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Integrated development process and requirements management approach to drive quality and reliability in medical product development.

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Content*

- ***Regulatory context*** in medical device development drives a System Engineering approach
- ***Paradigm*** for a data model for requirements, design, risk and test management to support system and reliability engineering

- Disclaimer*
  - The following principles are not a standardized Philips practice
  - It is a synthesis of observed and proposed principles based on the presenters' experience and current opinion and a tentative to merge these into a consistent model.

- Acknowledgement
  - To several colleagues who contributed to these insights

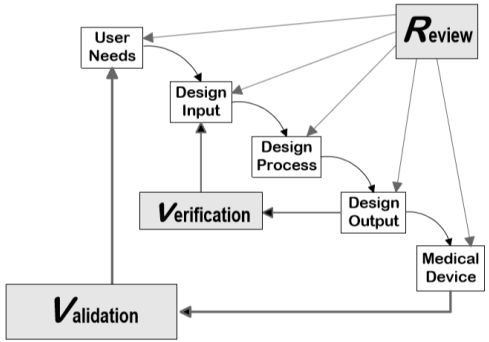
Regulatory bodies explicitly address system quality and reliability

And enforce a system engineering approach

- **Scope** of regulatory bodies :
  - **Protecting** the public health : assuring the safety, efficacy and security of medical devices
  - **Advance** the public health : helping to accelerate innovations to make more effective, safer, more affordable products

- **Requirements/specific areas of interest :**
  - Focus on **control of variability**
  - Include **quality, reliability, efficacy**, not just safety
  - Full **traceability of information** to demonstrate mitigation of all design risks
  - Documentation of **objective evidence**

