

Agile for Safety-Critical and Regulatory-Bound Products*

**Agile where you can kill someone*

Nancy Van Schooenderwoert, *Lean-Agile Partners*
Brian Shoemaker, *ShoeBar Associates*



© 2008-14 Lean-Agile Partners Inc. and ShoeBar Associates
All rights reserved.

Brian's Background

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



2

Nancy's Background

- 15 y safety-critical systems development
- 10+ y agile team coaching
- 5+ y agile enterprise coaching
- Industries: Aerospace, Medical Devices, Sonar Weaponry, Scientific Instruments, Financial Services
- Electrical Engineering and Software Engineering, embedded systems design & devel.



3

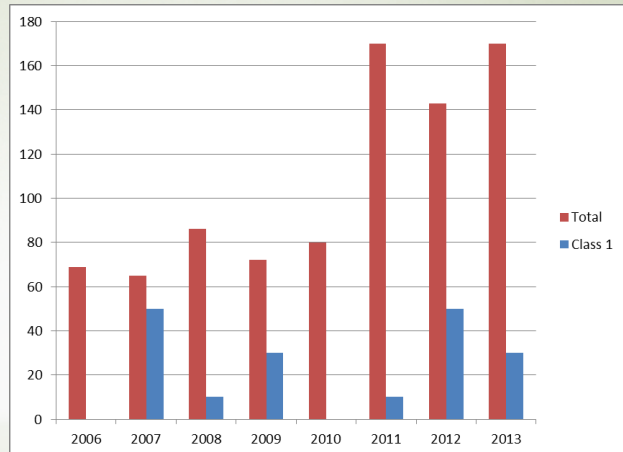
Safety-Critical Agile

- **Medical devices with SW provide a bleak picture**
- *Impact mapping: “frame” a product for all stakeholders*
- *Iterative safety analysis fits well with mapping*
- *Story mapping: translate our understanding*
- *Agile links the “silos” - and improves products significantly*



4

Software Related Recalls



Note: Figures are from FDA's medical device recall database (for US recalls). The Class 1 recalls are multiplied by 10 so they are readable on the same scale as total recalls.



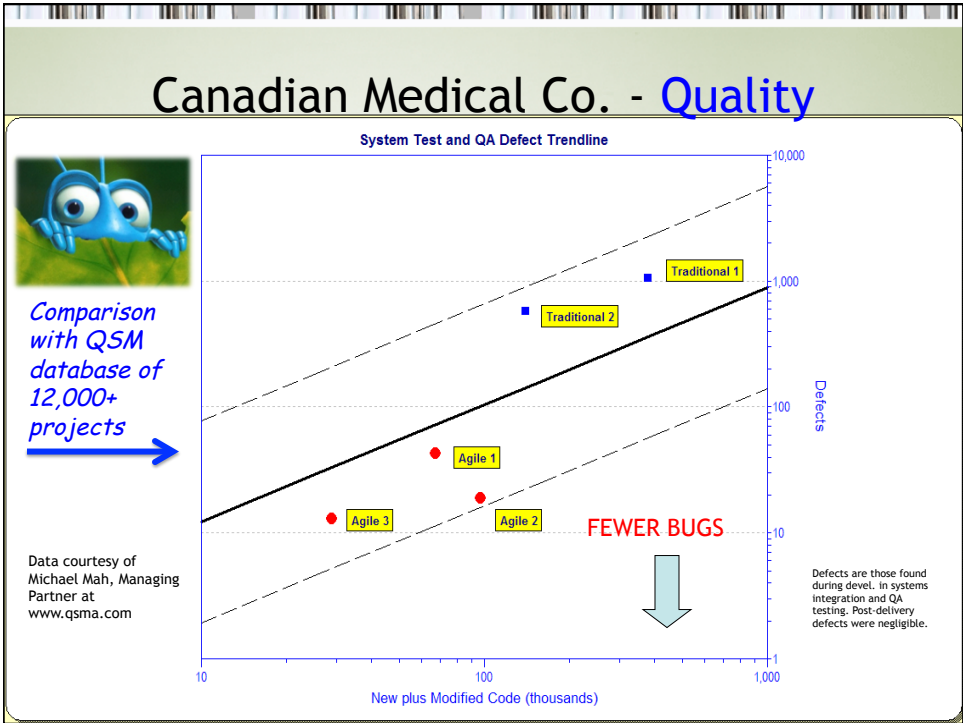
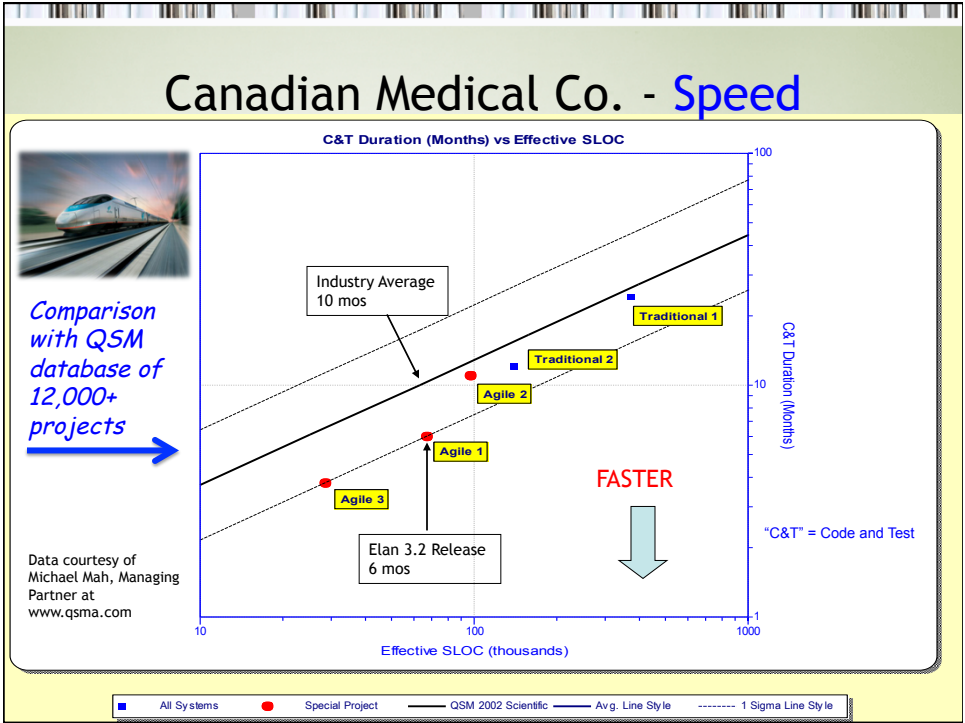
5

