The importance of a structured development process for connected medical devices

Erik Bockweg

Zign Innovations

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7 februari 2023 | FHI Leusden

Erik Bockweg

- 44
- Zign Innovations / Zign Manufacturing
- RuG, HvU
- Engie, Zign

- Jenny and Alex

Our company

- New Product Development
- (Connected) Medical devices
- Concept to Mass production
- Contract Manufacturing
- ISO-13485 certified*

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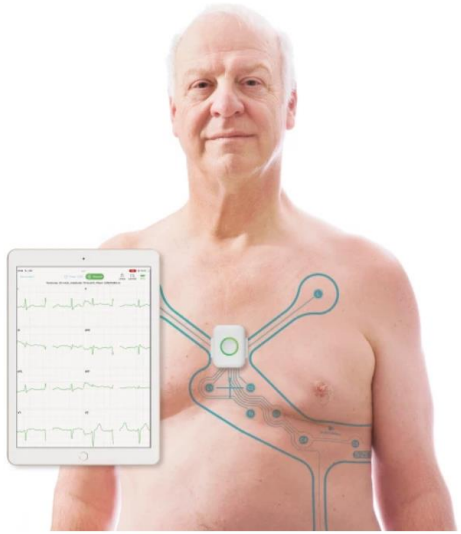
Higo™

Pediatric telemedical device

BRASTER®

Early-stage breast cancer diagnostics



Smart Medics

Hospital-grade 12-lead ECG diagnostic system for home and professional use.

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Question:

What makes a successful (Medical device) development project?

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>75% of all Medical device start-ups never make it to the market

Source: https://www.mdpi.com/2071-1050/11/7/1948

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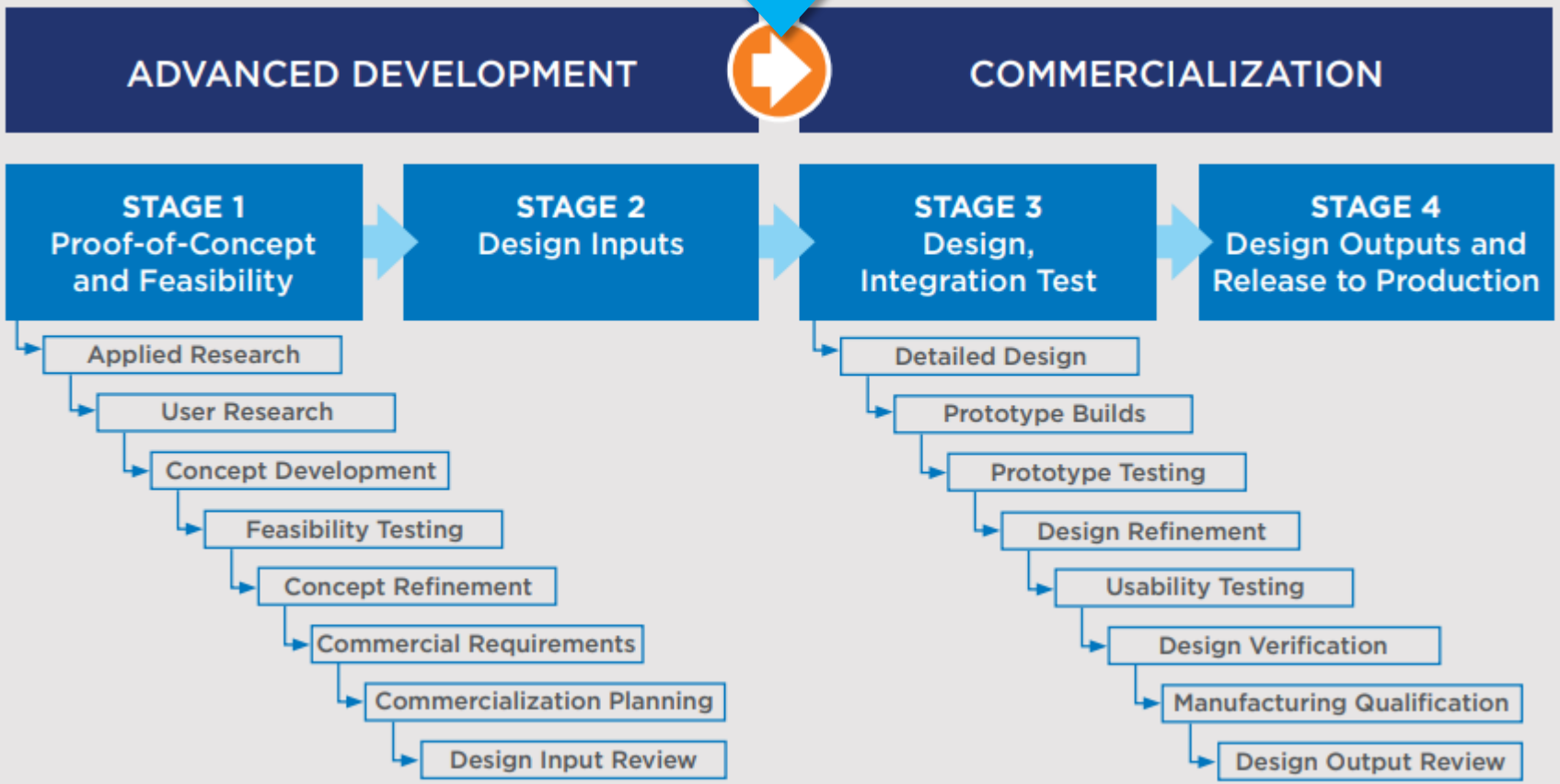
Product development 'Valley of Death'



