Agile Product Development for Digital Medicines
The Journey Continues

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INCOSE
Healthcare
Working Group

5th Annual Systems
Engineering in Healthcare
Conference

May 1-2, 2019
Minneapolis, MN

Eli Snell
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- Eli Snell leads the Software Solutions organization at Proteus Digital Health, responsible for software platform strategy and integration with corporate partners.

- Eli holds a B.S. degree in Computer Engineering and a M.S. degree in Electrical Engineering from California Polytechnic State University, San Luis Obispo.

Digital medicines ensure drugs work in the real world

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Did I take my drugs today?

How do my drugs affect my daily life?

Can my care team make the drug dose more specific?

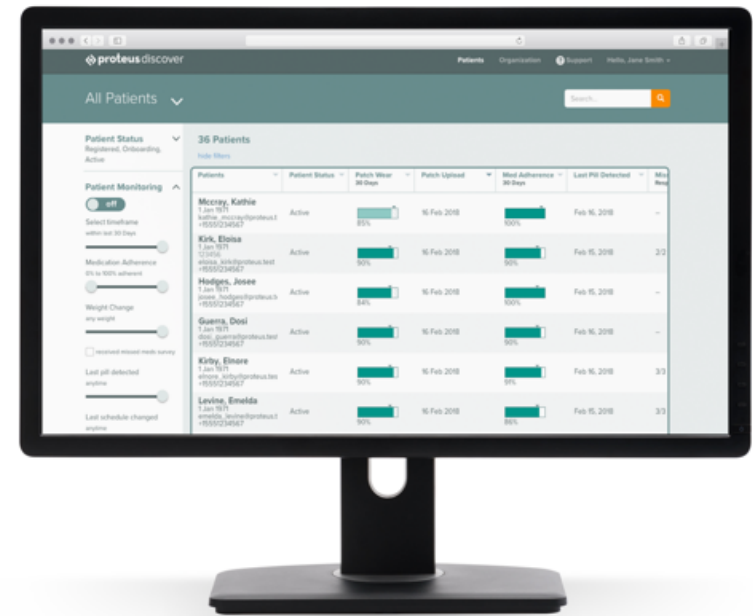**Is my drug taking delivering the outcomes I want?**

Used by Healthcare Teams

Used by Patients

Digital Medicines

Wearable Sensor

Patient Mobile App

Provider Web/EHR App

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Enabled by a unique ingestible sensor