It doesn't have to be this way

- Agile medical projects
 - Are significantly faster to completion
 - Have significantly fewer defects: ¼ as many!
- ... when compared to traditional projects
 - *Case Study of Extreme Programming used at a Canadian medical systems company...*

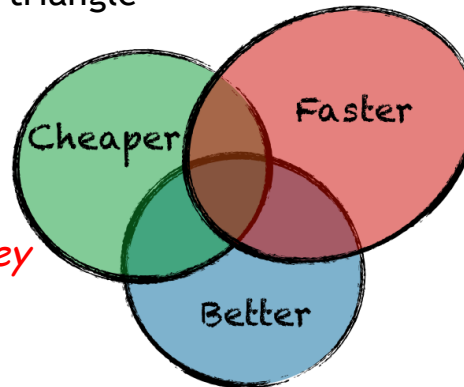


6



No need to “pick any two”

- This breaks the old triangle -
- Can have all 3!

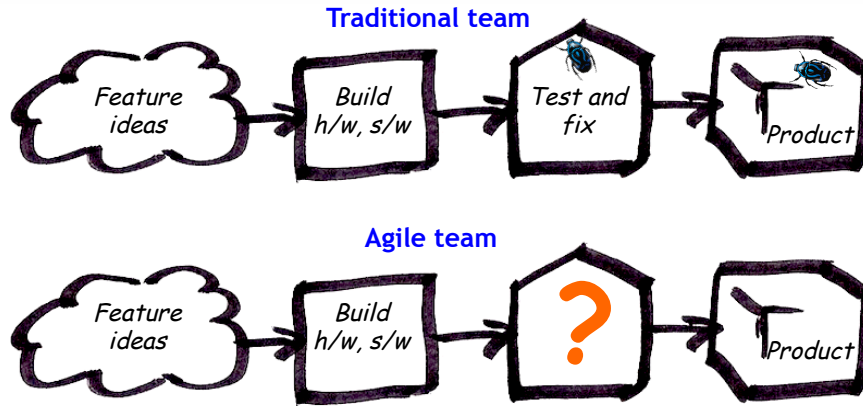


Our goal: Show you key practices that break this old rule

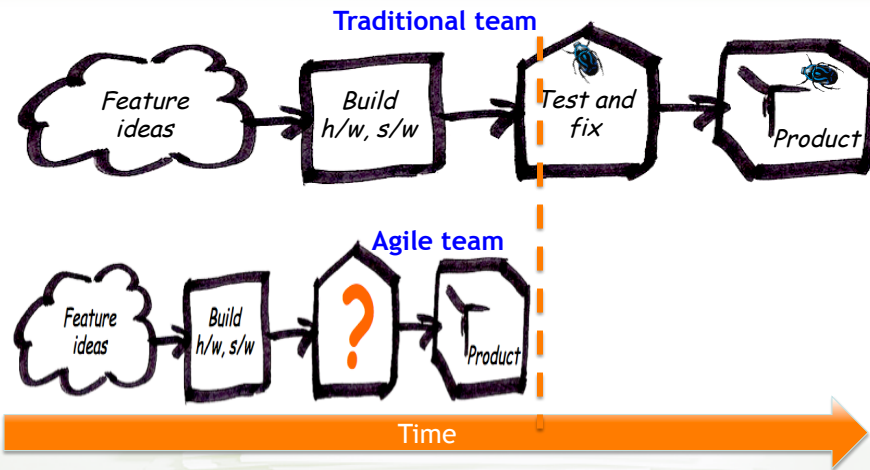
Applies to More than Medical!

- Chemical plants
- Power stations (esp. nuclear)
- Aviation systems (civilian & military)
- Automotive
- Other transportation systems
- (others as well)

What's going on?

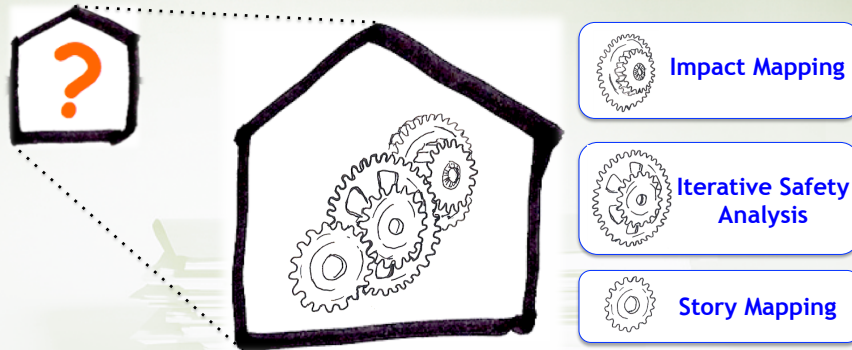


More work, and done faster?!



'More Faster' process step

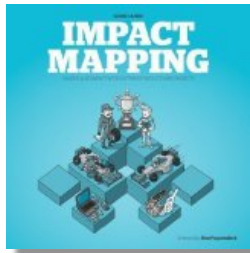
- What's inside that mystery process step?



Safety-Critical Agile

- *Medical devices with SW provide a bleak picture*
- **Impact mapping: “frame” a product for all stakeholders**
- *Iterative safety analysis fits well with mapping*
- *Story mapping: translate our understanding*
- *Agile links the “silos” - and improves products significantly*

Impact Mapping - Envision the Product!



Purpose

- Align product rationale with Company's goals
- Map business value creation
- Accommodate changes
- Comm - Marketing, QA, RA, Development

Who uses it?

- Senior business and technical leaders

Source: Gojko Adzic, 'Impact Mapping', 2012. Impact Mapping is derived from the "InUse" effect mapping method, planning visualization maps for training, Feature Injection, and iterative delivery - all created by others (details given in the book).



15

Keys of Impact Mapping

- **Why:** Why are we doing this?
- **Who:** Whose behavior do we want to impact?
- **How:** How should our actors' behavior change?
- **What:** What can we do to support the required impacts?



