GRENOBLE INP UGA

Génie industriel

École nationale supérieure de génie industriel

Introduction to the Fundamentals of Systems Engineering

2. Needs definition (Operational Analysis/View)

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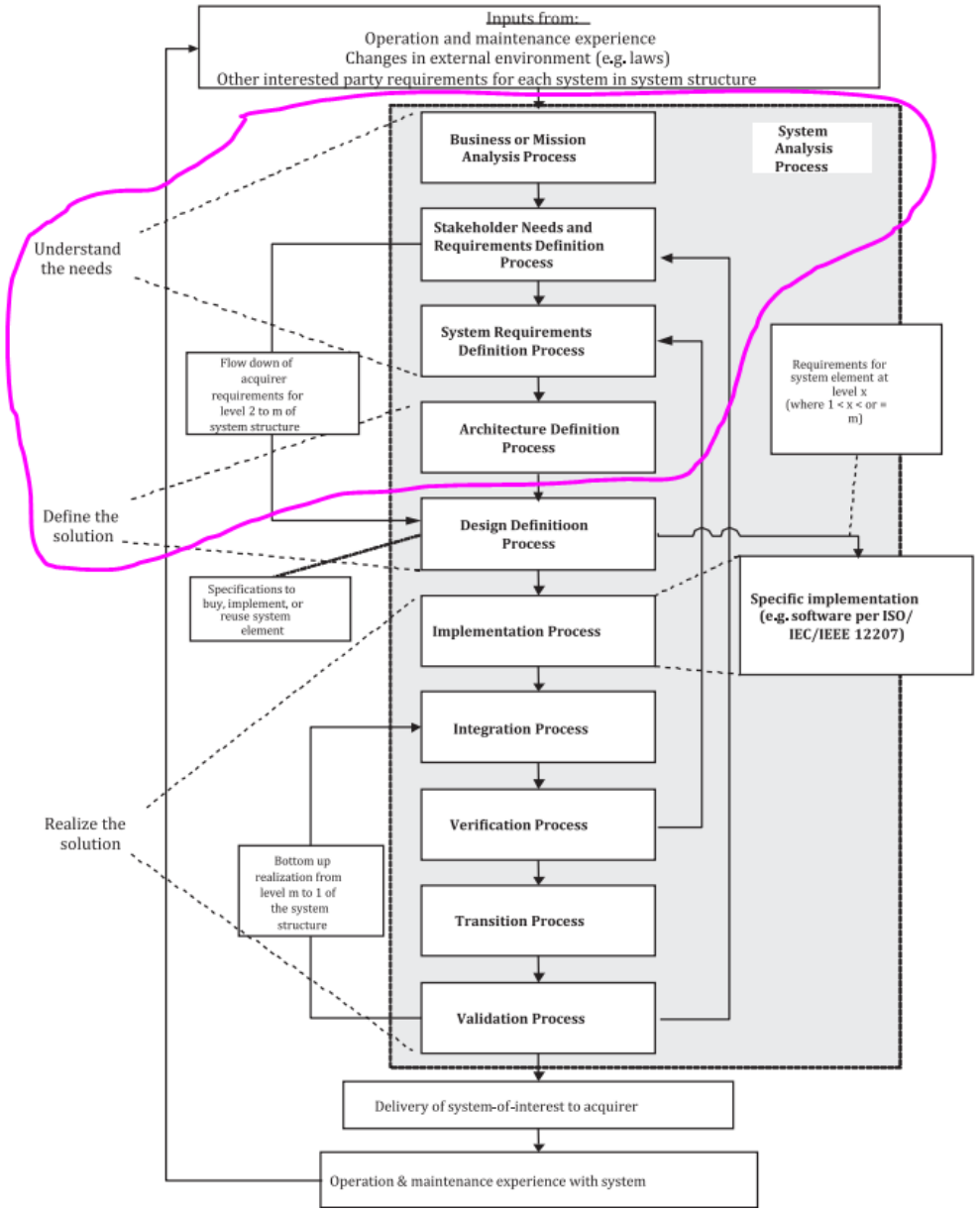
Agenda

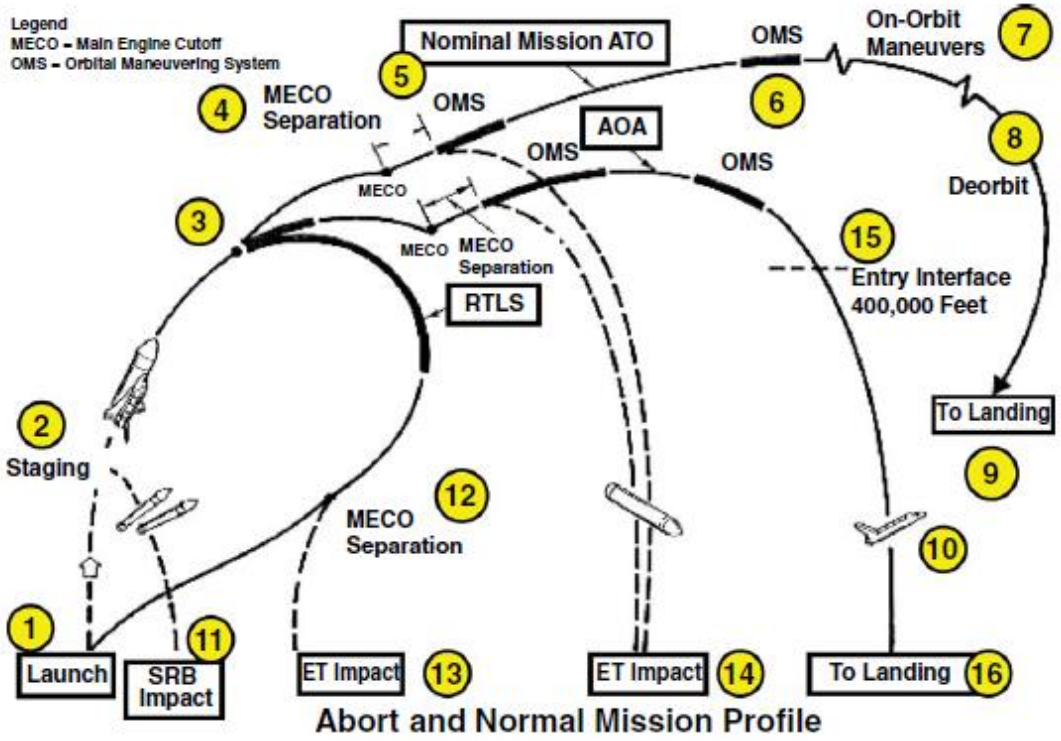

Inputs from:
Operation and maintenance experience
Changes in external environment (e.g. laws)
Other interested party requirements for each system in system structure
System Analysis Process
Business or Mission Analysis Process
Stakeholder Needs and Requirements Definition Process
System Requirements Definition Process
Architecture Definition Process
Design Definitioon Process
Implementation Process
Integration Process
Verification Process
Transition Process
Validation Process
Understand the needs
Define the solution
Realize the solution
Flow down of acquirer requirements for level 2 to m of system structure
Specifications to buy, implement, or reuse system element
Bottom up realization from level m to 1 of the system structure
Requirements for system element at level x (where 1 < x < or = m)
Specific implementation (e.g. software per ISO/IEC/IEEE 12207)
Delivery of system-of-interest to acquirer
Operation & maintenance experience with system

No universal recipe; it depends…

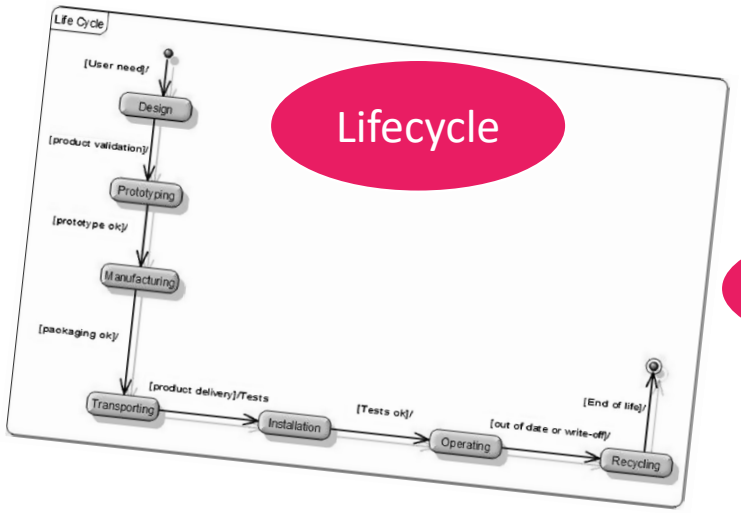
		Blank Page/Greenfield	Legacy/Brownfield
B2C			
B2B	*With a customer*		
	Without a customer		

Operational View

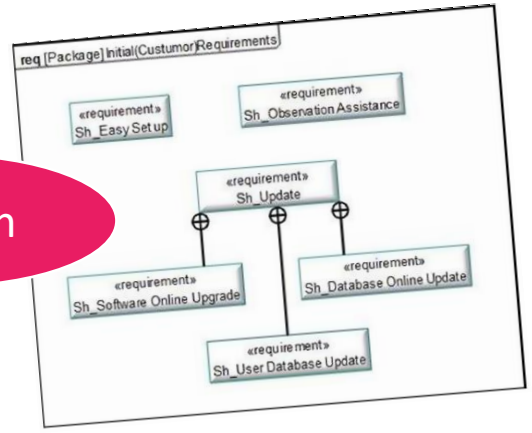
The Operational View is a description of the system from an external (end-users) viewpoint. It includes the analysis of the missions, lifecycle, stakeholders, services, constraints, external interfaces, scenarios, etc. The main deliverable is a set of needs (services and constraints) desired or imposed by external entities (a bit similar to your TPP).



