



# How Investors Can Encourage Startups to Work Constructively with the FDA

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FDA Public Workshop – Evolving Role of Artificial Intelligence in  
Radiological Imaging

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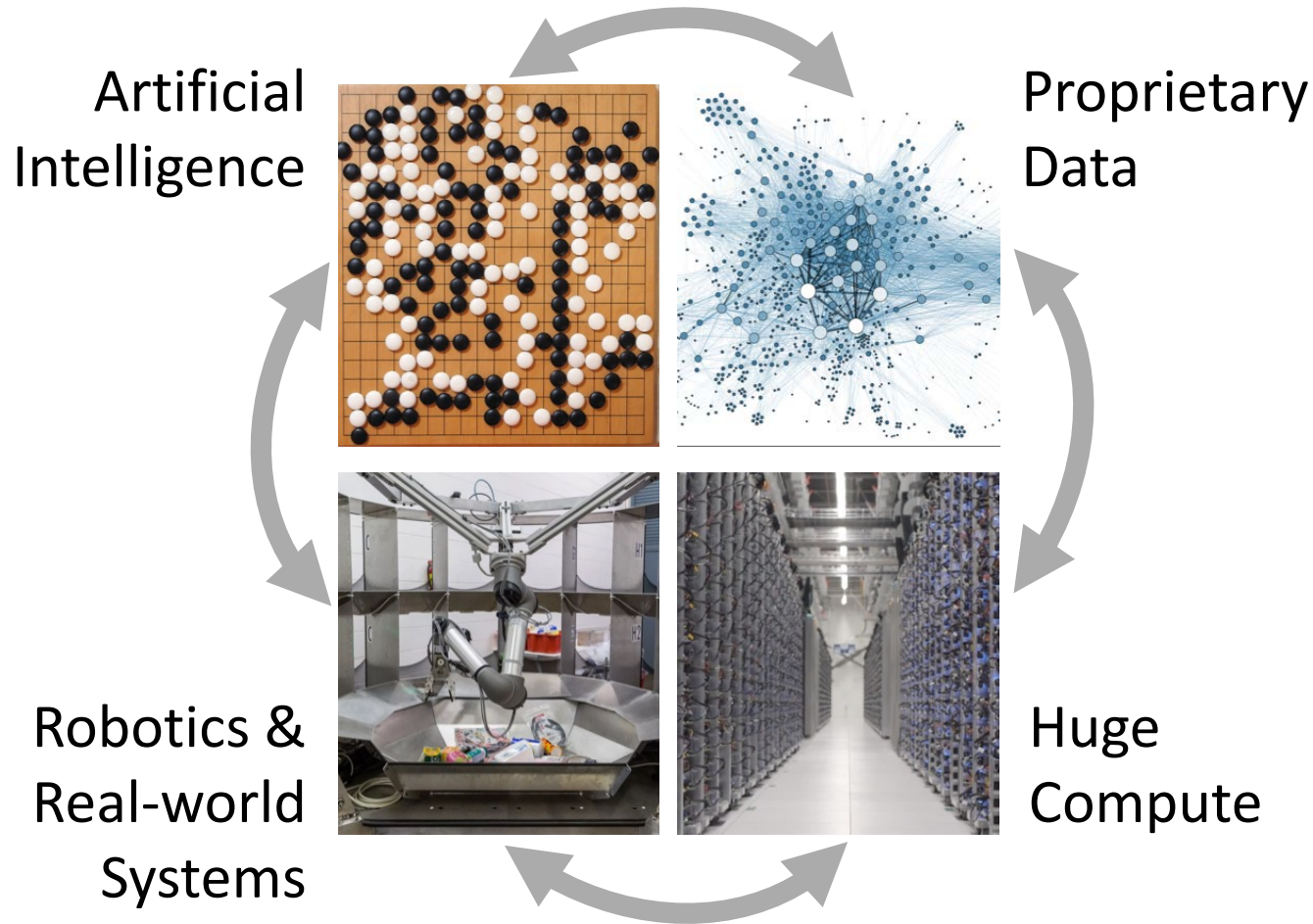
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# Who We Are: A Venture Firm Investing at the Intersection of AI and Challenging Problems



- \$1.7B under management across 8 funds
- Average check size for first money in ~\$2–5M
- Series Seed, Series A
- Investors in Caption Health, Subtle Medical, Freenome, many others!

We call this “Deep Tech”

# Why Is This Topic Important?

- Tech entrepreneurs have much to give.
- The world of regulated devices for healthcare is often new and intimidating.
- It's important that entrepreneurs and investors alike understand the regulatory process.

# Direct Entrepreneurs to Understand How Regulations Help Strengthen the Business



- It's not just a requirement. Companies benefit from strong clinical evidence. Credibility is key!
- Guide entrepreneurs to define what they should want to demonstrate and why it's important to clinicians and patients.
- The FDA regulates claims about the safety and effectiveness of technology – so knowing what you want to say to your customers is critical. The process gives you a chance to provide evidence!

# Understand the Regulations Early

- Learn what Class I, Class II, Class III, 510(k), *de novo* 510(k) classifications are and why they're important!
- Encourage entrepreneurs to hire a regulatory affairs expert EARLY in the company's history.
- Understand how the regulatory pathway may impact product requirements.

***Strong Product – RA collaboration is key!!***

# Be Transparent!

- Encourage a dialog between Investors / Board and the entrepreneurs early in the life of the company about claims and the likely path to those claims.
- Instill a value that building a solid relationship with the FDA reviewer and being candid is critical to success.
- Be up front and open about challenges, always.

# Understand What Regulations Mean for Your Fundraising Timeline and Goals



- Understand what personnel a company will need to hire to support a successful study:
  - VP/Director of Regulatory & Clinical Affairs and Field Specialists?
- Develop a timeline for these hires well ahead of when a study starts!
- Incorporate this information into the entrepreneur's projected cash needs.
- *Work to integrate the entrepreneur's regulatory strategy into the narrative of your company's story for investors, partners, potential board members – everyone!*



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**>C** | **Collective**