Innovation Ecosystem

Harry West, Columbia University

Our Team Spans Disciplines & Schools

Harry West, CU

Mechanical Engineering, Industrial Engineering and Operations Research, Product Design Methodology, Service and Experience Design

Philip Bayly, WUSTL

Mechanical Engineering, Biomedical Engineering, Cell and Tissue Biomechanics, Computational Modeling of Pelvic Floor

Naomi Chesler, UCI

Biomedical Engineering, Cardiovascular Mechanobiology & Biomechanics, Engineering Education, Diversity, Equity & Inclusion in STEM

Kristin Myers, CU

Mechanical Engineering, Mechanics of Soft Tissues, Preterm Birth, Hydrated Biomaterials

Christine Hendon, CU

Electrical Engineering, Imaging, Cardiac Electrophysiology

Tamer Ibrahim, Pitt

Bioengineering, Radiology, and Psychiatry, MRI Imaging

Christine King, UCI

Biomedical Engineering, Engineering Education, Health Systems

Katrina Knight, Pitt

Bioengineering, Computational Modeling of Pelvic Floor, Soft Tissue Characterization, Vaginal Mesh Design

Elisa Konofagou, CU

Biomedical Engineering, Radiology, Ultrasound Imaging, Elasticity Imaging, Soft Tissue Biomechanics

Aaron Kyle, Duke

Biomedical Engineering, Engineering Education, STEM Outreach, Medical Device Design Biomedical Instrumentation and Signal Processing

Helen Lu, CU

Biomedical Engineering, Biomaterials and Tissue Engineering

Spandan Maiti, Pitt

Biomedical Engineering, Mechanical Engineering & Materials Science, Computational Mechanics

Pamela Moalli, Pitt

OB/GYN, Bioengineering, Uryo/Gyn, Vaginal Mesh Expert, Female Pelvic Floor Health

Christine O'Brien, WUSTL

Radiology, Raman Spectroscopy, Maternal Hemorrhage, Wearable Devices

Michelle Oyen, WUSTL

Biomedical Engineering, Material Science, Mechanobiology of Implantation, Fetal Membrane Mechanics

Gordana Vunjak-Novakovic, CU

Biomedical Engineering, Medicine, Dental Medicine, Regenerative Medicine, Tissue Engineering, Organs on a chip

Yong Wang, WUSTL

OB/GYN, Radiology, Biomedical Engineering, Uterine Functional Imaging, Electrophysiology

Insulet Omnipod
Design + Engineering

CONTINUUM

2

Supersonic ID + UI

Innovation Ecosystem Extended Team

	CU	Pitt	UCI	WUSTL
Faculty	**Harry West** Christine Hendon Elisa Konofagou Helen Lu Kristin Myers Gordana Vanjak-Novakovic	**Katrina Knight** Tamer Ibrahim Spandan Maiti Pamela Moalli	**Christine King** Naomi Chesler Timothy Downing Wendy Liu	**Philip Bayly** Charlotte Guertler Christine O'Brien Michelle Oyen Yong Wang
Tech Transfer, Innovation, Design, and Entrepreneurship	**Orin Herskowitz** Dovina Qu Ivy Schultz	**Evan Facher** Kilichan Gurleyik Lindsay Jean Rodzwicz	**Errol Arkilic** David C. Tiemeier Jaune Odombrown	**Nichole Mercier**

Mechanical solutions are already commonplace

- Speculum
- Digital cervix dilation measurement
- Pessary
- Forceps
- Sutures
- Pelvic floor meshes
- Rehabilitation exercises

We can do a lot better!
We need a science to design current solutions to work better, and to create new solutions

We have strong hypotheses for future solutions

- The mechanical role and behavior of the cervix and pelvic floor.
- Measurements and models to predict which women are likely to give birth preterm.
- How nutrition affects hormones and in turn affects tissue stiffness.
- Exercises that change the conditioning of the tissues that will be stressed in the birthing process.
- Women come in different sizes - we know some of these parameters
- We can model the performance of some solutions in silico to optimize prior to clinical testing
- Telehealth solutions have regulatory and reimbursement support

