

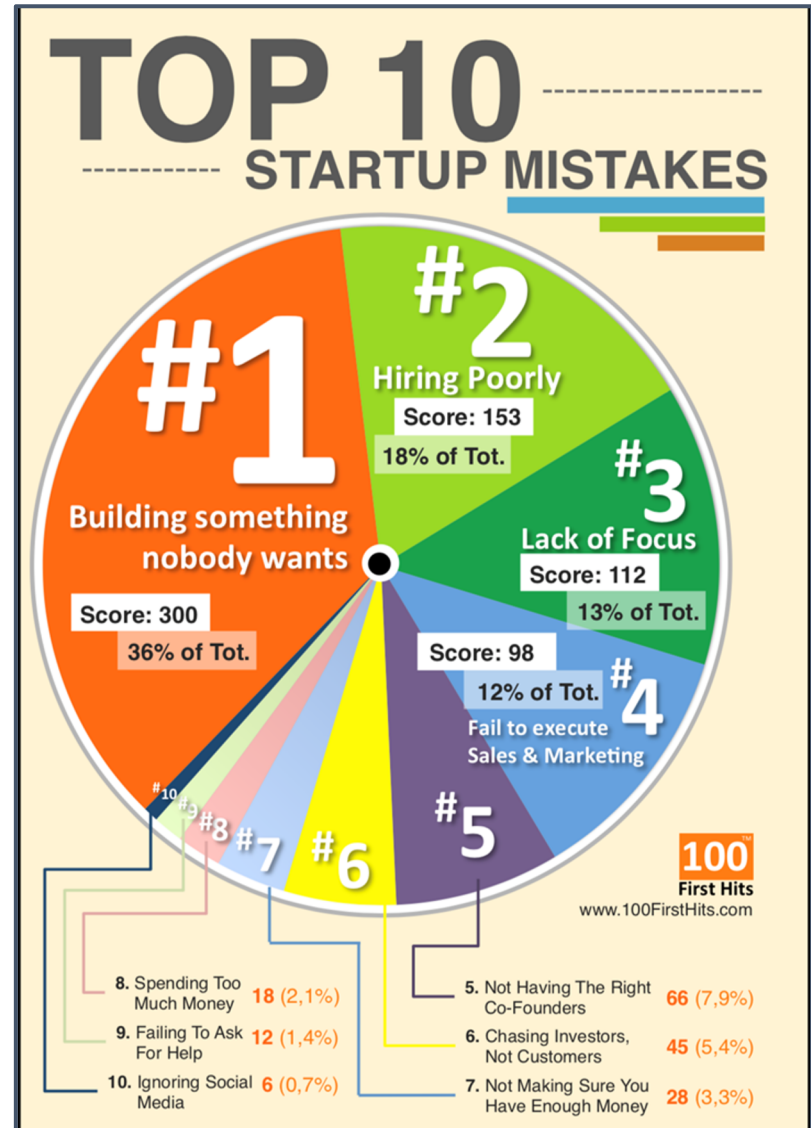
# NE I-Corps

New England Regional Innovation Node @ MIT

“How can we increase the **economic impact** of the research dollars invested every year?”



**Massachusetts  
Institute of  
Technology**



# MIT I-Corps Spark

- NSF I-Corps
  - Entrepreneurship course based on Steve Blank's Lean Startup model, a customer centric approach.
  - 7 week in-depth course, with up to \$50k support
- NSF I-Corps SPARK
  - Regional 3 week program at MIT
  - 24 customer interviews
  - Followed by Fusion with up to \$1500 support
  - Total of 9 regional I-corps nodes

# Other Regional Programs

- Bay Area Regional I-Corps Node (BA)
- DC/MD/VA Regional I-Corps Node (DMV)
- I-Corps South Node (SOUTH)
- Innovation Node-Los Angeles (IN-LA)
- Midwest I-Corps Node (MWIN)
- New England Regional Innovation Node (NE I-Corps)
- New York City Regional Innovation Node (NYCRIN)
- Southwest Innovation Corps (SWICORPS)
- UNY I-Corps Node (UNY)



# ERC Ecosystem Advantages

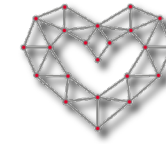
- ERC focus on technology translation
- Advisor incentives to promote PhD student participation
- Industry members as initial network for customer interviews
- Mentorship from ILO's and others in network
- Financial support from ERC to compete and develop in business plan competitions
  - TERMIS
  - Tigerlaunch



