Improve
QUALITY SERVICES

Lean principles for medical devices

April 2019
Johan van Berkel & Patrick Duisters

adviseren.

leren.

doen.

Versie 1.0.1

Agenda

- Introduction
- Background
- Determine topics
- Cover first topic
- Break
- Cover second topic
- (Optional) third topic or free discussion / questions
- QBM feedback

About Improve Quality Services

Consult

Train

Execute

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info@improveqs.nl

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Prof. Dr. Dorgelolaan 30, 5613 AM Eindhoven
Amsterdamsestraatweg 55A, 3744 MA Baarn

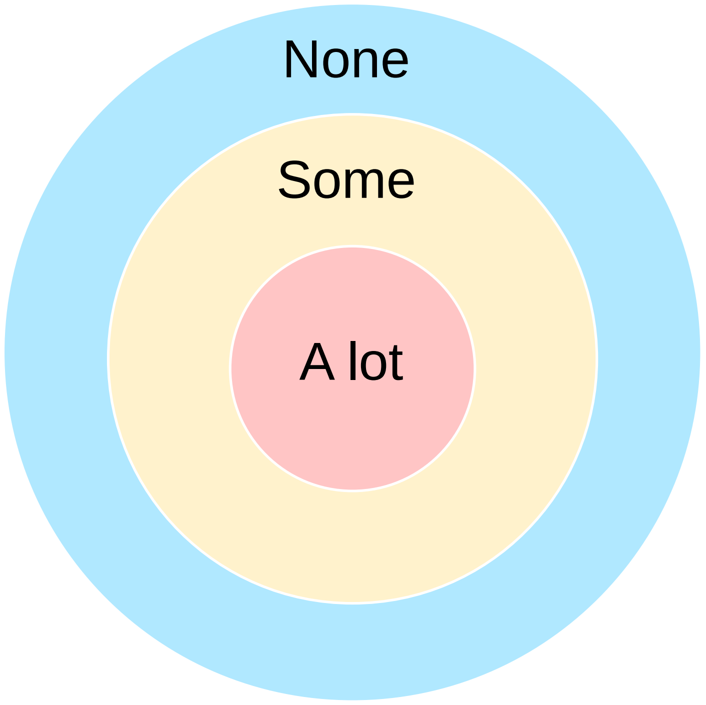
Who are you?

- Name, current position
- What do you hope to learn here?

Who are you?

- Circle exercise

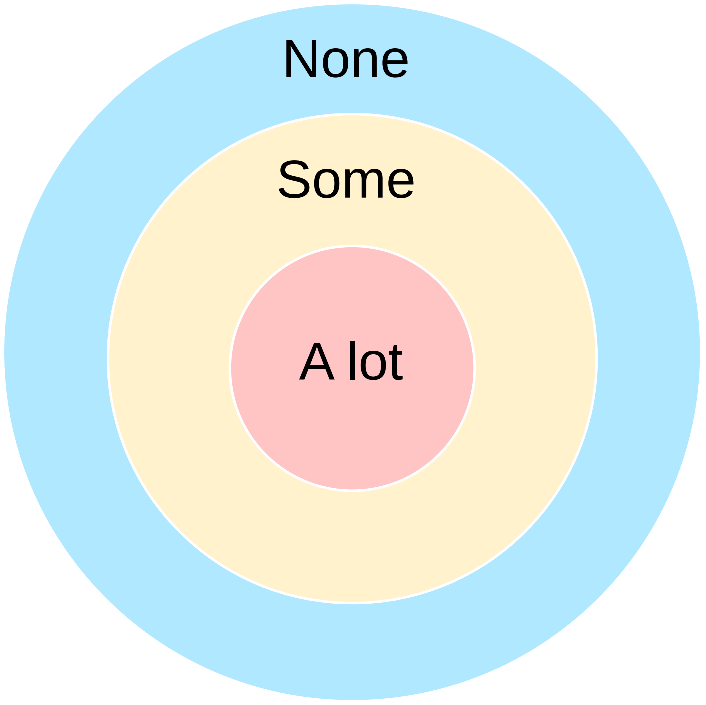
Experience with medical development?



Who are you?

- Circle exercise

Experience with LEAN principles?



About Patrick Duisters CTEL

- Over 20 years experience
  - Software Testing & Quality Assurance
  - Administrative, Technical, Medical, Financial, Governmental, Automotive
- Medical experience:
  - Interventional X-Ray (tester & process mgt)
  - Refurbished Systems (tool validation)
  - Philips Innovation Services (test architect)
  - Biocartis (test architect & usability)
  - Image Guide Therapy: Business Incubation (test architect & usability)
- Test Consultant & Trainer

About Johan van Berkel

- 13 years experience
  - Software and Hardware Testing
  - Embedded and Medical domain
- Medical experience
  - Image Guided Therapy Philips
    - Test Designer Geometric domain
  - Digital Computational Pathology
    - Verification Lead ART Scanner
    - Coaching of requirements engineers
- Test Consultant

Background

Background

A long time ago…

code of federal regulations

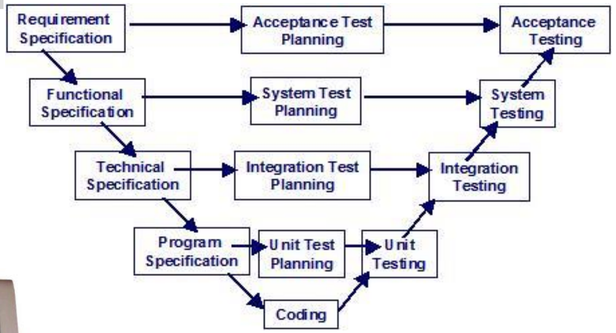
FOOD & DRUG ADMINISTRATION

21 CFR
Part 820
Quality System Regulation

Good Manufacturing Practice for Medical Devices

GMP PUBLICATIONS ★ QUALITY COMPLIANCE MATERIALS ★

"Helping Companies Meet and Exceed FDA and Total Quality Management Standards!"



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Background

Times change

NETFLIX

code of federal regulations

FOOD & DRUG ADMINISTRATION

21 CFR
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Good Manufacturing Practice for Medical Devices

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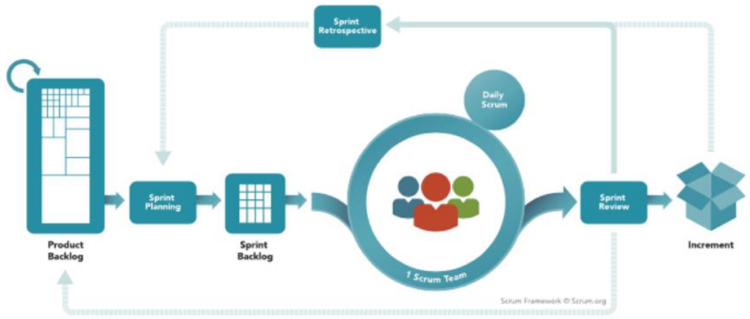

Spotify®

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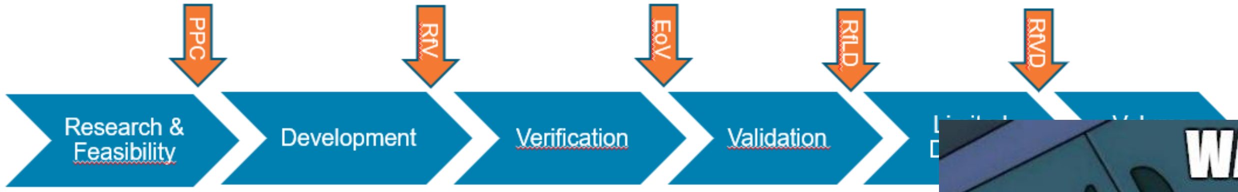
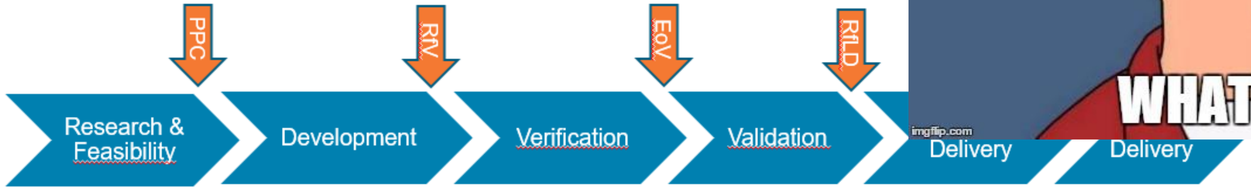
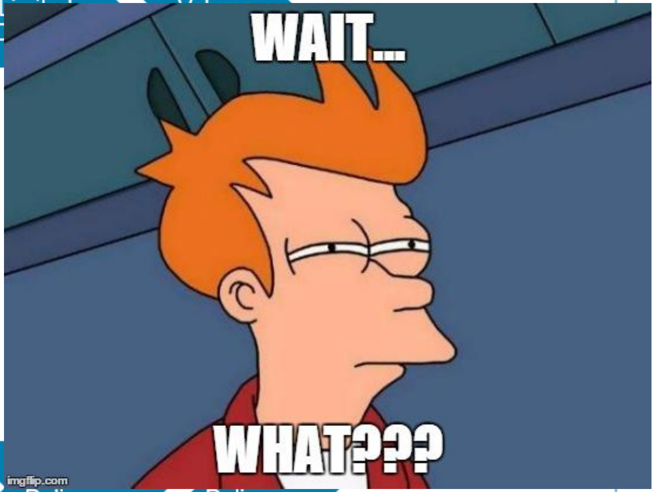
Background

