TEX-VAL Consortium:

Testing and qualification of the microphysiological systems through an academia-industry-government collaboration

July 2025

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American Tissue Chips Landscape (National Institutes of Health)

$500 Million and counting…

Establishment of NCATS December 2011

IQ MPS Consortium Members: AbbVie, Alnylam, Amgen, Astellas Pharma US, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squib, Daiichi Sankyo, Eisai, Eli Lilly, F. Hoffmann-La Roche, Genentech, GSK, Incyte, Janssen, Merck, Merck Healthcare KGaA, Novartis, Novo Nordisk, Pfizer, Sanofi, Servier, Takeda, Vertex, UCB

US Food and Drug Administration

2010 – 2012 Regulatory Science

NIH – FDA Joint Leadership Council on Advancing Regulatory Science

RFA-RM-10-006
- Heart and Lung Micromachine was one of 4 awards

NIH $18 M
FDA $2.25 M

2012 - 2017 Toxicity Studies

* DARPA $75 M

* AstraZeneca, GlaxoSmithKline and Pfizer Reference Set Compounds *(2014-2017)*

NCATS Tissue Chips for Drug Screening

RFA-RM-11-022
- 10 awards

RFA-RM-12-001
- 8 awards

NCATS $50 M

Common Fund, NIBIB, NCI, NICHD, NIEHS, ORWH $25 M

2016 - 2021 Accelerated Aging Models

* Center for Advancement of Science in Space (CASIS) or International Space Station – National Laboratory
$8 M in kind per launch
* NASA task orders with implementation partners

Tissue Chips in Space

RFA-TR-16-019
- 5 awards $12 M

RFA-TR-18-001 (joined by NIBIB)
- 4 awards $10 M

2018 – 2022 Disease Models for Efficacy Testing

Nociception, Addiction, and Overdose
RFA-TR-19-003
- 5 awards ($25 M HEAL)

Alzheimer's Disease-Related Dementias
RFA-NS-19-027
- 1 award $7.5 M

Disease Models
RFA-TR-16-017
NHLBI, NIAMS, NIBIB, NICHD, NIDCR, NIDDK, NIEHS, NINDS, ORWH
- 13 awards $75 M

RFA-DK-17-035 Type 2 Diabetes
- 3 awards $15 M

Clinical Trials on a Chip
RFA-TR-19-014
•10 awards $36 M

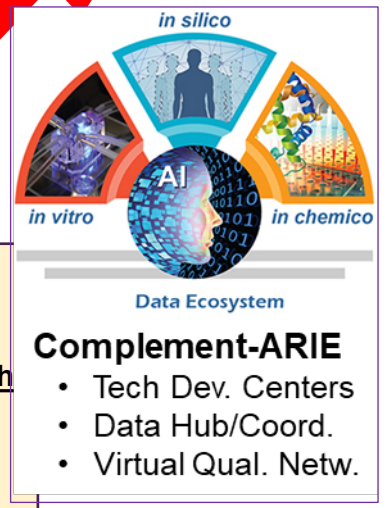
Intramural - Extramural Collaboration for Drug Screening with Bio-fabricated 3-D Disease Tissue Models
RFA-TR-21-015
• 2 awards

2016 – 2020 Building Confidence in MPS

Tissue Chips Testing Centers and Database Center
RFA-TR-16-006, RFA-TR-18-005, RFA-TR-18-006
- 2 TCTCs and 1 MPS Database Center $24 M

Self-sustaining beyond NCATS support

Translational Centers for Microphysiological Systems (TraCe MPS)
RFA-TR-23-001
•4 awards $35 M



Complement-ARIE
- Tech Dev. Centers
- Data Hub/Coord.
- Virtual Qual. Netw.

2010 2012 2016 2020 2022 2024

Slide adapted from Dr. Danilo Tagle (NIH/NCATS); data shown are for 2024

National Center for Advancing Translational Sciences

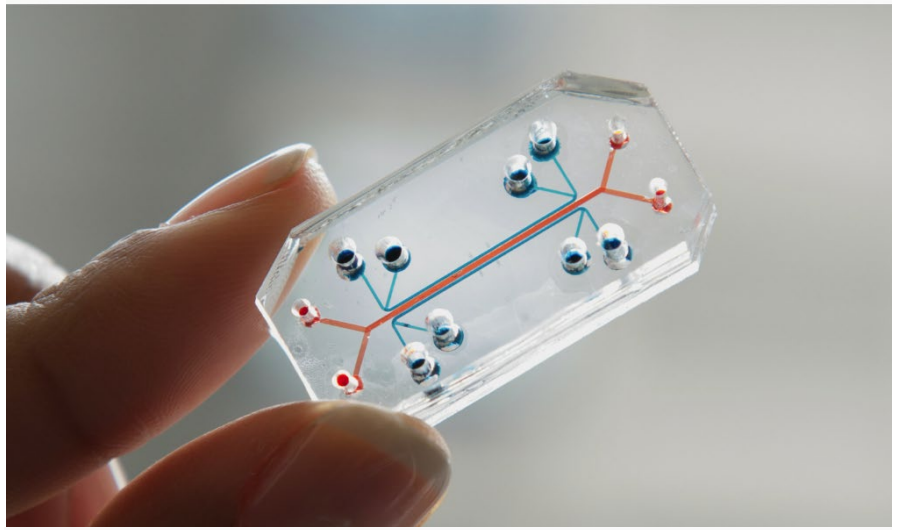
Biomedical Engineering Produces Really Interesting Science… and Gadgets… and News…