16

TENS Goals

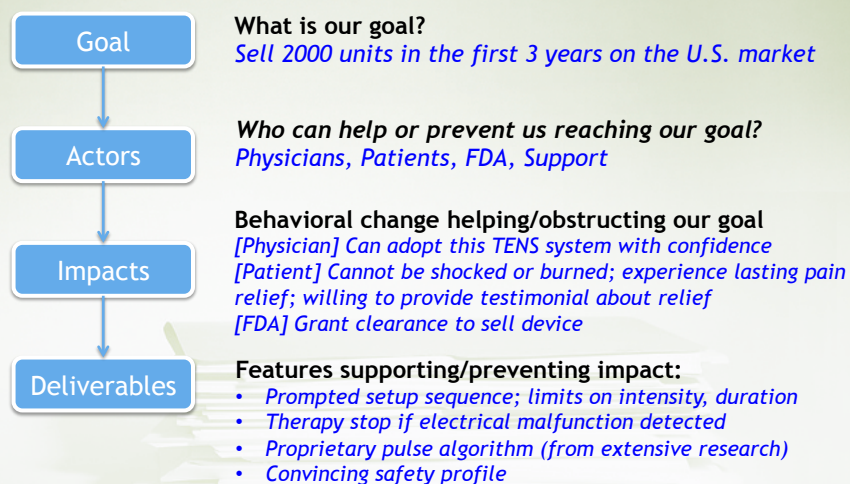
Our design goals map directly to the two requirements for a medical device:

- a) System must be effective
(relieves pain)
- b) System must be safe
(not likely to harm patient)

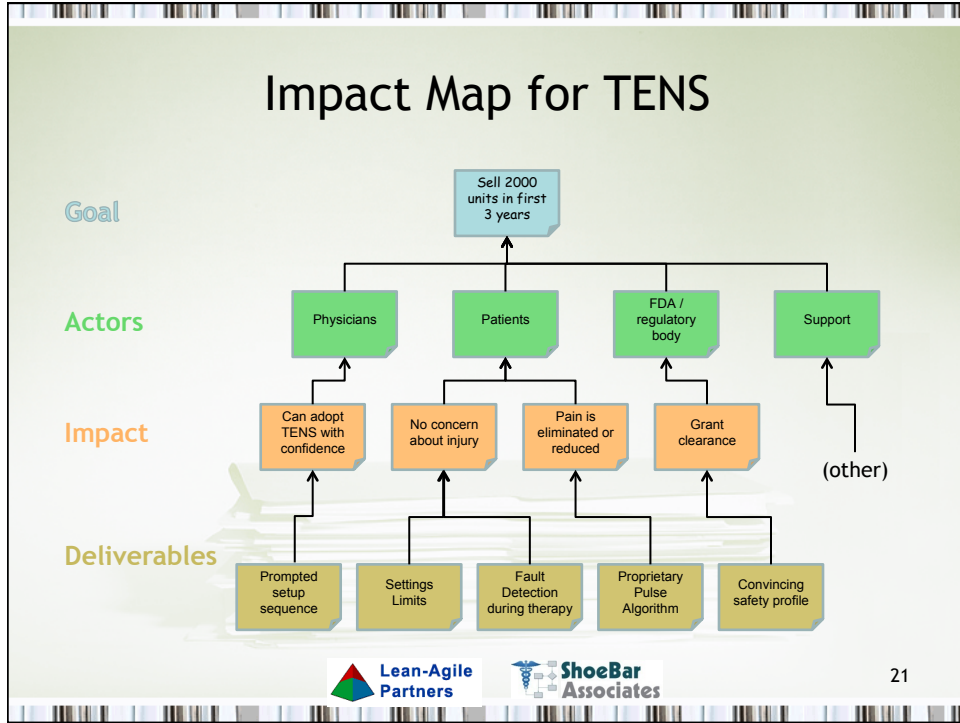


19

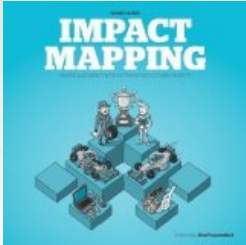
Impact Map for TENS





20



Impact Mapping - There's More

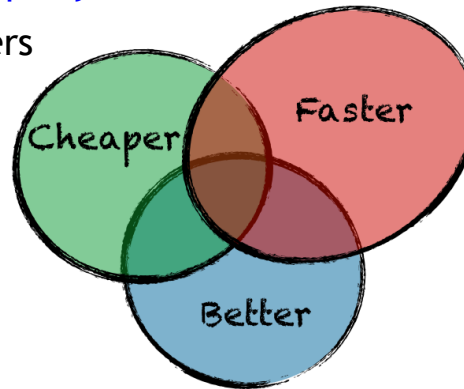


- We have covered only a portion of impact mapping - enough to get you started
- We have found the method extremely useful for linking marketing and customer requests to development
- We highly recommend reading the Gojko Adzic book to understand the questions to ask.



22

No need to “pick any two”

- **Impact Mapping helps by:**
- Aligning stakeholders
- Keeping our aim on moving target
- Focus on *behavior*

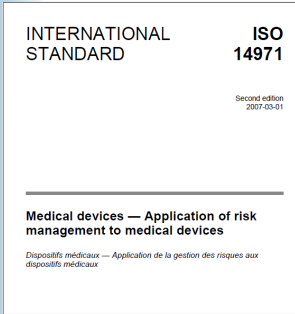


Safety-Critical Agile

- *Medical devices with SW provide a bleak picture*
- *Impact mapping: “frame” a product for all stakeholders*
- **Iterative safety analysis fits well with mapping**
- *Story mapping: translate our understanding*
- *Agile links the “silos” - and improves products significantly*



Risk Management - Design for Safety



Purpose

- Analyze product uses / design
- Anticipate potential safety issues
- Improve design to mitigate risks

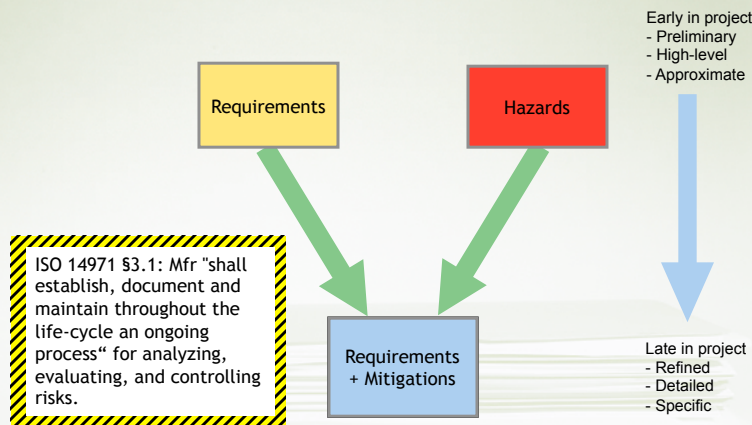
Who uses it?