➢Drive a **systems engineering approach**

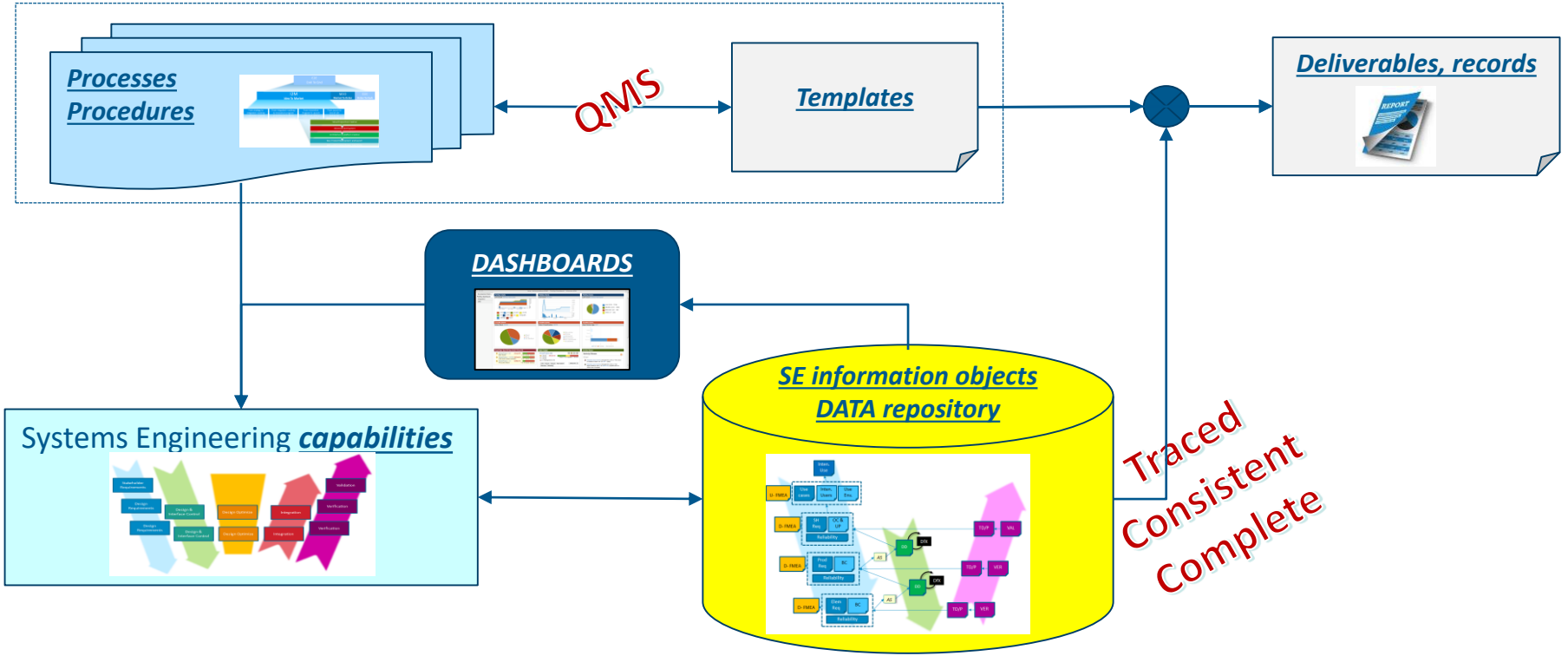


This raises several challenges in information management

- Managing system engineering ***details*** : the more documentation, the higher the ***non-compliance risk***
- High ***documentation load***, management of revisions & living documents
- Making ***trade-offs*** between business constraints and the perfect product
- Obtaining ***statistical rationale*** before product release, in particular for big systems

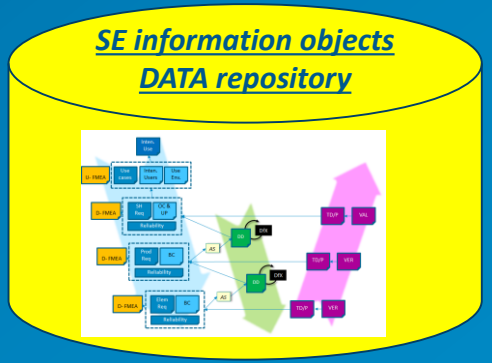
Proposed solution

Manage system engineering data objects in one repository.
Use as input for creation of deliverables and records.