QUARTZ

Published July 2, 2015

BEST IN SHOW

A microchip that mimics live human organs wins Design of the Year

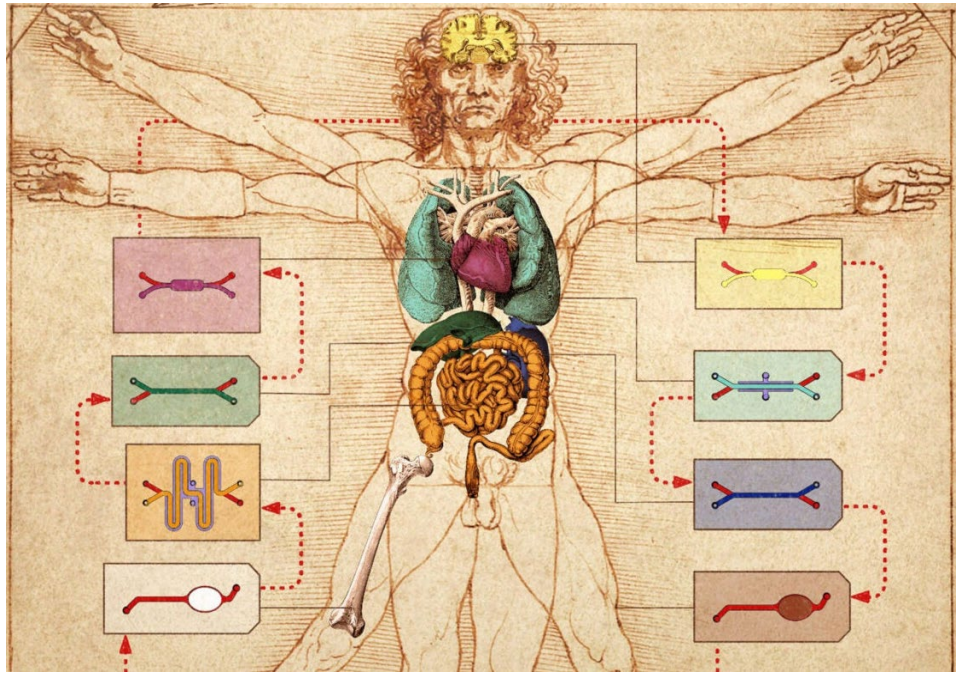


Cheaper, faster, more accurate and more humane

In today's model, pharmaceutical companies spend about US $1 billion to get a drug approved—a process that usually takes about 10 years. The usual drug lab tests involve either observing cells on a petri dish, or using lab animals. The accuracy rate of these methods are questionable because petri dishes do a poor job replicating human environments and the physiology of lab animals do not exactly mirror human physiology.

https://qz.com/443439/a-microchip-that-mimics-live-human-organs-wins-design-of-the-year/

Human body-on-chip platform lays a foundation for better, accelerated drug testing



Credit: Wyss Institute at Harvard University

"This is what we love to do at the Wyss Institute: make science fiction into science fact. And we hope our demonstration that this level of biomimicry is possible using organ chip technology will garner even greater interest from the pharmaceutical industry so that animal testing can be progressively reduced over time," said Ingber.

https://news.harvard.edu/gazette/story/2020/01/human-body-on-chip-platform-may-speed-up-drug-development/

U.S. FOOD & DRUG ADMINISTRATION

Home / Regulatory Information / Laws Enforced by FDA / Selected Amendments to the FD&C Act / Food and Drug Omnibus Reform Act (FDORA) of 2022

npr

NEWSLETTERS SIGN IN NPR SHOP

NEWS CULTURE MUSIC PODCASTS & SHOWS SEARCH

LISTEN & FOLLOW

FDA NEWS RELEASE

FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

For Immediate Release: April 10, 2025

"For too long, drug manufacturers have performed additional animal testing of drugs that have data in broad human use internationally. This initiative marks a paradigm shift in drug evaluation and holds promise to accelerate cures and meaningful treatments for Americans while reducing animal use," said FDA Commissioner Martin A. Makary, M.D., M.P.H. "By leveraging AI-based computational modeling, human organ model-based lab testing, and real-world human data, we can get safer treatments to patients faster and more reliably, while also reducing R&D costs and drug prices. It is a win-win for public health and ethics."

F

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Previous Statuto dies!

Previous Text:
"preclinical tests (includi

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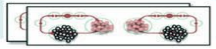
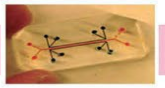
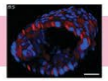
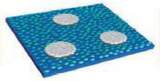
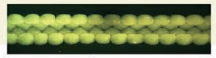
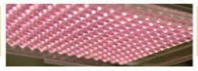
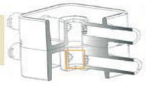
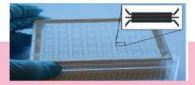
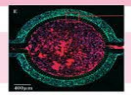
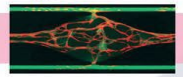
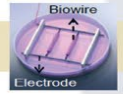
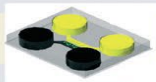
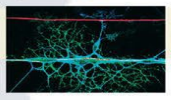
Materials on this slide were adapted from a presentation by Dr. Ilona Bebenek (FDA-CDER)

Companies that offer tissue chip technologies (supported by NIH)