Initial Vision for a Future Standard of Care

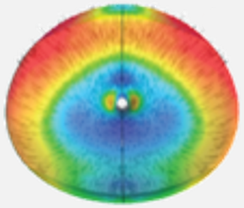
Preterm Birth

Risk of preterm birth

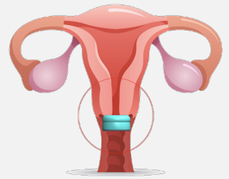
Ways to remotely monitor different reproductive tissues - including the cervix - and provide alerts for urgent events.

Ways to increase the competence of reproductive tissues – including the cervix— prior to term

Monitor Cellular Maternal Remodeling



EMMI

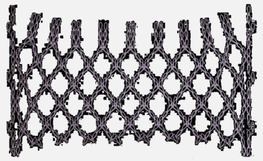


Pelvic Floor Disorders

Models to predict a woman's potential injury from delivery.

Interventions to minimize the risk of injury during delivery.

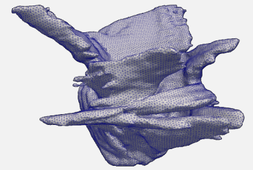
Systems to promote muscle-to-bone healing.



Healthy Aging

Protocols for birthing and recovery exercises for women.

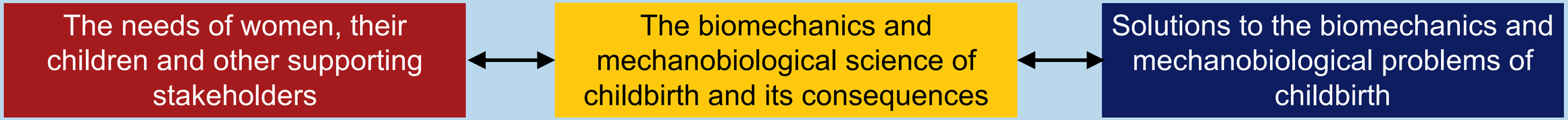
Devices to measure the biomechanics of women as they exercise.



Pregnancy → Birth → Postpartum // Older

Innovation Ecosystem Goal

Build a self-sustaining system of university, industry, and community partnerships to support the rapid development and commercialization of new solutions to the problems caused by the biomechanics and mechanobiology of childbirth and improve women's lives.



A system (and committed people) that applies engineering science to connect the needs of women to the design of better solutions

Strategy – An Inclusive Translational Process

Context

- **Build an ecosystem:** stakeholders, innovators, entrepreneurs, investors, and industry
- Including **women from underrepresented communities**
- **Understand and empathize** with their experience

Innovation

- **Attract, support, mentor and train** students, faculty, entrepreneurs, and industry to engage in developing solutions
- Provide support for entrepreneurs, clinical and commercial partners to **design, develop and test** so that we can…
- **Launch new solutions**.

Stakeholders Include the Community

- **Patients and their Community**
  - Women, Women of color
  - Women with pelvic floor disorders
  - Seniors
- **Care Providers**
  - OB/GYN doctors, doctors in underserved communities
  - Community health providers
- **Industry**
  - Startups
  - medical device, biopharma, and other companies
  - VC’s and other investors
  - Regulatory and reimbursement experts
- **Researchers and other experts**

The Necessity of Engaging Diverse Stakeholders

- **“Nothing About Us Without Us”**
- **The academy is a privileged place**. We cannot presume to understand the problems of diverse stakeholders without engaging with them.
- **Women Centered Design** is an empathetic design process where we design, engineer, and develop products grounded in the voice and vision of the women we are designing for.

Community Impact Advisory Board

- Envisions a safe, inclusive, and resilient community
- Includes translational research faculty, public policy practitioners, and community stakeholders
- Listening to the community
- Communication of IMWEL research and other work to the general public.
- Orchestrate outreach events to medical, government, women’s advocacy groups, and general public communities, to collaboratively create new science literacy and bioethics around mechanobiology and women’s health.

