



IMAGINE CAPSULE CAM

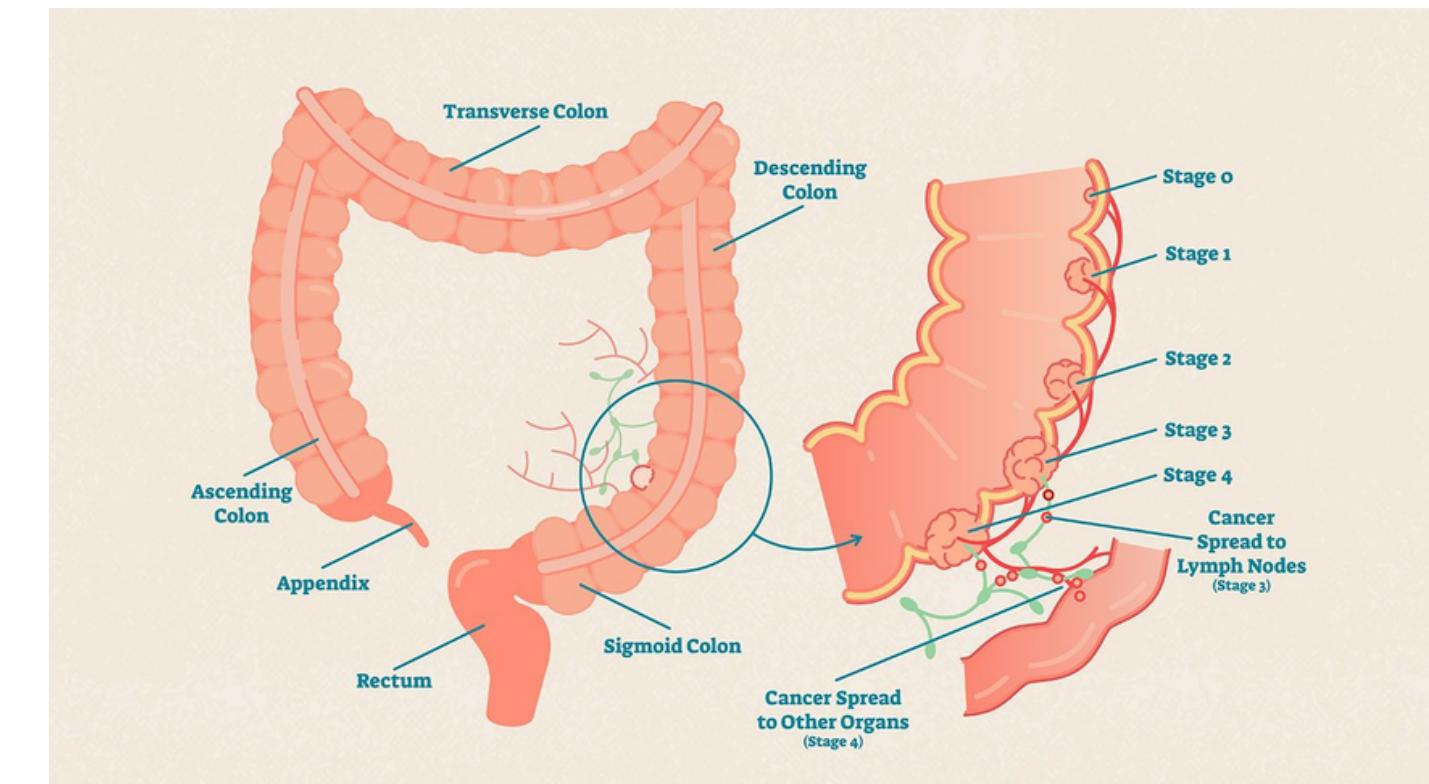
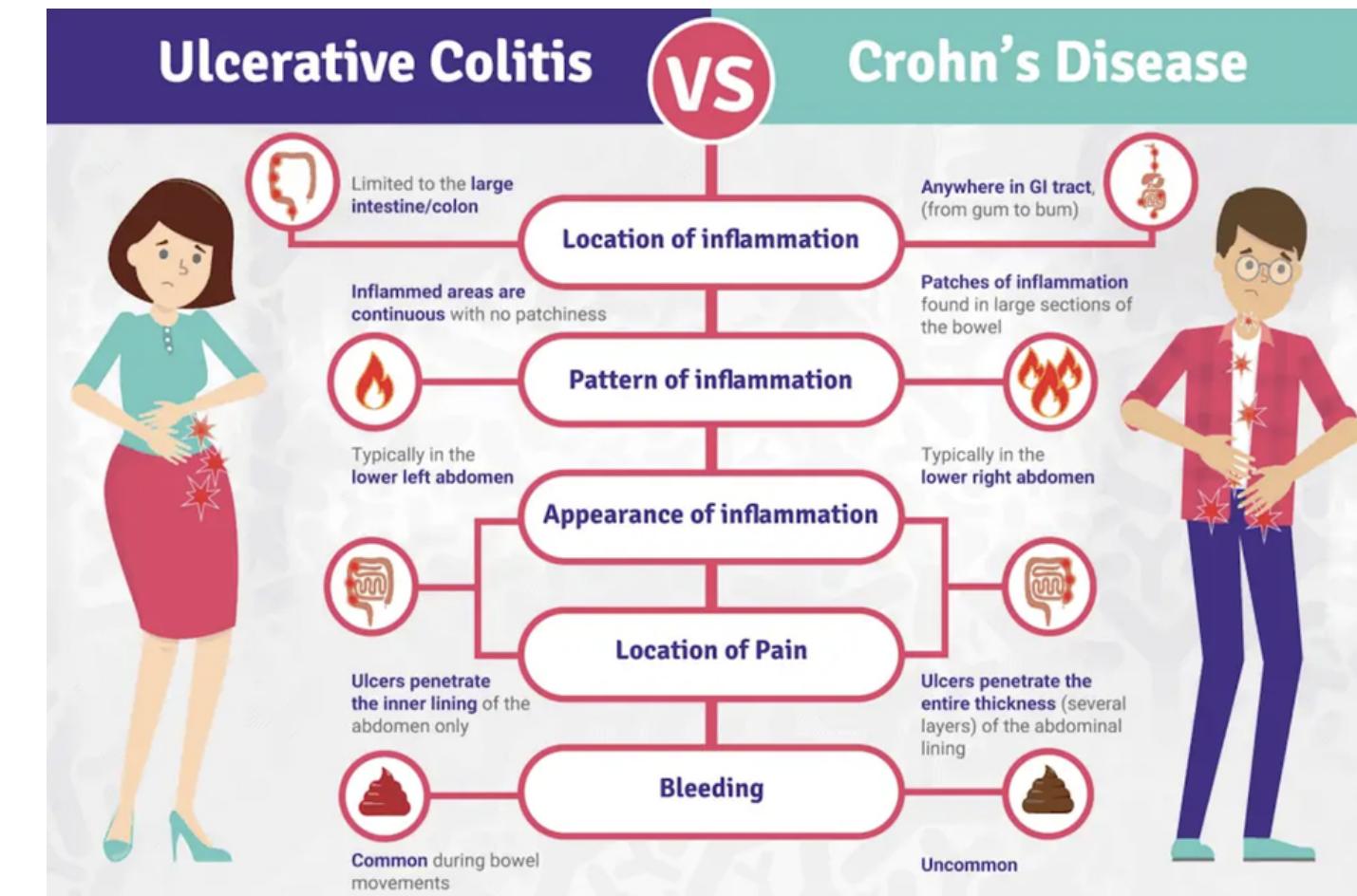
Re-Imagine your Health

Anagha Menon and Atmana Joshi

Introduction

Gastro-Intestinal Disorders

- Inflammatory Bowel Disease
 - Crohn's
 - Ulcerative colitis
- Colorectal Cancer
 - Malignant/Benign Polyps
 - Malignant/Benign Tumors



What needs to change?

