

John Sharp, Senior Manager @PCHAlliance



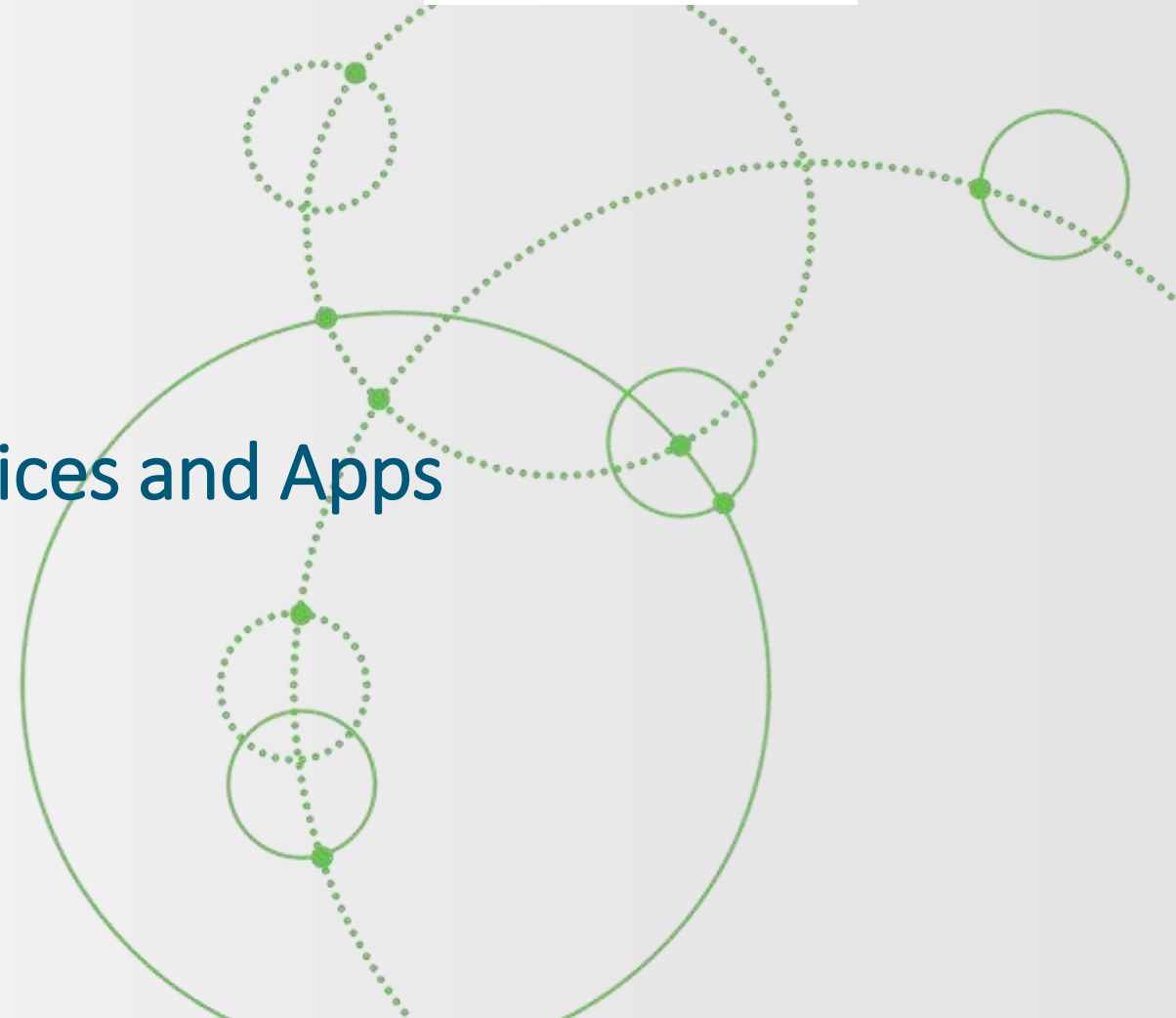
**Personal
Connected
Health
Alliance**



Building Consumer-Facing Health Devices and Apps and Doing it Right

HIMSS Delaware Valley Chapter 3/21/19

Disruptive Technologies: The Next Generation of Healthcare



Personal Connected Health Alliance

Help people make health and wellness an effortless part of daily life

- Focused on consumer-facing health technology
- More than 80 corporate members
- Key initiatives: digital therapeutics, behavior change, aging and tech and innovation
- Connected Health Conference – October 16-18, 2018, Boston
- Continua Design Guidelines for Patient Generated Health Data
- A HIMSS Innovation Company

#Connect2Health

My experience

- HIMSS staff since 2013
- Previously at the Cleveland Clinic in Clinical Research Informatics
- Advisor for Healthbox and the Medical Capital Innovation Competition
- Adjunct Professor, Health Informatics, Kent State University



