Fundraising Strategies for Digital Health Companies

ΣEB LifeSciences Working Group

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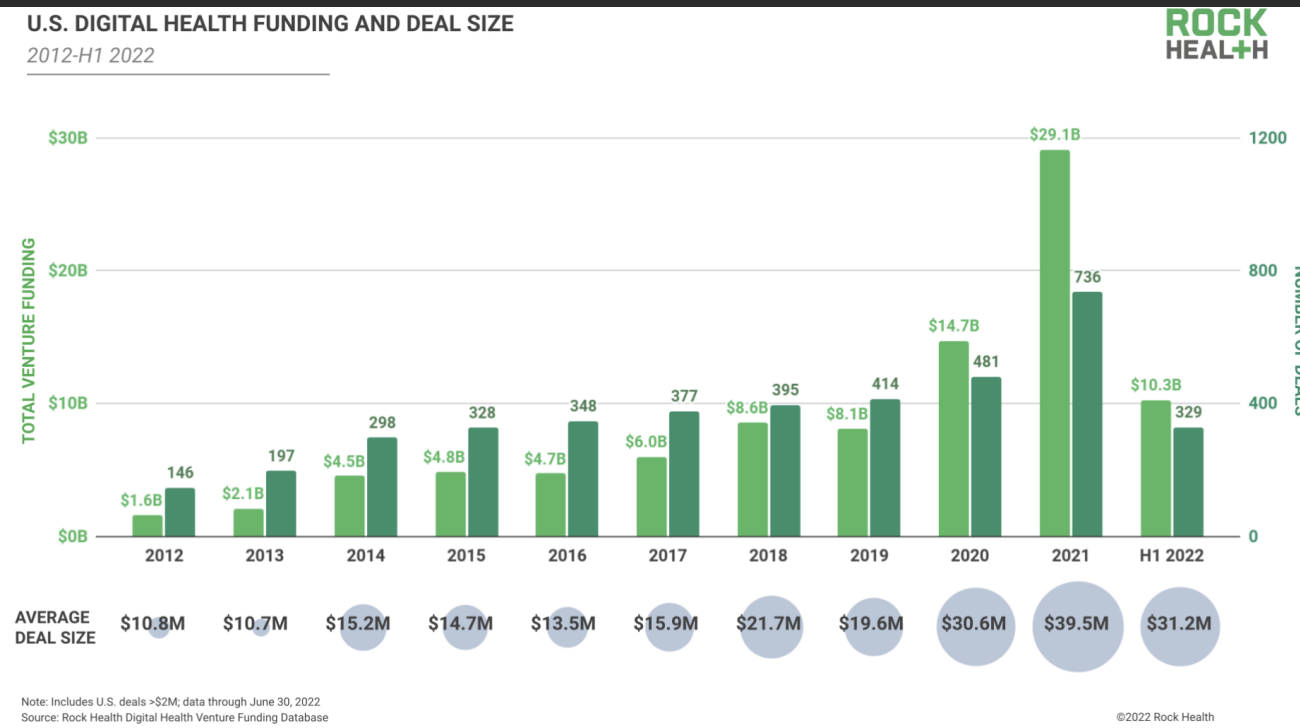
Funding for Digital Health in Choppy Watters Not a good time to fundraise

- Investors mainly supporting existing portfolio investments.
- Overall number of deals has declined significantly
- Smaller funding sizes and valuations



Digital Health or Digital Medicine?

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Digital Health or Digital Medicine?

Unregulated vs Regulated

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Digital Health or Digital Medicine?