At the heart of the prevention lies the need for early diagnosis.

Pain Point: The current gold standard for diagnosis of lower GI tract disorders is the colonoscopy or endoscopy, which is a highly invasive procedure.

Many patients put off having colonoscopies owing to this invasive nature, which means that diagnoses are only made at late stages of the disease – when treatment outcomes are poor.

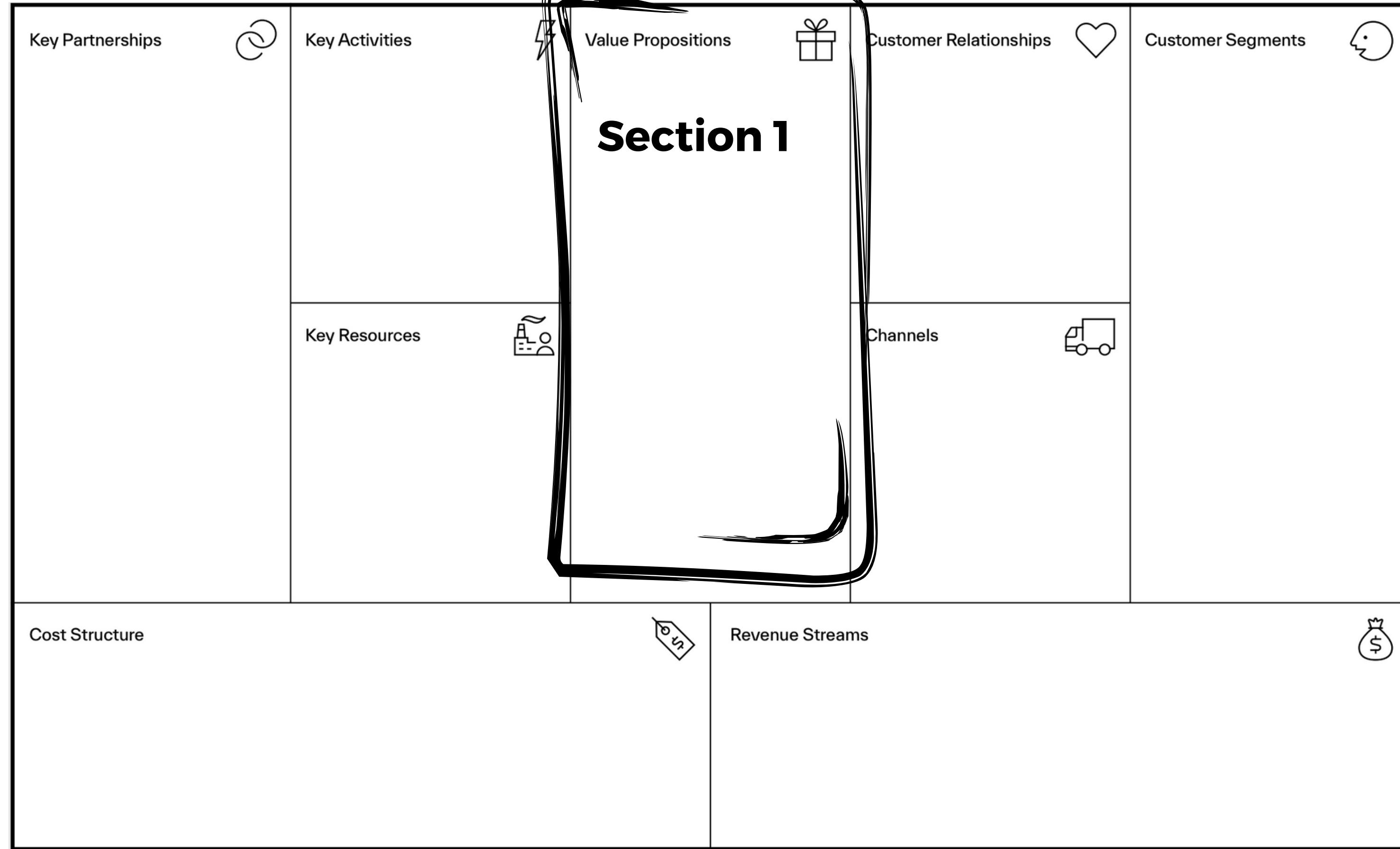
Introducing ImaGIne Capsule Cam:

A non-invasive diagnostic tool with AI augmented image analysis



- Orally consumable, wireless pill equipped with a 360-degree camera
- High fps (frames per second) to capture high quality images
- Equipped with small-scale biopsy capabilities through retractable microgrippers
- Augmented with AI/ML image analysis for more robust detection

Business Canvas



Value Proposition Rationale

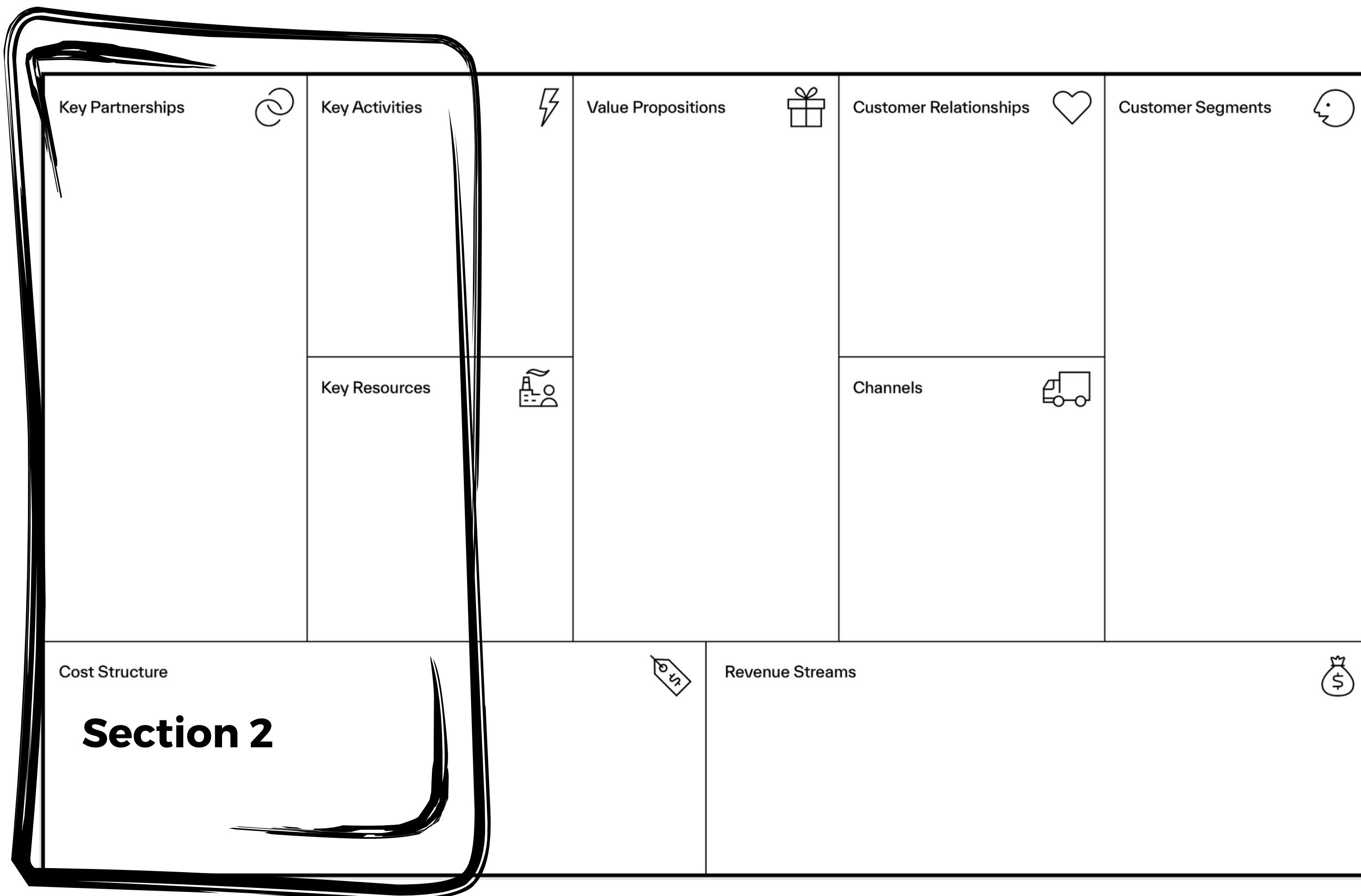
- **Customer Profile**
 - **Customer Gains**
 - Hassle-free prep, non-invasive, accuracy, early detection, cost-saving
 - **Customer Pains**
 - Difficult prep, lack of comprehensive imaging
 - **Customer Jobs**
 - Comfortable, accurate and cost-effective diagnosis
- **Value Map**
 - **Gain Creator**
 - High quality non-invasive diagnostics option
 - **Pain Reliever**
 - Reduced risk, time, and cost
 - **Service**
 - Motorized camera equipped with latest technology

