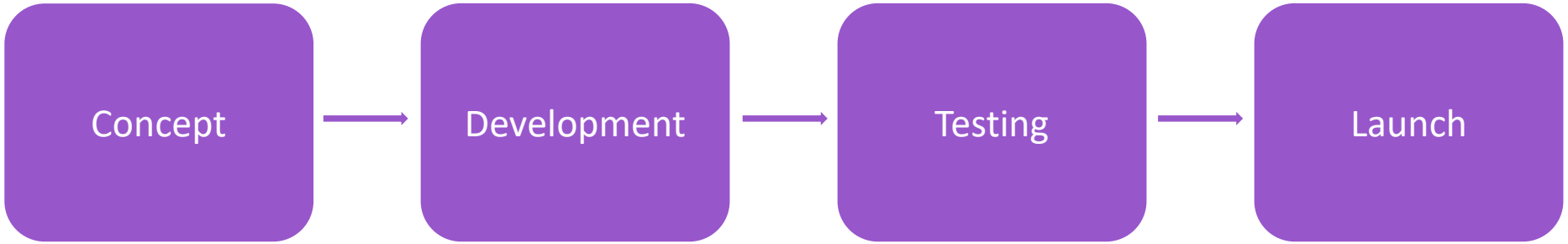
Lean Startup within Capella MBSE

November 16, 2023

Brent Bailey, PhD

Traditional Development Approach

Launch products into a well-defined market



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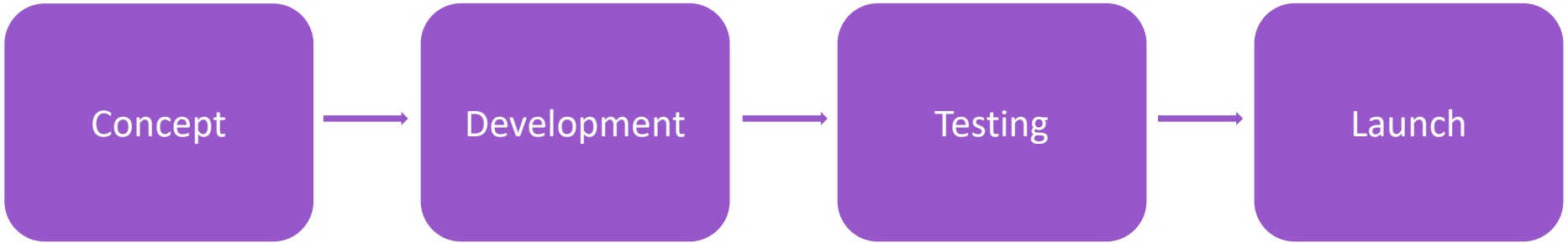

- Market research
- Interview customers
- Competitor research
- Decide on new features

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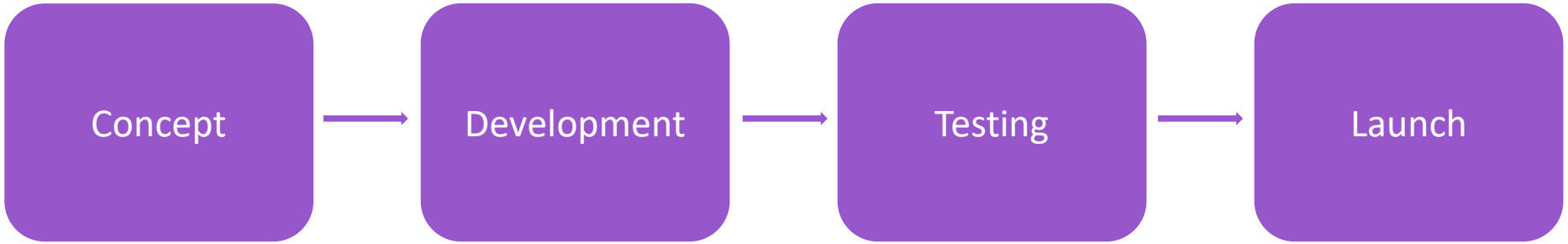

- Market Requirements Document
- Estimate schedule and costs
- Engineering starts development

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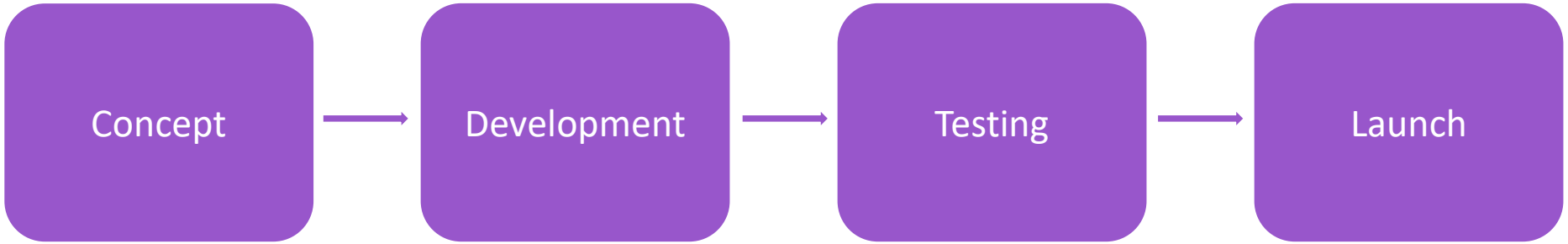

- Alpha build to ensure it works
- Beta build for V&V
- Regulatory submission

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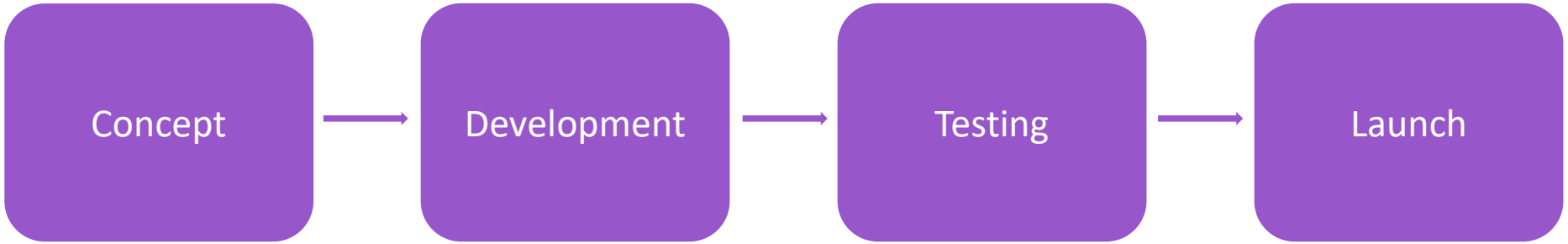

- Marketing
- Production and sales

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Problem

- What if you don’t know the market?
- Companies don’t fail due to lack of products but lack of customers

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Market Types

Sustaining

- Existing market

Disruptive

- New market
- Re-segment existing market for low-cost entrant
- Re-segment existing market for niche entrant

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Empowering Medtech Innovation

We help medtech innovators overcome challenging technology obstacles to create breakthrough products that improve health and save lives

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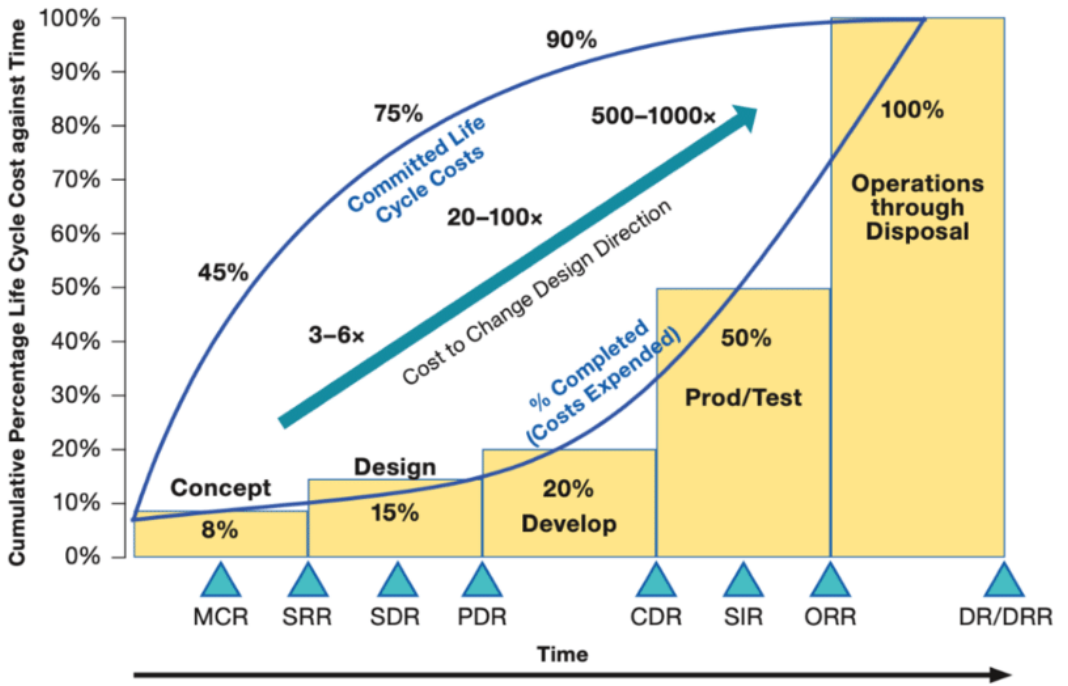
Life Cycle Cost

Impacts from early phase decisions



MCR	Mission Concept Review	**CDR**	Critical Design Review
SRR	System Requirements Review	**SIR**	System Integration Review
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PDR	Preliminary Design Review	**DR/DRR**	Decommissioning/Disposal Readiness Review

Adapted from INCOSE-TP-2003-002-04, 2015

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Life Cycle Cost

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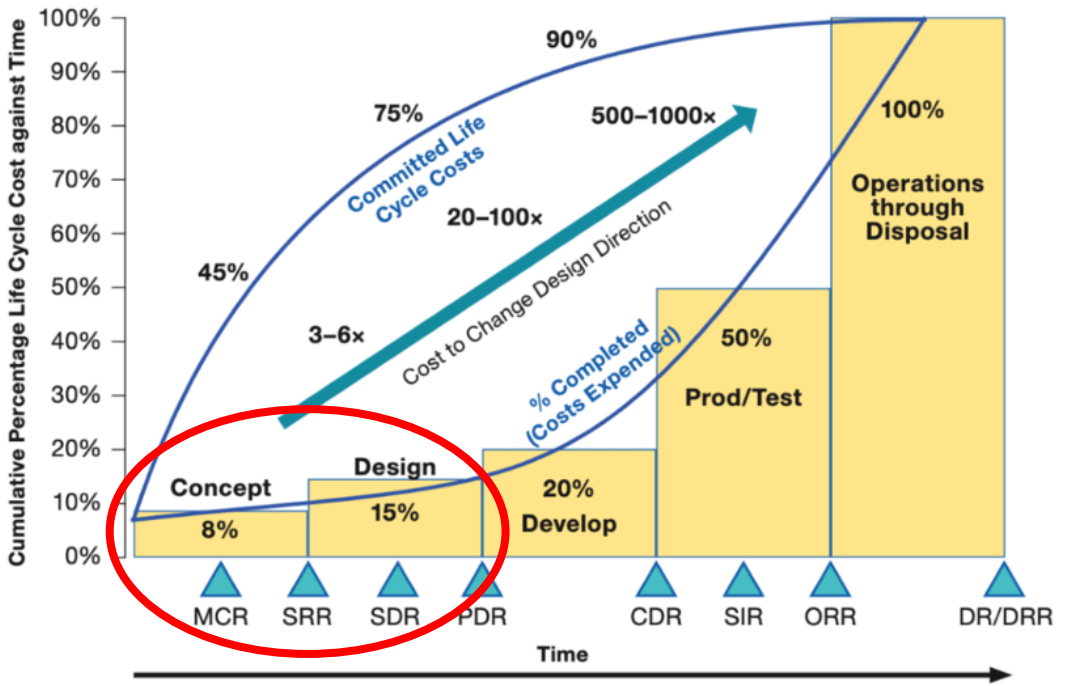

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Lean Startup

Learning instead of execution

- What problems do the customer have?
- Do customers perceive these problems as important?