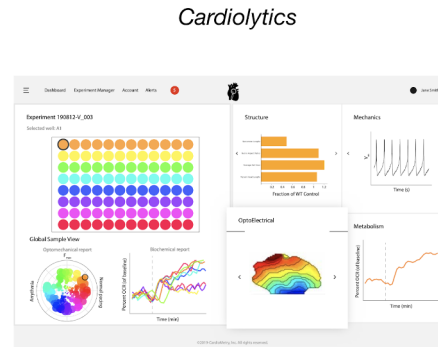
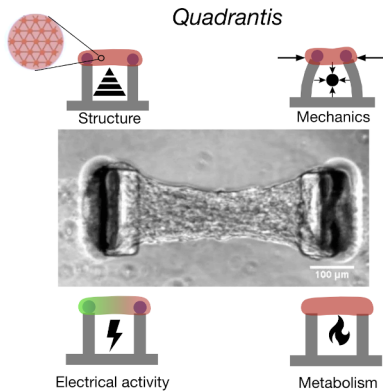


# CardioMetry

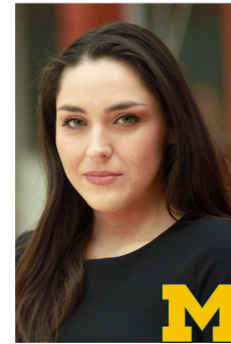
Know your heart.



CELL-MET



Engineered cardiac tissue platform to evaluate toxicity during drug development.



**Ayse Muniz**  
founder



**Ben Swanson**  
founder



**Josh Javor**  
founder



**Jenny Sun**  
founder



**Christos Michas**  
founder

\* All PhD Candidates working on tech development and business model refinement

# Interviews

1. Executive Vice President of Process and Manufacturing Sciences, Ankyra
2. Chief of Staff, Head of Business and Scientific Operations, GlaxoSmithKline
3. VP Preclinical R&D, Gemphire, ex-Pfizer
4. Strategic Alliance Manager, Bayer
5. Global Expert for Cardiovascular Safety, NDA Partners, Novartis, Roche, Sanofi
6. CEO, Stemina
7. Program Manager, ARMI/BiofabUSA, ex-USAMRDC
8. CEO, Nanosurface
9. Director Cardiovascular Safety Pharmacology at J&J PRD (Europe)
10. Chief Cardiovascular R&D, Novartis
11. CEO, MyoKardia
12. Director of Experimental Pharmacology and Toxicology, and Prof at Univ of Hamburg
13. Director of Pharmacology, Pfizer
14. CEO, Avery Therapeutics
15. CEO, Alchemy
16. Senior Director of New Venture, JnJ Innovations
17. Senior Research Scientist, Signalon
18. Senior Toxicologist, National Cancer Institute
19. Process Development Engineer, pharmaceutical manufacturing, Ex-Genentech
20. VP of research, Parke-Davis/Pfizer
21. CTO, TARA biosystems, ex-MyoKardia, ex-Merck
22. Director of Cardiovascular Biopharmaceutical R&D, Broadview Ventures
23. Director of Scientific Research, 23&Me, ex-Amgen
24. CEO, Cartox and Prof at UofM

Person Interviewed: R. G.

Title/Position: Chief of Staff, Head of Business and Scientific

Operations

Customer Type: Oncology Drug Development

Company(s): GSK

# OH2








<b>Hypotheses:</b> <i>Here's what we thought</i>	Oncological drugs have can have off-target toxicity, such as in the heart, and compounds need screened at early stages. Outsourcing may be common at some pharma companies and not others; we are unsure how decisions are made.
<b>Experiments:</b> <i>Here's what we did/asked</i>	<ol style="list-style-type: none"><li>1. Could you describe how early-stage compound evaluation is done?</li><li>2. (unprompted)</li><li>3. How is a decision to outsource made?</li></ol>
<b>Results:</b> <i>Here's what we learned</i>	<ol style="list-style-type: none"><li>1. Drugs aren't always screened for toxicity, but are rather evaluated. Some high-severity patient populations have to tolerate toxicity in exchange for efficacy (oncology).</li><li>2. In oncology, if you see signal of efficacy, you can file registration based on that data.</li><li>3. Outsourcing is common to "preferred" partners and others once rigorous trust is built.</li></ol>
<b>Action/Iterate:</b> <i>Here's what we will do next</i>	Interview companies that could be outsourced to as to their willingness and procedure for adopting a new assay. We presently view them as potential competition but their established contacts and reputation may be vital.