Unregulated vs Regulated

Depends on the Claims

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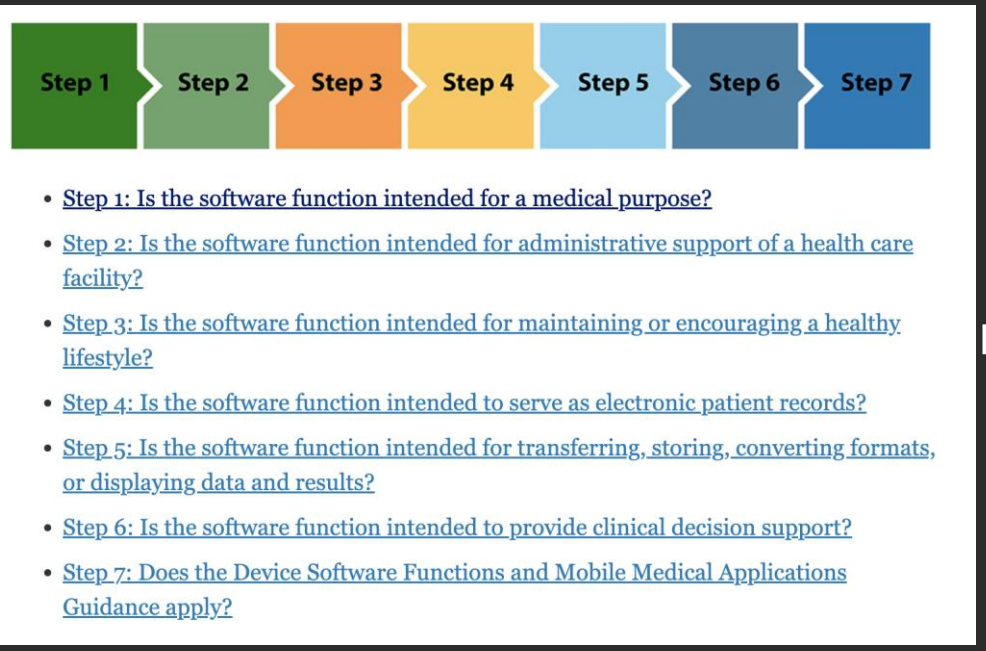
FDA Digital Health Policy Navigator



Icon	Outcome	Meaning
	LIKELY NOT A DEVICE	Device requirements do not apply if the software function is not a device.
	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION	Some software functions may meet the definition of a device, but because they pose a lower risk, the software function may fall within FDA's enforcement discretion policy (meaning that the FDA does not intend to enforce applicable requirements under the FD&C Act at this time).
FDA	**LIKELY THE FOCUS OF FDA'S REGULATORY OVERSIGHT**	The software function is a device and its functionality could pose a risk to a patient's safety if the device were to not function as intended. Devices may be subject to requirements such as premarket authorization (e.g., premarket notification (section 510(k) of the FD&C Act), De Novo (section 513(f)(3) of the FD&C Act), premarket approval (section 515 of the FD&C Act)), adverse event reporting (section 519 of the FD&C Act), among others.
	Your product may be a device. Go to Step #.	More information is needed to identify the relevant policies. Go to the next Step.

Regulated (FDA, CE): **Medtech Investors**
Usually $MM, Clinicals, Several Years

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Regulated (FDA, CE): Medtech Investors Usually $MM, Clinicals, Several Years

Example: Watch ECG for Atrial Fibrillation

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UnRegulated: Digital Health Investors Usually ‘000s Users, $M and 1-2 Years