Key Points Today

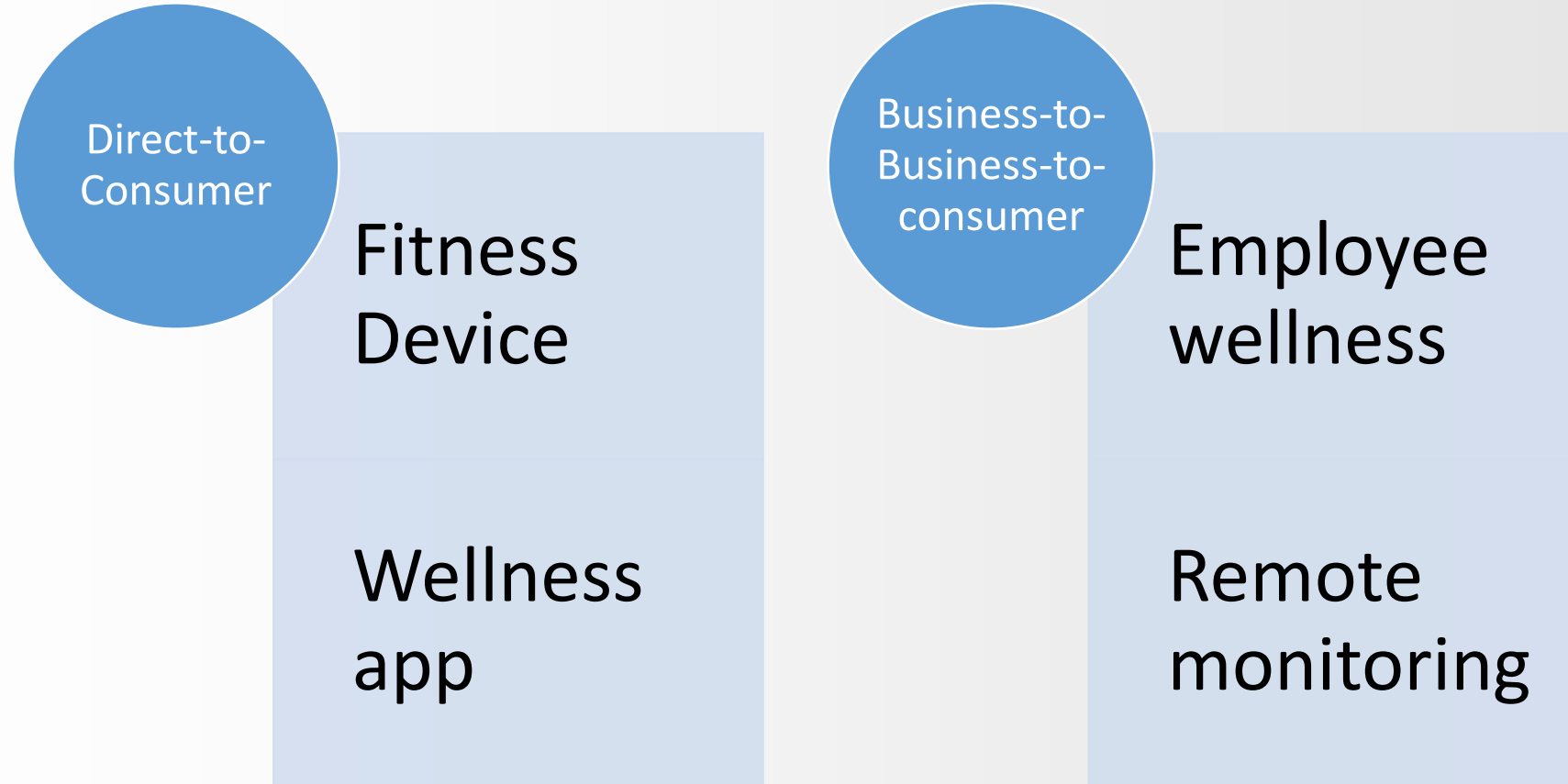
- Developing an app or device which solves a problem
- Which integrates into clinical workflow or consumer's lifestyle
- Understand the market
- Prototype, Pilot, Adopt, Scale
- Understand the regulatory pathway
- Importance of Evidence
- Changing Health Behaviors
- Data integration