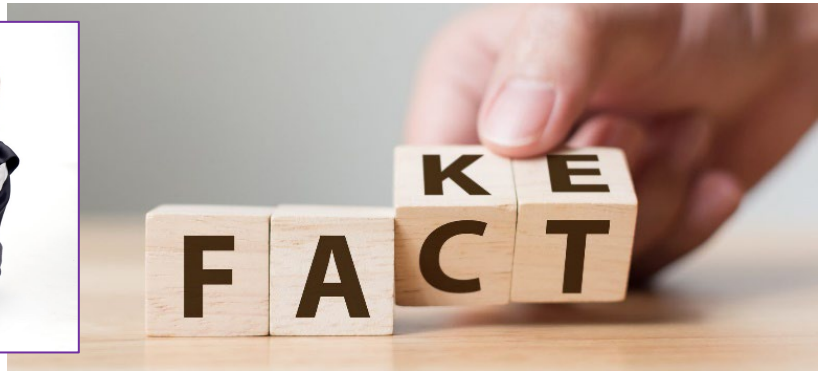
		Scientific founders	Selected products
Body on-a-Chip			
Hesperos®		Michael Shuler James Hickman	Multi-Organ Chip (2, 4 organs) (5-10 organs)*
TISSUSE Emulating Human Biology		Uwe Marx	2-Organ-Chip (2-OC) 4-Organ-Chip (4-OC) Human-on-a-Chip (HoC)*
Tissue interface on-a-Chip			
emulate		Donald Ingber	Lung on-a-Chip Airway on-a-Chip Gut on-a-Chip Kidney on-a-Chip Bone Marrow on-a-Chip
AlveoliX In-vitro models inspired by nature		Olivier Guenat	Lung-on-a-chip array
NORTIS		Thomas Neumann	Kidney on-a-Chip Vessel on-a-Chip
Quorum		Axel Guenther	Artery on-a-Chip
Parenchymal tissue on-a-Chip			
Hepregen		Sangeeta Bhatia	HepatoPac® HepatoMune™
organovo™		Gabor Forgacs Keith Murphy	ExVive3D™ Liver ExVive3D™ Kidney*
Aspect biosystems		Tamer Mohamed Konrad Walus Sam Wadsworth Simon Beyer	Lab-on-a-Printer™ 3DBioRing™ Airway
insphero		Jan Lichtenberg Jens M. Kelm Wolfgang Moritz	3D Insight™ Liver 3D Insight™ Islet 3D Insight™ Tumor
3D Biomatrix™ Three-Dimensional Cell Culture		Nicholas Kotov	PERFECTA3D® HANGING DROP PLATES
HμREL CORPORATION		Greg Baxter Robert Freedman	HμRELhuman™ HμRELflux™ HμRELTox™ HμRELflow™
KIYATEC®		Matthew R. Gevaert	3DKUBE™
VAXDESIGN		William L. Warren	MIMIC® Technology

		Scientific founders	Selected products
CNBio innovations		Linda G Griffith	LiverChip® LiverChip® 36
DRAPER		Joseph Charest	Microphysiological Systems
MIMETAS the organ-on-a-chip company		Jos Joore Paul Vulto Thomas Hankemeier	OrganoPlates®
SYNVIVO		Kapil Pant B. Prabhakar Pandian	SynTumor SynBBB SynRAM SynTox
4DBio 4DESIGN BIOSCIENCES		G. Wesley Hatfield Christopher Hughes Steven George Abraham Lee	Vascularized micro-organ (VMO) platform
AIM BIOTECH		Roger Kamm	3D cell culture chips
TARA		Milica Radisic Gordana Vunjak-Novakovic	Cardiac Biowire™ II AngioChip*
μOrgano		Kevin Healy	μOrgano
EHT Technologies		Thomas Eschenhagen	Engineered Heart Tissue (EHT)
myriamed		Wolfram-Hubertus Zimmermann	3D Cardiac Systems
AxoSim		Michael Moore	Nerve-on-a-Chip™
xona MICROFLUIDICS		Noo Li Jeon Carl W. Cotman Anne Taylor	Standard / Triple Chamber Neuron Device
MicroBrain BT		Bernadette Bung	Neuronal Diode
ananda		Margaret Magdesian	Neuro Device

National Center for Advancing Translational Sciences


IF YOU
BUILD IT,
THEY
WILL
COME
- FIELD OF DREAMS

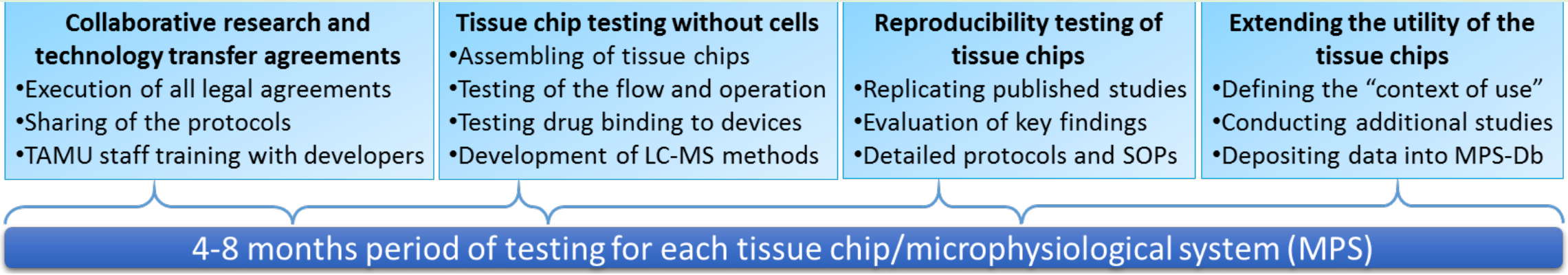

You've Built It.
Will They
Come?