Sequential development:



Iterative development:

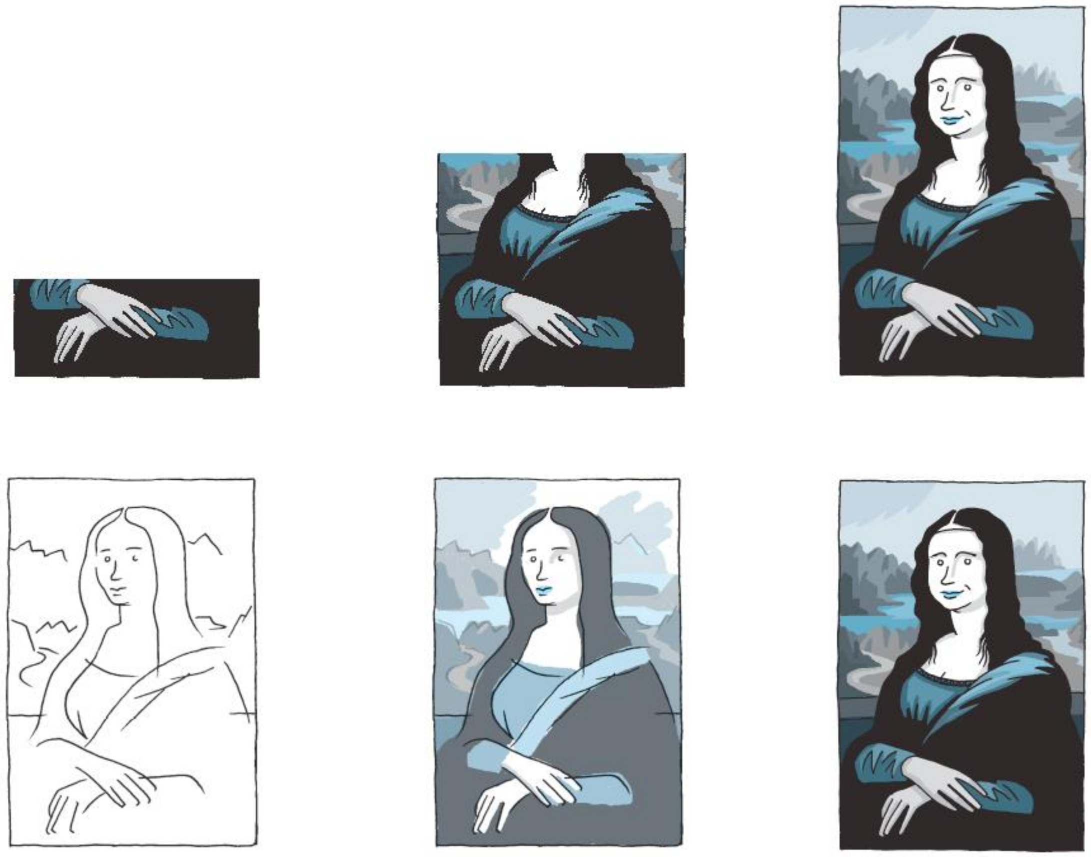




Background

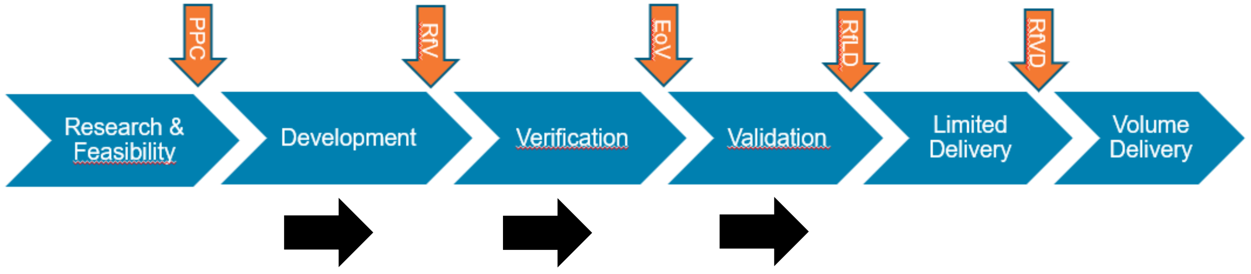
Incremental

Iterative



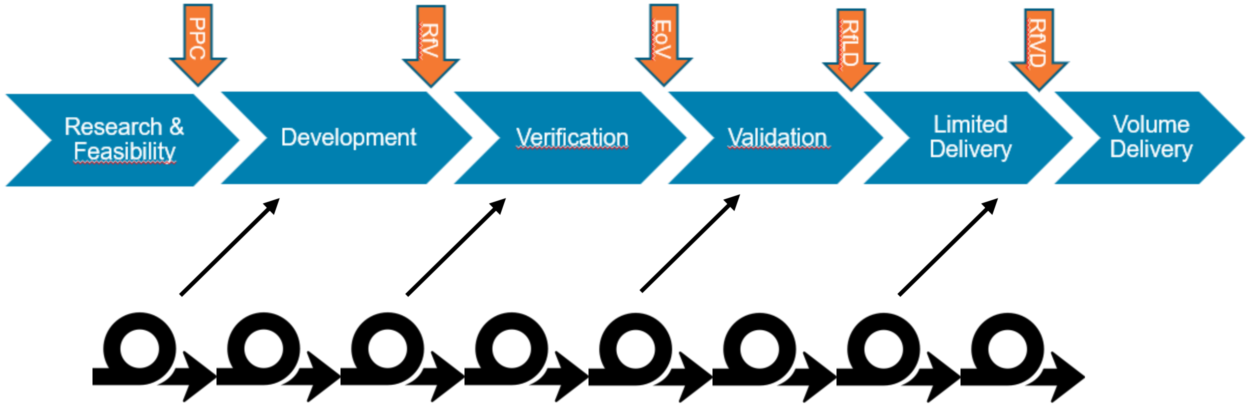
Background

Sequential development:



Implement Verify Validate

Iterative development:



“Everything, all the time”

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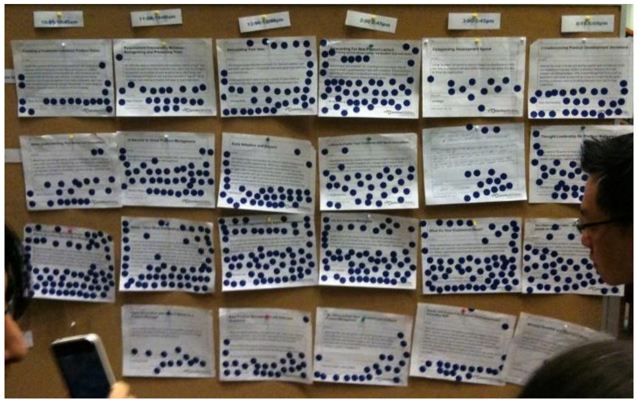
Determine topics

Brainstorm (20 min)
What related problems have you seen?

- Split up group (3-4 persons per team)
- Select top three most interesting topics
- Stick them on the board

Voting (5 min)

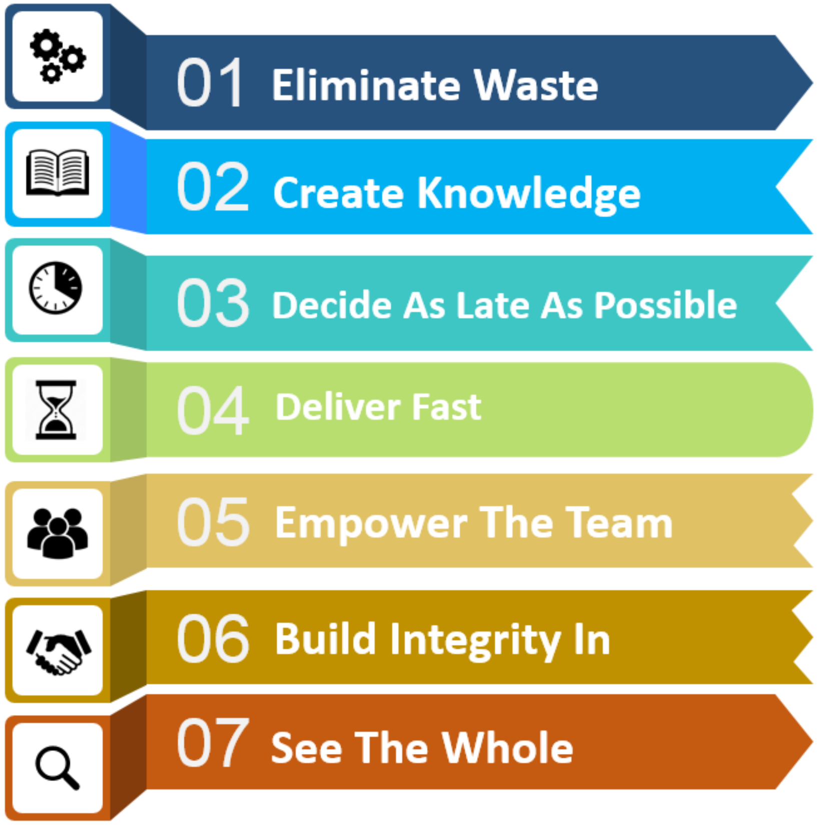
- Group similar topics
- Split in / out of scope of presentation
- Vote on the topics you like to discuss