Value Proposition Statement

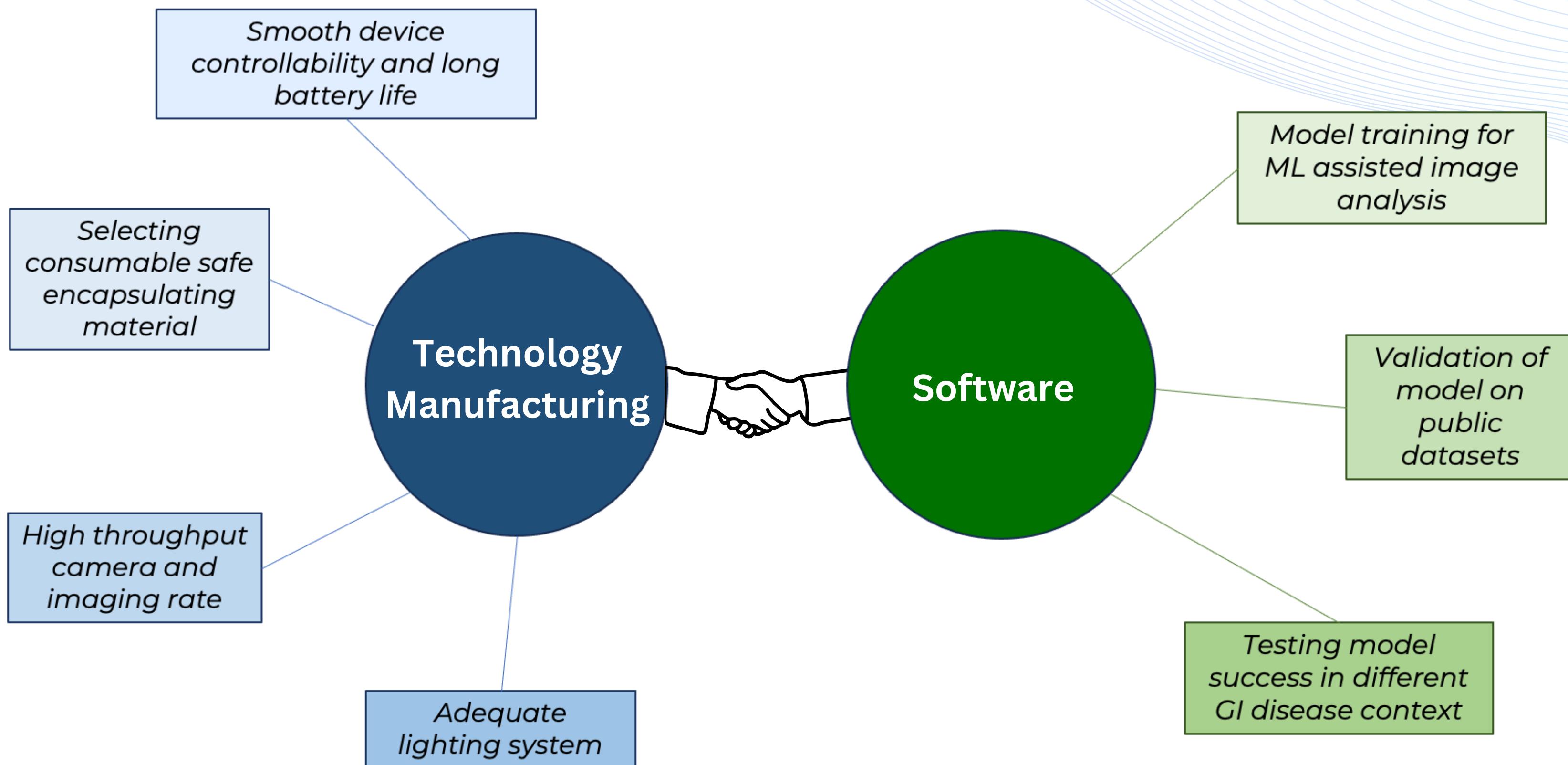
ImaGIne Capsule Cam

**Prioritizing your comfort, time, and health with our AI-powered
gastrointestinal screening device to offer superior imaging and improved
patient outcomes.**

Efficient . Economical . Empowering



Key Activities

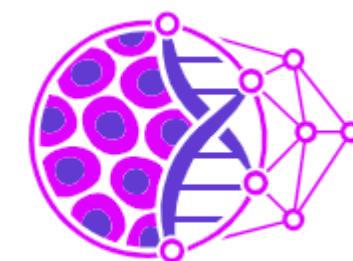
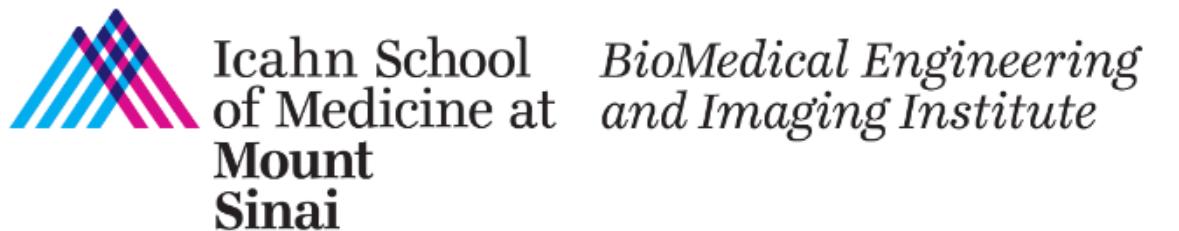