FAKE

TEX-VAL: Tissue Chip TESTING Center (funded by NIH)

Oct. 2016 – Sept. 2018 (TEX-VAL 1.0) **Oct. 2018 – Sept. 2020 (TEX-VAL 2.0)**

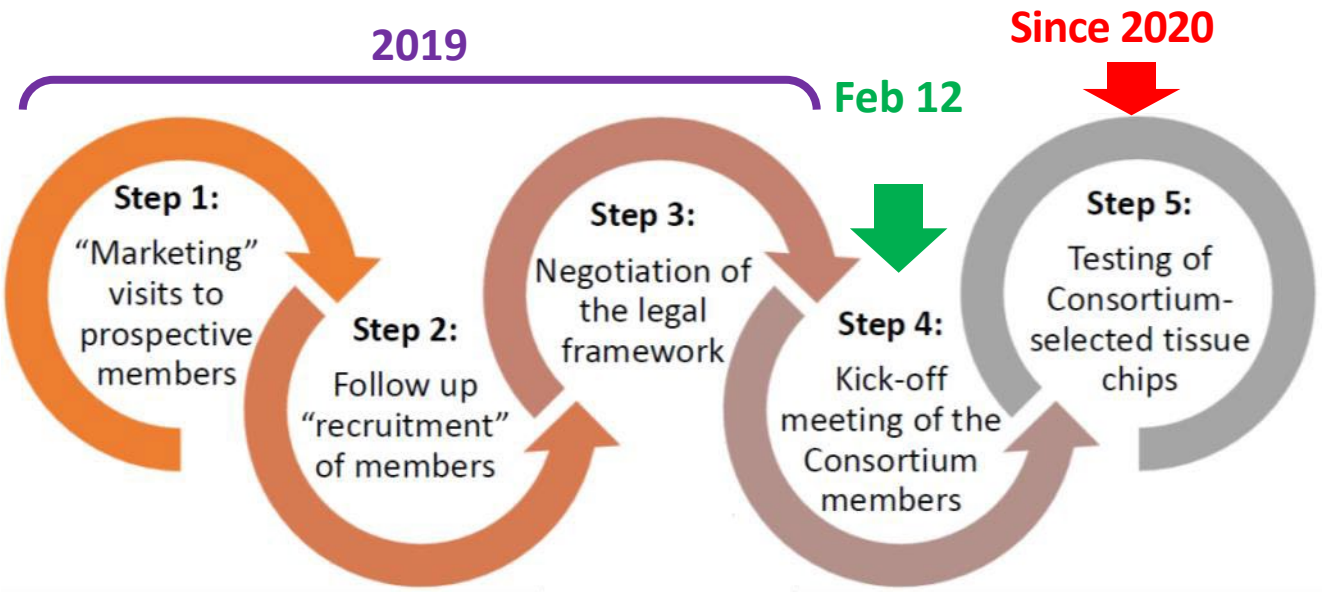
- Did we get these academic lab-made devices to work outside of the developer lab? **Mostly yes**
- Can we replicate the results from the developers? **Mostly yes**
- What was the biggest challenge to technology transfer? **Availability of the functional primary cells**
- Were the devices "ready" for testing drug safety in the "real world"? **Most were not**
- What was the most important "learning" from these studies? **Developers learning about the limits of their technologies and how to make them useful to the end-users**



TEX-VAL Tissue Chip Testing Center → Consortium

Aim 3: To establish revenue-generating activities for MPS validation beyond NIH funding:

- conduct site visits and seminars with stakeholders,
- identify interested parties for Consortium membership,
- negotiate a consortium agreement, and
- conduct tissue chip testing "*happily ever after… NCATS*"



Goals of the Consortium:

- Bring together industry, trade association and government agencies to define a work plan and deliverables
- Defining a ***work plan***: identifying ***common*** needs for "tissue chips": organs, platforms, cells, chemicals (+/- controls), phenotypes, etc.

Texas A&M University role:

Execute on a Consortium's ***work plan***:

- Procuring equipment and consumables
- Establishing the models in the lab
- Verifying reproducibility of cell sourcing
- Replicating key published findings
- Refining the models based on feedback

TEX-VAL Consortium: Is There a "Value Proposition"?

Members provide <u>to</u> TEX-VAL:

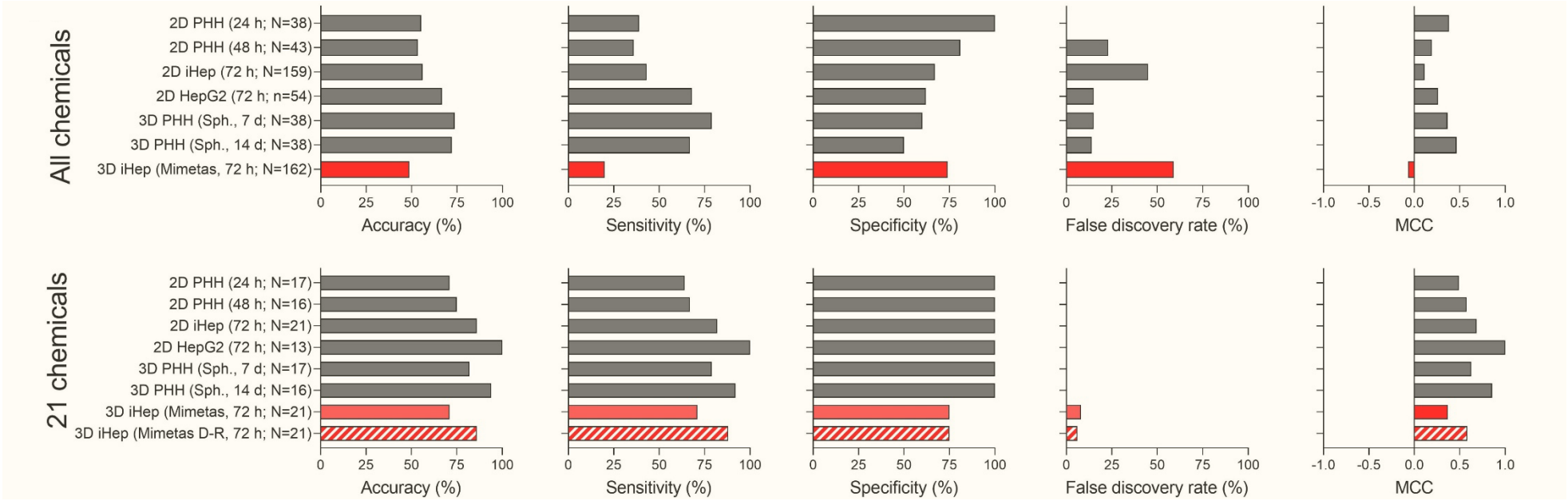
- Funding ($100,000/year/member)
  Texas A&M charges 0% overhead
- 2-3 scientists to participate in TEX-VAL activities (1-2/mtgs month)
- Input on the annual work plan (i.e., "this is what my organization needs to be accomplished this year…")