Out of scope topics can be discussed ad-hoc at the end of this session

Shifting perspective

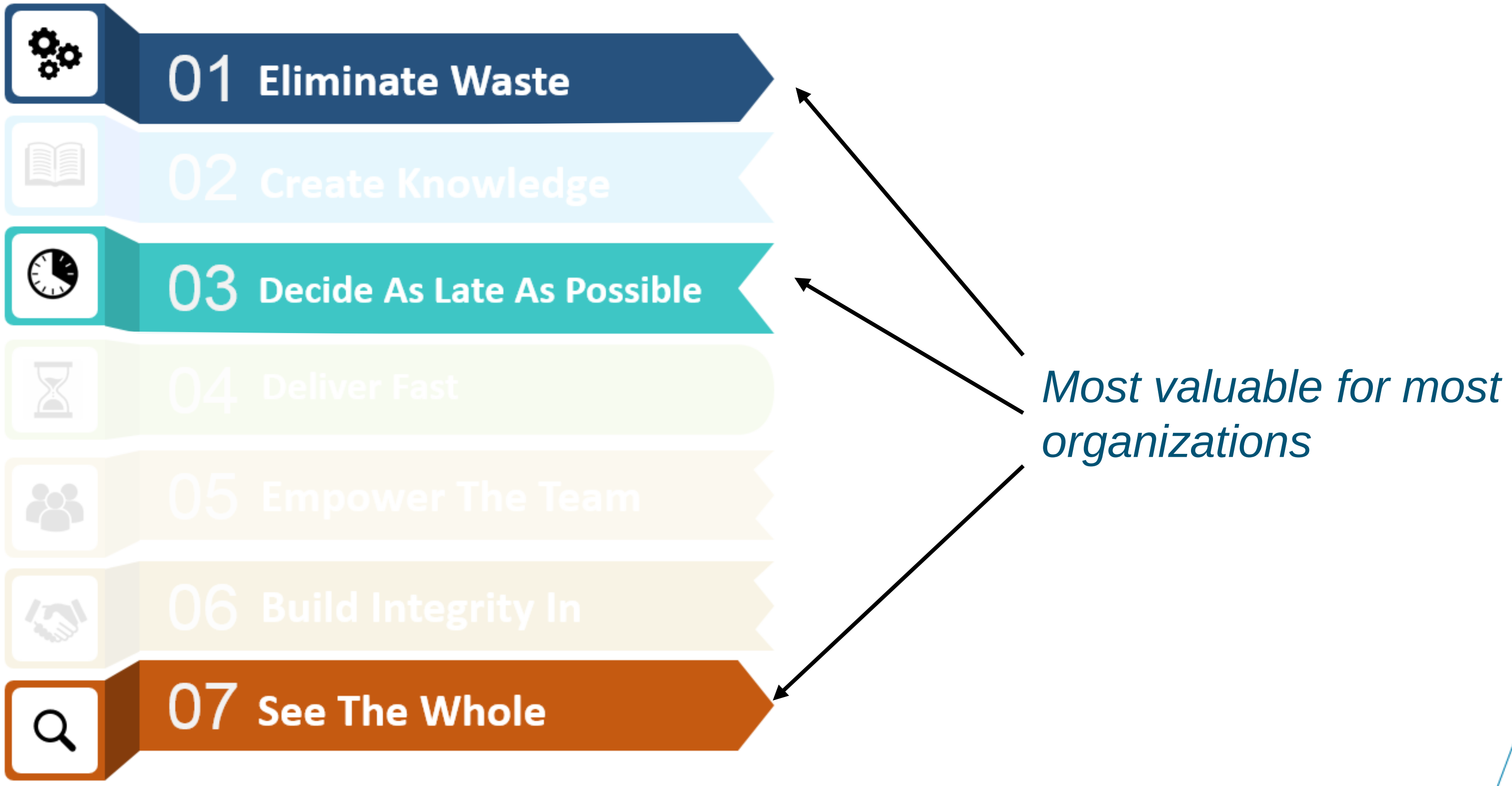
Lean principles for software development



Principles are goals that are considered worth pursuing, without describing how they should be pursued.

Shifting perspective

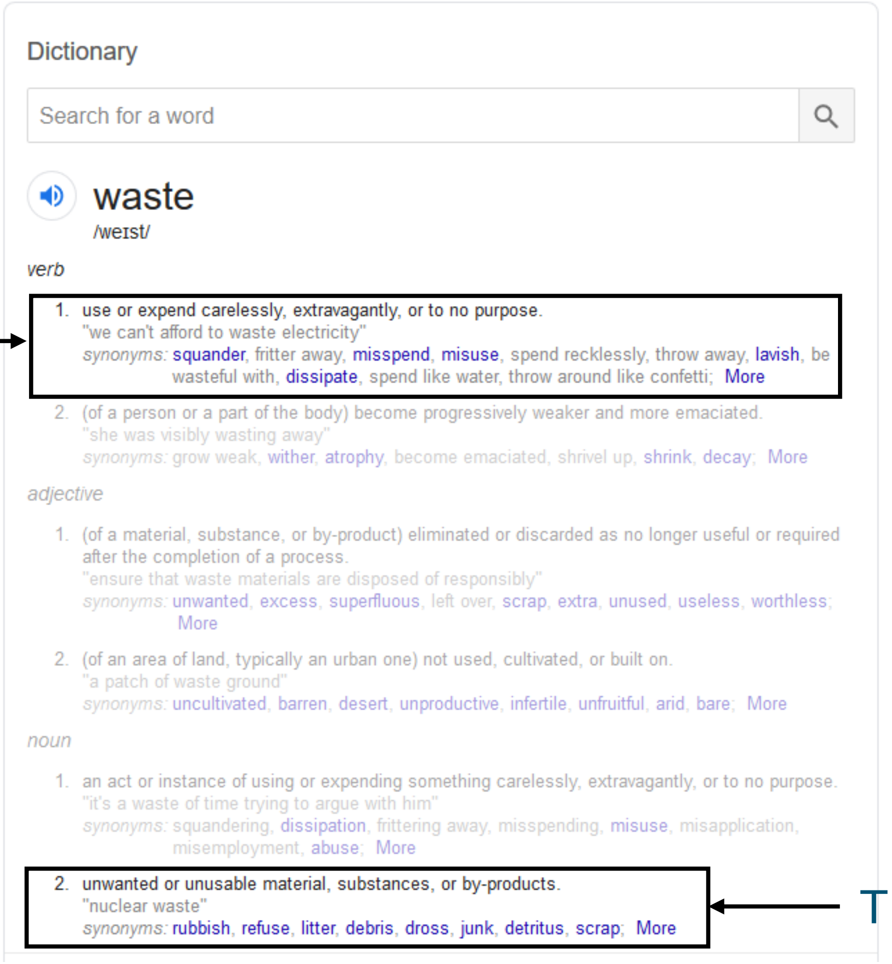
Limited number of principles covered in this context



Definition:

01 Eliminate Waste

Source of confusion…



Dictionary

Search for a word

waste
/weɪst/

verb

1. use or expend carelessly, extravagantly, or to no purpose.
   "we can't afford to waste electricity"
   synonyms: squander, fritter away, misspend, misuse, spend recklessly, throw away, lavish, be wasteful with, dissipate, spend like water, throw around like confetti; More
2. (of a person or a part of the body) become progressively weaker and more emaciated.
   "she was visibly wasting away"
   synonyms: grow weak, wither, atrophy, become emaciated, shrivel up, shrink, decay; More

adjective

1. (of a material, substance, or by-product) eliminated or discarded as no longer useful or required after the completion of a process.
   "ensure that waste materials are disposed of responsibly"
   synonyms: unwanted, excess, superfluous, left over, scrap, extra, unused, useless, worthless; More
2. (of an area of land, typically an urban one) not used, cultivated, or built on.
   "a patch of waste ground"
   synonyms: uncultivated, barren, desert, unproductive, infertile, unfruitful, arid, bare; More

noun

1. an act or instance of using or expending something carelessly, extravagantly, or to no purpose.
   "it's a waste of time trying to argue with him"
   synonyms: squandering, dissipation, frittering away, misspending, misuse, misapplication, misemployment, abuse; More
2. unwanted or unusable material, substances, or by-products.
   "nuclear waste"
   synonyms: rubbish, refuse, litter, debris, dross, junk, detritus, scrap; More

