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***Deliverable D6.1*: Coordination and best practice guidelines for REACH system integration activities and standards research (associated with task T 6.1).**

Abstract: In REACH, WP6 focusses on systems engineering and testing aspects such as system integration, verification, validation, and optimization. The present Deliverable (associated with Task T6.1) is concerned in a cross sectional manner with the overall methods, best practices, standards, cross-compatibility, and coordination/planning of system integration activities. REACH states a complex *system of systems* where individual project partners develop the individual systems (e.g. Touchpoints) and sub-systems (e.g. sensors) that need to be integrated with each other. To ensure a proper cross-compatibility (e.g. with Philips HSDP and other platforms that have the potential to establish our foothold in the EU in health care ICT-platforms), interfacing and integration of systems/sub-systems to a functional system of systems a set of tools and methods is introduced. Furthermore, based on the in WP1 developed Touchpoints and Engine concept, DIN (together with the in the development activities involved partners) conducted an identification analysis, and assessment of standards that are potentially relevant for the development of Touchpoints, Engine, and the resulting horizontal and vertical (e.g. system-system and human-system) interfaces. The identification of applicable standards in this early development phase will spur an efficient system engineering process. Finally Following the outcomes of Deliverable T1.4/D4 and the in the present deliverable in Chapter 2 clarified systems engineering approach, the testing approach was decomposed and an initial testing plan set up in tune with the REACH V-Model approach. Beyond this deliverable report, T6.1 (as a task that continues up to Month 48) will facilitate the uptake of the introduced guidelines, the subsequent detailing of interfaces and specifications by the implementation work teams (e.g. the Touchpoints/Engine associated work teams), and the monitoring of the technology maturation and integration processes.

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Tasks of the involved partners with respect to the deliverable (and respective tasks) presented in this report:

Partner	Short task description
TUM	• Systems engineering approach and integration and validation strategy, methods, best practice guidelines, etc. (Chapter 2) • Major contribution to development of initial testing plan (Chapter 4) • Detailing of overall WP6 and task activities, roadmap
DIN	• identification analysis, and assessment of standards that are potentially relevant for the development of Touchpoints, Engine, and the resulting interfaces (Chapter 3)
DTU	• Major contribution to development of initial testing plan (Chapter 4)
Tu/e	• Contribution with regard to system engineering and standards aspects
AM	• Contribution with regard to system engineering and standards aspects
AH	• Contribution with regard to system engineering and standards aspects
Philips	• Contribution with regard to system engineering and standards aspects

Please note: T6.1 is a task that continues and therefore the partners have not yet used all the allocated resources. Beyond this deliverable report, T6.1 (as a task that continues up to Month 48) will facilitate the uptake of the introduced guidelines, the subsequent detailing of interfaces and specifications by the implementation work teams (e.g. the Touchpoints/Engine associated work teams), and the monitoring of the technology maturation and integration processes. The outcome of this facilitation work will be laid down as updates to this deliverable report.

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Key expressions

Abbreviations for partners:

AH: ArjoHuntleigh
AM: Alreh Medical
CU: University of Copenhagen
DTU: Technical University of Denmark
EPFL: École Polytechnique Fédérale of Lausanne, Switzerland
HUG: Hôpitaux Universitaires Genève
PSS: Product Service System
SC: SmartCardia
SK: Schön Klinik
TU/e: Eindhoven University of Technology
TUM: Technical University of Munich
ZZ: ZuidZorg

Agile project management: Agile project management is compared to the V-Model approach a more flexible and versatile approach for project management including systems development/integration. In contrast to the V-Model approach it builds on a continuous iteration loop between development and testing (**InLoox, n.d.**).

D: Deliverable report.

Decomposition of testing approach: For each Touchpoint separate testing parts/instances (early detection, motivational techniques, and programmed interventions) were created and each of this testing instances represents a separate trial with an own hypothesis, own outcome measures, and an instance specific trial design.

Early testing: small user feedback and iteration loops to develop qualitative features

Engine: The "Engine" – in itself also modular with regard to its functionality – serves from the viewpoint of the end user as "invisible" back end system. In general the end users (elderly) are supposed to interact with the "engine" primarily in an indirect way through the Touchpoints.

Integration activities: cover in REACH both the integration of parts and components to Touchpoints and the Engine (systems) as well as the integration of selected Touchpoints with each other and the Engine (to a system of systems) for certain verification/validation test scenarios.

Interface specifications: besides the system architecture, and the design of individual components or systems, interfaces play a key role in guaranteeing cross-compatibility.

Interfaces: A key aspect in that context is the identification and analysis of interfaces. Interfaces state ways of communication between system elements. According to Langford (**Langford, 2012**) in systems, individual elements can interact and interface in terms of four, basic ways: Energy, Matter, Material wealth and Information ("EMMI"). In **Deliverable D4** (**Section 5.5**) three types of interfaces have been identified a key for REACH: system-system interfaces, human-system interfaces, and B2B interfaces.

Modularization: as defined for example by (**Baldwin & Clark, 2000**) can be considered as means to control the internal complexity of a system e.g. by reducing and clarifying the interfaces between system elements.

Performance specifications: e.g. specification of certain requirements the system must meet)

Sensing and data analytics process specifications: In REACH test with various types of sensors will be conducted in a variety of use case settings in different countries and under the control of different study leaders. In order to be able to exploit the resulting data sets efficiently by using data analytics algorithms, these data sets and the process of creating them must follow certain specifications.

