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October 29, 2020

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- Basics of Technology Transfer for Licensing Professionals
- Basic Patenting 101
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- Equity Based License Agreements
- Financial Conflicts of Interest
- Licensing University Technology 101
- Need to Know Basics of Technology Transfer for Support Staff
- Negotiation of License Agreements
- The Basics of Open Source Licensing
- Tips for Managing MTAs
- Valuation of Inventions and Patents

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AI and Precision Medicine:
IP and Licensing Opportunities

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Introducing Today's Presenters

Mary Lou Wakimura, JD
Hamilton Brook Smith Reynolds

Michael B. Dilling, PhD, CLP
Baylor College of Medicine

Steve Levine, PhD
Dassault Systemes

AI and Precision Medicine: IP and Licensing Opportunities

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Hamilton Brook Smith Reynolds

2
Offices

Boston
Seaport Innovation District

Concord
Route 128 Technology Corridor

1980
Year Founded

Broad Spectrum of Technology Specialties

Artificial Intelligence
Autonomous Vehicles
Bioinformatics
Biotechnology & Life Sciences
Biologics & Immunotherapeutics
Blockchain
Chemical Engineering
Pharmaceuticals
Chemistry
Material Sciences
Clean Technology
Medical Devices
Medical Imaging
Mechanical Engineering
Electrical Engineering
Semiconductors
Optics
Robotics
Mobile
Internet of Things
Network Infrastructure
Telecommunications
Computer Hardware
Computer Software
Business Methods

35
Attorneys,
Patents Agents,
Technology Specialists

Numerous
Firm accolades since 2010, including:

Speakers

Mary Lou Wakimura

Principal,
Hamilton Brook Smith Reynolds

Dr. Steven Levine

Senior Director,
Dassault Systèmes Health and Life Sciences

Dr. Michael Dilling
Director, Baylor Licensing Group,
Baylor College of Medicine

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Artificial Intelligence Fundamentals

Training Data

Analytics

Output

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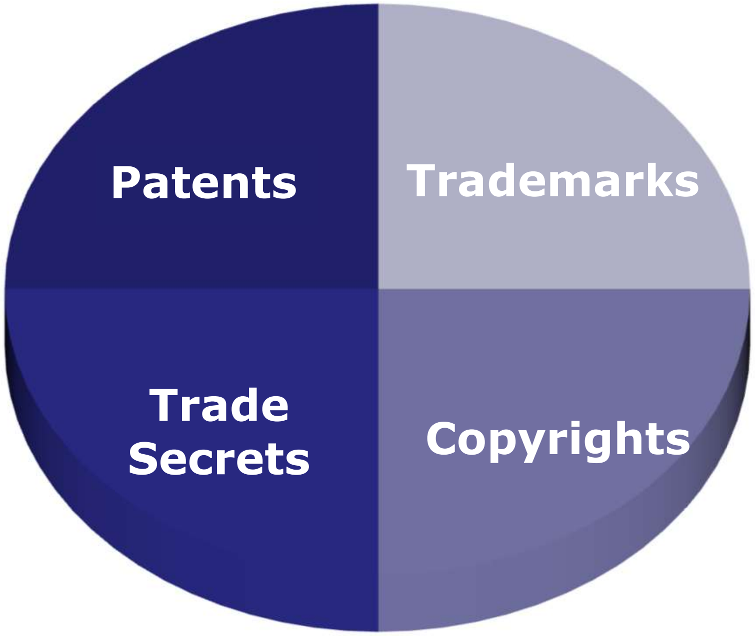
Intellectual Property Protection



Intellectual Property Protection

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Overall AI System	✓	✓	✓	✓
Analytic Software	✓	✓	✓	✓
Training Data		✓		

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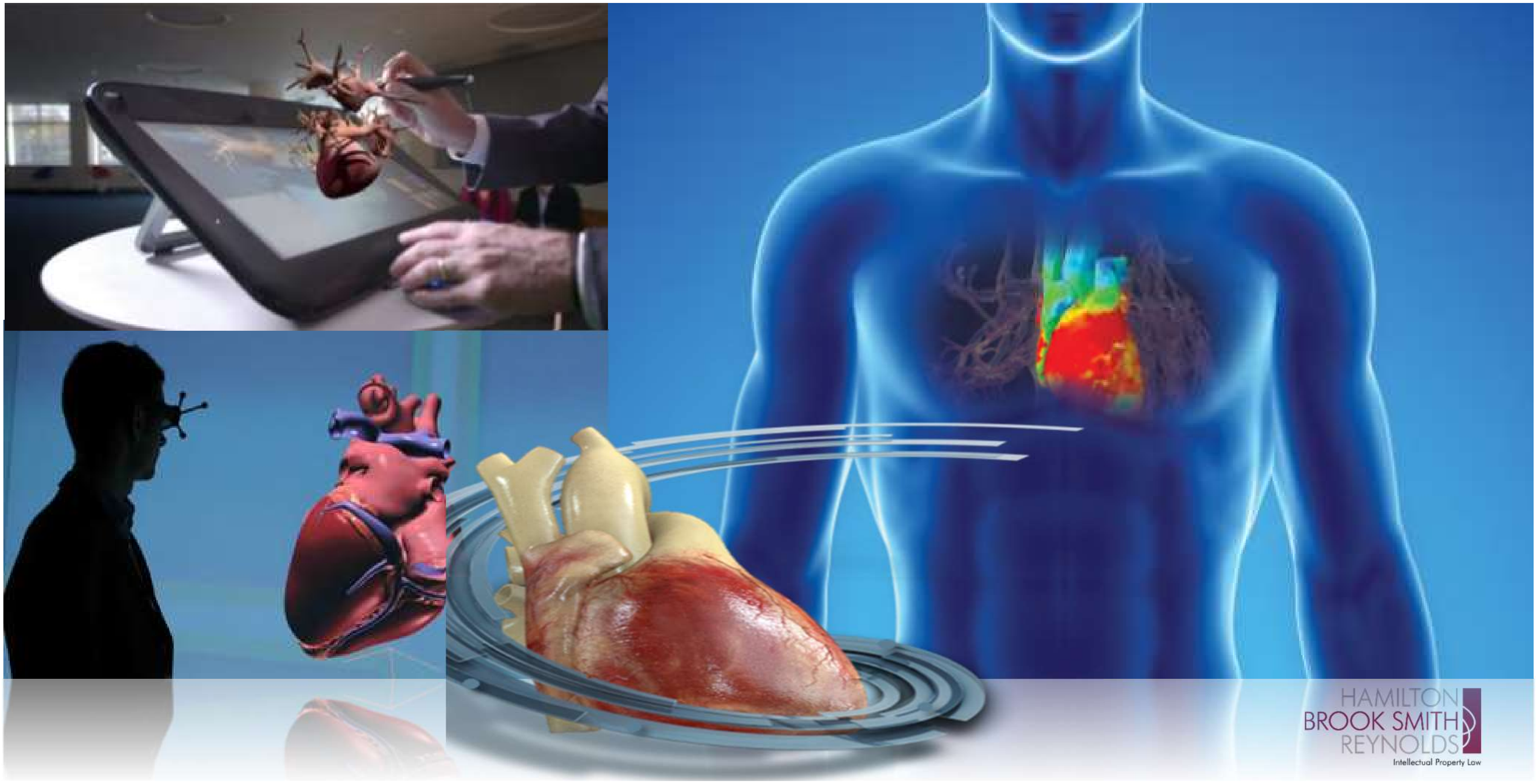
Case Studies: AI R&D Models

