



# Agile and Medical Devices

A story from a team at ResMed





# An Agile Journey

- Why use Agile for Medical Devices?
- Forming a team and those initial challenges and adjustments.
- Making Agile processes work in Medical Device Regulations.
- Why Conflict Resolution became important years later.



Why Agile?

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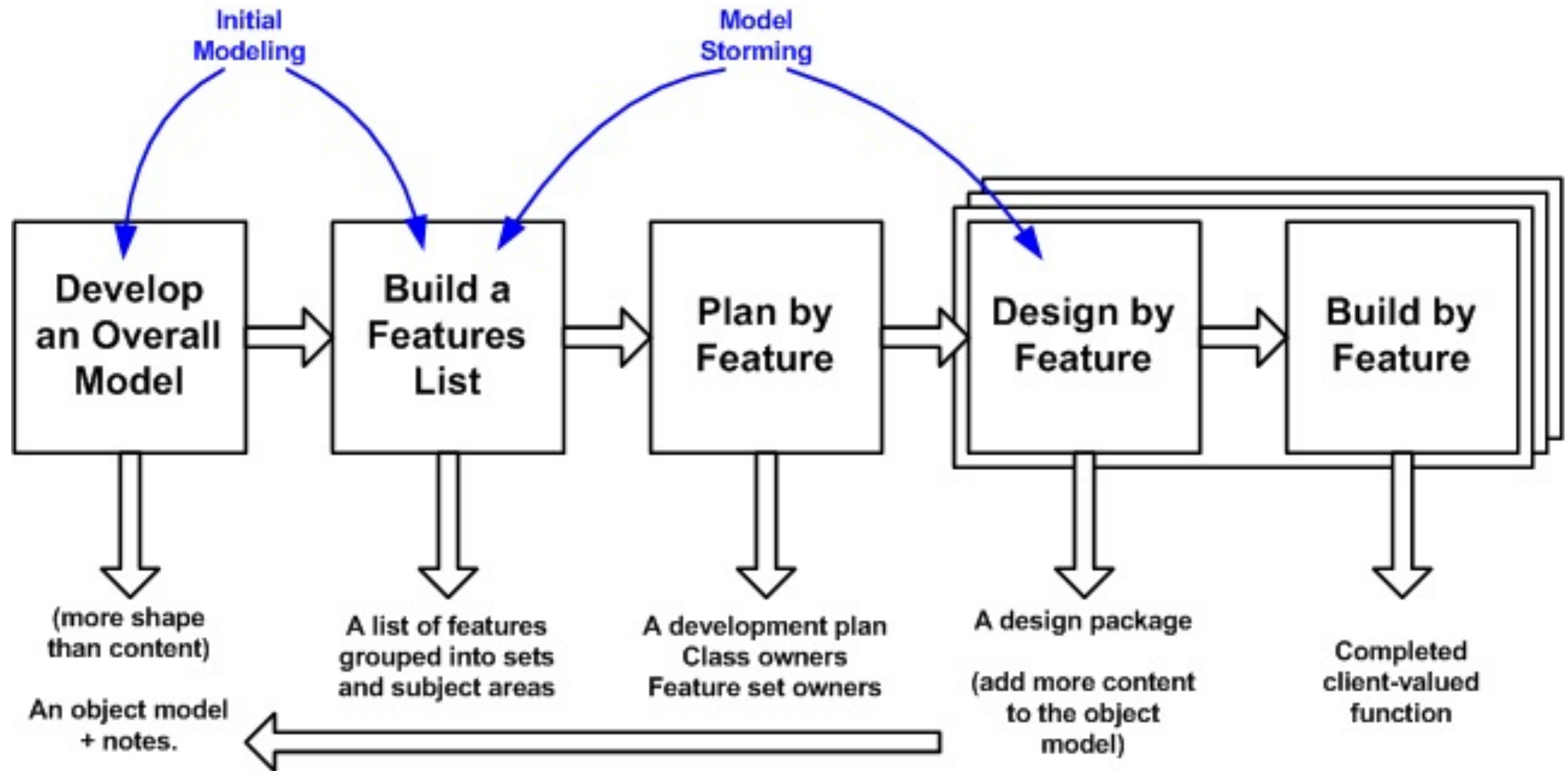
## PROGRAM

To download the PDF version, please click [here](#).