The world's smallest, safest, global regulator approved medical device

Drug Blend

Silicon: 0.9mg
Bananas: 5mg
per 100 grams

Copper: 0.02mg
Cashews: 2.2mg
per 100 grams

Magnesium: 0.01mg
Halibut: 107mg
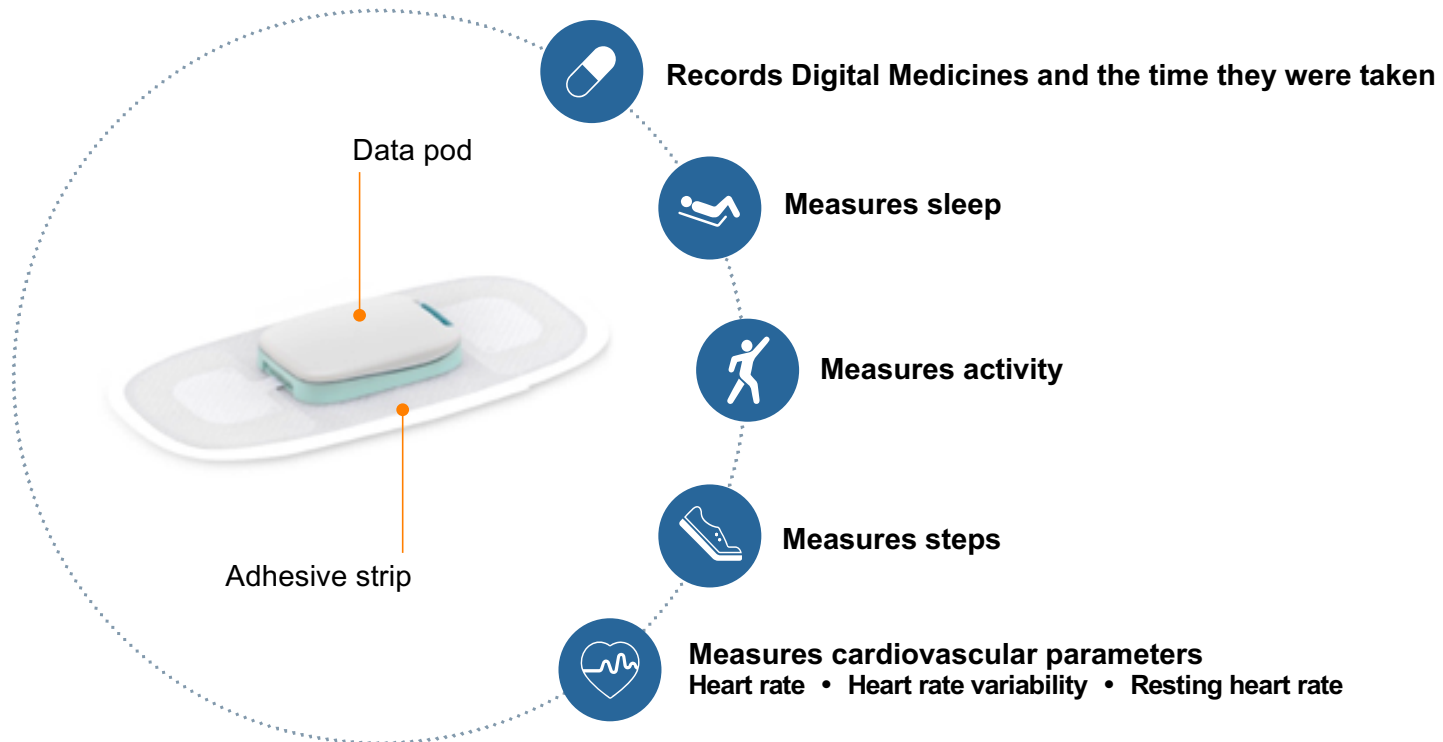per 100 grams

Proteus Ingestible Sensor

- **Cleared by FDA, CFDA, CE Marked in Europe**

- **Designed to be incorporated into medicines**

- **Supported by technology and data platforms**

Digital Medicine:

- Ingestible sensors enable digital medicines

- No change in size, shape or drug properties

Wearable sensor links drug taking to physiologic response

Beyond Digital Medicines, the Proteus Patch automatically captures relevant biometric data

Data pod

Adhesive strip

Records Digital Medicines and the time they were taken

Measures sleep

Measures activity

Measures steps

Measures cardiovascular parameters
Heart rate • Heart rate variability • Resting heart rate

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Three stages in our agile journey

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Presented in 2018

Scrum Essentials
- Scrum for Teams training for the entire Product organization and other key functions
- Formed new teams, emphasizing cross-functional participation
- Began following scrum best-practices at the team level