Understand the Context

Gather currently available contextual studies.

Conduct in-depth contextual inquiry with the range of stakeholders across gender, race, income, and geographies most affected including:

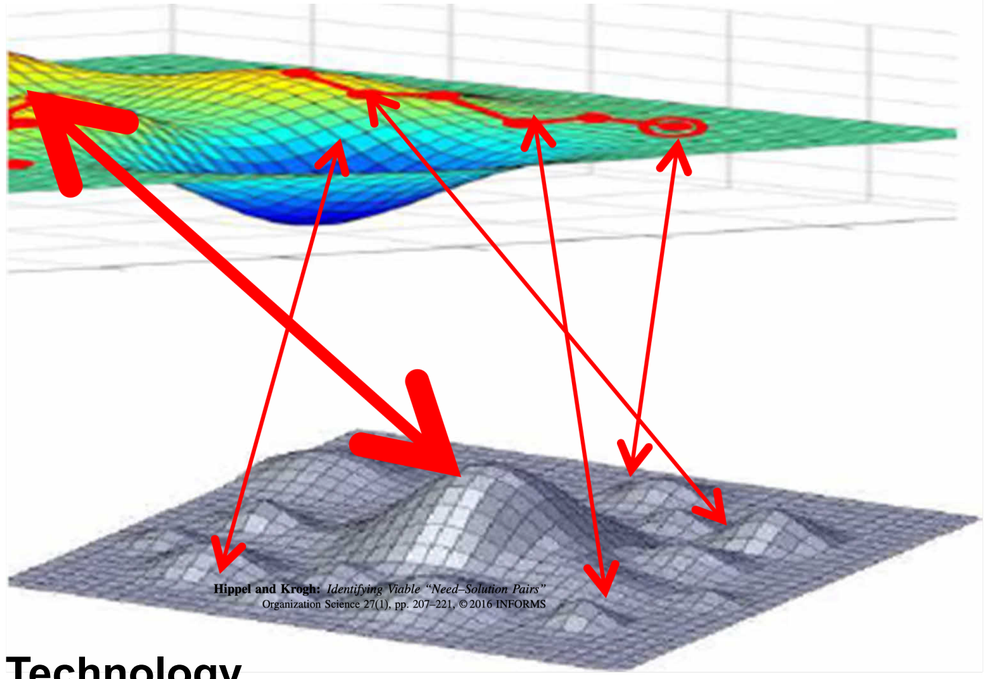
- Interviews
- Observational studies
- Workshops

Document and share results to inspire the design of new solutions.

Identifying Opportunities – Needs Solution Pairs

Human Needs

Unmet needs, women centered design, and early-stage commercialization guidance



Technology

New biomaterials, sensors, imaging tools, software, etc. based on fundamental knowledge from the Research Thrusts - **and other available technologies.**

Needs

↑

NEEDS SOLUTION PAIRS

↓

Solutions

✓

A pragmatic approach

CUSTOMER PULL	**TECHNOLOGY PUSH**
↓	↑
✓	✓
?	?

An Inclusive Translational System

Innovation Advisory Board

Understand and Identify Unmet Clinical Needs

- Community engagement
- Market research
- Customer discovery
- Clinical immersion

Design, Develop, Test

- Design challenges
- Innovation fellows
- L2M accelerator
- Industry collaborations

Partner to Validate & Deploy

- Start-ups
- Licensing
- Partnerships

Innovation Summit

Initial Vision for a Future Standard of Care

Preterm Birth:

- Devices to remotely monitor different reproductive tissues - including the cervix - and provide alerts for urgent events.

Pelvic floor disorders:

- Models to predict a woman's potential injury from delivery.
- Interventions to minimize the risk of injury during delivery.
- Systems to promote muscle-to-bone healing.

Healthy Aging:

- Devices to measure the biomechanics of women as they exercise.
- Protocols for birthing and recovery exercises for women.