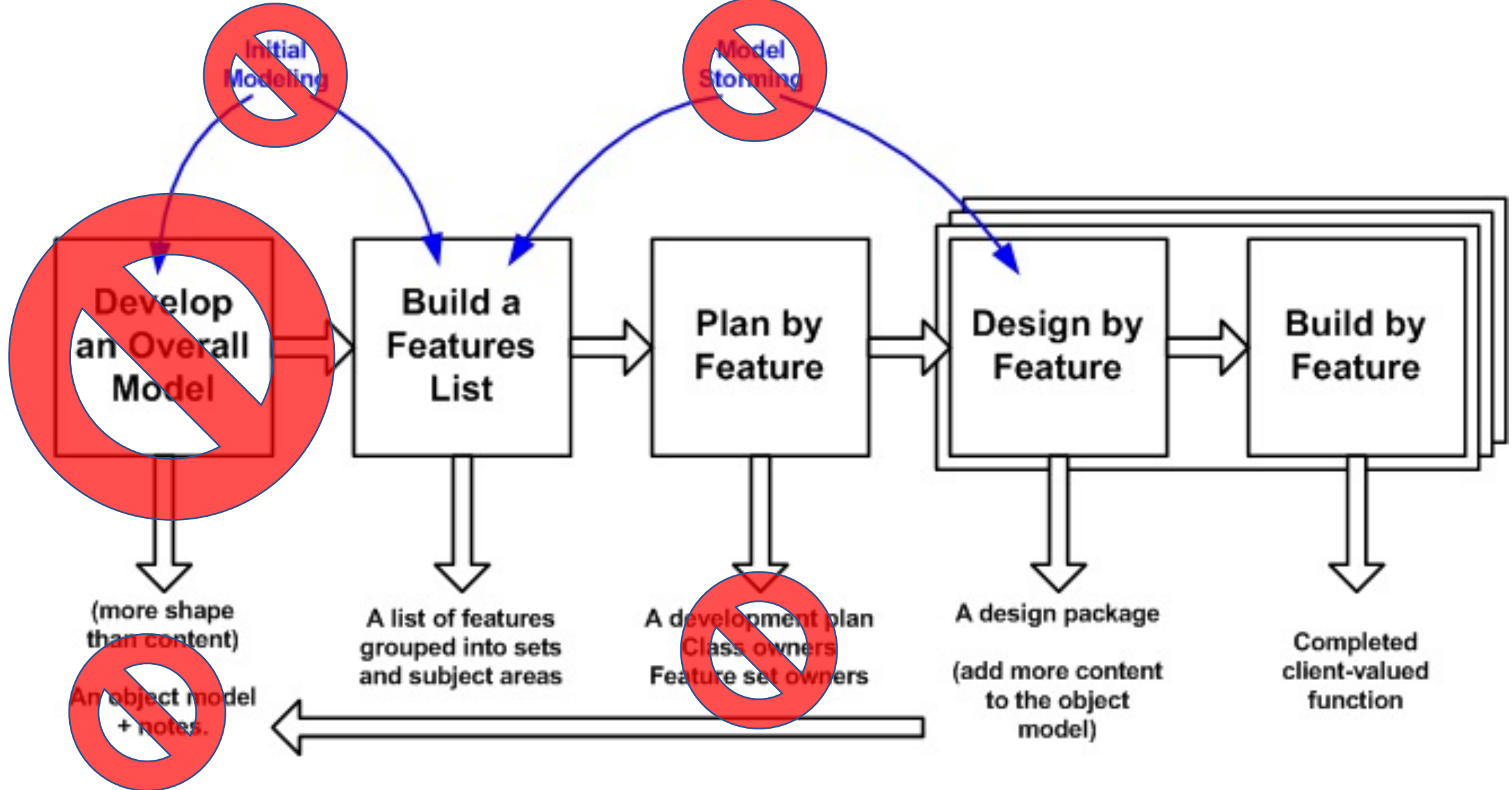
### DAY 1: Thursday 15th October, 2009

|         |   |   |
|---------|---|---|
| 9.00am  | <b>Panel: The journey towards the Agile enterprise</b><br>» Beverley Head ( <i>Moderator</i> )<br>» Nigel Dalton - Lonely Planet<br>» Katrina Rowett - Suncorp<br>» John Sullivan - Sensis                  |   |
| 9.45am  | <b>12 Agile adoption failure modes</b><br>» Jean Tabaka   |   |
| 10.45am | <b>Morning Tea</b>  |   |
| 11.15am | <b>What's it take to make an Agile transition?</b><br>» Shane Hastie - Software Education   | <b>7 habits of highly effective Agile developers</b><br>» Steve Hayes - Cogent Consulting |
| 12.00pm | <b>Panel: Waterfall is from Mars, Agile is from Venus</b><br>» Peter Whitfield - University of Sydney ( <i>Moderator</i> )<br>» Justin Freitag - Australia Post<br>» Todd Porter - Smart Service Queensland | <b>People driven Agile transformation</b><br>» John Sullivan - Sensis                     |





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CASE STUDY

# ResMed: Next-Generation Game Changing Market Solution

A DiUS and ResMed partnership has delivered a next-generation compliance management solution, EasyCare Online (ECO), to support ResMed's continued leadership and growth in the rapidly growing global sleep-disordered breathing market.



Central to the success of the custom software development project was an Agile and Lean approach that helped the DiUS-ResMed team to continually prioritise features and get the product to market on time with the most business value. Just as important was



# Why Agile?

- Got inspired by Agile Australia.
- FAIL: Tried Feature Driven Development in a half hearted way.
- FAIL: Outsourced online system development.
- SUCCESS: Outsourced online system development to an Agile services company.
- Let's try and emulate that!



A New Team



**Telit**  
HE910-D  
IMEI: 014334000377652  
Model: HE910-D  
ANATEL: 3120-11-2618  
FCC ID: R17HE910  
IC: 5131A-HE910  
Designed in Italy. Made in China