Specifications: As per the NASA Systems Engineering Handbook (which principally follow the V-Model approach; see (**NASA, 2007**) throughout design and sub-system implementation phases progressively specifications and standards for the design/composition of individual system elements as well as the interfaces connecting them have to be identified and detailed in order allow a proper functioning of the system as a whole in verification and validation test phases.

Standardization: Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context (DIN EN 45020:2007-03) System architecture specifications: High-level system architecture specifications were set up in **Deliverable T1.4/D4** (**Chapter 5**) clarifying the relations, interfaces, and the modular structure of the individual Touchpoints and their sub-systems and components with the Engine and the use cases to which.

System architecture specifications: High-level system architecture specifications were set up in **Deliverable T1.4/D4** (**Chapter 5**) clarifying the relations, interfaces, and the modular structure of the individual Touchpoints and their sub-systems and components with the Engine and the use cases to which.

System architecture: The structure of the overall system of systems is expressed by the REACH system architecture (following the terminology of the standard ISO/IEC/IEEE 42010:2011 (**International Standards Office, 2011**), see **Chapter 5**/ **Deliverable D4**) which decomposes the system, and defines links and information flows between the individual parts of the system and with the environment (stakeholders, use case settings, etc.).

Systems engineering: Langford (2012) characterizes systems engineering as the preparation of individual system elements for integration. System integration can efficiently be accomplished in a continuous, step by step manner (see, for example, the Continuous Integration Model as outlined by (**Northrop Grumman Corporation, 2011**) in which iteratively first selected components are integrated before subsequently larger sets of components are integrated in order to reduce the complexity of the integration process.

T: Task defined in the project proposal.

Technical specifications: detailed technical description of a system part of interface).

Technology validation: testing against system requirements

Technology verification: functional and usability testing

Touchpoints/Engine concept: structures the envisioned REACH product-service-system architecture, into manageable research and development clusters.

Touchpoints: The “Touchpoints” will act as “graspable” front end towards the end users (elderly). The Touchpoints will serve as data gathering devices as well as mediator of services and interventions coordinated by the Engine towards the end user. Each Touchpoint is modular and made up of several subsystems which allow to adapt the system both for a certain person or setting as well as over time.

TRLs, IRLs, SRLs: The concepts of Technology Readiness Levels (TRLs; see, for example, (**NASA, 2012**), and System and Integration Readiness Levels (SRLs/ IRLs, see, for example, (**Sauser, et al., 2006**)) can be used to track the maturity of the implemented sub-systems and their interfaces and integration with each other. In addition project management can facilitate a successful system integration

Use case setting: Use case setting refers to the four solution operators and this report called them the use case setting since they reflect concrete application scenarios.

V-Model: REACH basically follows the so called “V-Model” (see for example (**Firesmith, 2013**)) approach which is of particular importance when developing solutions for the health care markets where the use of a systematic development method is pertinent also with respect to later certification requirements (**Harer, 2014**). Following the “V-Model” approach a design phase is followed by an implementation phase where fist individual systems/sub-systems-components are implemented, then subsequently and step wise integrated to systems for verification and validation.

WP: Work package defined in the project proposal.

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1 Background and summary of tasks and activities related to T6.1/D61

In this Section, an overview over **WP6** and **Task T6.1** is provided. First in **Section 1.1** the relation and interdependencies of tasks in **WP6** are explained and **T6.1** is situated in this particular context. Then in **Section 1.2**, **Task 6.1** with its focus on the coordination of system integration activities, standards research, and testing planning is detailed. In **Section 1.3** the relation to and linking with of **WP6**/**T6.1** to other WPs is outlined.

1.1 Overview WP6: integration, verification, validation, and optimization

In REACH, WP6 focusses on systems engineering and testing aspects such as system integration, verification, validation, and optimization. Whereas **Task T6.1** is concerned in a cross sectional manner with the overall methods, best practices, standards, and coordination/planning of system integration activities, **Tasks T6.2** (pre-integration to mock-up) and **T6.6** (final integration to demonstrators/prototypes) focus on the actual integration work. Actual integration work systematically always start 3 month before a testing phase (**T6.3**: Pre-testing; **T6.4**: Pre-testing 2; **T6.7**: Final-testing) and it complements the work on individual technologies, components and sub-systems in smaller teams in the development work packages **WP2**-**WP5**.