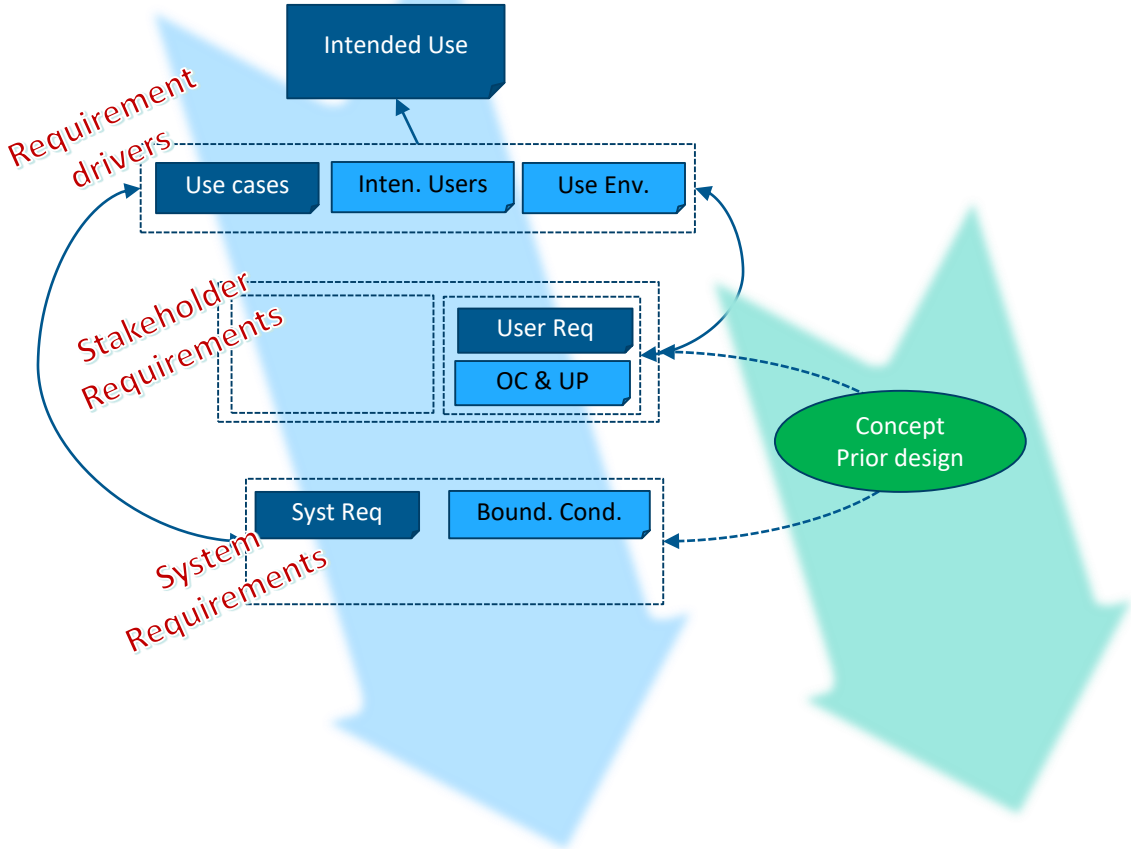


Paradigm for a system engineering data model

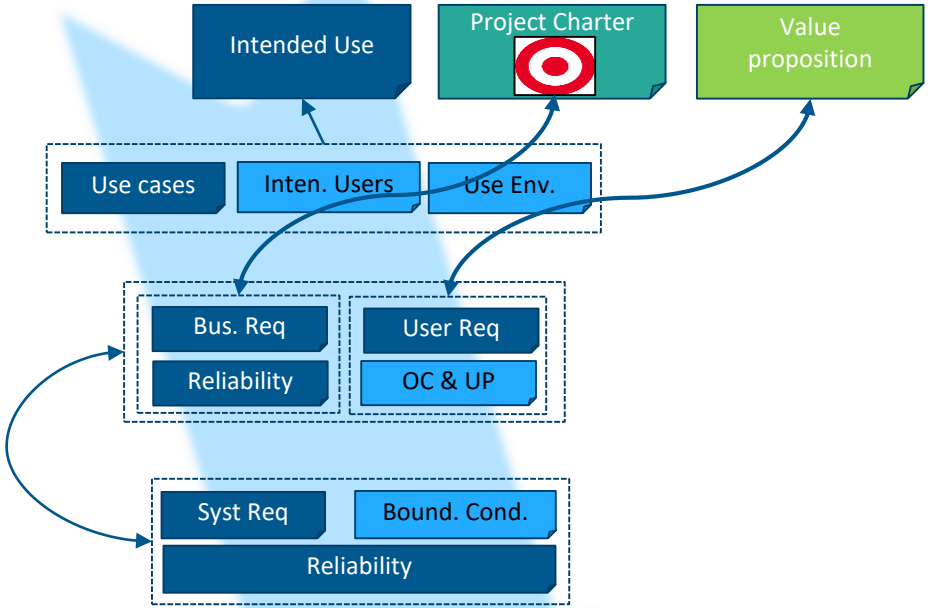
Including transparant and detailed reliability management