Existing Innovation Ecosystem - Pittsburgh

Over the past five years, **Pitt's Innovation Institute** has received patents on more than 450 technologies available for licensing. The Innovation Institute provides the education, mentoring and funding that helps Pitt innovators to progress from benchtop to bedside.

The **Coulter Translational Research Program** identifies, selects, develops, and commercializes promising projects undertaken together by bioengineers and clinical faculty that address unmet clinical needs and better patient care worldwide; and facilitates licensing of these technologies or supports start-up ventures.

The **Michael G. Wells Student Healthcare Competition** is open to all students (undergrad to postdocs) who are working on Pitt research projects or intellectual property. Students are supported by a faculty member and given the opportunity to pursue their entrepreneurial interests, build their resume, and get involved in Pitt technologies. The competition awards $35,000 in prizes to help advance discoveries toward commercialization.

Pittsburgh has extensive Innovation and Entrepreneurship Programs, including the **Blast Furnace Student Accelerator** which provides access to mentor networks, an inspirational co-working space, and a curriculum for student startups to prepare them to create and grow their business.

Existing Innovation Ecosystem - Pittsburgh

Fiscal Year 2021 by the Numbers

Innovation Institute

Invention disclosures
315

Transactions
109

Startups
17

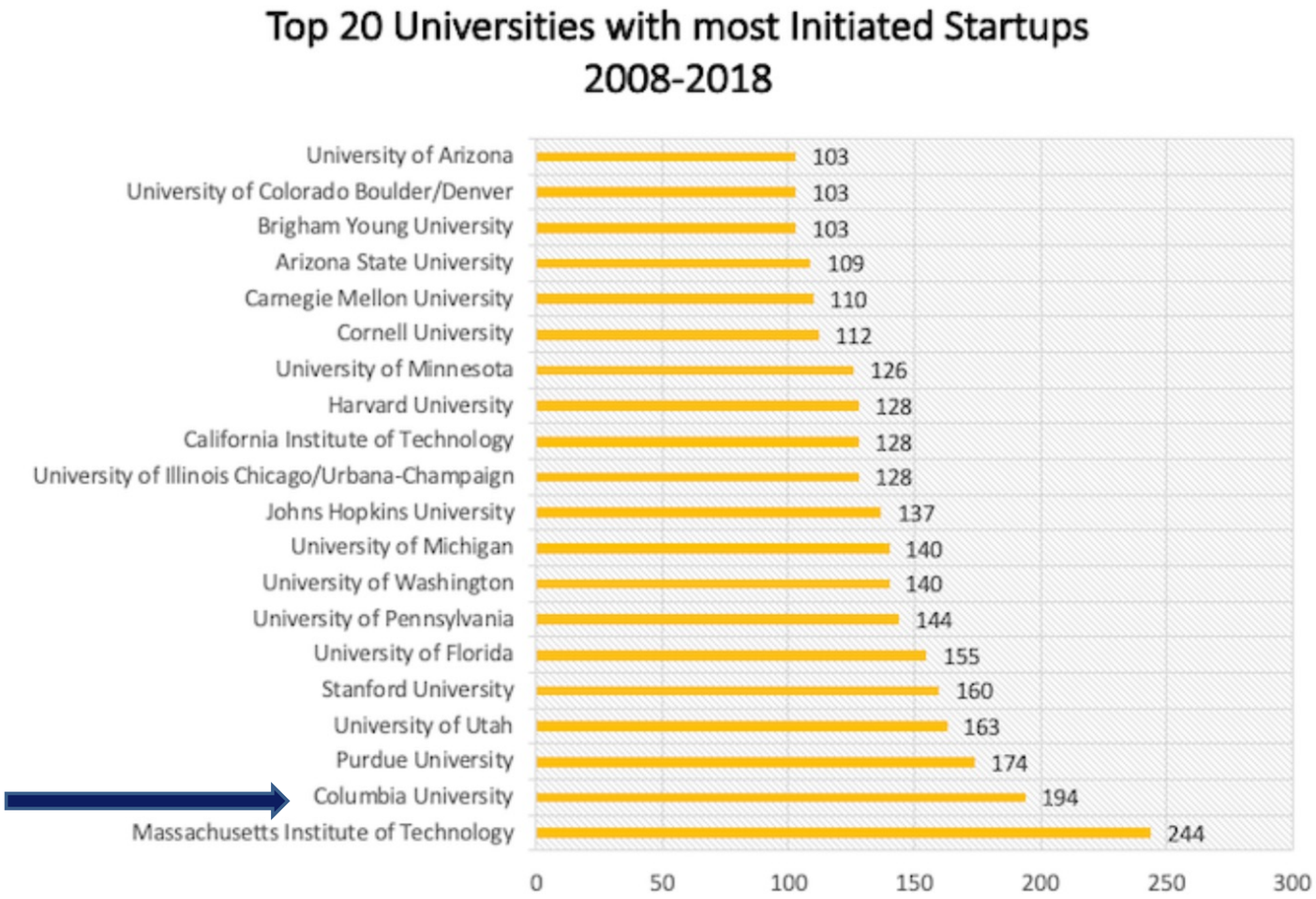
Patents
124*

Revenue
$12,620,437*

Existing Innovation Ecosystem Performance

Table 2. Ranking of Top 25 Universities for Innovation Impact