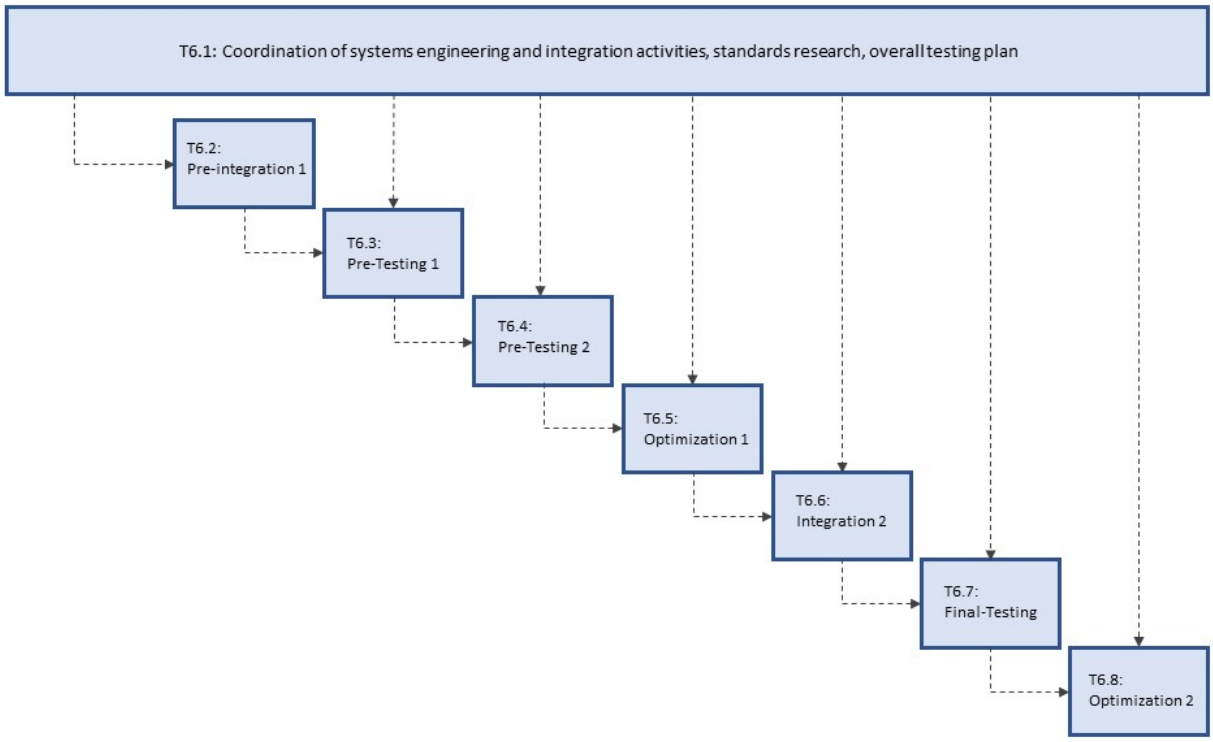

Figure 1-1: Relation of tasks within WP6

1.2 Task T6.1: Coordination of system integration activities and standards research

Within the testing tasks phases in **WP6**, both technology partners (e.g. for Touchpoint deployment) and the use case settings have resources allocated, in order to be able to jointly plan, design, conduct, and interpret the studies and test to be conducted. **T6.8** states a

relatively long phase at the end of the project in which the developments and test should be reviewed and the overall system should be (where relevant with additional test of development activities) optimized.

T6.1 is concerned in a cross sectional manner with the overall methods, best practices, standards research, and coordination/planning of system integration activities.

T6.1 covers following thematic fields:

1) Coordination of cross compatibility and system integration activities: In **Chapter 2** methods, tools, an overall strategy, and best practice guidelines are provided which will facilitate the coordination of cross compatibility and system integration activities. REACH states a complex system of systems (that is created in a highly multidisciplinary approach where individual project partners develop the individual systems (e.g. Touchpoints) and sub-systems (e.g. sensors) that need to be integrated with each other. REACH flexibly utilizes and combines in that context elements of the (1) V-Model approach, (2) Agile Management, and the (3) NASA systems engineering approach. To ensure a proper cross-compatibility (e.g. with Philips HSDP and other platforms), interfacing and integration of systems/sub-systems to a functioning system of systems a set of tools and methods is introduced. The tools and methods provided by this deliverable report (e.g. interface identification method; Product Breakdown Structure, assessment of Integration Readiness Levels) will be used by the (Touchpoints/Engine) implementation work teams as a common system detailing tools; the T6.1 participants will facilitate this process.

2) Standards research: In **Chapter 3**, based on the in **WP1** (see **Deliverable T1.4/D4**) Touchpoints and Engine concept, DIN (together with the in the development activities involved partners) conducted an identification and analysis of standards that are potentially relevant for the development of the Touchpoints, Engine and analytics functionality, the resulting horizontal and vertical (e.g. system-system and human-system) interfaces, and an overall interoperability. The identification of applicable standards in this early development phase will in combination with the in the previous chapter provided integration tools spur an efficient system engineering process.

3) Initial testing plan: In **Chapter 4**, Following the outcomes of **Deliverable T1.4/D4** and the in the present deliverable in **Chapter 2** clarified systems engineering approach, the testing approach was decomposed and an initial testing plan is set up, and it is shows how the 4 test phases relate to the V-Model phases. A set of testing dimensions are developed which shall govern the design and execution of test. With the overall system architecture detailed and the first early trials completed, it becomes obvious that it is impractical to test each Touchpoint with regard to its complex, subsequent chain of early detection, motivational techniques, and programmed interventions in a single trial. Instead, following **Review Recommendations R2-4**, a decomposition of the “testing problem” is suggested. For each Touchpoint separate testing parts/instances were created and each of this testing instances represents a separate trial with an own hypothesis, own outcome measures, and an instance specific trial design.

In order to allow testing as per the in **Chapter 4** specified testing instances, prior to each trial phase parts of the REACH system have to be integrated to mock-ups or prototypes.

Prior to each integration, the tools, best practice guidelines, and standards outlined in **Chapter 2** and **Chapter 3** will be used to efficiently integrate components and sub-systems.

1.3 Relation of WP6/T6.1 to other WPs

WP6 is closely linked to the system architecture (e.g. Touchpoint/Engine concept) developed in **WP1** (see **Deliverable T1.4/D4**) and provides the tools and methods to facilitate integration, verification, and validation. **WP6** complements the actual implementation activities (individual technologies, components and sub-systems) carried out in smaller teams in the development work packages **WP2**-**WP5**. Also, **WP6** needs to coordinate closely with the management activities of WP9, since for example an efficient communication and the identification of risks are key regarding system integration. Whereas standards research in the present work task (**T6.1**) focusses the identification of applicable standards (and potential standardization gaps) and provides inputs for the functioning, integration/cross-compatibility, and technical performance within REACH, standards research in **T9.4** focusses on the development of standards for the REACH external-environment and broader cross-compatibility and exploitation beyond the consortium and the project.