Quality System
- Revamped quality system to address compliance gaps and align with agile principles
- Created new Software Development Life Cycle SOP, with cross-functional participation
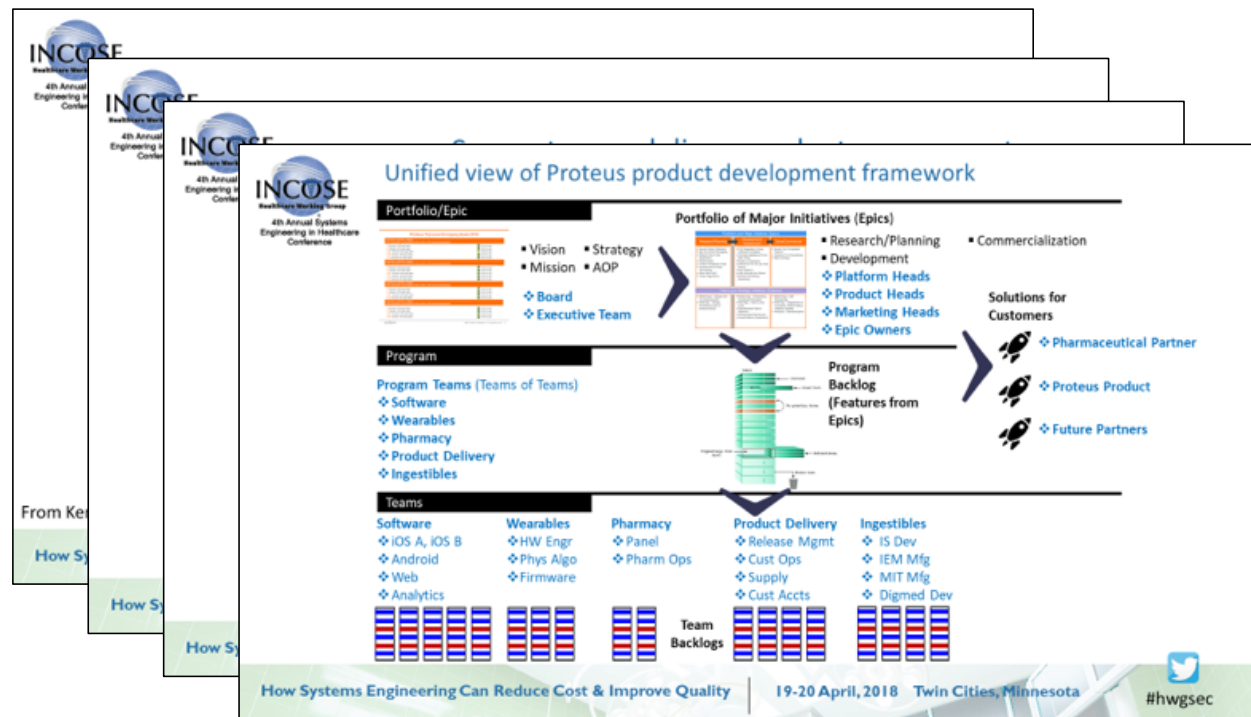- Updated tools and infrastructure to support the quality system

Scale
- Developed agile product development framework to coordinate across teams
- Formed "trains" to align similar teams

Scrum essentials and an agile quality system established a strong foundation

Topics covered in-depth at the 4th Annual Systems Engineering in Healthcare Conference in 2018