Source: https://www.battelle.org/docs/default-source/health/white-papers/783_valleyofdeath_white-paper.pdf?sfvrsn=899528eb_5

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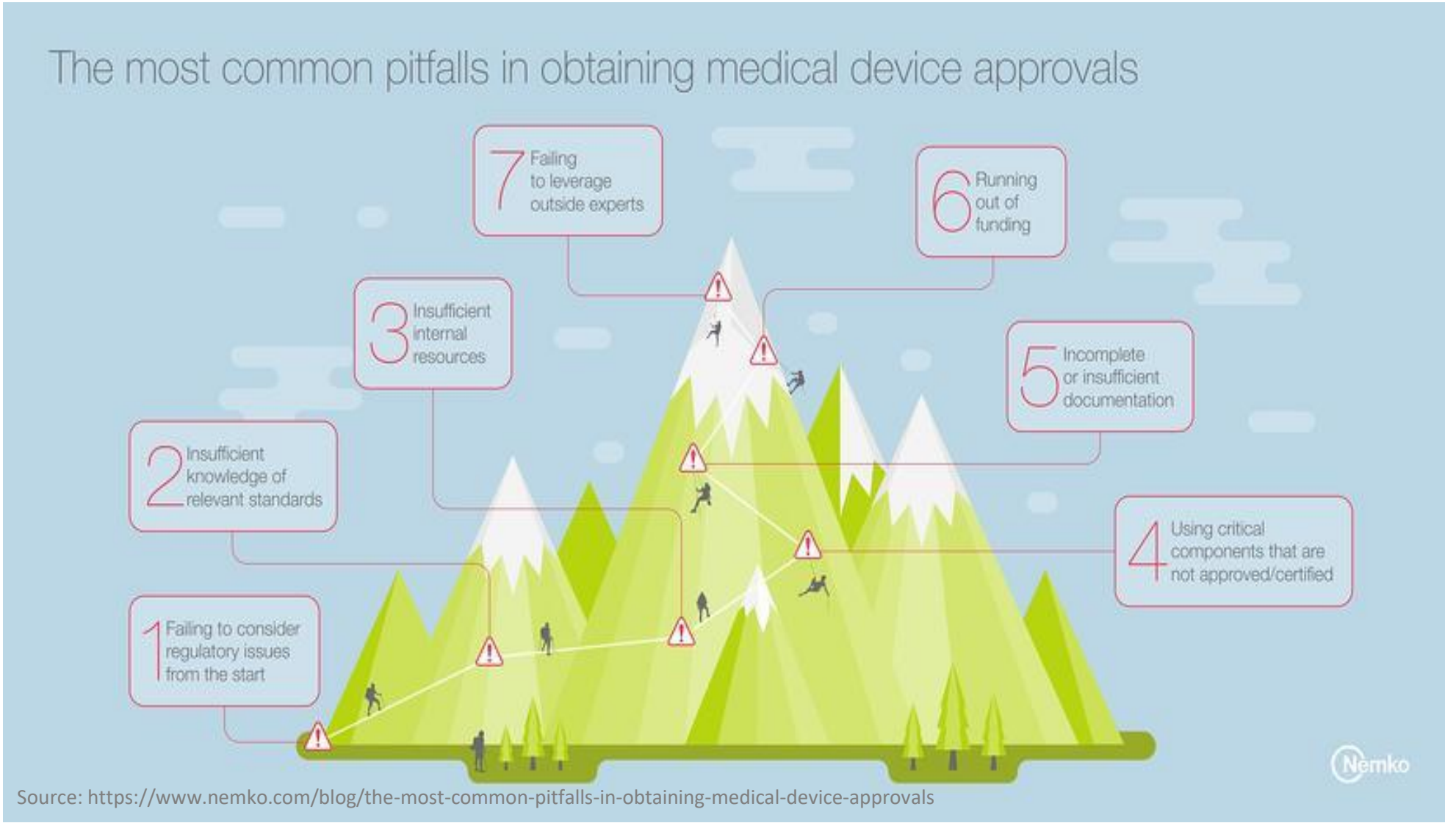

