# Leveraging Partnerships with FDA during and after COVID-19 : Advice for Startups

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# We Became Involved With Regulatory & Reimbursement Out Of Necessity

- Elora's history
  - Drug and Device industry, Global Regulatory Strategy
  - Notables: Eliquis (drug ~10B annual sales), Abilify MyCite (first drug with sensor with FDA Press Release)
  - Translating industry learnings to CMU medical product startups
- Courtney's history
  - Personal need
  - Novel technology
  - CMU alum
- How we met
  - Through Olympus and a personal connection (Elora's daughter)
  - Working together since 2016
  - Joint Swartz presentations since 2017

# Our Thought Process Has Evolved

- Regulatory and Reimbursement
  - Old way : Regulatory - THEN- Reimbursement
  - New way : Regulatory - AND - Reimbursement
- Understanding the startup world (navigate it in the least burdensome manner)
  - Start with drafting differentiation strategy and product claims
  - Understand FDA + CMS requirements to get desired claims
- Engage with the Agencies to align on development plan to get the right evidence at the right time to get desired claims

# FDA and CMS and you

**FDA quote:** *'Open lines of communication between FDA and industry will provide regulatory outcomes that best serve patients'*

**CMS quote:** *CMS maintains open channels of communication between outside entities and CMS components charged with making coverage, coding, and payment decisions.*

# We've Covered Regulatory and Reimbursement 101 For You 2017-2019.
# 2020 was canceled

Swartz Center for Entrepreneurship
Carnegie Mellon University

# What Is Regulated?

IBM Watson

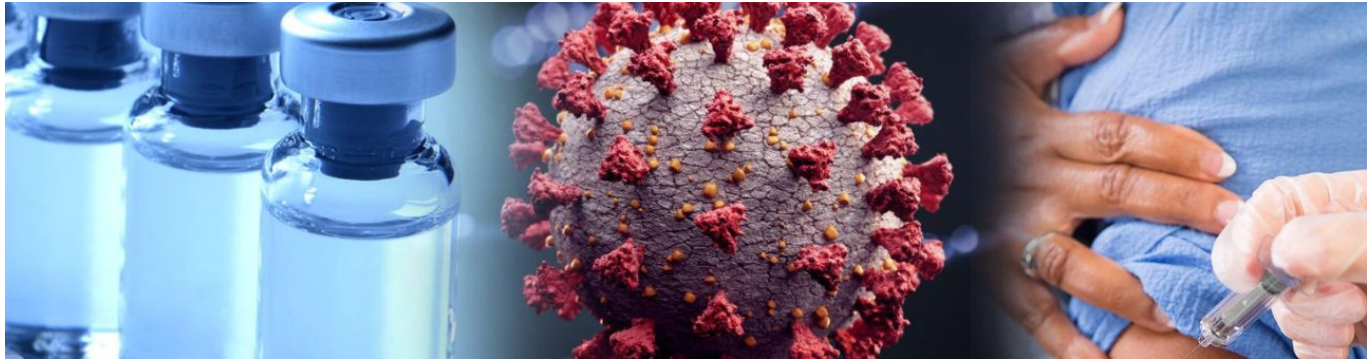
Jeopardy ≠ Medical condition

# What is the FDA? What is CMS?

Mission is to Protect & Promote US health

Mission to strengthen and modernize US healthcare system, to provide access to high quality care and improved health at lower costs.

**Often Feels Like**



**Expedite Regulatory and Reimbursement pathways**

## Due to the pandemic:

FDA has created several initiatives, regulations and engagement strategies for COVID products that will likely extend to other novel products

CMS has adopted COVID policies and guidelines that creates opportunities for novel technologies

# A well-differentiated product is based on its claims

Science
Technology
Innovation
IP

Unmet
need,
User voice

Safey
Effectiveness
Quality

Reasonable
Necessary
Value-added

**Differentiated Product**

Clinically meaningful
Patient-centered care
Cost-effective

# It's about the evidence to support claims and obtaining that is an efficient manner

EVIDENCE
(specially for
innovative devices))