- AI Focus Groups and Consortiums
- Living Heart Project: Dassault Systèmes
- Baylor College of Medicine

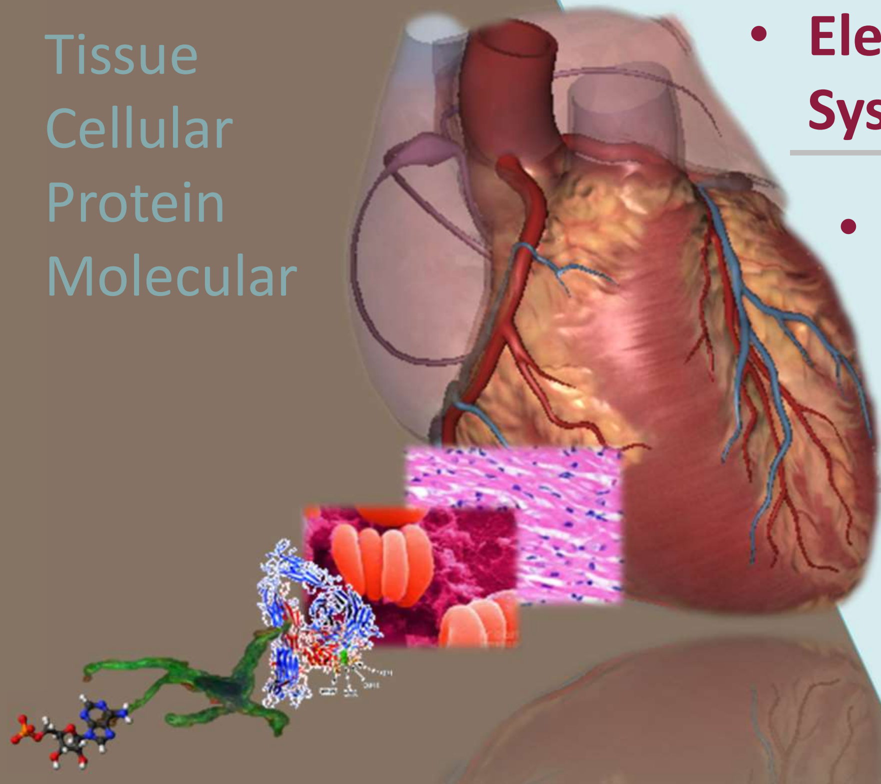
Living Heart Project:
Virtual Twins for Precision Medicine