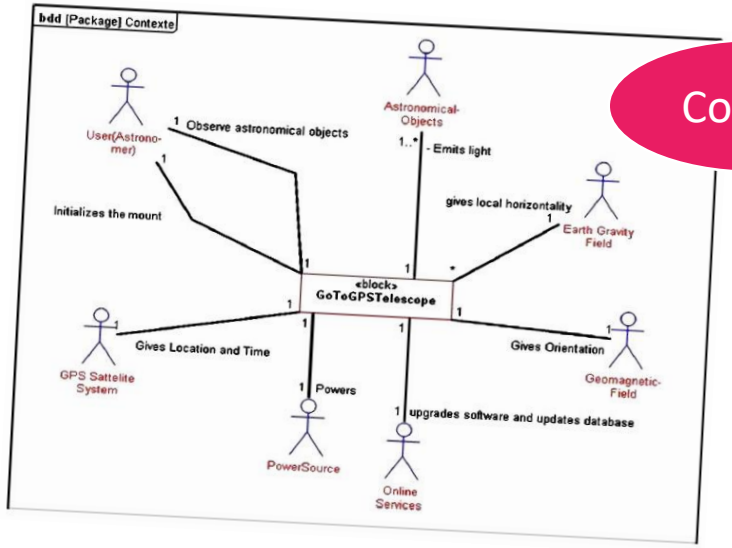
Operational View



Lifecycle

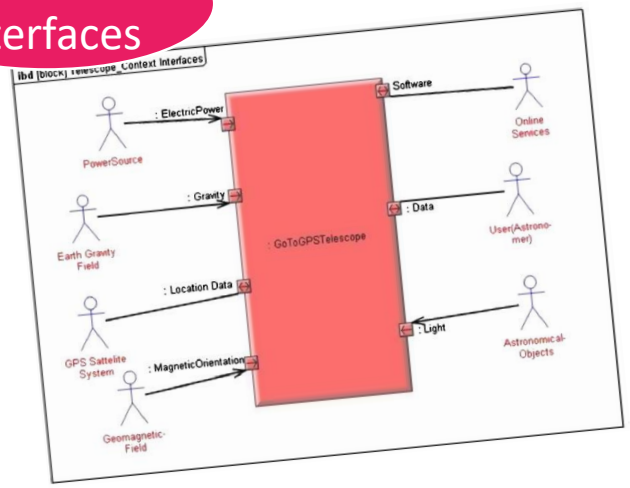


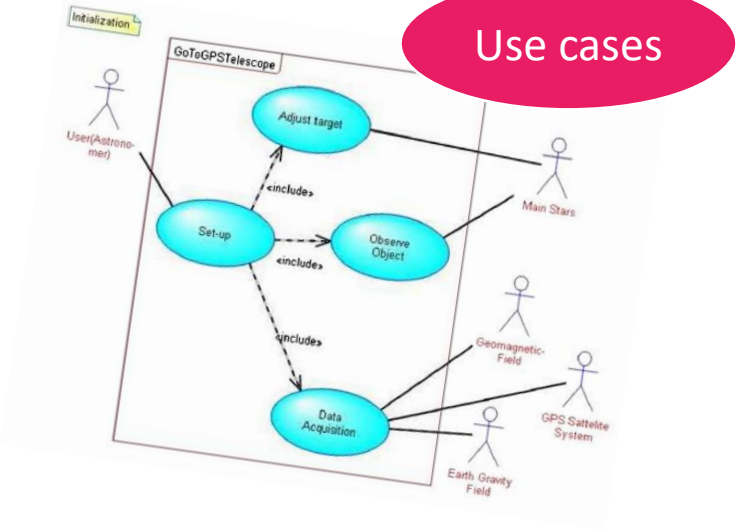
Mission



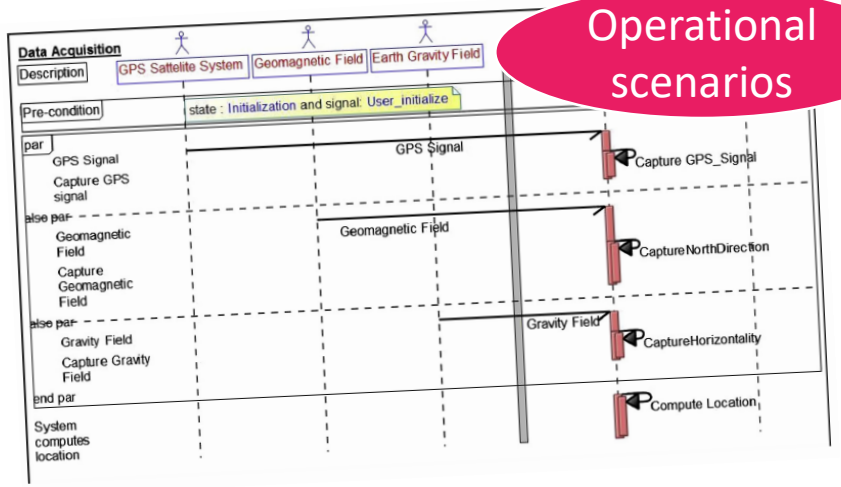
Context

External interfaces



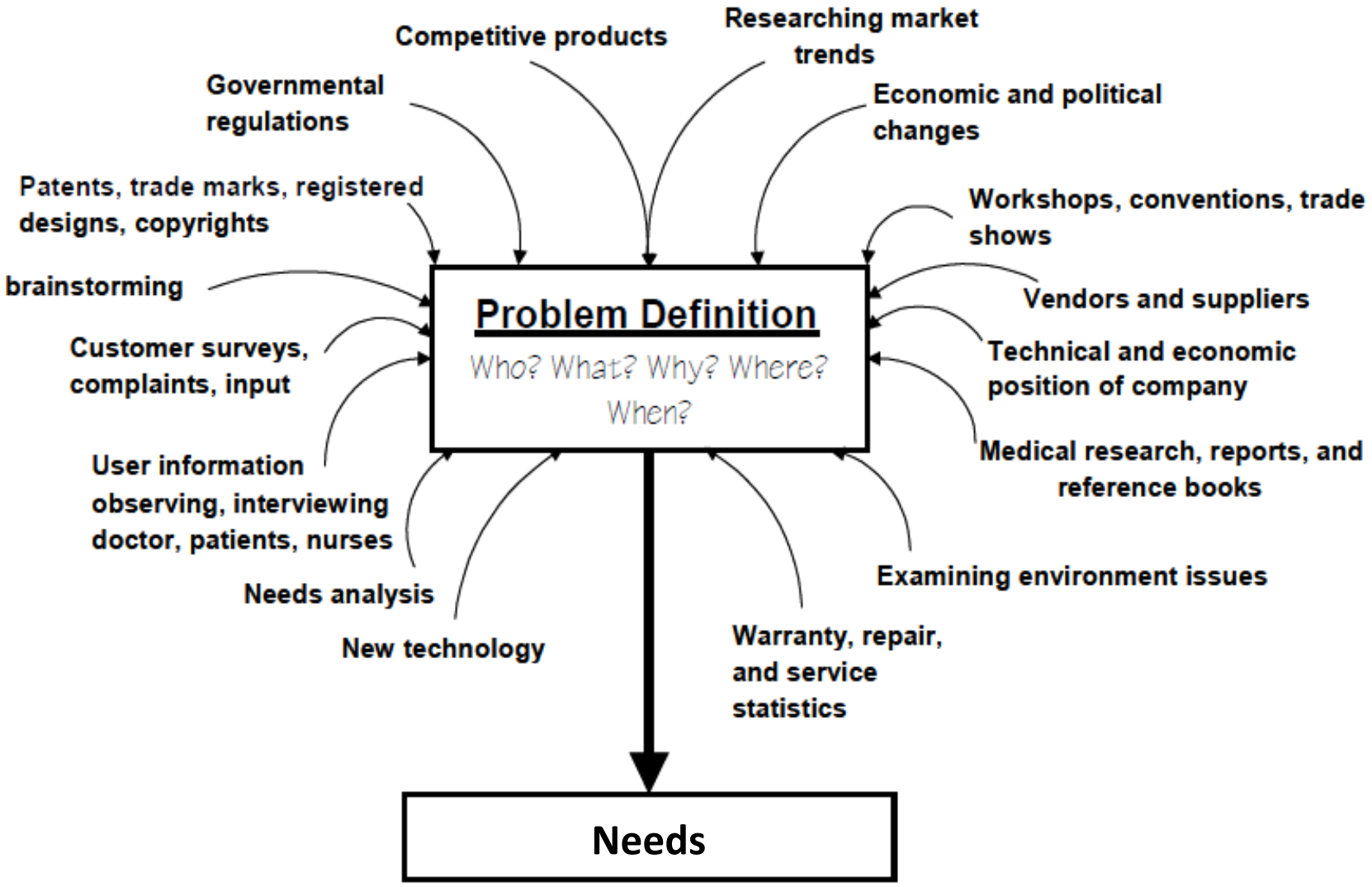


Use cases



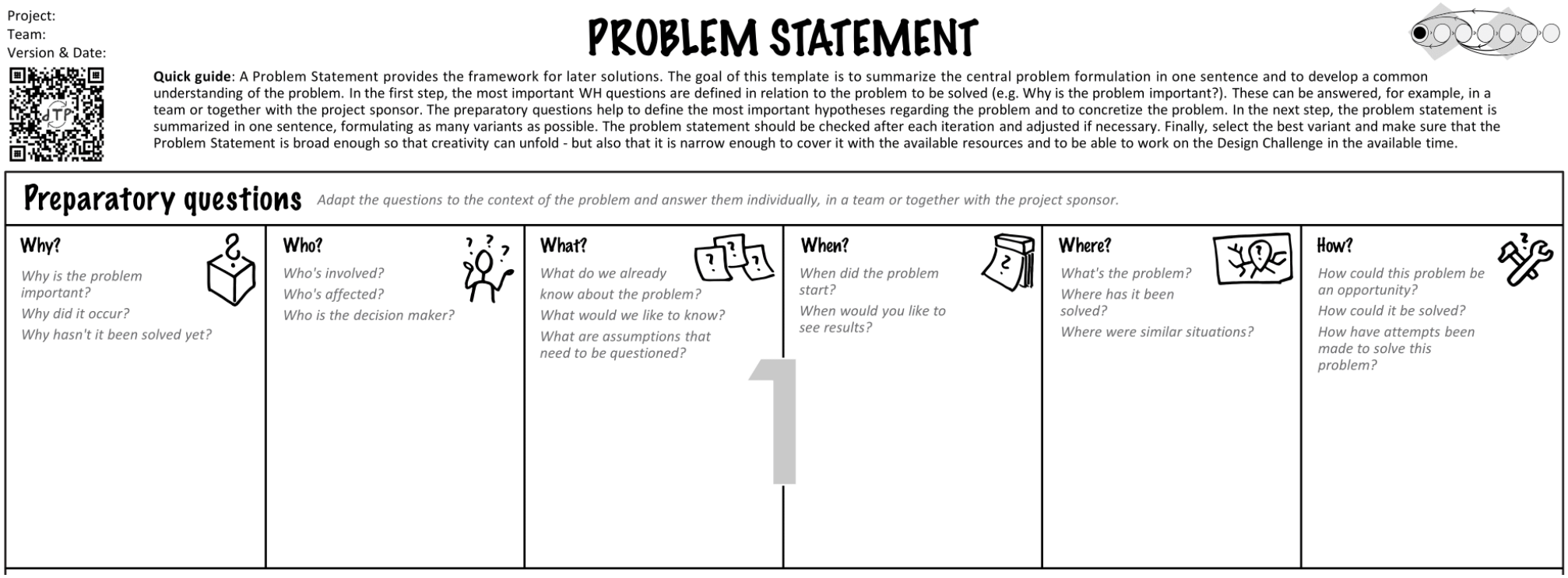
Operational scenarios

From Problem Definition to a Set of Needs



Problem/Mission Definition

A design challenge starts with the understanding of the problem/mission statement. However, before we begin to solve a problem, we must first understand it correctly. Develop common understanding of a problem with the clients and on the team. The problem/mission statement is a simple sentence that is neither too specific (solution agnostic) nor too general (5W: what, why, who, where, when).



Project:
Team:
Version & Date:

PROBLEM STATEMENT

Quick guide: A Problem Statement provides the framework for later solutions. The goal of this template is to summarize the central problem formulation in one sentence and to develop a common understanding of the problem. In the first step, the most important WH questions are defined in relation to the problem to be solved (e.g. Why is the problem important?). These can be answered, for example, in a team or together with the project sponsor. The preparatory questions help to define the most important hypotheses regarding the problem and to concretize the problem. In the next step, the problem statement is summarized in one sentence, formulating as many variants as possible. The problem statement should be checked after each iteration and adjusted if necessary. Finally, select the best variant and make sure that the Problem Statement is broad enough so that creativity can unfold - but also that it is narrow enough to cover it with the available resources and to be able to work on the Design Challenge in the available time.

Preparatory questions

Adapt the questions to the context of the problem and answer them individually, in a team or together with the project sponsor.

Why?
- *Why is the problem important?*
- *Why did it occur?*
- *Why hasn't it been solved yet?*

Who?
- *Who's involved?*
- *Who's affected?*
- *Who is the decision maker?*

What?
- *What do we already know about the problem?*
- *What would we like to know?*
- *What are assumptions that need to be questioned?*

When?
- *When did the problem start?*
- *When would you like to see results?*

Where?
- *What's the problem?*
- *Where has it been solved?*
- *Where were similar situations?*

How?
- *How could this problem be an opportunity?*
- *How could it be solved?*
- *How have attempts been made to solve this problem?*

Problem/Mission Definition

PROBLEM FRAMING CANVAS: Defining the Right Problem

MITRE | Innovation Toolkit

Look Inward

What is the problem?
Describe it

List some symptoms

Why haven't we solved it?
- ☐ It's new
- ☐ It's hard
- ☐ It's low priority
- ☐ Lack of resources
- ☐ Lack of authority
- ☐ A (situational) inequity
- ☐ Other: _____

Explain more…

How are we part of the problem?

What assumptions and biases surround this problem? *Individual, system, explicit, implicit…*

Which of these might be redesigned, reframed, or removed?

Who experiences the problem?

When and where do they experience it?

What consequences do they experience?

How do lived experiences of the problem vary?

Look Outward

Who else has it? *Colleagues, competitors, other domains, etc.*

*How do they **deal** with it?*

Who does not have it?
Colleagues, competitors, other domains, etc.

Why not?
- ☐ Avoided
- ☐ Mitigated
- ☐ Solved
- ☐ Transferred
- ☐ Other: _____

Who has been left out so far? *Let's broaden our perspective…*

Who benefits when…

…this problem exists?

…this problem does not exist?

Reframe

Stated another way, the problem is: _____.

Make it actionable: How might we _____ as we aim to _____?
(action that addresses the stakeholder/user problem) *(objective / desired condition to be achieved)*

itk.mitre.org | itk@mitre.org Problem Framing Canvas V3

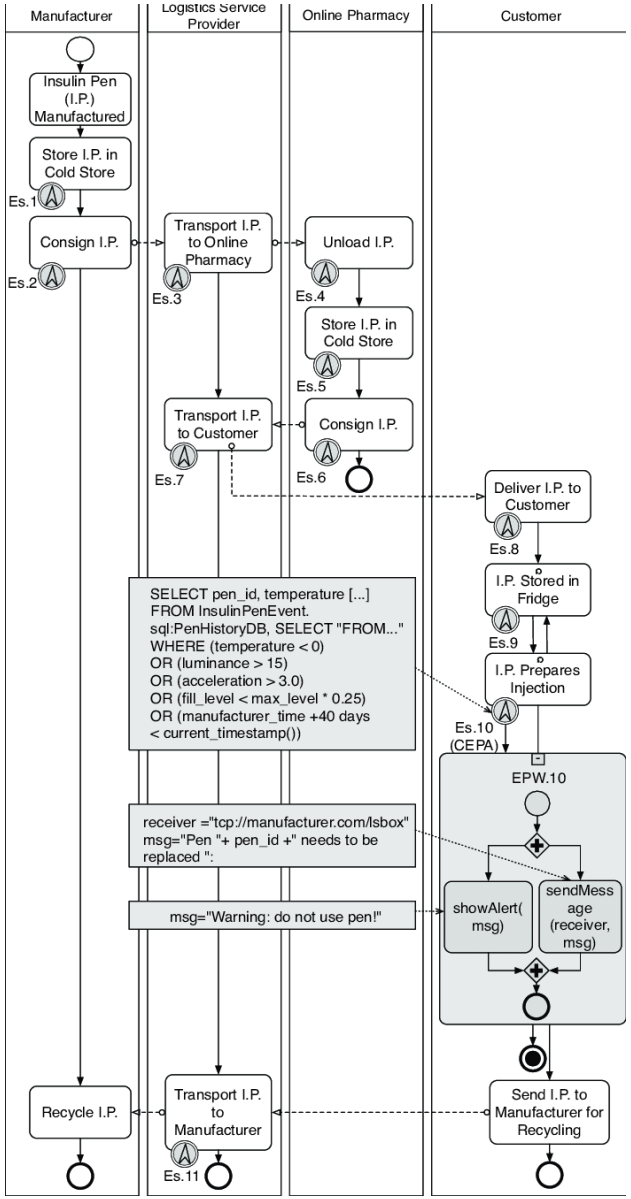
https://itk.mitre.org/toolkit-tools/problem-framing/

Problem/Mission Definition (e.g., OB-WAN)

The problem/mission statement is communicated in a single thought sentence that encapsulates the integrated set of needs, from which the elements of the set can be elaborated (decomposed and derived). Multiple sentences often indicate the organization is not able to agree on a single mission statement

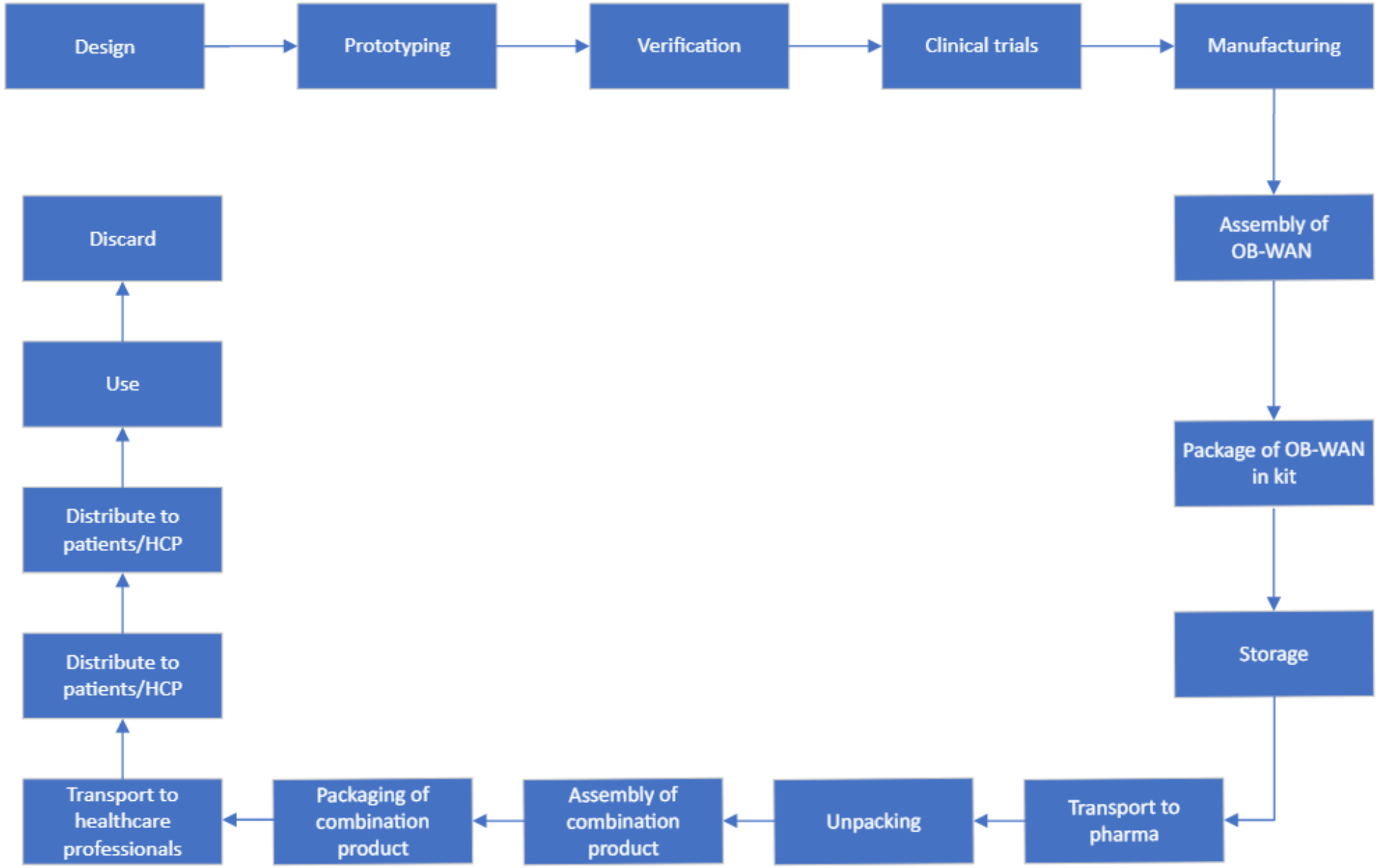
"The connected syringe is a manual single use device preventing accidental needle stick injury that is intended to be used in remote clinical trials ***(What)*** *where the participants (****Who****) will self-inject in their own homes (****Where****) to deliver a full dose, automatically document the correct completion of the clinical study trial protocol, that is, detect deviation from protocol, and minimize data collection errors while not modifying user injection experience (****Why****)."*

Lifecycle

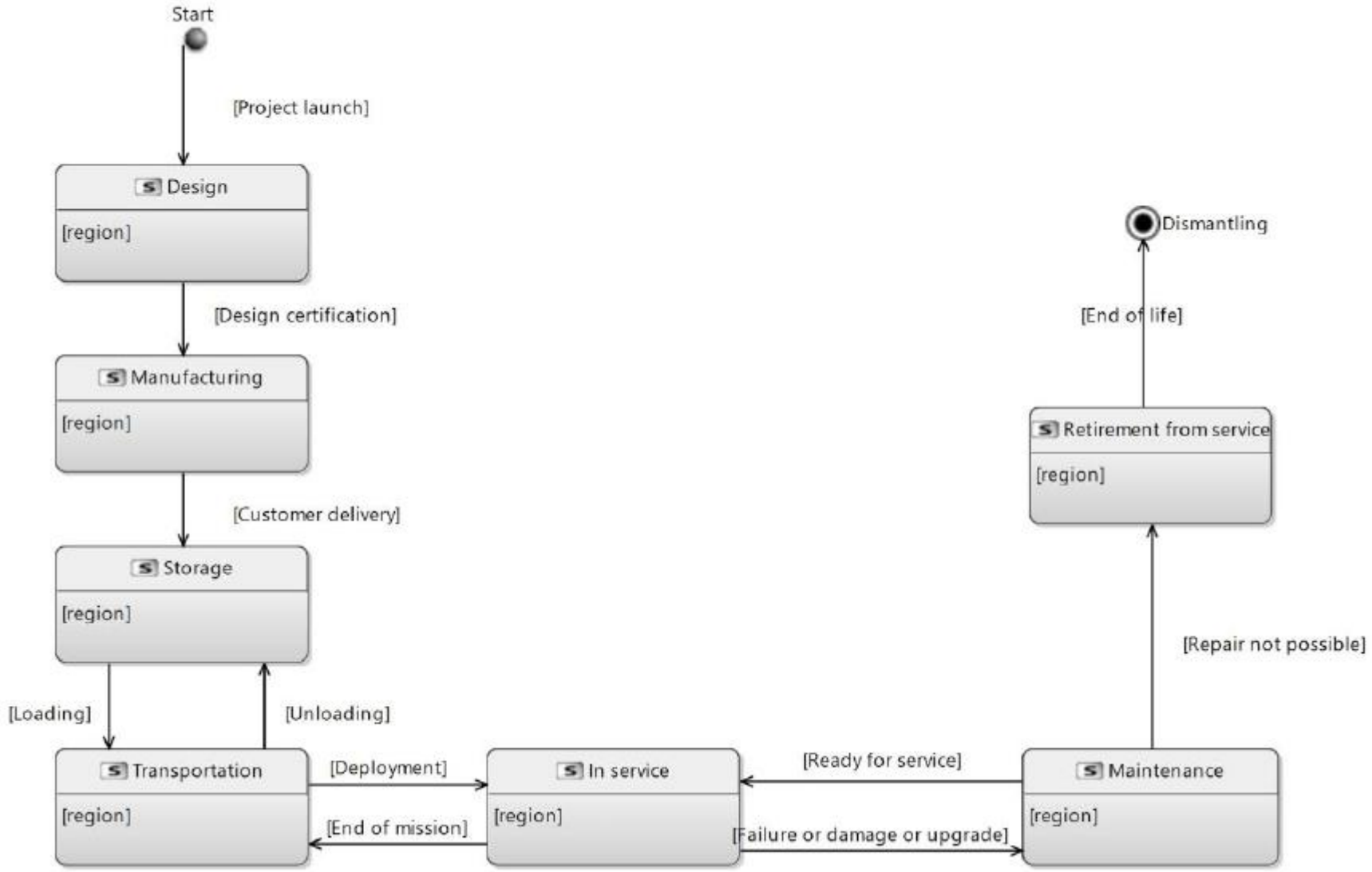


Identify the SOI lifecycle stages the stakeholder represents or is involved in. Lifecycle stages could be e.g. procurement, development, test, verification, validation, manufacturing, transportation, deployment, installation, transition, training, operations, logistics, maintenance, upgrades, or disposal. Often there is a distinct set of stakeholders and interfaces associated with each lifecycle stage. Each has unique needs and requirements. Not addressing a lifecycle stage could result in missing needs and requirements.