Key Partners



Mount
Sinai

*Innovation
Partners*





Software Innovations



Icahn School
of Medicine at
Mount
Sinai

BioMedical Engineering
and Imaging Institute



Financial

Grants

Partner Funding



National Institute of
Biomedical Imaging
and Bioengineering



Intangible

Device Approval



C.D.R.H Center for Devices and
Radiological Health

Key Resources



Physical

Source and Device material

Manufacturing unit



Human

Clinical Trials

Safety Officers

Medical Personnel



Intellectual Property

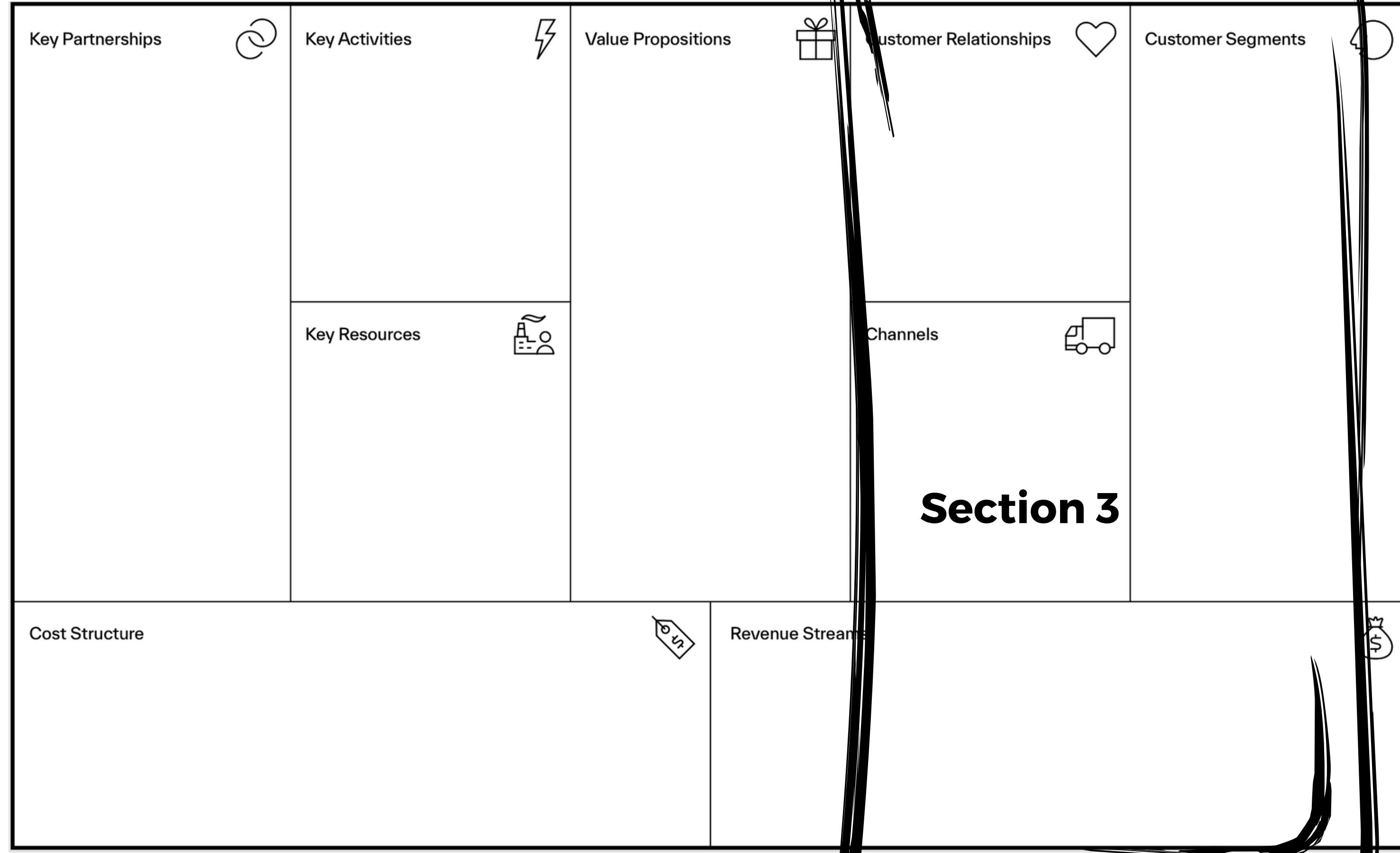


Mount
Sinai

Innovation
Partners

Cost Structure

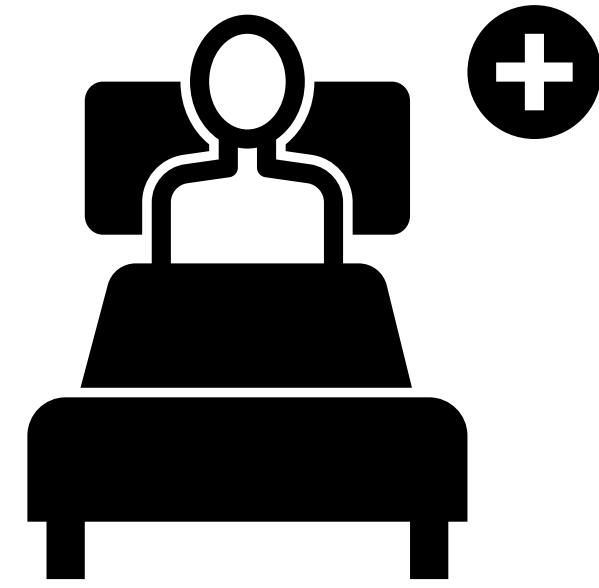
- Research and Development
 - Design, Software, Trials
- Manufacturing
 - Quality Control
- Regulatory
 - IP, License, Patent, Legal
- Marketing
 - Advertisements, Partnerships
- Distribution
 - Supply Chain, Inventory
- Customers
 - Support, Training
- Infrastructure
 - Maintenance, Analysis
- Administrative
 - Staff, Sales