Human Heart is Complex - Understanding it belongs to Everyone

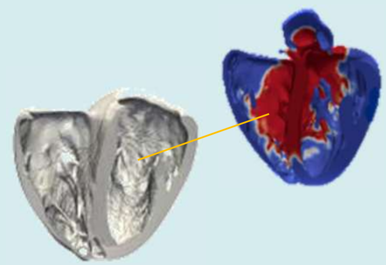
Multiscales

- Tissue
- Cellular
- Protein
- Molecular

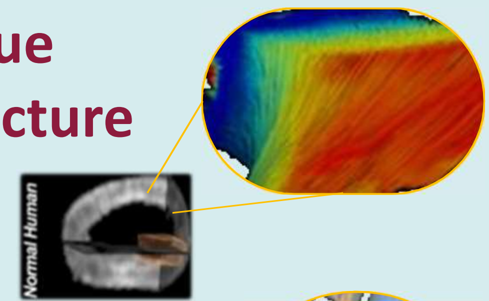


Multiphysics

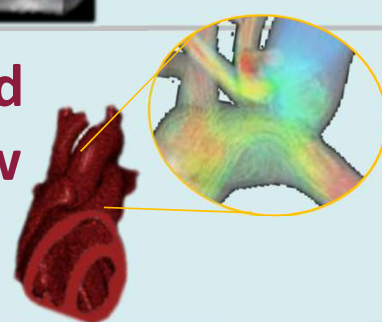
- Electrical System



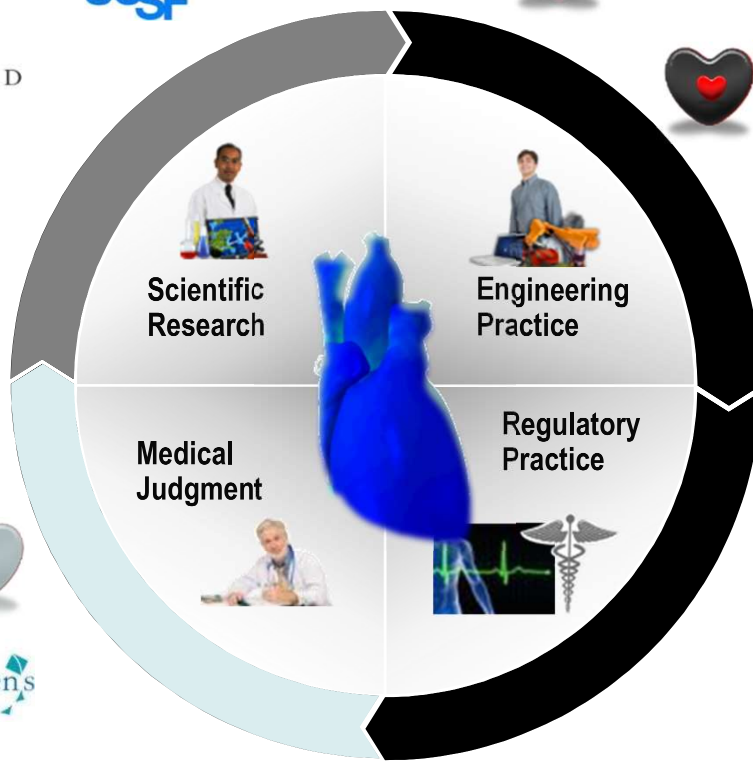
- Tissue Structure



- Fluid Flow



Training Data, Analytics and Knowledge



Duke University
Massachusetts Institute of Technology
UCL University College London Institute of Cardiovascular Science
The Visible Heart® Laboratory
VA
UniversitätsSpital Zürich
Inria
UCSF
Stanford University
Insigneo
Massachusetts Institute of Technology
Rady Children's Hospital San Diego
FEops
Medtronic
inSilicoMED
optimal device
zSpace
Philips
SORIN GROUP
ndc
ZYGOTE
FDA
MDIC Medical Device Innovation Consortium
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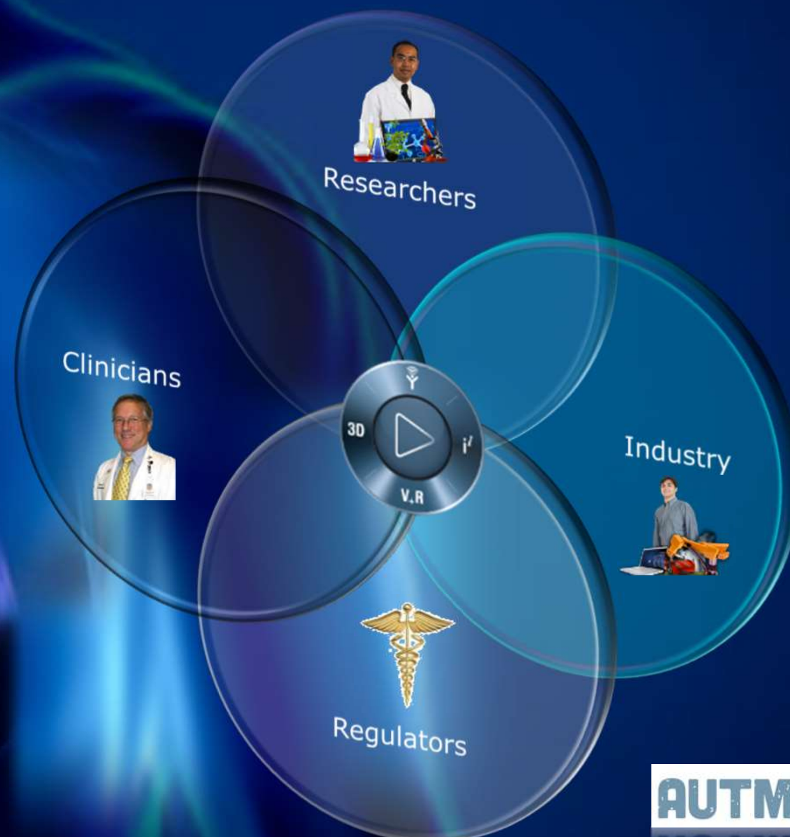
The Living Heart Project

Could we do this?

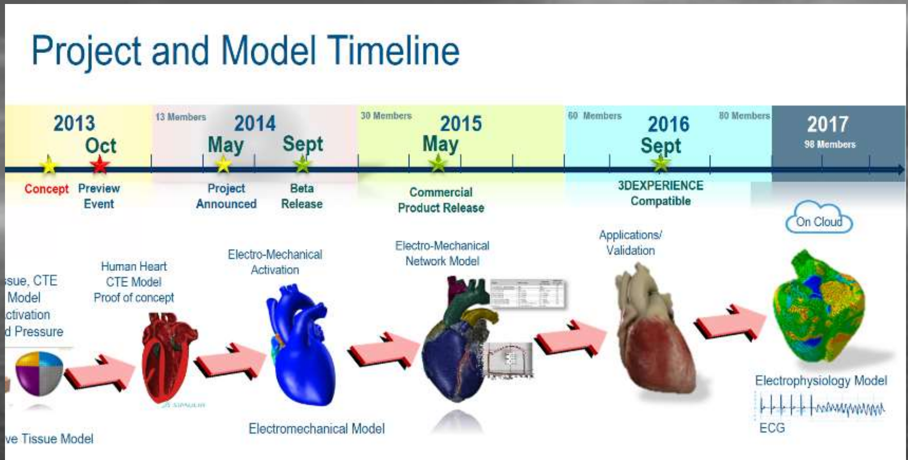
A physically realistic model of the human heart

Mission:

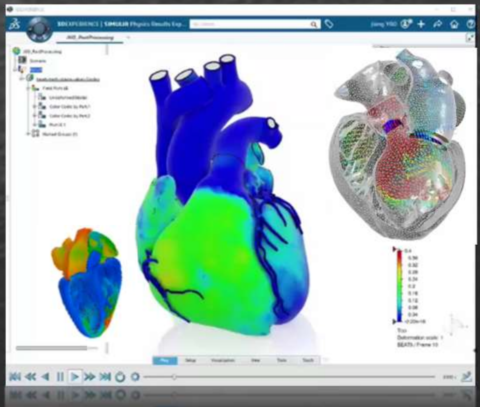
- **Advance** the development of safe & effective cardiovascular products and treatments by
- **Uniting** engineering, scientific, & biomedical experts to deliver validated models and
- **Translate** simulation technology into improved patient care