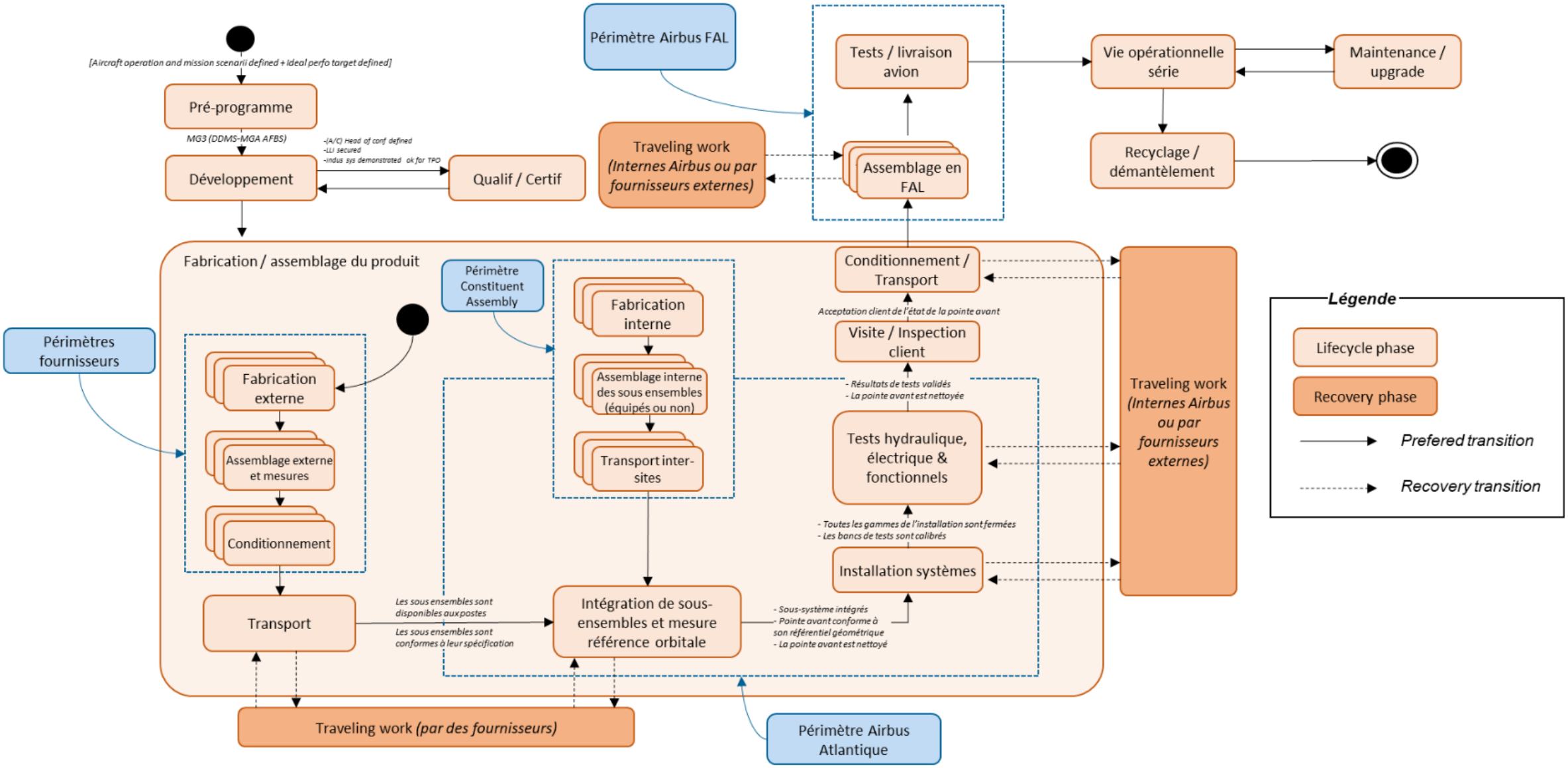
Lifecycle (e.g., Self-injection device)



Lifecycle (e.g., Drone for aircraft inspection)



Lifecycle (e.g., A320 Nose Fuselage)



Context

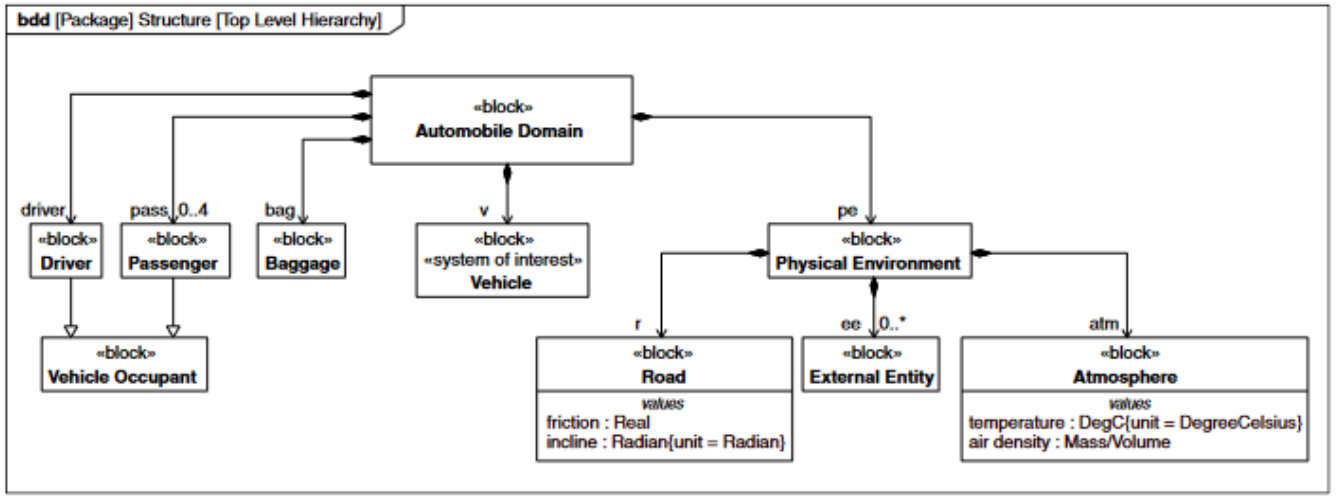


FIGURE 4.3

Block definition diagram of the *Automobile Domain* showing the *Vehicle* as the *system of interest*, along with the *Vehicle Occupants* and the Environment. Selected properties for the *Road* and *Atmosphere* are also shown.

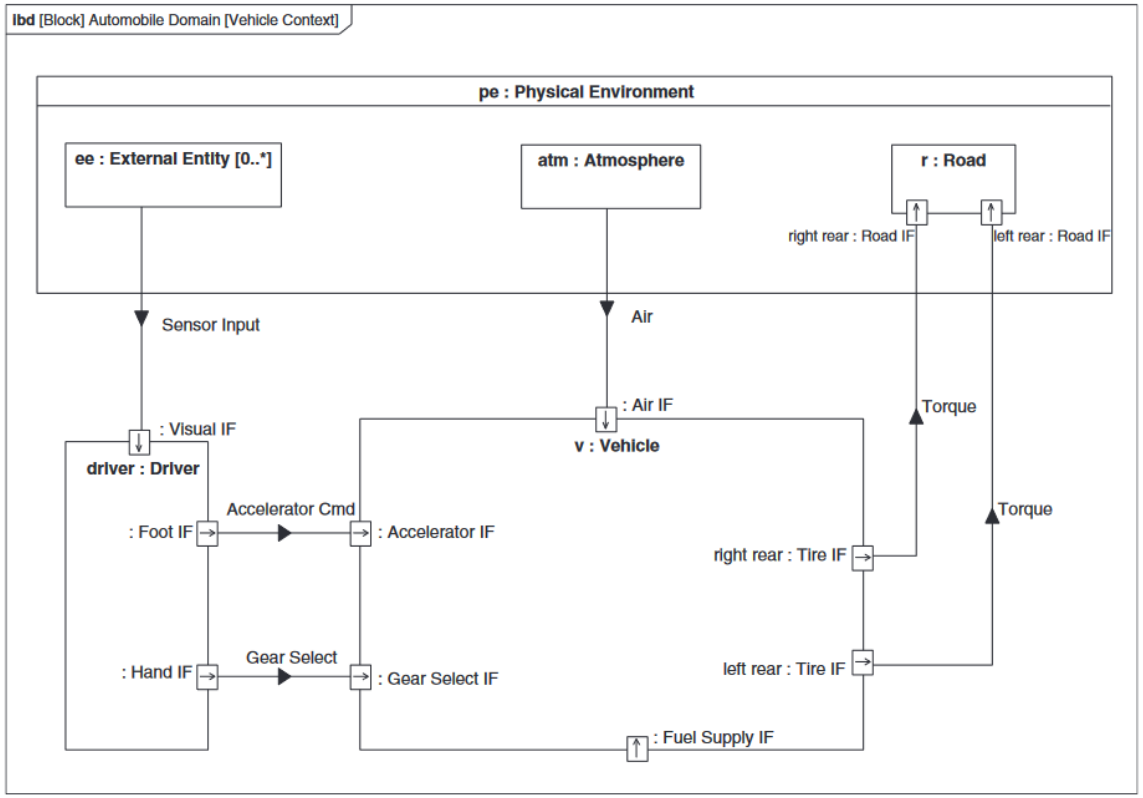


FIGURE 4.9

Internal block diagram for the *Automobile Domain* describes the *Vehicle Context*, which shows the *Vehicle* and its external interfaces with the *Driver* and the *Physical Environment* that were defined in Figure 4.3.

Context

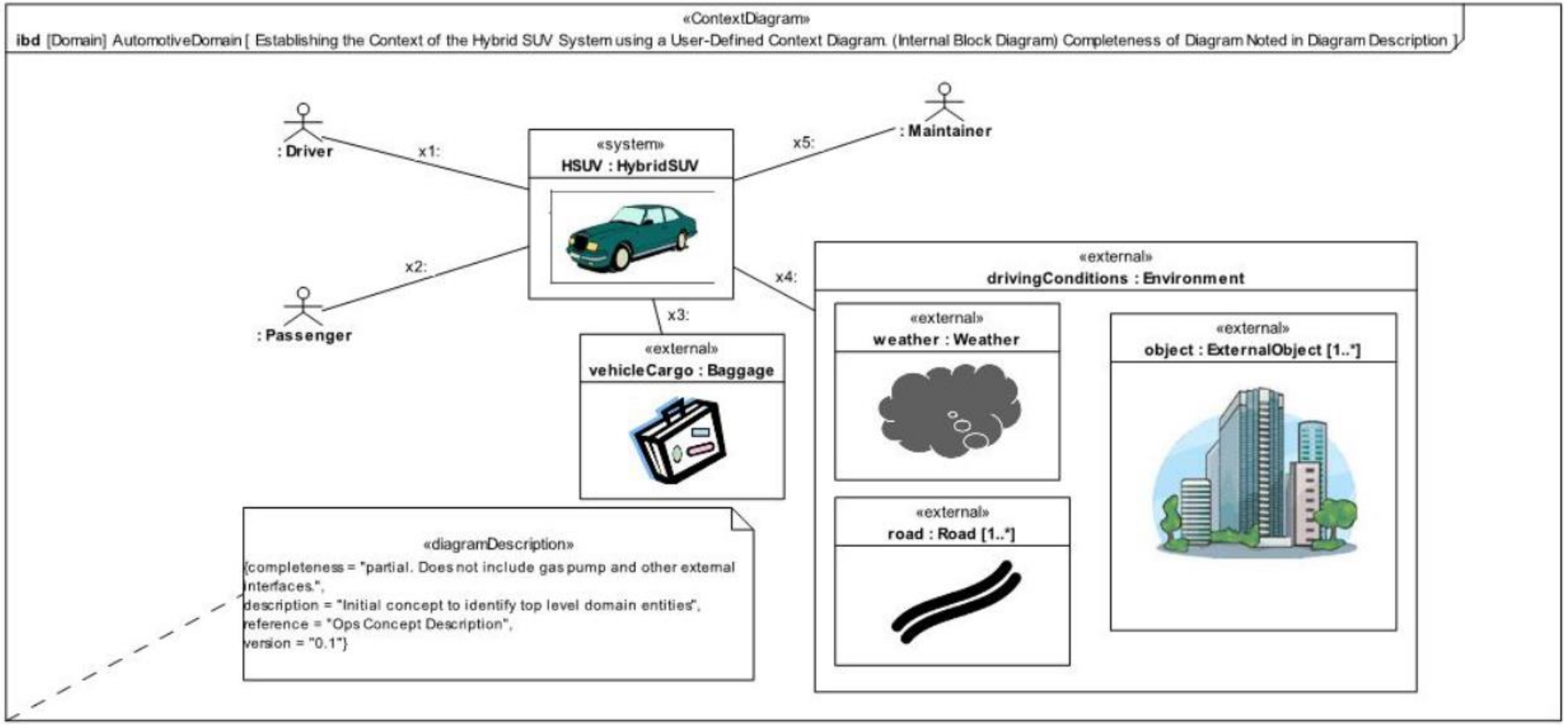
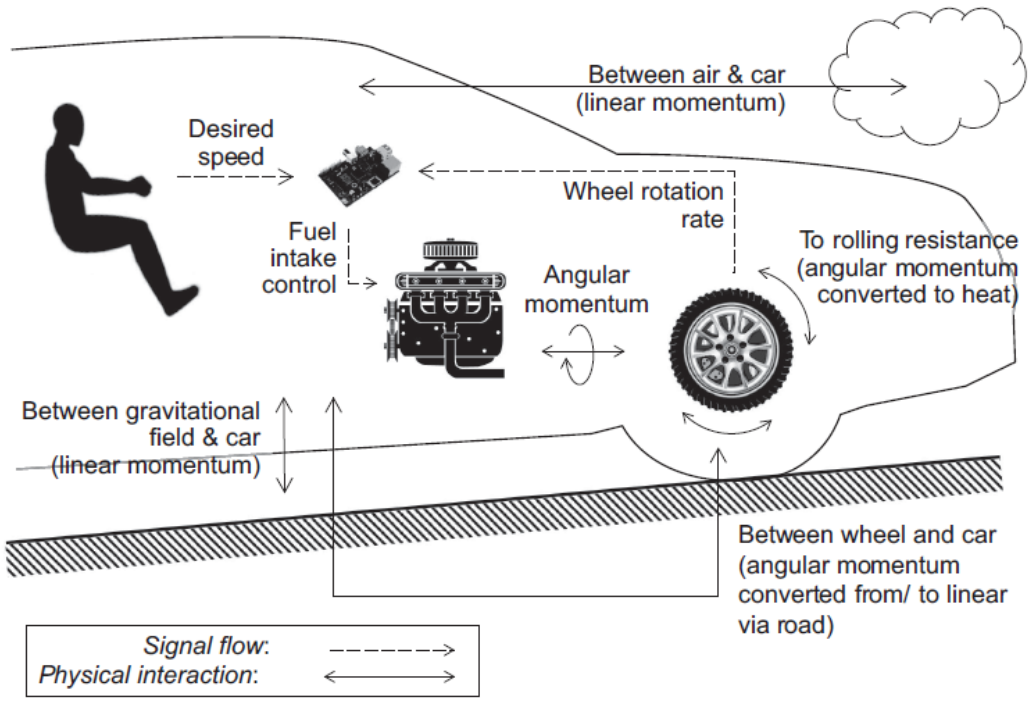
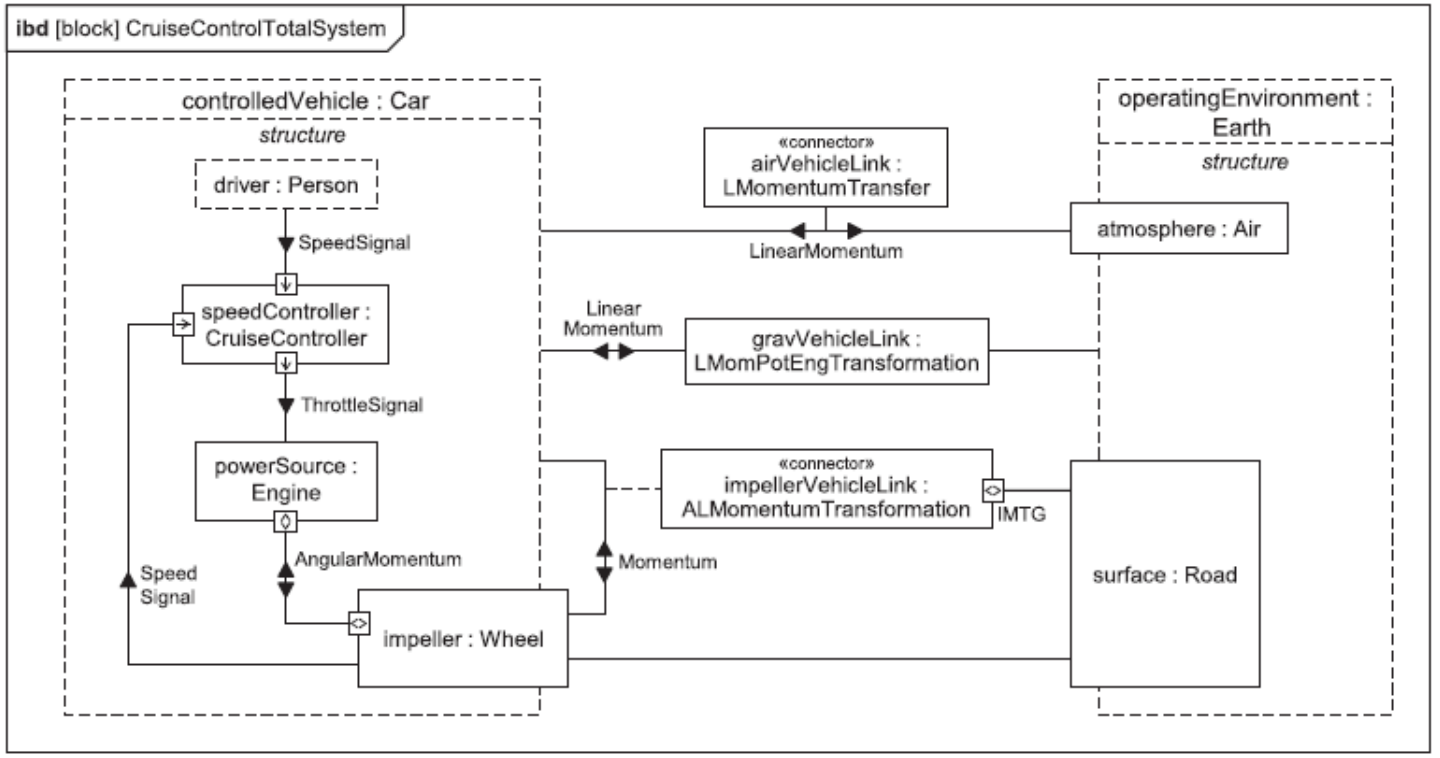