		Innovation Impact Score (PCA)	Total Research Spending ($m)	Innovation Impact Productivity Score	Innovative Impact Rankings (simple weighted average method)				
					Overall Rank	Comm Rank	Entrep Rank	Res Rank	Teaching Rank
1	University of California System	100.00	$4,998.8	2.00	1	1	1	1	1
2	University of Texas System	55.03	2,675.9	2.06	2	2	2	4	2
3	MIT	31.25	1,639.4	1.91	3	4	3	9	56
4	University of Washington	29.56	1,197.9	2.47	6	3	6	18	10
5	University of Michigan	28.70	1,362.5	2.11	5	10	7	10	7
6	University of Florida	28.11	565.1	4.97	7	7	9	28	4
7	Columbia University	27.24	753.8	3.61	4	8	5	5	27
8	University of Minnesota	24.92	916.2	2.72	8	15	15	15	6
9	Stanford University	24.53	946.1	2.59	9	11	8	12	39
10	University of Pennsylvania	23.25	908.1	2.56	11	13	10	14	35
11	Johns Hopkins University	22.86	1,632.0	1.40	12	16	16	6	29
12	University of Illinois U-C	21.02	1,014.9	2.07	13	20	17	11	22
13	University System of Maryland	20.30	1,018.2	1.99	15	35	14	26	3
14	University of Wisconsin-Mad.	19.32	1,120.6	1.72	18	14	35	24	16
15	Purdue Research Foundation	19.15	611.4	3.13	17	28	18	27	11
16	Northwestern University	18.56	554.1	3.35	14	6	22	19	59
17	New York University	18.09	546.5	3.31	16	9	31	22	32
18	University of Pittsburgh	17.83	732.4	2.43	21	21	20	30	23
19	Cornell University	17.29	801.6	2.16	20	22	27	16	50
20	North Carolina State University	17.12	464.4	3.69	23	29	12	36	28
21	Harvard University	17.08	827.9	2.06	19	32	29	7	53
22	Ohio State University	16.81	924.7	1.82	22	46	36	20	8
23	Duke University	16.77	897.7	1.87	24	19	34	13	64
24	University of Utah	16.45	386.8	4.25	26	23	11	48	48
25	State University of New York	16.36	949.3	1.72	25	34	26	33	13
	Median institution:	**4.17**	**160.0**	**2.68**					