Building a Realistic Simulation of a Human Heart



Global Community of Collaborators



Enterprise Solution – Accessible to all on the Cloud

Diverse Range of Applications

Universities in the Living Heart Project

HARVARD MEDICAL SCHOOL

TU/e Technische Universiteit Eindhoven University of Technology

Università Campus Bio-Medico di Roma

Duke University

FIU Florida International University

McGill

Ghent University

Massachusetts Institute of Technology

MAYO CLINIC

Oxford Brookes University

Carl von Ossietzky Universität Oldenburg

University of Minnesota

אוניברסיטת בן-גוריון בנגב
Ben-Gurion University of the Negev

울산대학교
University of Ulsan

Pontificia Universidad Católica de Chile

National University of Ireland, Galway
Ollscoil na hÉireann, Gaillimh

Tel Aviv University International

Stanford University

Magdi Yacoub Heart Foundation
Aswan Heart Centre

UCL

Universidade de Brasília

West Virginia

ETH Zürich

ZCCE

The Ohio State University 1870

University of Cape Town

University of Glasgow

RWTH Aachen University

TEXAS
The University of Texas at Austin

University of California San Diego

Stony Brook University

UCLA

University of Hohenheim

The American University in Cairo

UT Dallas

University of Southampton

UC San Diego

Herzkompetenz
Universitätsklinikum
Tübingen Zentrum

University of Washington 1861

University of Oxford

UCSF
University of California San Francisco

Lillehei Heart Institute
University of Minnesota

VŠP College of Polytechnics Jihlava

AUTM 2019 Annual Meeting

창원대학교
Changwon National University

California Medical Innovations Institute

भारतीय प्रौद्योगिकी संस्थान हैदराबाद
Indian Institute of Technology Hyderabad

Ohio State

Tel Aviv University

Singapore Polytechnic SP

universitäts klinikum bonn

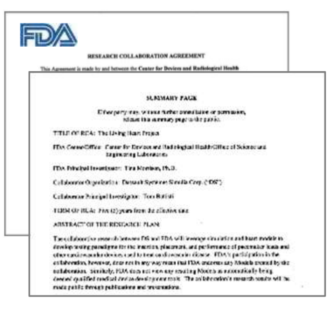
ENRICHMENT *in silico* Clinical Trial w/Living Heart as a Virtual Patient Population

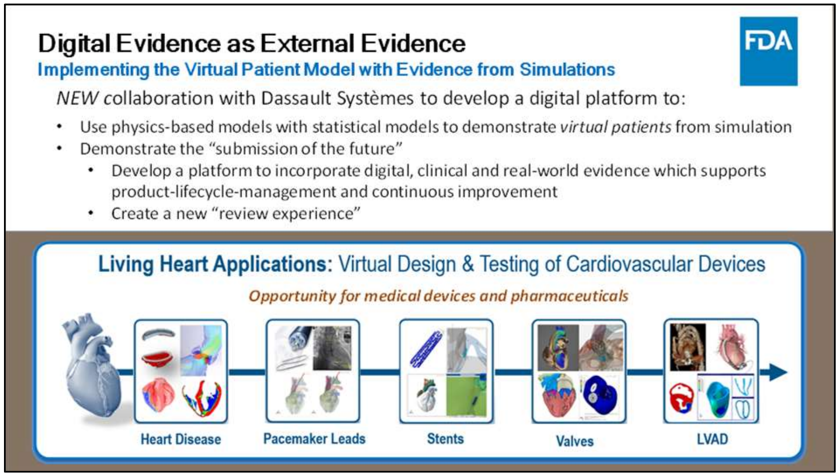
FDA - "Medical Device Review of the Future"

"The way we do business today… it's kind of is out of date. It's time to change the world. You are the people to help make that happen"

- Dr. Jeff Shuren, CRDH Director, US FDA February 28th ENRICHMENT Kickoff Meeting

5 yr. Collaboration Agreement





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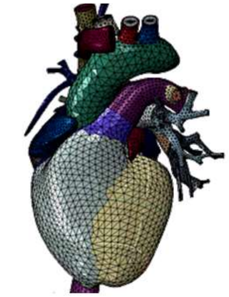
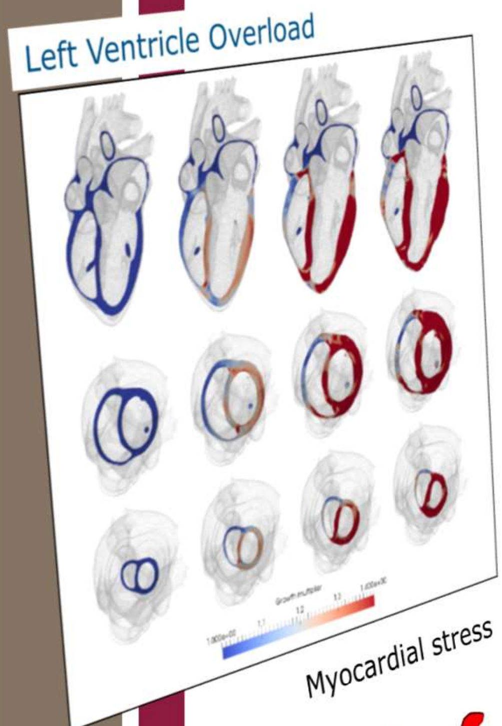
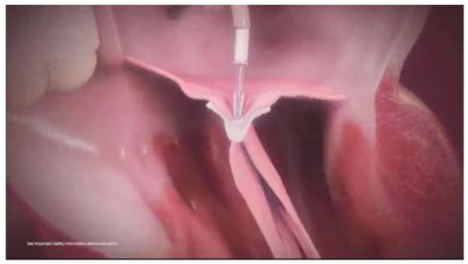
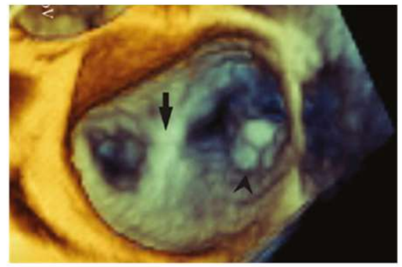
Generic Mitral Valve Repair Device