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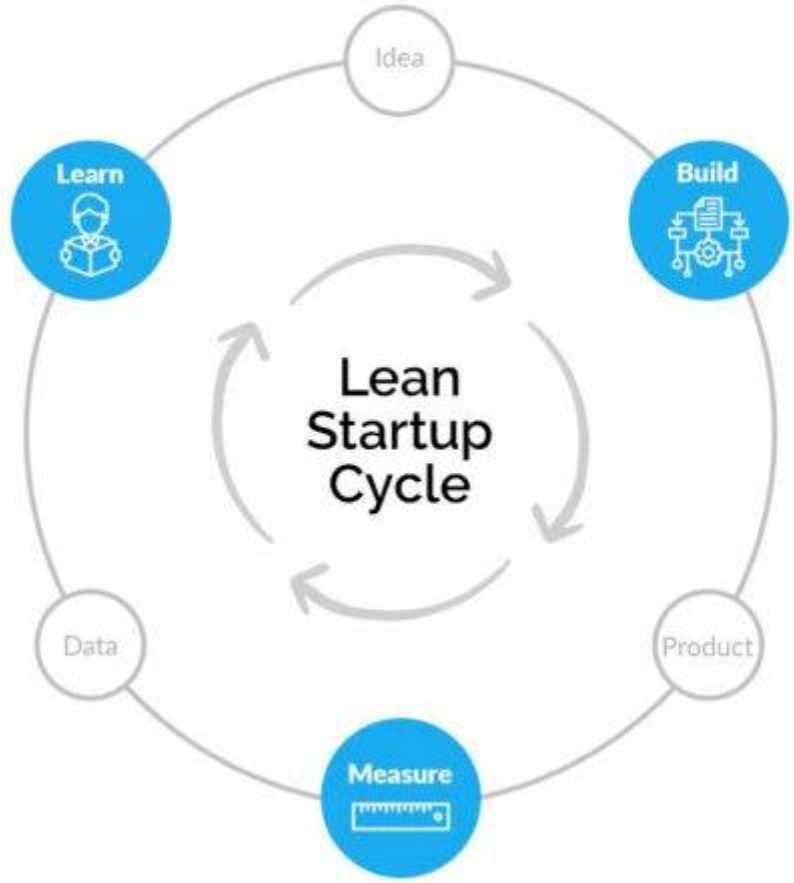
Minimum Viable Product

Version of a new product which allows a team to collect the maximum amount of validated learning about customers with the least effort.



TheLeanStartup.com

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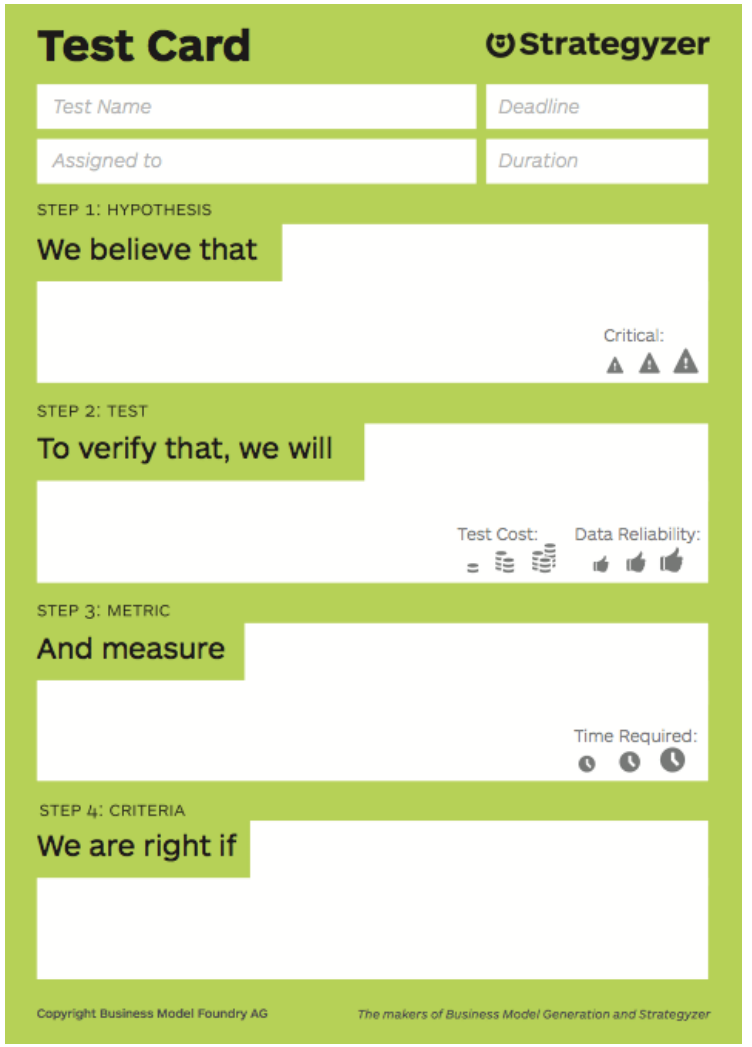
Test Hypothesis

Treat everything as an assumption



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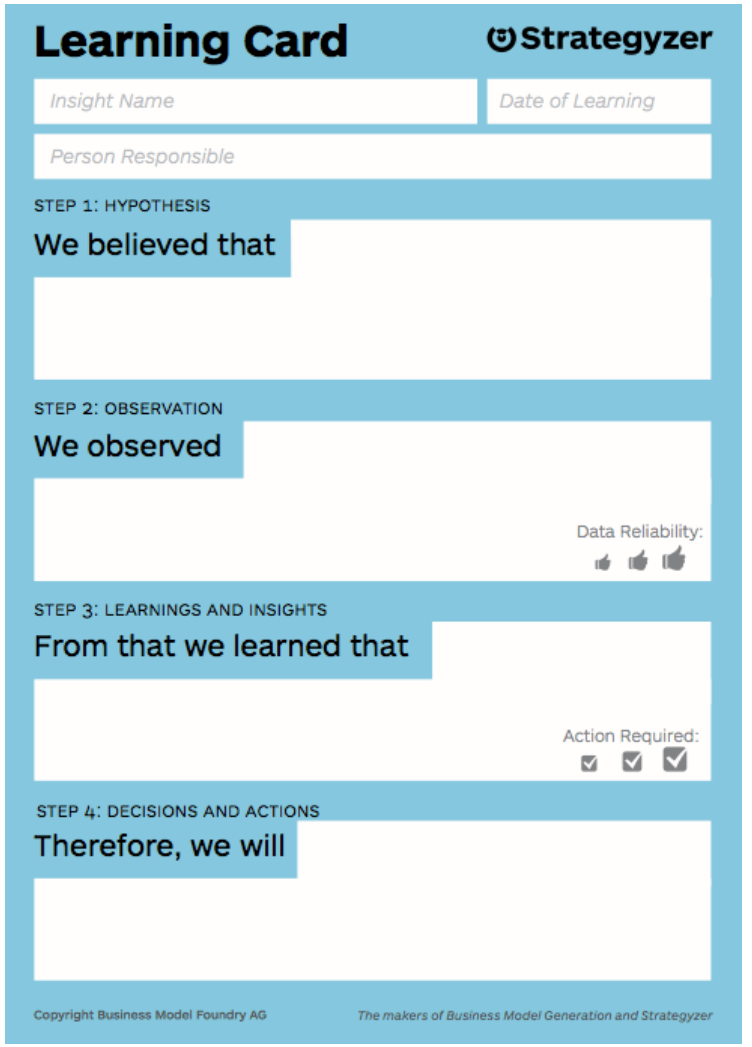
Capture your Learnings

Validated, invalidated or need to investigate further



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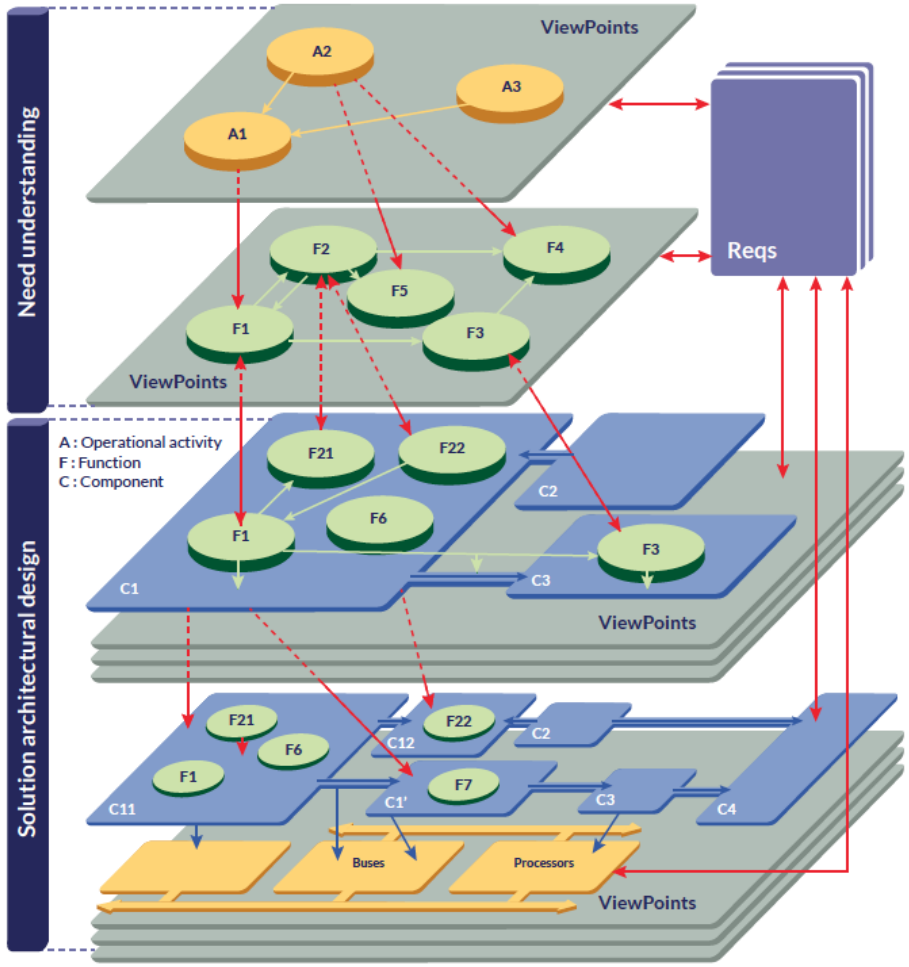