- Product designers, development teams
- Safety analysts
- Service / support

Source: ISO 14971:2007 (2nd ed) Medical devices - Application of risk management to medical devices



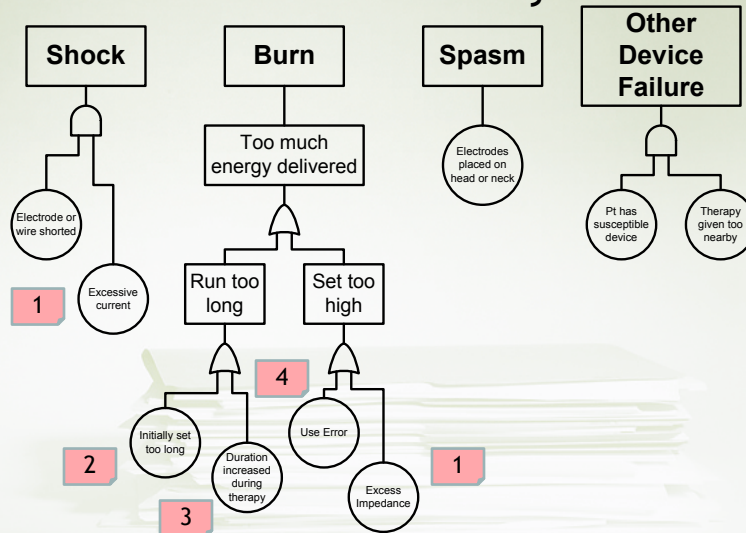
Risk Management MUST Iterate



Who Should Take Part?

- Electronic / Mechanical engineers?
- Physicians / Nurses?
- Patients who have used other TENS devices?
- Researchers who work on pain relief?
- Regulatory experts (review of other devices on market)?

Fault Tree Analysis



Risk Stories

(1) As a caregiver,
I want to ensure that therapy
will stop if short, open circuit,
or high impedance is detected,
to avoid harming the patient.

(3) As a caregiver,
I want the unit to prevent
setting duration longer once
therapy has begun,
to avoid harming the patient.

(2) As a caregiver,
I want the unit to limit the
therapy duration,
to avoid harming the patient.

(4) As a caregiver,
I want the unit to prevent
setting output too high,
to avoid harming the patient.



29

Is this a Once-Up-Front Activity?

- Standards and regulatory bodies EXPECT risk management to be iterative!
- Partway into development, key customers ask for ability to control the device via a remote.
 - How might your company answer?
 - What safety issues might this raise?
 - Would we revisit our hazard analysis?

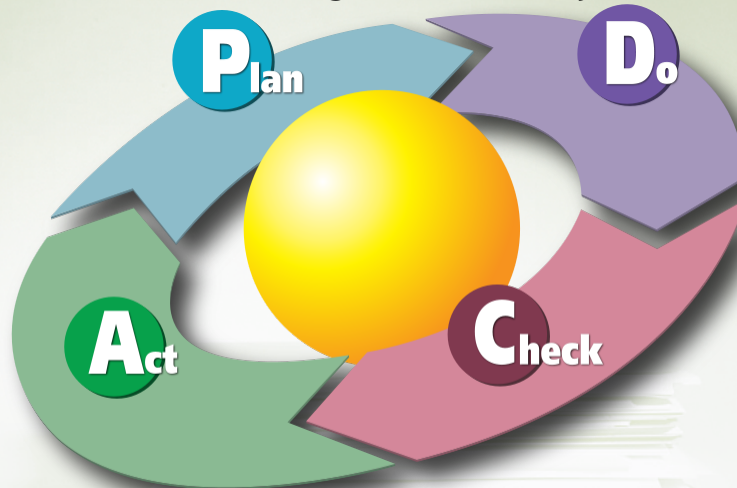


30

Is this process ever “complete”?

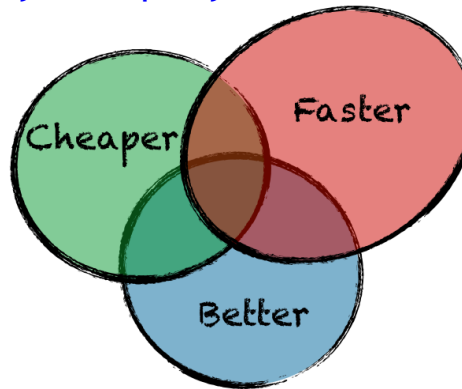
- Do we know enough about hazards when a project begins?
- Will we learn as potential users try out our design?
- What other analyses can we do when we have a detailed design?
- Might we bring in other stakeholders later in development?

Risk Management is Cyclic



No need to “pick any two”

- Iterative Safety analysis helps by:
 - Sharper focus
 - Incorporate new info “in flight”
 - *Avoid* recalls and accidents better than before

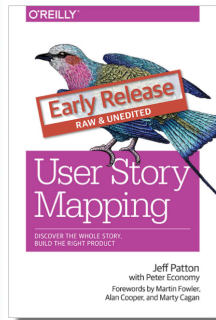


Safety-Critical Agile

- *Medical devices with SW provide a bleak picture*
- *Impact mapping: “frame” a product for all stakeholders*
- *Iterative safety analysis fits well with mapping*
- **Story mapping: translate our understanding**
- *Agile links the “silos” - and improves products significantly*



Story Mapping - Envision the Timeline



Purpose

- Ensure product will fit user needs
- Envision minimum viable product
- Plan releases
- Communication - Marketing, QA, RA, Development

Who uses it?

- Product managers/ marketers and hands-on technical teams

More Info: http://www.agileproductdesign.com/presentations/user_story_mapping/ Blog post describing Story Mapping. Jeff Patton has a book now in 'early release' which describes the Story Mapping technique.