531018958  
R319-154  
1

PA-25

095  
1000A  
CM

3.3  
J65  
K.0

01  
1000A  
CM





Remember  
who its  
all for

to all  
students &  
YP's

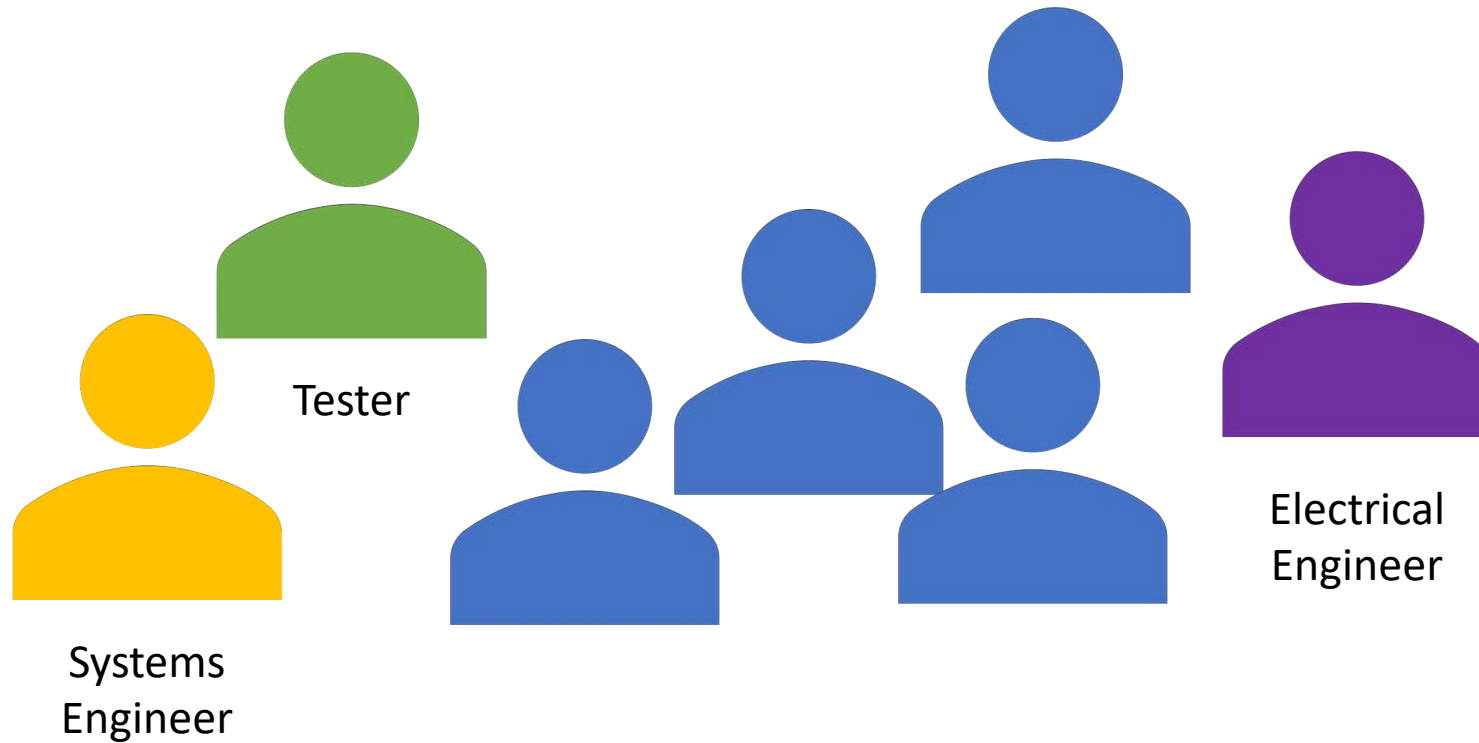
#partnerships  
1. ✓ 4.  
2. ✓ 5.  
3. ✓ 6.