Members receive <u>from</u> TEX-VAL:

- Access to all data, protocols, etc. (embargoed access for 1 year)
- Opportunity to engage in open discussions and learn from each other on how MPS are used
- Unlimited technical and scientific support from scientists experienced in 50+ MPS models
- Co-authorship on publications

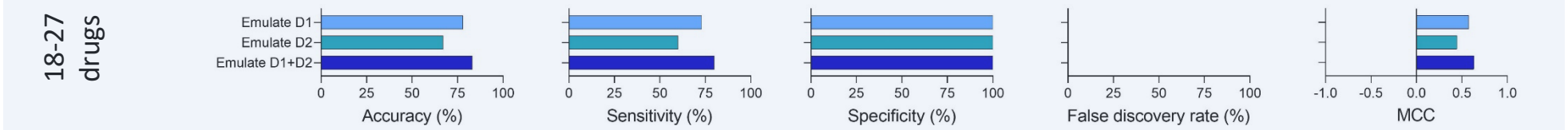
A need to "*Trust, But Verify*" for the VALUE of NAMs…
an Example of Vendor's Claims (Versus Reality) About the Prediction of Liver Toxicity

Kato et al (2022) *Toxicology in Vitro* 85:105464 (Supplemental Figure 3)



Data from:
Birczak et al (2021)
Toxicology
450:152667

OrganoPlate® 2-lane 96 (Mimetas)



	Model	True Positive	True Negative	False Positive	False Negative	Sensitivity (%)	Specificity (%)
27 Drugs	Chip donor 1	16	5	0	6	73 [51.4-86.8%]	100
18 Drugs	Chip donor 2	9	3	0	6	60 [35.3-80.3%]	100
18 Drugs	Chip both donors	12	3	0	3	80 [54.2-92.8%]	100
22 Drugs	Spheroid	8	2	1	11	42 [22.9-64.0%]	~~100~~ 67%

Data from:
Ewart et al (2022)

Emulate 4-cell "Liver-Chip"

Ewart et al *Commun Med (Lond)* 2022 Dec 6;2(1):154. doi: 10.1038/s43856-022-00209-1

TEX-VAL Consortium Member Organizations

2020	2021	2022	2023	2024	2025
sanofi	sanofi	sanofi	sanofi	sanofi	sanofi
Bristol Myers Squibb™	Bristol Myers Squibb™	Bristol Myers Squibb™			
				American Chemical Council℠	
American Chemical Council℠	American Chemical Council℠	American Chemical Council℠	American Chemical Council℠		
NIH National Institute of Environmental Health Sciences	NIH National Institute of Environmental Health Sciences	NIH National Institute of Environmental Health Sciences	NIH National Institute of Environmental Health Sciences	NIH National Institute of Environmental Health Sciences	NIH National Institute of Environmental Health Sciences
	Unilever	Unilever	Unilever	Unilever	Unilever
	MERCK	MERCK	MERCK	MERCK	MERCK
			Roche	Roche	Roche
				abbvie	abbvie
					Genentech
N=5+NCATS	N=7 +Unilever/+Merck	N=7	N=7 -BMS/+Roche	N=7 -EPA/+Abbvie	N=7 -ACC/+Genentech

TEX-VAL Consortium Members' Organs/Tissues of Interest

2020

Organ	#Asks
Liver	4
BBB	1
Kidney	3
GI	2
Repro	2
Cardio	1
Vascular	0
Lung	2

2021

Organ	#Asks
Liver	5
BBB	4
Kidney	4
GI	5
Repro	4
Cardio	1
Vascular	0
Lung	1

2022

Organ	#Asks
Liver	5
BBB	4
Kidney	4
GI	5
Repro	4
Cardio	1
Vascular	0
Lung	1

2023

Organ	#Asks
Liver	7
BBB	6
Kidney	4
GI	4
Repro	4
Cardio	2
Vascular	1
Lung	1

2024

Organ	#Asks
Liver	7
BBB	2
Kidney	5
GI	2
Repro	3
Cardio	1
Vascular	0
Lung	1
Ocular	1
Bone Mar.	1
Skin	1

2025

Organ	#Asks
Liver	7
BBB	3
Kidney	4
GI	3
Repro	1
Cardio	1
Vascular	2
Lung	3
Ocular	0
Bone Mar.	1
Skin	1
CNS/PNS	3

TEX-VAL Consortium: Is There a "Value Proposition"?

2020

		Chips
Kidney	Glomerulus (Mimetas)	360
	Tubule (Mimetas)	320
Liver	LAMPS (NortisBio)	90
Gut	Caco-2 (Mimetas)	206
	Enteroids (Mimetas)	405
Lung	Airway (U-Penn)	115

Total: 1,500

2021

		Chips
Kidney	Glomer. (Mimetas)	160
	Tubule (Mimetas CN-Bio Transwell)	524
Liver	Mimetas CNBio	1,072 110
Gut	Caco-2 (Transwell CNBio)	243
	Enteroids (Transwell CNBio)	456
BBB	Transwell	32

Total: 2,600

2022

		Chips
Kidney (Tubule)	Mimetas CNBio T12 Transwell	431 216 24
Liver	CNBio	623
Gut	Caco-2 (Transwell CNBio)	249
	Enteroids (Transwell CNBio)	392
BBB	Transwell	58
FMI	FMi-OOC (Han Lab)	120