Operational Analysis
What the users of the system need to accomplish

Functional & Non Functional Need
What the system has to accomplish for the users

Logical Architecture
How the system will work to fulfill expectations

Physical Architecture
How the system will be developed and built

www.eclipse.org/capella/

Capella

Open source solution for model-based systems engineering

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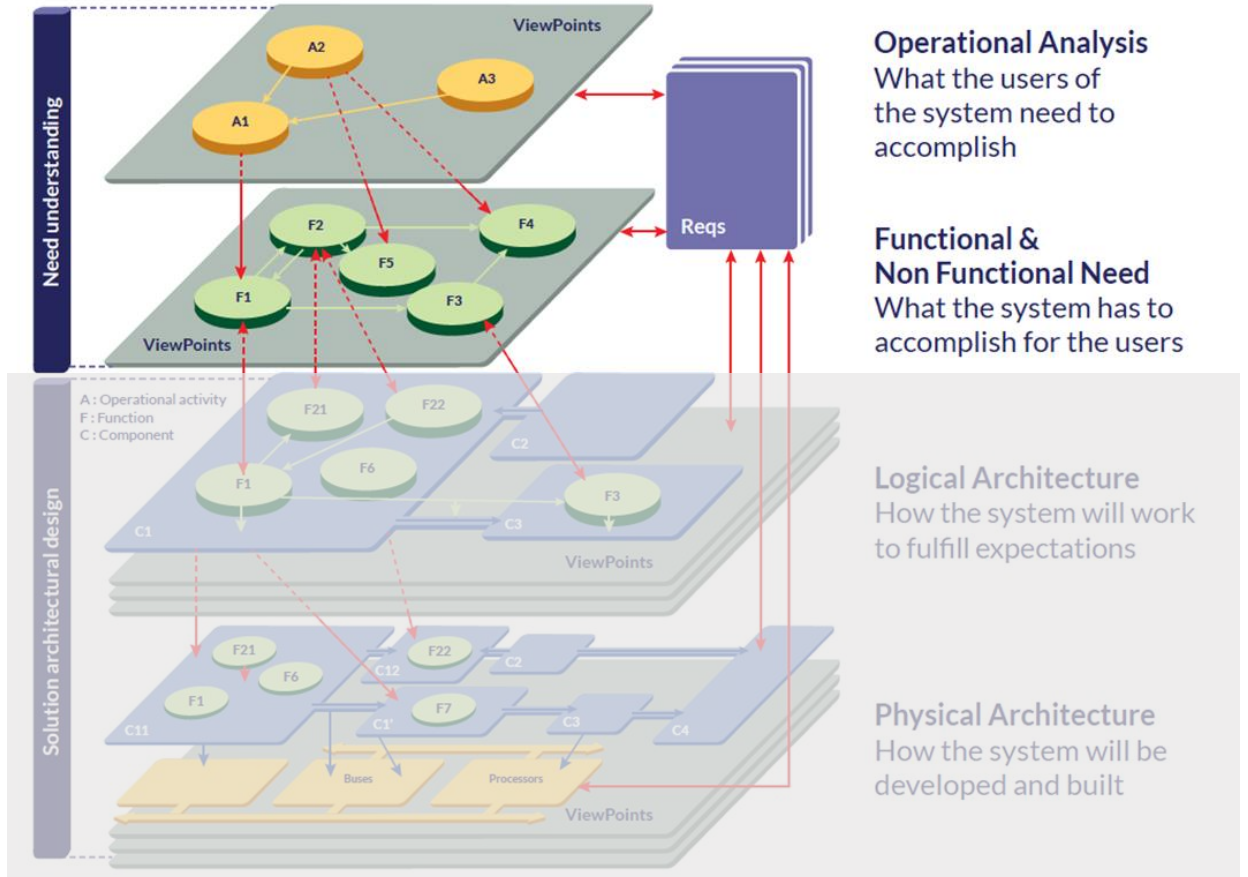
Need Understanding



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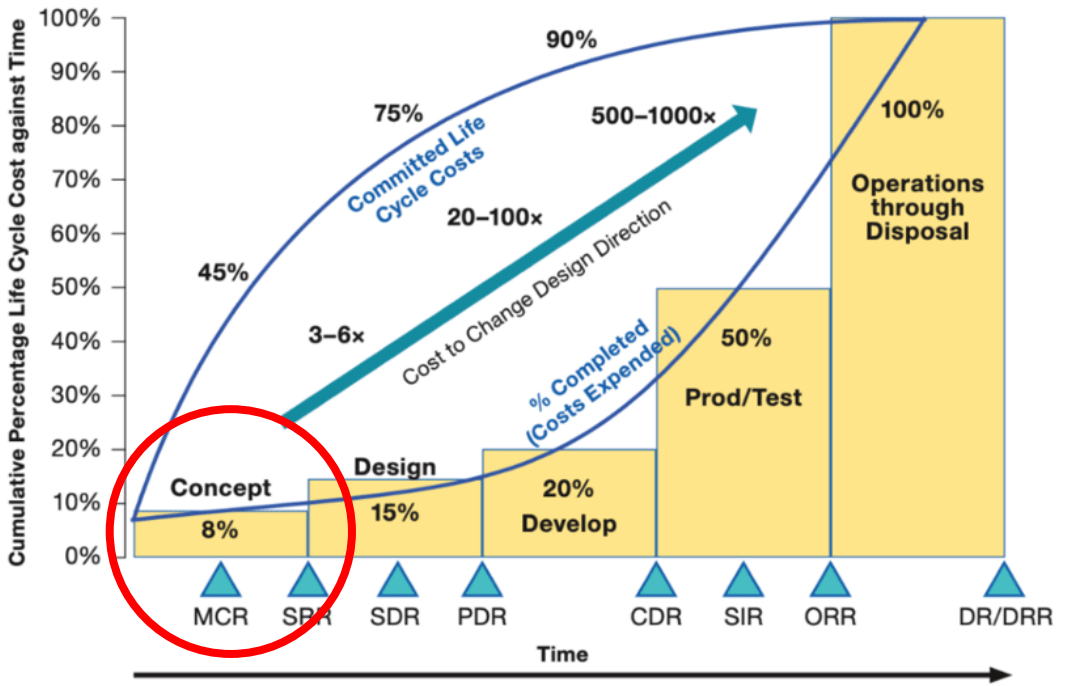
Life Cycle Cost

Needs Understanding phase



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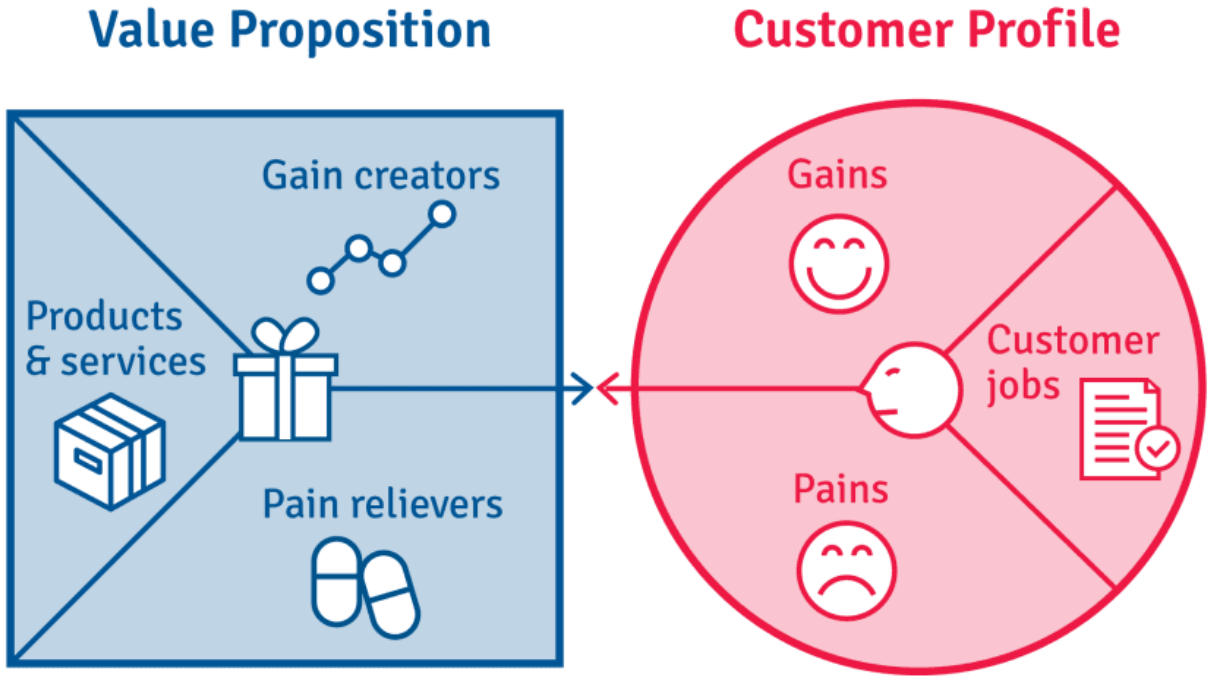
Value Proposition Canvas

Graphical representation of how the product or service provides customer value



www.strategyzer.com/vpd

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Operational Analysis

What the users need to accomplish

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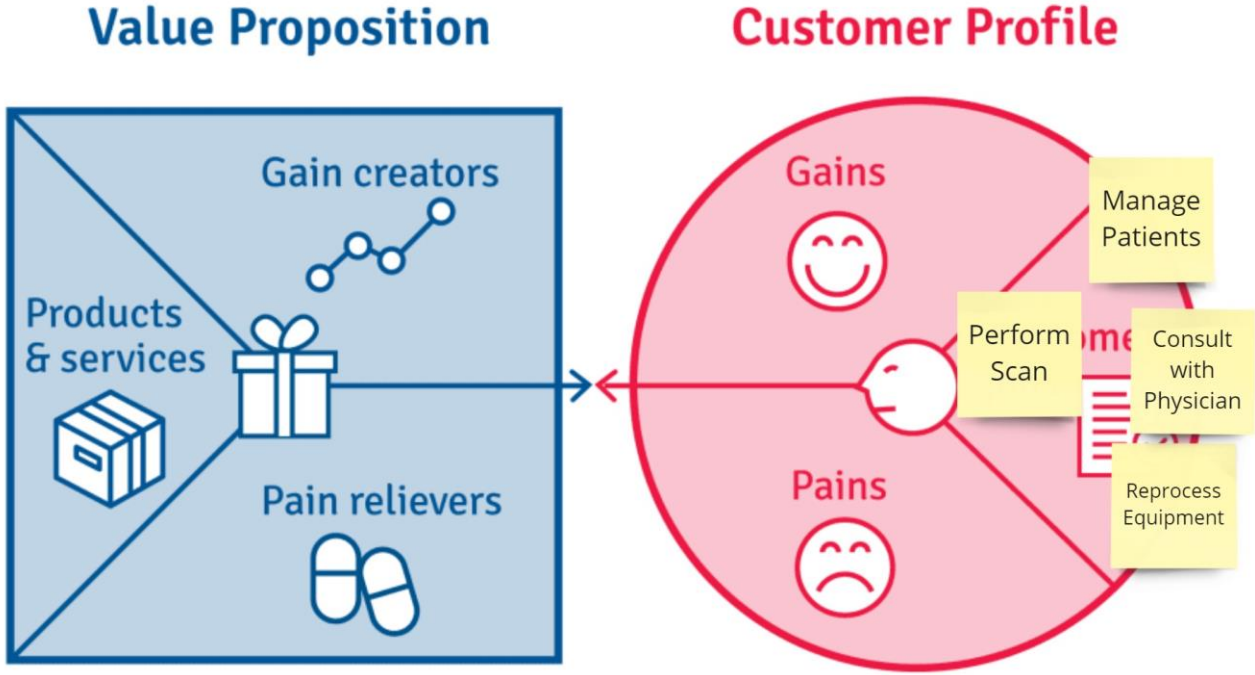
Customer Jobs:

What are the stakeholders trying to get done?