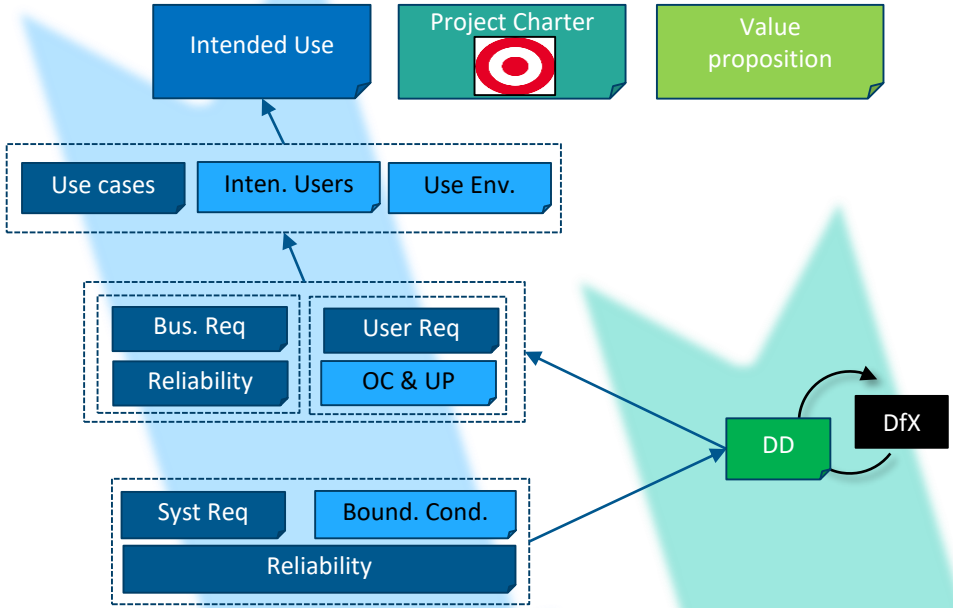
1. Perform & document detailed analysis of intended use with *use cases*
2. Develop *highest level requirements* and *conditions*



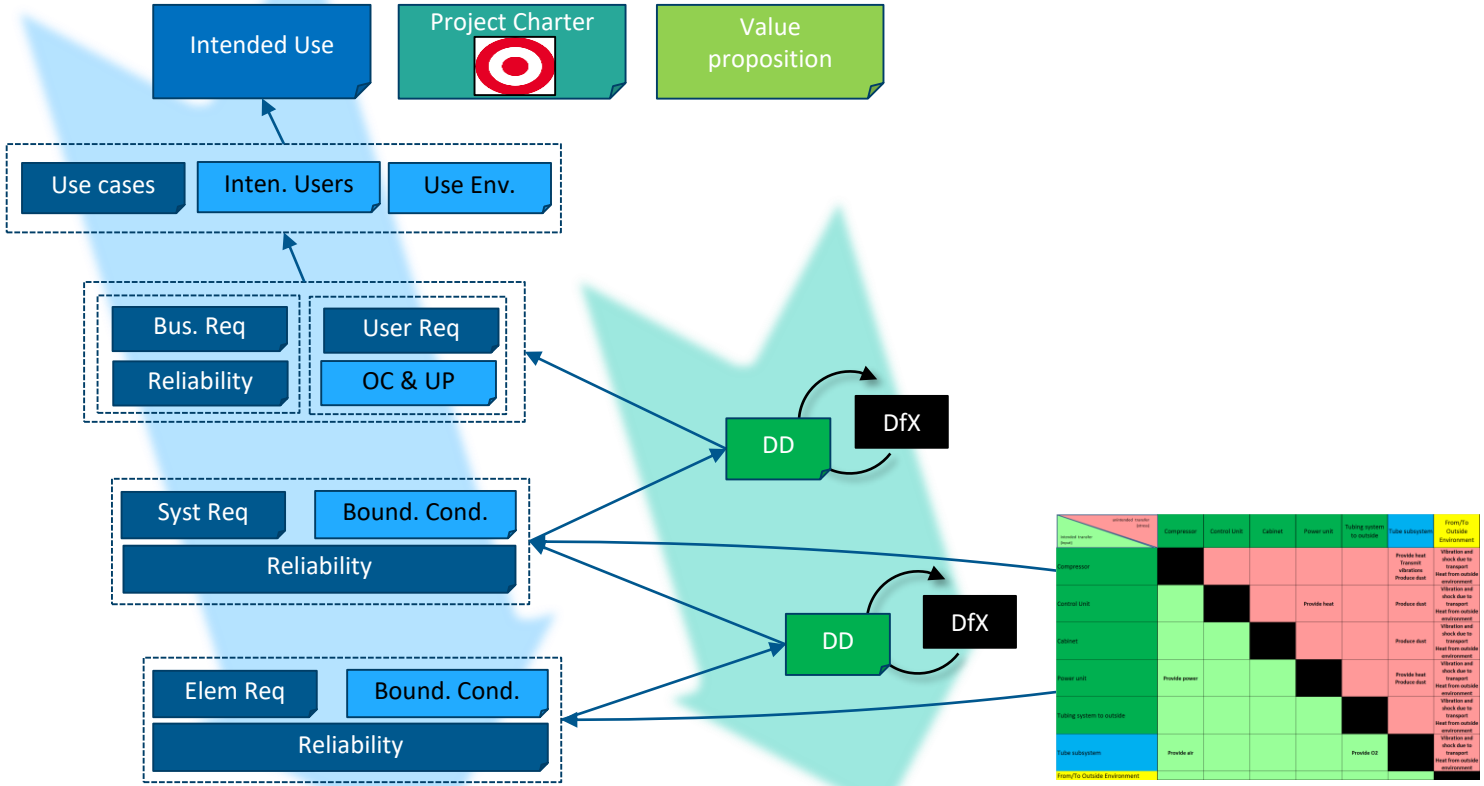
3. Develop *complete stakeholder* requirements from charter & VPH
4. Flow down *system reliability* requirements and *boundary conditions*