35

Keys of Story Mapping

- Start with your customer's activities using your envisioned product (horizontal axis)
- Vertical axis: increasing levels of completeness in implementation
 - First level is a releasable "walking skeleton"
 - Next levels flesh out more features
- Benefit: Avoids releases that are unusable due to dependence on less urgent stories not yet implemented



36

Example TENS Devices

Lean-Agile Partners

ShoeBar Associates

37

TENS Device Story Map

User Actions	Attach electrodes, connect leads	Power up device	Enter treatment settings	Begin therapy	Allow therapy to proceed	Disconnect when complete
		Give warning if electrode shorted	Prompt for Duration & display throughout	'Intensity' knob sets Voltage amt.	Deliver proprietary pulses	Therapy ends when time limit reached
Laboratory Tests					Display "Duration" countdown	Release 1
	Leads keyed for correct polarity	Confirm which leads connected	Duration must be < 30 minutes		Ensure pulse pattern is changing	
Feasibility Study					Manual stop if anything wrong	Release 2
	Ensure outputs initially = 0	Do complete power-on self test		Intensity must be < safe limit	Monitor pulse pattern for 'hot spots'	Duration can NOT be changed
Pivotal Study					Auto stop if pulses not changing	Stop therapy if electrical malfunction
						Release 3

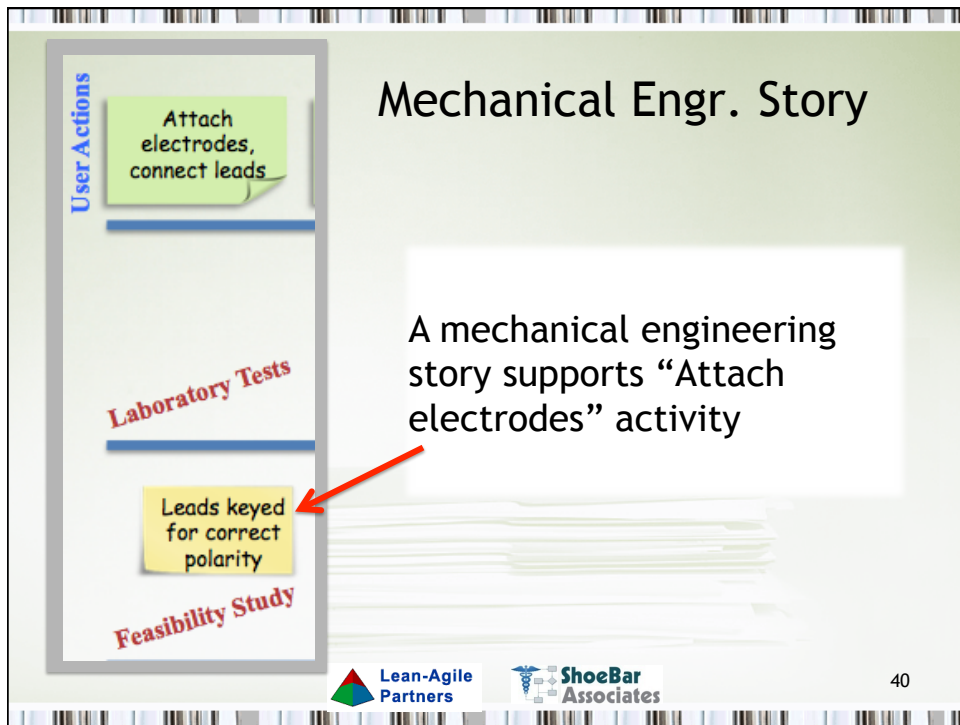
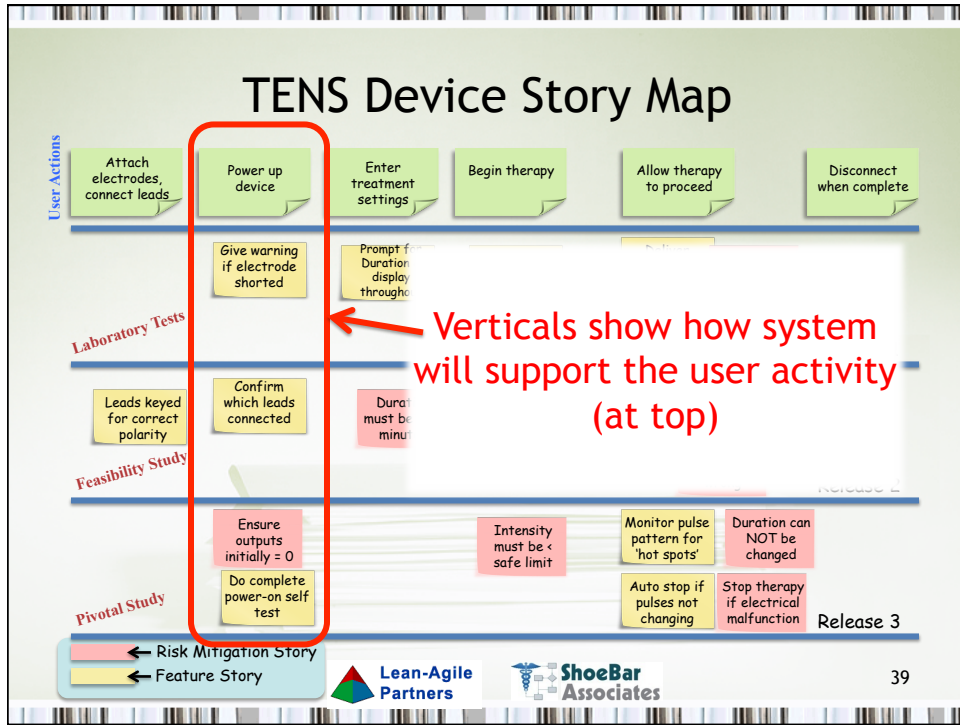
← Risk Mitigation Story