- Scrum Basics
- SDLC
- Team Structure
- Agile Framework

Three stages in our agile journey

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Scrum Essentials

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Quality System

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Scale

- System architecture to support multiple solutions on a common platform
- Team structures to support multiple solutions
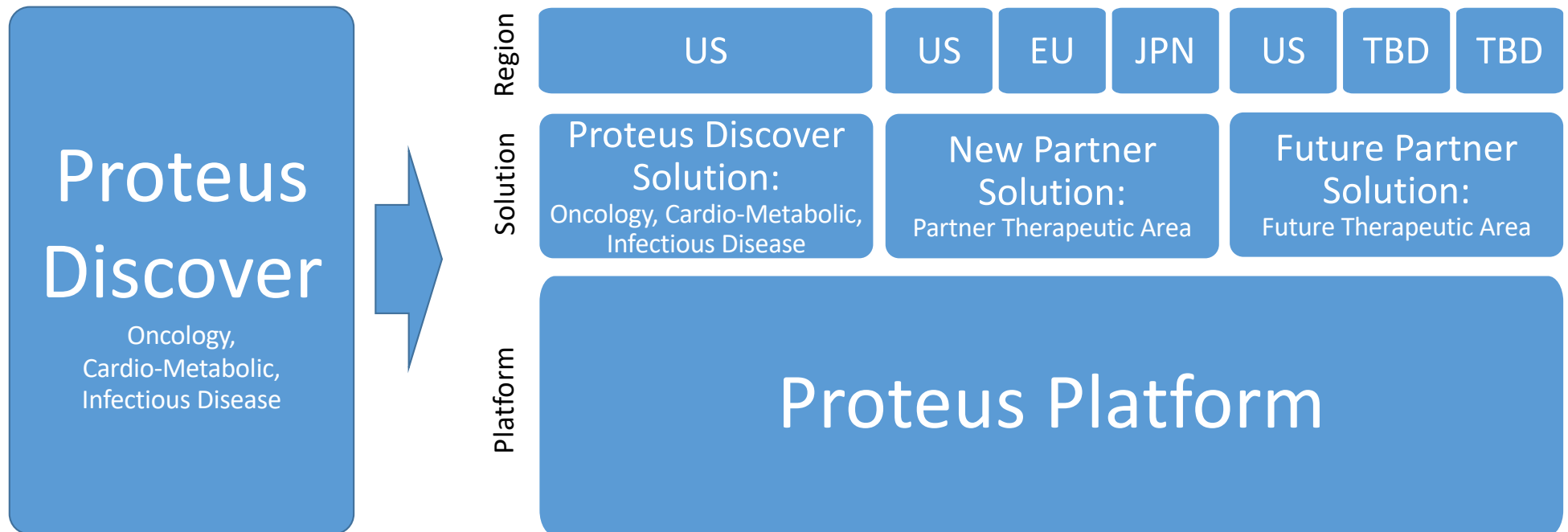- Agile processes to enable coordination across programs

Current Challenges

Challenges of scaling an agile organization

System
Architecture

Teams

Agile
Processes

Architect system to build solutions on a common platform, with regional variation

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Proteus Discover

Oncology, Cardio-Metabolic, Infectious Disease

Region

| US | US | EU | JPN | US | TBD | TBD |

Solution

Proteus Discover Solution:
Oncology, Cardio-Metabolic, Infectious Disease

New Partner Solution:
Partner Therapeutic Area

Future Partner Solution:
Future Therapeutic Area

Platform

Proteus Platform

Organize teams by Solutions and Platforms to plan, execute, and deliver products, solutions, and services

Solution Trains

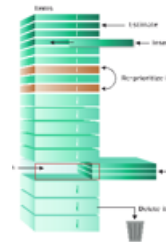### Discover Solution (Oncology, CMB, ID)
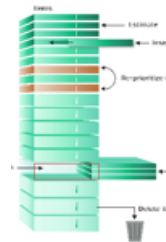
Train Leaders,
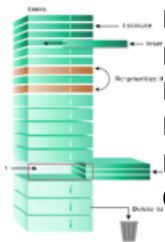Team Leaders

iOS
Android
Web

Partner Solution

Train Leaders,
Team Leaders

iOS
Android
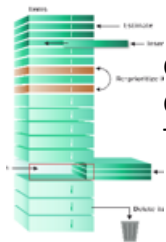Web

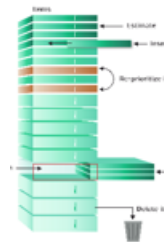## Platform Trains

Ingestibles Platform

IS Dev
IS Analytics
Mfg Automation
Process Int
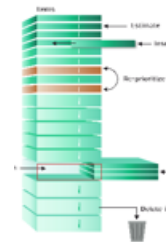Mfg SW
Operations

DigiMeds Platform

CMC Dev
CDMO
TechOps

Wearables Platform

Wearables Engr
Algorithms
Firmware

Software Platform

iOS
Android
Web
Cloud
Analytics
Systems

Update program ceremonies to enable scale

Program Backlog Grooming	• Prioritize and Define Features in the Program Backlog • Weekly
Scrum of Scrums	• Resolve Dependencies Between Scrum Teams • Weekly
Product Owner Sync	• Measure Progress, Adjust Priorities • Mid-Sprint
Program Review	• Share Metrics on Accomplishments • End of Sprint
System Demo	• Show Progress with Stakeholders • End of Sprint