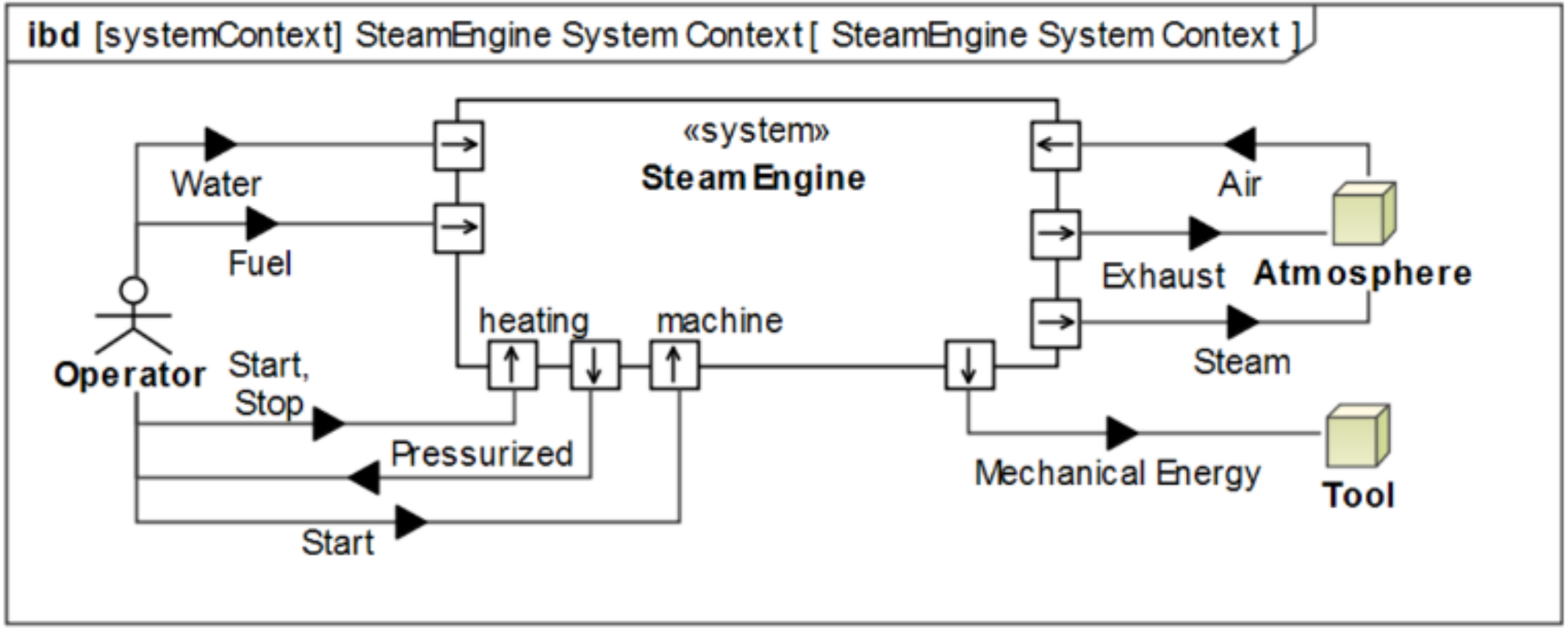
Figure D.4 Establishing the Context of the Hybrid SUV System using a User-Defined Context Diagram. (Internal Block Diagram) Completeness of Diagram Noted in Diagram Description

Context

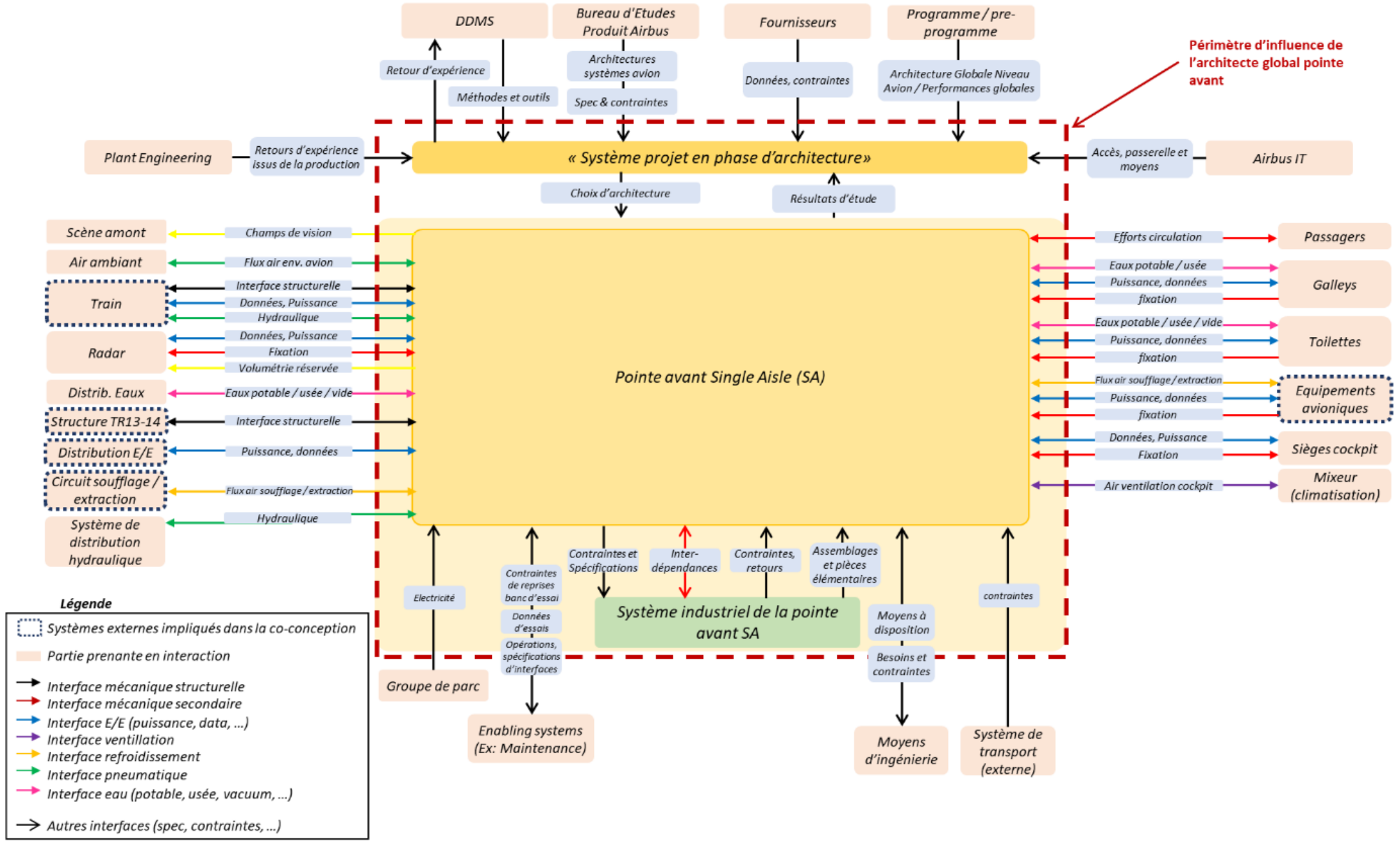

Between air & car
(linear momentum)
Desired
speed
Wheel rotation
rate
Fuel
intake
control
Angular
momentum
To rolling resistance
(angular momentum
converted to heat)
Between gravitational
field & car
(linear momentum)
Between wheel and car
(angular momentum
converted from/ to linear
via road)
Signal flow:
Physical interaction:


ibd [block] CruiseControlTotalSystem
controlledVehicle : Car
structure
driver : Person
SpeedSignal
speedController :
CruiseController
ThrottleSignal
powerSource :
Engine
AngularMomentum
Speed
Signal
impeller : Wheel
«connector»
airVehicleLink :
LMomentumTransfer
LinearMomentum
operatingEnvironment :
Earth
structure
atmosphere : Air
Linear
Momentum
gravVehicleLink :
LMomPotEngTransformation
«connector»
impellerVehicleLink :
ALMomentumTransformation
IMTG
Momentum
surface : Road

Context

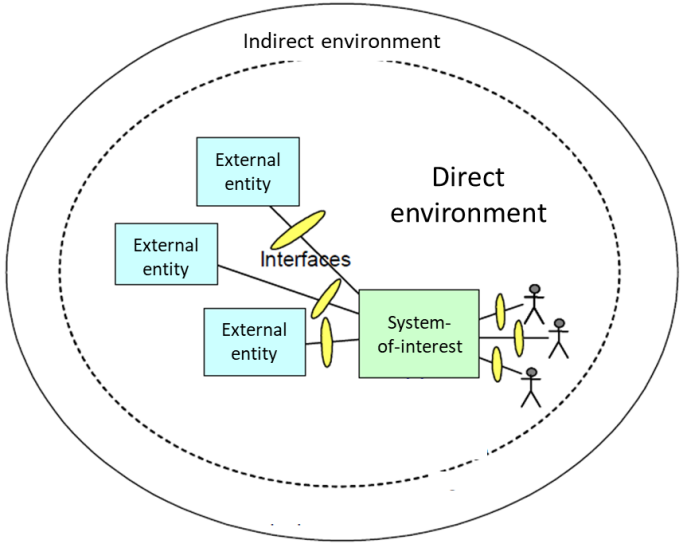

ibd [systemContext] SteamEngine System Context [SteamEngine System Context]
«system»
Steam Engine
Water
Fuel
Air
Exhaust
Atmosphere
heating
machine
Operator
Start,
Stop
Steam
Pressurized
Mechanical Energy
Tool
Start

Context


DDMS
Bureau d'Etudes Produit Airbus
Fournisseurs
Programme / pre-programme
Retour d'expérience
Méthodes et outils
Architectures systèmes avion
Spec & contraintes
Données, contraintes
Architecture Globale Niveau Avion / Performances globales
Périmètre d'influence de l'architecte global pointe avant
Plant Engineering
Retours d'expérience issus de la production
« Système projet en phase d'architecture»
Accès, passerelle et moyens
Airbus IT
Choix d'architecture
Résultats d'étude
Scène amont
Champs de vision
Air ambiant
Flux air env. avion
Train
Interface structurelle
Données, Puissance
Hydraulique
Radar
Données, Puissance
Fixation
Volumétrie réservée
Distrib. Eaux
Eaux potable / usée / vide
Structure TR13-14
Interface structurelle
Distribution E/E
Puissance, données
Circuit soufflage / extraction
Flux air soufflage / extraction
Système de distribution hydraulique
Hydraulique
Pointe avant Single Aisle (SA)
Efforts circulation
Passagers
Eaux potable / usée
Puissance, données
fixation
Galleys
Eaux potable / usée / vide
Puissance, données
fixation
Toilettes
Flux air soufflage / extraction
Puissance, données
fixation
Equipements avioniques
Données, Puissance
Fixation
Sièges cockpit
Air ventilation cockpit
Mixeur (climatisation)
Electricité
Contraintes de reprises banc d'essai
Données d'essais
Opérations, spécifications d'interfaces
Contraintes et Spécifications
Inter-dépendances
Contraintes, retours
Assemblages et pièces élémentaires
Système industriel de la pointe avant SA
Moyens à disposition
Besoins et contraintes
contraintes
Groupe de parc
Enabling systems (Ex: Maintenance)
Moyens d'ingénierie
Système de transport (externe)
Légende
Systèmes externes impliqués dans la co-conception
Partie prenante en interaction
Interface mécanique structurelle
Interface mécanique secondaire
Interface E/E (puissance, data, ...)
Interface ventillation
Interface refroidissement
Interface pneumatique
Interface eau (potable, usée, vacuum, ...)
Autres interfaces (spec, contraintes, ...)

External entities

The context of a system is the super-system (assumed with no external interface) that contains all external entities (i.e. belonging to the context) that have an influence or interaction on the system-of-interest.



An external entity…

- Can be a human, but also a software, hardware, environmental property, facility, standards, etc.
- Can directly interact with the SOI, but also indirectly influence it.
- Can receive a service (i.e., intended effect by its stakeholder) resulting from the interaction of the system with its environment under determined conditions of use or impose a constraint to the system.

External entities

External entities

https://www.youtube.com/watch?v=SAshKROIjtQ

External entities

Ravens Take Out Google Drone, Company Forced to Stop Home Delivery Service: VIDEO

written by Jonathan Howard | September 26, 2021 8:49 pm

External entities

- Weather properties (wind velocity, t°…)
- Regulatory (FAA standards,…)
- Other flying entities (small aircrafts, birds…)
- End-user (address, etc.)

Mapping lifecycle phases *VS.* External entities

Stakeholder (S)/ Lifecycle (L)	L1	L2	L3	L4	L5
S1	X		X		X
S2		X	X		
S3	X		X		X
S4		X		X	X
S5			X	X	X
Combined	XXX	XXX	XXX	XXX	XXX

Each column of the table represents an SOI lifecycle stage. Each row represents a stakeholder or an external system for the lifecycle stages in which the stakeholder or external system has a stake.

Stakeholders in a Value Map

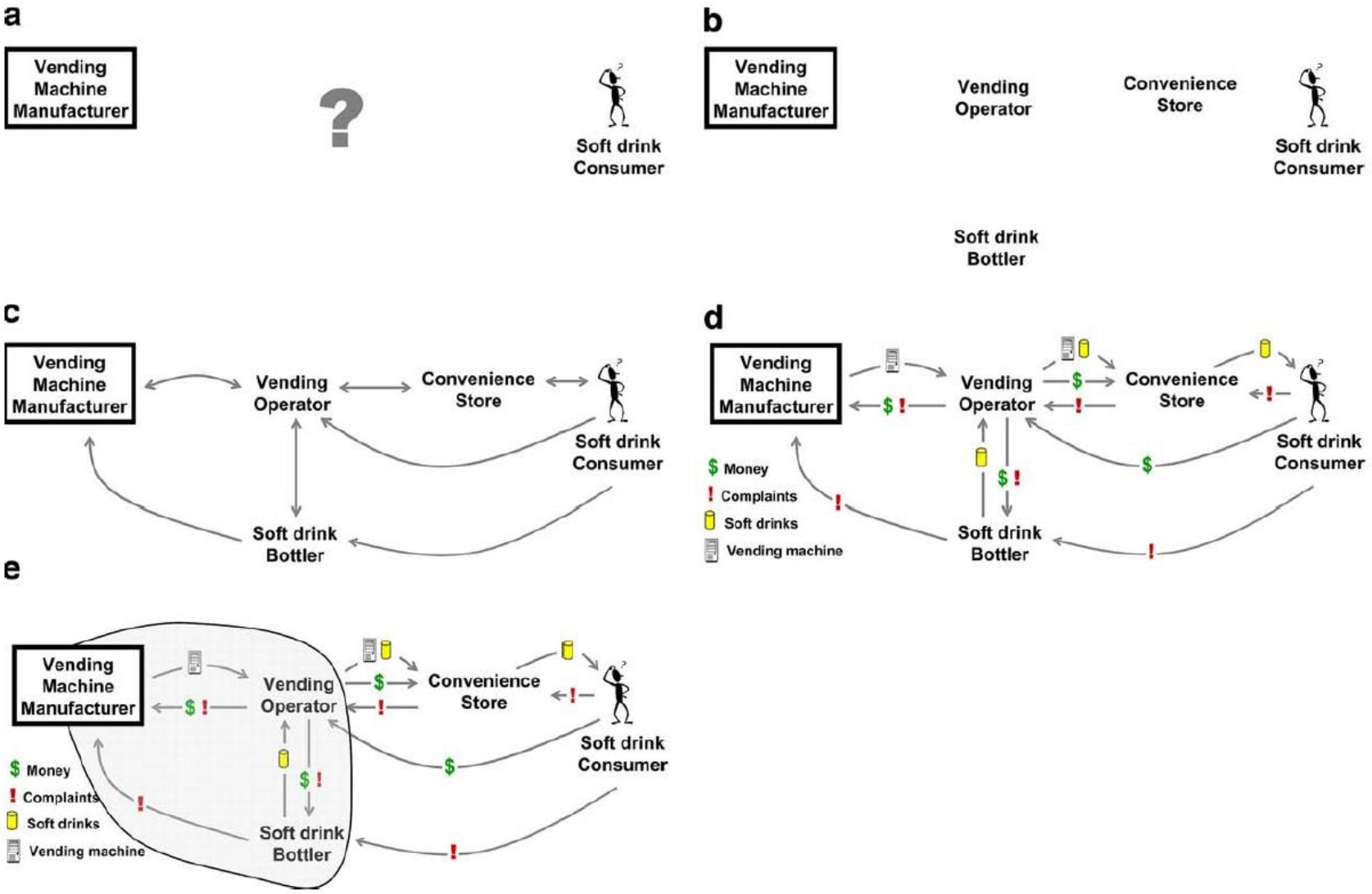


Fig. 2 **a** *CVCA Step 1*: Determine the business model for the vending machine. **b** *CVCA Step 2*: Delineate pertinent parties involved with the vending machine's life cycle. **c** *CVCA Step 3*: Determine how the vending machine's customers are related to each other. **d** *CVCA Step 4*: Identify the value propositions of the vending machine's customers and define the flows between them. **e** *CVCA Step 5*: Analyze the Customer Chain to determine the vending machine's critical customers and their value propositions. The vending operator and the soft drink bottler (*circled*) were determined to be the critical customers to the vending machine manufacturer

Rank Stakeholders

Not all stakeholders are equal. Based on their position and role, some stakeholders have more "power" and influence than others. For example, customers and the Approving Authorities. In this case, higher ranked stakeholder's needs and stakeholder-owned requirements will have more importance (higher priority) than lower ranked stakeholders.