2 Coordination of cross compatibility and system integration activities

In this Section, methods and tools (**Section 2.1**) and best practice guidelines (**Section 2.4**) are provided which will help the coordination of cross compatibility and system integration activities. REACH combines components of the V-Model approach (**Subsection 2.3.1**), Agile Management (**Subsection 2.3.2**) and the NASA systems engineering approach (**Subsection 2.3.3).**

2.1 Methods, Tools, and Terminology

REACH states a complex *system of systems* (see **Deliverable D4** for a detailed system overview) that is created in a highly multidisciplinary approach (ICT partners, device partners, sociologists, care professionals, sociologist and human factor specialist, data scientists, etc.) where individual project partners (or sets of project partners) supply or develop the individual systems (e.g. Touchpoints) and sub-systems (e.g. sensors) that need to be integrated with each other.

In order to ensure a proper cross-compatibility, interfacing and integration of systems/sub-systems to a function system of systems following tools and methods are used in the context of REACH:

1. System architecture: The structure of the overall system of systems is expressed by the *REACH* system architecture (following the terminology of the standard ISO/IEC/IEEE 42010:2011 (**International Standards Office, 2011**), see **Chapter 5**/ **Deliverable D4**) which decomposes the system, and defines links and information flows between the individual parts of the system and with the environment (stakeholders, use case settings, etc.).

2. Interfaces: A key aspect in that context is the identification and analysis of *interfaces*. Interfaces state ways of communication between system elements. According to Langford (**Langford, 2012**) in systems, individual elements can interact and interface in terms of four, basic ways: Energy, Matter, Material wealth and Information ("EMMI"). In **Deliverable D4** (**Section 5.5**) three types of interfaces have been identified a key for REACH: system-system interfaces, human-system interfaces, and B2B interfaces.

3. Modularization: (as defined for example by (**Baldwin & Clark, 2000**) can be considered as means to control the internal complexity of a system e.g. by reducing and clarifying the interfaces between system elements.

4. Standards and specifications: As per the NASA Systems Engineering Handbook (which principally follow the V-Model approach; see (**NASA, 2007**) throughout design and sub-system implementation phases progressively specifications and standards for the design/composition of individual system elements as well as the interfaces connecting them have to be identified and detailed in order allow a proper functioning of the system as a whole in verification and validation test phases.

5. Systems engineering: **Langford** (**2012**) characterizes systems engineering as the preparation of individual system elements for integration. System integration can efficiently be accomplished in a continuous, step by step manner (see, for example, the Continuous Integration Model as outlined by (**Northrop Grumman Corporation, 2011**) in which iteratively first selected components are integrated before subsequently larger sets of components are integrated in order to reduce the complexity of the integration process.

6. TRLs, IRLs, SRLs: The concepts of Technology Readiness Levels (TRLs; see, for example, (**NASA, 2012**), and System and Integration Readiness Levels (SRLs/ IRLs, see, for example, (**Sauser, et al., 2006**)) can be used to track the maturity of the implemented sub-systems and their interfaces and integration with each other. In addition project management can facilitate a successful system integration

7. V-Model: REACH basically follows the so called "V-Model" (see for example (**Firesmith, 2013**)) approach which is of particular importance when developing solutions for the health care markets where the use of a systematic development method is pertinent also with respect to later certification requirements (**Harer, 2014**). Following the "V-Model" approach a design phase is followed by an implementation phase where fist individual systems/sub-systems-components are implemented, then subsequently and step wise integrated to systems for verification and validation.

8. Integration activities: cover in REACH both the integration of parts and components to Touchpoints and the Engine (systems) as well as the integration of selected Touchpoints with each other and the Engine (to a system of systems) for certain verification/validation test scenarios.

Objective of this Deliverable report (**Deliverable T6.1./D25**) is to set up basic guidelines and processes that allow for an efficient integration of the individual products, systems, components, and parts developed by the partners and work groups in REACH for the planned verification (e.g. Pre-testing I and II) and validation activities (final demonstration). Beyond this deliverable report, **T6.1** (as a task that continues up to Month 48) will facilitate the uptake of the introduced guidelines, the subsequent detailing of interfaces and specifications by the implementation work teams (e.g. the Touchpoints/Engine associated work teams as outlined in **Deliverable D4** (**Chapter 3**), and the monitoring of the technology maturation and integration processes.

2.2 REACH: a system of systems

The Touchpoints and Engine concept which was developed and detailed in **WP1** (**Deliverables 1-4)** is a system of systems. In this system of systems various Touchpoints can flexibly be combined with an integrating ICT and data analytics system ("Engine") to fulfill certain use cases or scenarios.

1. Touchpoints/ Engine:

- TP1: Personal Mobility Device
- TP2: Active Environment
- TP3: Socializing and Nutritional Monitoring and Intervention

- TP4: Gaming and Training
- TP5: Wearables
- E: integrating ICT and data analytics system

At present 5 Touchpoints are planned to be realized for demonstration purposes (however, the system will be open to additional Touchpoints to be added beyond the project).