- Functional
- Social
- Personal



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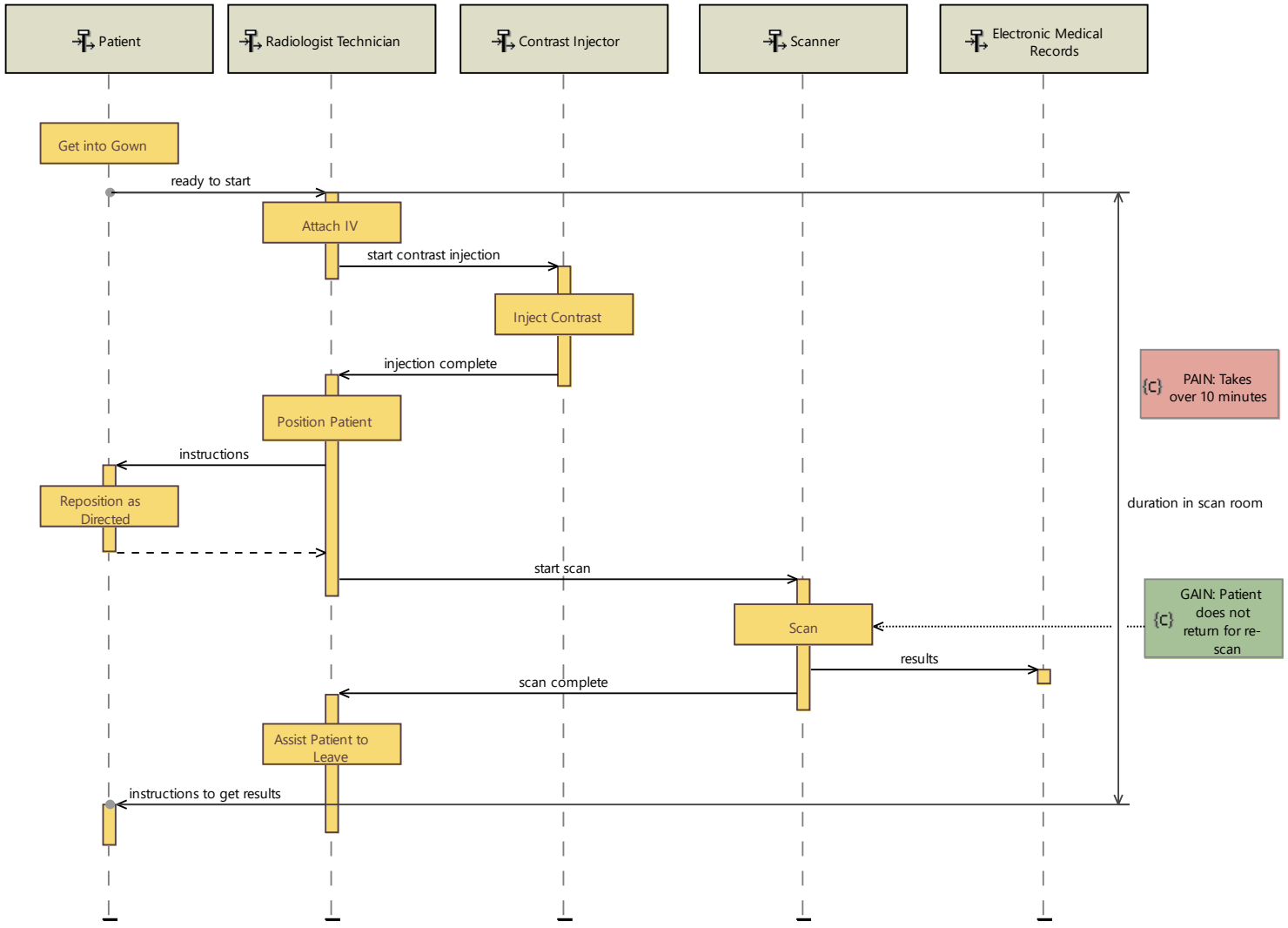

MVP: Analogous Device Site Visit

Observe the actors and entities with analogous devices

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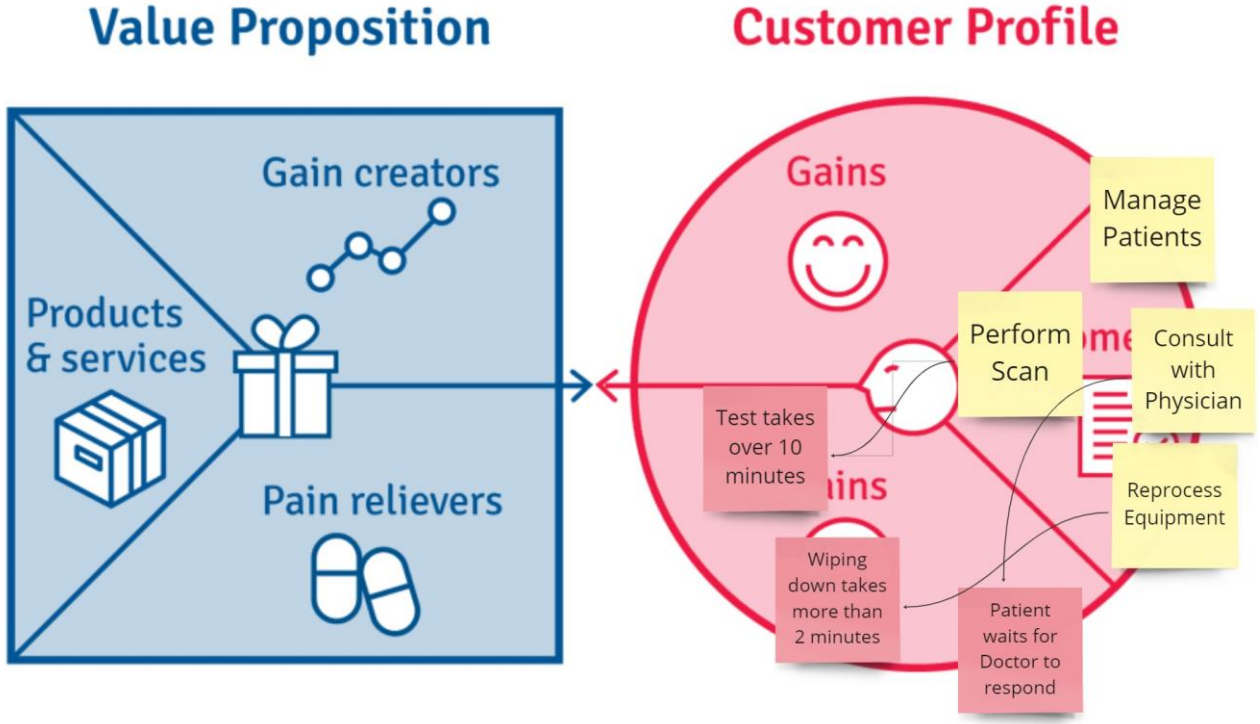
Pains:

Annoyances they would like to avoid

- Undesirable outcomes
- Obstacles
- Risks

Make these quantitative so we know understand the value



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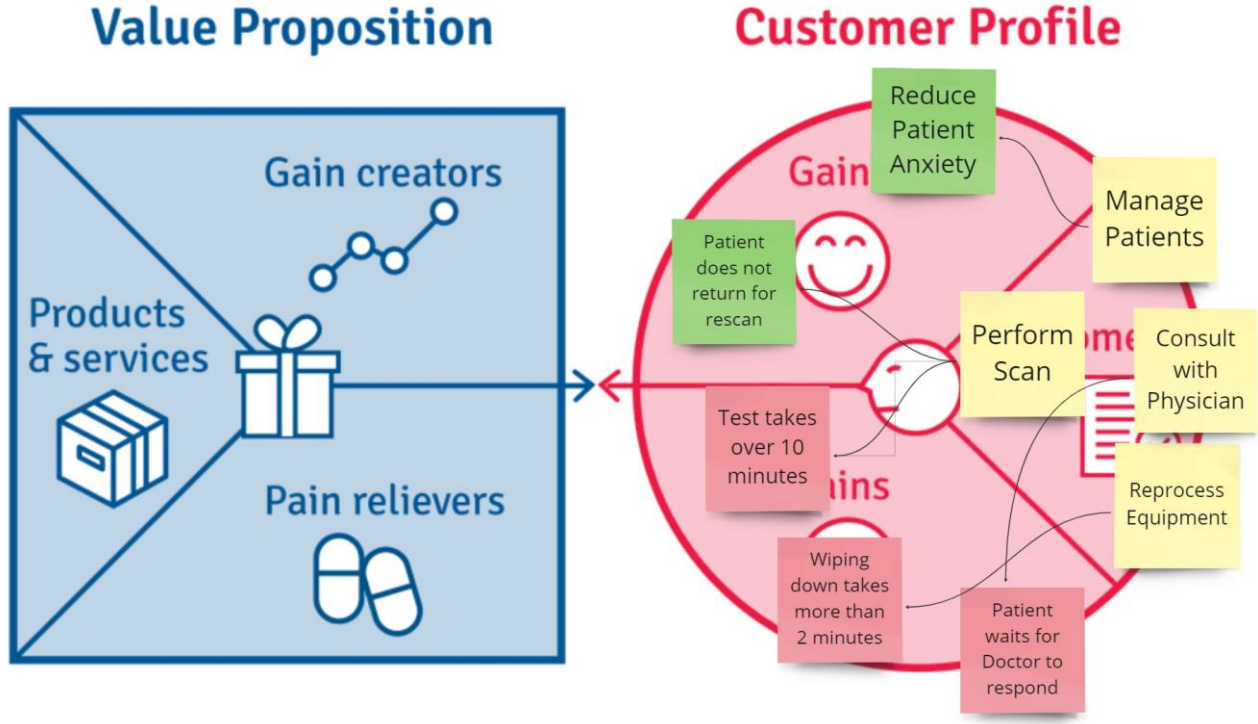
Gains:

What outcomes or benefits do they want?