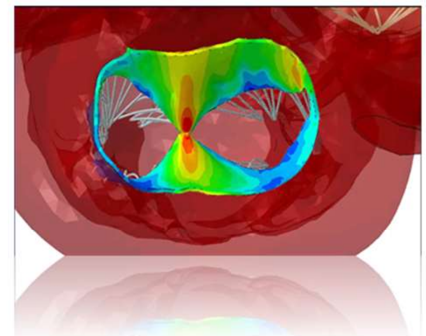


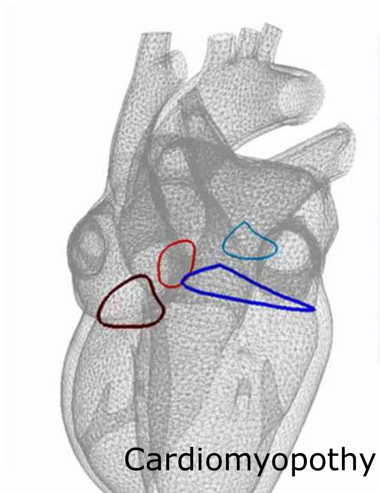




Courtesy Edwards Life Sciences



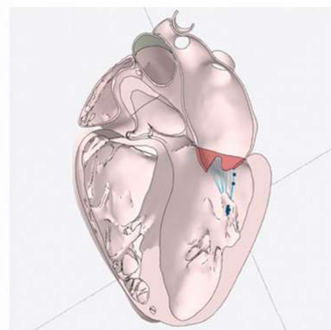




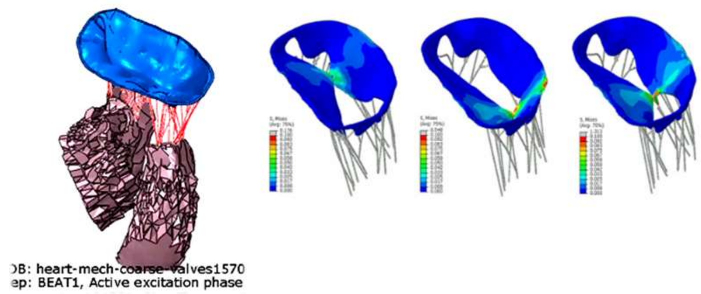
Cardiomyopathy

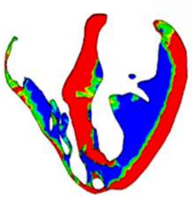
The Living Heart Project:
Modeling pathologies of systolic and diastolic heart failure

M. Genet · L.C. Lee · B. Baillargeon · J.M. Guccione · E. Kuhl



Mitral Valve Regurgitation





CALIFORNIA MEDICAL INNOVATIONS INSTITUTE

The Living Heart Project

50 member Working Group collaborating on parametric Mitral Valve model

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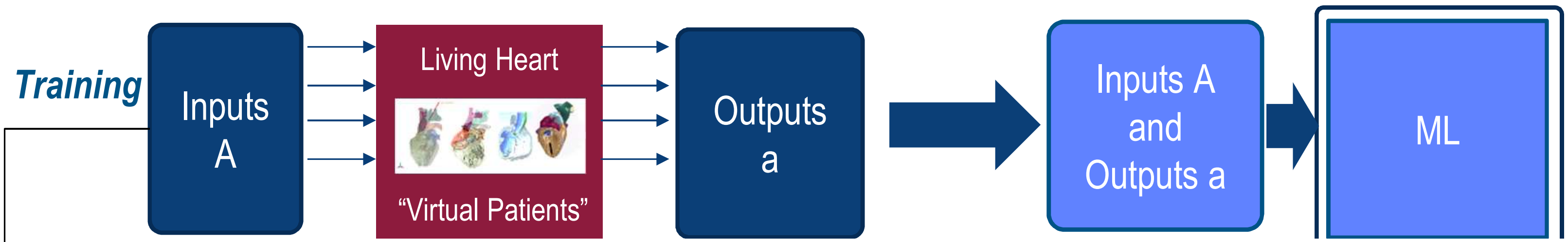
IP Mgmt: Living Heart to Train AI System



Org 2

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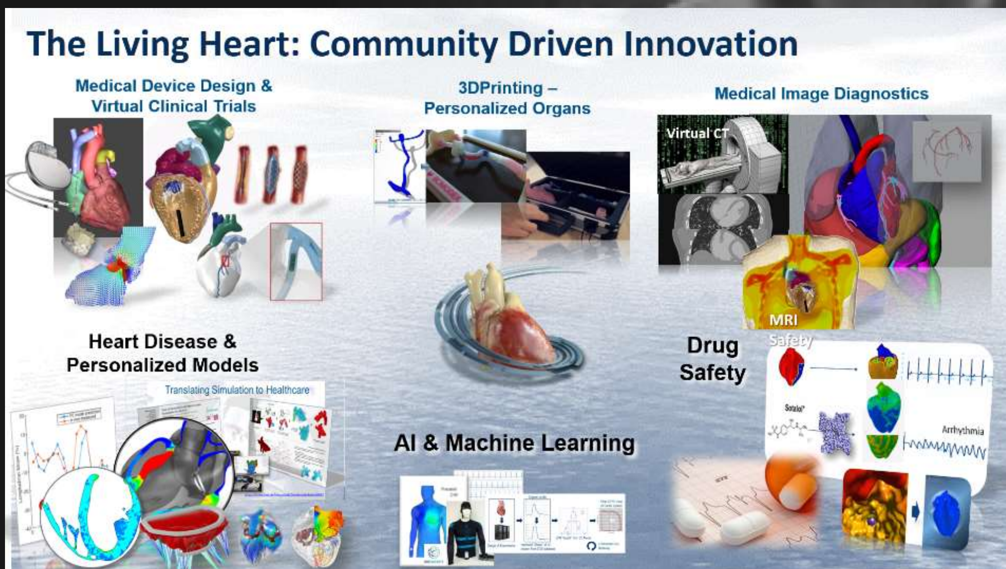
Overall AI System	✓	✓	✓	✓
Analytic Software	✓	✓	✓	✓
Training Data		✓		