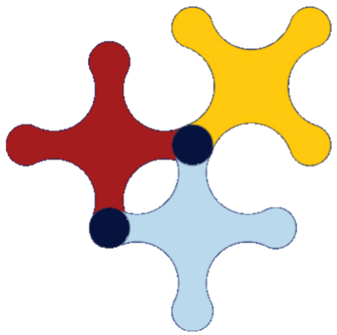


https://gwbcenter.imgix.net/Publications/Resources/gwbi-university-impact-report-ranks-exec-summary.pdf

https://www.ipwatchdog.com/2020/04/07/evolution-university-technology-transfer/

Building an Integrated Innovation Ecosystem

- **Learn from each other and integrate** parts of our technology transfer programs
- **Build awareness of both the need and the opportunity** across our universities
- **Promote and reduce the risk of commercialization**



IMWEL Design Challenges

- IMWEL will introduce a separate track for Women's Health in design challenges **across our four universities** s
- Open to undergraduate and graduate students
- Students work on:
  - **Problems they relate to**
  - **Inspired by technologies they are aware of**
- We will provide:
  - A shared **context of the challenge of women's health**
  - and **technology mentoring from IMWEL faculty**
- The results of the design challenge will be featured during the IMWEL Innovation Summit

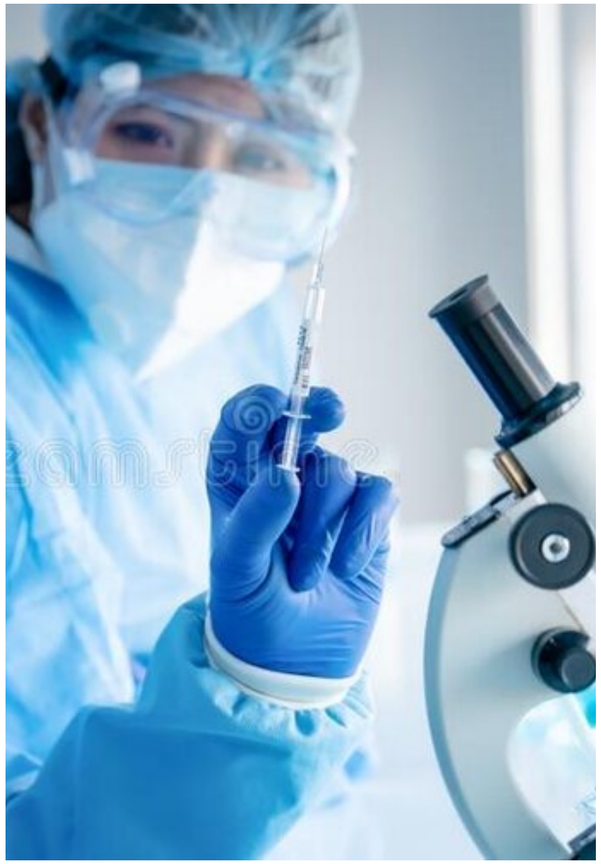
IMWEL Lab-To-Market Accelerator

- Initially, we will fund 1 – 2 dedicated IMWEL teams from **across the four universities** to run through Columbia's existing BioMedX program, with ~$75K each.

  (Over the last 10 year BiomedX has awarded $5M to support 60 projects involving clinician/engineer collaborations. Approximately a third have already exited and received more than $80M in follow-on funding. Two have received FDA clearance and are in use.)

- In year two, IMWEL will launch a full **Lab-to-Market Accelerator dedicated to women's health**.

- Teams in the accelerator will receive **funding and training**.



Accelerator Training Program

Validation **Integration and Community** **Launch**

Validate → MVP/Killer Experiment

8-12 week bootcamps, combining elements of:

- Foundations of Lean Launchpad, including customer discovery, product-market fit, and value proposition
- **Training on working with diverse communities**
- Tutorials and workshops on key technical and business aspects for building an MVP

Integration → Network → Community

Ongoing community and networking support via:

- Mentorship and advisory from top business and technical experts
- **Community-building events including stakeholders**
- Peer network of founders and alumni
- Fireside chats and guest talks from serial entrepreneurs

Launch → Scale

Targeted support to launch and scale through:

- Funding guidance (e.g. SBIR/STTR support, introductions to VCs)
- Formation support (incorporation, IP, ownership and rights, immigration)
- Business Ops intensives (e.g. cash flow management, people operations, business development)

IMWEL Innovation Fellowships

- Fellowships **across the four universities** for early-career individuals from **traditionally underrepresented groups**
- Preparation for careers in women's health entrepreneurship and commercialization
- Innovation Fellows will form a cohort each year to join our **entrepreneurship bootcamps**
- They will learn from guest speakers **and from each other**, receive resume and pitch coaching, and work with the IMWEL innovation teams
- This new initiative has **already received funding** commitments from two foundations

DICE DIVERSITY & INCLUSION IN COMMERCIALIZATION & ENTREPRENEURSHIP

Columbia's Program for Diversity and Inclusion in Commercialization and Entrepreneurship (DICE) prepares early-career individuals from traditionally underrepresented groups for careers in life science entrepreneurship and commercialization. DICE is administered by Columbia Technology Ventures, the technology transfer office for Columbia University.

FIRESIDE CHAT SPEAKERS

Alyssa Jarvi, PhD
Foresite Capital

Elizabeth Wayne, PhD
Carnegie Mellon University

Bryan Wilson, PhD, MBA
Merck

Brenna Rauw
12Bridge

TESTIMONIAL

"As a first-generation student (both high school and college) from a low-income household, the concepts of commercialization and entrepreneurship have often felt inaccessible and unapproachable. The fireside chats with experts of diverse backgrounds made the information relatable and helped me gain invaluable insight on previous paths I have pursued and what I could potentially achieve in the future." — Amanda Moy, Biomedical Informatics

IMWEL Maternal Health Startup Fellows

- Recruit **serial entrepreneurs** who identifies as a women and / or underrepresented minority, with experience commercializing Maternal & Women's Health innovations
- Startup Fellow would join IMWEL for 1 year as a "postdoc" to **work with teams of innovators** across the institutions to accelerate their technologies to market
- Objective is for the Startup Fellow to **launch a startup** based on one of these technologies by end of first year, leaving the program to serve as interim CEO
- This new initiative has **already received funding** commitments from two foundations

Engaging with Industry

Critical to IMWEL's success are our **partnerships with community stakeholders, physicians, and industry**

Through our **membership program**, industry partners will have opportunities to engage in **fundamental research, commercialization of new technology, education, and outreach**

Industry Partners

- We have engaged with a network of startups working in women's health who have agreed to help the IMWEL program and are also positioned to benefits from our outcomes, including:

RenoVia

Diagnostic devices for women with pelvic floor disorders

NextGen Jane's smart tampon monitors reproductive health issues

pregnolia®

Measure the stiffness of the cervix for a more complete characterization of cervical status.

Industry Partners

- We have engaged with a network of startups working in women's health who have agreed to help the IMWEL program and are also positioned to benefits from our outcomes, including:

Materna Medical

Empowering women to protect and restore their pelvic health

viscus BIOLOGICS

Innovative biological platforms for wound repair

ORGANON

Control and treatment of abnormal postpartum uterine bleeding (Alydia technology acquired by Organon, a Merck spin-off 2021)

Labs, Investors, Industry Partners, Agencies

In addition to the Industry Partners listed above we have established relationships with:

- Alexandria Launchlabs
- Harlem Biospace
- Wayfinder Incubator
- Deerfield Catalyst
- Deerfield Management
- Upstate Capital Association of NY
- MSquared Associates
- NYSTAR
- Iris Foundation
- Other Foundations

Benefits of Membership for Partners + ERC

- **A platform of bi-directional knowledge transfer and communication**
  (We get insights into knowledge gaps and advice on what to focus on, our partners get early knowledge of test results and new inventions)

- **Facilitated engagement with Center faculty** and students
  (working groups, seminars, workshops, career days, innovation summit)