- Required
- Expected
- Desired

Make these quantitative so we know understand the value



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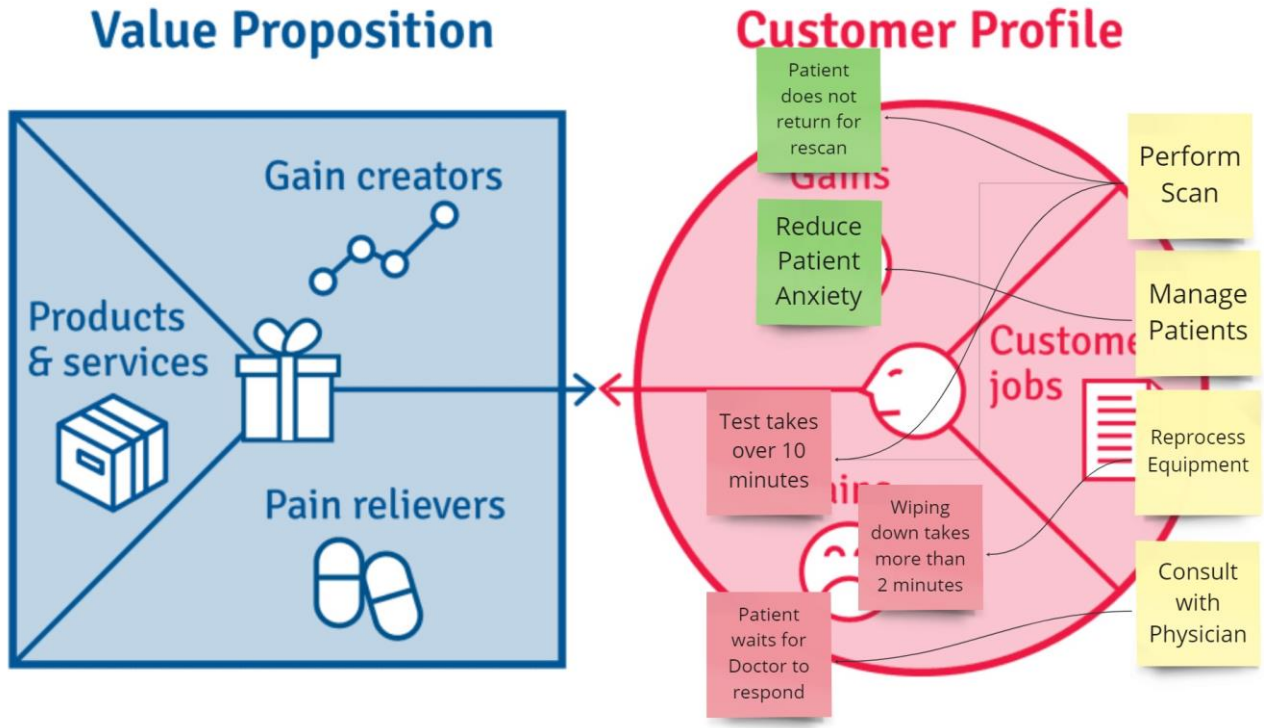
Ranking

All Stakeholders
- Business
- Patient & Users



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No facts exist inside the building, only opinions

Patient Arrives

Patient arrives at hospital (ER) after event.

Patient Assessed

Physician decides patient needs to be admitted/ transferred from Emergency to general ward, writes orders for medication

Patient Admitted

Patient details entered into EMR. Clinical Nurse Lead assigns bed

MVP: Analogous Device Storyboard

Based on sequence diagrams and functional chains

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MVP: Problem Interview

Get to real motivations

- Demographics
- Ranking
- Walkthrough of storyboard
- Open ended questions

Don’t mention solutions

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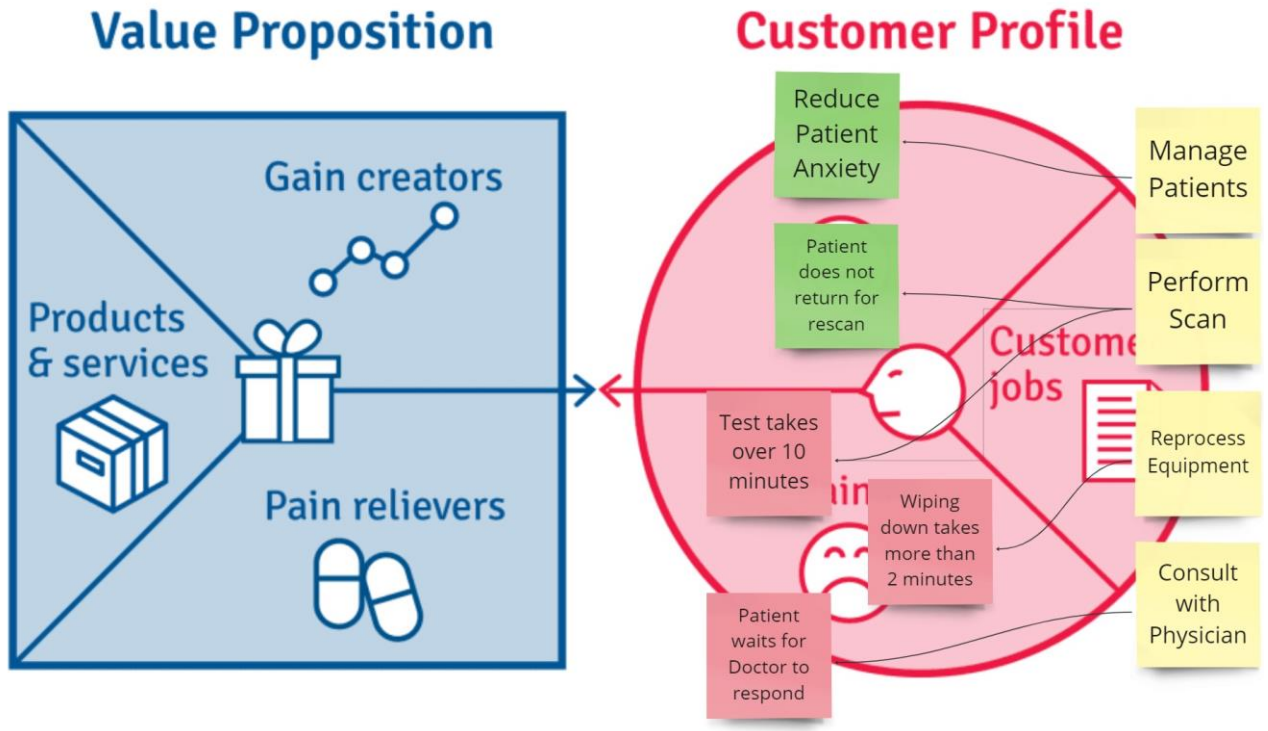
Problem Validation

Understand what the stakeholders value



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System Needs Analysis

What the system has to accomplish for the users

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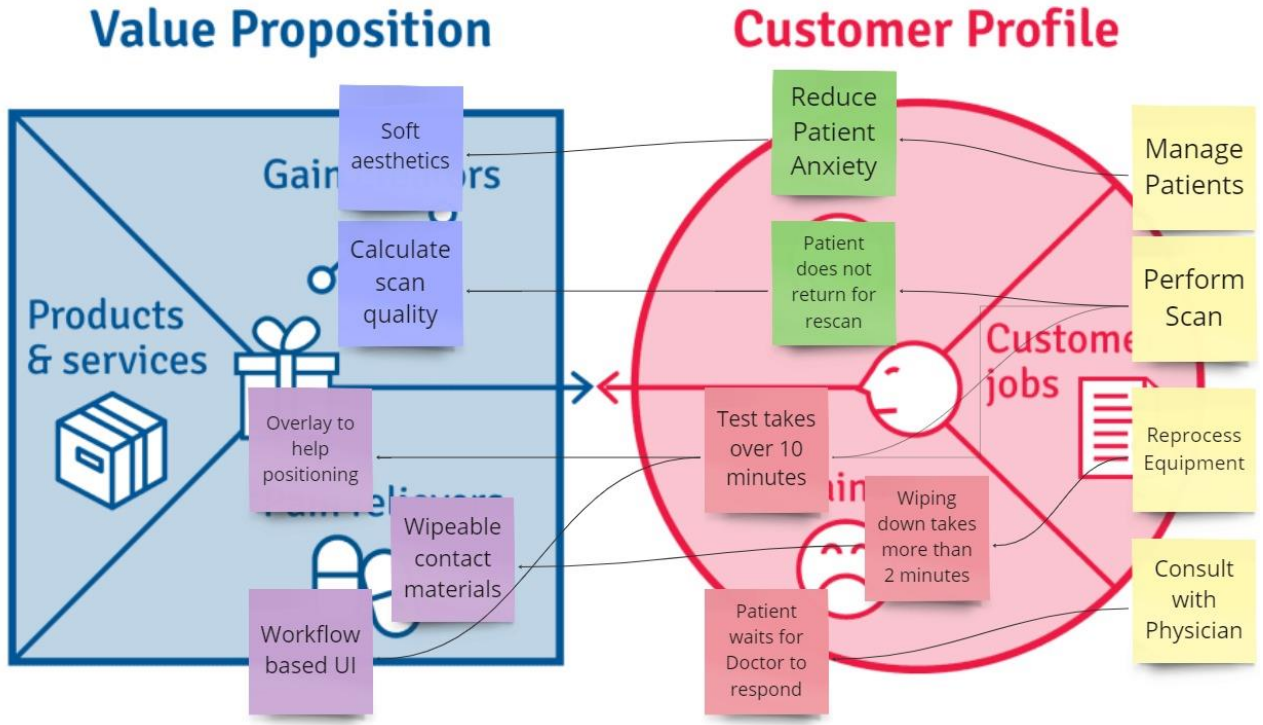
What would the Magic do?

Describe how the products and services alleviate the pains or produce benefits



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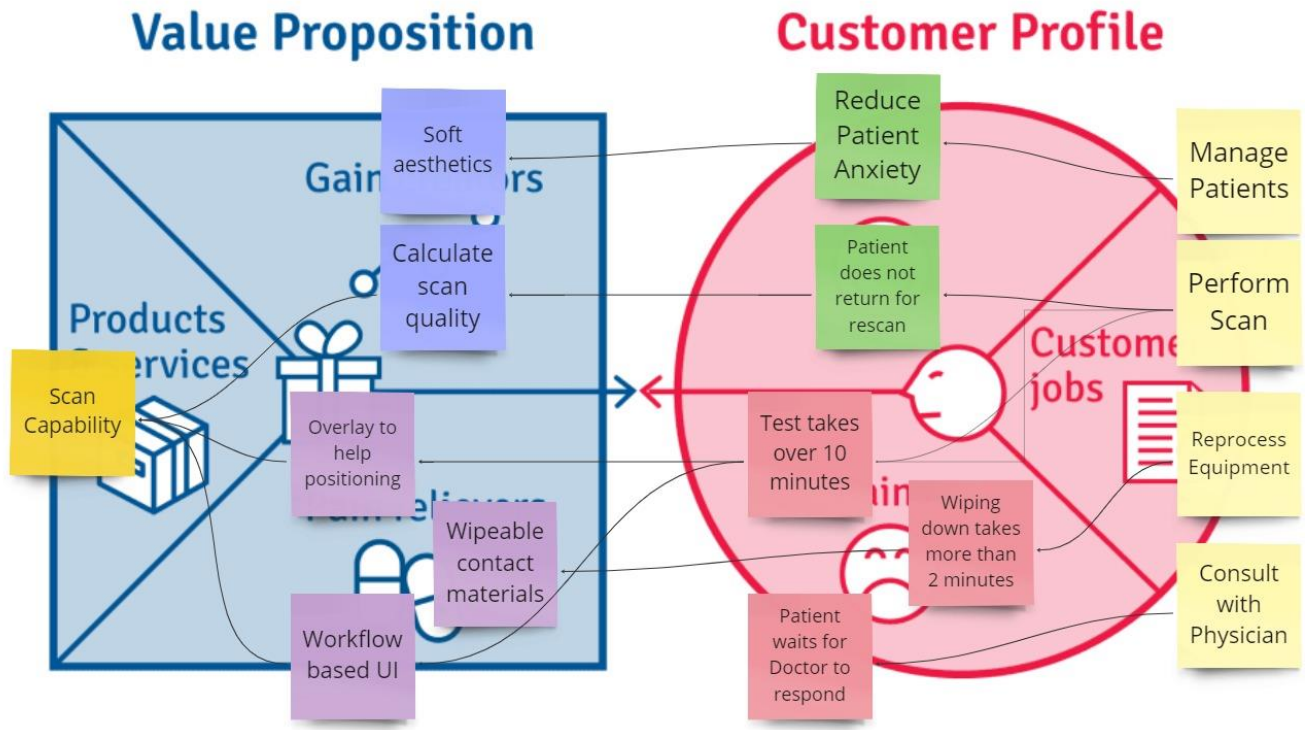
Capabilities Definition

Associate functional gain creators and pain relievers to capabilities.



