Medical Device Innovation Through Agile

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Nancy Van Schooenderwoert, *Lean-Agile Partners*

Brian Shoemaker, *ShoeBar Associates*

New Book

A new book of case studies in the use of Agile Methods for regulated medical product development. This new book is a follow-up to our earlier book *Agile Methods for Safety-Critical Systems: A Primer Using Medical Device Examples*.

The new book augments that introductory discussion with practical examples from companies that have employed an Agile approach to regulated medical product development. The cases we examine provide a variety of lessons for businesses looking to gain the benefits of Agile. Taken together, the stories also suggest the breadth of applications of Agile when you start to think outside the box of software development.

Complete info for buying it:

http://agilemethodsforsafetycriticalsystems.com/

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Who We Are

Brian Shoemaker

- *Originally an analytical chemist*
- *15 y in clinical diagnostics: analytical support → assay development → instrument software validation*
- *6 y as SW quality manager (5 in clinical trial related SW)*
- *16 y as independent validation consultant to FDA-regulated companies – mostly medical device*
- *Active in: software validation, Part 11 evaluation, software quality systems, auditing, training*

Nancy Van Schooenderwoert

- *Originally an electronics and software designer*
- *15 years safety-critical embedded systems development experience*
- *Since 2002: Agile coaching of teams and managers in regulated industries*
- *Industries: Aerospace (Flight simulation), Medical Devices, Sonar Weaponry, Scientific Instruments, Industrial Controls, Financial Services*
- *BSCE (Computer Engineering) from Rochester Institute of Technology*
- *Active in Agile New England & Agile Alliance; speaker at conferences worldwide*

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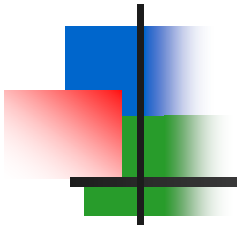

Thesis

Agile methods,
grounded on solid principles,
open up innovation in an
industry which *demands*
innovation.

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Innovation Through Agile

- Common themes - the principles we cite - appear in the cases we studied
- Autonomation & optimizing across organization: essential to Atomic Object / Neurometrix
- Trusting collaboration & autonomation allowed Inpeco to excel
- Flexible planning, shortened feedback loops: key to the Sanofi long view case
- All cases: innovation in process at least as important as innovation in product

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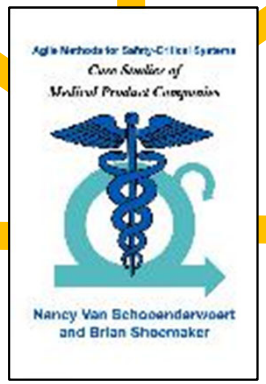
Case Study Companies

Clinical Trial Data Mgmt SW

Pharma – Med Device Grp

SW Contract Dev – embedded systems

Lab Automation Systems



SW Contract Dev – Pain Relief

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Common Themes

How the companies applied Agile and Lean differed – but certain basics were common among them

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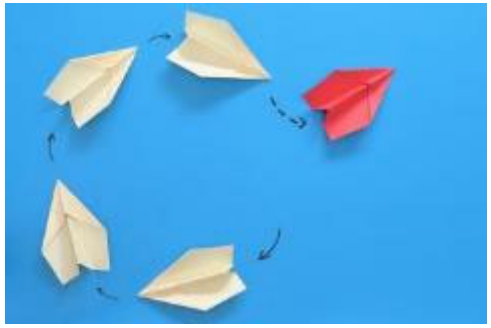
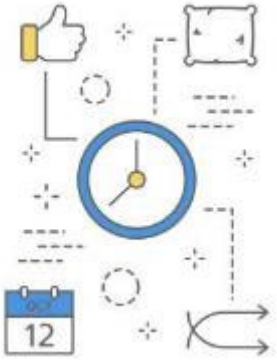
Some of the Principles