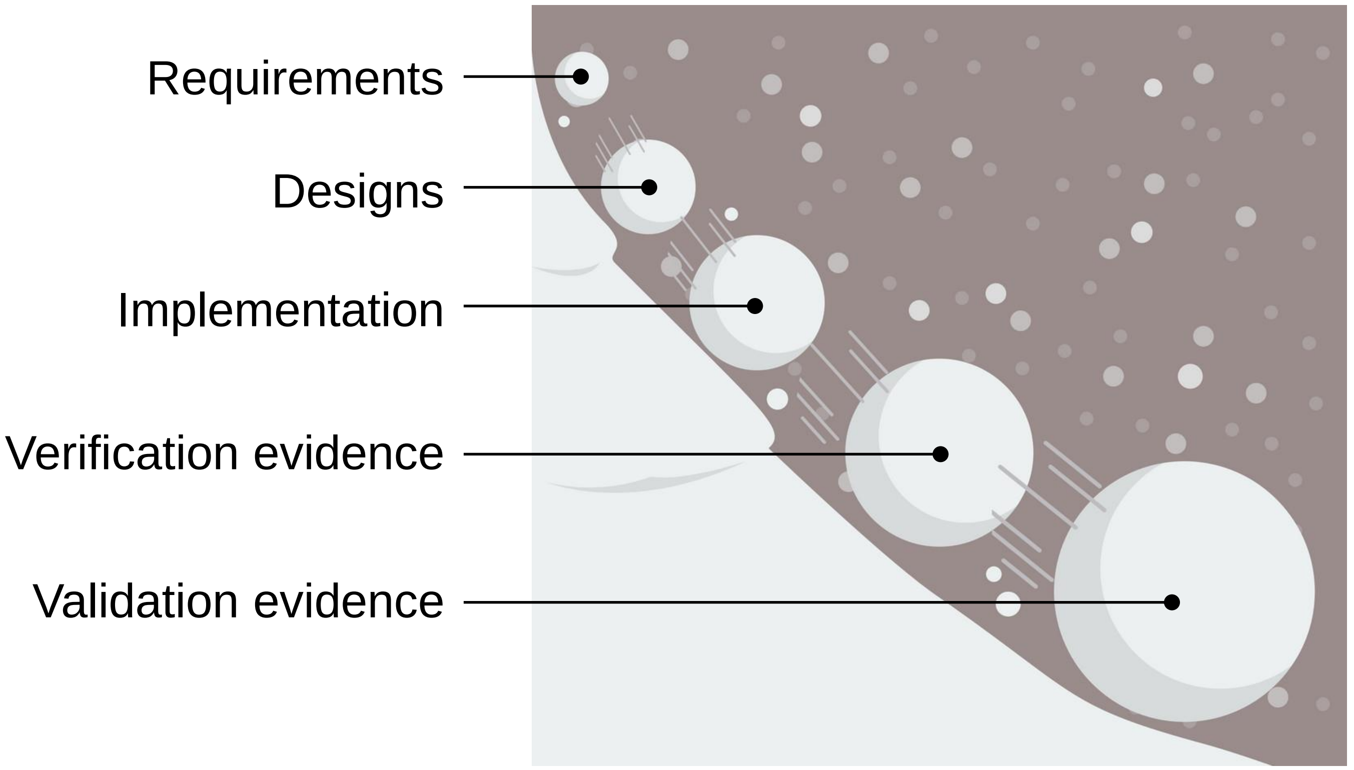
Lean as a whole → (verb 1)

This principle → (noun 2)

Symptoms:

01 Eliminate Waste

Requirements are most impactful:



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Symptoms:

01 Eliminate Waste

Waste in requirements results in

- Test coverage too high (unneeded effort)
- Test coverage too low (requires refactoring across entire DHF)
- Cumbersome submission (difficulty answering questions)
- Endless discussions

Plethora of causes:

- Incorrectly purposed
- Missing/Redundant
- Superfluous/Deficient

Solutions:

01 Eliminate Waste

Incorrectly purposed

Not all requirements are created for the same purpose
Different purpose ➔ Different process

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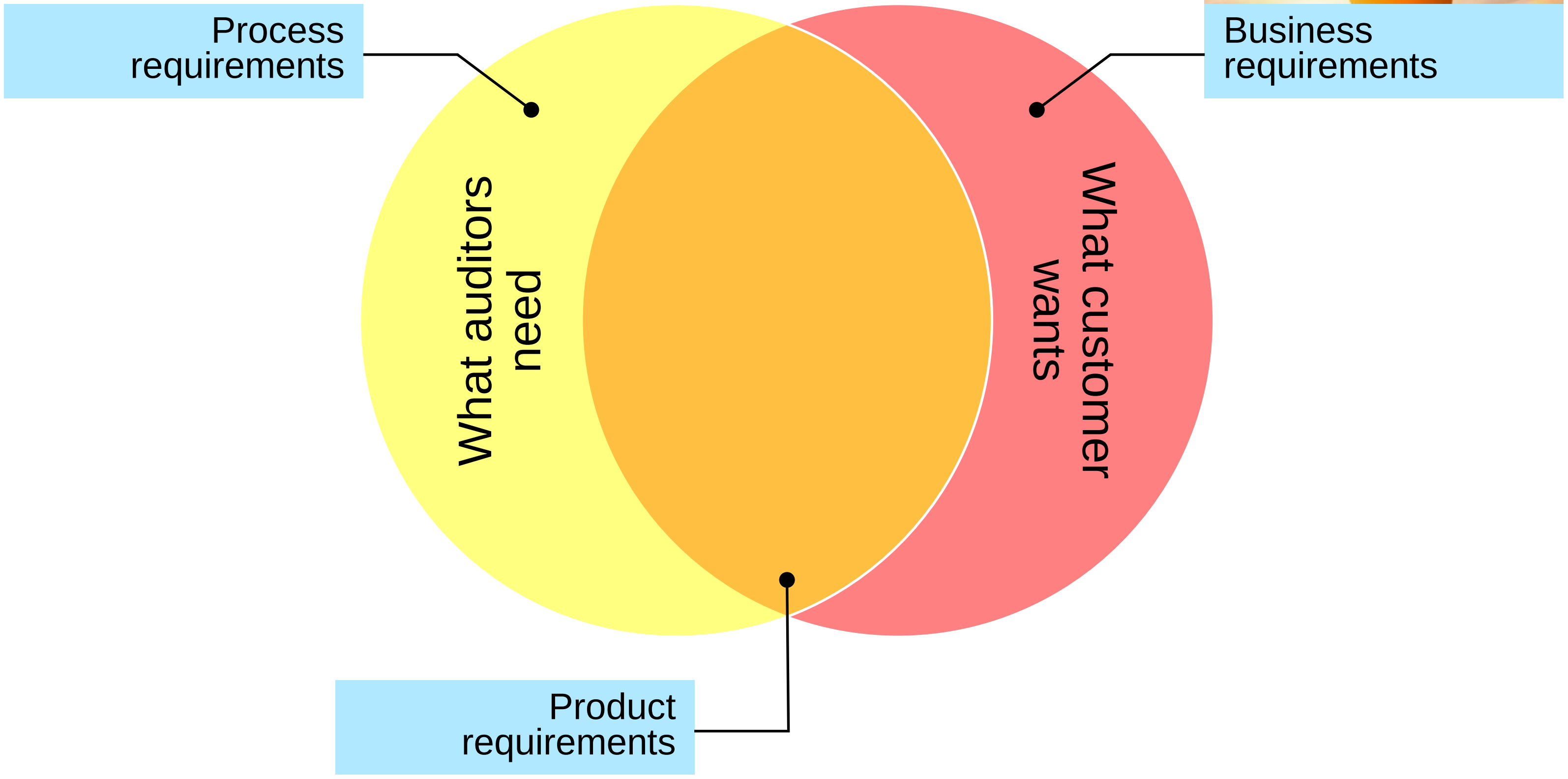
Solutions:

01 Eliminate Waste

Incorrectly purposed

Why do we create requirements:



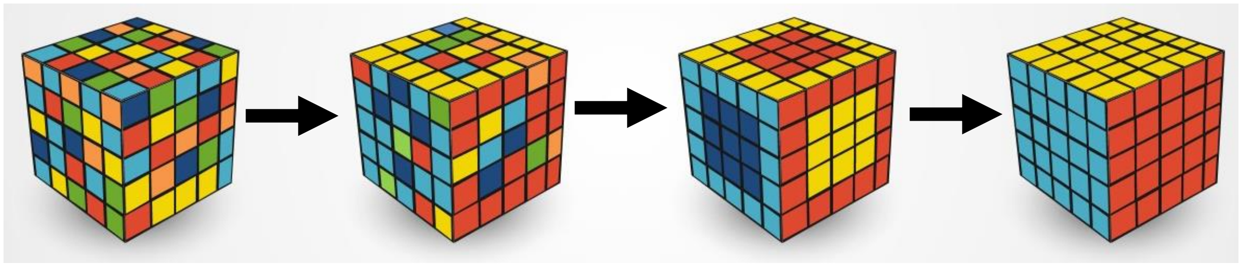
Solutions:

01 Eliminate Waste

Redundant / Missing

Combing the desert?