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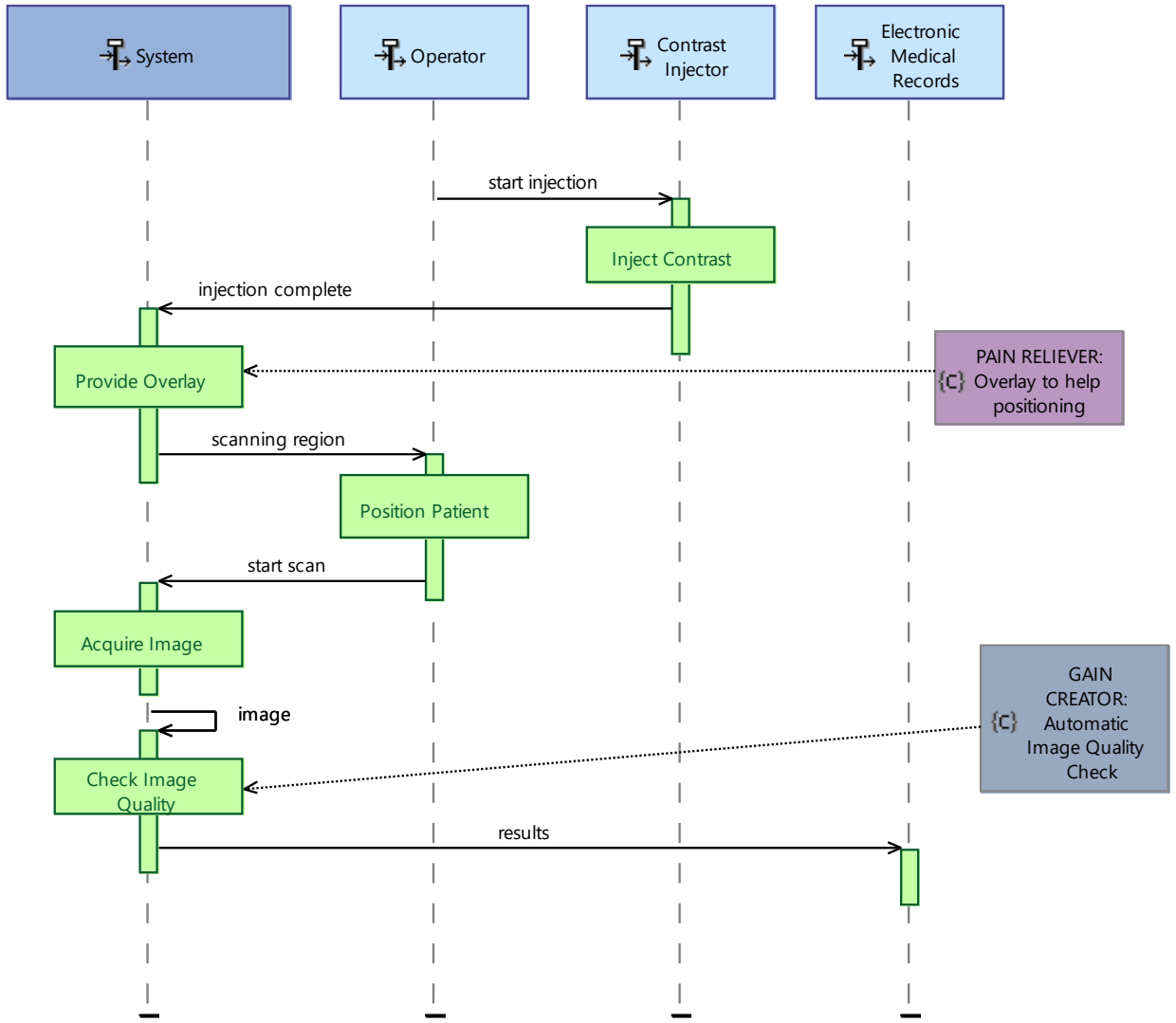

Capability

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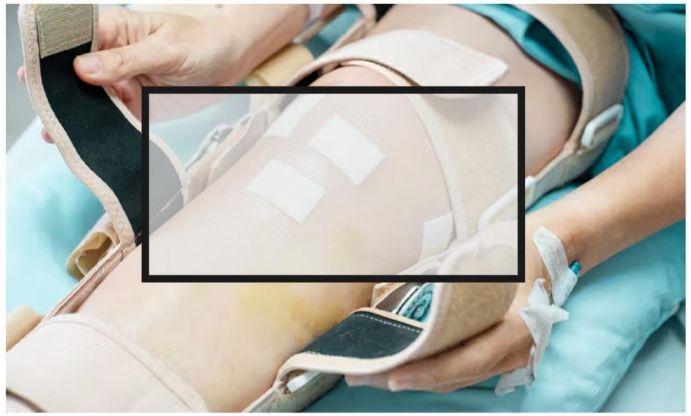
Connect Contrast

Connect contrast injector after patient arrives in scan suite.



Display Overlay

The monitor will display an overlay in real-time of the scan region

Position Patient

Patient position is done using overay

MVP: Product Storyboard

Based on System Needs sequence diagrams and functional chains

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MVP:
Solution Interview

Stakeholders determine if the proposed solution addresses their problems

Reconfirm the problem

Do the gain creators and pain relievers satisfy your problems?

Would the updated storyboard workflow be acceptable?

What are the strengths and weaknesses of proposed solution?

Would you use it?

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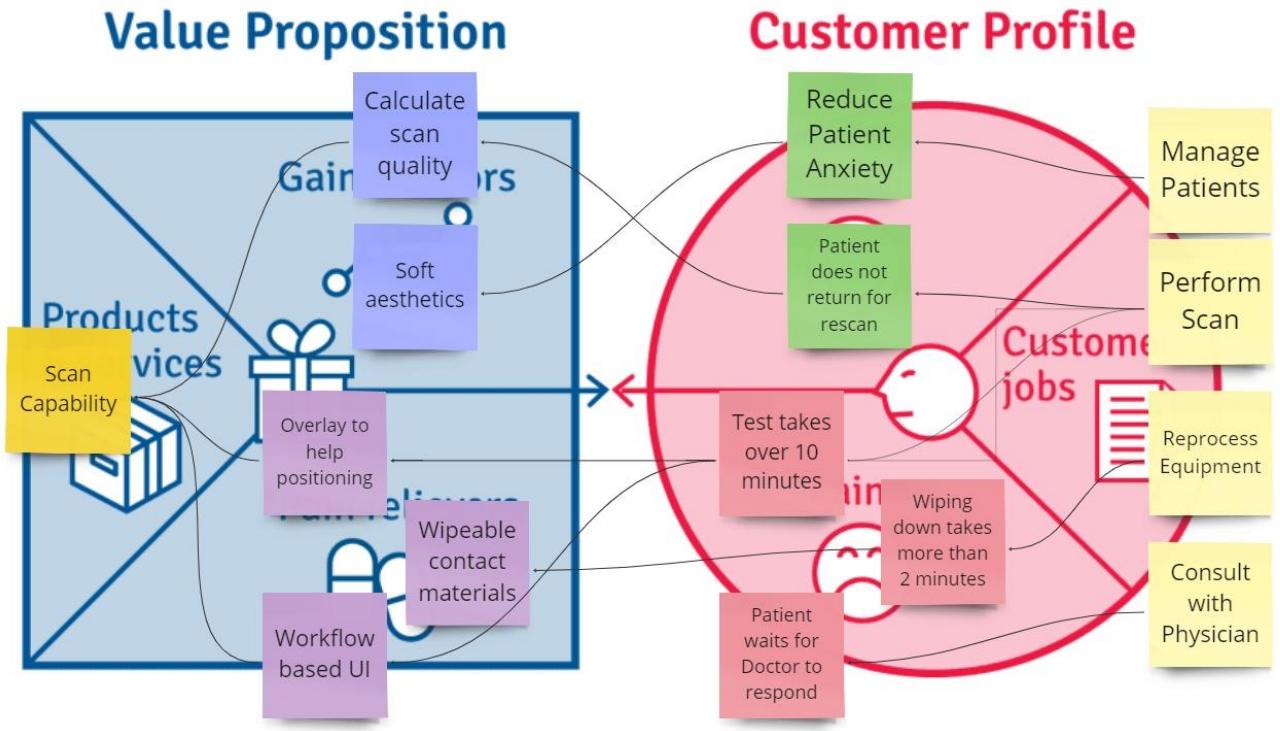
Solution Validation

Stakeholders determine problem-solution fit



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Value Proposition

Unique value proposition for each stakeholder

A single statement describing the benefits a customer would expect from the product or service

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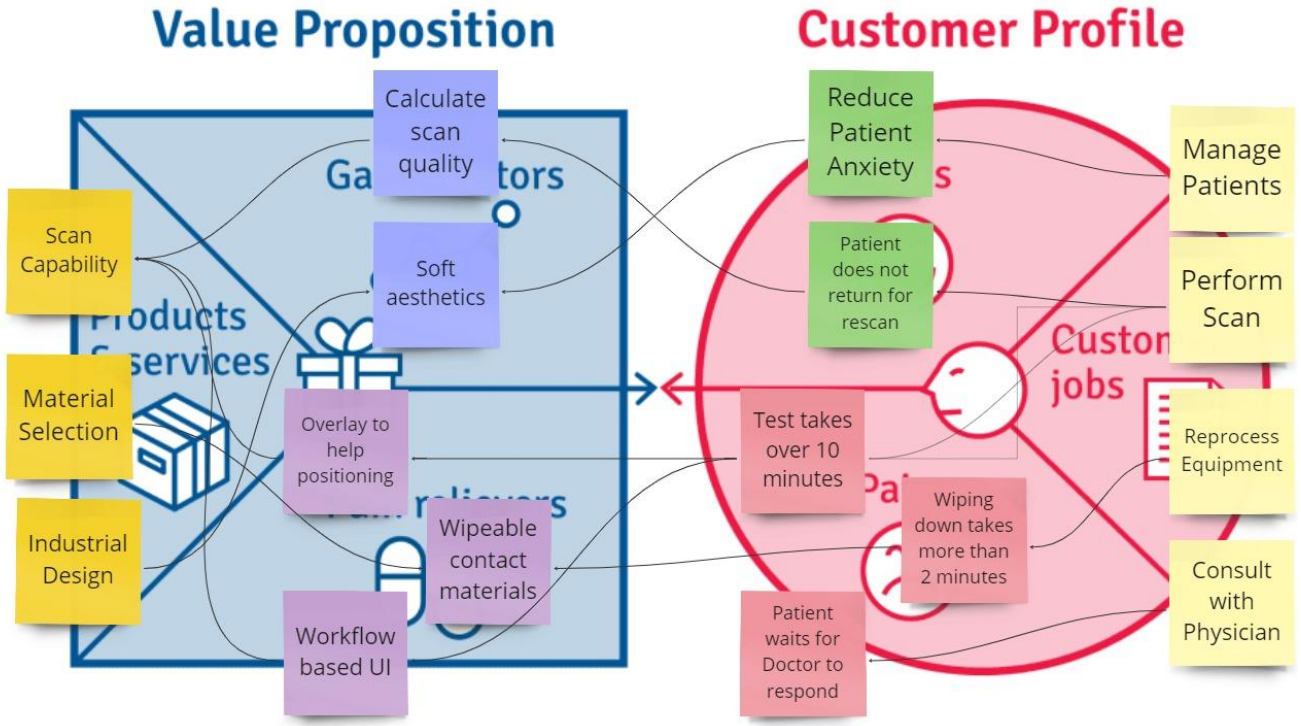
Non-Functional Strategy

How do we expect to provide non-functional gain creators and pain relievers.