Collaboration based on Trust



Feedback Loops



Flexible Planning

Autonomation

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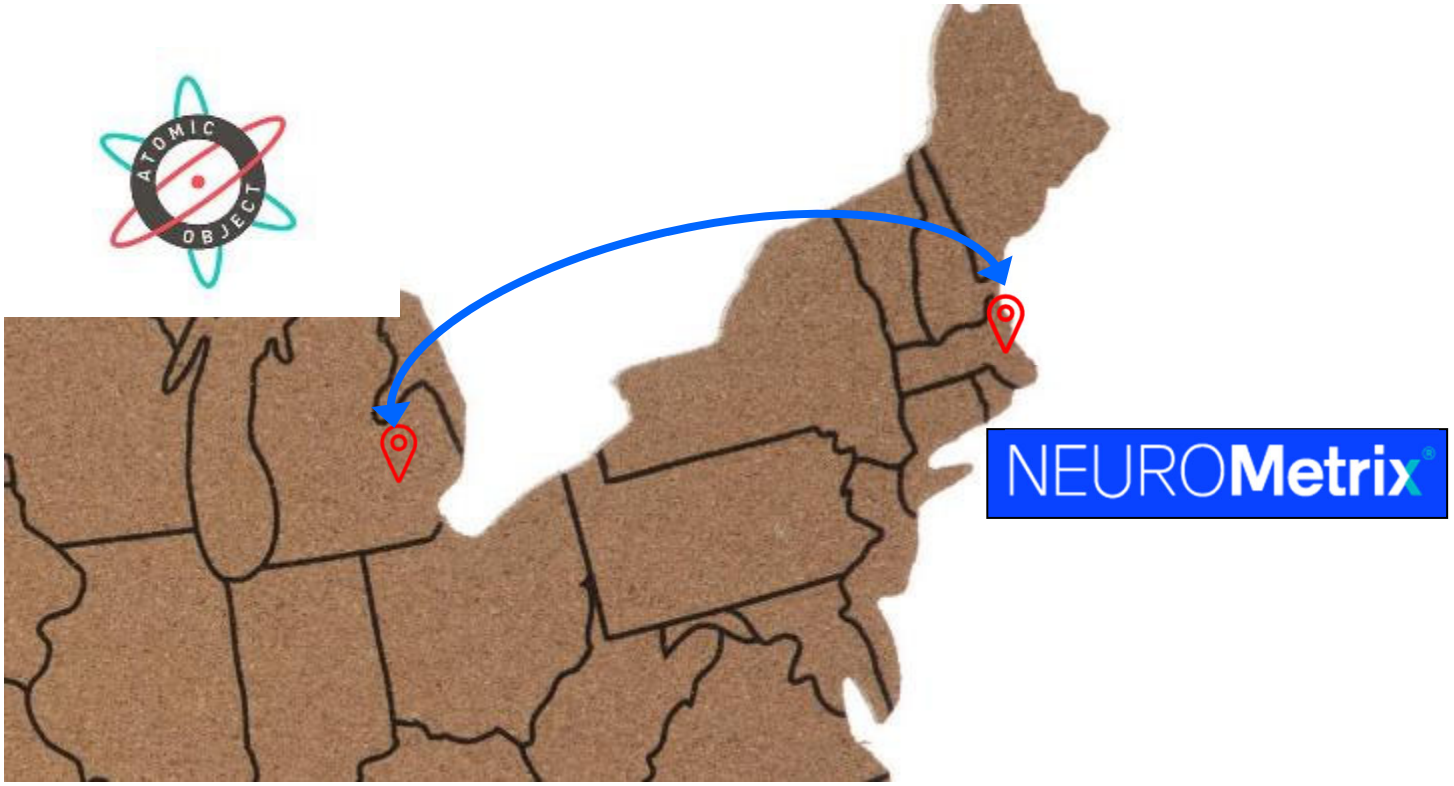
Issue – Not Quite Next Door



To optimize: frequent communication via Basecamp tool

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Only Part of the Product

AO worked on the mobile app …

… which communicates with the Neurometrix device

NEUROMetrix®

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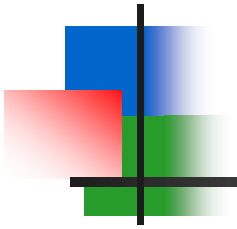

Investment in client relationship

- Agile process as non-negotiable
  - Alignment on use of Agile process is critical, so is raised early
  - Some clients need more info; some object to Agile's nature
- Autonomation needs real investment
  - Whether it's creation of a good software test suite, or that plus the need to decouple the hardware layer, Autonomation is crucial to Agile's quality, and it is expensive
  - AO gets the client to understand early that the payoff is far bigger than the cost of these investments

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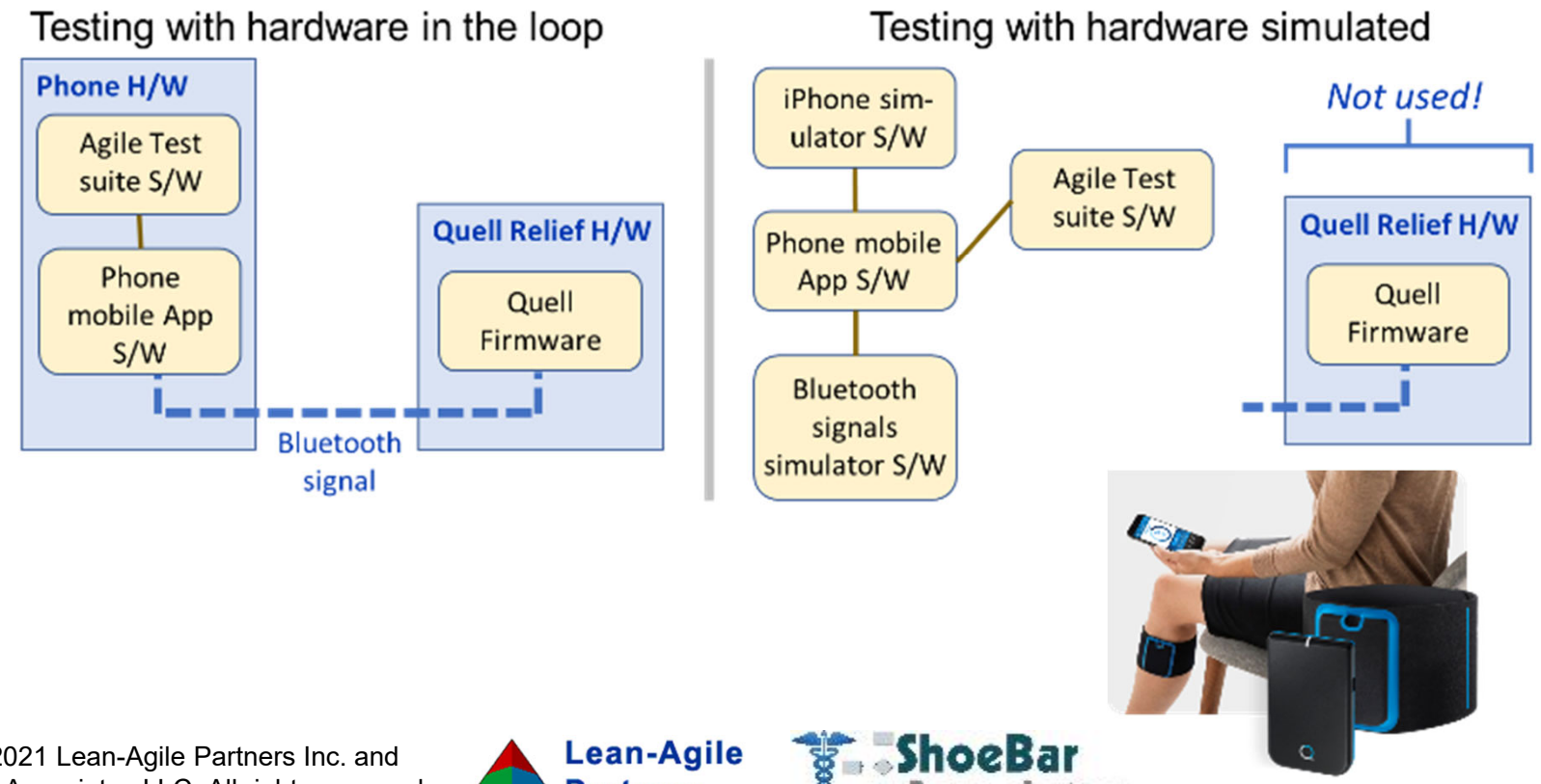
Autonomation – Simulate the H/W