- Access to unique Center resources: **testbeds** and other facilities

- Support for **talent recruitment** by member companies & organizations,
  (design challenges, internships, sponsored research, recommendations)

Intellectual Property Management

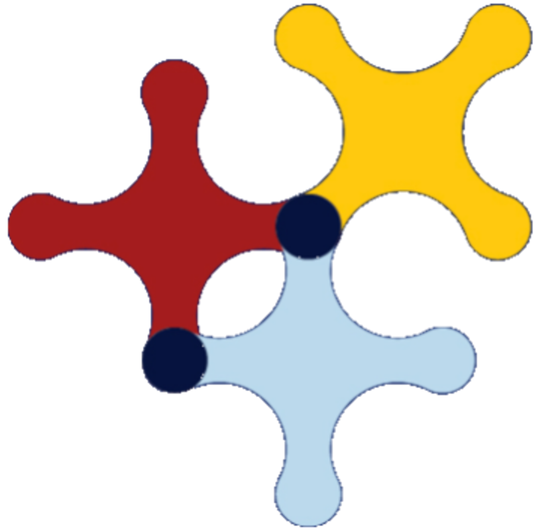
- IP protection is a crucial step in the innovation process and encourages commercialization
- We will adopt best practices:
  - **Balance 'Open Science' principles and commercial innovation objectives**, as defined by our advisory boards and ERC IP Policy
  - Joint inventions between university and industry/community partners will parallel the "visiting scientist" approach (i.e., independent inventions treated as such)
  - Members will be entitled to "early look" and opportunities for **joint IP development** and sponsored research
- The IMWEL universities have experience with shared IP and have a strong **track record of translating IP into societal and economic impact**
- Any conflict of interest must be disclosed to the Center's Executive Committee which will manage risk

Innovation Advisory Board

- Manage project selection
- Feedback and close oversight of IMWEL translational projects
- Progress assessment towards commercialization: technical, regulatory, reimbursement, market and management
- Connection to partners along the product development pipeline
- Comprising representatives from IMWEL leadership, partner companies, key stakeholders
- **Responsibility to grow partnerships and community engagement**
- Monthly review of progress

IMWEL Innovation Summit

- Annual event paired with IMWEL's annual conference
- A pacing event forcing innovation progress and encouraging ongoing engagement with our community throughout the year
- Bringing together stakeholders including mothers of color and people who have been hurt in childbirth
- Learning from each other
- Sharing progress
- Lab to Market focus



The IMWEL Innovation Summit will foster communication across the ERC, our partners and our community.

Community and Stakeholder Engagement is at the Core of our Innovation Ecosystem

- Facilitate a spectrum of ways to engage with **community partners**, from empathy with needs of our stakeholders and needs finding and fundamental science exploration, to technological innovation and product development in collaboration with industry

- Balance of **Open Science** and **Commercial Innovation**

- Provide **diverse opportunities** for students to become scientists, technologists and entrepreneurs; both independently and through connections forged with our industry partners

Outcomes

Years	Goals	Milestones	Metrics
1-2	Understand Identify unmet needs Build network	Pilot grants Design challenges Innovation Fellowship Launch Accelerator Innovation summit Advisory board	# Programs (race, gender) # Innovation Fellows (race, gender) # Startup Fellows (race, gender) # Students participating (race, gender)
3-5	Design Develop Test Expand network	Design and develop prototypes Support tests (preclinical, clinical) License technology Expand Fellowships Sponsored research (with research partners)	# Invention disclosures # Agreements with industry # Licenses $ Follow-on funding # Start-ups (race, gender of leaders)
6-10	Validate and deploy through partnerships Scale nationally	Clinical testing FDA clearance and approval Commercial manufacturing	# Exits # FDA approvals # Fulltime jobs # Women cared for

Outcomes

A self-sustaining system of university, industry, and community partnerships that supports the rapid development and commercialization of new solutions to the problems caused by the biomechanics and mechanobiology of childbirth and improves women’s lives.

Innovation Ecosystem Q&A