The rank of stakeholders is used to resolve any needs or requirements that are conflicting or cannot be met by the proposed solution within the defined constraints. Higher ranking stakeholders are often paying customers, sponsoring agencies, acquirers, and the Approving Authorities who will have the authority to accept, qualify, certify, or approve for use the SOI.

Rank Stakeholders

Project:
Team:
Version & Date:

STAKEHOLDER MAP

Quick guide: The Stakeholder Map gives an overview of all stakeholders, i.e. organisations and people who have a claim or interest in the problem and a potential solution. In a first step, start by determining the use cases. This can be a product, a project or the collaboration of different departments. In a further step, list all stakeholders involved. Thanks to well thought-out questions, we can also sharpen our understanding of the various stakeholders. Followed by the creation of a stakeholder map, where the various stakeholders are placed on the map. Subsequently, enter the relationship between the stakeholders and formulate the findings. Often it makes sense to first create the stakeholder map in the project team and later in the process to question the most important actors and to question the assumptions.

1 Use case

Define the use case.

Are there different customers with different application scenarios/ use cases?
What happens before and after?
What are extreme use cases?

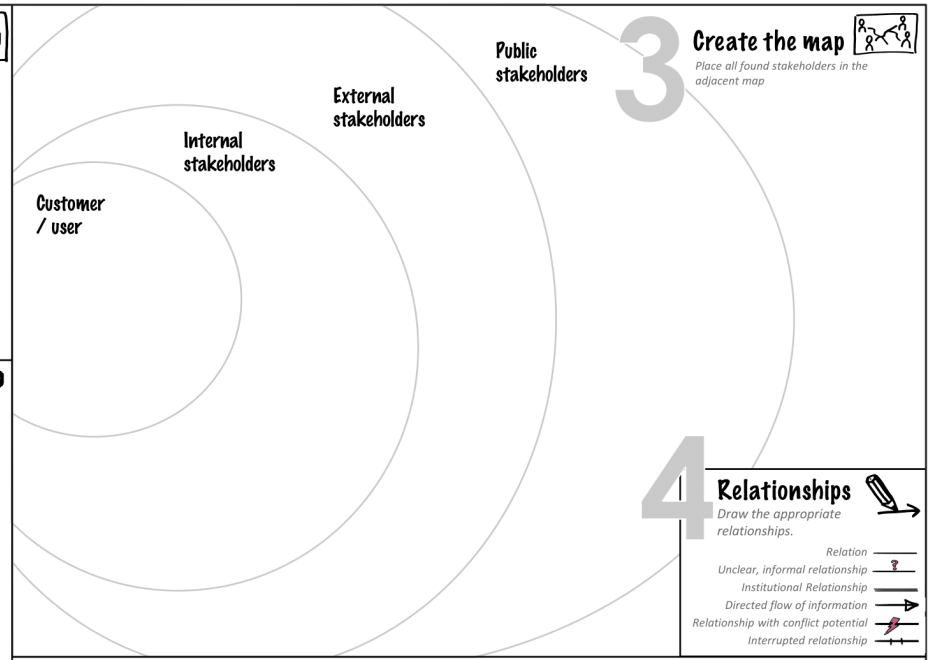
2 Stakeholders

Conduct brainstorming to identify all stakeholders

Who are we working with?
Who provides us with valuable ideas?
Who's blocking the idea?
Who benefits from a success/failure?

3 Create the map

Place all found stakeholders in the adjacent map



4 Relationships

Draw the appropriate relationships.

- *Relation*
- *Unclear, informal relationship*
- *Institutional Relationship*
- *Directed flow of information*
- *Relationship with conflict potential*
- *Interrupted relationship*

5 Findings

Describe your findings from the Stakeholder map.

THE DESIGN THINKING TOOLBOX PREMIUM TEMPLATE WWW.DT-TOOLBOOK.COM/ SHOP

Project:
Team:
Version & Date:

EXTREME USER/LEAD USER

Quick guide: With the Extreme User/Lead User concept, new, innovative ideas and user needs can be found that are not yet known to the average user. The first step is to identify such a potential Extreme User. This is based on attributes in which such a "user" could be interesting, e.g. age, experience etc... In the next step, enter the range and consider where and how best to learn more about the Extreme User. Then enter the user and determine the respective priority in the fourth step. On this basis, interviews can be conducted with the Extreme Users and the findings collected accordingly. When collaborating, questioning and observing extremes and lead users, pay special attention to workarounds or previously unknown solution alternatives. Document these findings to learn more about the problem or a broader audience. From this, ideas and trends can be derived that are relevant for the solution of a problem.

1 Characteristics

Define the values of the descriptive property

2 Range

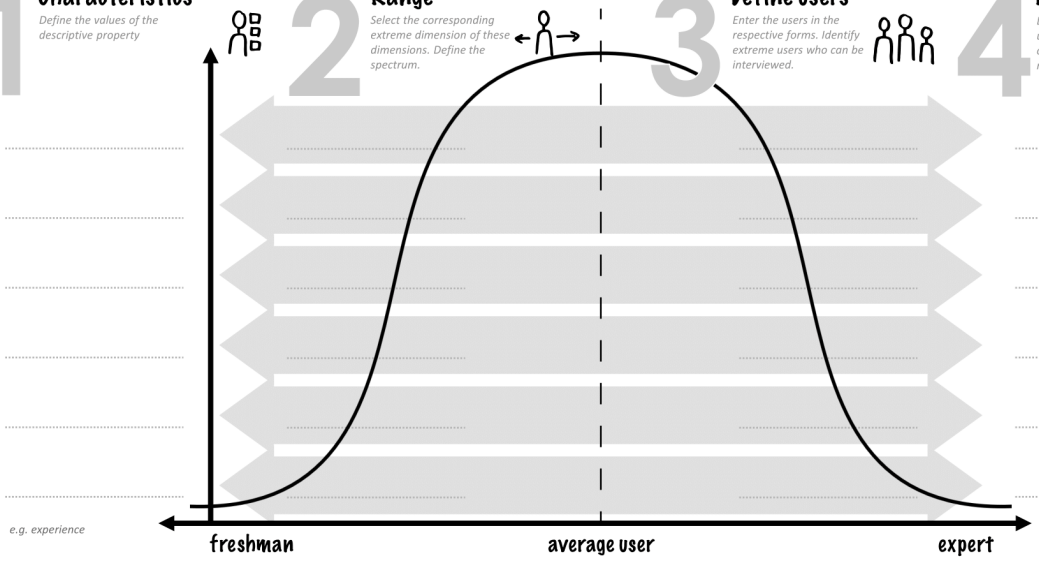
Select the corresponding extreme dimension of these dimensions. Define the spectrum.

3 Define users

Enter the users in the respective forms. Identify extreme users who can be interviewed.

4 Prioritize

Determine the priority; use a numerical scale or a division into low, medium and high.



5 Findings

Describe your findings from the observations / interviews.

6 Ideas

Derive ideas and trends from your insights.

THE DESIGN THINKING TOOLBOX PREMIUM TEMPLATE WWW.DT-TOOLBOOK.COM/ SHOP

Rank Stakeholders

MITRE | Innovation Toolkit

COMMUNITY MAP: Build a shared understanding of the environment

Identify all the potential allies, audiences, and influencers for the topic. *These may be individuals, organizations, or groups.*

https://itk.mitre.org/toolkit-tools/community-map/

Rank Stakeholders

MITRE | Innovation Toolkit

STAKEHOLDER MAP & MATRIX: Get to know the people with an interest in the project

Stakeholder Name	Contact Person	Impact	Influence	Importance	Contribution	Block	Engagement
	Phone, Email, Website, Address	How much does the project impact them? (Low, Medium, High)	How much influence do they have over the project? (Low, Medium, High)	What is important to the stakeholder?	How could the stakeholder contribute to the project?	How could the stakeholder block the project?	Strategy for engaging the stakeholder

https://itk.mitre.org/toolkit-tools/stakeholder-map-and-matrix/

Rank Stakeholders

MITRE | Innovation Toolkit

STAKEHOLDER POWER CATEGORIES

Assess	Notice and reflect
Stakeholder list	**What does status quo power look like in this effort?** How might it be changed or disrupted?
Q1 **Highly impacted but hold little power.** Prioritize Q1 so they can shape the outcomes that will directly affect them **Q2** **Highly impacted and hold lots of power.** Likely already at and accustomed to being the only ones at the table; they may need help sharing power with those in Q1	**How might we increase participation, ownership, and self-governance of those who are highly impacted (Q1 and Q2) by the effort?**
Q3 **Lightly impacted and hold little power.** Could be consulted for their experience **Q4** **Lightly impacted but hold lots of power.** Should be involved (might be gatekeepers, key allies, or advocates); they may need help sharing power	**How might we reduce barriers to participation?** • Alternatives for those without internet access • Changing meeting times & locations • Meals • Monetary compensation • On-site childcare • Transportation • Something else: ______________________
Impacted by the effort (LOW – HIGH) Power over the effort (LOW – HIGH)	**Is our team representative of those who are highly impacted (Q1 and Q2) by the effort?** If not, how might we improve?

Assess

What have we learned/discovered about which stakeholders are important to prioritize?	**Next Steps** *(These can be internal or external actions)* For ____________________, we need to ____________________________ *(stakeholder name/quadrant)* *(team action)*

itk.mitre.org I itk@mitre.org Stakeholder Power Categories V1

https://itk.mitre.org/toolkit-tools/stakeholder-power-categories/

Use of Checklists/Guiding Questions

- Who pays?
- Who profits?
- Who produces?
- Who tests (is involved in design and system verification and validation)?
- Who uses or operates?
- Who maintains?
- Who regulates?
- Who accepts, approves, certifies, or qualifies the SOI?
- Who owns or controls external systems that interfaces with the SOI?
- Who owns or controls enabling systems the SOI interacts with?
- Who is involved or who may be impacted by in the disposal of the SOI at end-of-life?
- Who else cares?

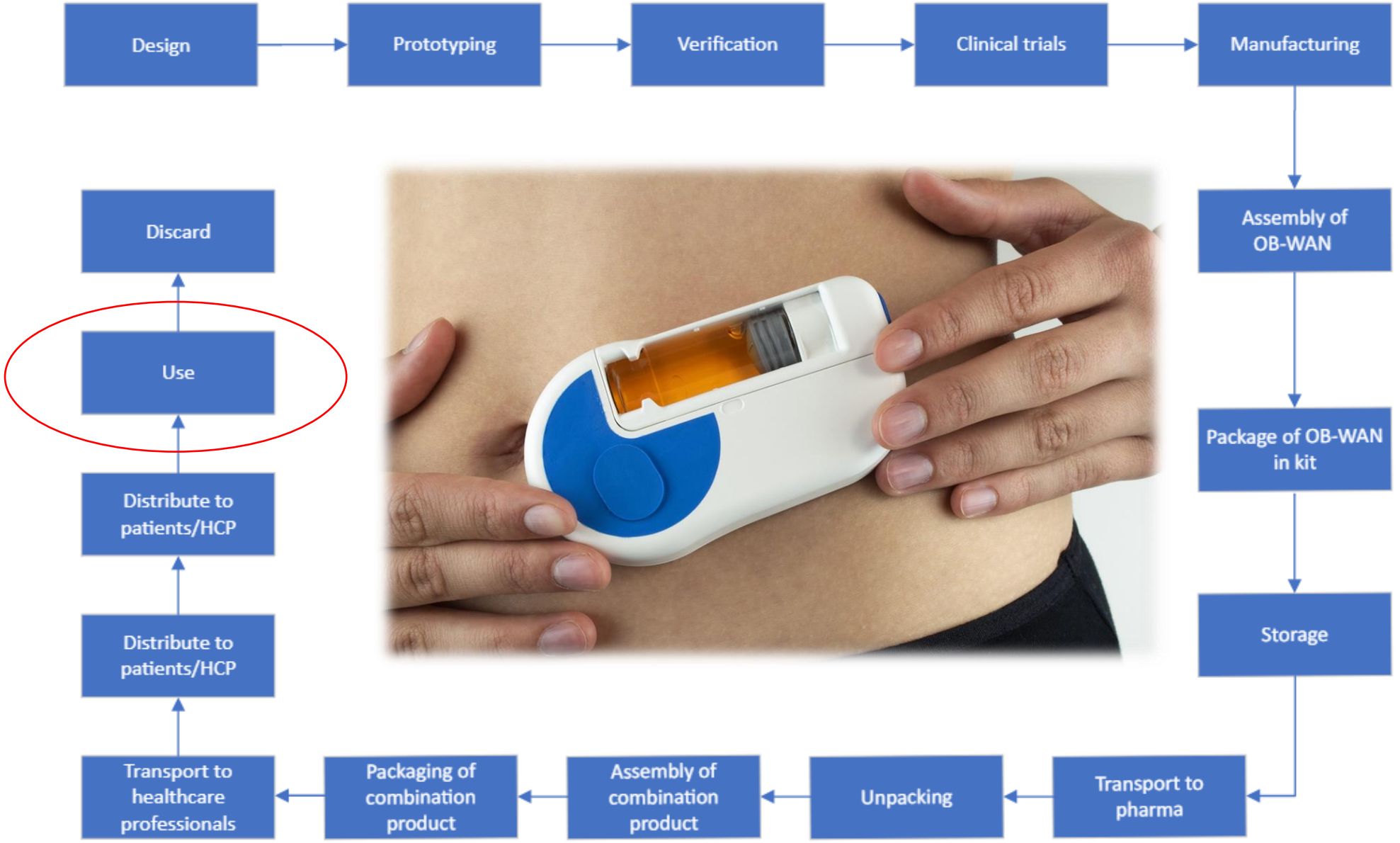
Use of Checklists/Guiding Questions

- What are the relevant standards and regulations?
- What are the production processes/workmanship/facility limitations?
- Are there required design approaches (industry, mechanical, electrical, software, business management, etc.)?
- How will the SOI be verified and validated (labs, facilities, etc.)?
- What are the Human Factor considerations for the SOI?
- What are the critical technologies and what is their maturity?
- What are the existing systems that the SOI must interact with? Have those stakeholders been involved in elicitation?
- What are the higher-level requirements allocated to the SOI?
- What are the budget and schedule constraints?
- What is the operating environment of the SOI?