Do it systematically…



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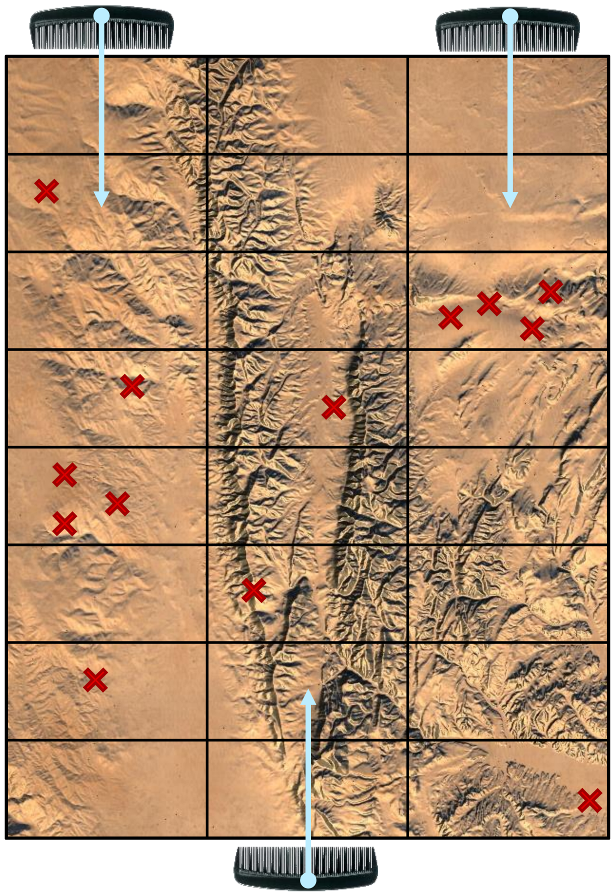
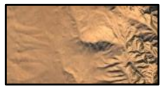
Solutions:

01 Eliminate Waste

Redundant / Missing

Mutually Exclusive, Collectively Exhaustive



	High level goal or characteristic of the product
	*Capability supporting the intended use*
✖	*(Non-)functional requirement*

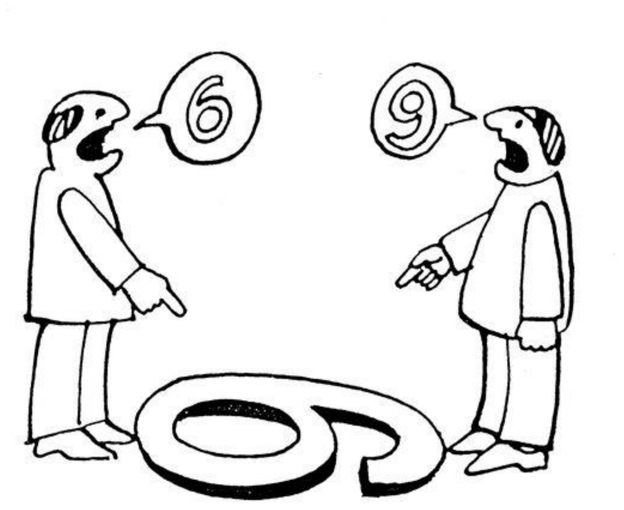
- Use characteristics that are useful for you
- Define capabilities at high level
- Use customer/user terminology
- Allow requirements to emerge ad-hoc
- Requirement doesn't fit? Tweak the model!

Solutions:

01 Eliminate Waste

Superfluous / Deficient

The how/what paradigm trap:



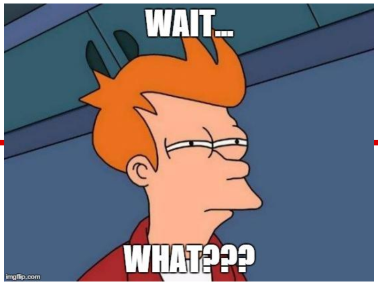
$$\begin{tikzcd}
\boxed{\text{Requirement}} \arrow[r, bend right, "\text{How?}"'] & \boxed{\text{Implementation}} \arrow[l, bend right, "\text{Why?}"']
\end{tikzcd}$$

Solutions:

01 Eliminate Waste

Superfluous / Deficient

The how/what paradigm trap:



Requirements are expected to contain "some degree of implementation"

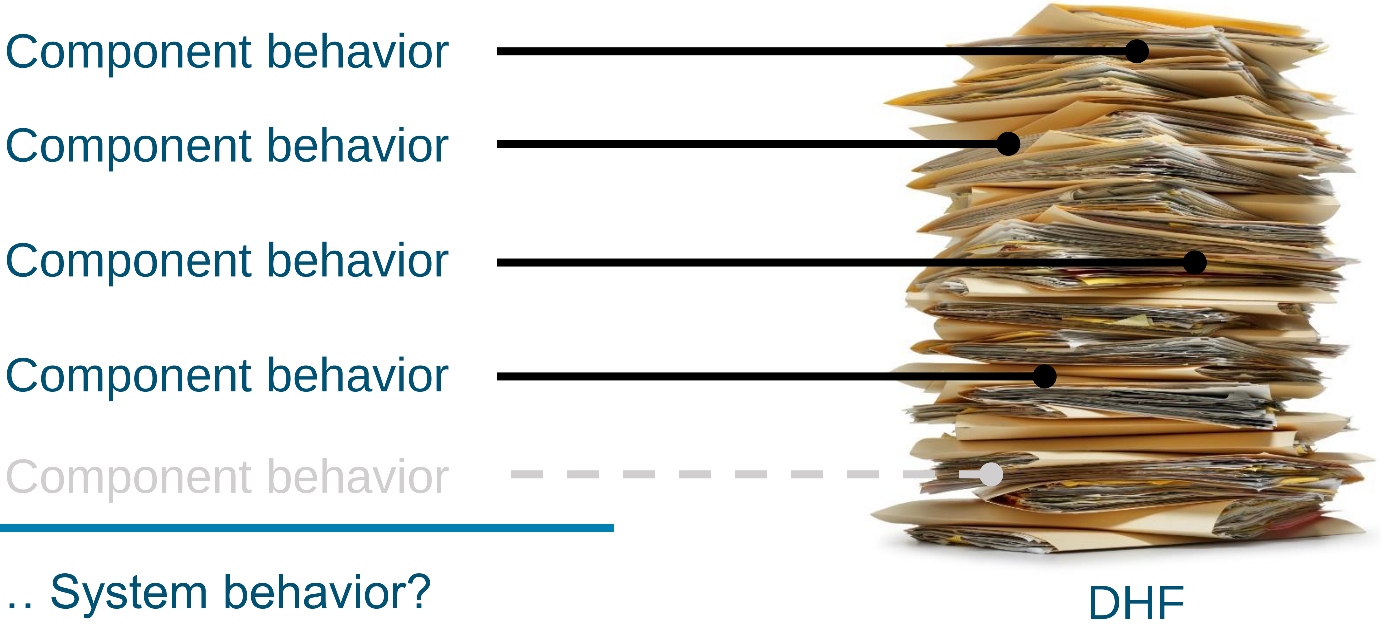
$$\begin{tikzcd}
\boxed{???} & \boxed{\text{Requirement}} \arrow[l, "\text{Why?}"'] \arrow[r, shift right, "\text{How?}"'] & \boxed{\text{Implementation}} \arrow[l, shift right, "\text{Why?}"'] \arrow[r, "\text{How?}"'] & \boxed{???}
\end{tikzcd}$$

Solutions:

01 Eliminate Waste

Superfluous / Deficient

"Just use designs to figure out the details…"



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Solutions:

01 Eliminate Waste

Superfluous / Deficient

Define what constitutes as a requirement:

- Serves a purpose (product, process, business)
- Executable or observable by its user(s)
- Detailed at the level it is expected to be verified
- Coverable by approx. 1-3 test cases

Maintenance costs are determined by level of regression

Stable definition ➔ Less discussion ➔ Less changes ➔ Less regression

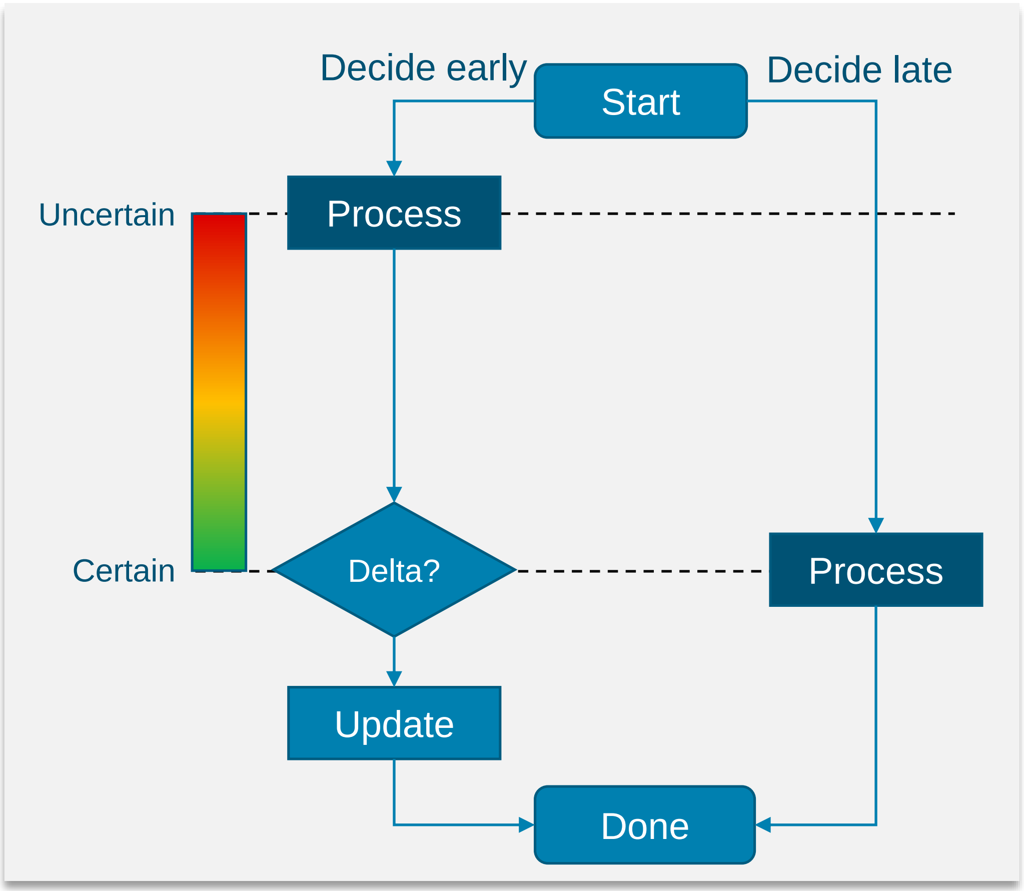
Also helps with change management

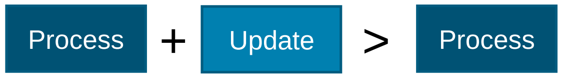
What is changed ➔ update requirements ➔ update / execute related tests