Source: https://www.nemko.com/blog/the-most-common-pitfalls-in-obtaining-medical-device-approvals

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The issue

- ***Prioritization*** *of (naturally) limited resources*
- ***Time pressure***
- Inmature / incomplete **product vision**
- *Unaware of the* ***regulatory requirements*** *in the medical field*
- *Focus on getting to market quickly;* ***build fast, fail fast***
- *Certification, regulatory stuff can be dealt with* ***afterwards***

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What do we need?

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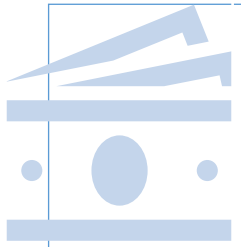
A structured development process, leading to

Fullfilling user needs



Realizing the business case

Meeting regulatory requirements

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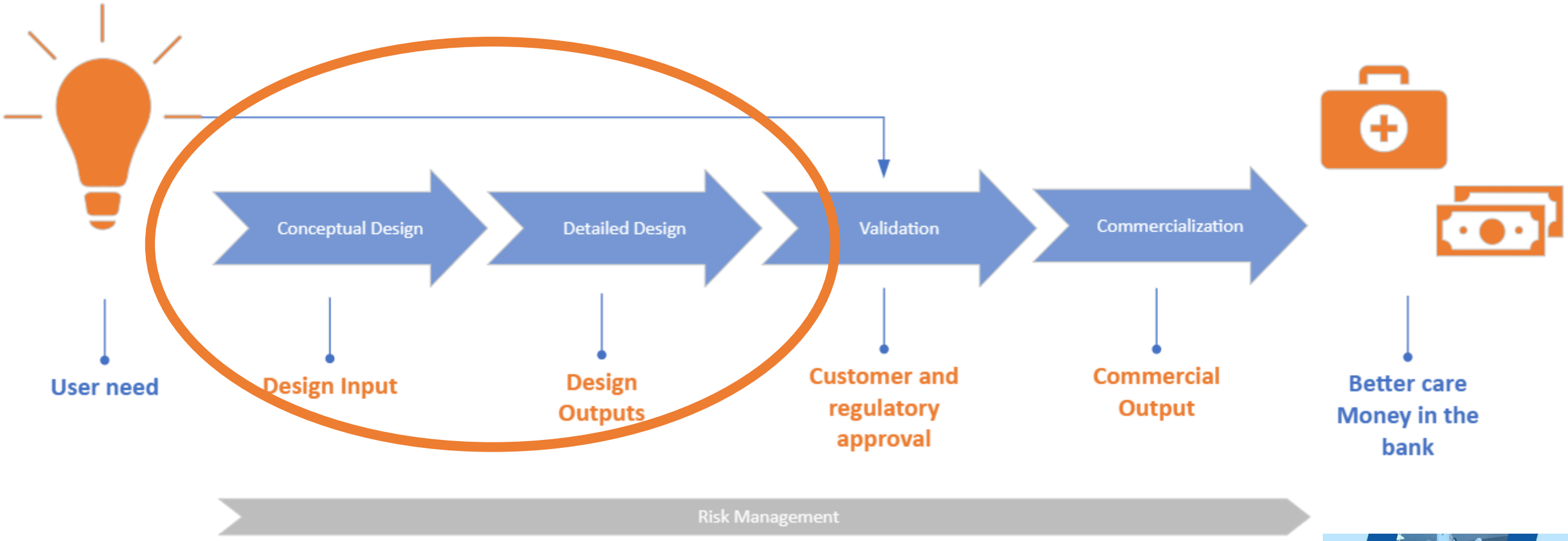
A standard phased approach