2. Use Case Settings:

- UCS1: Lyngby (home care)
- UCS2: ZZ (home care and community care centers)
- UCS3: SK (rehabilitation facility)
- UCS4: HUG (geriatric hospital and care home)

3. Scenarios:

- Out & Active: covers elderly (or parts of a patient journey) at home at risk that obviously need to be motivated and activate to train cognitive and functional abilities
- Re-habit: covers elderly (or parts of a patient journey) in a care or –rehabilitation institution
- Invisible Dr.: covers mere digital early detection and monitoring for healthy elderly

A detailed description of the scenarios can be found in **Deliverable T1.3/D3**. The scenarios are broader than the use case settings and may cover a journey through several use case settings along the care continuum.

Touchpoints can be flexibly combined to fulfill certain scenarios (e.g. patient journeys) and/or to act, assist, and prevent within a certain use case setting. So, for example, Touchpoint 1 functionality (Personal Mobility Device) along with Touchpoint 3 (Socializing and Nutritional Monitoring) may be in a home care setting (Lyngby or ZZ) given at hand the elderly in order to monitor the onset of conditions such as functional decline, risk of falls, and frailty and implicitly counteract such trends. Also over time combinations of Touchpoints for “evolutionary” scenarios are possible; i.e. Touchpoint 5 (wearables) may be a first (an relatively cheap device) device for early detection provided to elderly at risk, complemented then once the concrete risk was detected by the system by one or a set of other suitable Touchpoints that provide the necessitated activation and motivation functionality. **Figure 2-1** shows how the various Touchpoints may serve in combination towards a certain use case setting and **Figure 2-2** shows how various Touchpoints maybe combined to respond to overarching scenarios.

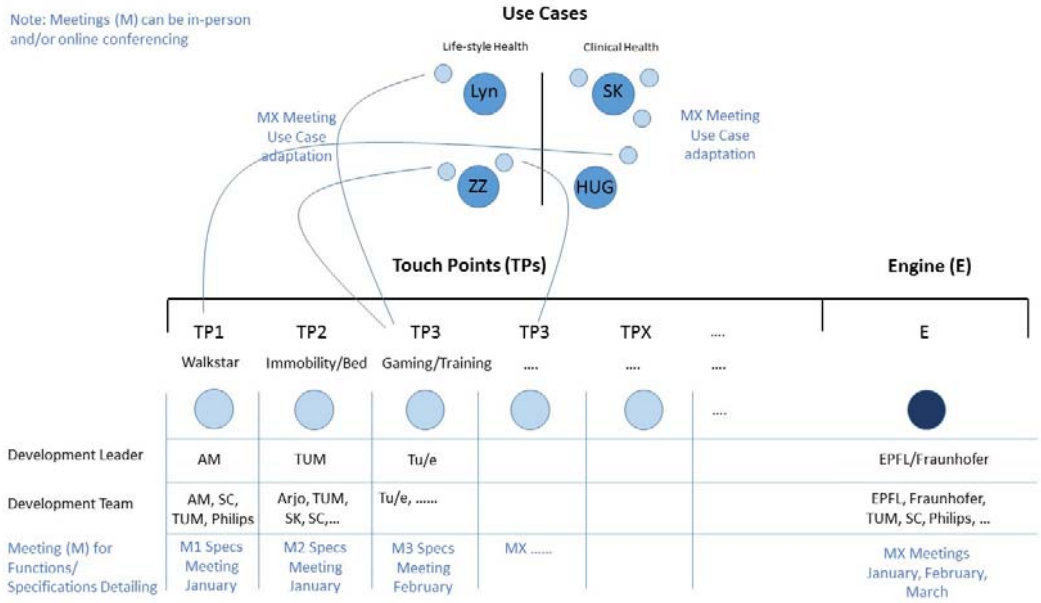

Figure 2-1: Various Touchpoints may serve in combination towards a certain use case setting