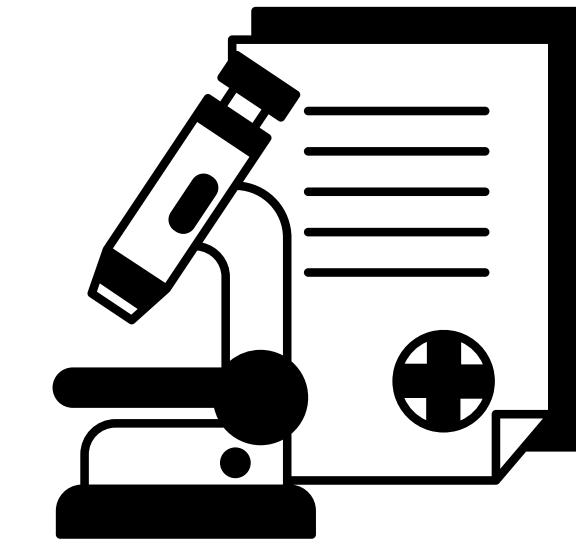
Customer Segments



Healthcare
Professionals



Patients



Researchers



Payers

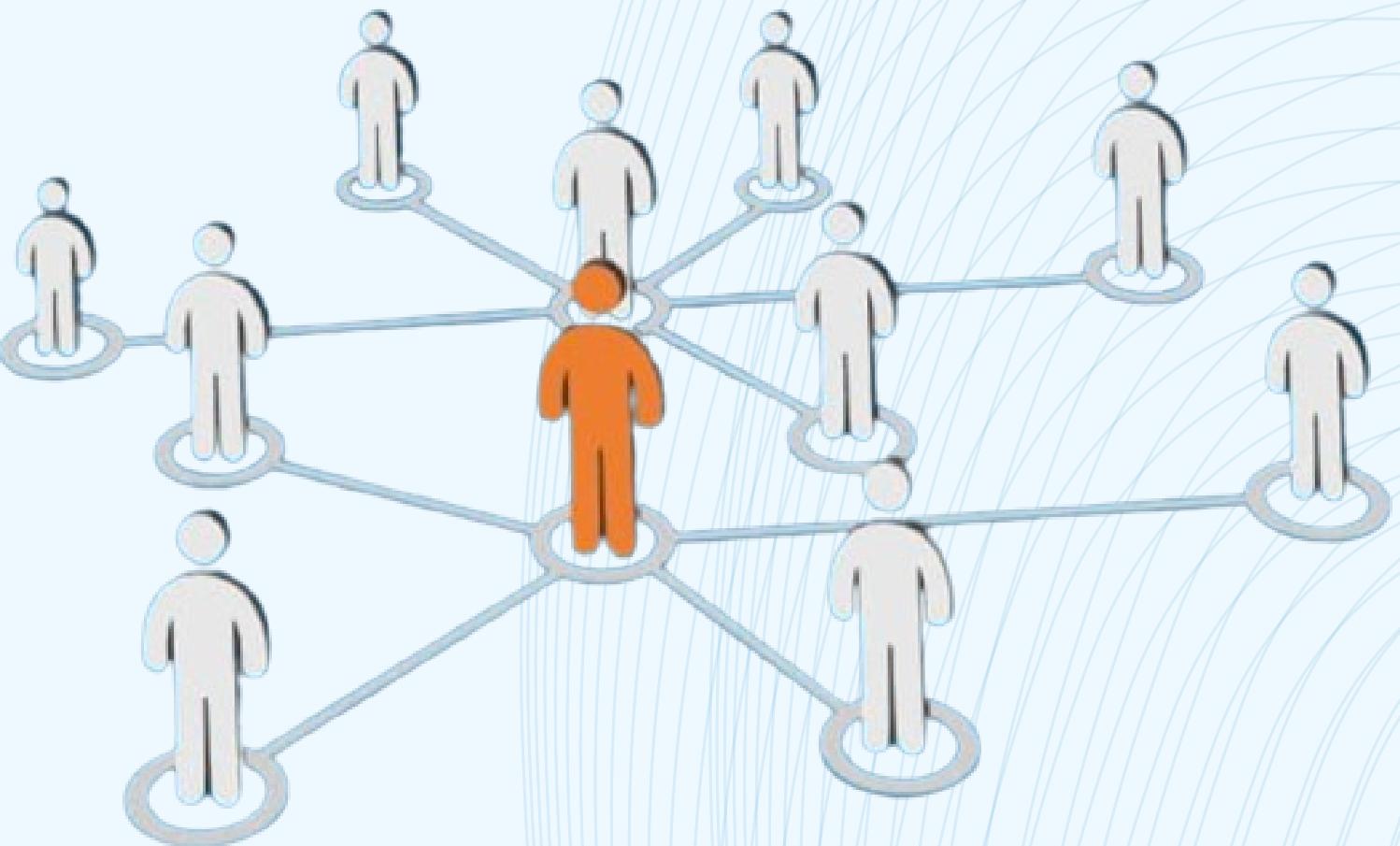
Channels

Distribution Channels

- Manufacturers
- Hospitals
- Private Practices

Marketing Channels

- Websites
- Healthcare (Clinicians and patients)
- Sales and Technical Support



Customer Relationships

- **Getting Customers**
 - Partnerships with providers and hospitals
 - Marketing, advertisements
 - Healthcare technology conferences
- **Keeping Customers**
 - Quality support and training
 - Focus on customer need
 - Customer engagement
- **Growth**
 - Continuous research and development
 - Data and feedback driven improvements
 - Strategic partnerships

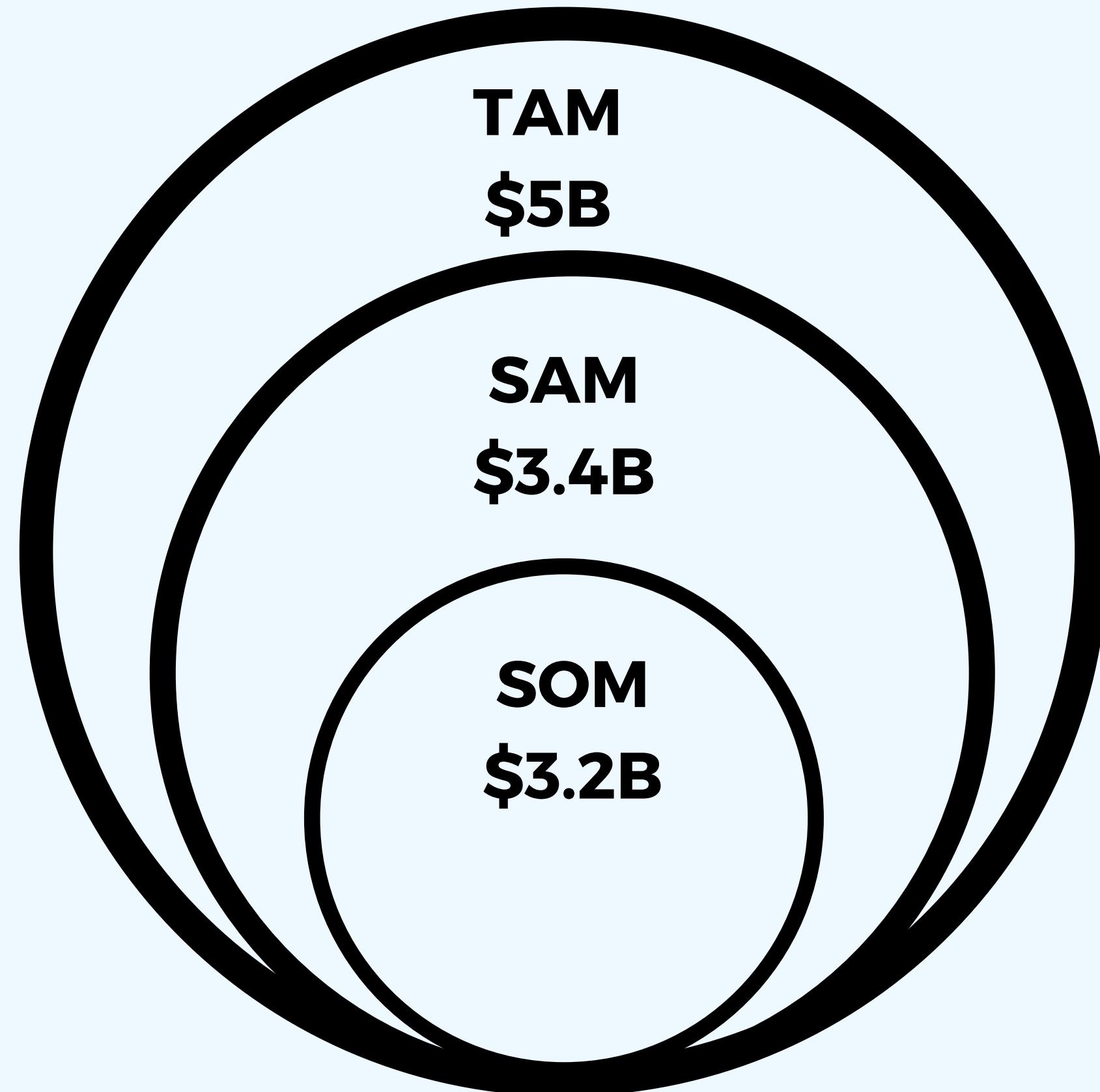
Revenue Streams

- Grants
- Philanthropy
- Competitions/Innovation Programs
- Investments
 - External Collaboration, Venture Capital, Angel Investors
- IP Licensing
 - Larger device manufacturers, Research Institutions
 - Upfront payments, Royalties
- Patient-based Revenue
 - Insurance, Healthcare Facilities