Total: 2,100

2023

		Chips
Kidney	CNBio	252
	Transwell	240
	Mimetas	160
Liver	CNBio	216
	Mimetas	288
Gut	Traswell	1,014
BBB	Traswell	529
	Traswell	249

Total: 3,000

2024

		Chips
Vascular	IdenTX (3 & 40), Mimetas	574
Liver	Elplasia (96), TissUse, CN Bio LC12, Mimetas (2 & 3 Lane)	1,435
Kidney	96-well TW/ plate	3,872
Gut	96-well TW	1,312
Lung	96-well TW	196
BBB	24/96-well TW	810

Total: 8,200

Evidence-Based Qualification by TEX-VAL Consortium

1. Comparative analysis of models and cell types/sources:

a) MPS are compared to “industry standard” (e.g., 2D) and each other

b) Testing cells from different vendors/individuals

2. Comprehensive but sensible phenotyping of each experiment:

a) Imaging (phase-contrast and fluorescent/confocal)

b) Biochemical data (accepted basal function/injury biomarkers)

c) Analytical chemistry (transport/metabolism, PK modeling)

d) Model-omics (basal and treatment-induced effects)

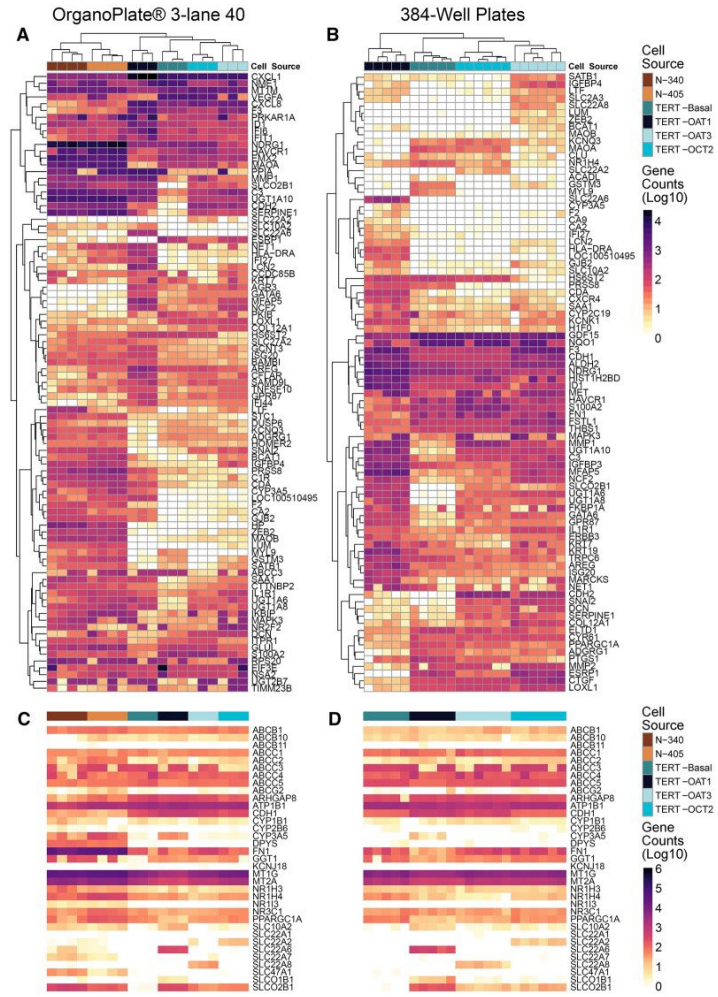
3. Cost-benefit analysis for both “set up” and “operation”:

a) “Upfront” costs (buy vs lease equipment)

b) Operating costs (equipment and consumables, failures…)

c) Cost to phenotype (what other instruments are needed?)

4. Keeping the “domain of applicability” broad (drugs & chemicals)



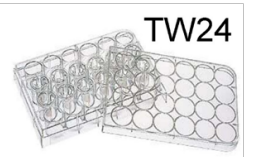
Sakolish et al Toxicol Sci. 2023 Oct 30;196(1):52-70

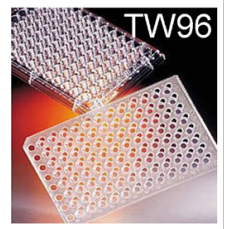
TEX-VAL Consortium's Cost-Benefit Analysis: What is a "Value Proposition" of different model

EXAMPLE for BBB models

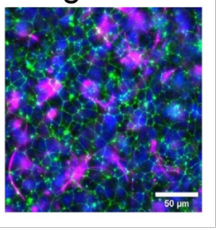
Comparative Analysis of Cost and Performance Among Different Models

	Model type	BMECs (side)	Astr.+ Per.	Flow (μL/s)	Top TEER (Ohm*cm2)	Top TEER day #	Top TEER (# days)	Peff (cm/s)	Cost per sample
TEX-VAL BMECs only	TW24 (24 samples)	Top	N	-	~2700	D9	3-4	1.0×10^{-7}	$20
	TW96 (96 samples)	Top	N	-	~4000	D10	2-3	3.1×10^{-8}	$7
	CNBio TC12 (12 samples)	Bottom	N	0.5	~2400	D9	1-2	2.4×10^{-7}	$80
		Bottom	N	1.5	~2400	D9	1-2	1.6×10^{-7}	$80
		Bottom	N	2.5	~2500	D9	1-2	1.6×10^{-7}	$80
FCDI BBB	TW24 (12 samples)	Top	Y (iPSC-derived)	-	~1700	D5	1	2.7×10^{-7}	$450
TAMU BMECs+ ScienCell A+P	TW24 (24 samples)	Top	Y (primary)	-	~3500	D9	3-4	7.5×10^{-7}	$23
	CNBio TC12 (12 samples)	Bottom	Y (primary)	2.0	~2600	D9	2	1.6×10^{-7}	$83
	TW96 (96 samples)	Top	Y (primary)	-	~3000	D9	2-3	2.5×10^{-7}	$8