Challenges: (a) Quell device was under development;
(b) many different phones needed to run the mobile S/W



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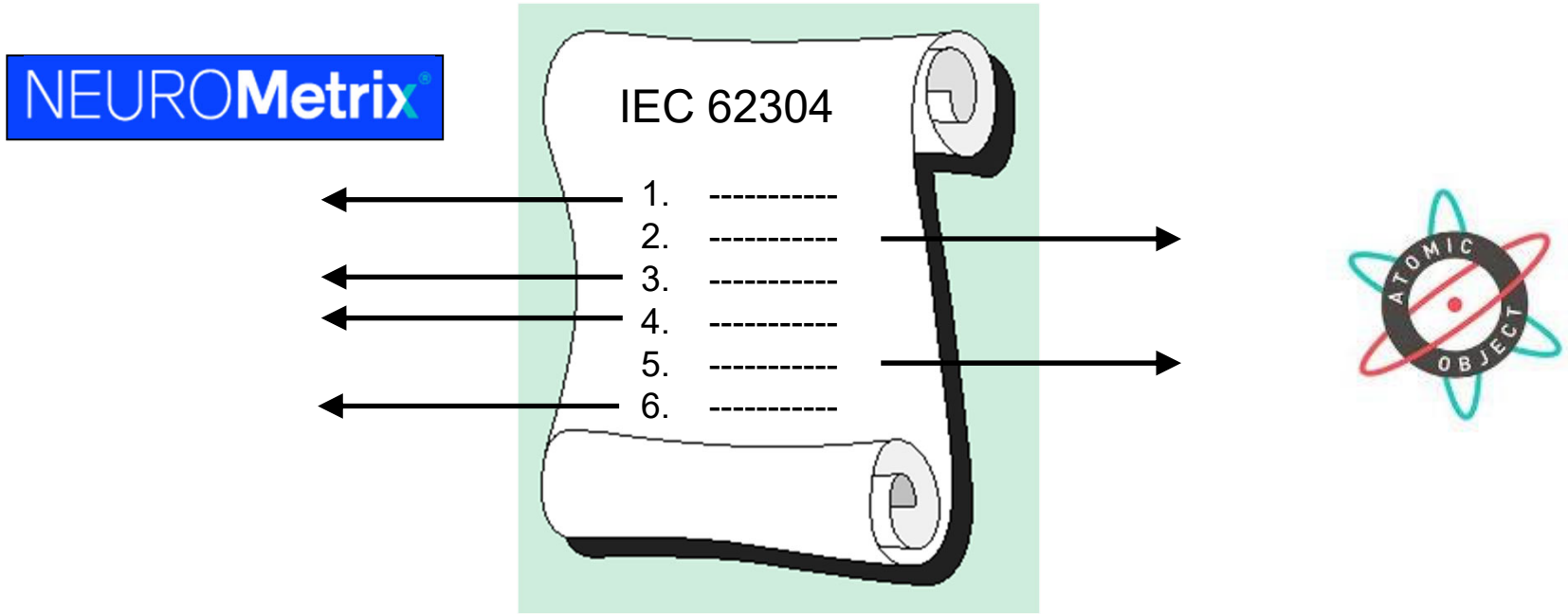
Design Control – Who does what?