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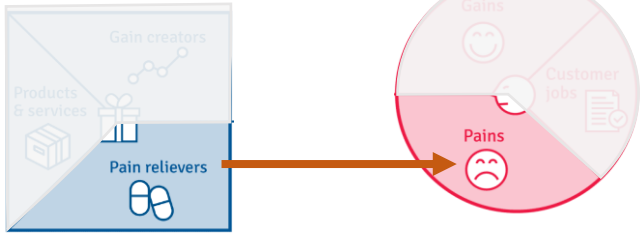
Value Propositions

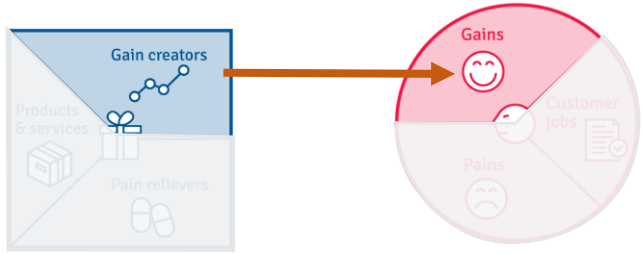
Our 

_____ help 

_____ who want to

_____ by 

_____ and



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Stakeholder Requirements

System Requirements

Textual Requirements

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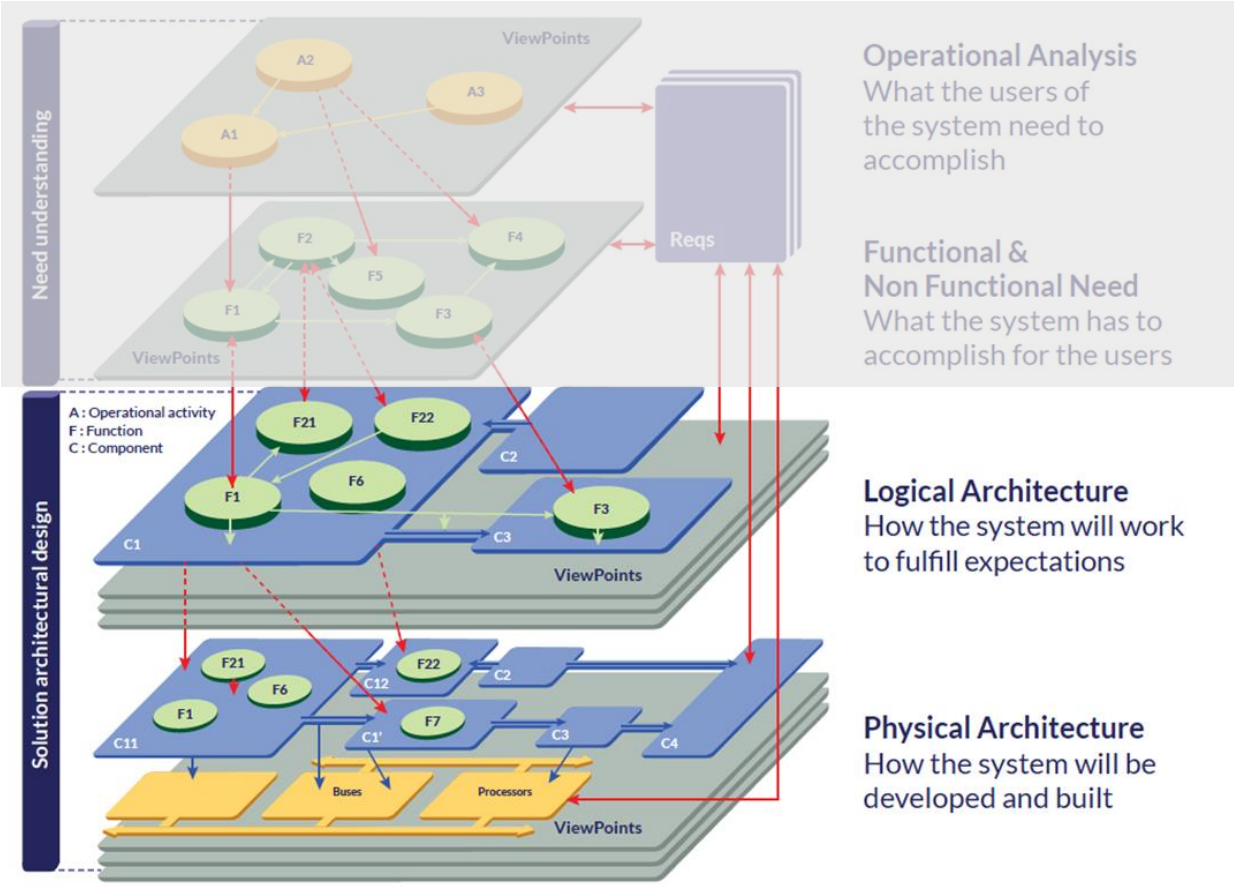
Solution Architecture Design



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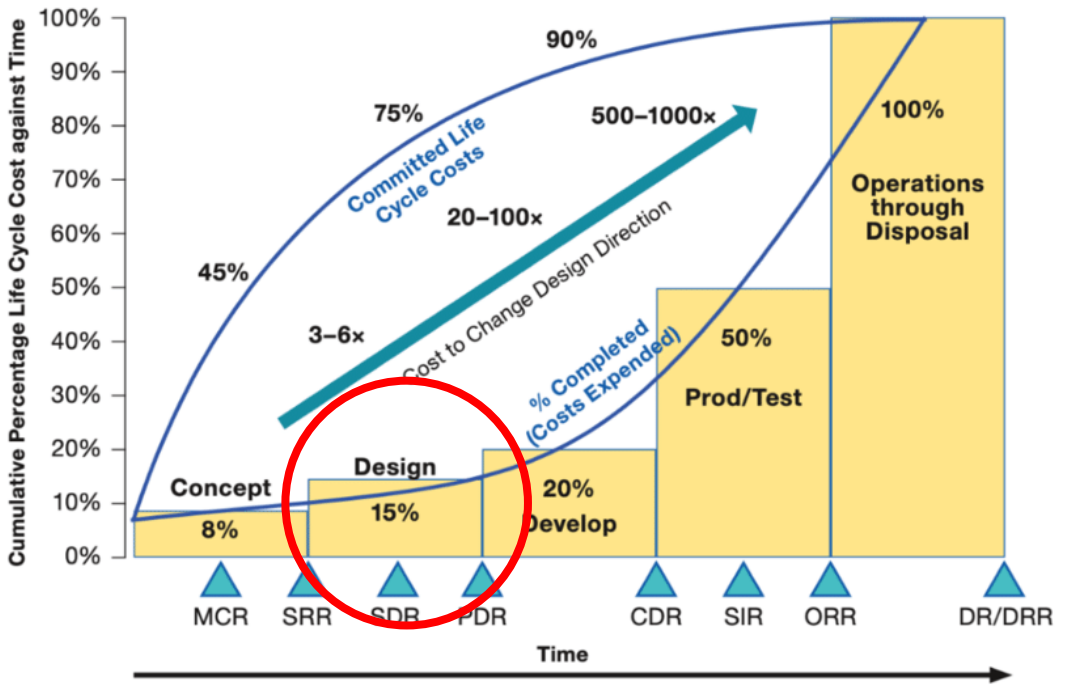
Life Cycle Cost

Solution Architecture Design phase



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Logical Architecture

How the system will work to fulfill expectations

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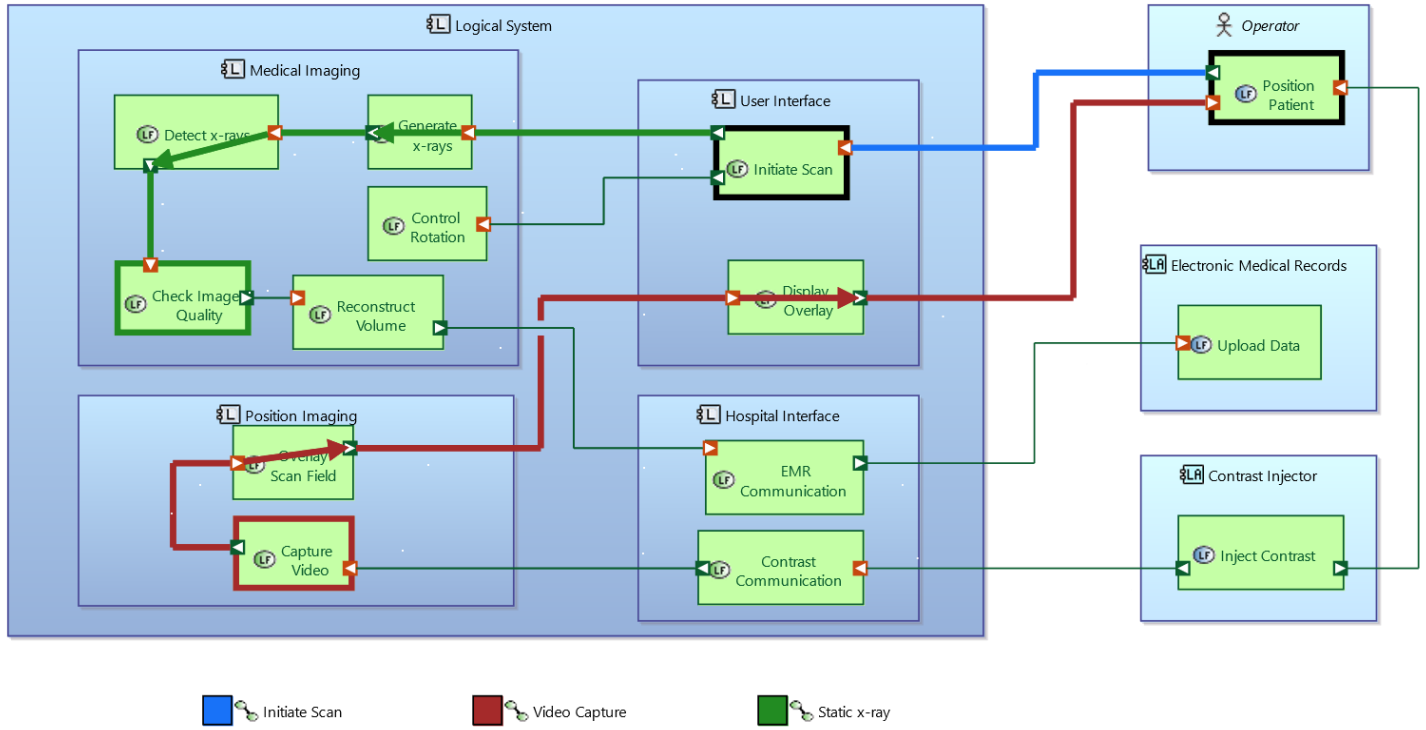