How to meet regulatory requirements *concerning product development*

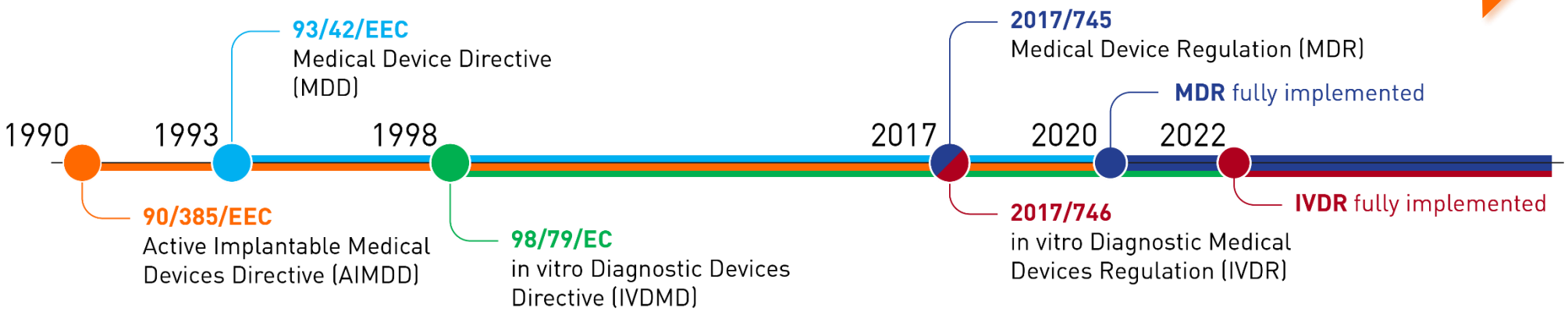
A product needs to be SAFE

Annex I: General safety requirements

You, manufacturer, need to PROOF this

Annex II: Technical documentation

From 26 May 2020, new devices intended to be marketed in Europe (EU) must comply with the Medical Device Regulation 2017/745 (MDR).



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Summary of Annex II of the MDR

6.	**PRODUCT VERIFICATION AND VALIDATION**
6.3.	Electrical safety and electromagnetic compatibility EMC (if applicable)
6.3.1.	Planning and overview of performed tests
6.3.2.	Test reports of performed tests
6.3.3.	Evaluation of data and test results
6.4.	Software verification and validation (if applicable)
6.4.1.	Description of the software development process (e.g. according to EN 62304)
6.4.2.	Description of the software design (e.g. according to EN 62304, EN 62366)
6.4.3.	Validation of the software as used in the finished device: e.g. a. summary results of verifications, validations and tests performed (in-house or in a simulated or in a real user environment)

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Harmonized standards

MDR:

“Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.”

IEC 60601

IEC **62304**

EN ISO **14971: 2012**

ISO **13485: 2016**

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How to practically do that?