Developing
something that
solves a problem

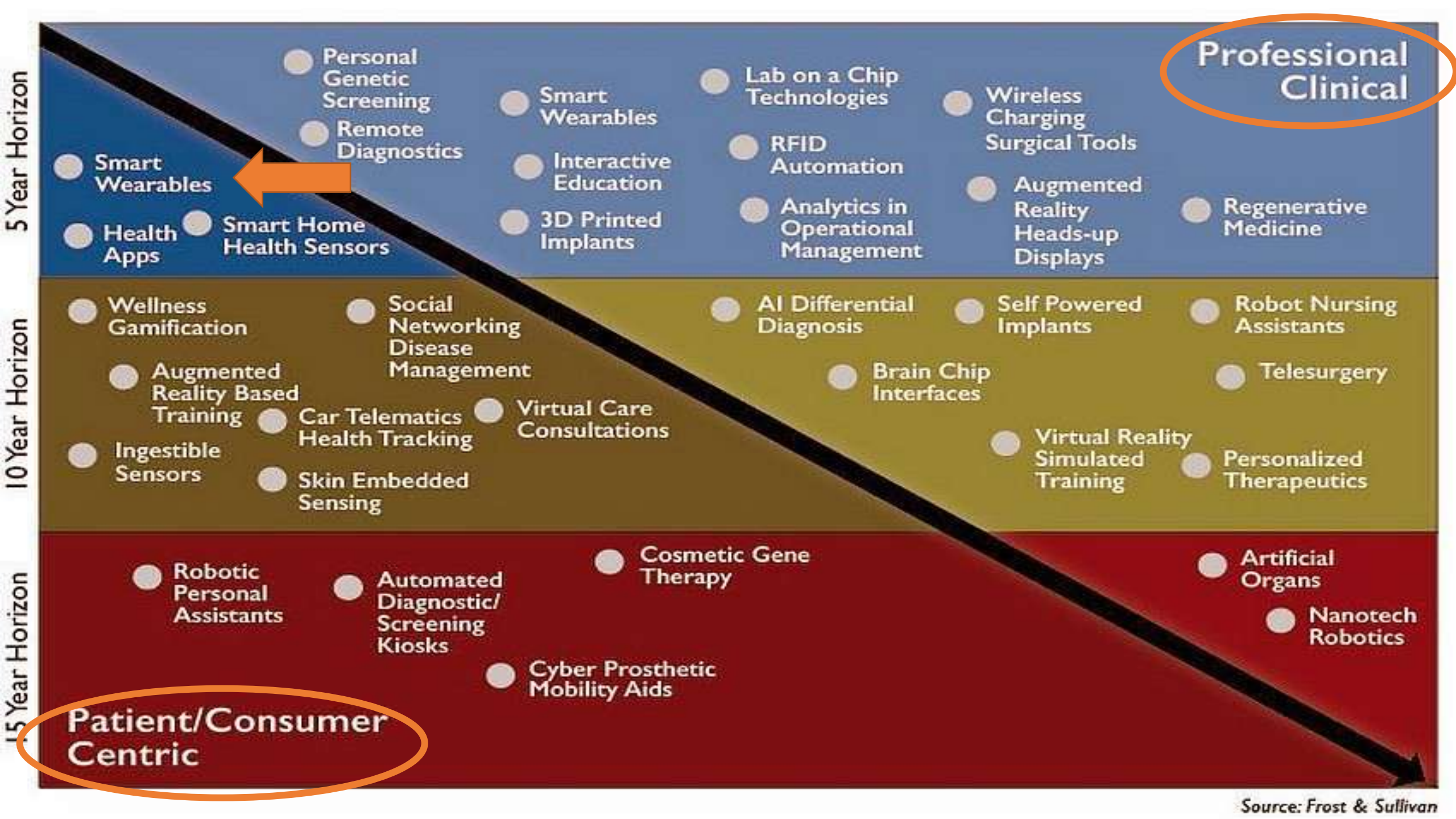


Developing a Solution



Understanding the Market



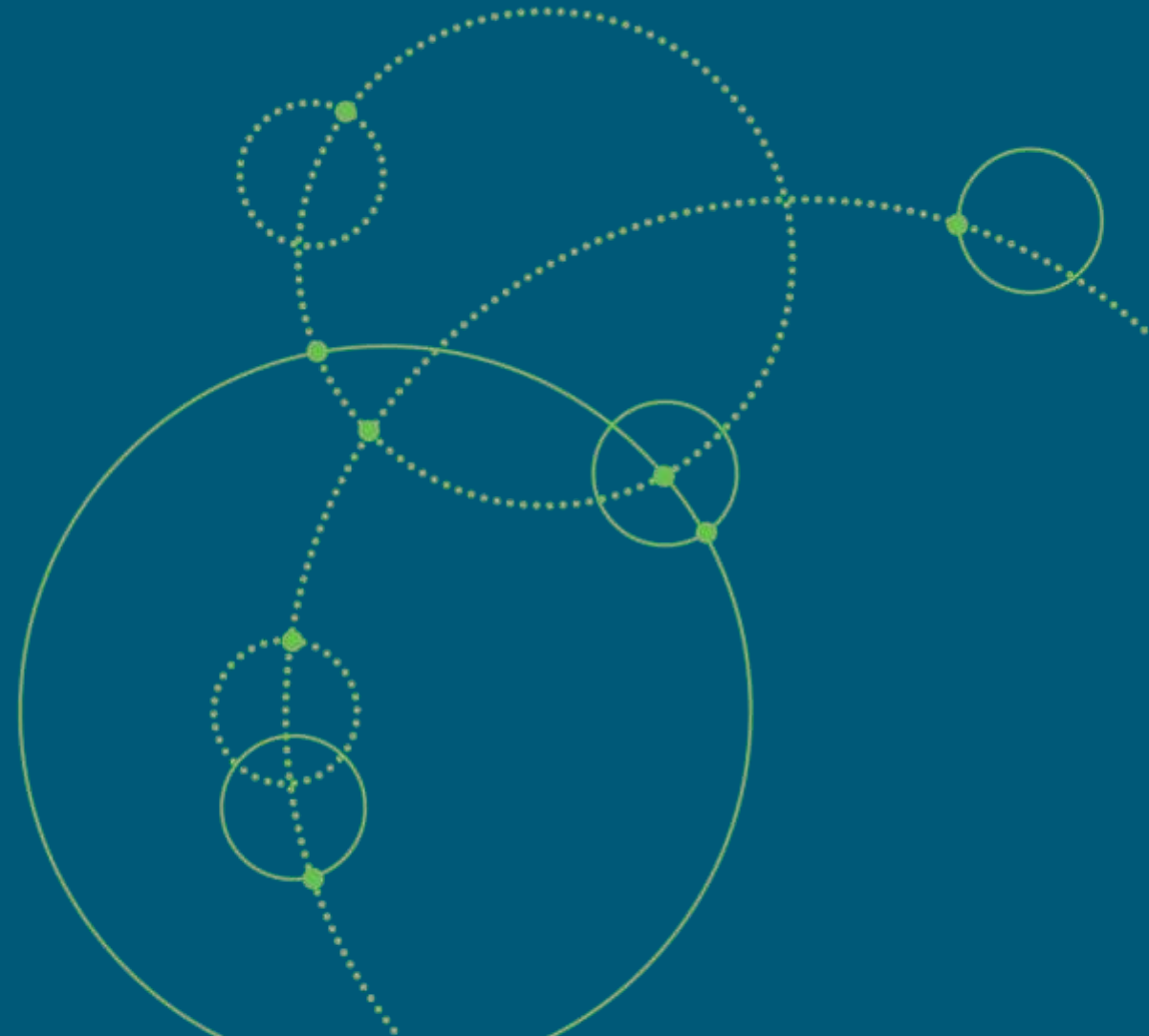


➤ **Prototype**

➤ **Pilot**

➤ **Adopt**

➤ **Scale**



When to **Prototype**, **Pilot**, or **Adopt and Scale** a Solution

Has the digital solution shown rigorous clinical and business effectiveness in similar circumstances and for particular therapies, patients and conditions?

No

Yes

Has it been tested in any form within any healthcare system with promising results?

Are there any doubts of effectiveness at scale within your system?

Yes

Digital Pilot

Yes

No

Are you just trying to provide it might be possible?

Are you trying to provide clinical effectiveness?

Are you trying to prove effectiveness at scale?

No

Digital Prototype

Rapidly test MVPs to prove concept. Move to feasibility study if promising
Consider a Pilot Next

Feasibility