Use of Checklists/Guiding Questions

Lifecycle Stage	Potential Stakeholders
Define	Paying customer, sponsor, project team, project manager, procurement, research and development, suppliers, regulating authorities, public, marketing, end users, operators, compliance office, regulators, owners of enabling systems, owners of external systems, Approving Authorities
Develop	Project team, subject matter experts (SMEs), system architects, design engineers, suppliers, procurement, etc.
Produce	Production organization, process engineers, quality control, production verification, product acceptance, supply chain
Integrate, Verify, and Validate	Test engineers, system integration engineers, system verification engineers, system validation engineers, operators/users, owners of enabling systems, facility personnel, contracting, Approving Authorities, regulators, safety personnel, security personnel
Operate	Transporters, installers, users, operators, safety engineers, security engineers, owners of external systems, IT, regulators, quality, mission assurance
Sustain/Maintain	Customer/technical support, replacement part providers, service technicians, trainers, IT, quality engineer, inspectors, CM, those conducting post development system verification and system validation activities.
Dismantle/Dispose	Operators, waste management, regulators, public

Stakeholders

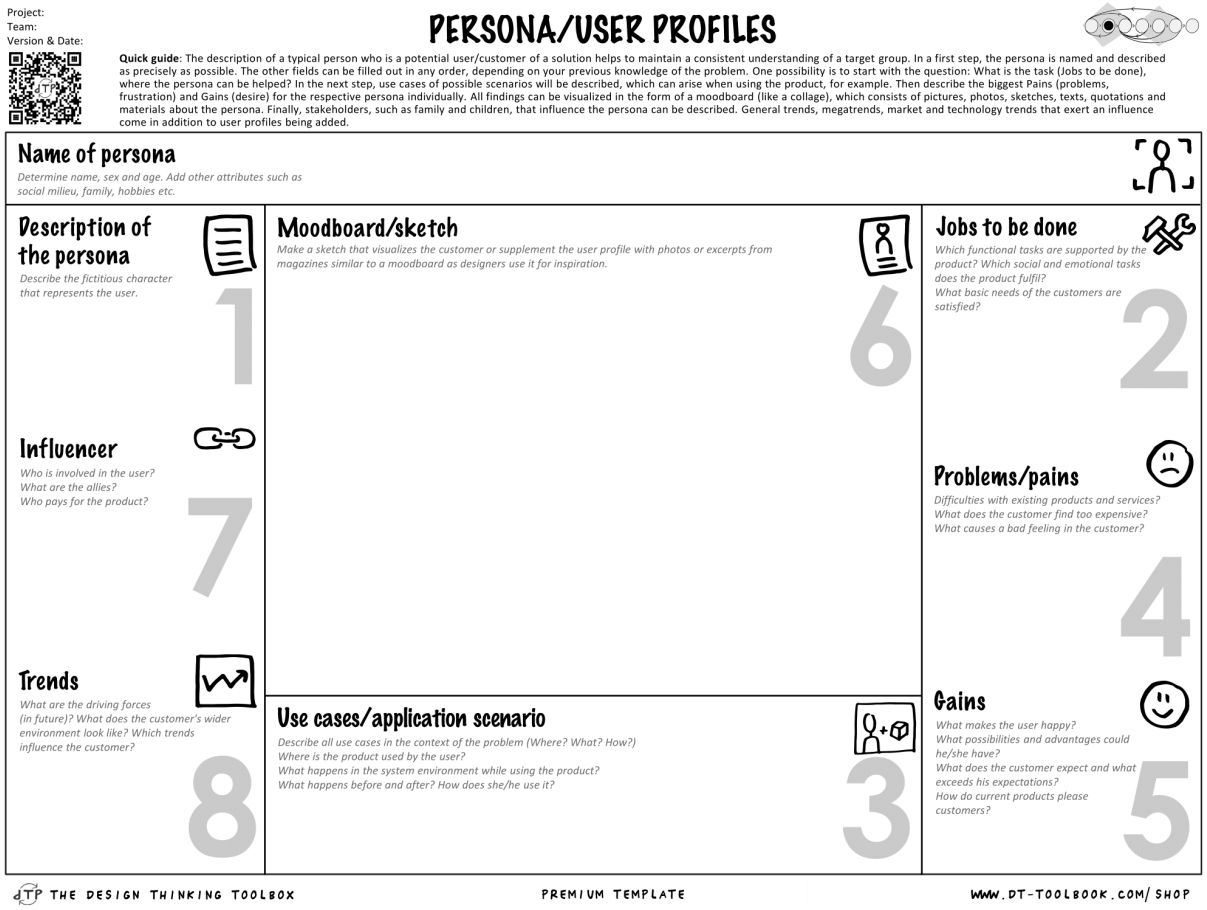


Brainstorming of external entities

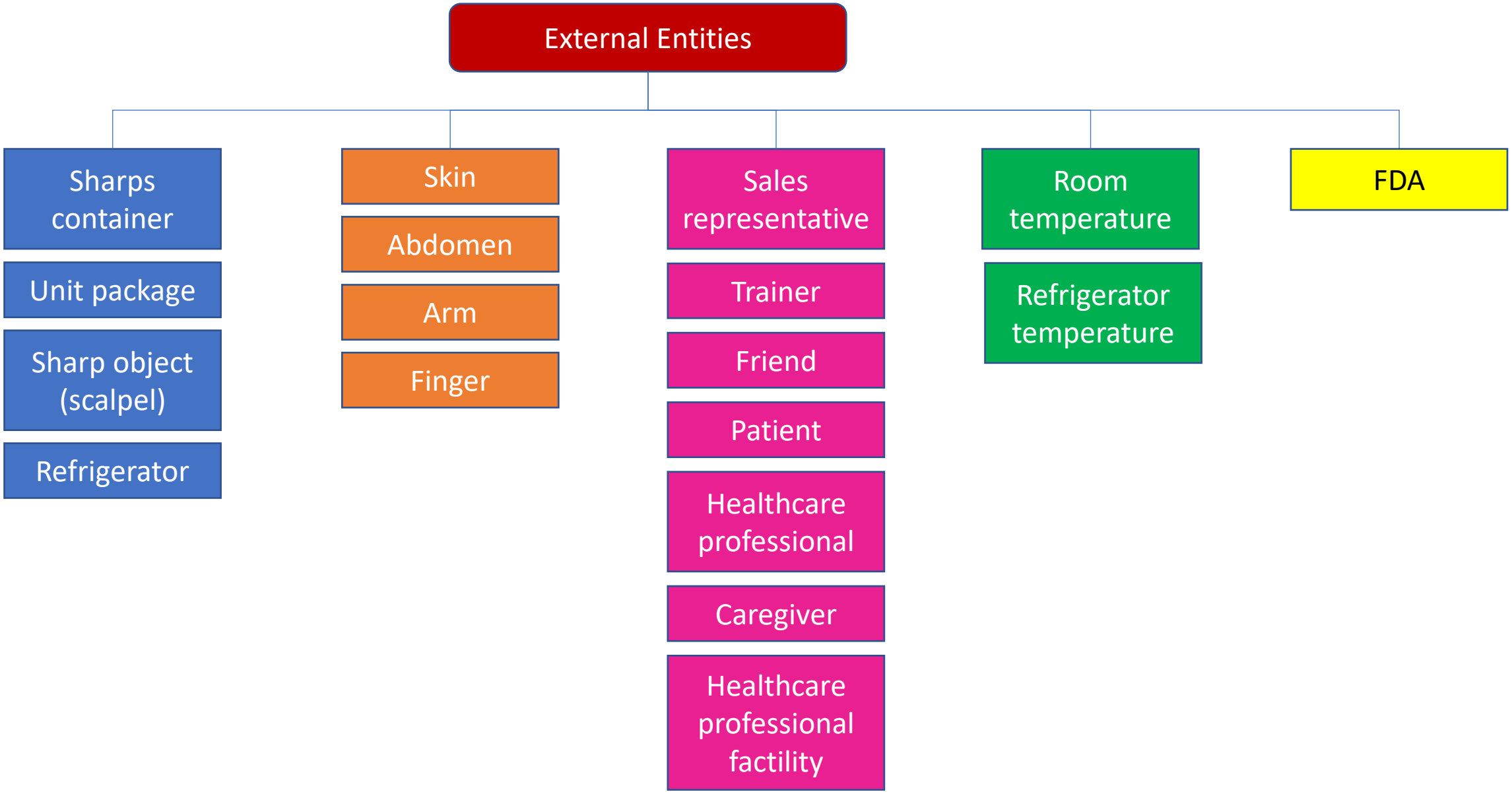
Clustering of external entities

Groups of external entities

Often there will be multiple members of a stakeholder group, e.g., users, operators, marketing, sales, safety, regulators, customers, the “public” who will be buying, using, operating, or maintaining a product or may be affected by the product in some way. It may not be practical to collaborate with every member of the group to elicit their needs and requirements. In this case a means must be implemented to name a representative of the group concerning their needs and requirements.



Classes of external entities



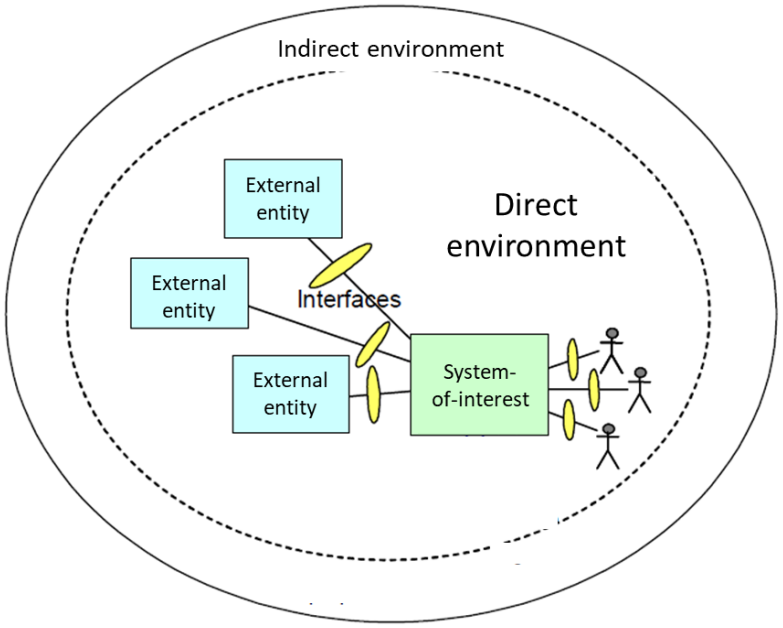
Stakeholders register

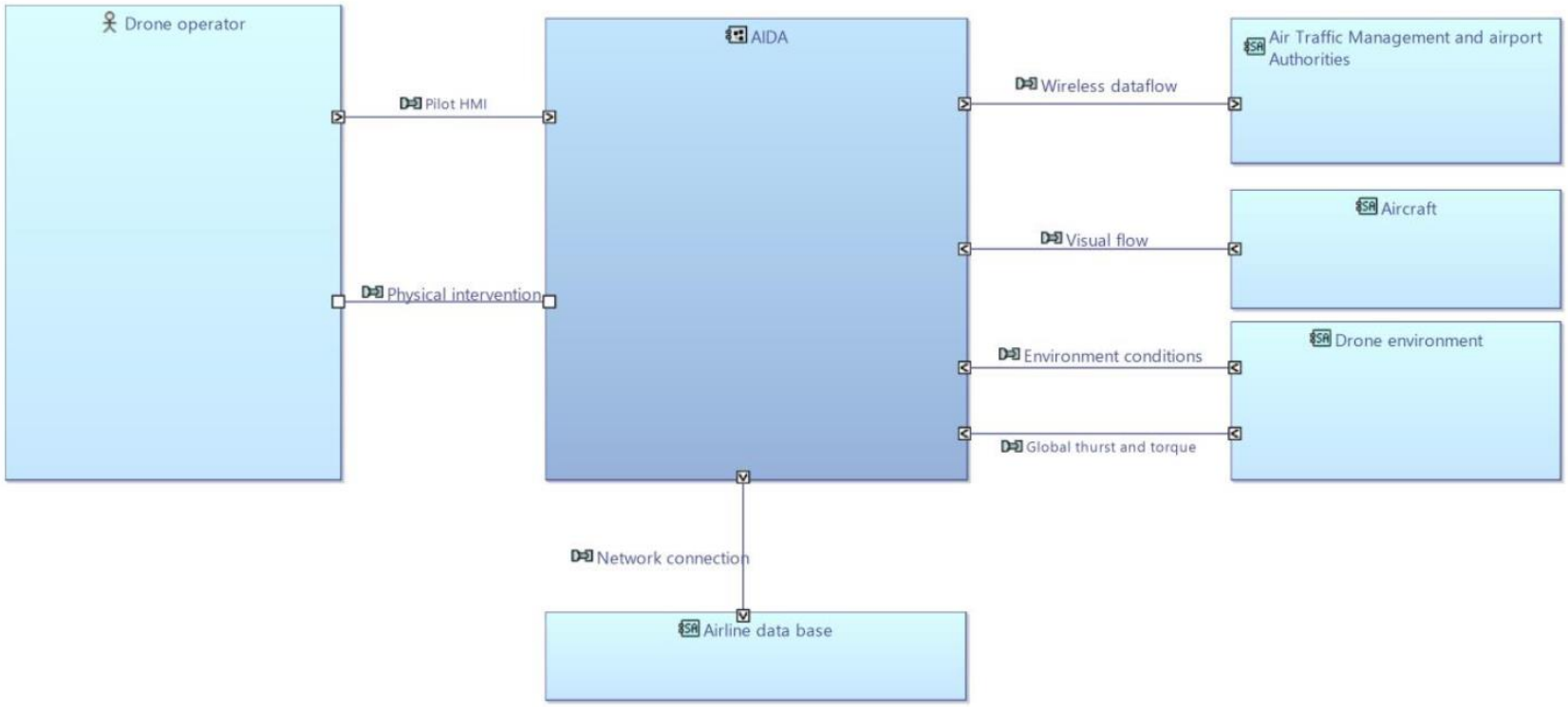
The project must identify and manage the stakeholders or classes of stakeholders who will participate with the project team to develop the system-of-interest. One approach that can be used to record the list of external entities is to develop a stakeholder register that includes key information for each stakeholder involved in some way with the SOI. Key information for each stakeholder includes:

- Stakeholder's name, location, mailing address, email, phone, fax, etc.
- Stakeholder's organization and job title.
- Whether or not the stakeholder is internal or external to the organization.
- How are they involved? What is their "stake"? Are they an Approving Authority? Are they decision makers, end users, controller of assets or resources, influencer, interested party, procurement, legal, compliance?
- What lifecycle(s) are they primarily concerned with or involved in? In what way?
- What information the project needs from the stakeholder.
- What information the stakeholder needs from the project.

External interfaces

During the identification of external entities for each lifecycle stage, you must pay particular attention to any interactions of the SOI with external entities. These interactions could represent interfaces.





External interfaces

During the identification of external entities for each lifecycle stage, you must pay particular attention to any interactions of the SOI with external entities. These interactions could represent interfaces.

- Which external systems are existing versus which are being developed concurrently with the SOI?
- Who are the stakeholders for the external systems?
- Have they been involved in the elicitation activities?
- Have all the interactions (inputs/outputs) between the SOI and external systems been defined?
- Is an existing external system likely to change how it interacts with the SOI across the interface boundary during the development or after the SOI is in use? How will the project team know if it does change? How will the proposed changes impact the SOI?
- For new systems being developed concurrently, what is the process to be followed to document and agree on the specific interactions. Who is responsible for recording the interactions and getting approval? Who will have configuration control of those definitions? What is the schedule for doing so?
- For software systems, what standard, application programmer's interface (API), etc. apply to the interactions?

Services / System Functions / Effect-Functions

Observe usage of the term *capability*. Traditionally, the term *function*—as in *form, fit, and function*—has been used by Engineers to characterize *what* a system is expected to accomplish. However, there is a gross disparity between the true definition of a *function* and what the User expects the system to *accomplish*. Here's the difference.

A Word of Caution 1.1

Form, Fit, and Function: An Implied Catch Phrase for Failure!

The phrase *form, fit, and function*, which is deeply ingrained as a paradigm in everyday Engineering, is a well-intended concept that is subject to misinterpretation. By virtue of the sequence of terms, people sometimes interpret the phrase as the sequence of steps required to perform Engineering:

- Step 1—Design the physical system—*form*.
- Step 2—Figure out how to get the pieces to *fit* together.
- Step 3—Decide what the system must do—*function*.

Evidence of this paradigm is illustrated in Figure 2.3. PURGE the *form, fit, and function* paradigm from your mind-set! The phrase simply identifies three key attributes of a system, product, or service that must be considered, nothing more!

Simply stated, a *function* represents an *action* to be performed such as Perform Navigation. A function is a *unitless* term that does not express a level of performance to be achieved. In general, it is easy to "identify functions" via *functional analysis*—sounds impressive to uninformed customers. The challenge is specifying and bounding the level of performance a function must achieve. Although *functions* and *functional analysis* are certainly valid within their own context, from a current SE perspective, the concept of functional analysis as a primary driving SE activity is outdated. The reality is functional analysis is still valid but only as a supporting SE activity. So, *how do we solve this dilemma*?

The solution resides in the term *capability*. A capability is defined as follows:

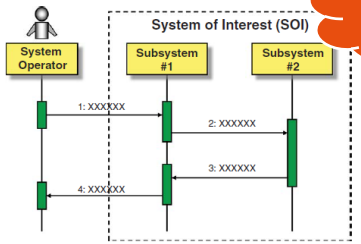
- **Capability**—An explicit, inherent feature *activated* by an external stimulus, cue, or excitation to perform an action (function) at a specified level of performance until terminated by external commands, timed completion, or resource depletion.

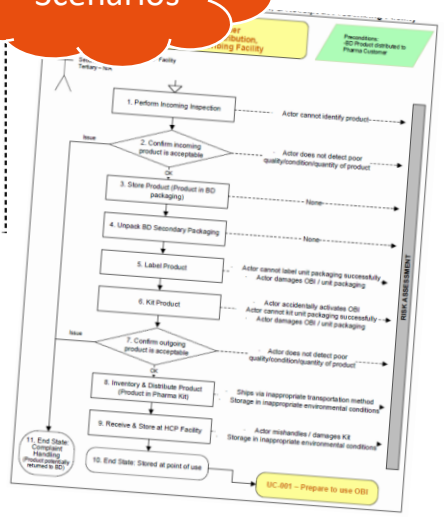
The definition of services consists in adopting an external "Black-box" view on the system of interest (SoI) and to specify the effects – intended by its stakeholders – of the interaction of the SoI with its operating environment.