## Key Learnings (Summary)


<b>Hypotheses:</b> <i>Here's what we thought</i>	Cardiotoxicity screening is major pain-point in drug development timeline. Big and small companies may be adopters of new tech. Outsourcing and in-house tech development are both common. Our business model may have explosive growth rates that encourage VC funding approach. In silico models are too far away to consider yet.
<b>Experiments:</b> <i>Here's what we did/asked</i>	<ol style="list-style-type: none"><li>1. What are biggest pain-points in drug development?</li><li>2. How is new technology adopted in pharma and who is involved?</li><li>3. What are exciting game-changers in performance assessment?</li></ol>
<b>Results:</b> <i>Here's what we learned</i>	<ol style="list-style-type: none"><li>1. Toxicity and efficacy testing are both big in oncology because patients have to tolerate a lot of toxicity. Early-stage efficacy data may allow you to file registration.</li><li>2. Adoption is slow, tech must be heavily validated, and regulators and customers must be well-educated. Small companies can't afford to take the risk, so big pharma usually does (even if reluctantly).</li><li>3. <i>In silico</i> modeling is presently hampered by inaccurate models as data inputs. If model accuracy is improved, such as with hiPSCs, <i>in silico</i> models could be game-changers and could generate a lot of value.</li></ol>



# The Business Model Canvas

<h3>Key Partners</h3>  <ol style="list-style-type: none"> <li>NSF Engineering Research Center for Cellular Metamaterials (CELL-MET) &amp; associated academic partners</li> <li>Stem cell repositories (Allen Institute, StemCell)</li> <li>Cloud-based infrastructure provider (e.g., Google, Amazon)</li> <li>Cardiotoxicity patient advocacy groups</li> <li>FDA and regulatory consultants</li> <li><b>In silico model experts/providers for validation of in vitro data</b></li> </ol>	<h3>Key Activities</h3>  <ol style="list-style-type: none"> <li>Repeatable fabrication and maintenance of stem-cell-derived cardiac tissues according to industry standards</li> <li>Rapid, reproducible and reliable pharmacological studies to validate effects of customer's chemical compounds</li> <li>Automated extraction of data and conversion to technical analysis report</li> </ol>	<h3>Value Propositions</h3>  <p>Providing customers:</p> <ol style="list-style-type: none"> <li>Cost savings in holistic development timeline from early identification (\$2.2M to bring new asset to mkt, 81 drugs removed over last 20 yrs due to cardiotoxicity).</li> <li>More accurate cardiotoxicity screening models <b>backed by in silico predictions</b> (animal and 2D models have low physiological relevance).</li> <li>More detailed cardiac performance assay (FDA regulation only requires action potential information, whereas our product provides this and many other metrics, which could become additional future regulations).</li> <li>Easy access to in-depth, technical analysis from online platform and a team of cardiac tissue engineering experts.</li> </ol>	<h3>Customer Relationships</h3>  <ol style="list-style-type: none"> <li>Single-plate assays (characterize performance to ~100 samples per assay).</li> <li>Annual contracts with highly customizable assays and analysis.</li> <li>On-site consulting &amp; support for Cardiolytics.</li> <li>Establish partnerships with cardiotoxicity advocacy groups to educate customers and to improve regulation.</li> </ol>	<h3>Customer Segments</h3>  <ol style="list-style-type: none"> <li><b>Decision-makers</b> Directors of Safety/Toxicity</li> <li><b>Influencers</b> Research Scientists</li> <li><b>Buyer</b> Purchasing department/CFO</li> <li><b>End User</b> Research Scientist</li> </ol> <p><u>Market Segments</u> Oncological drug developers (toxicity screening), <b>especially big companies.</b> All drug developers (toxicity screening) Cardiovascular drug development (efficacy and screening) Personalized Medicine sector <b>CROs specialized in or in need of in vitro models for disease and drug studies</b></p>
<h3>Key Resources</h3>  <ol style="list-style-type: none"> <li>Access to high quality and consistent hiPSC cell lines.</li> <li>Tissue incubation facility for tissue maturation prior to use.</li> <li>Quadrantis tissue measurement system.</li> <li>Digital infrastructure for secure, online database and platform</li> <li><b>Proprietary data analysis techniques.</b></li> </ol>		<h3>Channels</h3>  <ol style="list-style-type: none"> <li>Online, intuitive analysis tool, Cardiolytics, for accessing and visualizing processed data.</li> <li>Technical support from team of experienced cardiac tissue engineers (more access to contracted customers).</li> <li><b>Scientific Conferences</b></li> <li><b>Network with regulator connections</b></li> </ol>		


### Cost Structure



- Disposable lab supplies for tissue culture
- Lab facilities in Boston Area and associated utilities
- Quadrantis tool maintenance.
- Staffing (technician and software developer)
- R&D for automation and compound validation.
- Subscription to secure online platform.

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### Revenue Streams



- Single-plate assays (i.e., the data produced from the assay).
- Enhanced analysis and technical support.
- Annual contracts/collaborations.
- Reduced staff costs and higher assay throughput from automation.
- Increasing value of platform as it evolves from subsequent experiments.

# Key Take-Aways

- For an ERC PhD student
  - Cardiometry and Cell-MET have provided a vehicle for entrepreneurial development
  - Think about research in a translatable way
  - Business model generation
  - Entrepreneurial communication
  - Meetings with tech transfer and patent education
- For Cardiometry
  - Established network and key relationships
  - Refined business model
  - Developed tools for attracting customers and investment
  - Enhanced our relationship with Cell-MET and Cell-MET partners