Test to see if it might work using shortest period and to get quality feedback from end users fast
Consider Efficacy Pilot Next

Efficacy

Use more traditional clinical trial approaches to determine if outcomes are achieved
Consider a Scale Test or Adopt and Scale Next

Scale Test

Select "Early Adopters" for scaled pilot and determine adjustments to scale
Consider Adopt and Scale Next

Adopt and Scale

Adopt solution and invest in change management and communication tactics to rapidly scale

Partnering with Health Systems



- Good news – many have innovation centers as a point of entry
- Find a physician or administrator as a champion
- Not your typical funding pitch
- Do they have the problem you are trying to fix?
- Does it save time for physicians?
- Is there a potential ROI? Does it take cost/complexity out of the system?
- Does it integrate with their EMR or other key systems?

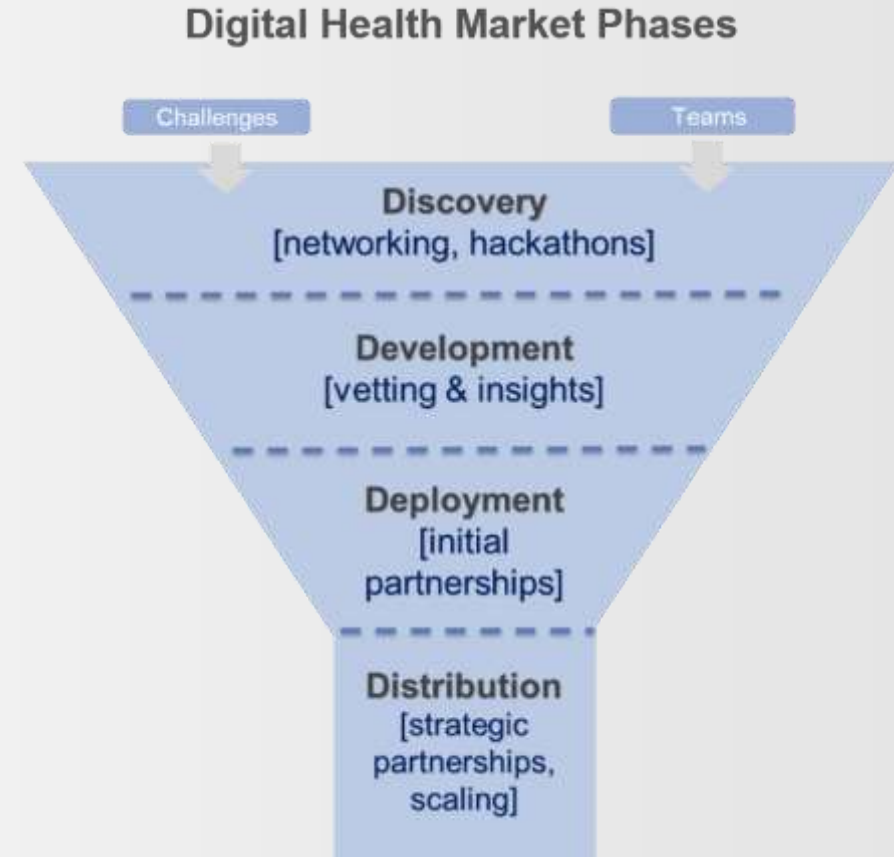
Is the IT department
the wood chipper
for Innovation?