Clarifying responsibilities made collaboration much easier

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Innovation Takeaways,

NEUROMetrix

- Autonomation
  - The device hardware decoupled from mobile phone s/w
  - Testing of mobile phone s/w on multiple phones via automated test suite
- Optimizing across organization
  - Division of 62304 responsibilities to the entity best positioned to handle them
  - Investing up front in client relationship – risks losing a sale in favor of being able to deliver smoothly & sustainably

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A serious challenge

Automation to connect with multiple instruments in a lab!

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An example system

Analysis instruments by various mfrs, all on a common track

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Strong reasons to change

Internal triggers


Manual testing


Inefficient documentation


Multiple System test


Asynchronous delivery

External triggers

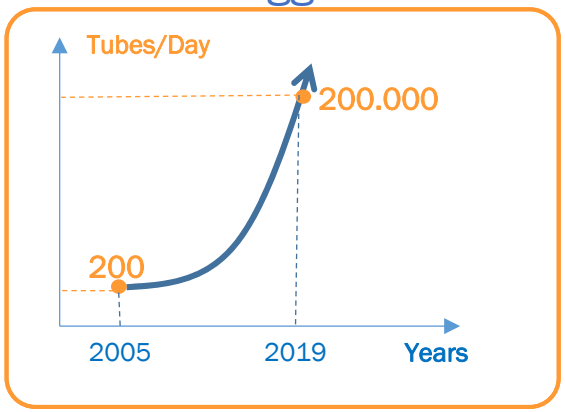

Cybersecurity


Dynamic Cust Reqmts


Privacy


IVD-R

Business triggers



Moving forward…

Continuous Integration & Frequent Delivery
Multidisciplinary team & product development *Platform*
Virtual reproduction of complex systems

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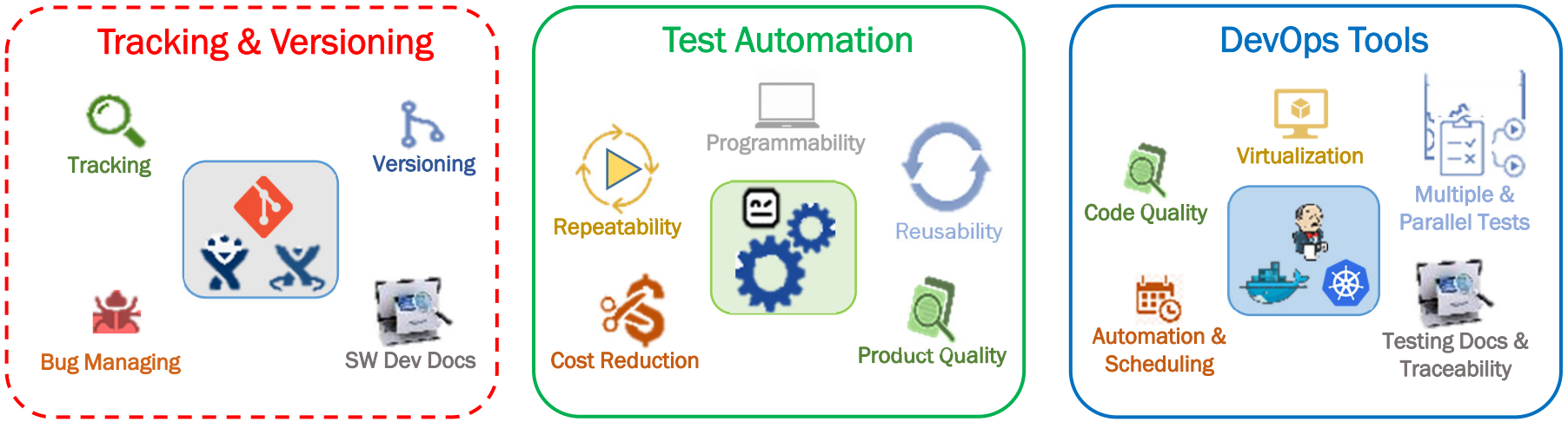
Change Enablers



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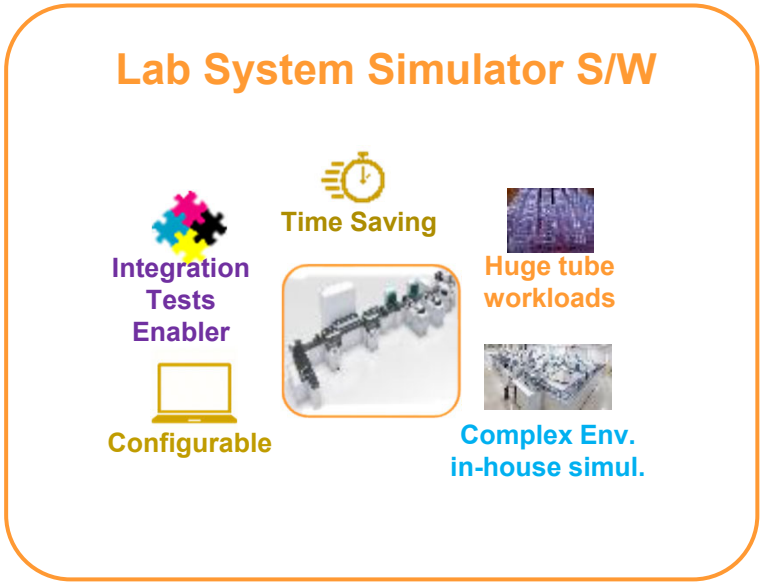
The biggest change enabler



Originally developed to demonstrate system to potential customers,

S/W Leader saw opportunity to adapt it to test complete system without the hardware present.