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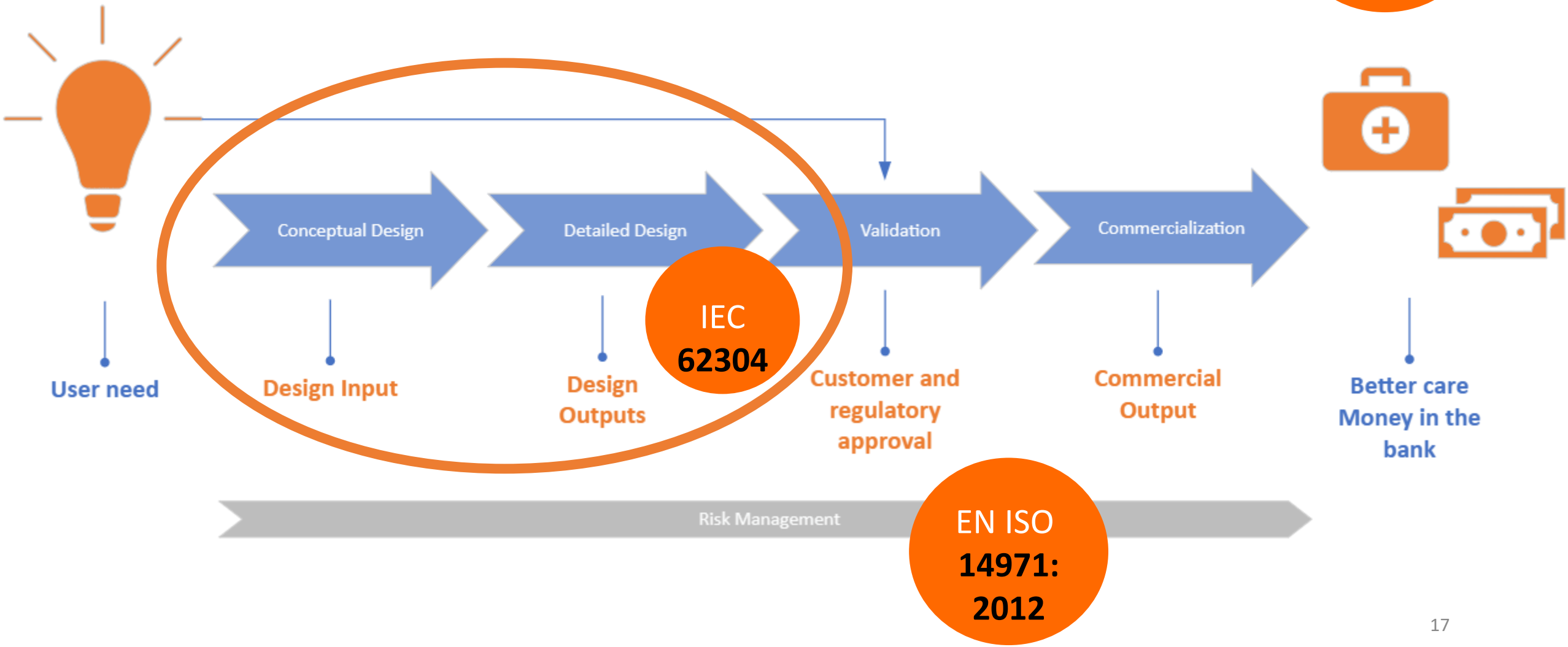
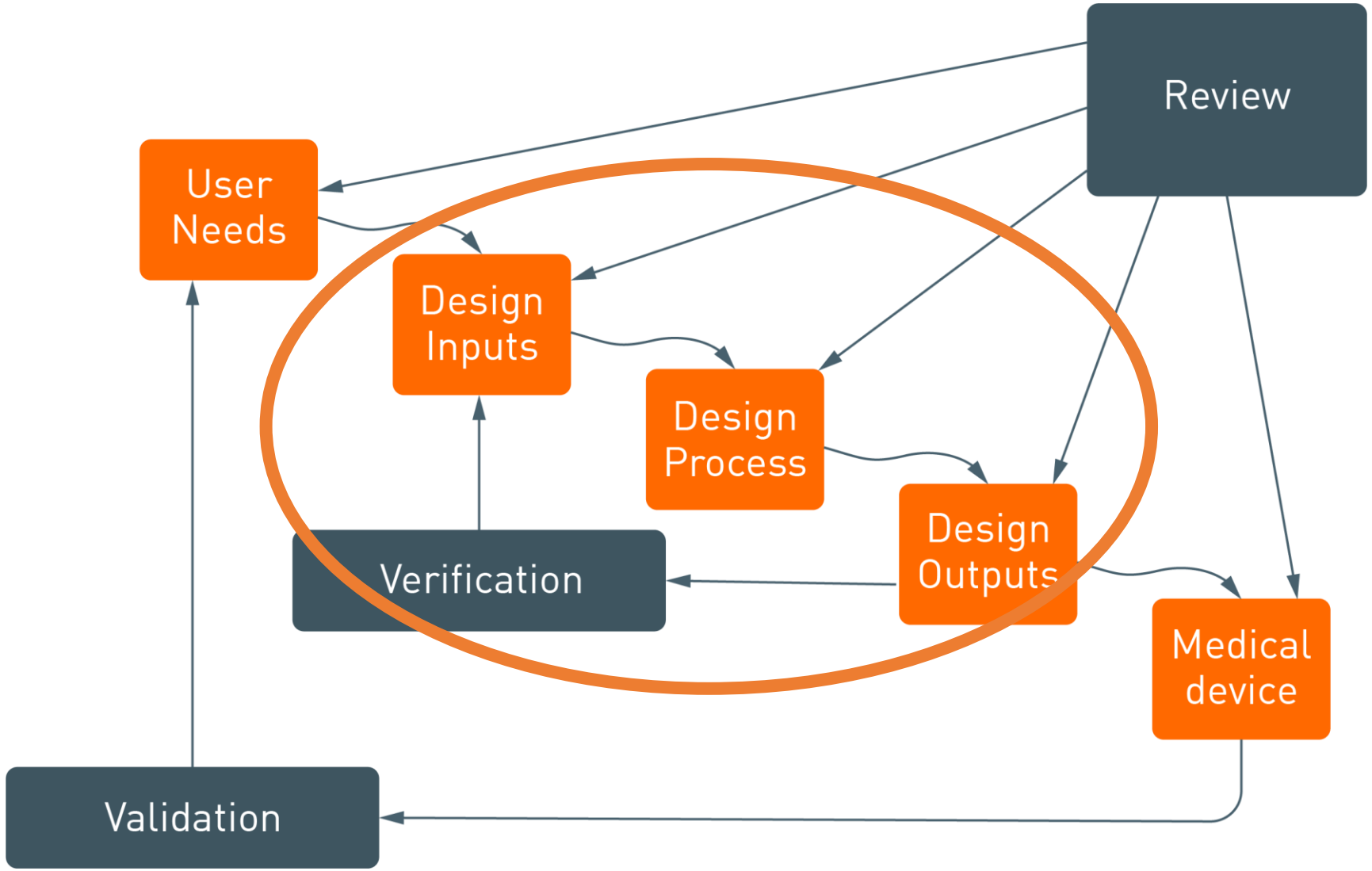
Processes cf Standards