Org 1

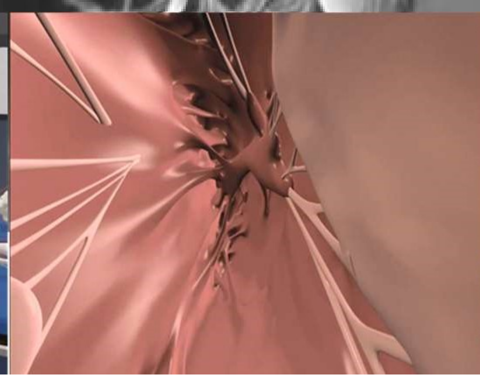
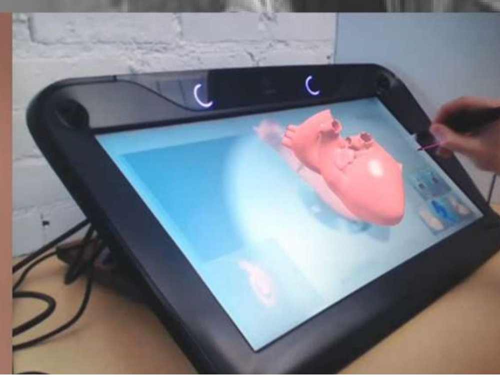
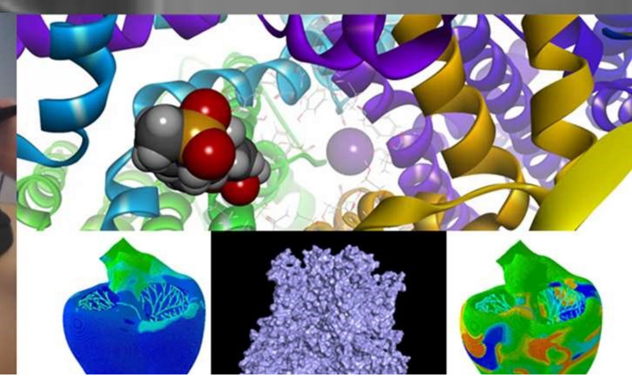
The Living Heart Project

www.3ds.com/heart

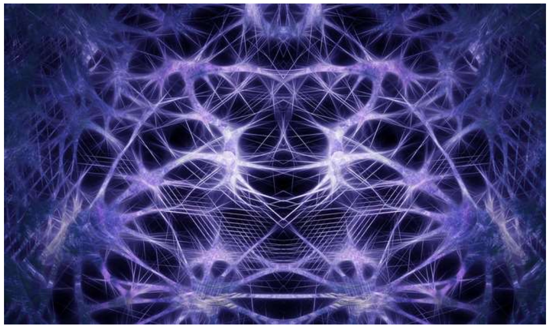


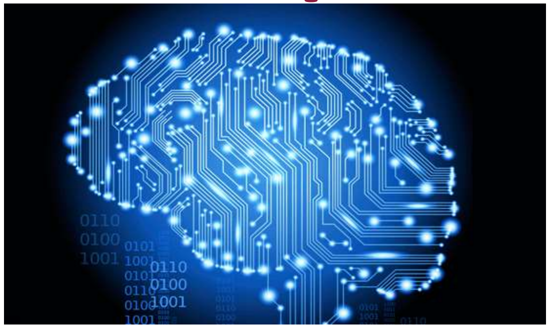
Published Technical Papers

- Structural Responses of Integrated Parametric Aortic Valve in an Electro-Mechanical Full Heart Model
- Effect of myofibre architecture on ventricular pump function by using aneonatal porcine heartmodel: from DT-MRI to rule-based methods
- Intra-myocardial alginate hydrogel injection acts as a left ventricular mid-wall constraint in swine
- Numerical evaluation of transcatheter aortic valve performance during heart beating and its post-deployment fluid–structure interaction analysis
- Numerical Simulations of MitraClip Placement: Clinical Implications
- Intramyocardial Injections to De-Stiffen the Heart: A Subject-Specific in Silico Approach
- Method for Calibration of Left Ventricle Material Properties Using Three-Dimensional Echocardiography Endocardial Strains
- Prediction of Left Ventricular Mechanics Using Machine Learning
- Machine learning in drug development: Characterizing the effect of 30 drugs on the QT interval using Gaussian process regression, sensitivity analysis, and uncertainty quantification
- Classifying drugs by their arrhythmogenic risk using machine learning
- Multiscale characterization of heart failure
- Relationship of Transmural Variations in Myofiber Contractility to Left Ventricular Ejection Fraction: Implications for Modeling Heart Failure Phenotype With Preserved Ejection Fraction
- Investigating the Role of Interventricular Interdependence in Development of Right Heart Dysfunction During LVAD Support: A Patient-Specific Methods-Based Approach
- A modular inverse elastostatics approach to resolve the pressure-induced stress state for in vivo imaging based cardiovascular modeling
- Construction and Validation of Subject-Specific Biventricular Finite-Element Models of Healthy and Failing Swine Hearts From High-Resolution DT-MRI
- Predicting the cardiac toxicity of drugs using a novel multiscale exposure-response simulator
- Personalised computational cardiology: Patient-specific modelling in cardiac mechanics and biomaterial injection therapies for myocardial infarction
- Fluid-Structure-Interaction in a Beating Human Heart Model
- Implementation of a Multiscale Multiphysics Framework to Model Whole Heart Electrophysiological and Mechanical Behavior
- Electro-Mechanical Modeling of Transcatheter Aortic Valve Deployment in the Simulia Living Heart Human Model
- Partial LVAD restores ventricular outputs and normalizes LV but not RV stress distributions in the acutely failing heart in silico
- Modeling Pathologies of Diastolic and Systolic Heart Failure
- The Living Heart Project: A Robust and Integrative Simulator for Human Heart Function
- Human Cardiac Function Simulator for the Optimal Design of a Novel Annuloplasty Ring with a Sub-valvular Element for Correction of Ischemic Mitral Regurgitation
- Distribution of normal human left ventricular myofiber stress at end diastole and end systole: a target for in silico design of heart failure treatments