don't be  
a chicken

# Stories not Features

As a User  
I want a way to do behaviour  
So that I can get outcome

# Cross functional team





# RETRO

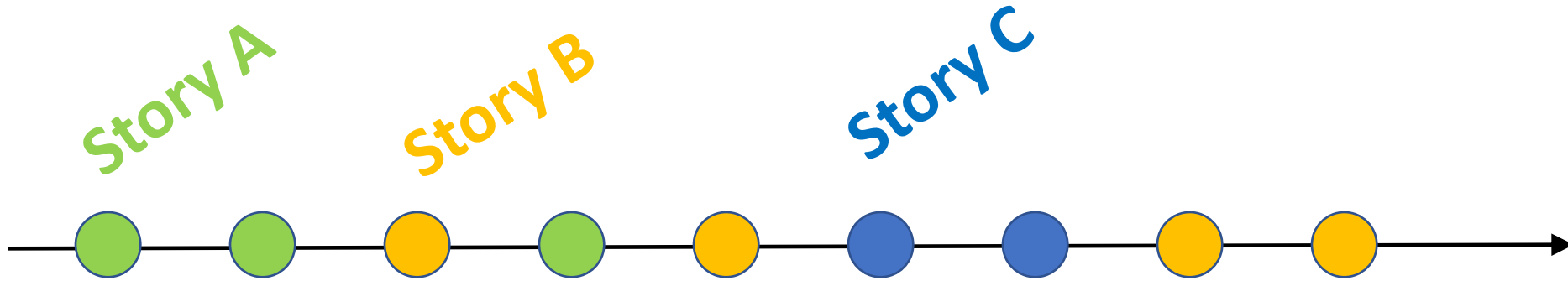


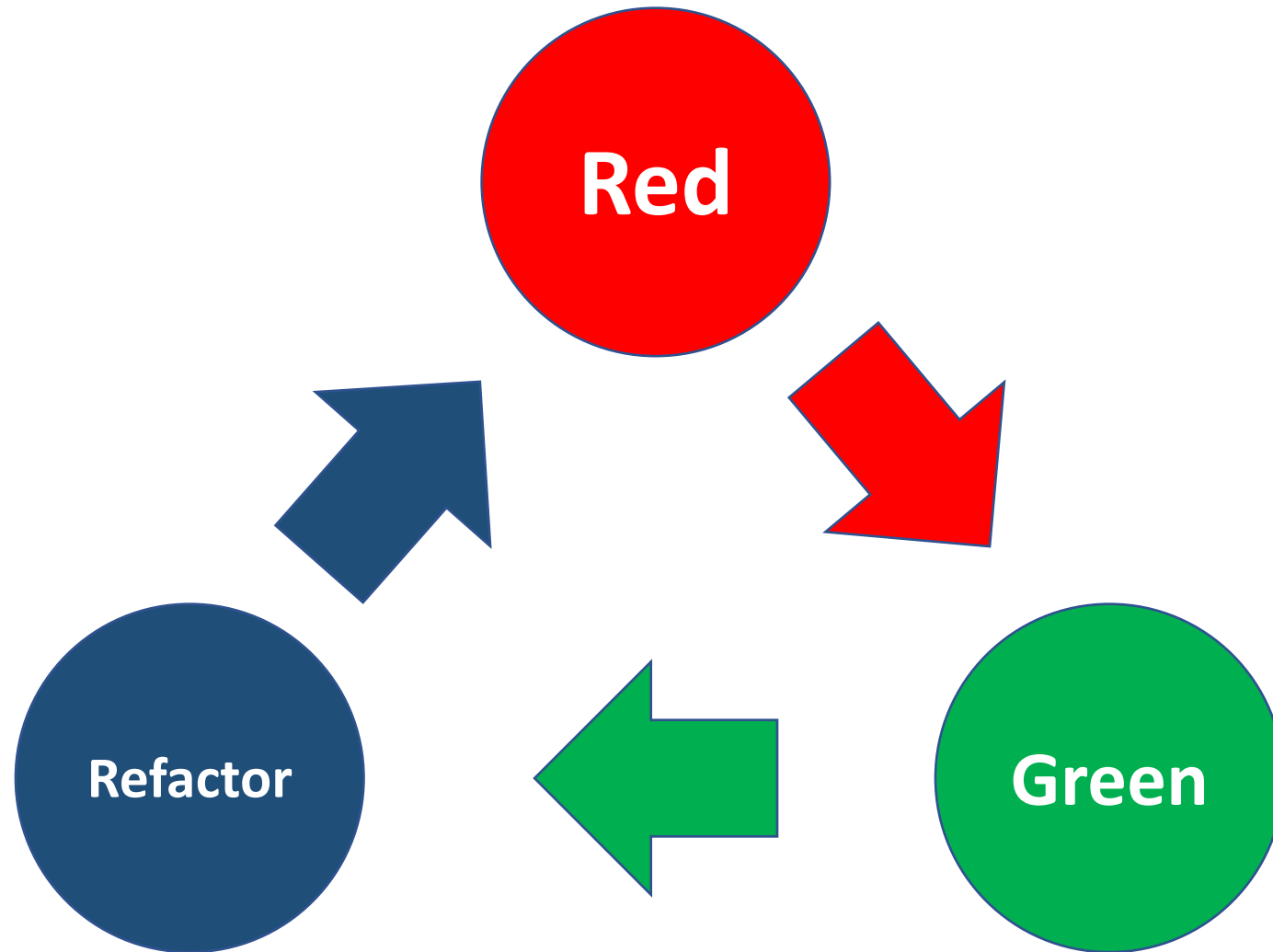
- Paul not at Retro

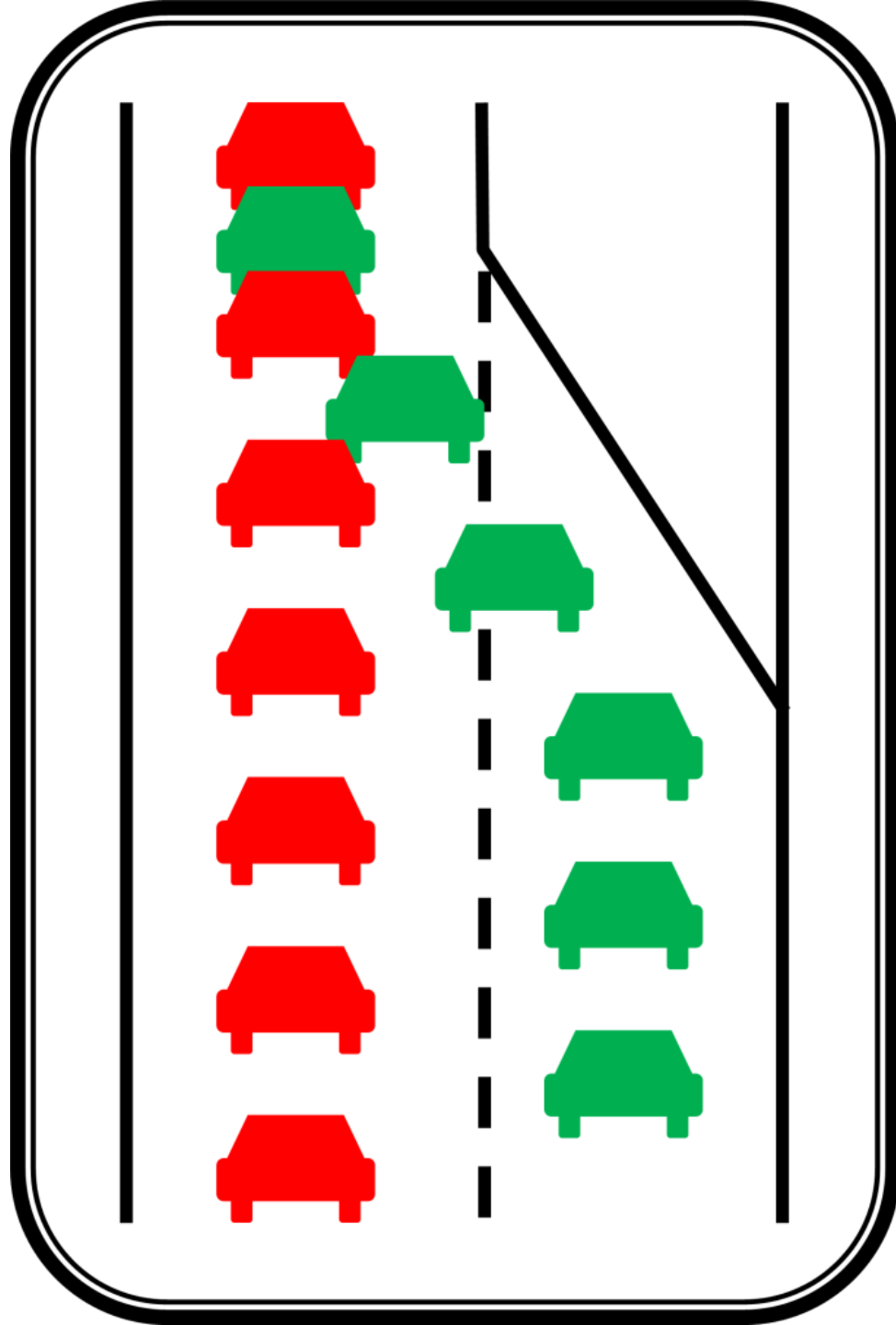


- Paul missed RETRO
- Cards without estimates / unplanned work
- Spikes with commits
- Estimates for estimating
- IT blocking internet

# Integrate all the time!









# A New Team

- Brought in an experienced coach to kick start the team.
- Focused on Stories not Features.
- Honest and open Retrospectives.
- Short term actions followed through.
- Trunk based development.
- Practicing Test Driven Development.
- Lots of collaboration!



# Regulations

| Risk level     | Classification(s)  | Examples   |
|----------------|--|--|
| Low            | Class I  | <ul style="list-style-type: none"> <li>• Surgical retractors</li> <li>• Tongue depressors</li> </ul>   |
| Low to Medium  | Class I - supplied sterile<br>Class I - with a measuring function<br>Class IIa | <ul style="list-style-type: none"> <li>• Sterile surgical gloves</li> <li>• Medicine cup with specific units of measurement</li> <li>• Dental drills; ultrasound machines; digital or infrared thermometers</li> </ul> |
| Medium to High | Class IIb  | <ul style="list-style-type: none"> <li>• Surgical lasers</li> <li>• Diagnostic X-ray</li> </ul>  |
| High           | Class III  | <ul style="list-style-type: none"> <li>• Prosthetic heart valves</li> <li>• Absorbable surgical sutures</li> <li>• Hip prostheses (for example, replacement of hip joint)</li> </ul>                                   |
| High           | Active implantable medical devices (AIMD)                                      | <ul style="list-style-type: none"> <li>• Pacemakers</li> <li>• Artificial heart</li> </ul>   |







Feature: Test pricing # features/pricing.feature:1

Customer provides details and the system returns a pricing.

To test that we have verified the following scenarios:

Scenario Outline: Test pricing for source, destination, pax -- @1

Given Customer specified from "Bergen" to "Oslo" with "10"

When She queries for price

Then She expects the pricing to be "200"

Scenario Outline: Test pricing for source, destination, pax -- @1

Given Customer specified from "Oslo" to "Bergen" with "5"

When She queries for price

Then She expects the pricing to be "100"

1 feature passed, 0 failed, 0 skipped

2 scenarios passed, 0 failed, 0 skipped

6 steps passed, 0 failed, 0 skipped, 0 undefined

Took 0m0.002s

If Agile is to deliver production ready code - why aren't all features HW tested on check-in

Do we have consensus about current state of CD

Why Discuss it now

Can some steps be removed?

Steps to be removed combined & simplified ???

TL Team Leader

UPDATE document templates

Can we remove this log generating template?

Not built tested in parallel?

Building old versions of folder struct

Integ tests run for hrs of hours - binary

Do we run upgrade / downgrade manually?

Regular build on a Project

Midnight Passes

Release Readiness Check

Release criteria Passes Ready to SI

Release is branched for new SI

Release is built for an SI

Test Results complete on SI

Push test results to DB

Run Document Generation Job

Smoke test on binary

Does R.R. check on appropriate test fields?

Can we auto make these two together?

Sanity test?

Test Result Failed on SI

Draft Release record

Where is the Data-base?

Spotting early holes in system due to process change

Smoke Test

SI was created even though integ to Dev II FAILED

How does make release fails testable?

# Regulations

- Medical Device regulations describe a waterfall development process.
- Three Amigos as a formal approval for requirements.
- Collaborative design discussions. Photograph the whiteboard as a record.
- Behaviour Driven Development nicely documents our behaviour in detail and can be run all the time.
- Releases needed a lot of investment. Still could improve a lot.