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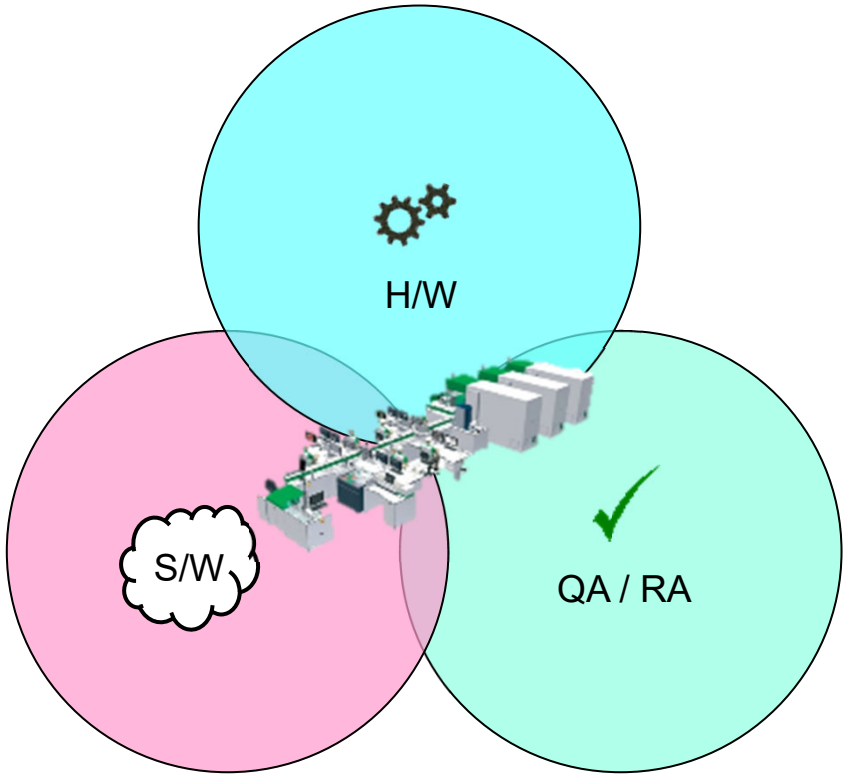
Collaboration Was Vital



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Foundations for change

- Leaders in S/W and QA drove the Agile initiative
  - Their initial Agile push was too fast, too broad
  - They and other groups collaborated to reboot it, and built foundations to sustain it, which were successful!
- Foundations:
  - Study/ training
  - Cross-functional teams for knowledge transfer
  - Support from the Quality group
  - Tool setup

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Innovation Takeaways,

- Trusting Collaboration
  - Leaders in S/W and QA learned about Agile, plus they already knew much about the company's workings
  - Despite having to "reboot" their Agile process, the initial attempt created a collaborative spirit
- Autonomation
  - Re-purposing the customer-demo software app into a simulator enabled a parallel approach to developing s/w for each machine
  - Simulator decoupled s/w dev from h/w dev, allowing autonomation for the s/w testing, and especially its regression testing

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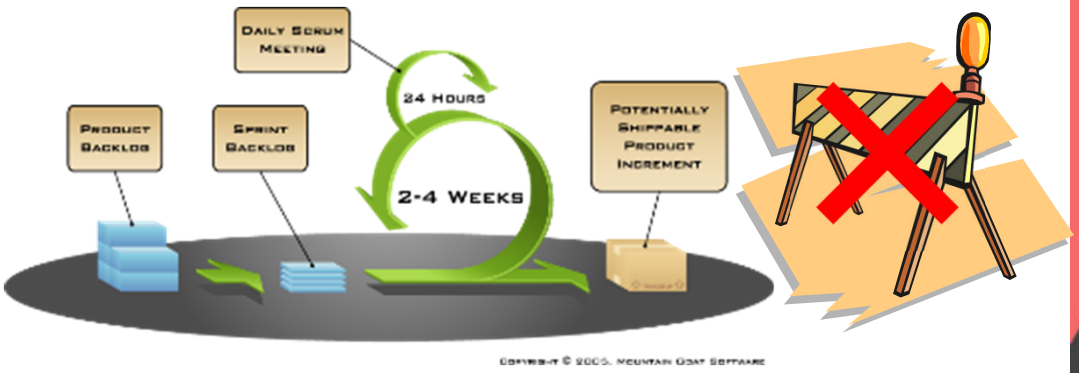
Agile vs. Planning at Sanofi

Are they compatible?