AI Licensing/Collaboration Practices in BioMedicine: The AI Explosion





“Here is a hint, based on some preliminary statistics on AI innovation. According to the WIPO Technology Trends 2019-Artificial Intelligence Publication, we know that machine learning is the dominant AI field “and is included in more than one-third of all identified inventions.”

AI published applications grew by 400% in the past decade. At the USPTO, AI technologies are part of about 26% of annual patent filings, which is a 34% increase in the share of AI patent filings since 2005. And we have doubled the number of examiners at the USPTO reviewing AI applications.”

- Andrei Iancu, USPTO

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The AI Explosion: Where is the Innovation Happening?

- "At the USPTO, inventions from the United States obviously dominate. IBM files the most, by a significant number. Microsoft, Amazon, Intel and Google follow. Many of these companies of course, also have a presence in Israel and develop some technology here. And companies from Japan, India, China, and Korea also have significant AI filings at the USPTO."

- "In recent years, by the way, filings from Israel ranked next, right after these large nations. So despite its smaller size, Israel has had more AI filings at the USPTO in some years than Canada, Germany, Great Britain, France, and the rest of the world."

  - Andrei Iancu, USPTO

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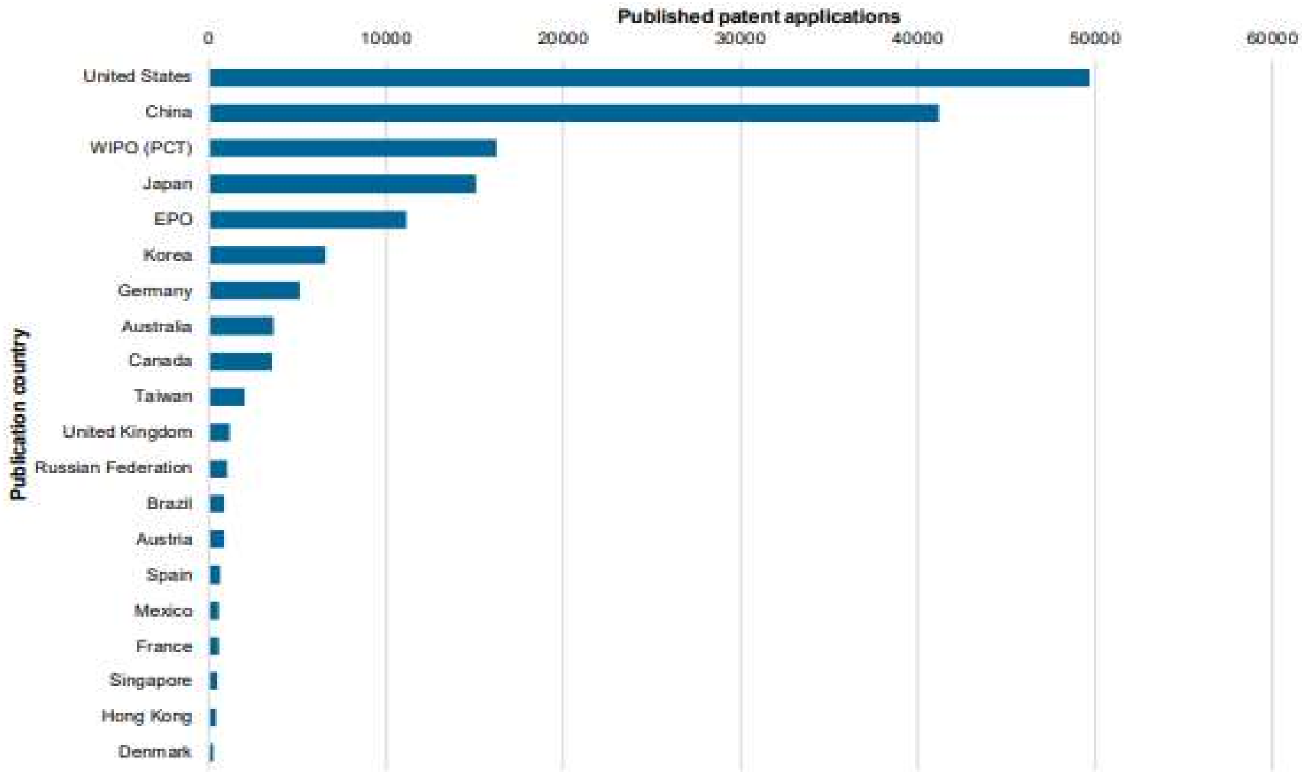
The AI Explosion: Where is the Innovation Happening?



Source: https://www.iam-media.com/market-developments/everything-you-wanted-know-about-ai-patents-were-afraid-ask-part-2

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Academic Medical Centers & AI: How Are We Relevant?

- The AI Explosion will strongly impact academic technology commercialization.
  - This is next "frontier" in licensing and commercial partnerships. If AI hasn't impacted your practice yet, it will.

- How will academic medical centers play a role?

  - Companies in the medical AI space want access to our data
    - AI algorithms depend on teaching datasets. The more high-quality data they ingest and analyze, the better they can become.
    - Example: Company developing an AI tool for more sensitive analysis of mammography data.
      - Lower error rates, fewer false positives/negatives.
      - Company approaches academic medical center desiring access to data.

We Want Your Data!