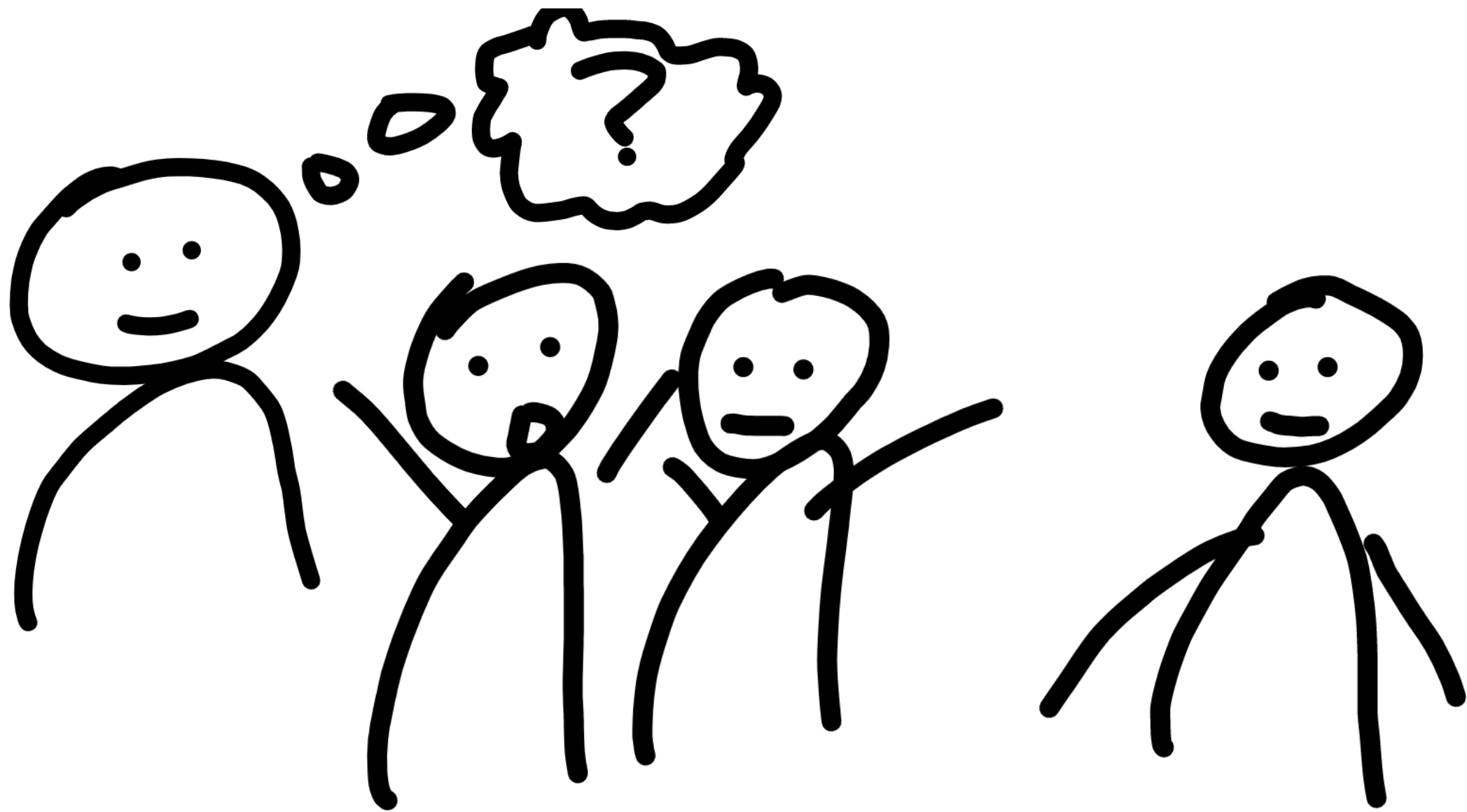


# A Shock to the System

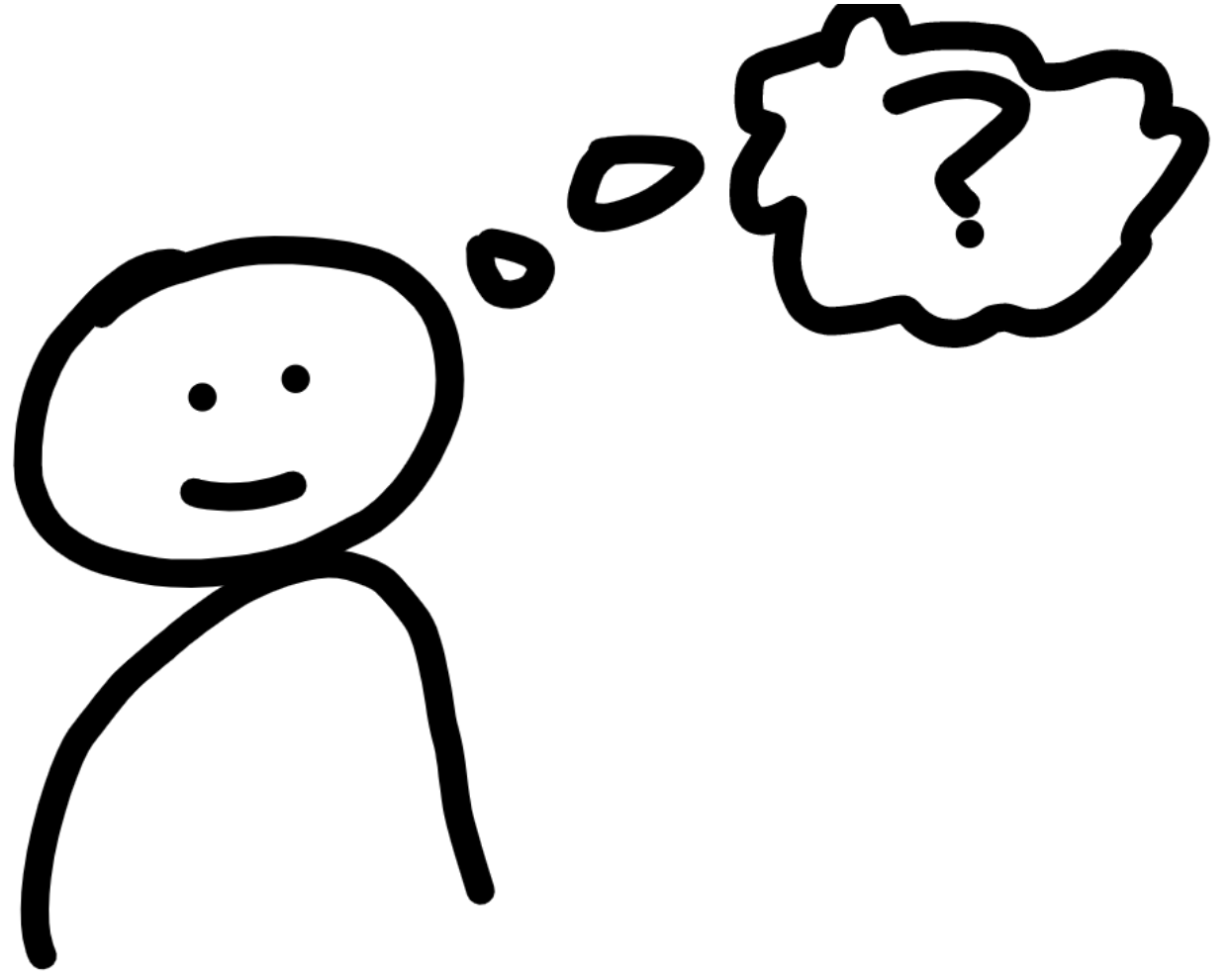


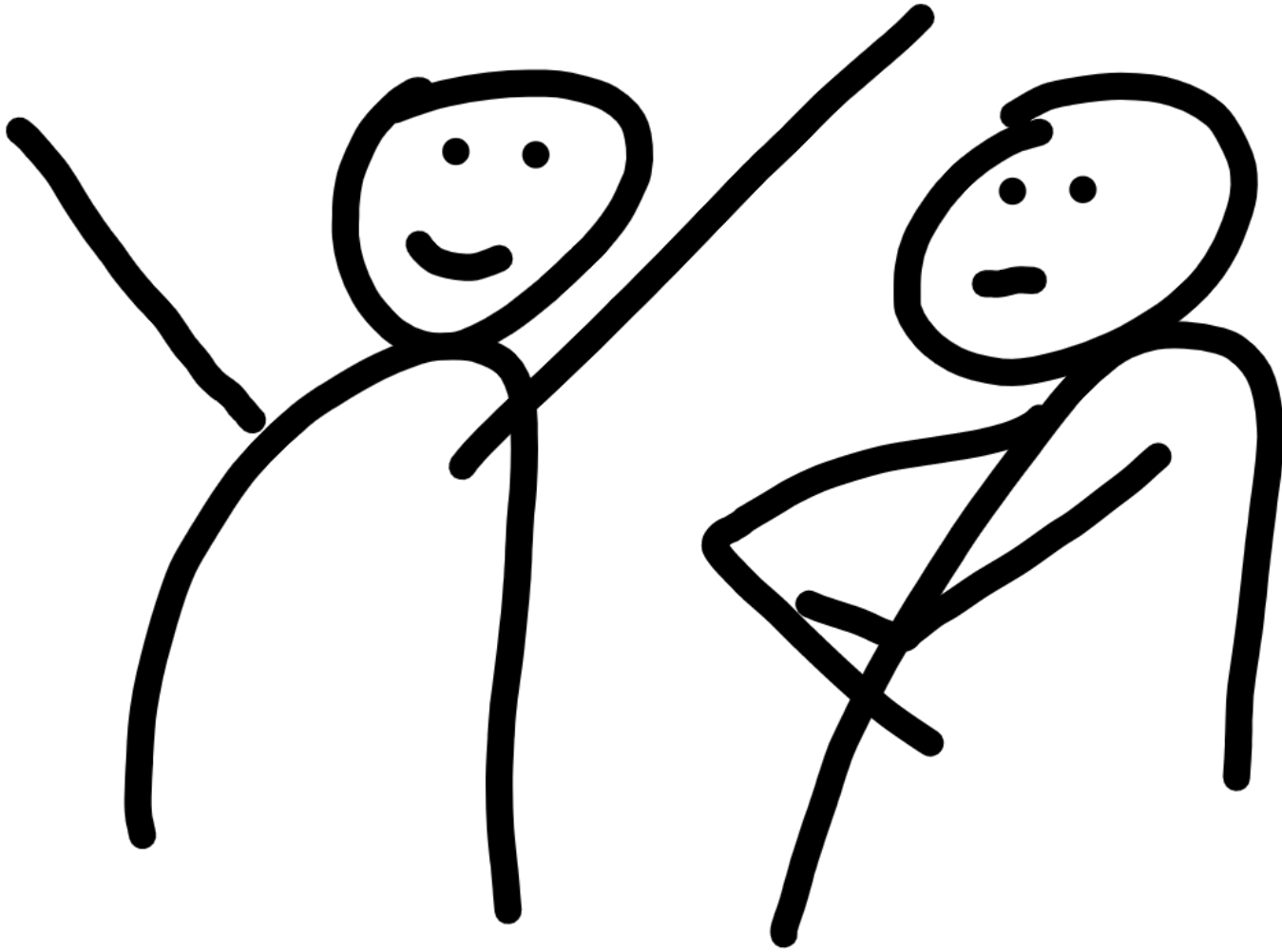




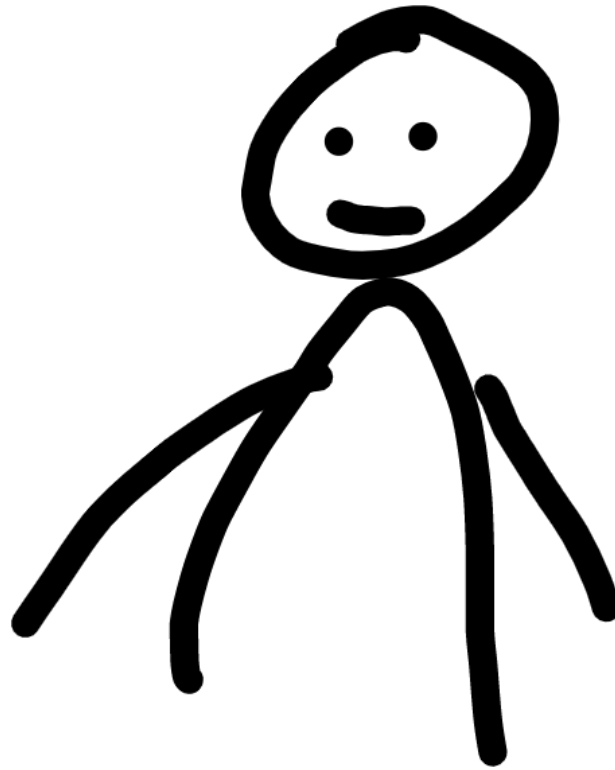
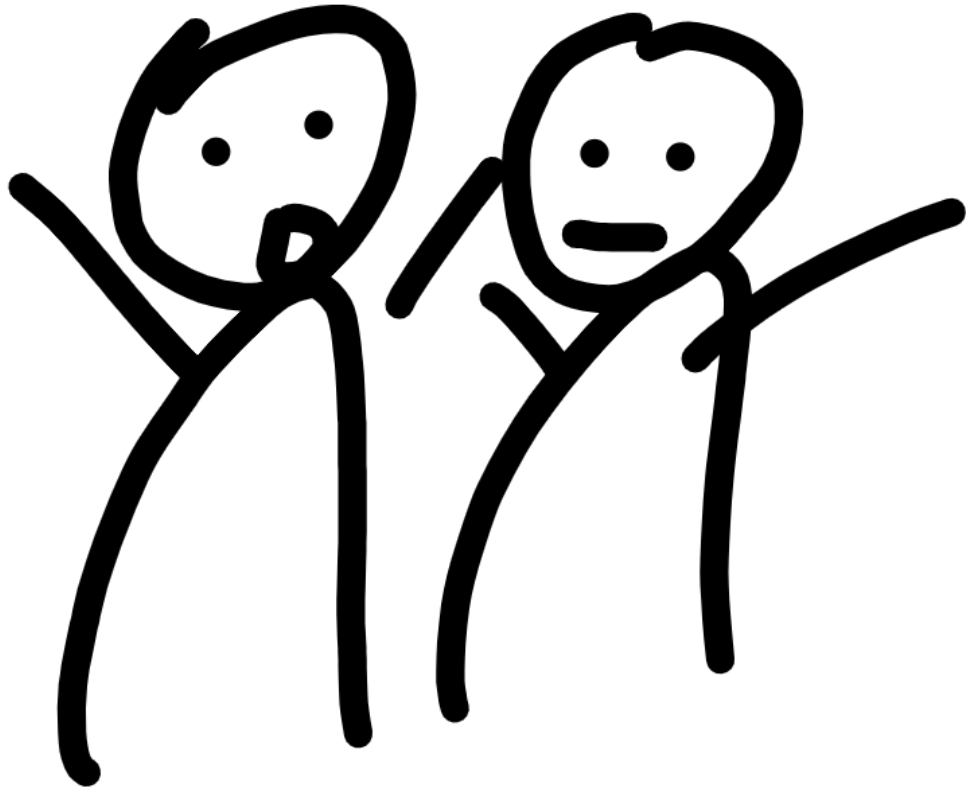


What don't I  
understand  
about the other  
option(s)?