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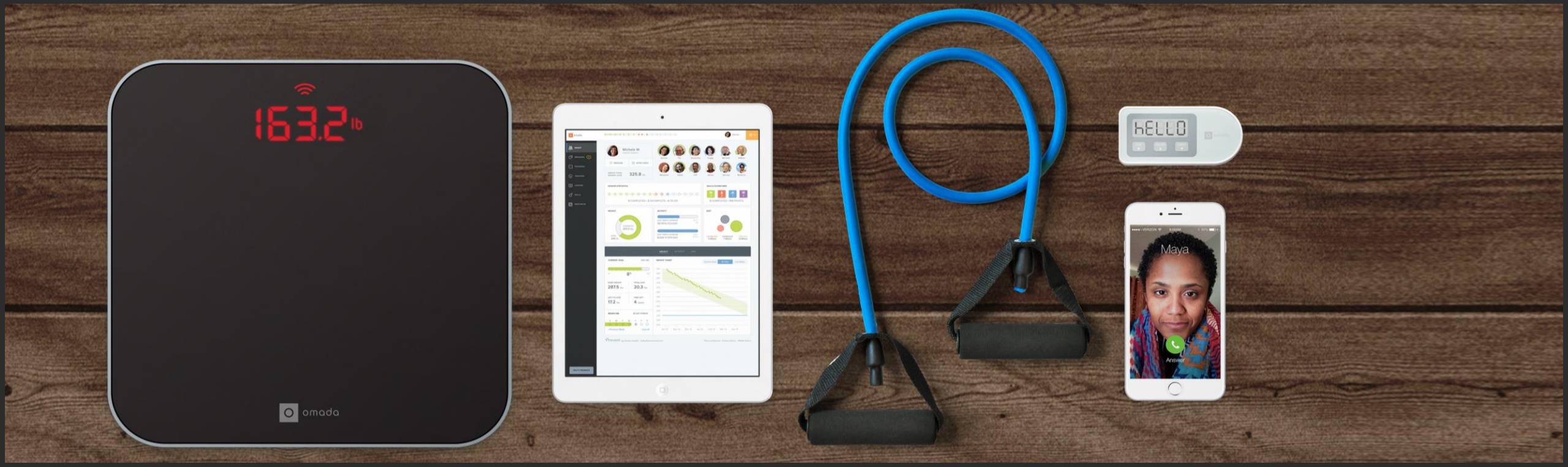
UnRegulated: Digital Health Investors Usually ‘000s Users, $M and 1-2 Years

Example: Weight Management Exercise Platform



Hybrid:
Start with Unregulated, Transition to Regulated once you have enough data