Nonclinical

Clinical

FDA

Effectiveness, Safety,
Quality
Benefit > Risk

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Coding
Coverage
Payment

# What Do The FDA and CMS Have In Common? YOU!!

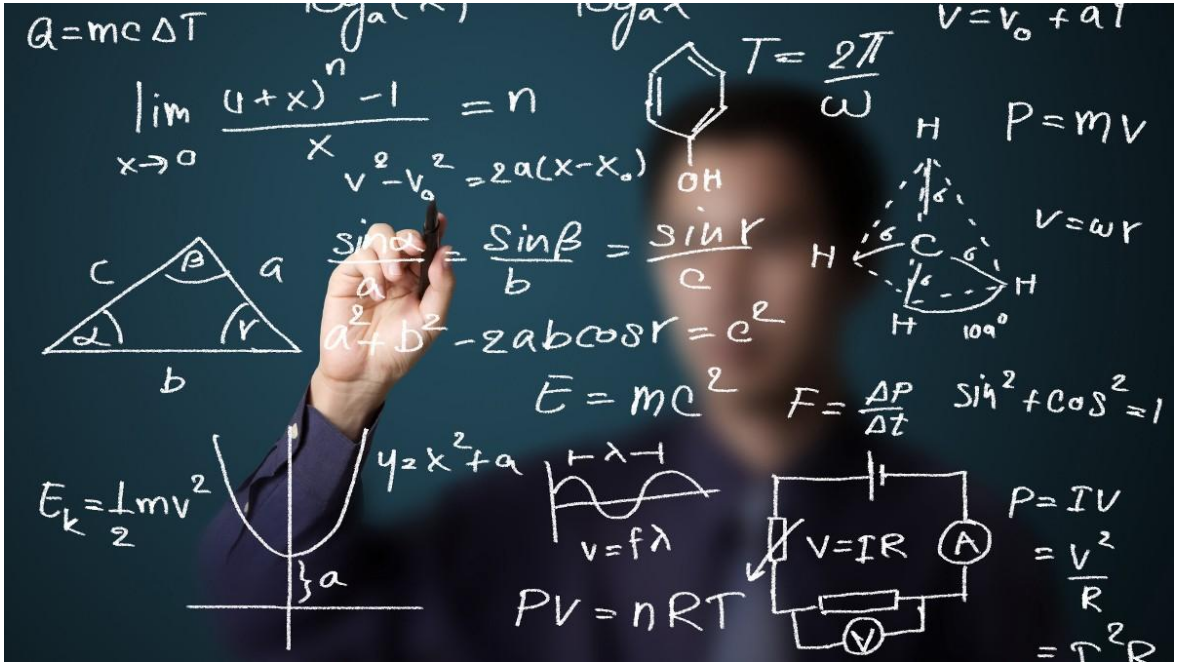
“…….Ideally, Sponsors and FDA work **collaboratively** ….. having a shared public health goal of early availability of safe, effective, and high-quality (products) to the American public….. “