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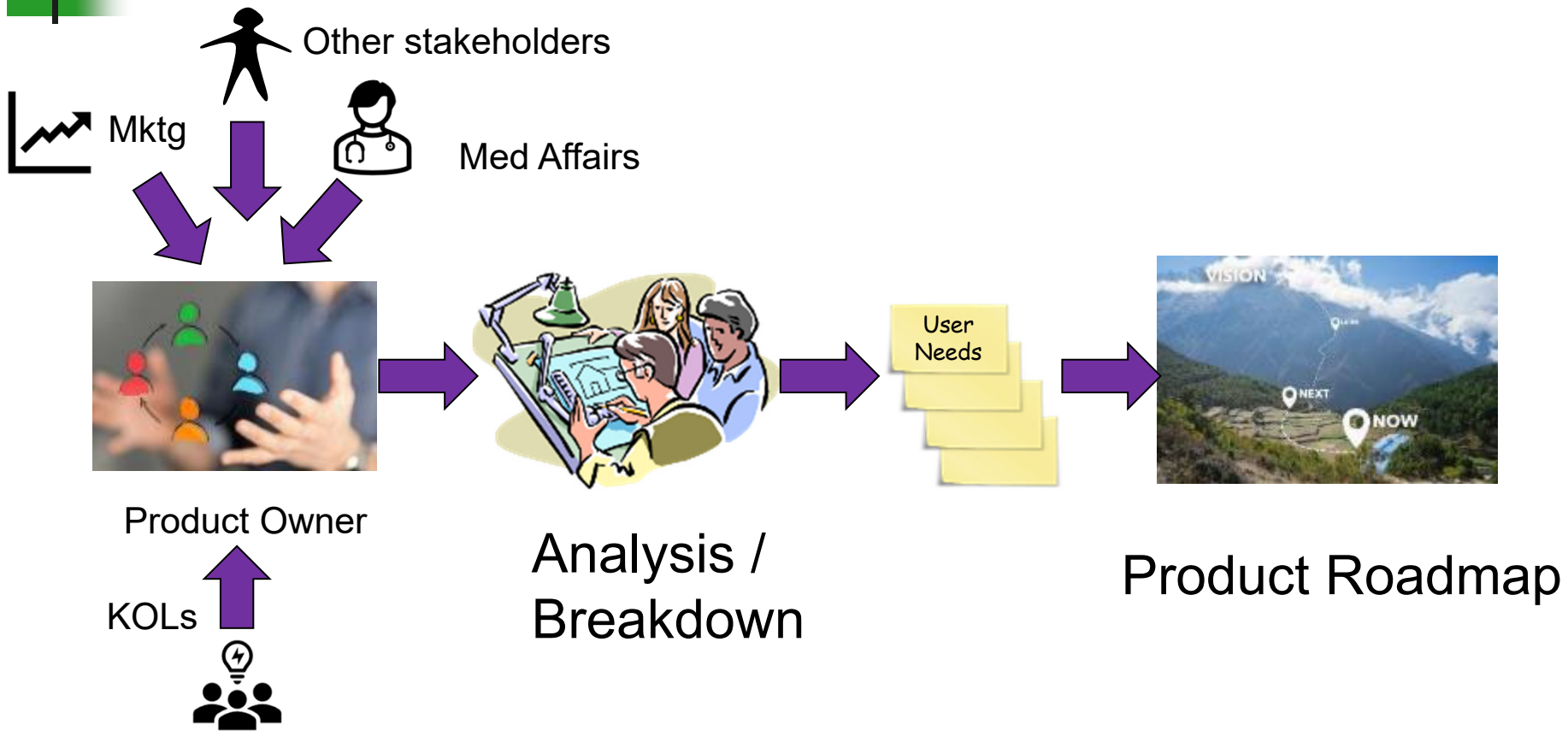
Product Owner – Flexible Planning



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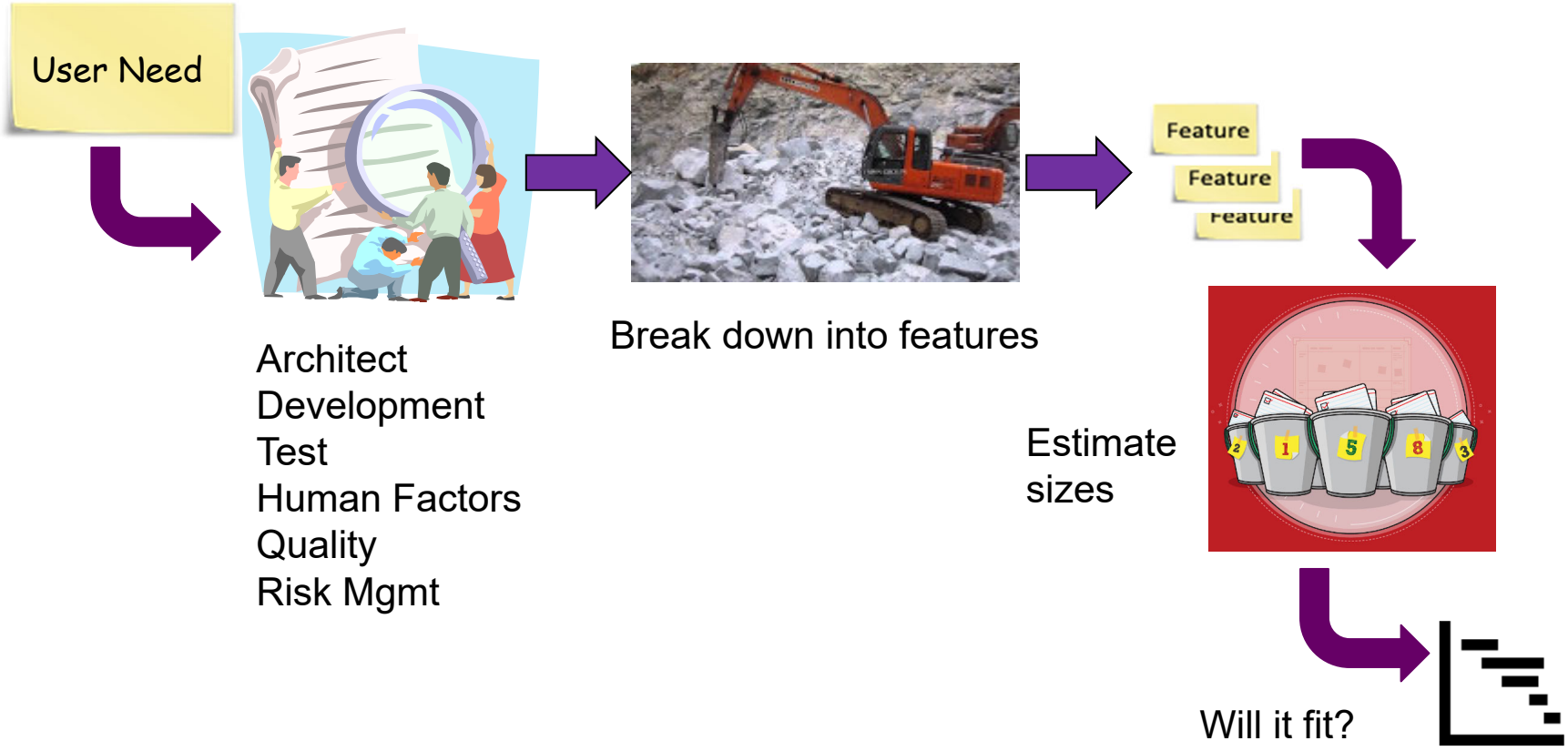
Release Planning Follows