Getting to Scale

- Right partners
- Technology that scales
 - Wearable production
 - Managing thousands of users
- Business model
- Appropriate funding
- Turn Solutions into Strategy
- Potential exit

See [Can We Achieve Scale in Innovation? – NEJM Catalyst 2017](#)





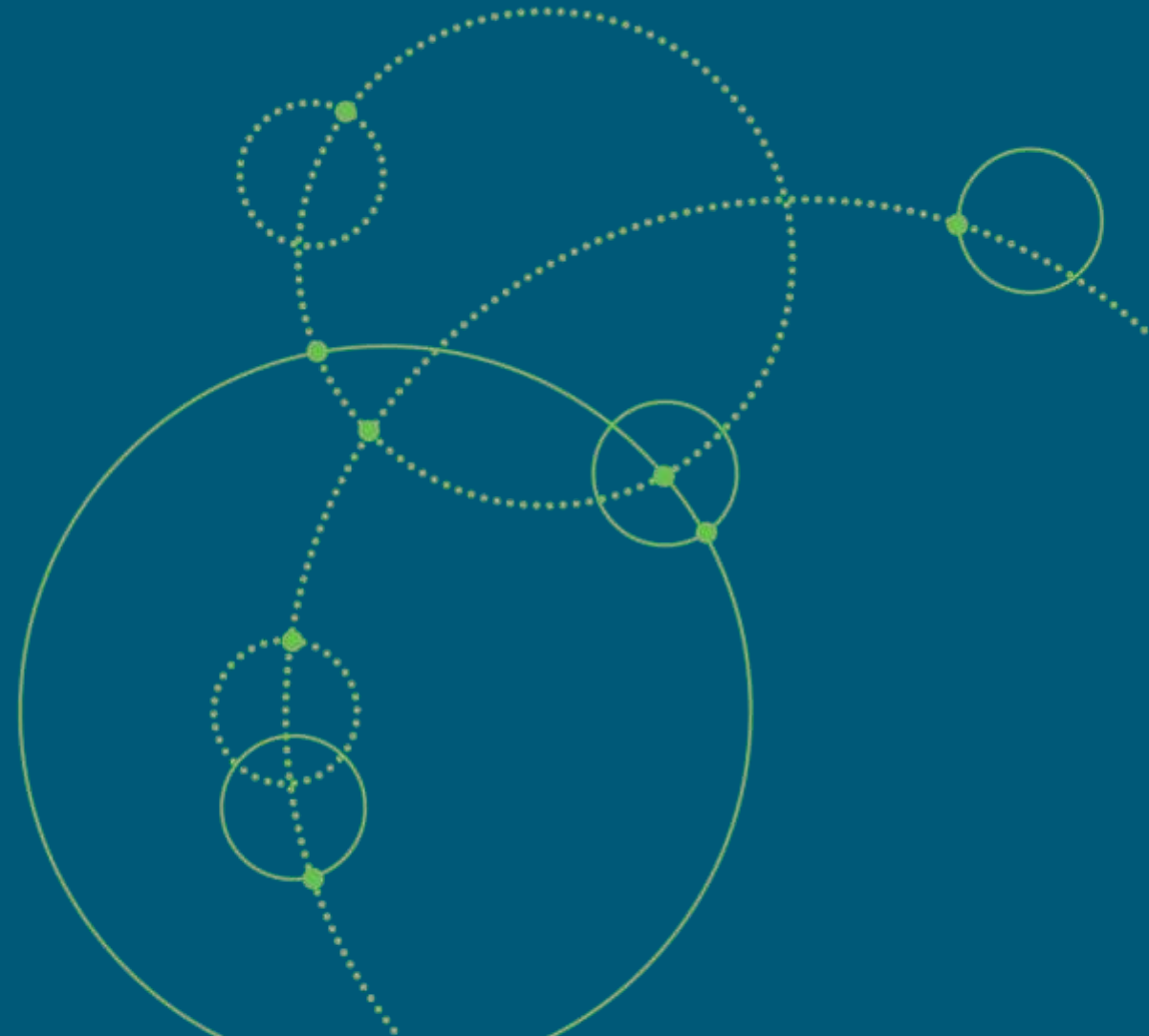
Now part of the HIMSS family

- ✓ Innovation consulting
- ✓ Fund management/Strategic Investing
- ✓ Commercialization Analysis

Headquartered in Chicago



Regulatory Pathway



Clinical Apps and Devices

- ❖ Software as a Medical Device (SaMD) – now defined by the FDA
- ❖ software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device
- ❖ SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- ❖ Mobile apps that meet the definition above are considered SaMD