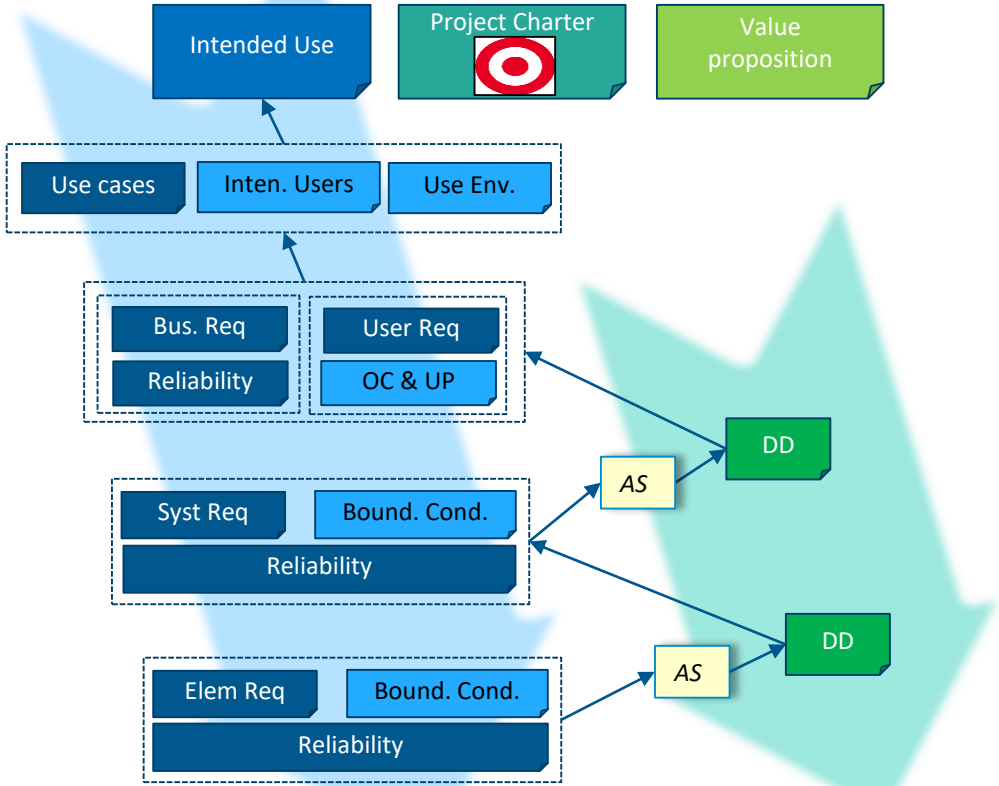
5. Separate *design detail* from requirements. Use *design decisions* as *gate* between levels. Document the *traces and rationale*. (apply DfX tools)