MRD.200	Internal	As a HCP, I want to prepare the OBI setup at the following conditions: Temp Range: 5-40°C RH: < 90% Duration: < 3 hours	Normal Use
MRD.299	VOC	As a HCP, I want the drug to be delivered subcutaneously.	Customer Need
MRD.69	VOC	As a HCP or Patient, I want to have the drug delivered automatically at least 24 hours after OBI activation.	Competitive Benchmark
MRD.37	VOC	As a Patient, I want the device to be inconspicuous so that I do not feel embarrassed when wearing it.	Marketing
MRD.50	VOC	As a Patient, I want all OBI feedback to be discreet to avoid patient stigmatization (e.g. no large buzzer sound in a public setting).	Compliance per ISO 11608-1 Compliance per ISO 11608-5
MRD.53	Regulatory	As a HCP, I want to know if the device is working properly during setup (i.e. any malfunction preventing complete drug delivery) prior to sending the Patient home.	Safety Compliance

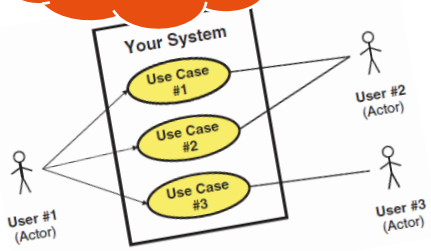
Services / System Functions / Effect-Functions

Scenarios

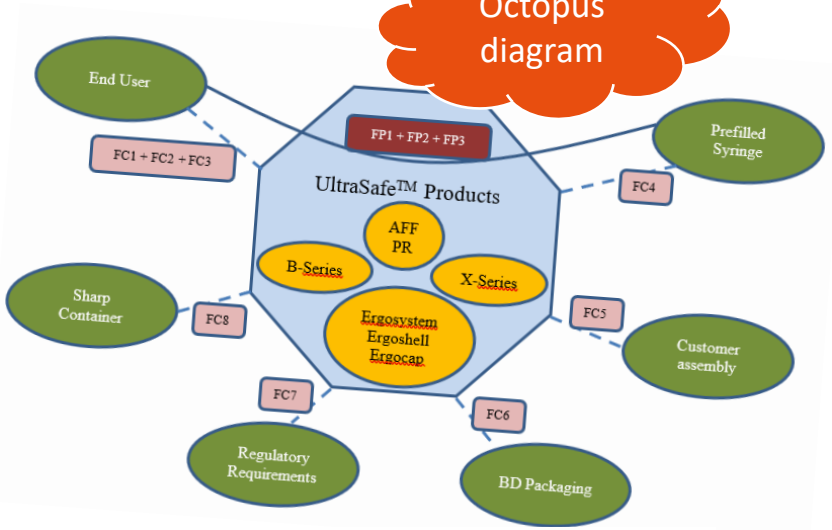




Use cases

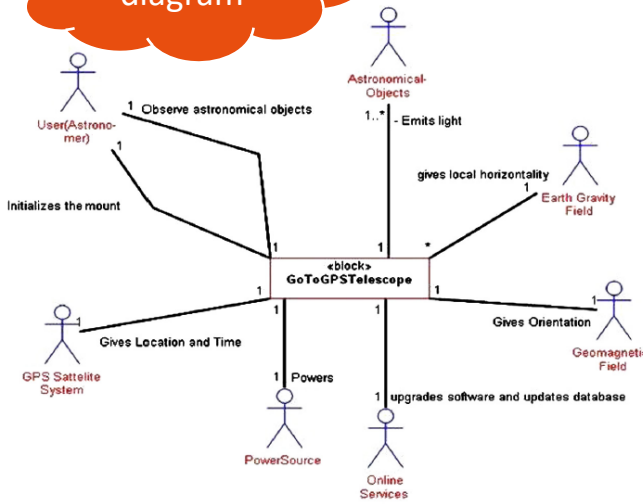


Octopus diagram

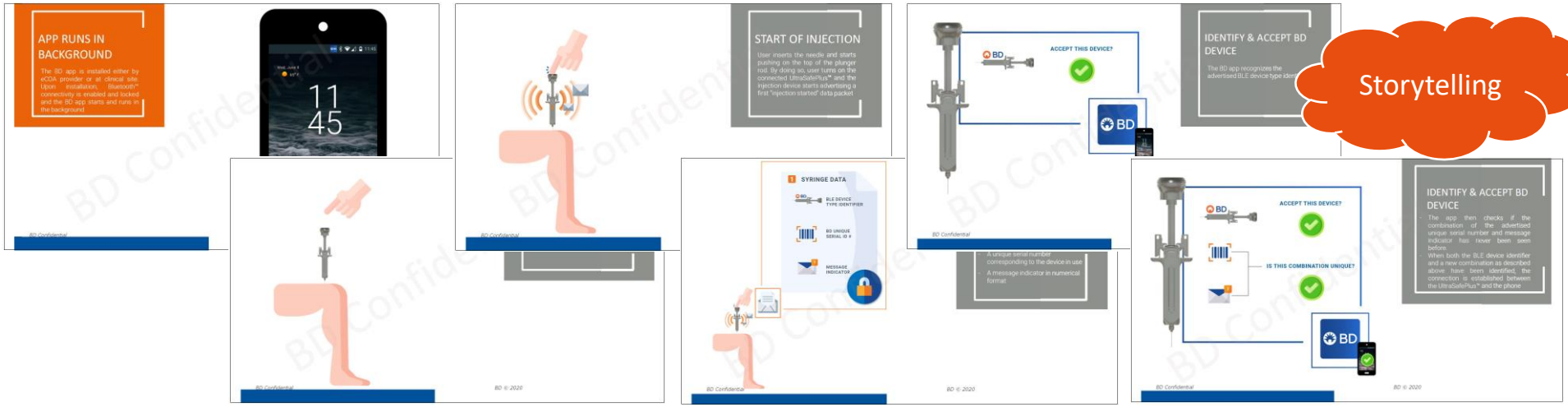


Principal functions	
FP1	Protect user from accidental needle stick injury
FP2	Complete activation of safety feature
FP3	Allow injection at the right injection depth

Context diagram



Storytelling



Focus on Stakeholders

For each lifecycle stage, ask the stakeholders to describe a "day-in-the life" of the SOI. This could include multiple use cases or scenarios. Address both nominal and alternate nominal cases. For use cases, capture the initial conditions and state of the SOI at the end of the use case.

Use Case Name: Manual filling of the LVDS for Oncology Drug

Summary: **(Brief overall summary of the intention of this Use Case)**

This use case describes the transfer of the oncology drug from the Primary Container as received from the Pharmacy into the Flexible Bag in the Falcon LVDS. This is a precondition to performing the Inject Oncology Drug use case.

Actors: **(List the primary actors in the use case)**

Health Care Provider (HCP)

Preconditions: **(State what conditions must be true for the Use Case to begin execution)**

The HCP has received the oncology drug and the Disposable Module from the Pharmacy.

Postconditions: **(State what conditions must be true when the Use Case ends under normal conditions)**

The oncology drug has been successfully transferred from the Primary Container to the Flexible Bag in the Disposable Module.

Assumptions: **(State any assumptions that need to be made for the Use Case to execute either Normal or Alternate Courses)**

The Pharmacist has been trained in and follows aseptic techniques required for transferring the drug.

The connection from the drug syringe to the Disposable Module can be a septum/needle, or a luer lock with check valve, as examples.

Normal Use Case Course: **(List the time-ordered steps that the Actors take to execute the Use Case, considering only the main normal course. Do not consider exceptions, these are handled in the Exceptions section. Avoid IF-THEN-ELSE or other programmatic constructs when possible, these may be handled as Alternate courses).**

1. The Pharmacist removes the Disposable Module from its packaging.
2. The Pharmacist removes the oncology drug and the supplied syringe from packaging
3. The Pharmacist fills the syringe with the desired and appropriate volume of the oncology drug for the patient
4. The Pharmacist inserts the syringe needle in the Disposable Module connector
5. The Pharmacist presses the syringe plunger to deliver the oncology drug into the LVDS Flexible Bag
6. The Pharmacist removes the syringe and disposes of the syringe in a suitable biohazard container
7. The Pharmacist discards the primary container following the IFU from the drug manufacturer

Alternate Courses: **(List any flows or logic alternative to the Normal. When possible, note the Normal Use Case step where the course modification applies).**

N/A

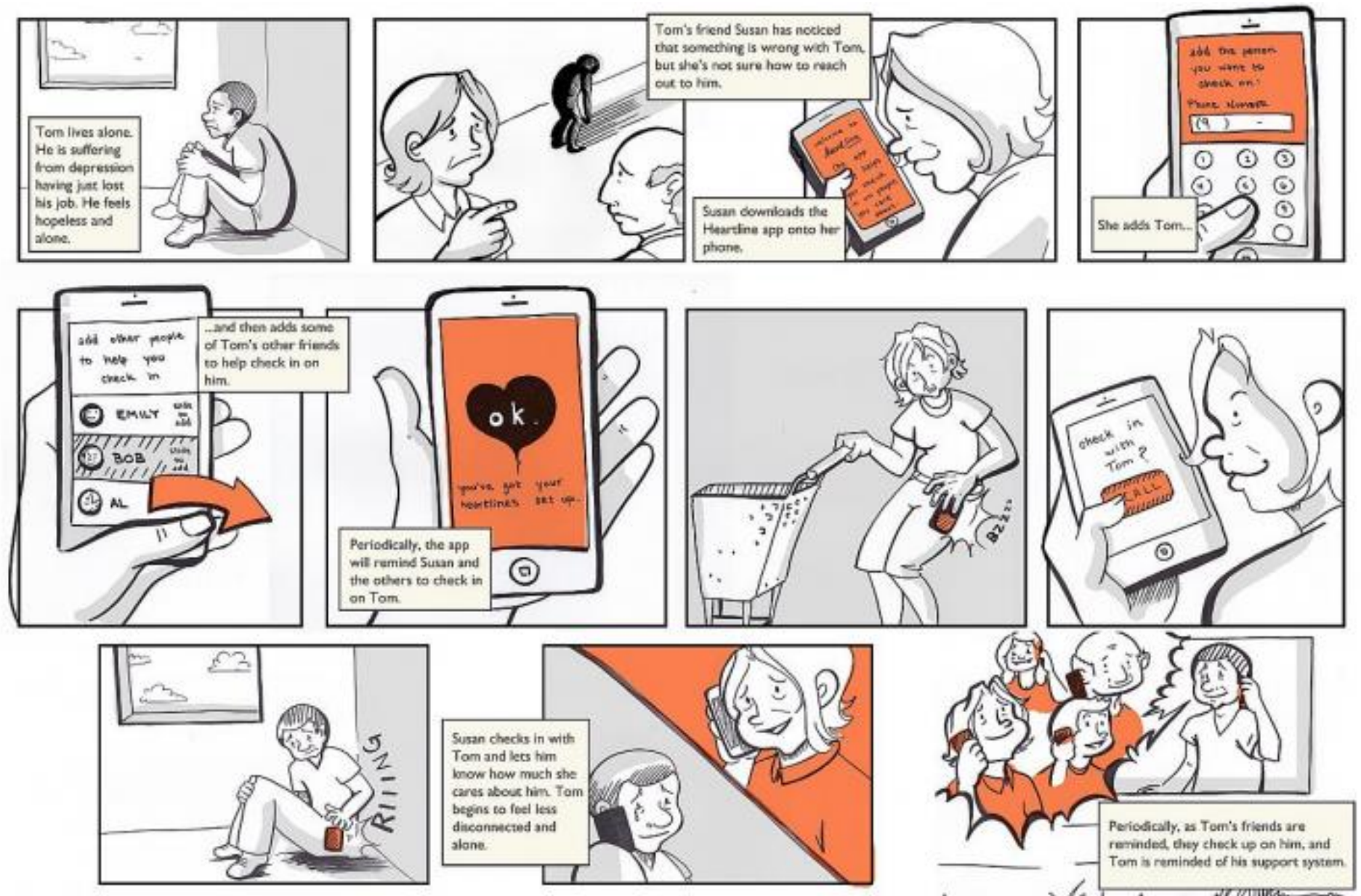
Exceptions: **(List any unexpected or abnormal conditions that may be encountered during execution of Normal or Alternative Use Cases. When possible, note the Normal or Alternate Use Case step where the exception applies).**

Step 1: The HCP must check the labeling on the drug to check that it is the correct drug for the correct patient, and that it is not past the expiry date. If these conditions are not true, the drug cannot be used.

Open Issues: **(List any open issues that need to be resolved for successful adoption of this Use Case. Ideally all open issues should be closed at project completion and this section will be empty).**

1. Will the syringe be 20 mL, or less – so the HCP will have to repeat filling the syringe multiple times to fill the Flexible Bag?
2. Will the syringe always be filled completely, or we fill with just 20 mL? What if syringe is less than 20 mL and we need to repeat multiple times to reach the prescription volume?

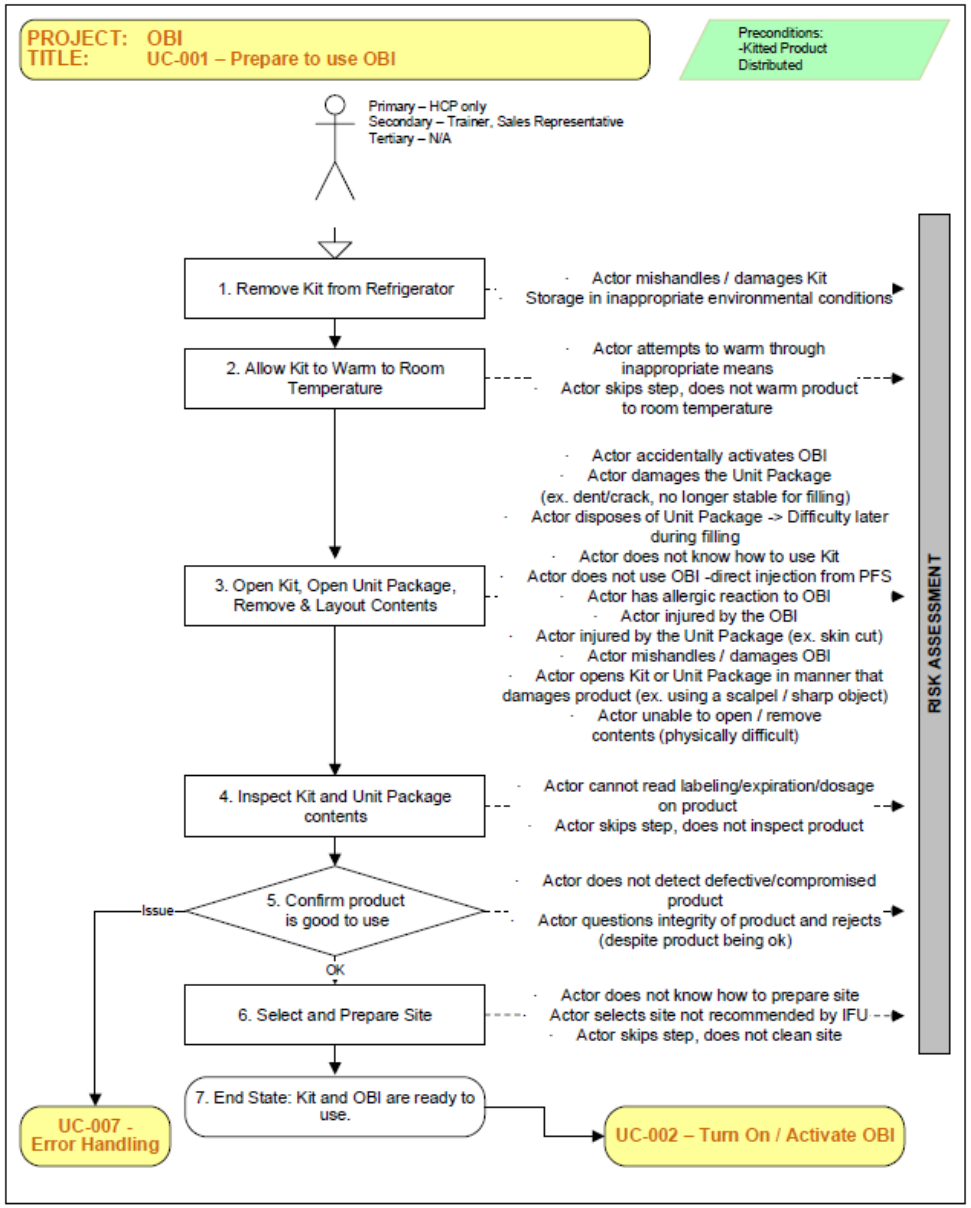
Storyboarding



Use case / Operational Scenario

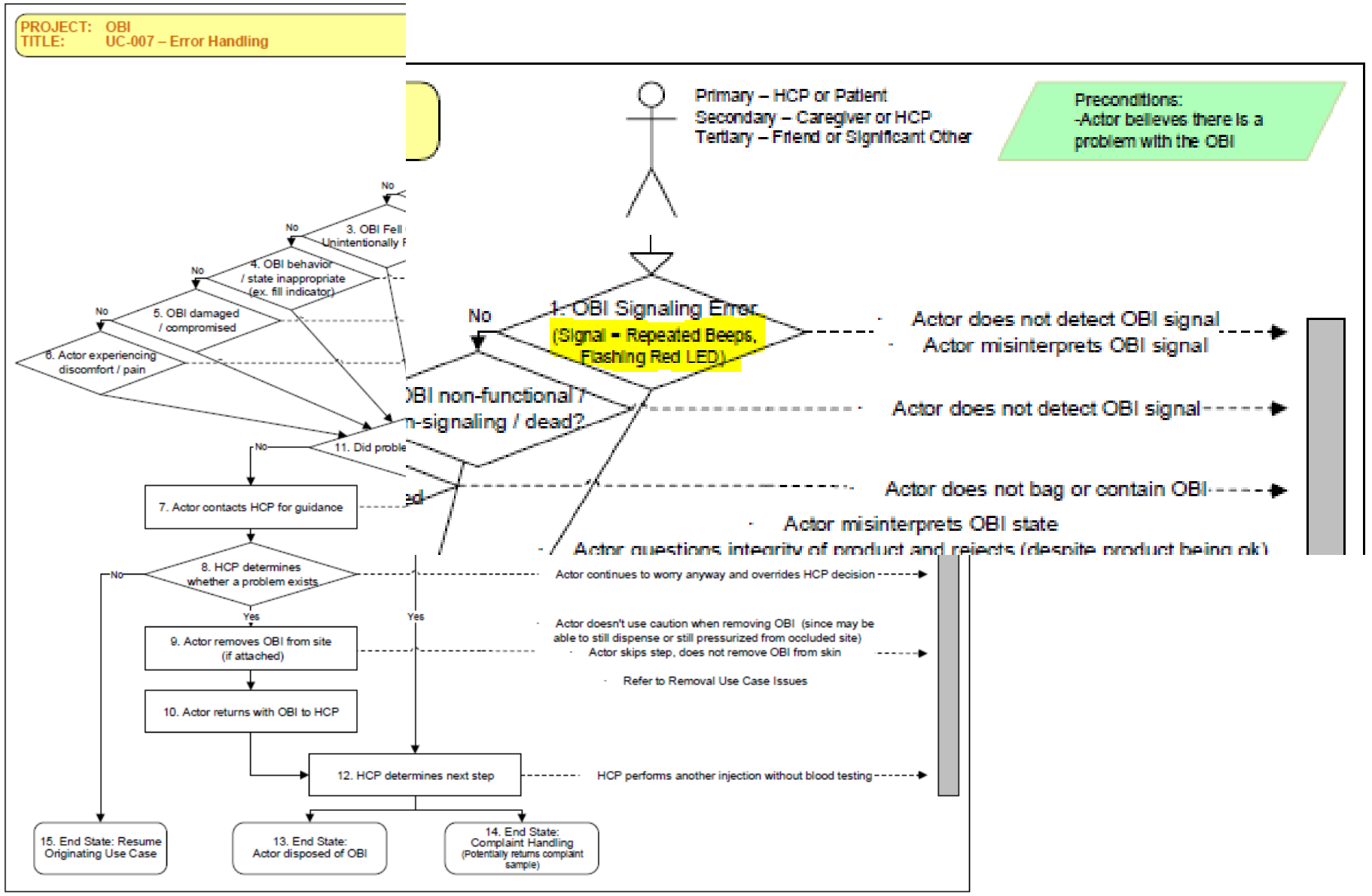
In addition to the nominal and alternate nominal scenarios, also ask the stakeholder about off-nominal scenarios- what could go wrong, or currently what often goes wrong? (*The off-nominal scenarios will be a major source of risk -> Failure Modes and Effects Analysis (FMEA)).*

The resulting use cases or scenarios provide key insights into the stakeholder needs and stakeholder-owned system requirements concerning features, capabilities, functionality, performance, interaction with other systems, standards, regulations, physical attributes, etc.



