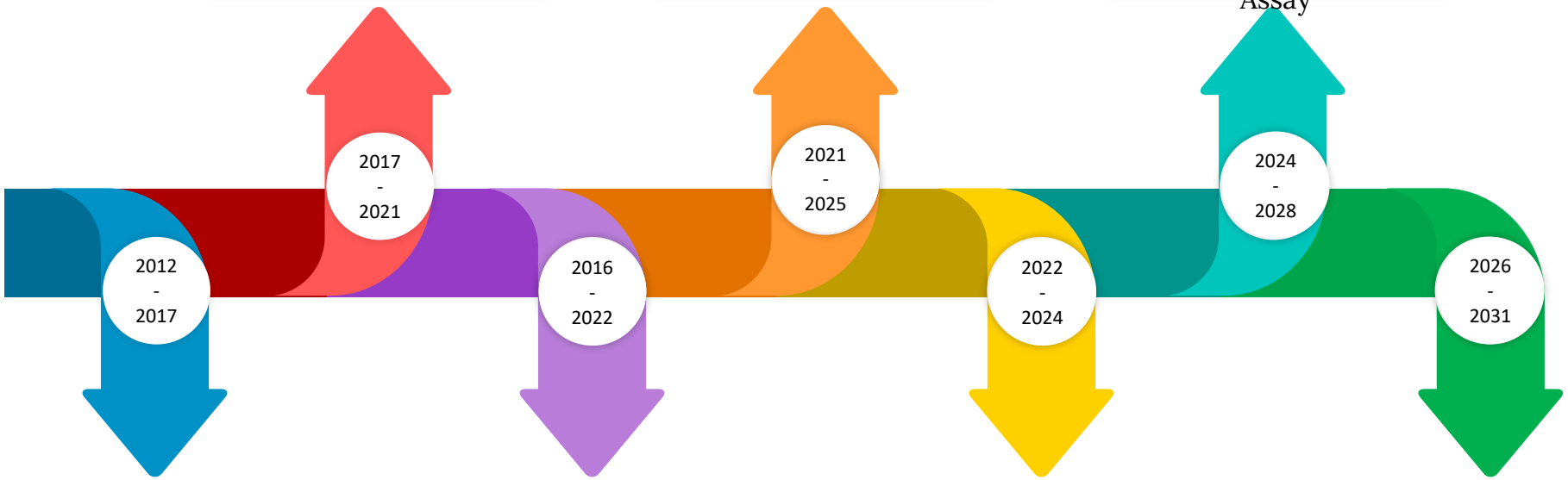
Hesperos 5-organ chip
Sci Trans Med (2019), 19:



Evatar
Liver + Female Reproductive System (ovary, fallopian tubes, uterus and cervix)
Nature Communications (2017) 8:14584- 14597

https://ncats.nih.gov/tissuechip

NIH Tissue Chips for Drug Screening Program At A Glance 2012-Current



Safety Pharmacology
Assessing toxicity where no physiologically and pharmacologically relevant models are available

Disease Modeling and Efficacy Testing
Capture the pathophysiology, mutation spectrum and phenotypic diversity of human diseases and conditions

Building Confidence
Tissue Chip Testing Centers
MPS Database

Clinical Trials on a Chip – Precision Medicine
Inform clinical trial design, planning and execution

Building Community
MPS World Summit
International MPS Society

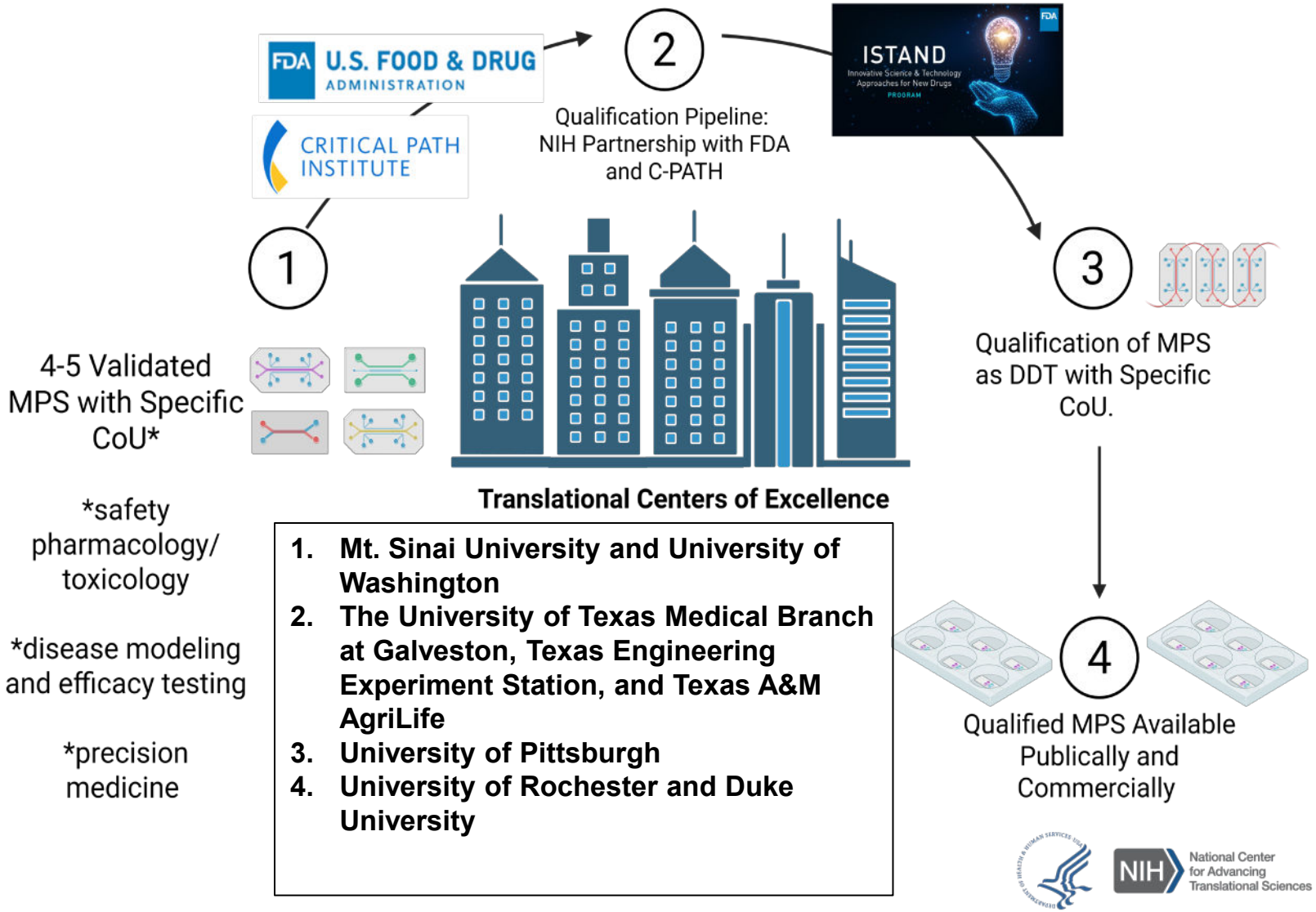
Regulatory Acceptance
Translational Centers for MPS
Botulinum Toxin Potency Assay