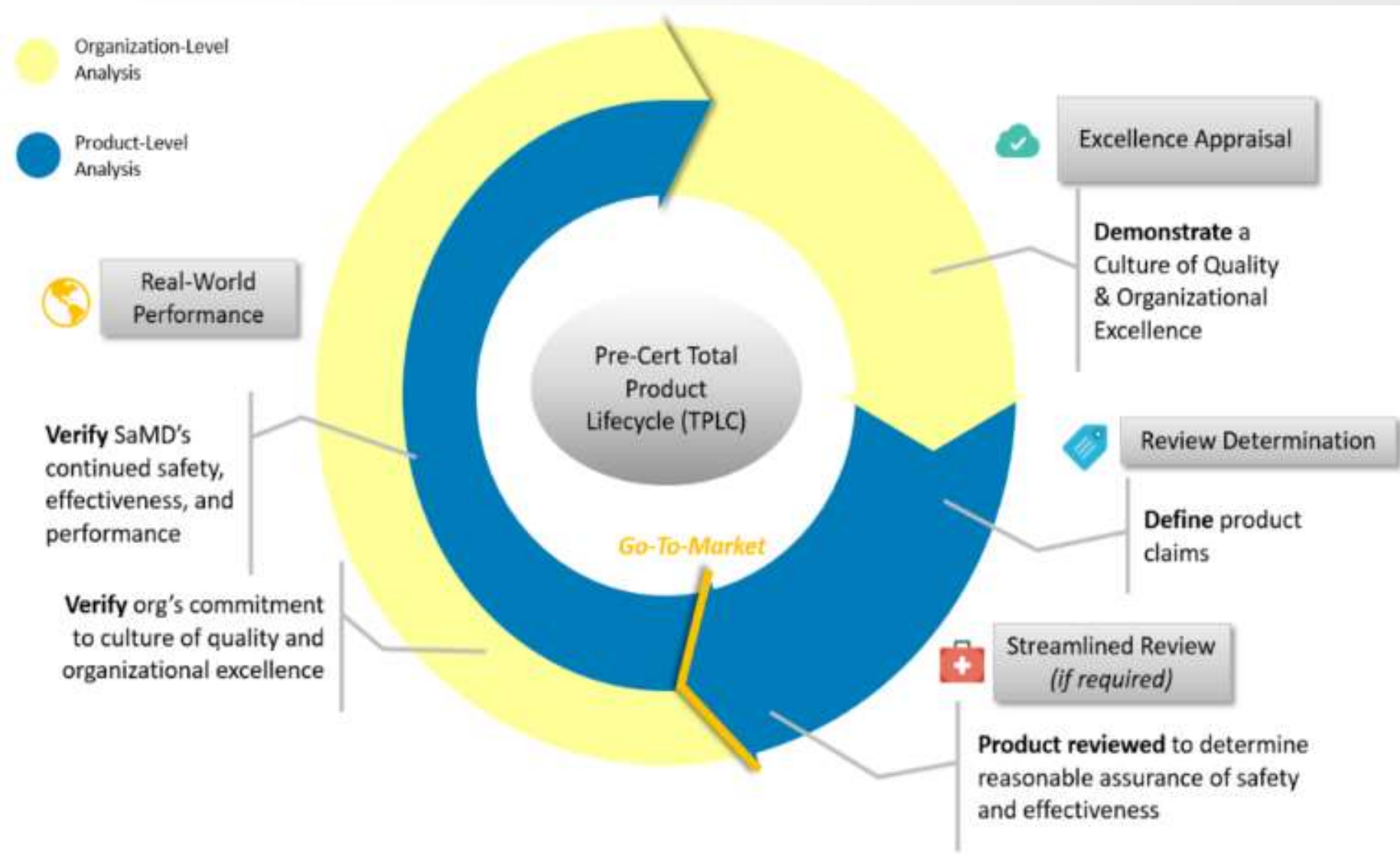


Software as a Medical Device – Examples



- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- provide means and suggestions for mitigation of a disease (clinical decision support)
- be an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

Digital Health Software Precertification (Pre-Cert) Program



Who Is Currently Involved in the Pre-Cert Pilot Program?