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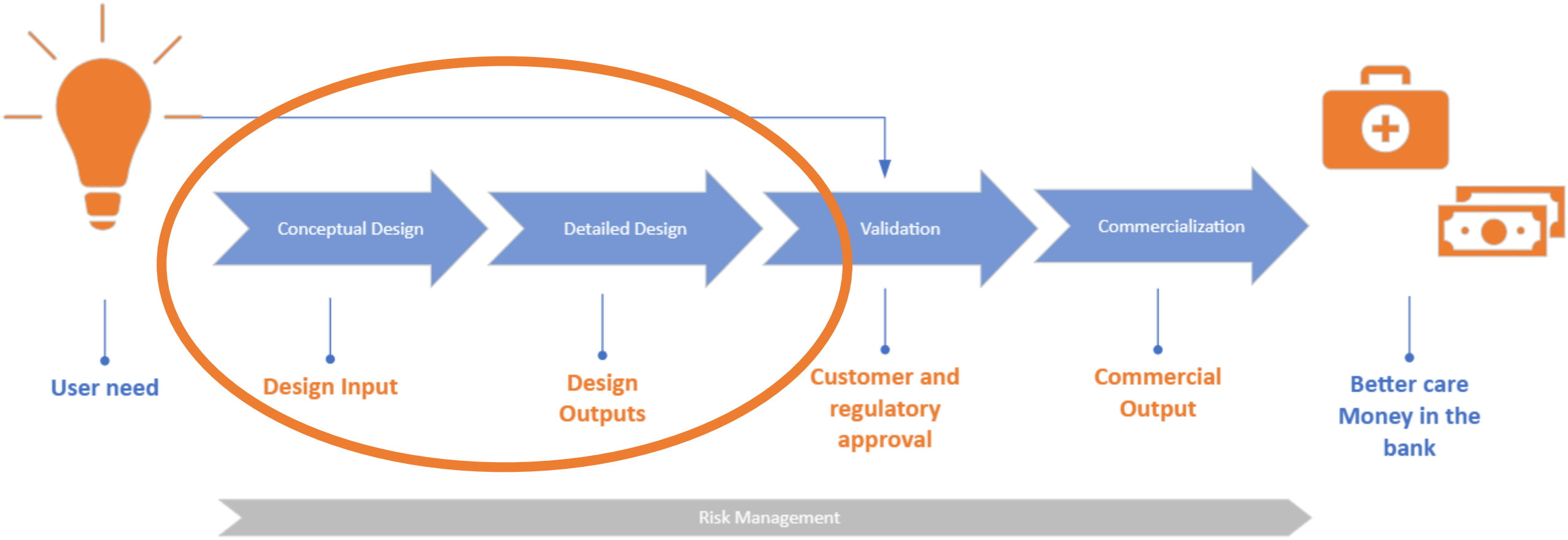
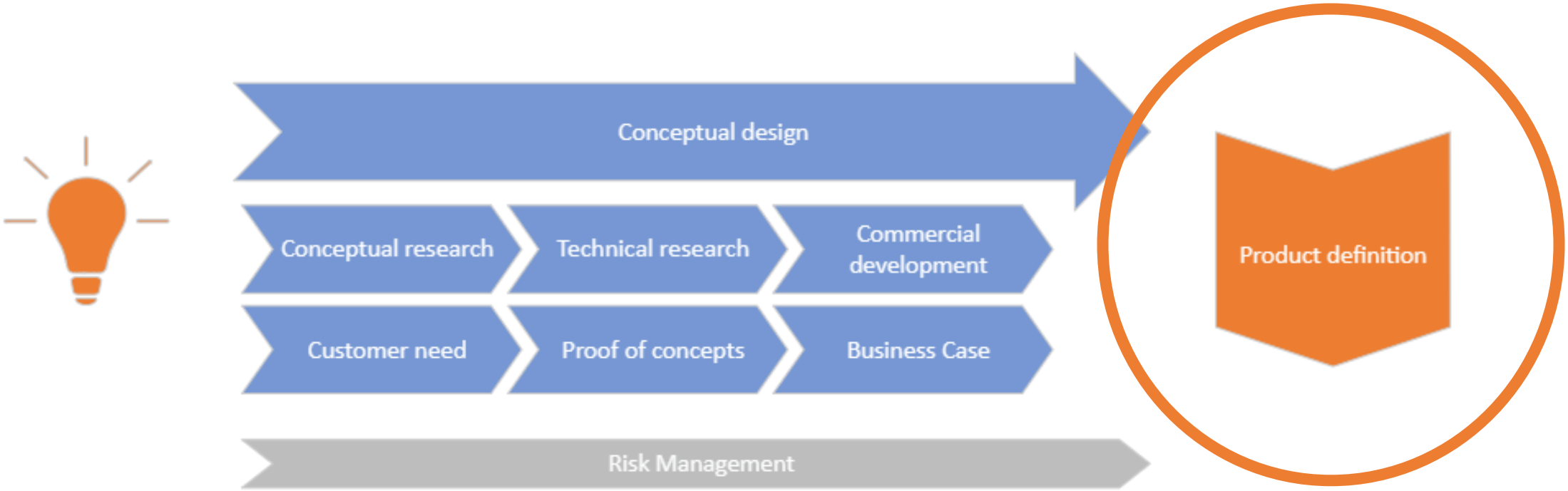
Development process