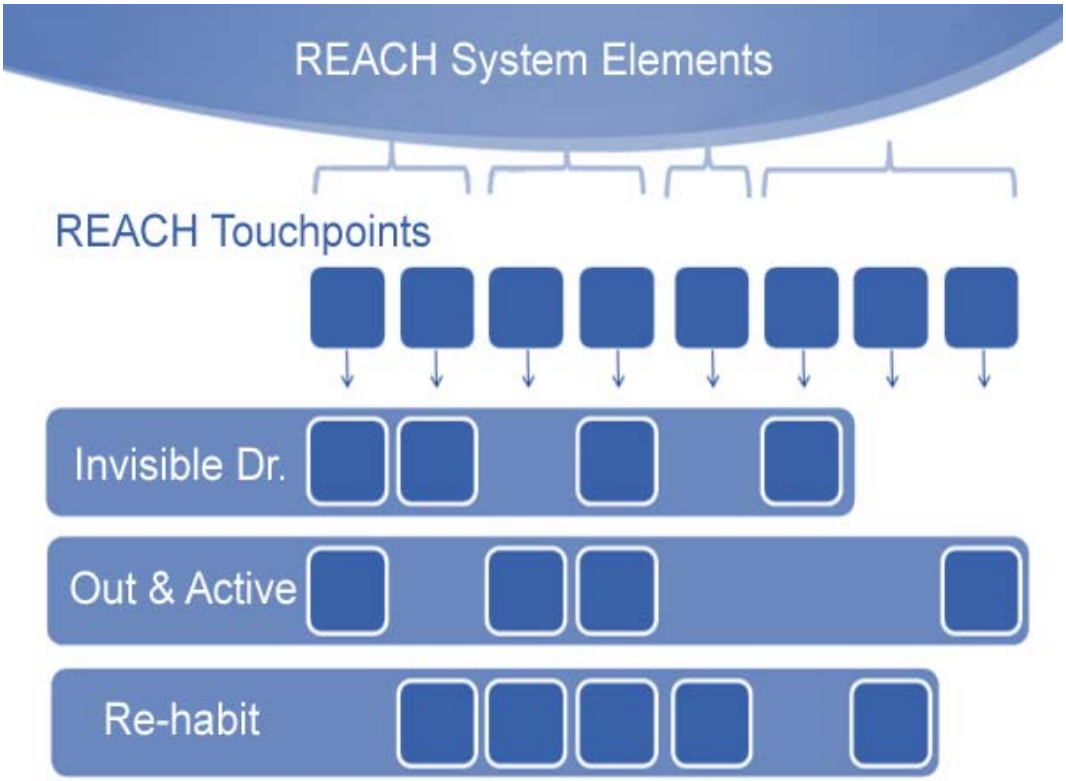

Figure 2-2: Various Touchpoints maybe combined to respond to overarching scenarios (see also Deliverable T1.3/D4)

Beyond the combination of systems of systems to fulfill the need of REACH scenarios and use case settings the individual systems (e.g. Touchpoints) follow a modular approach which allows that each Touchpoint can be configured and personalized with specific sensors, mechanical components, and or services towards a specific elderly user. This approach also

allows SMEs as for example AM to exploit their capability in making custom-made products and at the same time profit from and make use of an overarching set of sensors, processes, and services which are pre-defined and where they can exploit mass production effects. The Product Breakdown Structure (PBS) developed in **T1.4** (**Deliverable D4; Chapter 5**) exemplarily for Touchpoint 1 (will be developed accordingly for the other Touchpoints as well) can be used to identify, analyze, and specify the interfaces between the components of a Touchpoint system (see **Figure 2-3**).

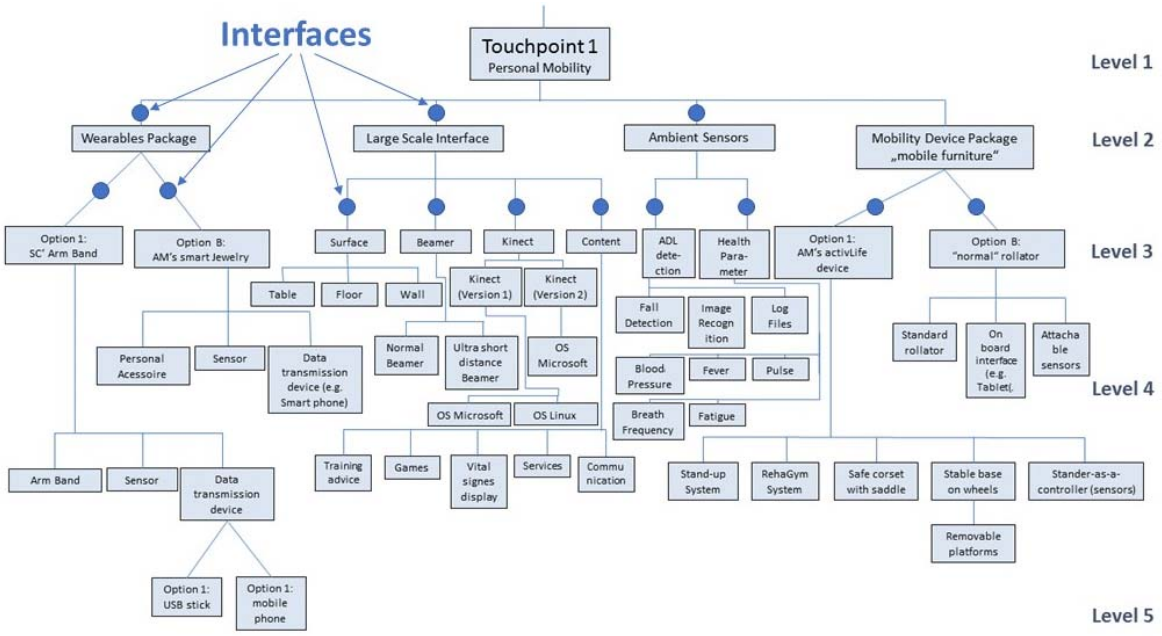

Figure 2-3: The PBS can be used to identify, analyses, and specify the interfaces between the components of a Touchpoint system.

The PBS for the total REACH systems (see **Figure 2-4**) principally follows a “star structure” where the individual systems don’t have direct, multiple links with each other, but are linked through one link to the Engine. This way of modular organization allows for separate work and also business/exploitation teams to be created around each Touchpoint and minimizes interdependencies. The interface between the Touchpoints and the Engine is a purely digital Application Programming Interface for information and data exchange. The detailing of its specifications will be accomplished in the implementation phase of the project.

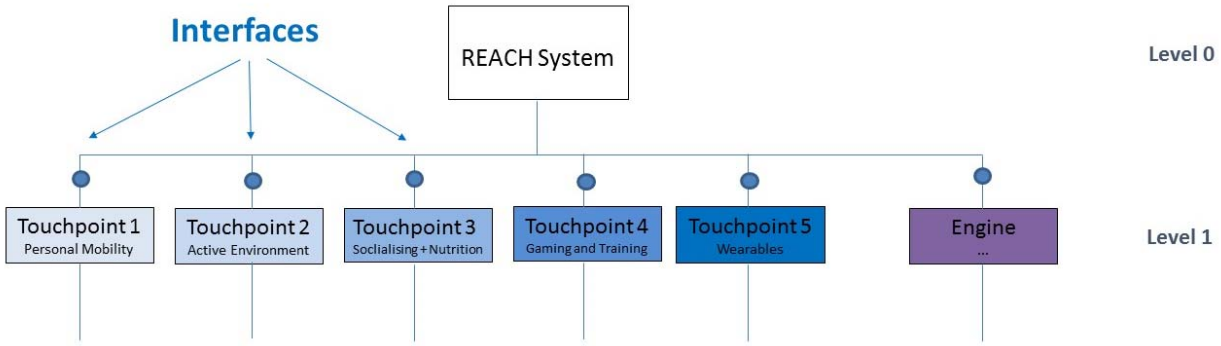

Figure 2-4: The PBS for the total REACH systems principally follows a “star structure” linked through one (in this case digital) link only to the Engine.