← Feature Story

Lean-Agile Partners

ShoeBar Associates

38



Risk mitigation story

Enter treatment settings

Prompt for Duration & display throughout

Duration must be < 30 minutes

This story came from the Risk Analysis, not from users

In prior iteration, mitigation was via lab procedures

Lean-Agile Partners | ShoeBar Associates

41

New need for safety analysis

Remote control to enter or change settings

← New feature requested for Release 4

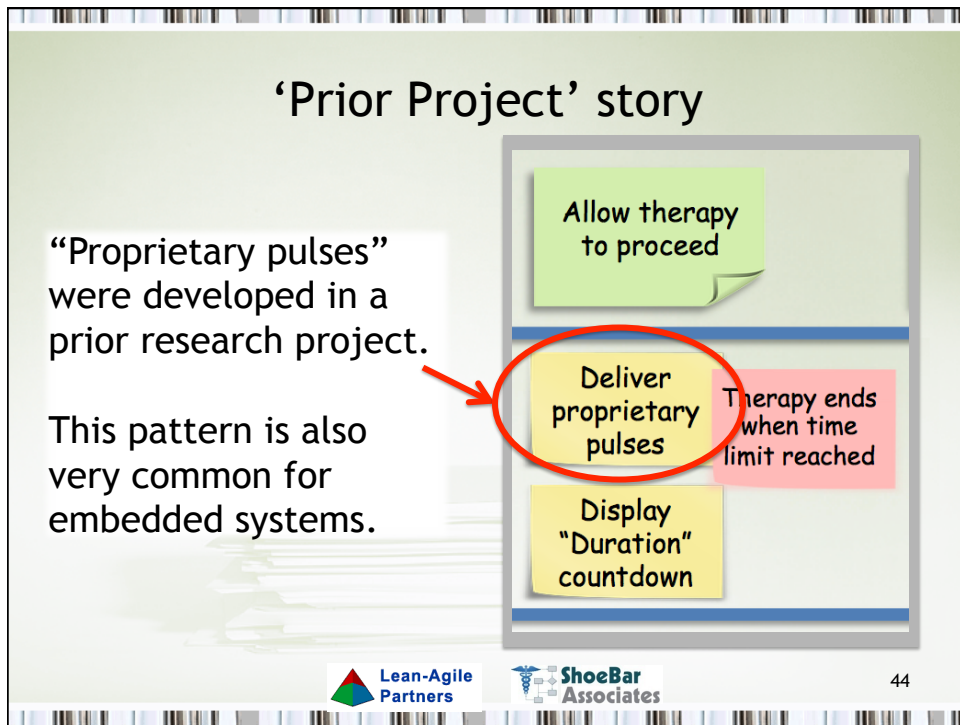
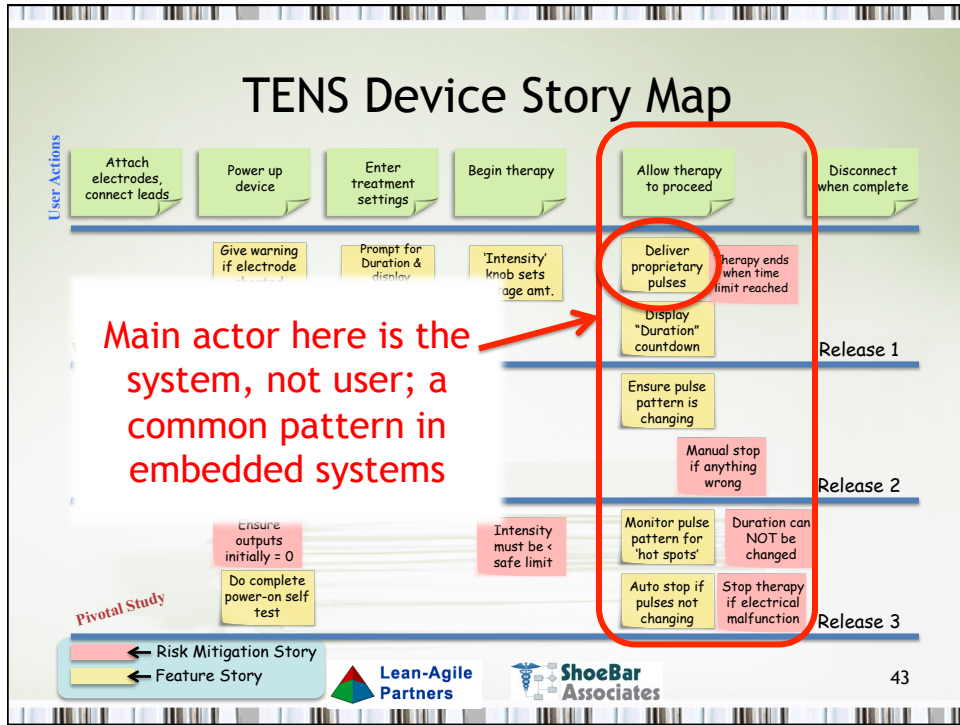
Next iteration of safety analysis gives new Risk Mitigation stories

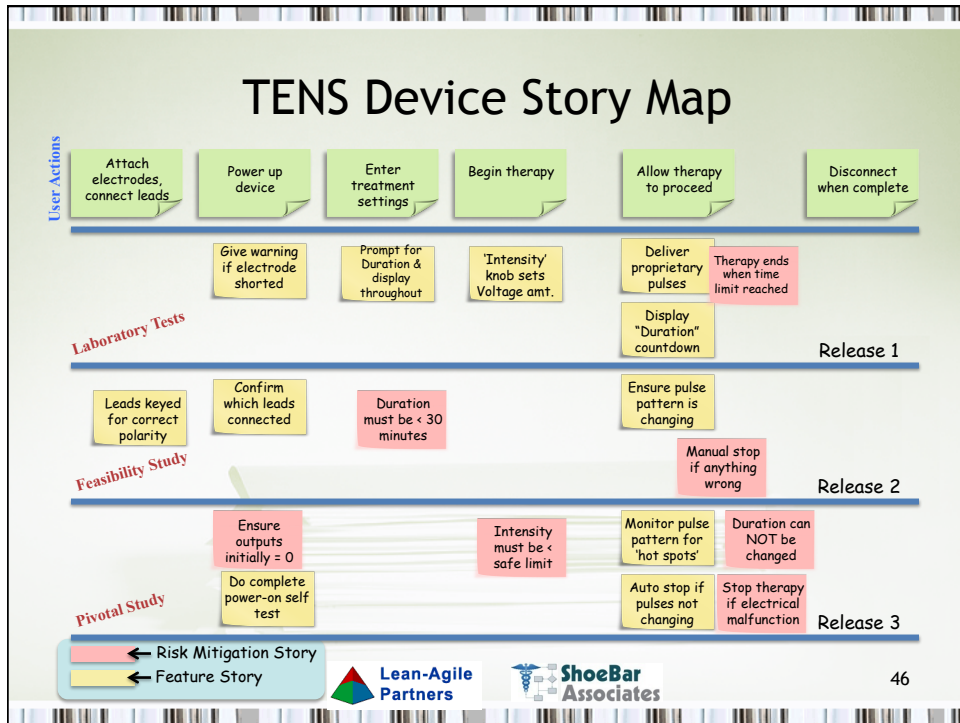
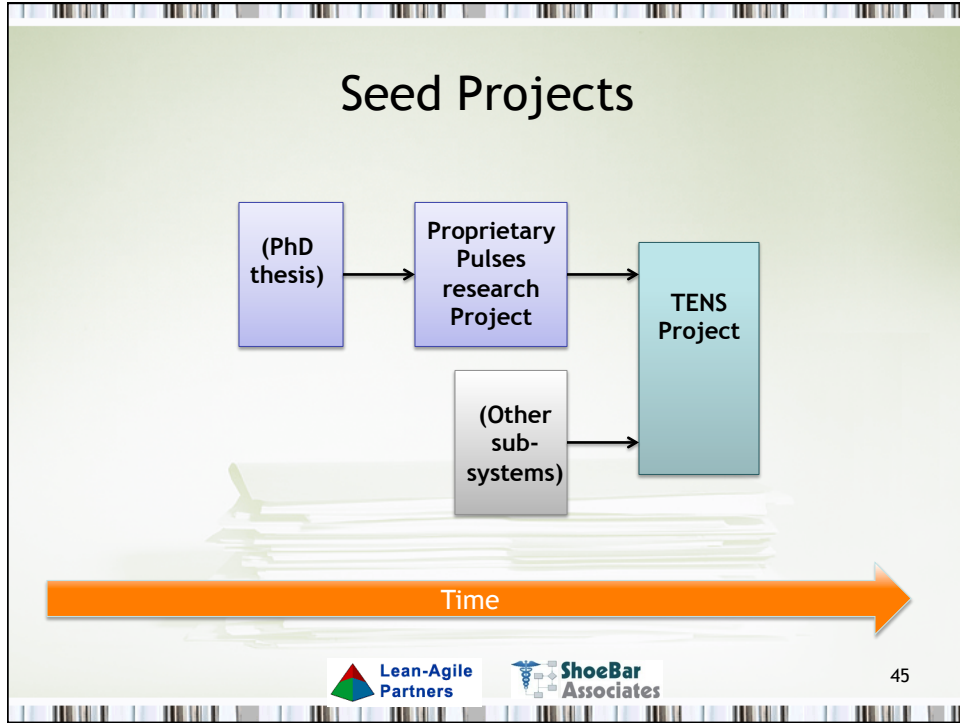
Warning if weak signal