The ‘fuzzy’ phase…



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The pitfalls in definition

- ***Prioritization** of (naturally) limited resources*
- ***Time pressure***
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Product definition

Definition, describing what the system should do (Functional) and within which boundaries (Non functional).

So also:

What is the medical device classification and which standards apply?

Explicitly NO technical ‘solutions’.

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Product definition

Abbreviation	Document name
SSRS	System Requirements Specification
SSTS	System Test Specification
IRS	Interface Requirement Specification

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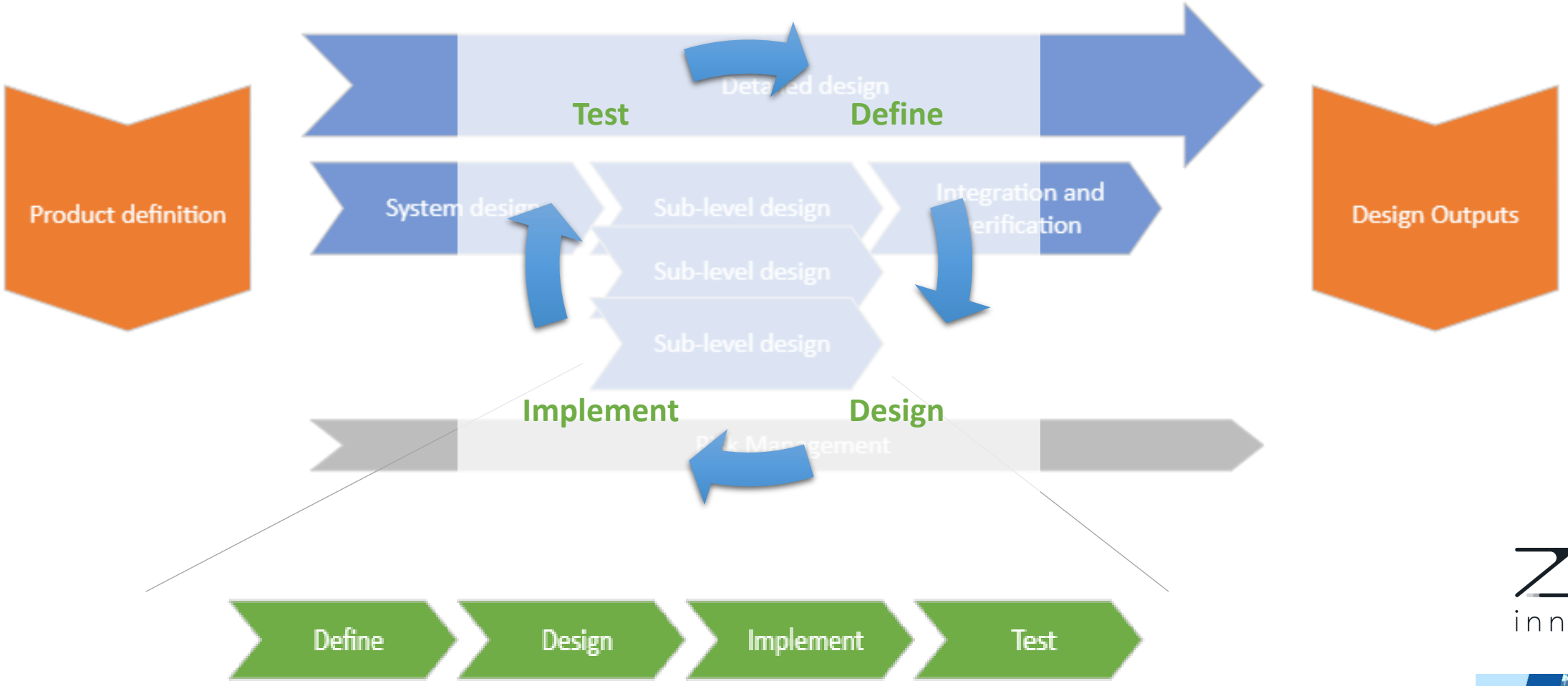
The design phase