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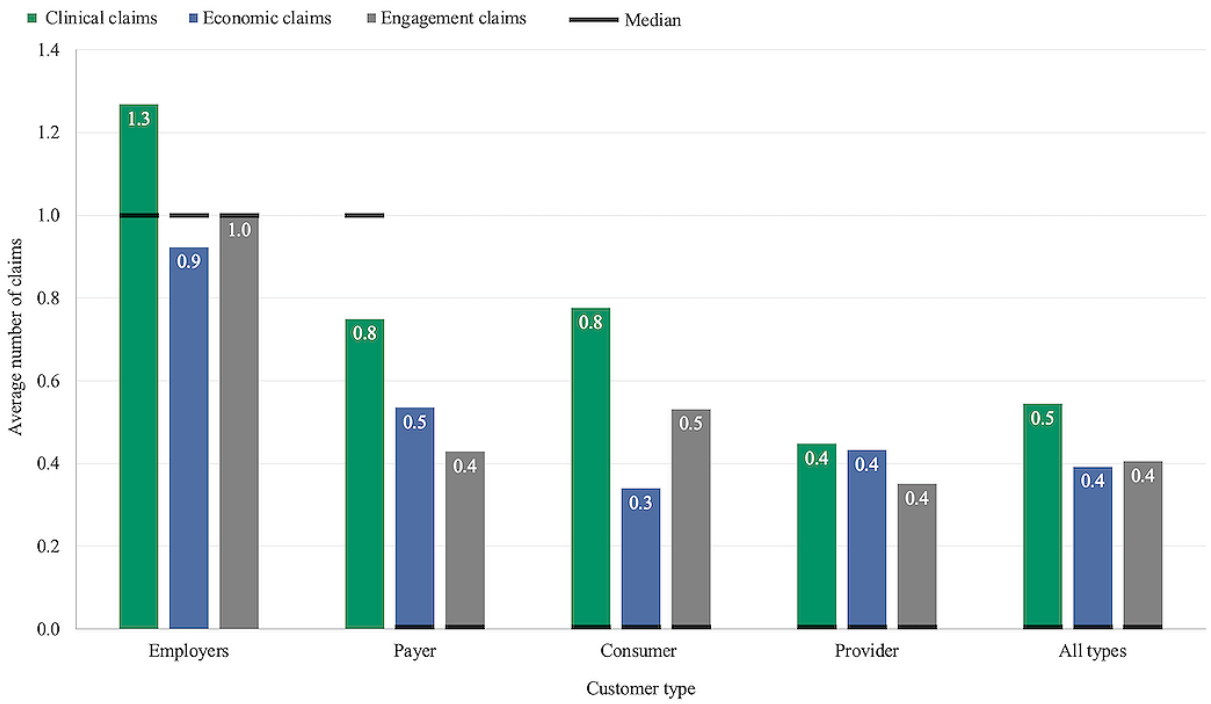
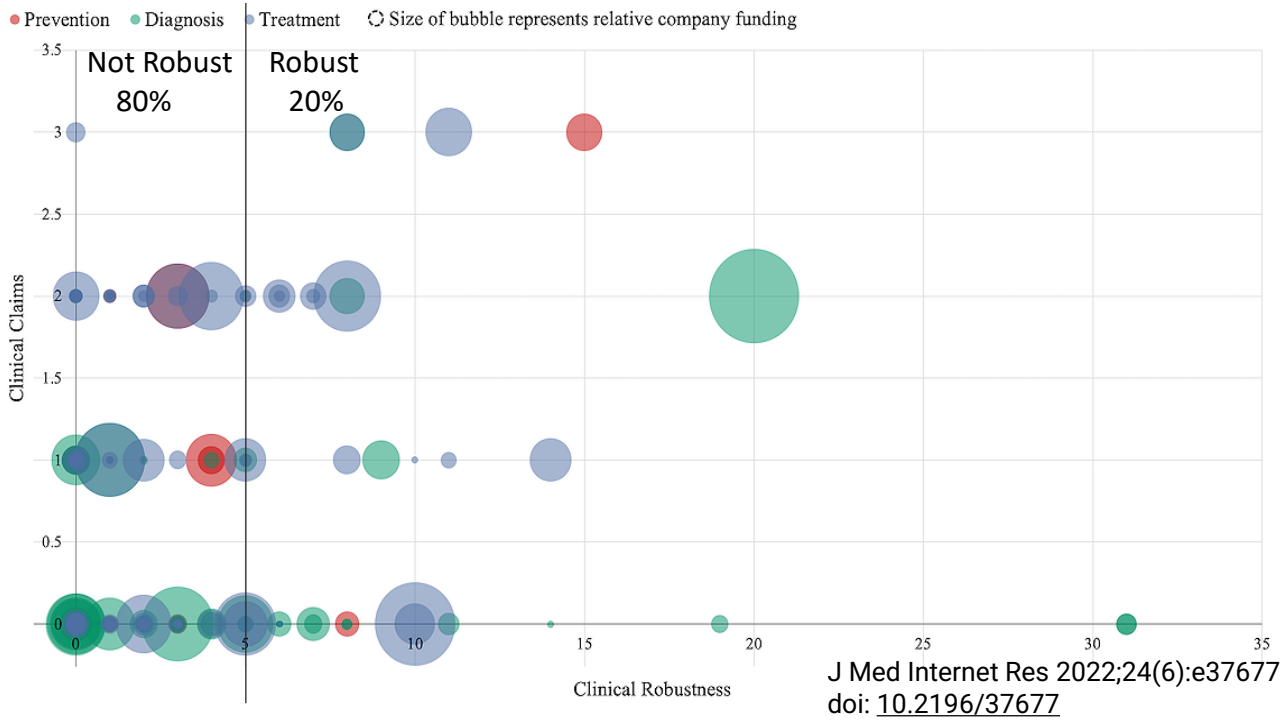
Gap between Marketing and Evidence

- Vast majority (80%) of VC funded DH companies lack meaningful evidence. 44% have zero Claims.
- It's time to get serious. Deflation eminent (personal opinion)





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Unregulated
Go FAST

-Make sure you have the right claims if any
-Try to acquire users as soon as possible
-Try to acquire contracts, if possible

Regulated
Build Clinical Evidence

-Prove that science works
-Build Quality System and Design History early
-Engage Academic Centers and KOLs
-Run Outcomes Clinical Study

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Contracts Contracts Contracts !

Try to get 1-2 contracts before going out to fundraise. **It helps a lot**.

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