Encrypt wireless signal

Lean-Agile Partners | ShoeBar Associates

42





Export Shows Traceability

ID	Type	Actor	Goal	Value	Wkspc	AC	AC Details	Trace
BG1	Bsns Goal		Sell 2000 Units in First 3 Years		IM			
A2	Actor	Physician			IM			BG1
I6	Impact		Can adopt TENS with confidence		IM, SM			A2
D10	Deliv		Prompted Setup Sequence		IM, SM			I6
UA17	User Act.	Physician	Enter treatment settings		SM			D11, D12
UA19	User Act.	Physician	Allow therapy to proceed		SM			D13, D14
RM38	Risk Story	Physician, Patient	Ensure therapy stops on electrical malfunction (FTA-1)	Pt will not be harmed	SM			UA19
						Impedance response	Given therapy is occurring, When cks detect hi Z, Then therapy shall be stopped	

Output exported from SpecLog impact/story mapping tool and rearranged manually.



47

Benefits of Story Mapping

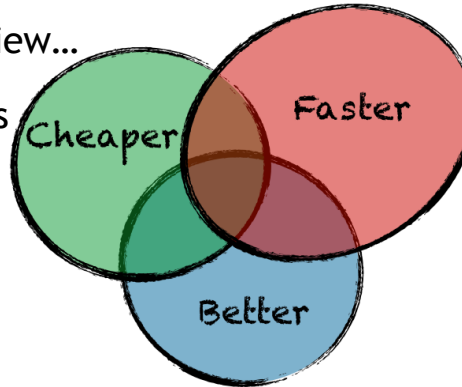
- All stories trace to user activities
- Specific stories can be identified as risk mitigations
- See where H/W, S/W features interleave
- Column-wise view helps see evolving support for each user activity



48

No need to “pick any two”

- Story mapping helps by:
 - Showing timeline view...
 - Show user activities plus tech features
 - Support cross-functional dialogue

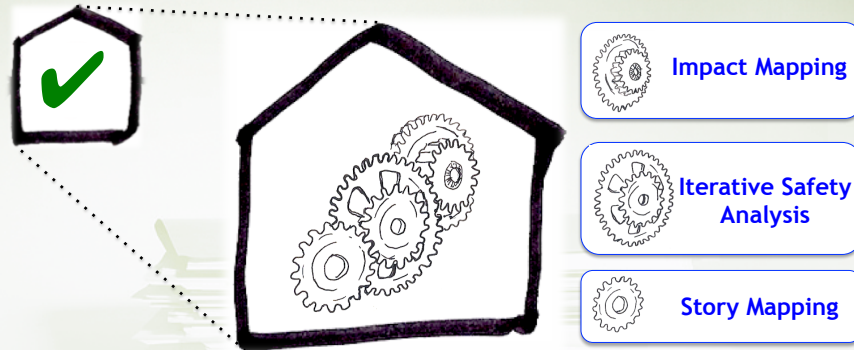


Safety-Critical Agile

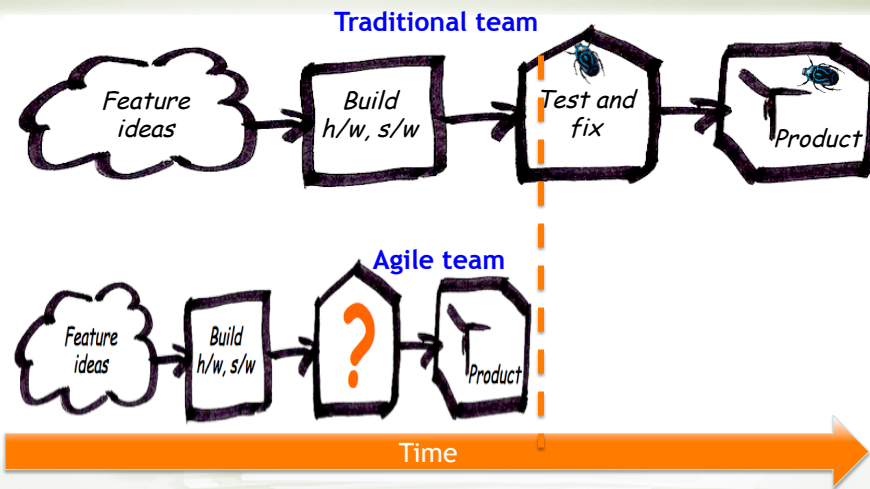
- *Medical devices with SW provide a bleak picture*
- *Impact mapping: “frame” a product for all stakeholders*
- *Iterative safety analysis fits well with mapping*
- *Story mapping: translate our understanding*
- **Agile links the “silos” - and improves products significantly**