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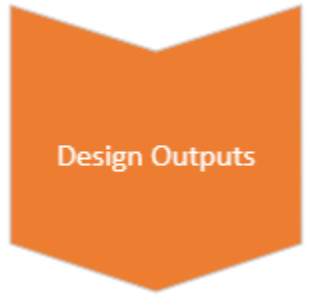
Example of outputs for Software



Abbreviation	Document name
SRS	Software Requirements Specification
SDD	Software Design Description
STS	Software Test Specification
STR	Software Test report

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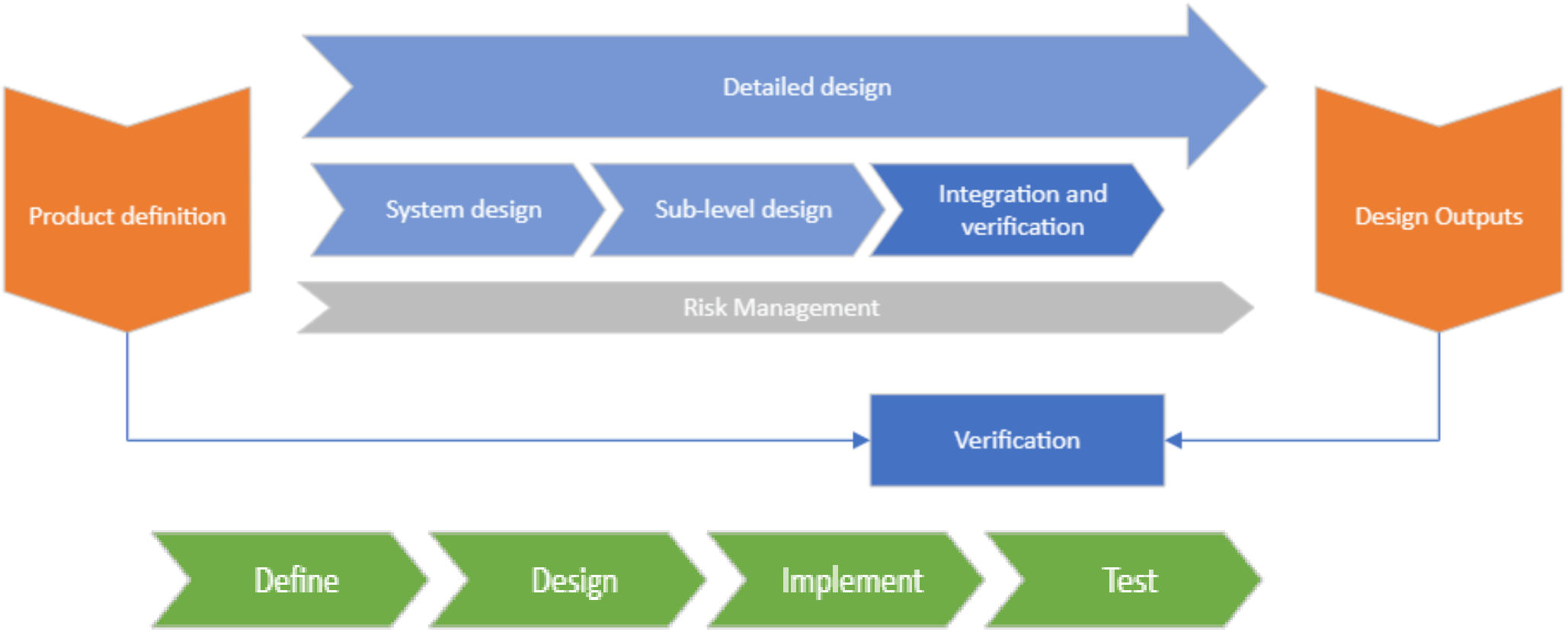
Verification



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The importance of a structured dev process

- Ensure quality output
- Ensure all requirements are met (including regulatory)
- Ensure the product delivers the value (user needs and BuCa)
- Ensure all documentation is in place for certification
- Cost-efficient development

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Thank you!

For more information about Zign, talk to my collegues in the hall, booth 16 (middle)

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