Use case / Operational Scenario

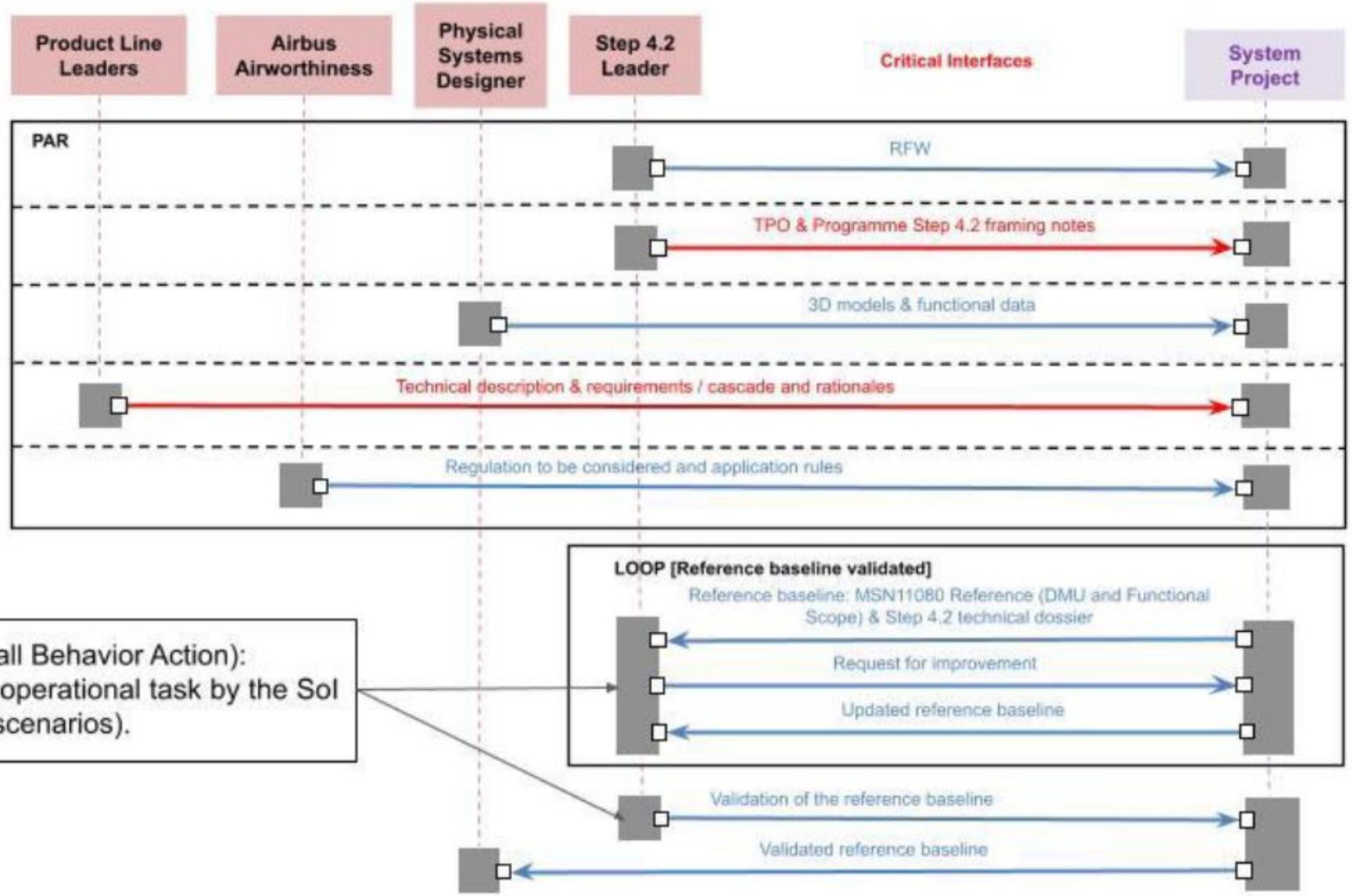
7.8 Error Handling



Use case / Operational Scenario

Operational phase behavior (Activity):
Can be used to describe the operational scenario (use case)

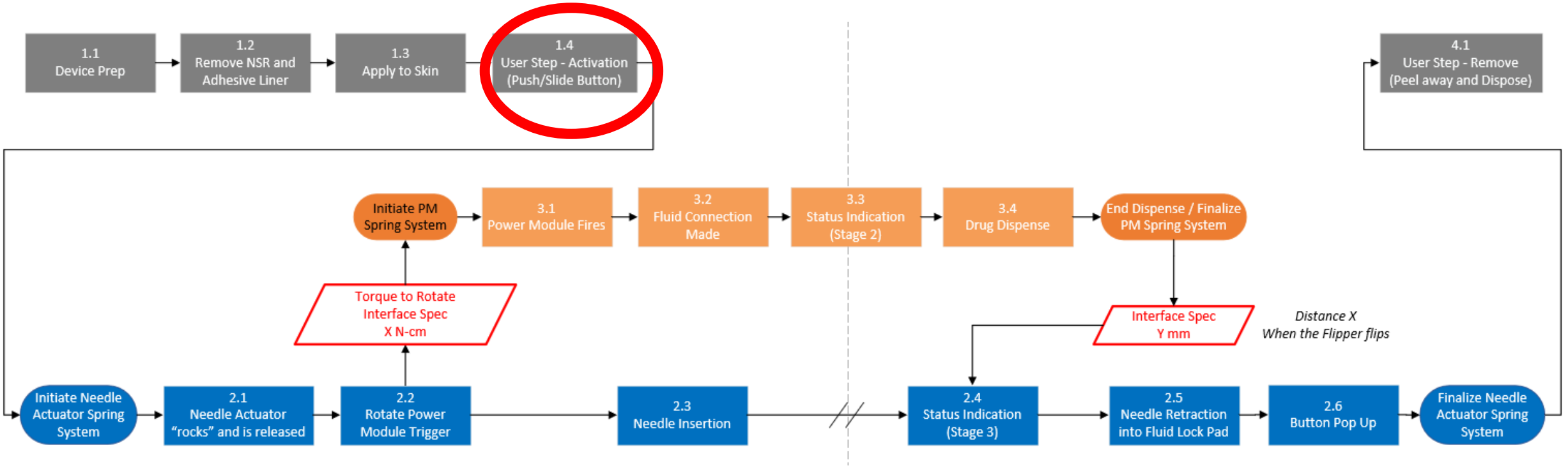
Use Case "To create the A320 Nose Section Step 4.2 reference baseline"



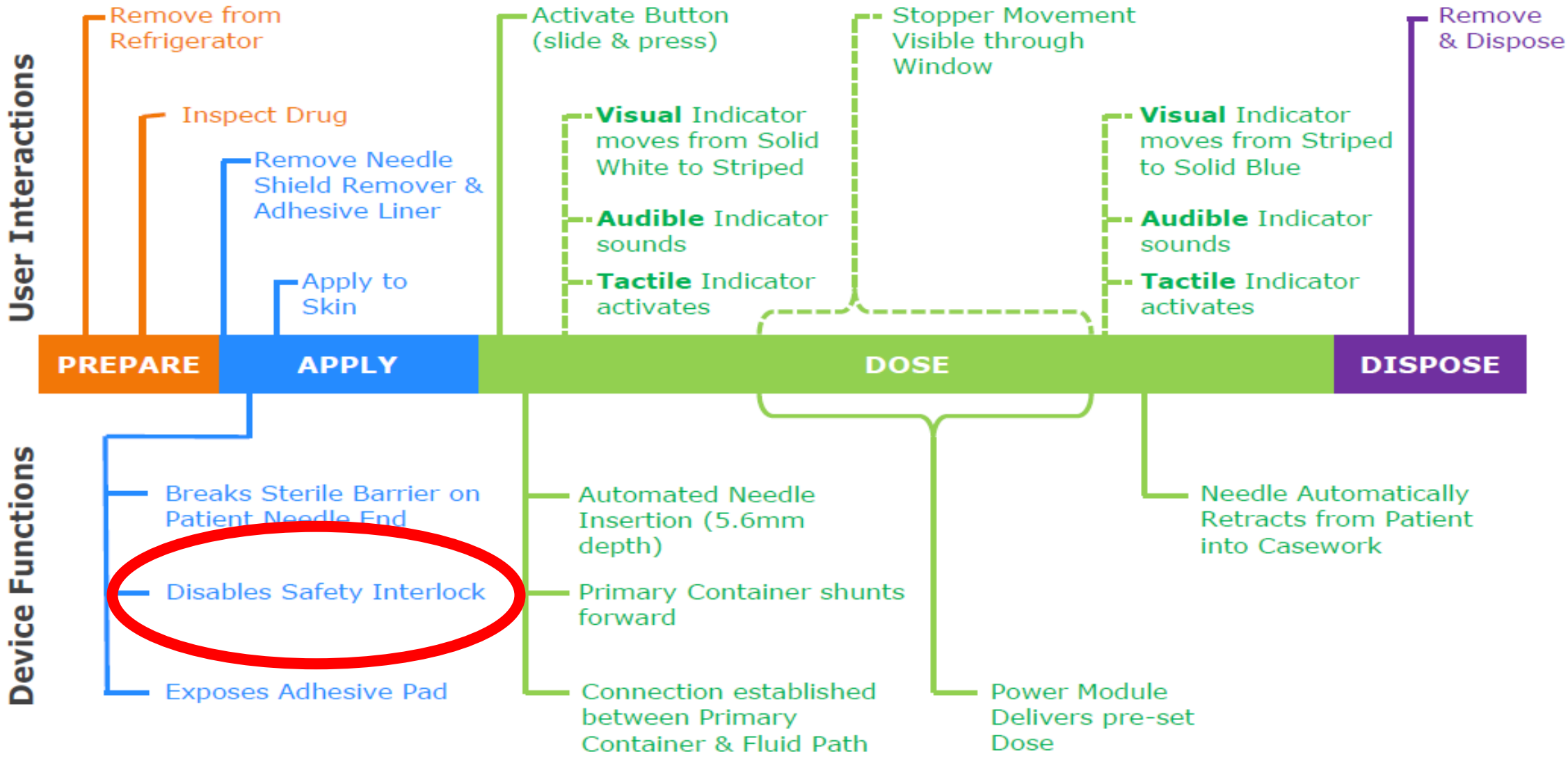
Operational task invocation (Call Behavior Action):
It represents the execution of an operational task by the SoI or a stakeholder (grey boxes on scenarios).

Use case / Operational Scenario

The goal of elicitation is to provide an implementation-free understanding of the stakeholders' needs by defining what is expected (specification) without addressing how (design) to satisfy the set of needs.



Use case / Operational Scenario



Set of Needs (Services and constraints)

Unique ID

Source

Statement

Source of additional services/constraints

MRD.200	Internal	As a HCP, I want to prepare the OBI setup at the following conditions: Temp Range: 5-40°C RH: < 90% Duration: < 3 hours	Normal Use
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MRD.53	Regulatory	As a HCP, I want to know if the device is working properly during setup (i.e. any malfunction preventing complete drug delivery) prior to sending the Patient home.	Safety Compliance

Expected deliverable

Need priority

It is common for a specific stakeholder to consider some aspects of the SOI more important than others. During elicitation activities, it is important to ask the stakeholders to prioritize what they are asking for. Some things will be especially important to the stakeholder, while other things may be "nice-to-haves" or "desires", but not critical to the system being able to achieve the agreed to mission. There will be some things that the stakeholder may be able to "live without" given budget or schedule constraints or conflicting stakeholder needs and stakeholder-owned requirements.

Stakeholders need to make clear which things are critical for the system to be able to meet its intended purpose in the operating environment. When there is a difference in opinion as to priority or criticality, the ranking of the stakeholder must be considered.

When recording stakeholder inputs, it is important to record within the SOI's integrated dataset the priority of their needs and the rationale concerning the designation.

Need rationale

For each need elicited from the stakeholders, it is important to capture the rationale concerning “why”.

Rationale helps understand intent. To understand the real need, stakeholders may have to be asked “why?” multiple times.

- If the need or requirement is based on an assumption, that assumption should be included in the rationale attribute.
- If the need includes a number, the rationale should also include a description from which that number was derived.

⇒ If a stakeholder cannot provide a rationale, why include the need or requirement in the set?

Considerations for the Elicitation of Needs

The elicited needs and requirements will frequently include *ambiguous terms and phrases* like *user friendly, robust, easy to use, works fast, safe, affordable, pleasant, easy to test, cost-effective manufacturing, works just like the last one only better, etc*. It is common for stakeholders to state their needs at a high level of abstraction resulting in ambiguity as to their exact intent as it applies to the SOI.

Considerations for the Elicitation of Needs

Stakeholders often state their needs as implementation statements or solutions rather than address the problem and needs concerning a solution to the problem. The focus should be on the "what" not "how". When a stakeholder states a specific implementation or solution, ask *"Why?"* and *"What does that implementation or solution allow you to do?"* A common approach is to ask "why" multiple times. The answers to the questions will help uncover the real needs. In addition, avoiding implementation allows the project team to be more innovative in defining an effective design solution.

Considerations for the Elicitation of Needs

Stakeholders will often address needs for lower-level system elements that make up the SOI, rather than focusing on the integrated system. For some it is hard to address higher levels of abstraction. It is common for engineers to jump to an architectural and design solution, rather than spend the time to understand the problem. For any given SOI, have the stakeholders focus on what would be observable externally, rather than diving into the internal architecture and design of the SOI.

Considerations for the Elicitation of Needs

Stakeholders will often have both explicit AND implicit needs. Stakeholders will often focus on functionality, performance, and user interfaces, assuming everything else will be addressed by the developing project team. The stakeholders assume the project team knows what they are assuming. The stakeholder's expectations for their implicit needs are often the same as for what they have explicitly stated. If the implicit needs are not met, the system may fail system validation, even though those needs and requirements were not explicitly stated. To avoid this issue, the project team must ask questions concerning areas of interest not explicitly stated by the stakeholders. For example, what quality attributes do they need the SOI to have? What standards or regulations need to be adhered to? What are the drivers and constraints?

Considerations for the Elicitation of Needs

What are the drivers and constraints? Drivers and Constraints can include:

- Design constraints (parts, materials, organizational design best practices, etc.).
- Design standards (industry, domain, business management, business operations).
- Production constraints (existing technology, facilities, equipment, cost, throughput, etc.).
- Human factors (human/machine interface - HMI).
- Regulations (law).
- Operating environment (natural, induced).
- Operating environment (social, cultural).
- Existing systems: (interactions, interfaces, dependencies).
- Technology Maturity.
- Cost.
- Schedule.

Considerations for the Elicitation of Needs

Stories, scenarios, use cases, system concepts, ops concepts, concepts of operation, etc. often focus on functionality, performance, and interactions with other systems, but are often incomplete, not addressing other "non-functional" needs such as quality needs (-ilities), e.g. maintenability, availability, security, reliability…, design and construction standards, regulations, and physical characteristics. These other needs must also be included - otherwise the integrated set of needs and resulting set of design input requirements will be incomplete.

Validation of the Needs

- Has an acceptable elicitation process been followed?
- Validation of a need statement determines whether a need statement clearly communicates the intent of the lifecycle concepts or source from which it was derived or transformed.
- All relevant stakeholders have been involved in the elicitation activities.
- All lifecycle stages have been addressed.
- All interactions with external entities identified during elicitation have been recorded.
- The elicitation outcomes are communicated at the right level of abstraction.
- Are they an implementation-free understanding of the needs and requirements by defining what is expected (design inputs) without addressing how (design outputs)?
- Rationale has been captured for each need.
- The priorities and critically of the stakeholder needs and stakeholhave been established and recorded.

Validation of the Needs

- Any conflicts and inconsistencies have been captured and a plan for resolution developed.
- Do the needs correctly and completely capture what the stakeholders need the SOI to do in the operational environment in terms of form, fit, function, compliance, and quality?
- Issues and risk have been recorded and a plan for mitigation has been established.
- Ambiguous terms such as user-friendly, easy-to-use, fast, high quality, good tasting, affordable, robust, etc. have been resolved.
- Are the needs written correctly?
- Does each need statement trace to a source?
- Does each source have a corresponding need statement?
- Would the set of needs, if met, solve the problem?

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Génie industriel

École nationale supérieure de génie industriel

Introduction to the Fundamentals of Systems Engineering

2. Needs definition (Operational Analysis/View)

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