- Data is the "new oil**": **Teaching datasets fuel AI in medicine: We have the patient datasets (imaging and non image-based) needed to train AI algorithms.
  - The "right" dataset (specific patient populations/clinical outcomes) can be differentiating. The algorithm gets its power through ingestion/analysis of data.
  - But, leveraging the data isn't simple:

- Raw image data may lack annotation to make it useful to AI algorithm.
- Datasets in academic medicine can exist in/on:
    - Different physical locations
    - Different servers
    - Collected on EMR systems that may not be uniform.
  - Your institution may have the relevant dataset to facilitate a commercial relationship, but…
    - Access
    - Data uniformity
    - Patient consent form uniformity
- Patient consent forms – right to provide third party access?

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We Want Your Data!

Teaching datasets in academic medicine.

- What type of dataset are you sharing with a third party?
  - Limited dataset:
    - Contains some, but not all, protected health information (PHI) parameters
    - Not directly identifying PHI that can be used to link to a patient.
    - May have:
      - Dates of treatment, admission, discharge
      - Birth date, date of death
      - Age (including age 90 or over)
      - Geographic subdivisions such as state, country, town, city, etc.
      - Unique codes or identifiers that are not direct identifiers or replicates of a part of direct identifiers.
  - De-identified data:
    - May not contain any of the 18 elements that constitute PHI.

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We Want Your Data! But, Should You Provide It?

- <u>Back to the example</u>: Company developing AI algorithm for mammography wants access to our mammography image datasets to train their algorithm.
  - Assume dataset in a form that can be utilized; patient consent allows third party access to data.

  - <u>What does the academic institution get from the relationship?</u>
    - <u>Revenue</u> for providing data.
    - <u>Co-development</u> of algorithm if we make contributions to improve it.
    - The "right" data set can be a differentiating factor.
    - <u>Publication</u> in peer-reviewed journal if results demonstrate positive outcome.
      - Improved sensitivity, fewer false positives/negatives.
    - <u>Opportunity to improve patient care</u> at your site
      - Exclusivity; your site becomes exclusive site for deployment of company's tool in your region.
      - Opportunity to deploy company's tool under more favorable terms.
  - <u>Importance of mission alignment</u>
    - Enhancement of research, patient care, or educational missions.

The Power of Pooled Datasets/Hubs

Individual institutions will have impact, but real change will come from huge pooled datasets under development.

Example: EPIC developing COSMOS: BCM is an EPIC client.

- Clients deposit de-identified patient datasets. Can't sell COSMOS-associated datasets.
- Potential to be the single largest repository of patient data in the world.
  - Aiming for 200M patients, depends on participation.
- Power: physicians treating patients with rare conditions can coordinate treatment.
- Power: Combine charts from same patient treated at different sites. Resolution of conflicting information.

Analyses of huge datasets will "raise the bar" for patient care.

- Medication compliance: Identification of contra-indicated medications.
  - Identification of adverse events.
- Monitor institution-associated outcomes: Strong incentive for lagging institutions to improve/implement current state-of-the-art care.
  - Can be viewed as a threat.
- Improved triage: Viz:AI – identifies strokes from CT scans. Alert that patient requires immediate stroke care.

Licensing Practices in the AI Sector

- It's a different world for licensing professionals at academic medical centers
  - Traditionally, our world has revolved around:
    - Licensing patented therapeutics, devices, vaccines & diagnostics;
    - Licensing non-patent research tools (mice, other modified biological materials);
    - For most of us, not a huge amount of activity in the AI sector; a deal here and there.

- The AI/neural network world is a combination of:
  - Making software available through <u>open-source formats</u>.
    - Promoting utilization; reputational enhancement; recruitment
  - <u>Pursuing patent portfolios</u>
    - Big tech companies pursue patent portfolios for defensive reasons
      - The "other guys" patent everything, so we must as well.
      - Concept of mutually-assured destruction.
  - Most academics can't compete at this level, most academic patenting practices in the AI space will be for niche algorithms.

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Licensing AI IP Developed at Your Institution

- Example 1: Research team at your institution develops new AI neural network algorithms that mimic the way the brain actually responds and processes information related to visual and auditory stimuli using data collected in real-time from animal models.
- From an IP standpoint, what do you have?
  - Potential patentable subject matter
    - Sufficient written description? Enablement?
    - Demonstration of utility?
  - Copyrightable content
    - Authorship determination might not be trivial for computer-generated content.
  - Trade secret?
    - Perhaps invention not patent eligible? Developers plan to disclose parts of the work in publications, but retain "secret sauce" elements.
    - Traditionally an area where academic licensors don't have much track record.
  - Does your institution's IP policy adequately capture rights?

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- <u>Example 1 (cont.)</u>:
  - Research team wants to do a start-up:
  - Want to license institution-owned IP and do additional development within the company.
  - Hire engineers into company:
    - Salaries in the academic setting difficult to hire and retain software engineers.
    - "Brain drain" of personnel from the academic setting to industry a real challenge.
      - Can't pay them enough; can't keep them.
    - Present stage of company: Vehicle for software development.
  - <u>Appropriate license terms</u>
    - <u>Option vs. license</u>
    - Equity? Royalty on net sales of services/products?
    - Software very early –potential downstream uses not at all clear.
    - Fields of use?
    - Rights to improvements/derivative works?

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- Example 2: Research team develops micro-scale proteomics assay platform for oncology biopsy samples + develops new AI algorithms to leverage 'omics information to guide patient treatment decisions (treat the patient with the right regimen the first time).
- What do you have?
  - Patentable subject matter:
    - Microscale proteomics assay methodology (what is truly proprietary to university vs.
    - Algorithm for guiding patient treatment decisions
  - Copyrightable subject matter:
    - Code
  - Trade secrets?
  - Development of datasets to teach algorithm.
- License to existing company vs. start-up
  - PI wants a start-up. But, big players already in the space.
  - License to existing player once approach proven.

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Take Home Tips:

- Use a combination of IP
- Exercise Licensing or Sharing of Training Data
- Watch for additional players

Discussion

Questions
&
Answers

HAMILTON
BROOK SMITH
REYNOLDS
Intellectual Property Law