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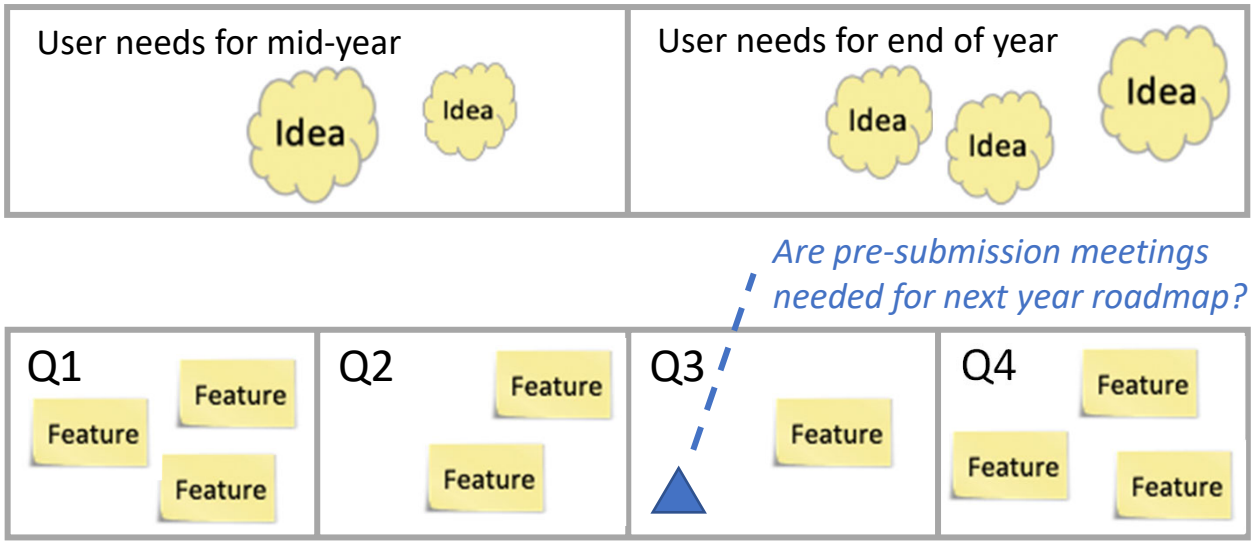
Mapping – Per Quarter