2.3 REACH's system integration management approach

In this chapter, REACH's system integration management approach is explained. REACH flexibly utilizes and combines in that context elements of the (1) V-Model approach, (2) Agile Management, and the (3) NASA systems engineering approach. The V-Model approach provides the predominant development and integration plan "baseline" strategy. In the following, first the three utilized approaches are outlined separately before it is shown how they are combined in the context of the design, detailing, implementation, integration, and testing of REACH's "Touchpoints and Engine concept".

2.3.1 The V-Model approach

Due to the criticality of personal data and the legal impact of medical feedback handled by REACH it is recommended to follow the so-called V-Model for the REACH system integration. The V-Model approach is also of particular importance when developing solutions for the health care markets where the use of a systematic development method is pertinent also with respect to later CE certification requirements (Harer, 2014). As per the "V-Model" approach in the first project phases ("Design") requirements are developed and formalized, the overall system is de-composed into sub-systems and detailed, before the sub-systems are then implemented and step by step integrated and in a series of subsequent testing activities (and if necessary in an iterative manner) verified and validated.

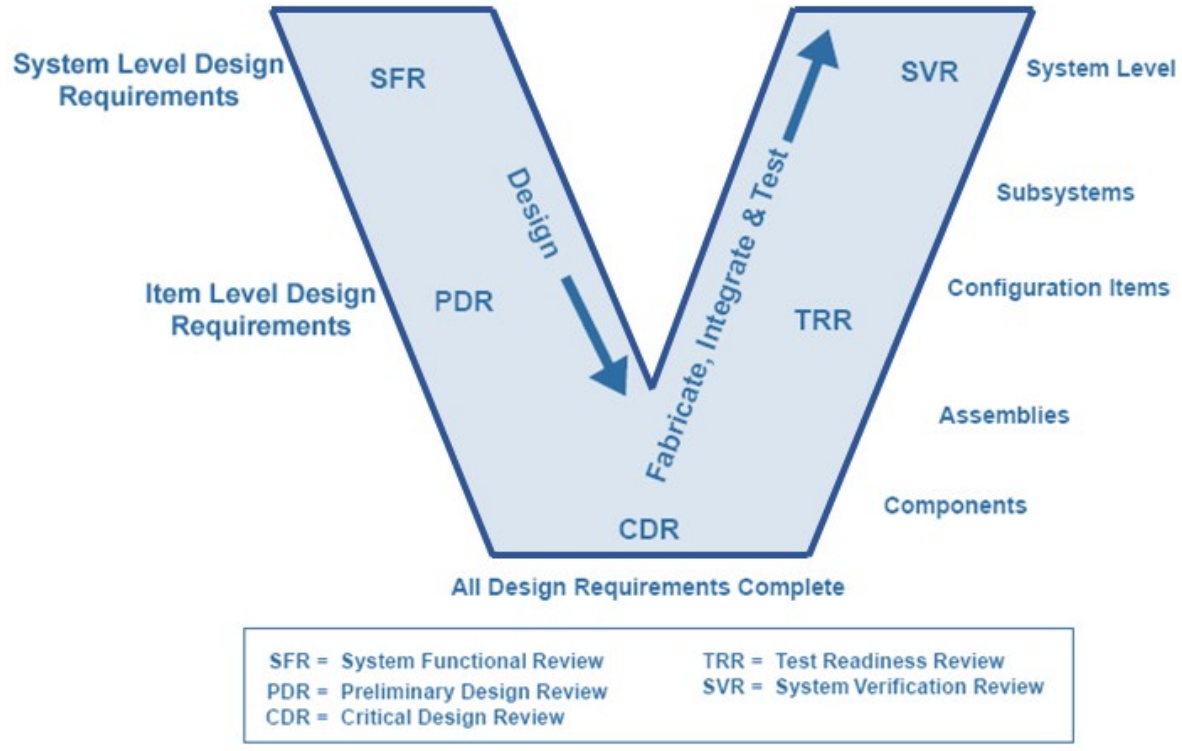

Figure 2-5: Explanation of the V-Model approach (Image: after Osborne, et al., 2005)

2.3.2 Agile Project management elements: combine V-Model with elements of agile project management

Agile project management is compared to the V-Model approach a more flexible and versatile approach for project management including systems development/integration. In contrast to the V-Model approach it builds on a continuous iteration loop between development and testing (**InLoox, n.d.**). Agile project management considers that sometimes in complex and multidisciplinary projects - such as REACH - it is not possible to develop the project along the clear, stringent sequence of activities that the V-Model suggests. Instead agile project management follows a more flexible and incremental approach, where for example in smaller project teams in a fast and agile manner “dirty” porotypes of components or subsystems are built and immediately tested. The testing/user feedback of many small iteration cycles is the used to evolve the project/product in a bottom up and “emergent” manner (see, for example, (**VersionOne, n.d.**), (**Moran, 2015**), (**Nicholls, et al., 2015**)).