FCDI BBB Isogenic Kit



Example: TEX-VAL Work Plan for 2024

#1. Completion of the 2023 "Large Experiment"

- BBB testing with compounds (96-well Transwell)
- Analytical chemistry + gene expression analysis on all models
- Comparison of the results within and across models/tissues

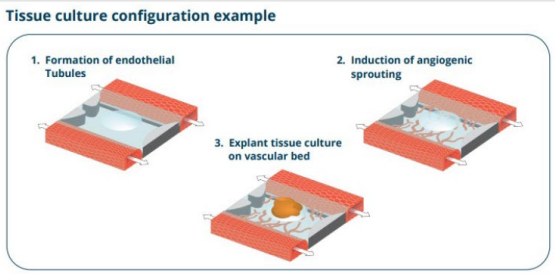
#2. Renal Transport:

Studies on renal secretion/reuptake using 96-well Transwells (an *in vitro-in silico* renal clearance model)

#3. Liver:

- **#3.1. Mimetas OrganoGraft:**
  - Establish vascularized perfusable model first
- **#3.1. AimBioTech – IdenTX chips (compare to OrganoGraft)**
- **#3.2. Dynamic42 – liver multi-cellular model?**
- **#3.3. Cholestatic liver injury model:**
  - HepaRG cells vs PHH vs iHeps: in CNBio LC12 vs Mimetas vs 2D
- **#3.4. Cross-species comparisons (Human, Dog, Rat, Cyno):**
  - CNBio LC12 vs 2D 96-well plates
  - [pre-clinical species experiments are NOT charged to TEX-VAL]
- **#3.5. Onboarding of the TissUse system** (liver):
  - Pharma Ring Trial (Tox and ADME)
  - Adding liver spheroids as a comparator to MPS and 2D

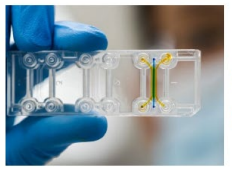
MIMETAS



$1,584/plate
$25/chip

aimbiotech

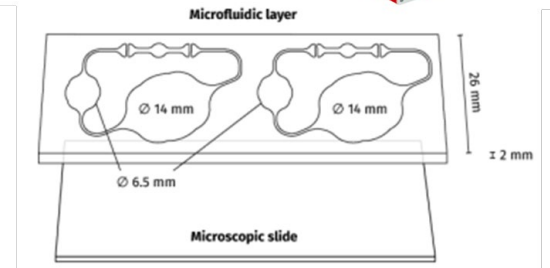
IdenTX devices



$440/25 slides with 3 chips
$6/chip

$1,750/5 plates with 40 chips
$9/chip

HUMIMIC Chip2



Example: TEX-VAL Work Plan for 2025

Organs	Options	Platforms	Questions
Liver	Vascularized liver spheroids	IdenTX	Extending vascular model
	Multi-species spheroids	TissUse vs 2D vs 2.5D (300 Microns/Elplasia)	Species and platform comparison
	Liver +GI or +Kidney	TissUse vs Transwell (gut/kd) + MPCC (liver)	Multi-Organ Model
	Liver	CN Bio PhysioMimix LC48 (Q3-Q4?)	Higher throughput CN Bio liver model
Vasculature	Further characterization	IdenTX	EPC passage number vs perfusable vessels, vessel permeability
	Addition of spheroids (hepatocytes, T/B lymphocytes)	IdenTX	Multi-Organ Model
	Perfusion with immune cells +/- large molecules	IdenTX	Incorporation of immune cells and effects of large molecules
Kidney	TERT-RPTEC/OAT1 vs multi-donor primary RPTEC vs MatTek EpiKidney	2D vs Transwells	RPTEC comparisons (primaries from different donors vs cell lines) Increase # of small molecules tested
	Liver + Kidney (TissUse vs Transwell+MPCC)	TissUse vs Transwell	Multi-Organ Model DMPK, platform comparison
Lung	Model Comparisons	MatTek vs Transwell vs “home-made” chips (Sakolish et al 2022)	Different regions (bronchial, alveolar) Different donors/Different species

TEX-VAL Consortium – Is it a Success?

- A robust collaboration of diverse stakeholders who continue their participation each year
- The "value proposition" exists for "**try before you buy**" operations through TEX-VAL
- Example "LEARNINGS" of the Consortium:

a. Selecting models for testing (organs/tissues of interest)
b. Can MPS be used for ADME/PK (individual chemicals and mixtures)?
c. Can MPS be used for barrier function studies (effect of a gel layer)?
d. Are there required/reproducible cells to seed each MPS?
e. What is the "value of information" vs complexity/cost?
f. What phenotyping methods are needed to test "performance"?
g. What is the "true" operational cost and throughput (# of replicates)?
h. What other equipment is needed (in addition to the "tissue chips")?