Definition:

03 Decide As Late As Possible

Avoiding decisions for as long as possible in order to save rework:





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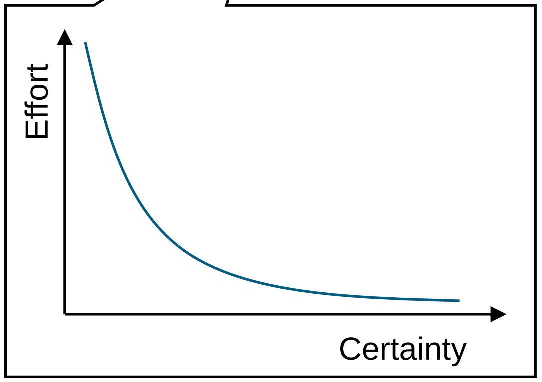
Symptoms:

03 Decide As Late As Possible

Focusing on the wrong thing…

..Causes heavy refactoring…

Process + Update > Process



…Or worse…

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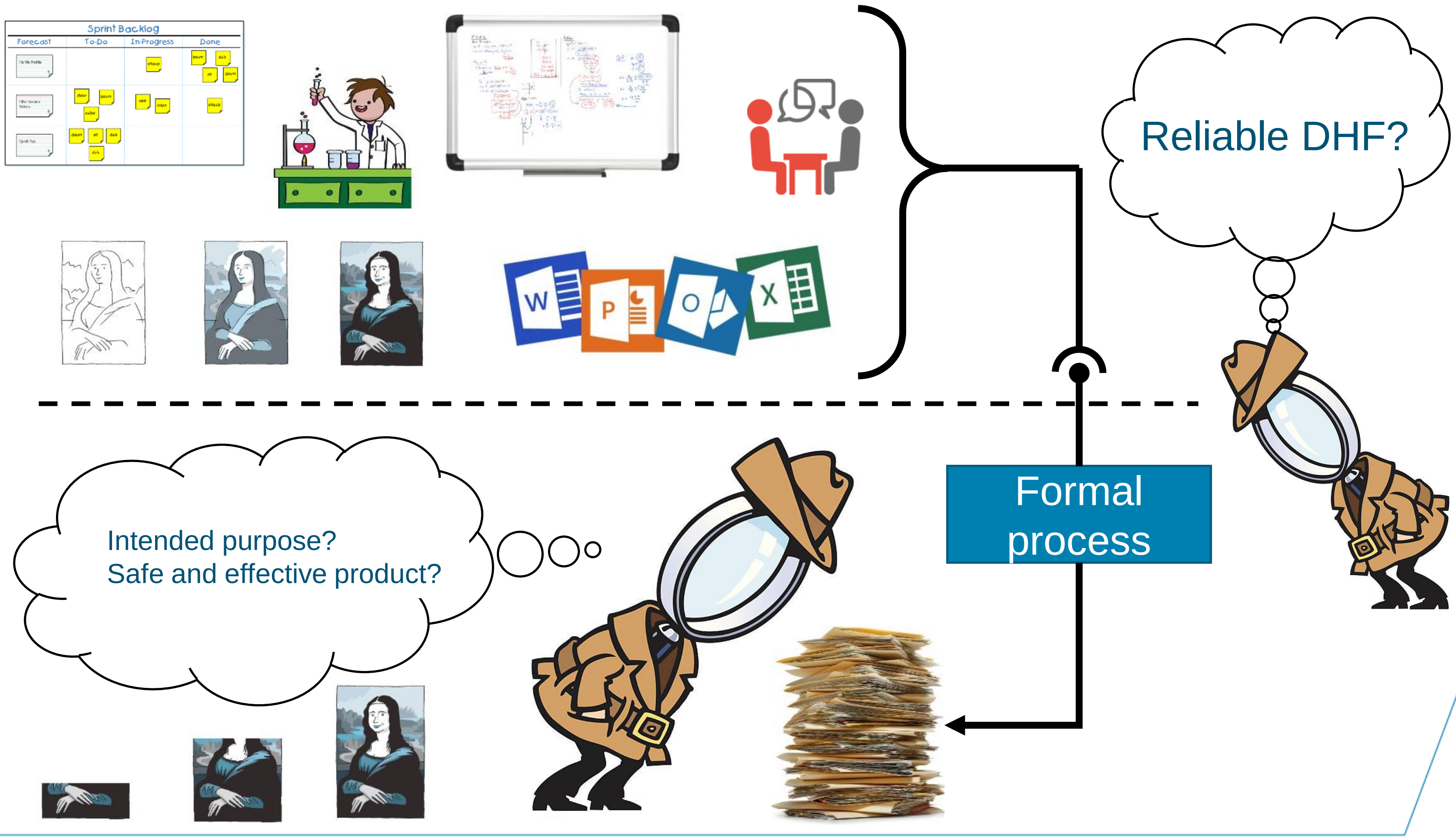
Solutions:

03 Decide As Late As Possible

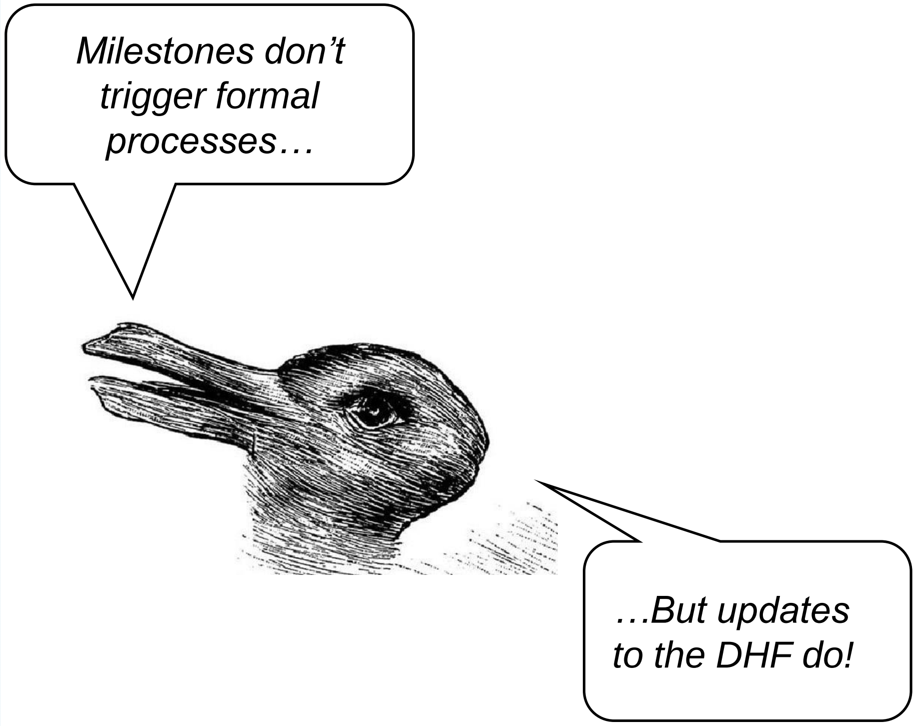
Differentiate between formal and informal processes and documentation

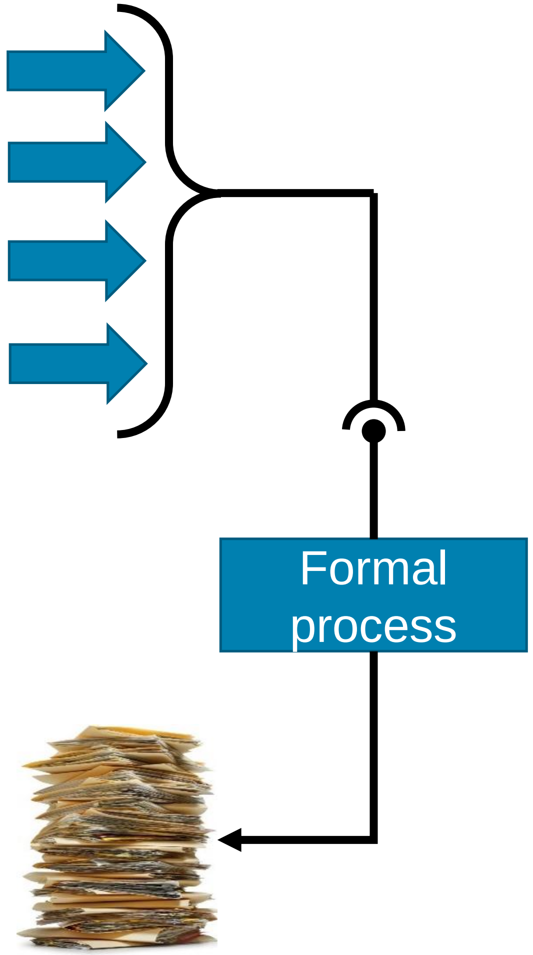


Solutions:

03 Decide As Late As Possible

Differentiate between formal and informal processes and documentation


Milestones don't trigger formal processes…
…But updates to the DHF do!