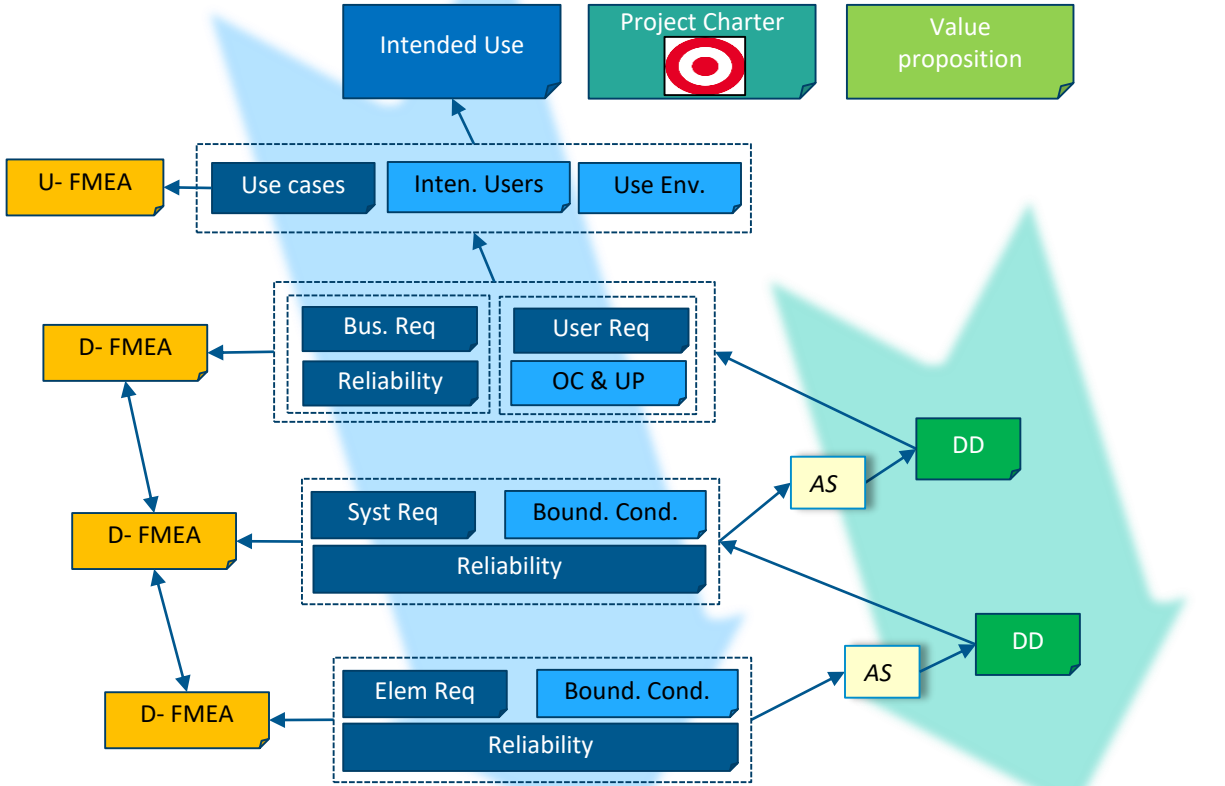
6. Flow down requirements and boundary conditions through *design and interaction* analysis. Distinguish requirements *hierarchy*