"Success" = decision to onboard (**or not**) an MPS in a Consortium member's lab

1. Comparative Analysis of Proximal Tubule Cell Sources for In Vitro Studies of Renal Proximal Tubule Toxicity. Sakolish C, Tsai HD, Lin HC, Bajaj P, Villenave R, Ferguson SS, Stanko JP, Becker RA, Hewitt P, Chiu WA, Rusyn I. Biomedicines. 2025 Feb 24;13(3):563. **Free PMC article.**
2. Comparative analysis of Caco-2 cells and human jejunal and duodenal enteroid-derived cells in gel- and membrane-based barrier models of intestinal permeability. Moyer HL, Vergara L, Stephan C, Sakolish C, Ford LC, Tsai HD, Lin HC, Chiu WA, Villenave R, Hewitt P, Ferguson SS, Rusyn I. Toxicol Sci. 2025 Apr 1;204(2):181-197.
3. Comparative analysis of the physiological and transport functions of various sources of renal proximal tubule cells under static and fluidic conditions in PhysioMimix T12 platform. Sakolish C, Moyer HL, Tsai HD, Ford LC, Dickey AN, Bajaj P, Villenave R, Hewitt P, Ferguson SS, Stanko J, Rusyn I. Drug Metab Dispos. 2025 Jan;53(1):100001.
4. An in vitro-in silico workflow for predicting renal clearance of PFAS. Lin HC, Sakolish C, Moyer HL, Carmichael PL, Baltazar MT, Ferguson SS, Stanko JP, Hewitt P, Rusyn I, Chiu WA. Toxicol Appl Pharmacol. 2024 Aug;489:117015. PMID: 38917890
5. Reproducibility and Robustness of a Liver Microphysiological System PhysioMimix LC12 under Varying Culture Conditions and Cell Type Combinations. Lim AY, Kato Y, Sakolish C, Valdiviezo A, Han G, Bajaj P, Stanko J, Ferguson SS, Villenave R, Hewitt P, Hardwick RN, Rusyn I. Bioengineering (Basel). 2023 Oct 14;10(10):1195. **Free PMC article.**
6. Analysis of reproducibility and robustness of a renal proximal tubule microphysiological system OrganoPlate 3-lane 40 for in vitro studies of drug transport and toxicity. Sakolish C, Moyer H, Tsai H, Ford L, Dickey A, Wright F, Han G, Bajaj P, Baltazar M, Carmichael P, Stanko J, Ferguson S, Rusyn I. Toxicol Sci. 2023 Oct 30;196(1):52-70. **Free PMC article.**
7. Evaluation of Metabolism of a Defined Pesticide Mixture through Multiple In Vitro Liver Models. Valdiviezo A, Kato Y, Baker ES, Chiu WA, Rusyn I. Toxics. 2022 Sep 27;10(10):566. **Free PMC article.**
8. Analysis of reproducibility and robustness of OrganoPlate® 2-lane 96, a liver microphysiological system for studies of pharmacokinetics and toxicological assessment of drugs. Kato Y, Lim AY, Sakolish C, Valdiviezo A, Moyer HL, Hewitt P, Bajaj P, Han G, Rusyn I. Toxicol In Vitro. 2022 Dec;85:105464. doi: 10.1016/j.tiv.2022.105464. **Free PMC article.**
9. Microphysiological Systems Evaluation: Experience of TEX-VAL Tissue Chip Testing Consortium. Rusyn I, Sakolish C, Kato Y, Stephan C, Hewitt P, Bhaskaran V, Davis M, Hardwick R, Ferguson S, Stanko J, Bajaj P, Adkins K, Sipes N, Hunter E, Baltazar M, Carmichael P, Sadh K, Becker R. Toxicol Sci. 2022 Jul 28;188(2):143-152. **Free PMC article.**
10. A Model of Human Small Airway on a Chip for Studies of Subacute Effects of Inhalation Toxicants. Sakolish C, Georgescu A, Huh DD, Rusyn I. Toxicol Sci. 2022 May 26;187(2):267-278. **Free PMC article.**
11. Prediction of hepatic drug clearance with a human microfluidic four-cell liver acinus microphysiology system. Sakolish C, Luo YS, Valdiviezo A, Vernetti LA, Rusyn I, Chiu WA. Toxicology. 2021 Nov;463:152954. **Free PMC article.**
12. Heart Muscle Microphysiological System for Cardiac Liability Prediction of Repurposed COVID-19 Therapeutics. Charrez B, Charwat V, Siemons BA, Goswami I, Sakolish C, Luo YS, Finsberg H, Edwards AG, Miller EW, Rusyn I, Healy KE. Front Pharmacol. 2021 Aug 4;12:684252. **Free PMC article.**
13. Editorial overview of the special issue on application of tissue chips in toxicology. Rusyn I, Roth A. Toxicology. 2021 Feb 28;450:152687. **Free PMC article.**
14. Analysis of reproducibility and robustness of a human microfluidic four-cell liver acinus microphysiology system (LAMPS). Sakolish C, Reese CE, Luo YS, Valdiviezo A, Schurdak ME, Gough A, Taylor DL, Chiu WA, Vernetti LA, Rusyn I. Toxicology. 2021 Jan 30;448:152651. **Free PMC article.**
15. Human in vitro vascularized micro-organ and micro-tumor models are reproducible organ-on-a-chip platforms for studies of anticancer drugs. Liu Y, Sakolish C, Chen Z, Phan DTT, Bender RHF, Hughes CCW, Rusyn I. Toxicology. 2020 Dec 1;445:152601. **Free PMC article.**
16. Predicting tubular reabsorption with a human kidney proximal tubule tissue-on-a-chip and physiologically-based modeling. Sakolish C, Chen Z, Dalaijamts C, Mitra K, Liu Y, Fulton T, Wade TL, Kelly EJ, Rusyn I, Chiu WA. Toxicol In Vitro. 2020 Mar;63:104752. **Free PMC article.**
17. Tissue-Engineered Bone Tumor as a Reproducible Human in Vitro Model for Studies of Anticancer Drugs. Sakolish C, House JS, Chramiec A, Liu Y, Chen Z, Halligan SP, Vunjak-Novakovic G, Rusyn I. Toxicol Sci. 2020 Jan 1;173(1):65-76. **Free PMC article.**
18. Technology Transfer of the Microphysiological Systems: A Case Study of the Human Proximal Tubule Tissue Chip. Sakolish C, Weber EJ, Kelly EJ, Himmelfarb J, Mouneimne R, Grimm FA, House JS, Wade T, Han A, Chiu WA, Rusyn I. Sci Rep. 2018 Oct 5;8(1):14882. **Free PMC article.**