'More Faster' process step

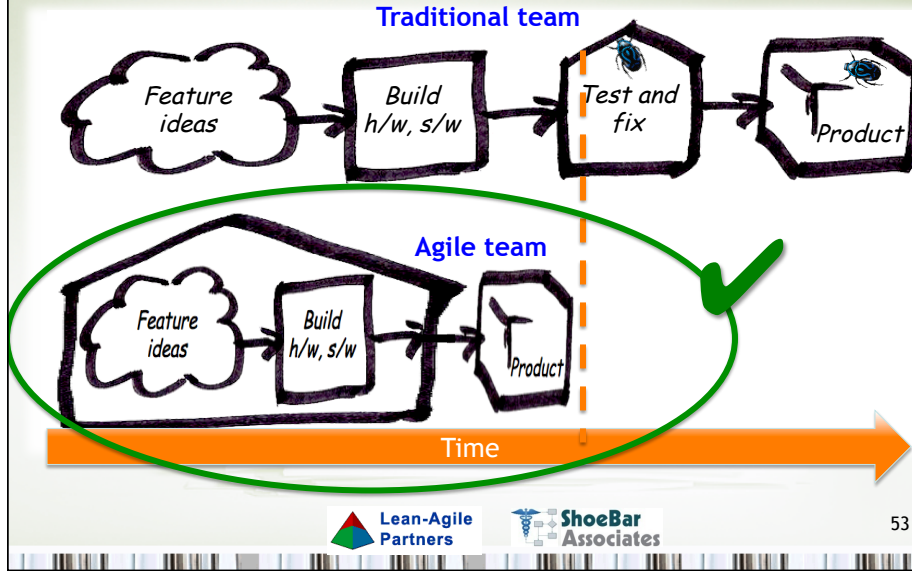
- Not a mystery process step anymore!



More work, and done *faster* - YES



More work, and done faster - YES



These are a foundation

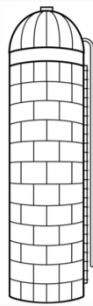


- You still need TDD, CI, Retrospectives, etc.
- ← This foundation complements them!

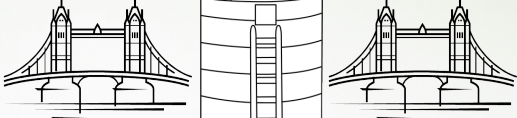
TDD = Test Driven Development; CI = Continuous Improvement

Mapping - We Have to Bridge Silos

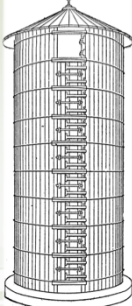
R&D / Engrg

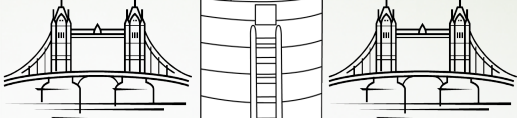



Clinical / Support




Marketing





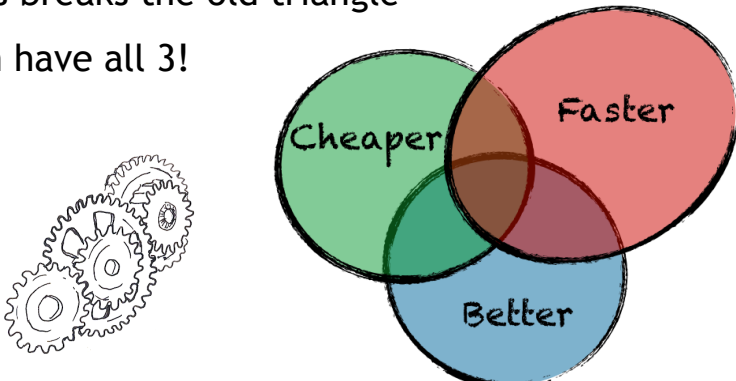






55

No need to “pick any two”

- This breaks the old triangle -
- Can have all 3!







56

Consider

- No regulatory body requires waterfall methods
- No regulatory body prohibits Agile methods
- TIR-45 (from AAMI): info on being Agile and compliant in medical products
- FDA: You must demonstrate conformance to pre-determined requirements, but you can pre-determine them at any time

NOTE: We've explored all these topics in a white paper available on our web sites, <http://www.shoobarassoc.com> and <http://leanagilepartners.com/>
AAMI = Association for the Advancement of Medical Instrumentation



57

Future: Internet of (Medical) Things

- 10 Billion **Internet-of-Things** devices today,
- 30 Billion expected by 2020
- Among fastest growing **IoT** devices:
 - Mobile, in-home medical devices
 - Intelligent sensors: transportation and buildings
- **Radically better quality needed to support this explosive growth!**



Source: <https://www.abiresearch.com/press/more-than-30-billion-devices-will-wirelessly-conne>



58

Contact Us!



Nancy Van Schoonderwoert
LeanAgilePartners
nancyv@leanagilepartners.com

@vanschoo



Brian Shoemaker
ShoeBar Associates
bshoemaker@shoobarassoc.com

@brian_shoe



59

References

Current software-driven medical device examples taken from

<http://www.massdevice.com>, <http://medcitynews.com>,
<http://www.benzinga.com>, <http://www.devicespace.com>, and
<http://www.firstwordmedtech.com>.

Medical device recalls obtained by searching the FDA recalls database at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

Van Schoonderwoert, Nancy, 100-to-1 Ratio for Agile Defect Prevention Over

Traditional Methods, available on <http://leanagilepartners.com/publications.html>

AAMI TIR45:2012 "Technical Information Report: Guidance on the use of AGILE practices in the development of medical device software", Association for the Advancement of Medical Instrumentation, August 2012. (available at <http://my.aami.org/store/>)

Adzic, Gojko, *Impact Mapping*, 2012, London, Provoking Thoughts.

ISO 14971:2007 (2nd ed) Medical devices - Application of risk management to medical devices

ANSI/AAMI/IEC TIR80002-1:2009, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software, 26-Oct-2009.



60

Resources

- For assistance in regulatory submission documentation: Shoebar Associates (<http://www.shoebarassoc.com/>)
- For Agile coaching for safety-critical product development: Lean-Agile Partners (<http://leanagilepartners.com/>)
- For more info on QSM data comparisons, contact Michael Mah: michael.mah@qsm.com
- Tool mentioned that supports both Impact Mapping and Story Mapping: see TechTalk's SpecLog at <http://www.speclog.net/>