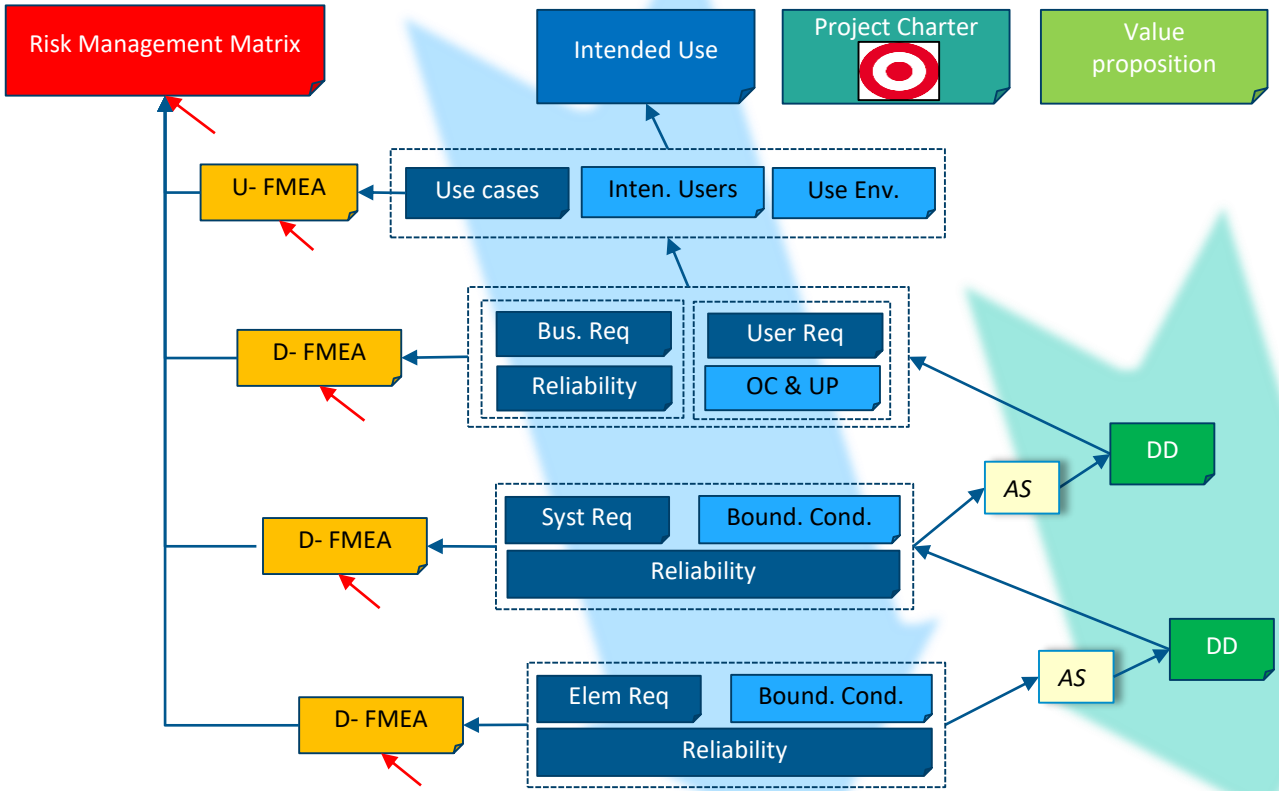
7. Document *analysis statements* to provide rationale for decomposed requirements