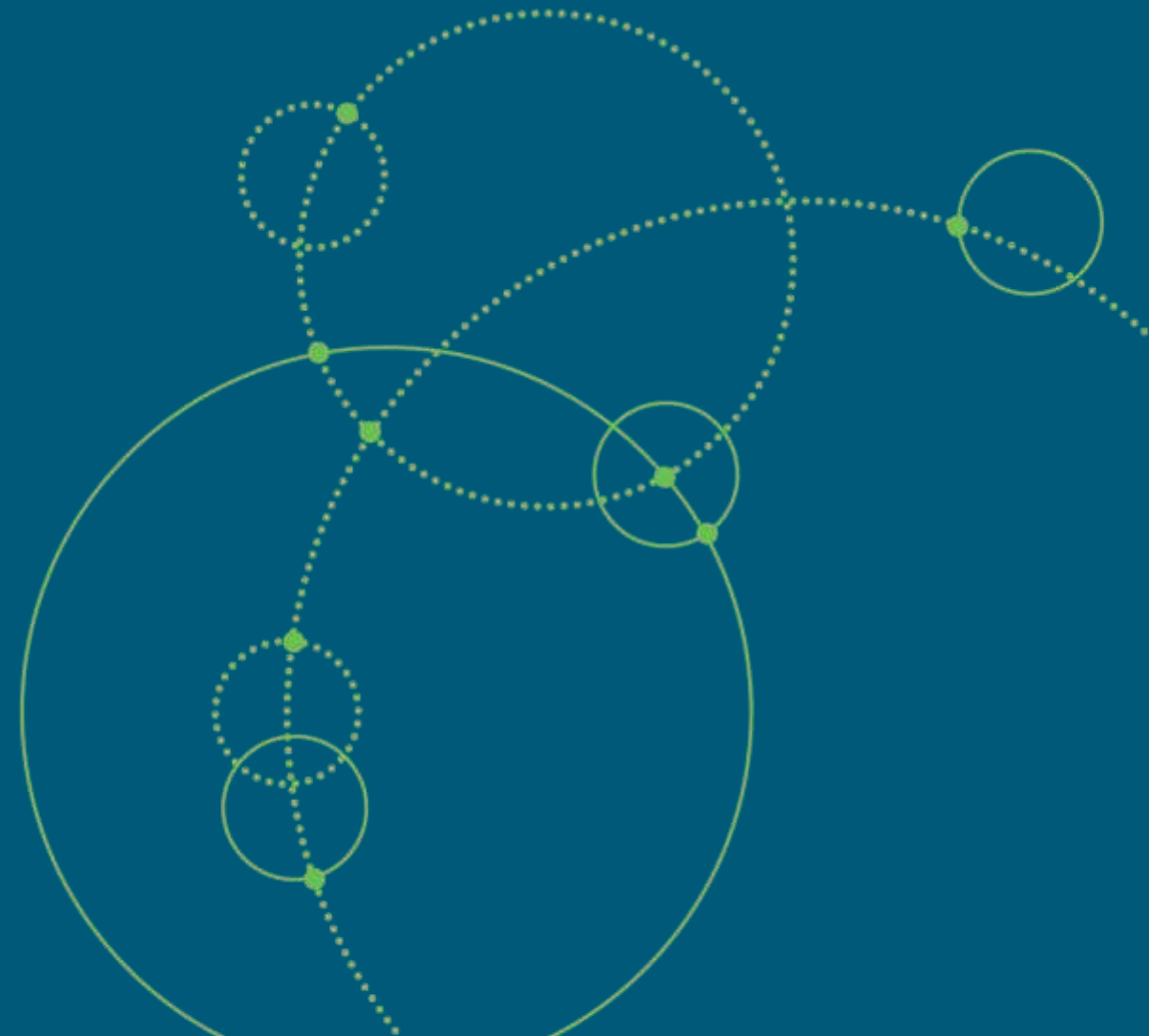
- Apple
- Fitbit
- Johnson & Johnson
- Pear Therapeutics
- Phosphorus
- Roche
- Samsung
- Tidepool
- Verily



When to Conduct a Study and IRB

Type of Study	Conduct a study?	Need IRB review?
Clinical efficiency	Yes, validation	No
Clinical Decision Support	Yes	Yes, since it directly impacts patient care
Patient Education	Maybe	Apply for an exemption from the IRB
Wellness device	Yes, validation and outcomes	Probably not
Medical device used for remote monitoring	Yes, validation and outcomes	Yes
Mobile app to manage a chronic condition	Yes, validation and outcomes	Yes
Mobile device to manage a chronic condition	Yes, validation and outcomes	Yes, may also be subject to FDA review
IoT or supply chain	Some validation	No

Developing Evidence



Deloitte Center for Digital Health Solutions

Evidence of health technology benefit for providers

A mobile working solution for community nurses



A telehealth hub across 210 care homes



Evidence of health technology benefit for patients



Patients using technology to manage their COPD:





Network of Digital Evidence

- Combine the rigor of Evidence Based Medicine (EBM) with emerging healthcare technologies to help create ***evidence-based digital medicine***
- More than 40 health systems participating
- Monthly newsletter
- www.nodehealth.org
- New article on Clinical Validation in Digital Biomarkers