Market Scan

Market Scan

For the entire
United States of
America

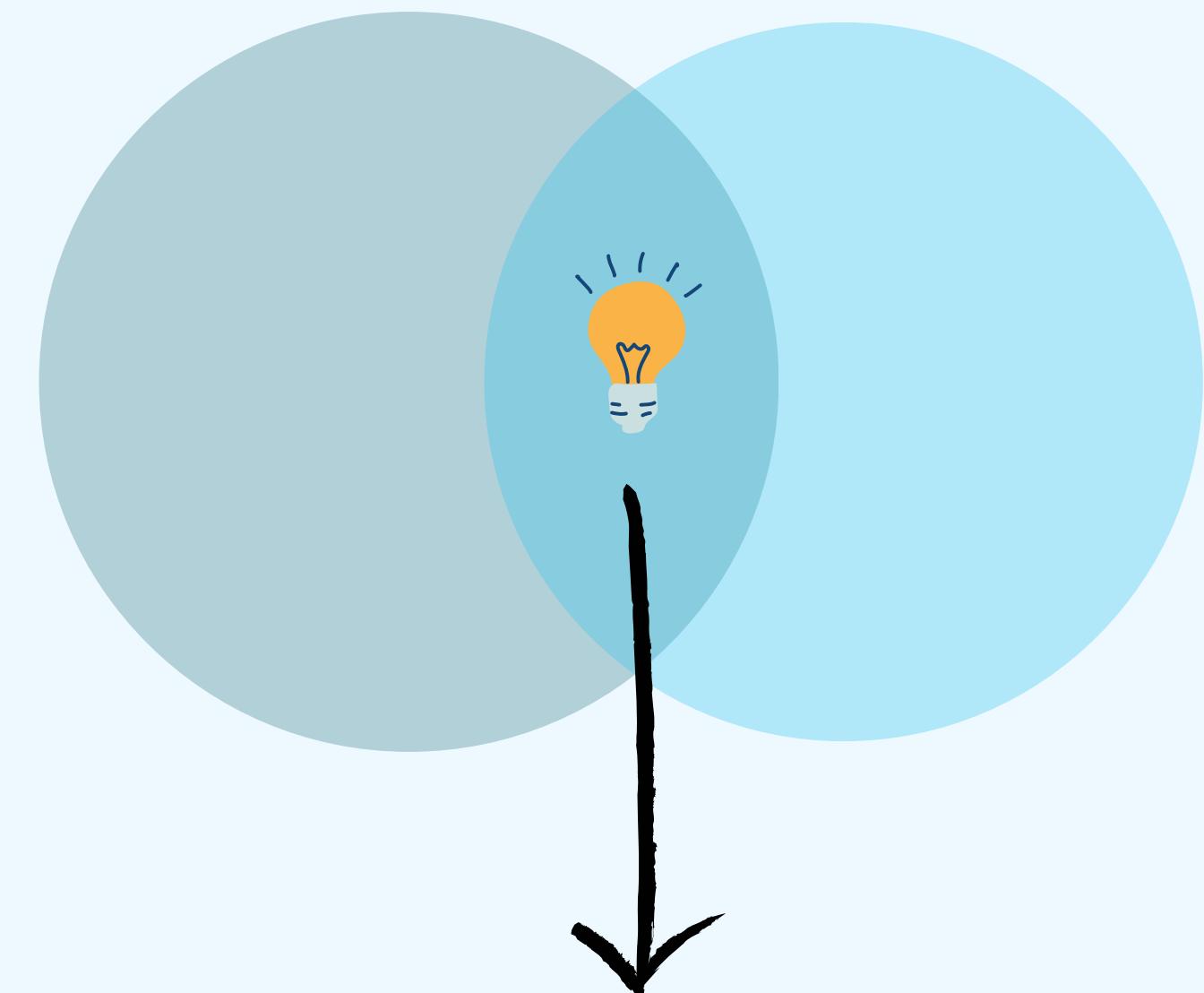


Market Analysis

ImaGIne Capsule Cam is not the first to the market! But what sets it apart?

Technologically advanced pill cams

AI image analysis tools for traditional colonoscopy



ImaGIne Capsule Cam sits at the intersection of two fields

Direct and Indirect Competitors

Medtronics

Cosmo Pharmaceuticals

Shanghai Zhongren Biological Medicine Science & Technology

Futudent

Wision AI

Pro - Forma Budget

Income	2023	2024	2025	Rationale
Grants	\$296,000	\$1,970,000	\$0.00	NIH SBIR Grant (https://www.nibib.nih.gov/research-program/small-business-programs)
Icorp	\$50,000	\$0.00	\$0.00	I-Corp Grant (https://icorpsnortheasthub.org/#:~:text=Promising%20ventures%20may%20continue%20to,across%20the%20Hub%2Dmember%20institutions.)
Family and Friends	\$0.00	\$0.00	\$0.00	None
Investors	\$500,000.00	\$1,000,000	\$1,500,000	Angel Investor
Licensing	\$0.00	\$500,000	\$3,000,000	Licensing to Medtronic \$500,000 Upfront + 2%-10% Royalty from Sales (Arbitrary, No data available for annual pill came sales)
Total Income	\$846,000	\$3,470,000	\$4,500,000.00	
Expenditure				
Variable Costs				
API Calls	\$0.00	\$75,000	\$150,000	0.25 cents per 1000 API Calls (https://developers.google.com/google-ads/api/docs/rate-sheet)
Advertising	\$0.00	50,000	125,000	Arbitrary
Taxes	\$72,756	\$298,420	\$387,000.00	8.6% Income Tax (IRS)
	\$129,438	\$530,910	\$688,500.00	Self-Employment Tax 15.3% for 2023 (IRS)
Loan(Interest)	\$3,000	\$3,000	\$3,000	50K Loan at 6% (Source: https://www.bankrate.com/loans/small-business/average-business-loan-rates/)
Fixed Costs				
Cloud Services	\$33,558	\$67,116	\$134,232	Average Cost of Cloud Services for a Start Up (https://www.starterstory.com/ideas/cloud-computing-business/startup-costs)
Rent	\$0.00	\$40,000	\$40,000	Use Mount Sinai and MSIP Headquarters prior to partnership formation, following which incubator spaces will be used
Legal fees	\$50,000	\$100,000	\$200,000	Arbitrary
License fees	\$20,000	\$40,000	\$80,000	Arbitrary
Salaried	\$500,000	\$1,000,000	\$2,000,000	(\$200k AI/ML Developer + \$150k Biomedical Engineer + \$150k Material Scientist)
Total Expenditure	\$808,752.00	\$2,204,446	\$3,807,732	
Net	\$37,248	\$1,265,554	\$692,268.00	