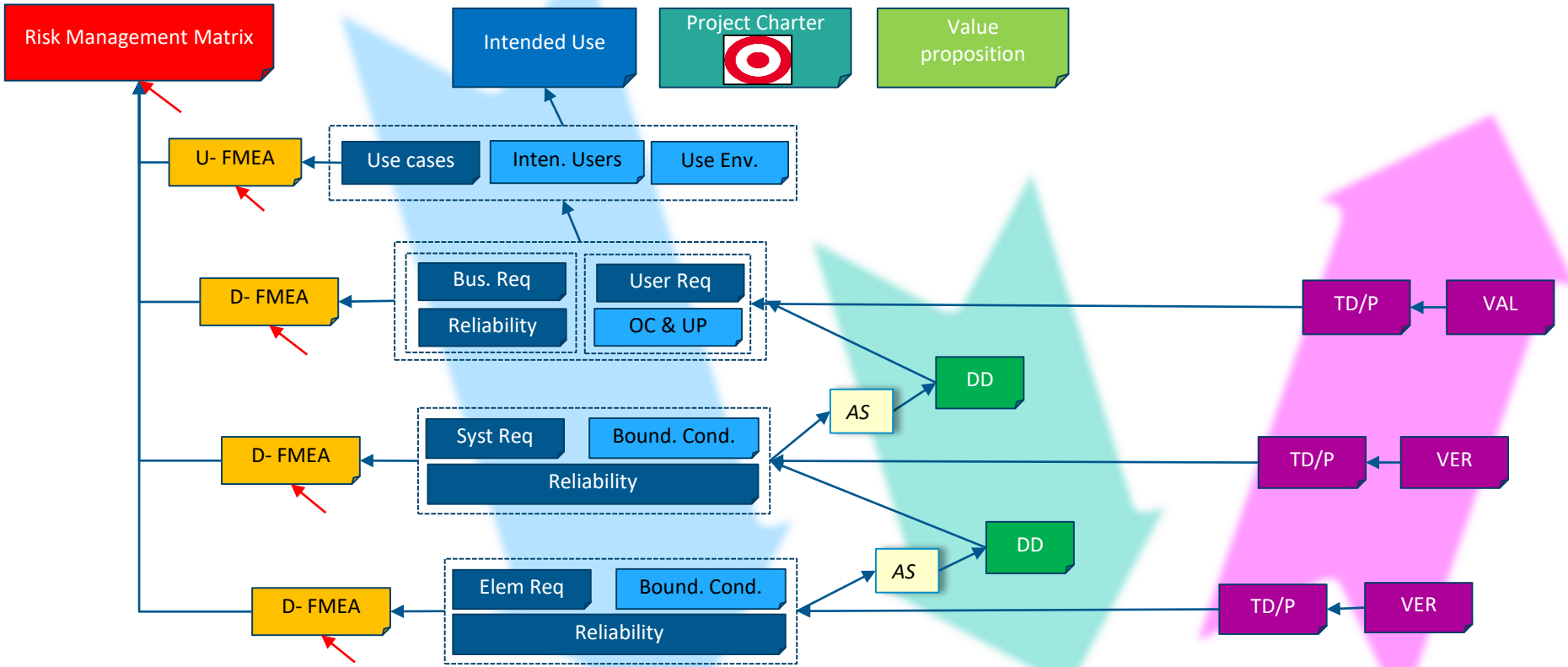
8. Execute *FMEA at all levels*. Failure mode is the *denial* of the requirement (consider boundary conditions). Ensure FMEA consistency



9. Manage *risks*. Add *escalated* FMEA items to RMM. *Mitigations* are new requirements or design decisions.



10. Define *V&V* at all levels. Document (reliability!) requirements as function of *verification strategy (I, A, D, T)*



Paradigm for reliability requirements

Adequate use of verification types to state verifiable requirements at all levels

Use of Acceptance Criteria

- Target and business level : State **comparatively** or as statements to be **confirmed after release but before project closure**.

  The reliability growth of the <.2.> system shall be no worse than <.1.> system after <…> time of monitoring
  Acceptance : *E.g. comparison of reliablity growth graphs after period of monitoring or integration testing*

- System Level : State to support verification by **Analysis**

  The estimation of the MTTF associated with failures due to <. failure modes.> of the <..elements..> shall be <…value…>
  Acceptance : *Point to aggregation of test results at lower design levels on specified/prioritized failure modes*

- Element, part level : State to support quantitative verification by **Test, Analysis**

  The probability of survival of the <…> motor unit shall be at least <…>% after <…time unit, e.g. hrs, turns…>
  Acceptance : *E.g. based on results from accelerated life test*

  The predicted failure rate of the <…> PCBA shall be less than <…>
  Acceptance : *Refer to standards based prediction*

Questions ?
Working at Philips ?

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