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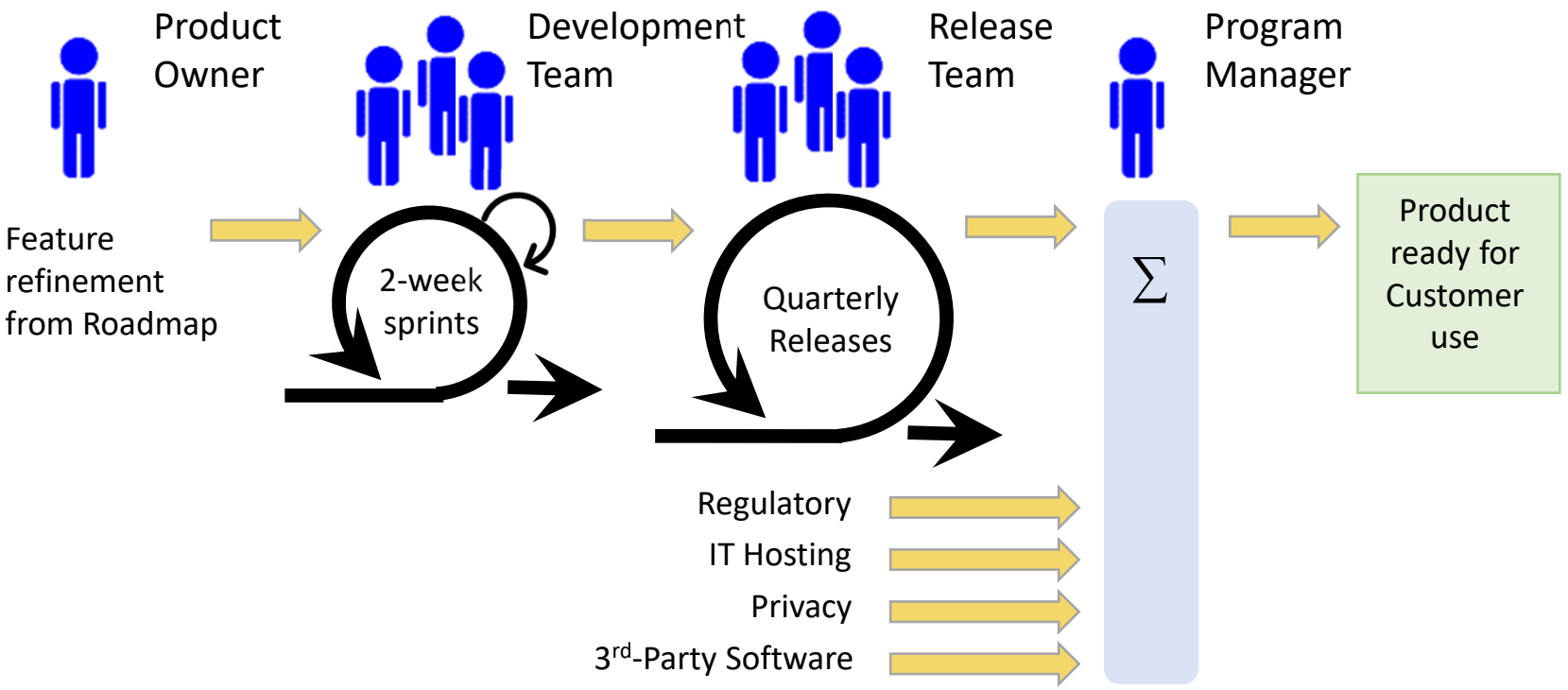
Two levels of teams



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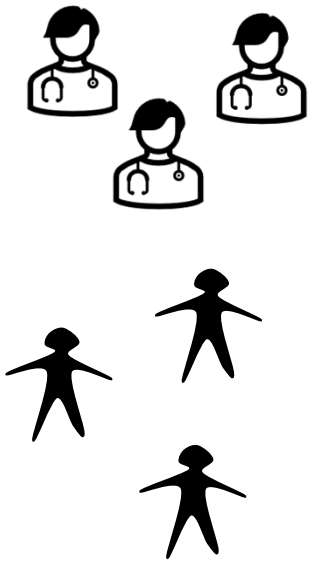
Shorten Feedback Loop

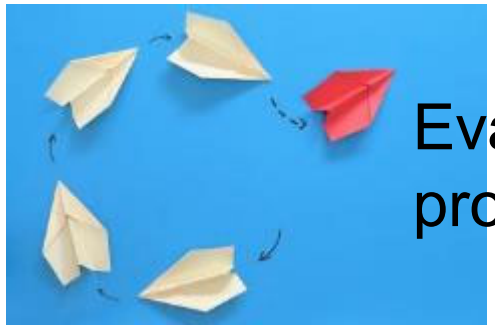
UI Options

A

vs

B





Evaluate prototype

Avoids freezing the option too early – before knowing how clinicians & patients accept it

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Innovation Takeaways, SANOFI

- Flexible planning
  - Coarse initial plan – mid-year goal, end-year goal
  - Refined to quarterly major features as more knowledge is accumulated
- Shortened feedback loops
  - Accumulation of knowledge in smaller cycles feeds production of small, clear steps forward (at the User Story level)
  - Steps forward are taken when there is confidence they're correct
  - Fine-grained tests allow unforeseen changes to be accommodated with less likelihood of introducing new defects

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Summing Up

- Atomic Object / NeuroMetrix
  - Autonomation
  - Optimization across the Organization
- Inpeco
  - Trusting Collaboration
  - Autonomation
- Sanofi
  - Flexible planning
  - Shortened feedback loops

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Summing Up

- Understanding the principles is not enough
- Understanding the context is not enough
- You need to choose the practices that are best able to realize a *principle* in a *specific context*

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Our Services

Nancy Van Schooenderwoert
Lean-Agile Partners, Inc.
31 Payson Road #1, Belmont, MA 02478
+1 781-860-0212
NancyV@leanagilepartners.com
https://www.leanagilepartners.com

- Lean-Agile coaching for software and hardware teams
- Safety-critical, regulated coaching is our specialty
- Lean-Agile coaching for stakeholders and senior managers

Brian Shoemaker, Ph.D.
Principal Consultant, ShoeBar Associates
1420 West Lake Rd, Branchport, NY 14418
+1 781-929-5927
bshoemaker@shoebarassoc.com
https://www.shoebarassoc.com

- Software quality systems
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Contact us

Nancy Van Schooenderwoert
LeanAgilePartners
nancyv@leanagilepartners.com

@vanschoo

Brian Shoemaker
ShoeBar Associates
bshoemaker@shoebarassoc.com

@brian_shoe