Functional Chains

- Interactions with Actors
- Interactions with External Entities
- Internal Chains

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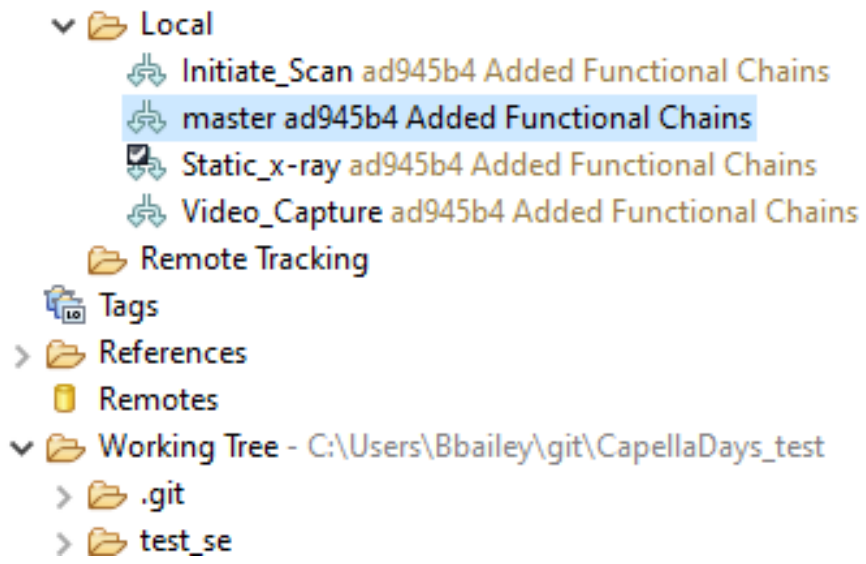

Branches

Using Git or other version control

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Physical Architecture

learnings

How the ~~system~~ will be developed and built

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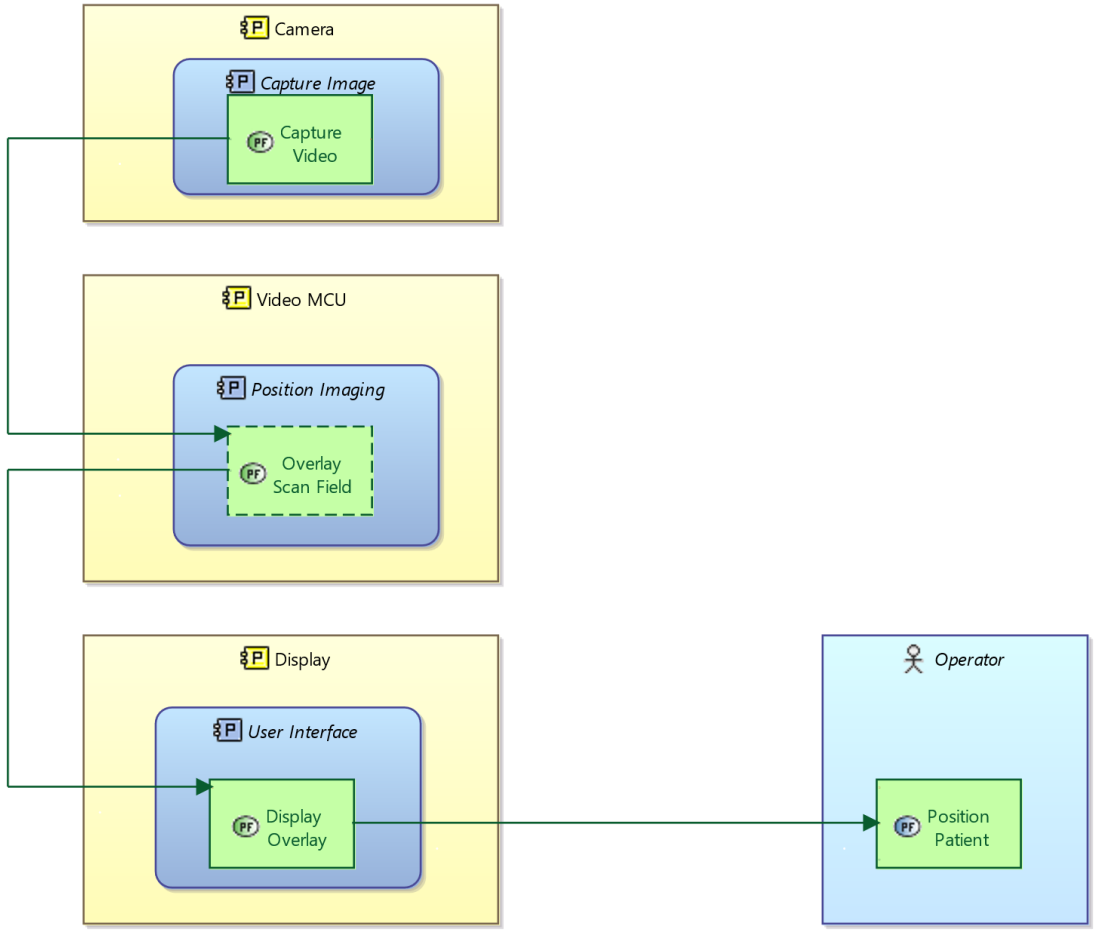

MVP: Build prototypes for learning

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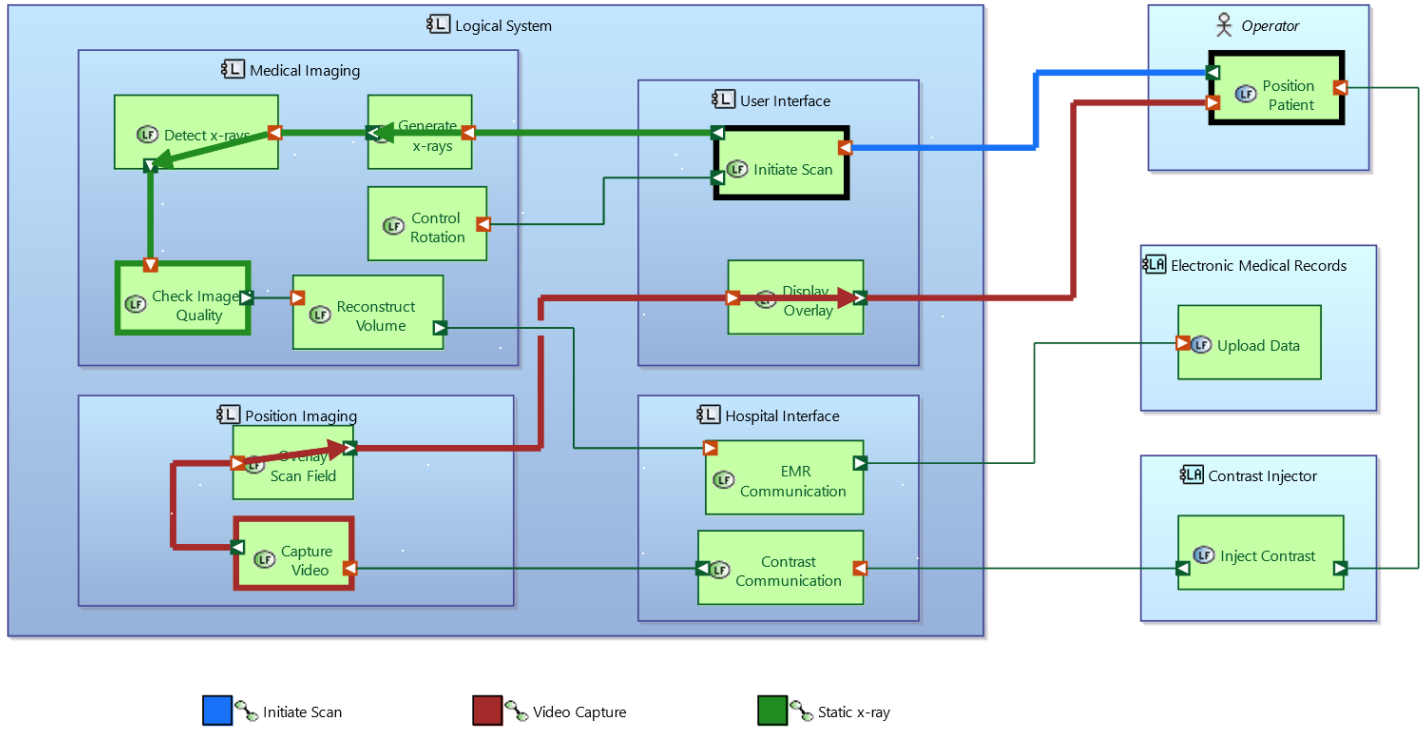

Preliminary Design Review

When all functional chains are de-risked sufficiently

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Physical Architecture

How the system will be developed and built

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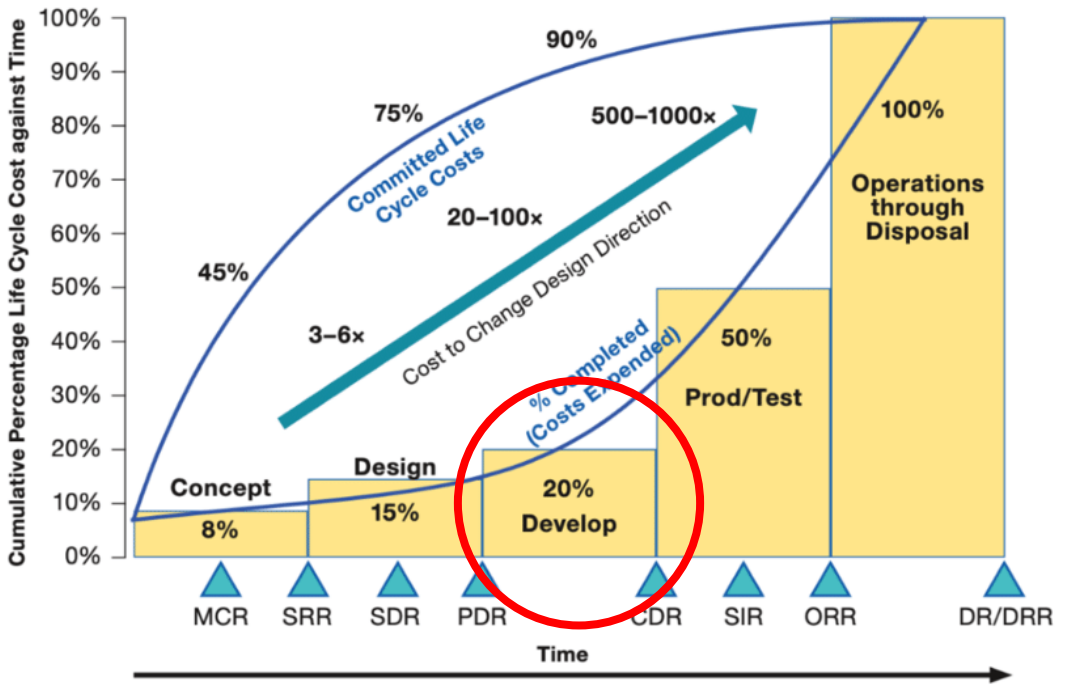
Life Cycle Cost

Physical Architecture level



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Conclusion

Lean Startup techniques

- Focus on the users and other stakeholders
- Arrive at an effective system architecture
- Integrate into Capella MBSE

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