The Challenge of Health Behavior Change

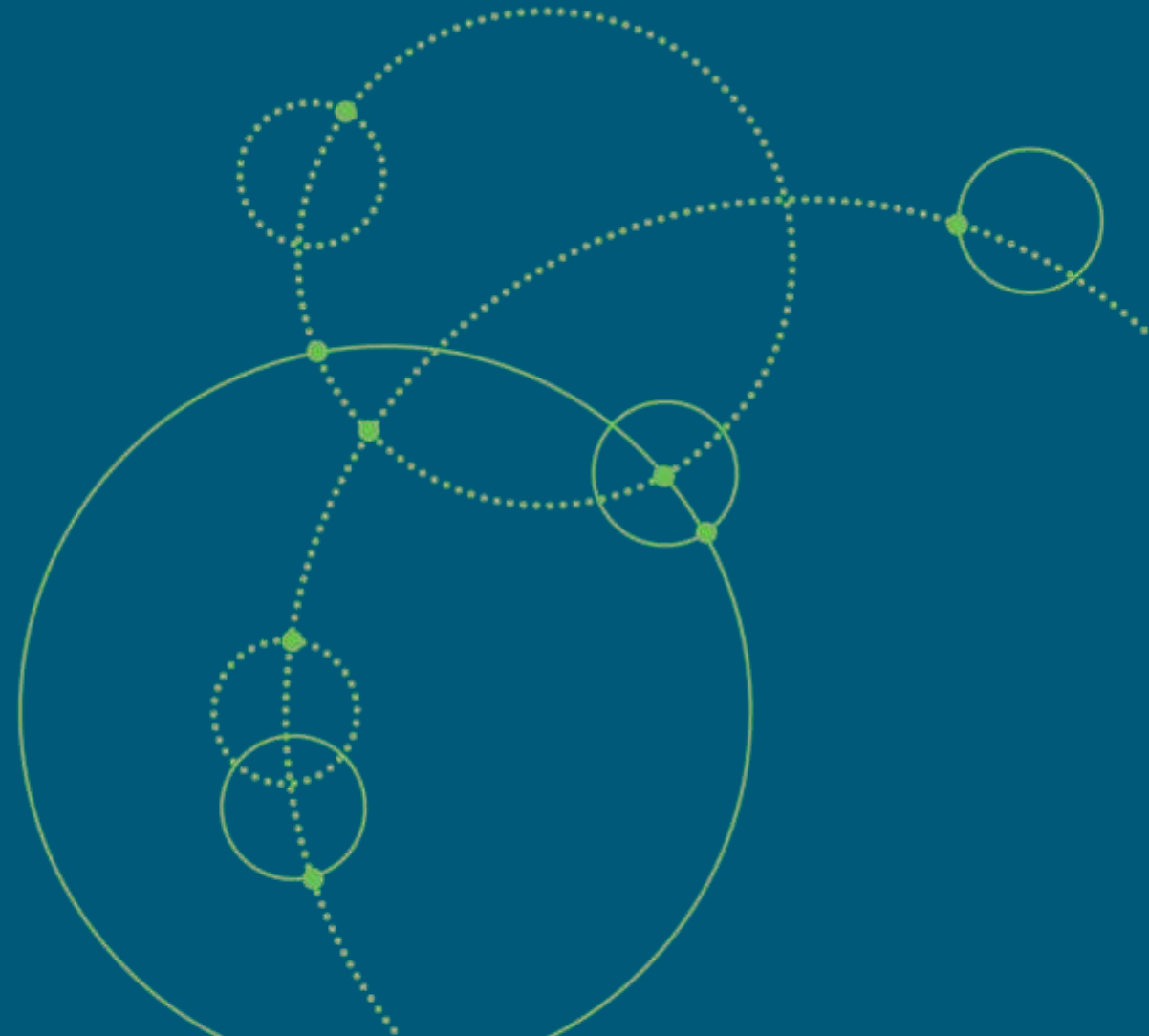


The experts - Society of Behavioral Medicine

A multidisciplinary organization of clinicians, educators, and scientists dedicated to

- promoting the study of the interactions of behavior with biology and the environment
- then applying that knowledge to improve the health and well-being of individuals, families, communities, and populations.
- From medication adherence to weight loss to smoking cessation and more...
- www.sbm.org

Data Integration



Continua Design Guidelines

- ❑ Authentic interoperability – connectivity requiring minimal effort on the part of the user
- ❑ Open source development model – the Continua Design Guidelines are universally accessible, non-proprietary and not for profit
- ❑ Flexibility – designed to provide maximum choice for developers and end users (healthcare buyers, individual clinicians and consumers)
- ❑ Wisdom of the market – the market in aggregate has more wisdom than any individual stakeholder; thus the Continua Design Guidelines are developed through a consensus process
- ❑ Now uses FHIR standard
- ❑ <http://www.pchalliance.org/continua-design-guidelines>

Apple Health Kit



As an EHR and app integration tool.

When a customer provides permission for your app to read and write health and activity data to their Health app, your app can become a valuable health data source.

Also uses FHIR

Instructions for how to integrate with Apple Watch

<https://developer.apple.com/healthkit/>



Fast Healthcare Interoperability Resource

Exchangeable content is defined as a resource

- A common way to define and represent them, building them from data types that define common reusable patterns of elements
- A common set of metadata
- A human readable part

Uses RESTful Web services

Patient Generated Health Data on FHIR from Continua



What's Next?

- ❑ Technology uses yet to be discovered
 - ❑ More functions for wearables
 - ❑ Implantables, ingestibles
 - ❑ Apps for more conditions
 - ❑ Digital Health Platforms
- ❑ New business models
- ❑ More evidence including on health behavior change
- ❑ More customer convenience
- ❑ Broader partnerships

Digital transformation

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Contact

[LinkedIn.com/in/johnsharp](https://www.linkedin.com/in/johnsharp)

[@johnsharp](https://twitter.com/johnsharp)

jsharp@himss.org



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Thank you