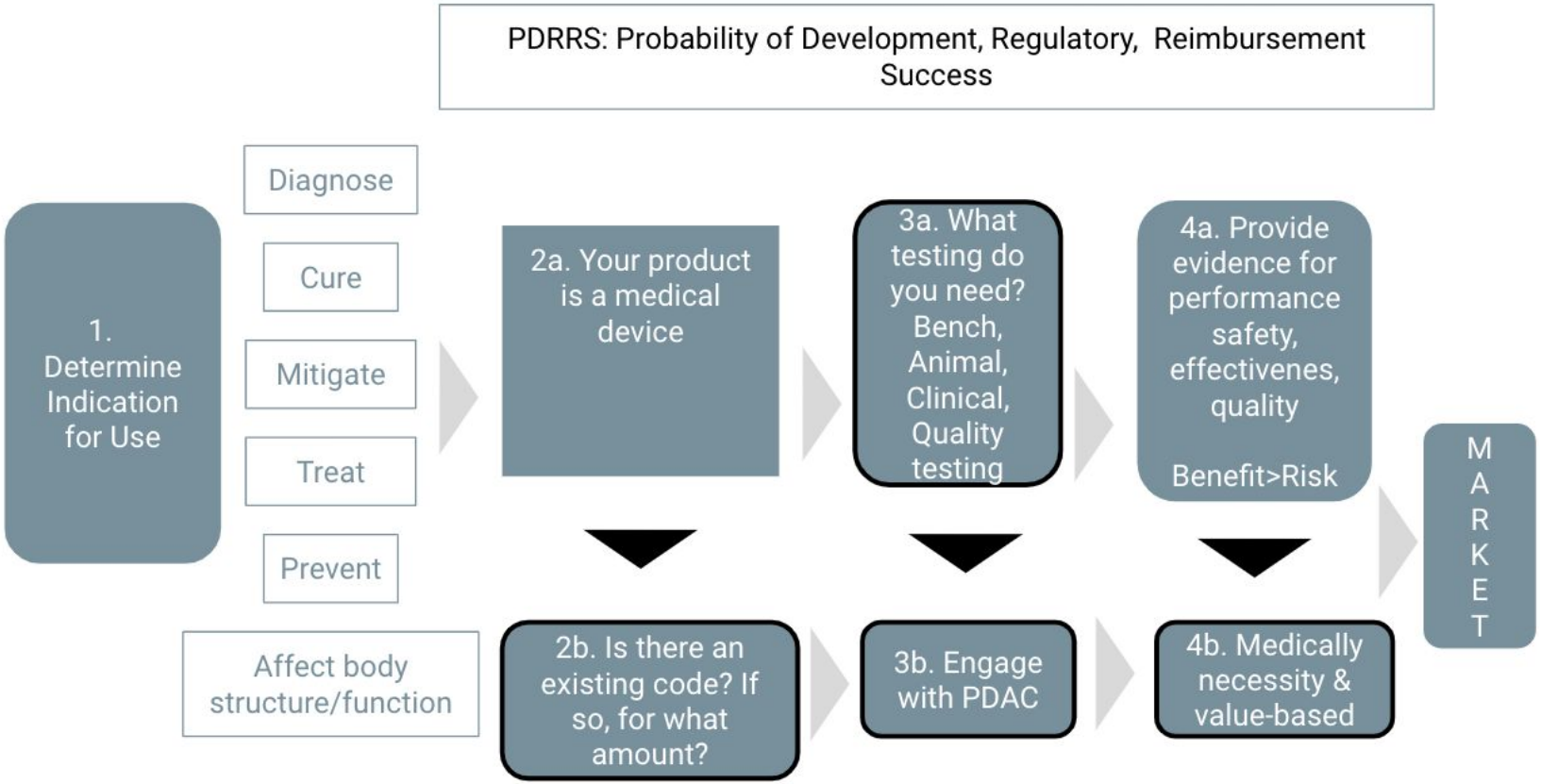
-Food and Drug Administration

# Could My Product Be Regulated?

Interactive Workshop

# Calculating Probability Of Success




PDRRS: Probability of Development, Regulatory, Reimbursement Success
1. Determine Indication for Use
Diagnose
Cure
Mitigate
Treat
Prevent
Affect body structure/function
2a. Your product is a medical device
2b. Is there an existing code? If so, for what amount?
3a. What testing do you need? Bench, Animal, Clinical, Quality testing
3b. Engage with PDAC
4a. Provide evidence for performance safety, effectivenes, quality
Benefit>Risk
4b. Medically necessity & value-based
MARKET

# Entrepreneur Action Items

- Identify your patient demographic
- Work through the decision tree
- Contact Division of Industry and Consumer Education (DICE)
- Find an existing CMS code (if applicable)

# Entrepreneur Resources: Get started

## FDA

- Information for Industry (Drugs), Device Advice
- CDER/CDRHLearn
- druginfo@fda.hhs.gov
- DICE@fda.hhs.gov
- FDA Guidance page
- CFR Title 21

## CMS

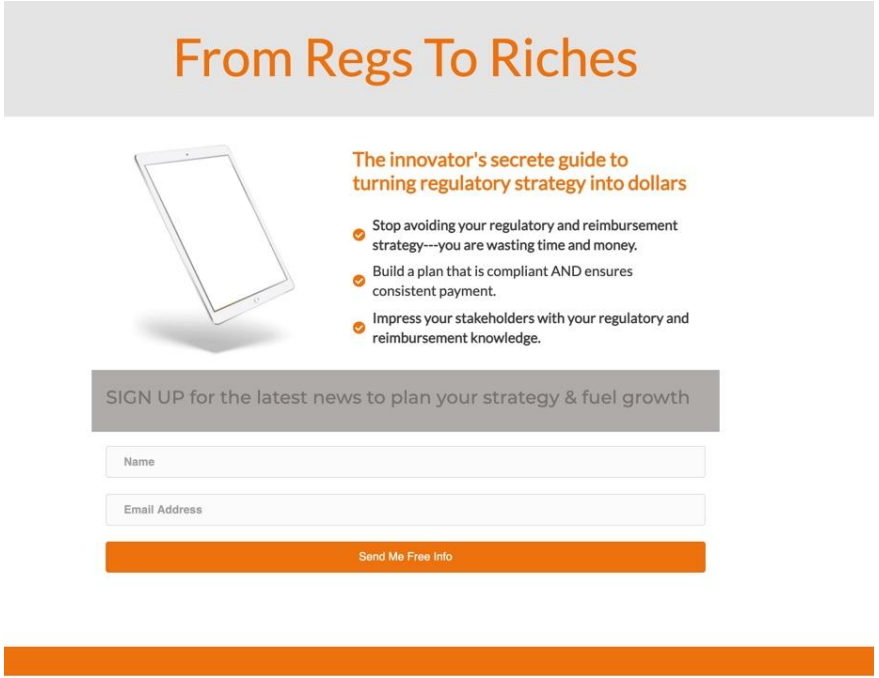
- PDAC-Medicare Contractor for Pricing, Data Analysis and Coding
- Noridian
- CGS
- Innovator's guide

INNOVATORS' GUIDE TO NAVIGATING MEDICARE

| | | | |
|---|---|---|---|
| Food | Drugs | Medical Devices | Radiation-Emitting Products |
| Vaccines, Blood, and Biologics | Animal and Veterinary | Cosmetics | Tobacco Products |

# Sign Up For Free Information

https://regstoriches.com/



# Questions?