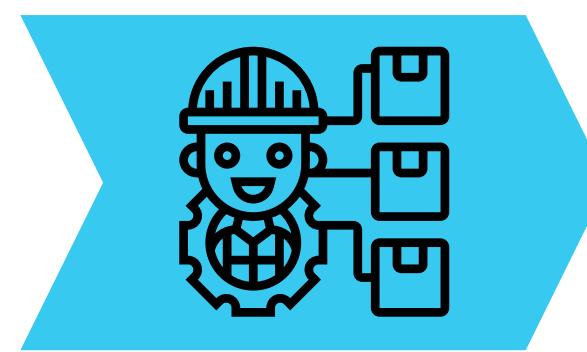
Supply Chain Diagram

Supply Chain



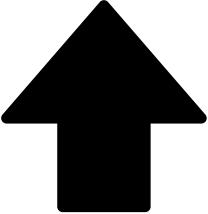
Supplier

- Camera Component Suppliers
- Biopsy Component Suppliers
- Electronic Component Suppliers
- Software and Data Storage



Manufacturing

- ImaGIne Capsule Cam Manufacturing Facilities



Distribution

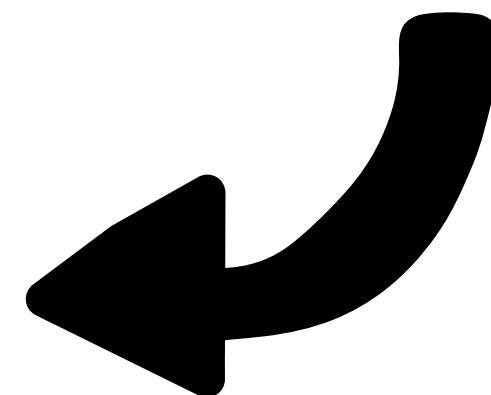


- Medical Equipment Distributors

Customers



- Healthcare Facilities
- Healthcare Professionals
- Patients (Indirectly via Healthcare Providers)



Payers

- Insurance Companies

Demand Generation & Financing

IP and Regulatory Issues

Anticipated with external partnerships:
(Capsovision, Medtronics)

1. Conflict of Interest (COI)
2. Regulatory Risks
(materials used)
3. Legal risks

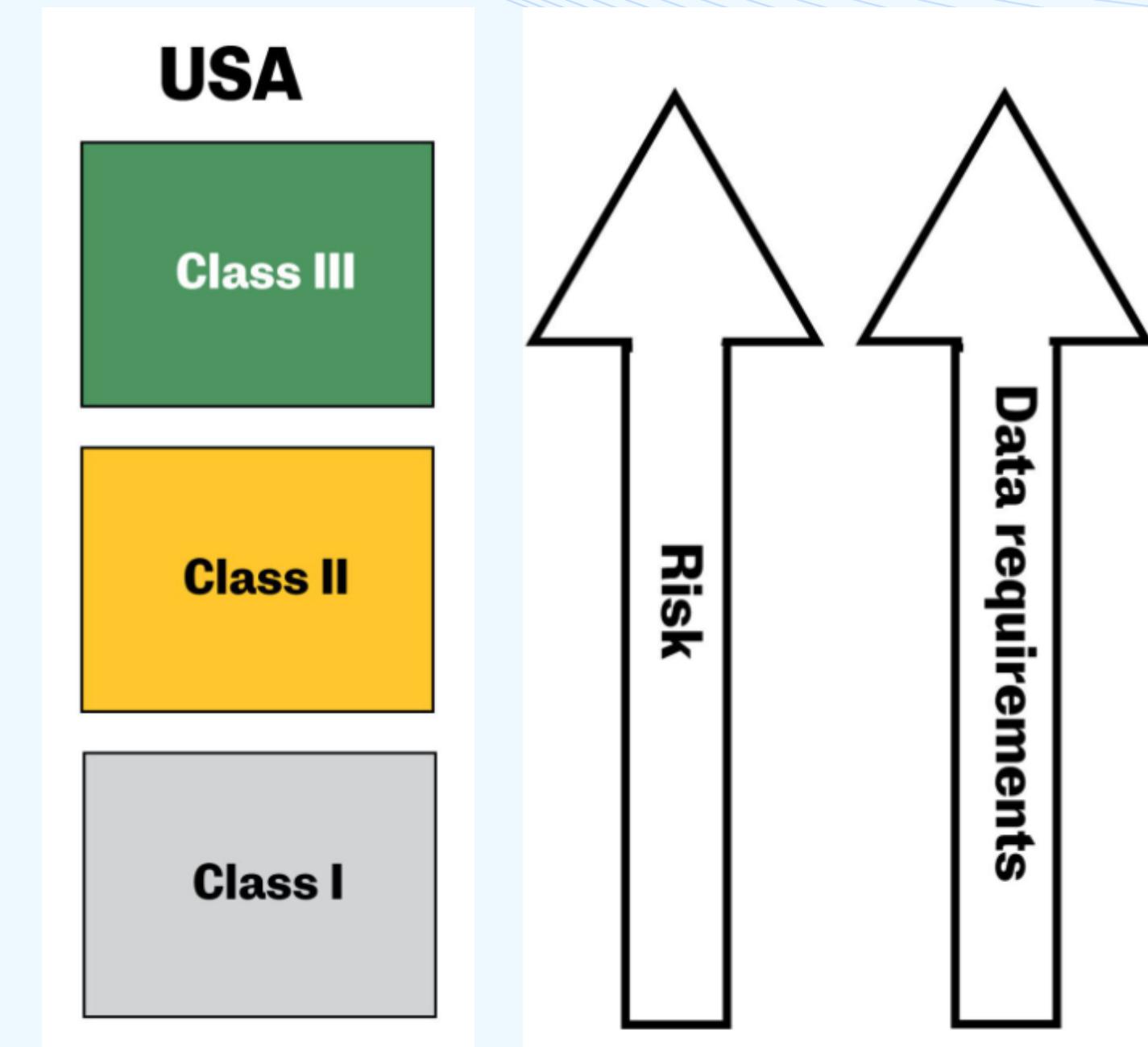


Image sourced from MaRS Startup Toolkit

Expert Opinions

Interview Summary

Physicians

Area of Focus



1. All physicians emphasized the need to scale down focus to specific area of the GI tract
2. Many supported the use of capsule cams in the small bowel, which is difficult to access via endoscopy
3. AI image analysis is very robust and adds huge value to the device

Health Challenges



1. Not feasible in patients with intestinal projections - risks pill getting stuck
2. Complicated in Crohn's disease patients: what stage is the patient coming in?
3. Suitable in certain situations in geriatric patient populations

AI/ML Academics, Engineers

Imaging



1. Need existing publicly accessible datasets related specific GI disorders
2. Data labels to identify conditions within a disorder need to be well defined
3. Large scope for AI augmented medical devices!