Most Recent Program
Tissue Chips in Space 2.0

National Center for Advancing Translational Sciences

Translational Centers for Microphysiological Systems (TraCe MPS)

- To accelerate the translational use of MPS in drug development through **regulatory acceptance and adoption for industrial use**
- Letter of Agreement between NCATS and FDA (Critical Path Institute)
- Qualifying MPS as DDT that are **fit-for-purpose for industry needs** and have **specific context of use (CoU) that will meet regulatory qualification**



TraCe-MPS: ISTAND SUBMISSIONS to FDA

Innovative Science and Technology Approaches for New Drugs (ISTAND) Program

- Accepts submissions for qualification of types of drug development tools (DDTs) that are out of scope for existing DDT qualification programs for biomarkers, clinical outcome assessments, and animal models.
- Pilot launched by FDA in 2020; became permanent 7/31/2025
- 25% of the accepted LOIs were from TraCe-MPS awardees

Translational Centers for MPS ISTAND Submissions

Project #	Project Name	Submission Stage/Status
DDT-IST-000034	Liver acinus MPS (LAMPS) for determining drug candidate dosing in clinical trials of liver disease	2025-06-23– LOI Accept and QP invited 2025-02-20 – LOI Reviewable 2025-01-09 – LOI submission
DDT-IST-000047	Human chorio-decidual interface organ on chip for derisking positive rodent DART studies for new modality investigational new drug candidates	2025-11-13 – LOI Accept and QP invited 2025-07-15 – LOI Reviewable 2025-07-07 – LOI submission
DDT-IST-000045	Human Kidney Chip for Assessment of Relative Nephrotoxicity	2025-11-13 – LOI Accept and QP invited 2025-07-03 – LOI reviewable 2025-06-24 – LOI submission
DDT-IST-000044	Quantifying hepatotoxicity using the liver acinus microphysiological system (LAMPS) for determining drug candidate dosing in clinical trials of liver disease	2025-11-25 – LOI Accept and QP invited 2025-07-03 – LOI Reviewable 2025-06-19 – LOI submission

*As of January 5, 2026

Botulinum Toxin Potency Assay using Tissue Chips (BoT PATCh)

NCATS-FDA MOU 225-23-003

- Letter of Agreement specific to Bot PATCh
- Development, regulatory qualification and commercialization of alternative approaches methods (NAMs) that specifically utilizes the neuromuscular junction Tissue Chips (TC) platforms that will replace the LD50 assay (mouse lethality bioassay (MLB) as a potency assay for botulinum toxin (RFA-TR-22-031, RFA-TR-22-032)
- Cooperative agreement U44TR004795 PI Geisse (Curi Bio) High-Throughput NMJ Assay for Botox Potency Screening
- Cooperative agreement U44TR004811 PI Kronauge (Hesperos) Human Neuromuscular Junction Platform to Evaluate Botulinum Toxin Potency
- NAMs developed and validated. LOIs submitted to ISTAND FDA

NIH Tissue Chip Consortium

Partnership + Collaboration = Program Success

Acting Director
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IQ Consortium MPS Affiliate: AbbVie, Alnylam, Amgen, Astellas, AstraZeneca, Biogen, Bristol-Myers Squibb, Company, Celgene, Eisai, Eli Lilly, Genentech, GlaxoSmithKline, Janssen Pharmaceuticals, Merck & Co., Merck KGaA, Mitsubishi Tanabe, Novartis, Pfizer, Sanofi, Seattle Genetics, Takeda, Theravance, Vertex

Trans-NIH MPS Working Group:

>55 Program Officers from NCATS, NCI, NHLBI, NIA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCR, NIDCD, NIDDK, NEI, NIEHS, NIMH, NINDS, ORWH/OD

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