Put the ideas onto  
a whiteboard

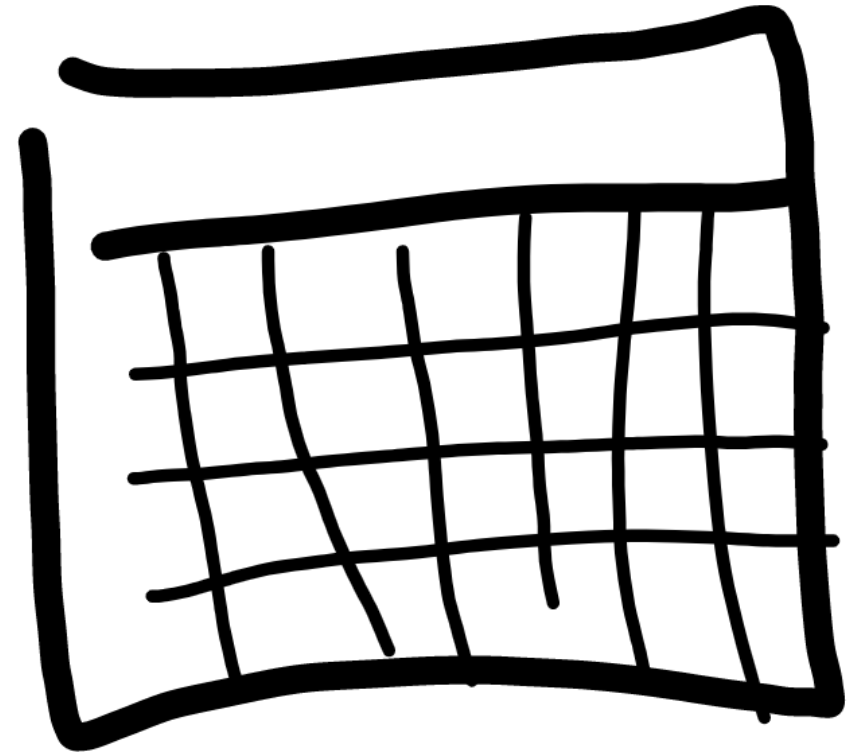


What risks is  
each person  
worried about?



Which option is  
easier to test?

Is this the new  
standard going  
forward? Let's  
document it!







# Conflict!

- Losing a key role exposed where we lacked safety.
- The team's default thinking was to find the “best” solution and didn't leave room for disagreement.
- Needed to intervene with training and support to avoid conflict becoming personal.
- Enabled teams to overcome conflict with empathy instead of technical skill.



a new beginning



@AgileGeoff