Computation



1. Using deep neural networks is useful, but requires high computational power
2. Raises questions on scope/scale in academic settings where funding is limited
3. Narrow focus for better model usability

Upcoming Interviews

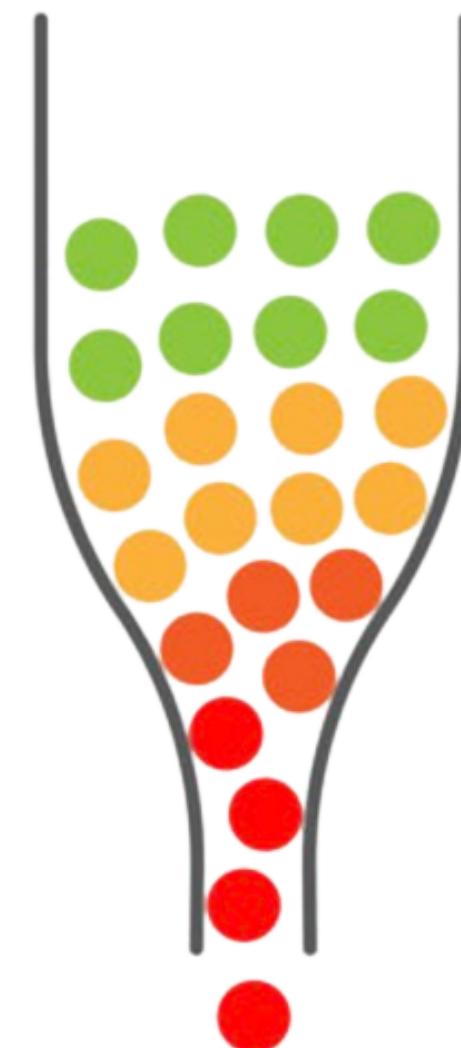
Scheduled:

1. Colorectal Cancer Alliance (CCA) - Senior Director of Prevention and Screening
2. GI Specialist (expertise in pouchitis, post invasive treatment infections)
3. GI Specialist (expertise in extra-intestinal manifestations in IBD)

Pivot: Changing our focus moving forward

Challenges

- Using the ImaGIne Capsule Cam for whole GI tract imaging does not seem feasible given the nuance and variation in manifestation of disease in different portions.
- Training AI models to identify larger sets of images for more than one subtype of disease requires huge financial and computational resources.



Our Focus

- We propose to re-define our area of focus to specifically the small bowel, an area of the GI that is difficult to image through traditional colonoscopy and sigmoidoscopy.
- We redefine our AI/ML analyses tool to disease subgroups specific to the small bowel: polyps, adenomas etc.

Re-structure: disease focus, direct competitors and market value analysis

Summary and Discussion

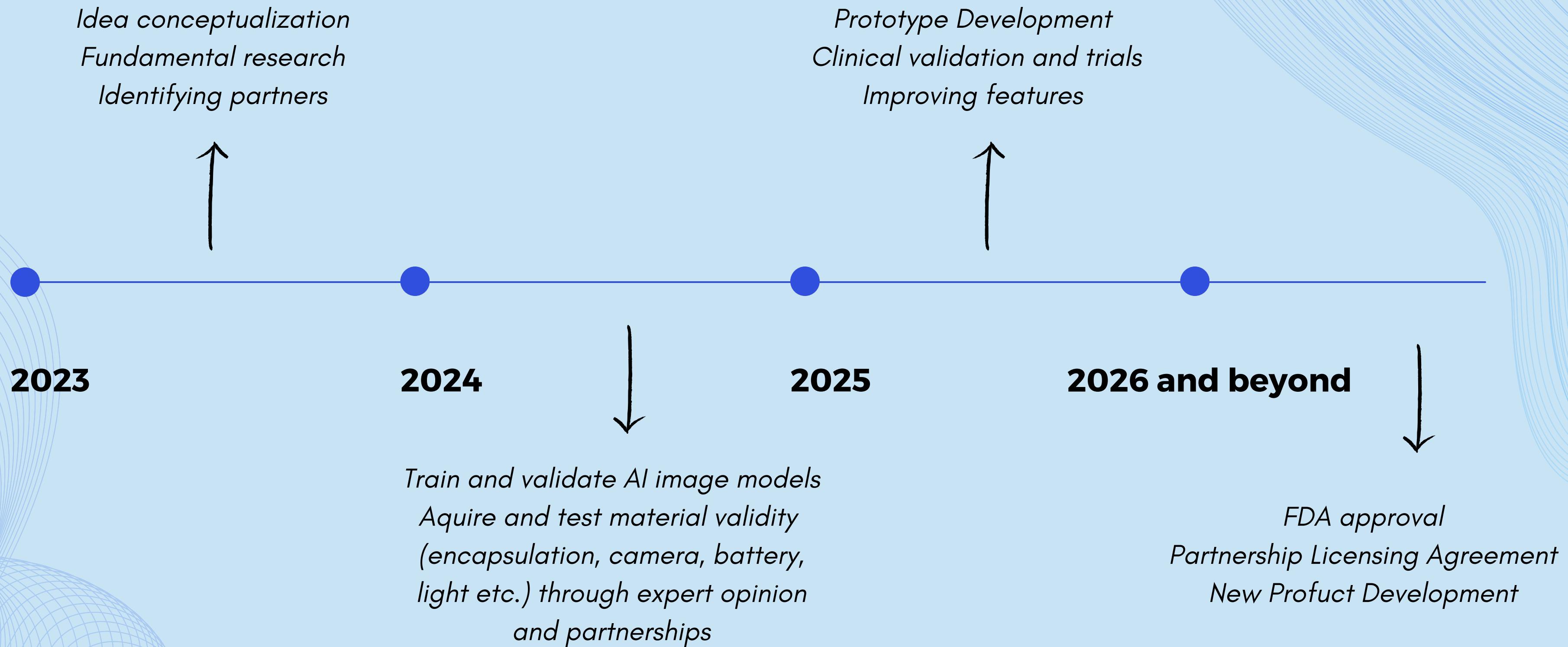
Lessons Learnt

- Narrowing our scope and redefining our area of focus
- The importance of expert interviews and validation
- Truly understanding the customer base is vital

Future Directions

- GI section specialized pill cams
 - Small-bowel, Colon, Esophageal
- Continuous design improvements to increase comfort
 - Battery Life
 - Temperature sensing
 - pH monitoring
- Collaboration with AI-centered research labs and companies
 - Algorithm and software improvements
 - Improving patient data analysis
- Increasing affordability and access
- Market expansion outside US

Timeline



Thank you!

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- 2.Sharma, S., Ramadi, K.B., Poole, N.H. et al. Location-aware ingestible microdevices for wireless monitoring of gastrointestinal dynamics. *Nat Electron* 6, 242–256 (2023). <https://doi.org/10.1038/s41928-023-00916-0>
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- 5.Nagai M, Suzuki S, Minato Y, Ishibashi F, Mochida K, Ohata K, Morishita T. Detecting colorectal lesions with image-enhanced endoscopy: an updated review from clinical trials. *Clin Endosc.* 2023 Sep;56(5):553-562. doi: 10.5946/ce.2023.055.6.
https://www.utsouthwestern.edu/edumedia/edufiles/about_us/admin_offices/technology_development/resources/intro-licensing-2016.pdf Diffusion of an innovation: growth in video capsule endoscopy in the U.S. Medicare population from 2003 to 2019 | BMC Health Services Research | Full Text (biomedcentral.com)
<https://www.nibib.nih.gov/research-program/small-business-programs>
<https://icorpsnortheasthub.org/#:~:text=Promising%20ventures%20may%20continue%20to,across%20the%20Hub%2Dmember%20institutions. https://s3.amazonaws.com/scienceexchange-assets/addf/Financing+101+for+Biotech+Startups+FINAL.pdf> Rate Sheet and Non-Compliance Fees | Google Ads API | Google for Developers Self-Employment Tax (Social Security and Medicare Taxes) | Internal Revenue Service (irs.gov) <https://www.starterstory.com/ideas/cloud-computing-business/startup-costs>
<https://www.statista.com/statistics/1206510/projected-ibd-population-in-select-countries-north-america-europe/>
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