Integrating partners into the planning framework enables frequent stakeholder input and high levels of transparency
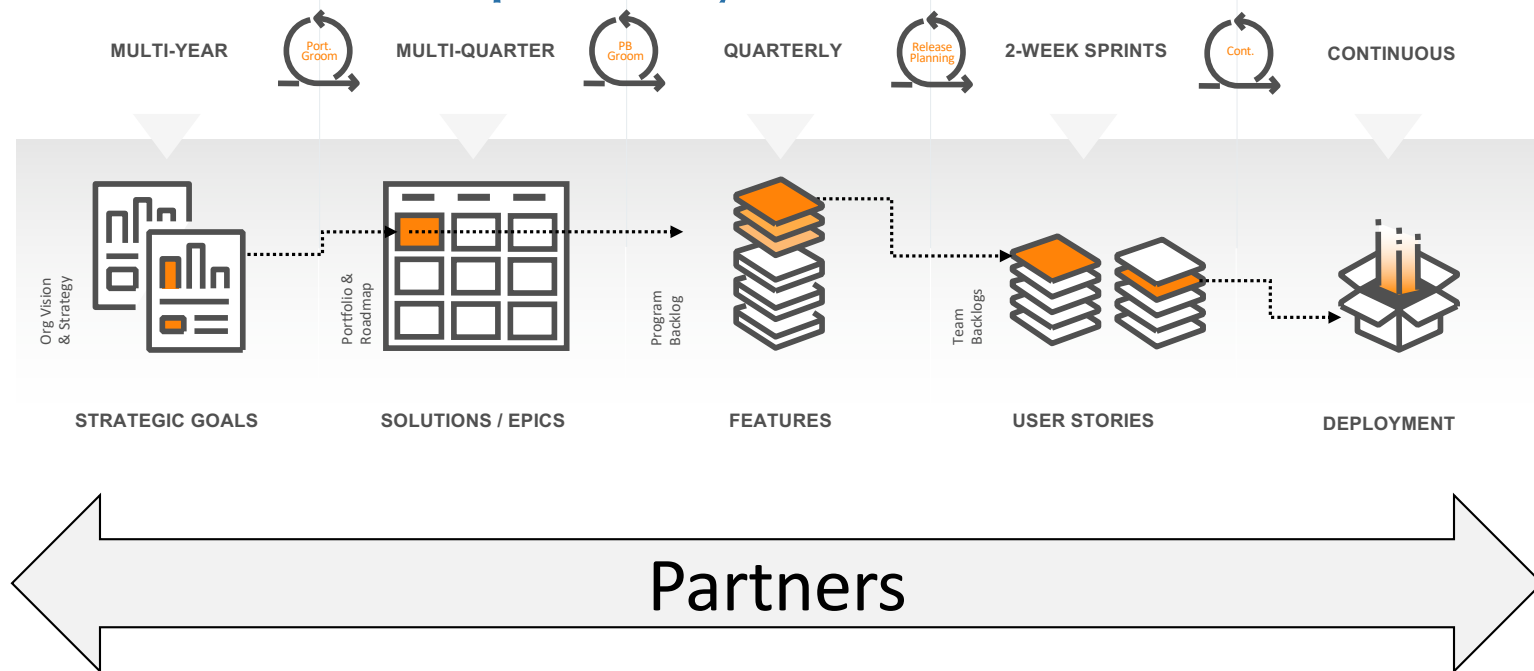
Conclusion: Scaling an agile organization requires retooling

- Modify system architecture to support building multiple solutions on a common platform

- Form programs with small, fully staffed scrum teams and strong leadership

- Update agile processes to support flow of work from corporate goals to team-level stories and provide a framework for coordination across teams

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