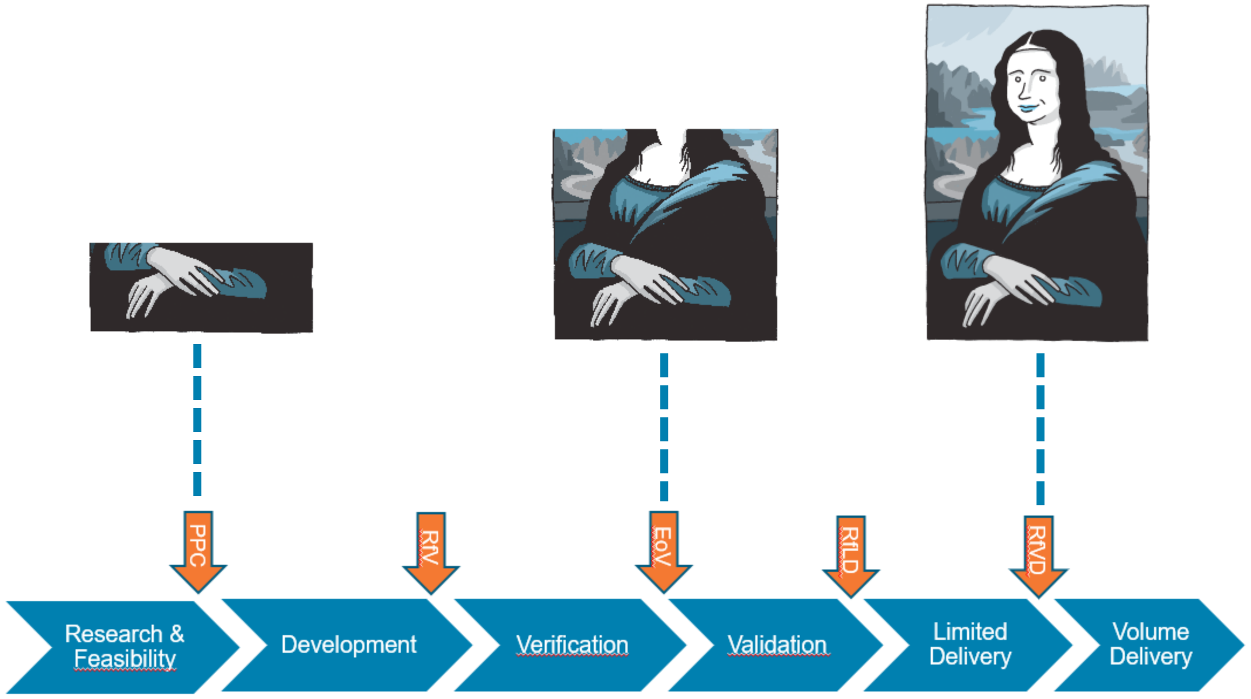


Solutions:

03 Decide As Late As Possible

Only update parts of the DHF that:

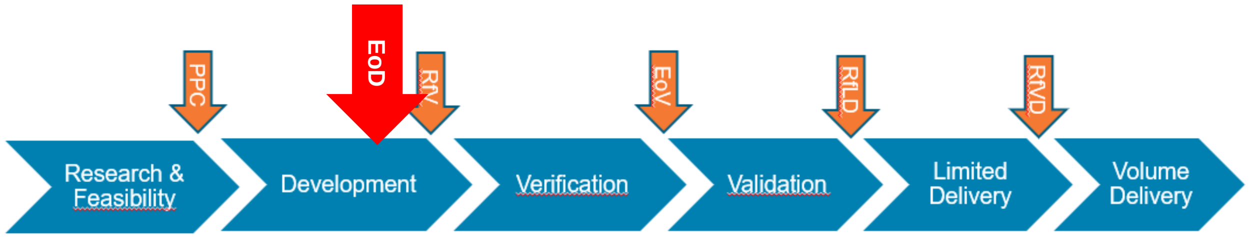
- Are needed for milestone progression
- Are properly understood (low risk of change)



Solutions:

03 Decide As Late As Possible

Introduce an informal "End Of Development" milestone



- Mitigates the risks of iterative development:

Narrow view during sprints

+

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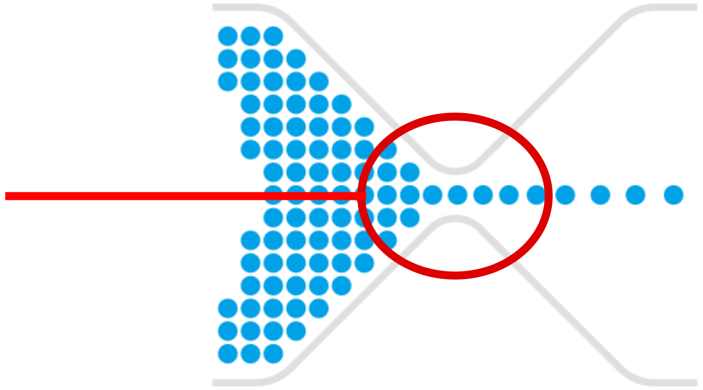
Definition:

07 See The Whole

Optimizing processes and actions, based on the impact it has on the entire chain:

Optimize this



To avoid doing this

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Symptoms:

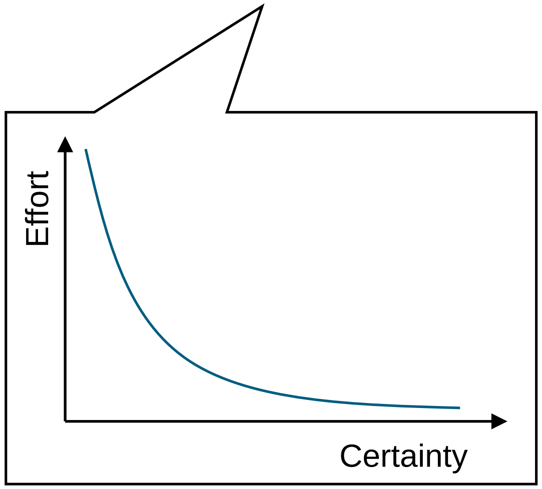
07 See The Whole

Assumptions in requirements & too detailed test cases

Inefficient test execution

Refactoring due to assumptions:

Process + Update > Process



Solutions:

07 See The Whole

- Learn and adapt
- Write requirements / tests conform their maturity

- Exploratory modeling
- Exploratory testing

- Create test design
- Define traceability

High effort

Informal

Formal

- Create test cases

Low effort

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Symptoms:

07 See The Whole

Overzealous prioritizing of product implementation over maturity

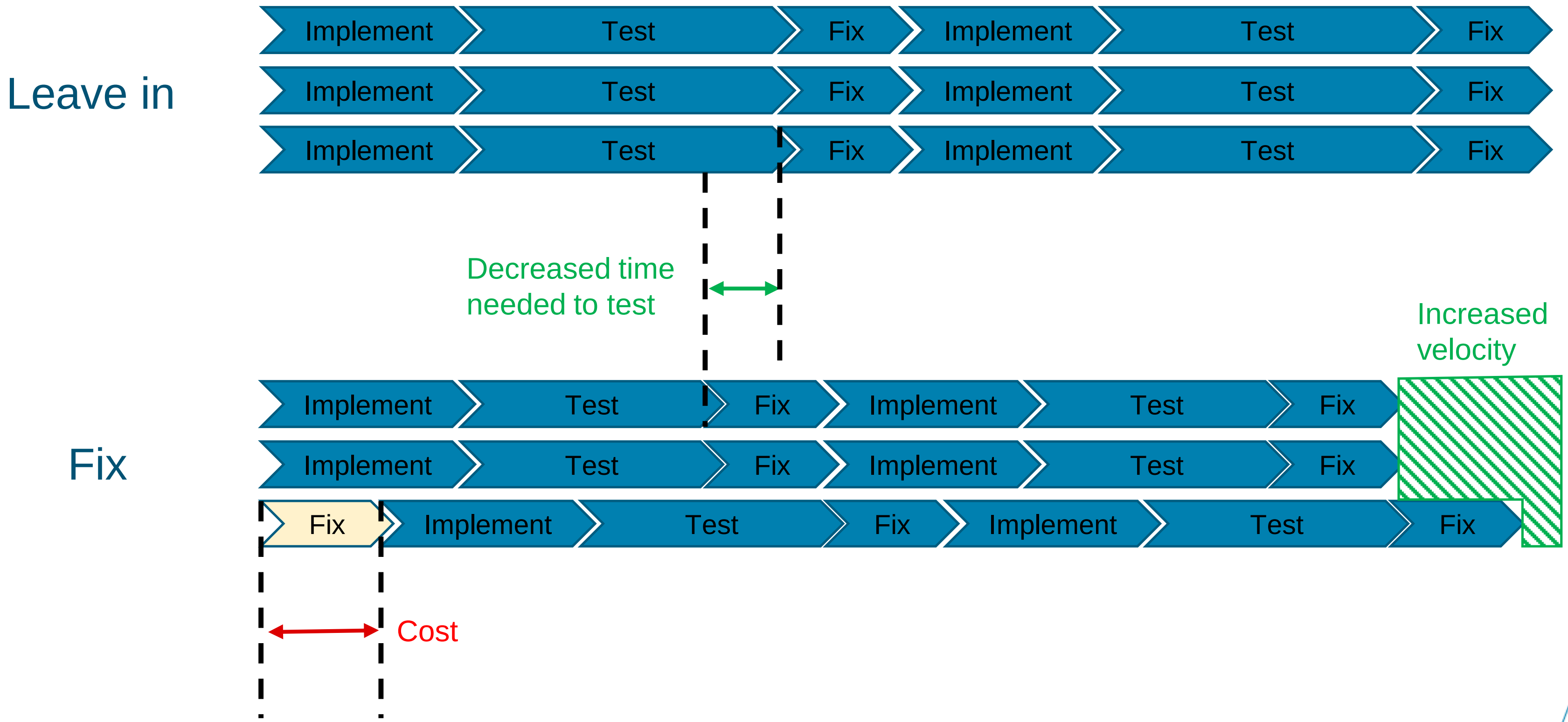
Increases test execution time

Obstructs drawing conclusions

Solution:

07 See The Whole

Prioritize test lead time over new implementation



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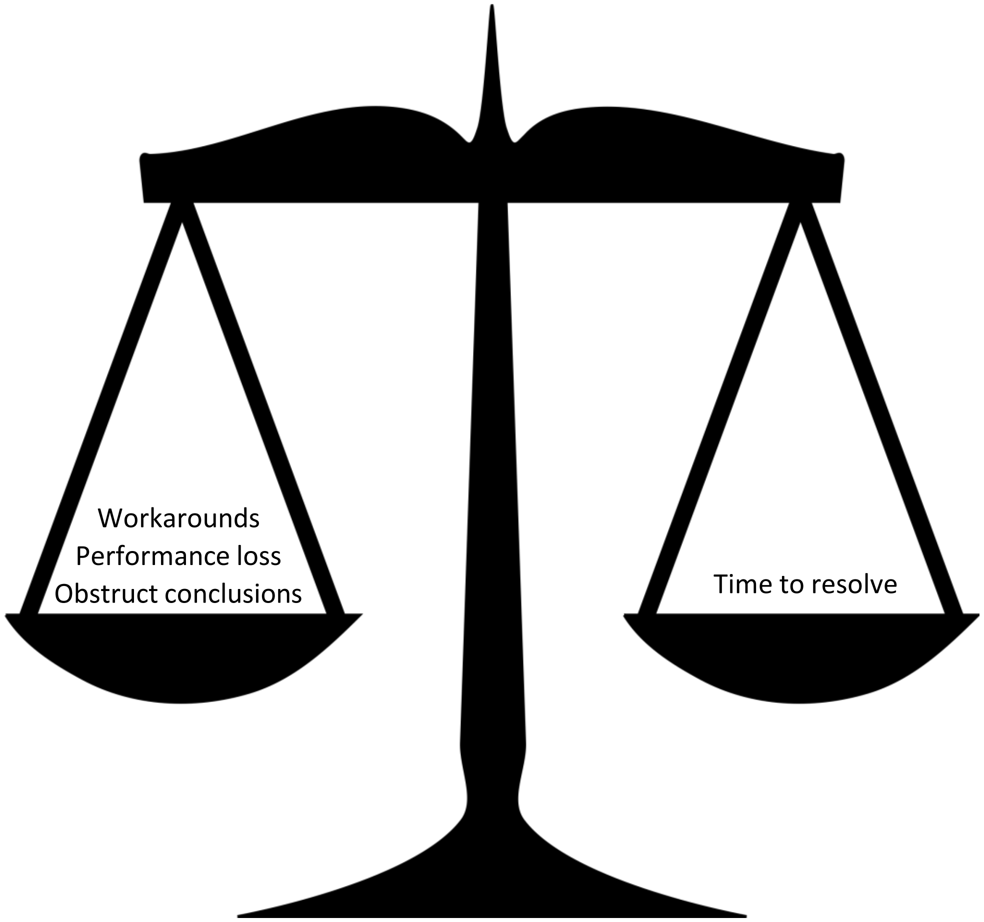
Solution:

07 See The Whole

Prioritize test lead time over new implementation



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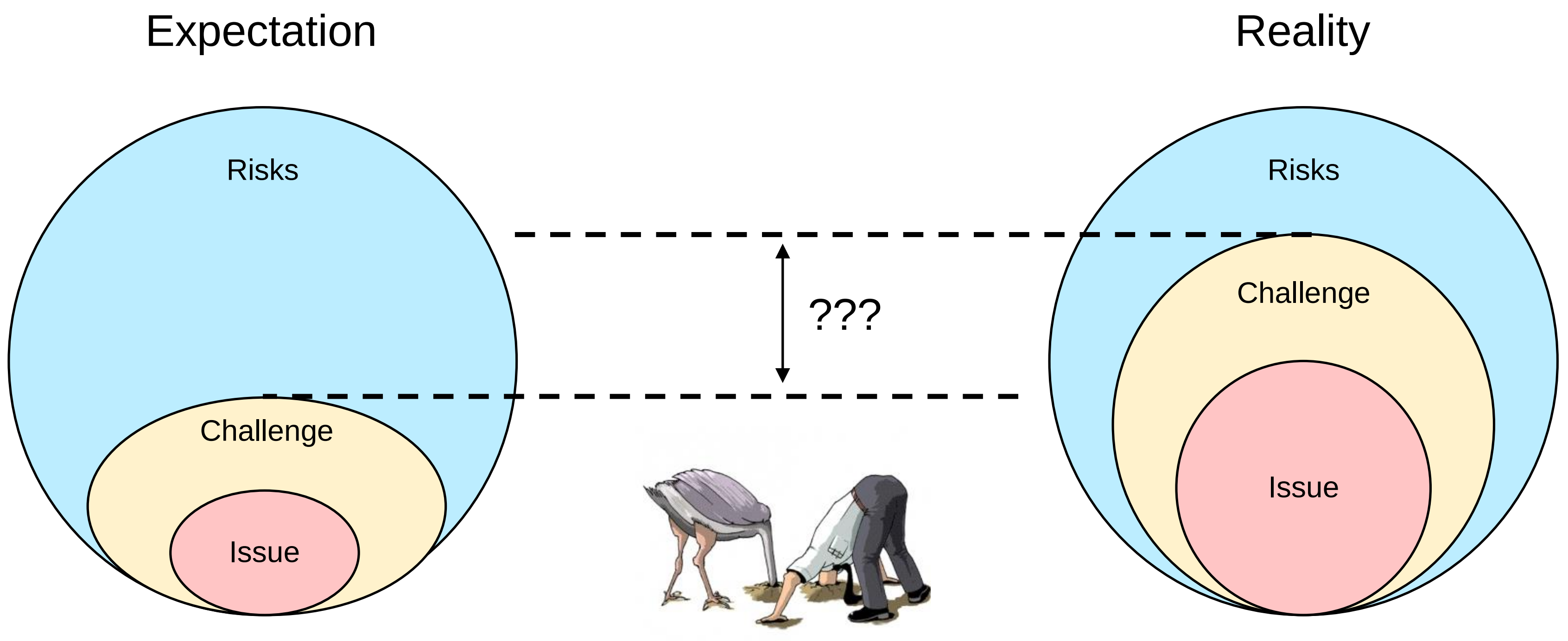
Symptoms:

Risks related to later phases are missed or downplayed

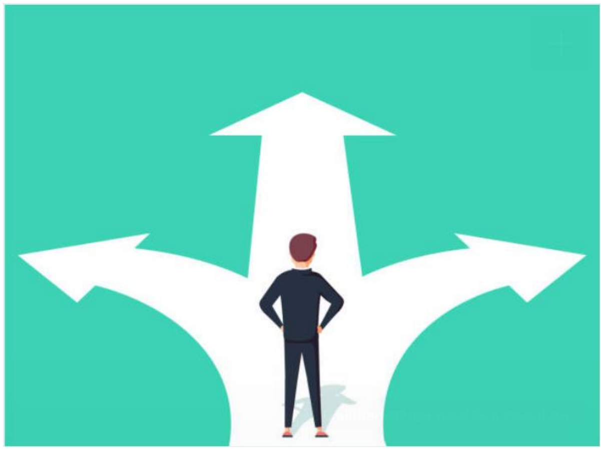


Solution:

07 See The Whole

Involve stakeholders as earlier as possible

$$\begin{tikzcd}
 & & \text{False alarm} & & \\
\text{Risk} \arrow[r] & \boxed{\text{Confrontation}} \arrow[ur] \arrow[dr] & & & \text{Non-issue} \\
 & & \text{Challenge} \arrow[r] & \boxed{\text{Investigation}} \arrow[ur] \arrow[dr] & \\
 & & & & \text{Issue}
\end{tikzcd}$$



Ad-hoc discussion

QBM feedback