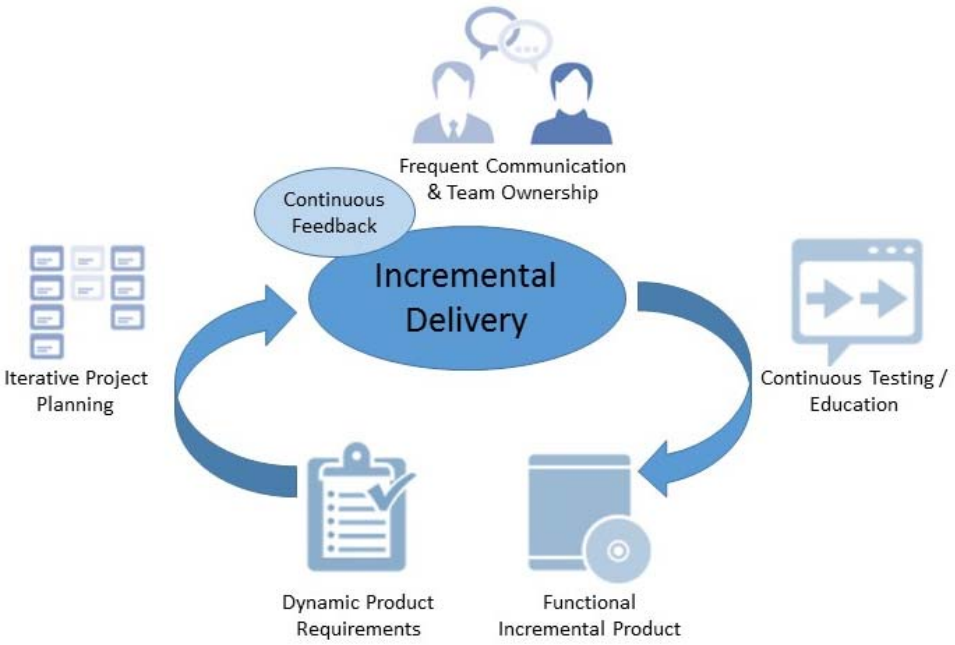

Figure 2-6: Explanation of the V-Model approach (Image: after InLoox, n.d.)

2.3.3 NASA systems engineering approach: design, implementation, integration, verification, and validation

NASA systems engineering guidelines (**NASA, 2007)** postulate a systematic development and integration process in which Design (concept, detailing) is followed by Design Realization (product implementation, product integration) and the Evaluation Process (product verification, product validation). During the design and product implementation phase the specifications for the components and interfaces are more and more detailed in order to allow for an as straight forward as possible system integration. Verification first evaluates the technical functioning of individual sub-systems whereas validation evaluates the “mission readiness” of a largely integrated system. Similar as in the V-Model the

development, integration, and verification/validation process should follow clear and pre-defined protocols.

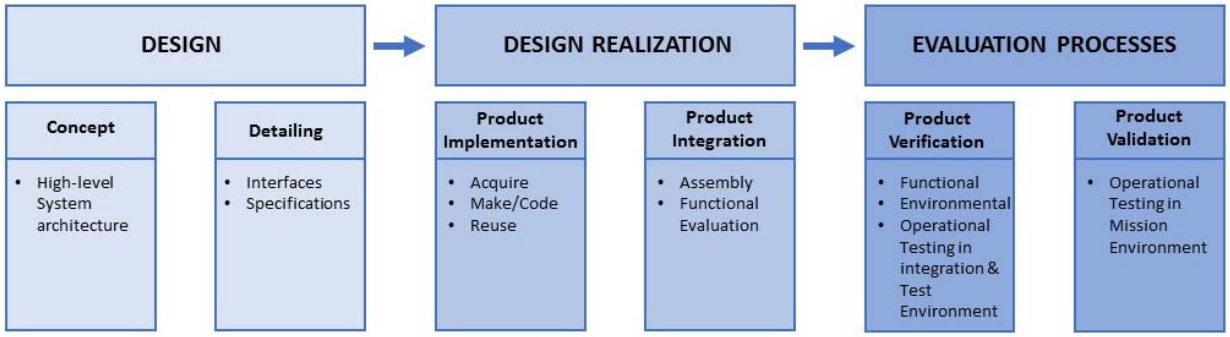

Figure 2-7: NASA systems engineering guidelines postulate a systematic development and integration process in which Design is followed by Design and the Evaluation Process (Image: own interpretation based on (NASA, 2007, p. 71)

2.3.4 REACH's systems engineering approach

REACH flexibly utilizes and combines elements of the (1) V-Model approach, (2) Agile Management, and the (3) NASA systems engineering approach. The V-Model approach provides the general development and integration plan strategy. In this structure, as per the Agile Management Approach small and short test with mock-ups of smaller parts of the systems (early testing, pre-testing 1) are allowed to develop and emerge in an experimental manner the systems qualitative features. The NASA systems engineering approach is followed to develop and detail in a systematic manner the components' and interfaces' specifications and to plan with pre-testing 2 and final testing the verification and validation of the system. With regard to REACH as a System of Systems (**Section 2.2**) and the REACH system architecture specified in Deliverable T1.4/D4, a key aspect of our system integration approach is to give the Touchpoints and Engine work teams as much freedom as possible with regard to the Touchpoint-internal design and composition (and thus see them as "real" modules as defined in **Section 2.2.4**), but on the other hand require a commitment for clearly defined interfaces to other parts of REACH an date REACH environment (including its users and other stakeholders).

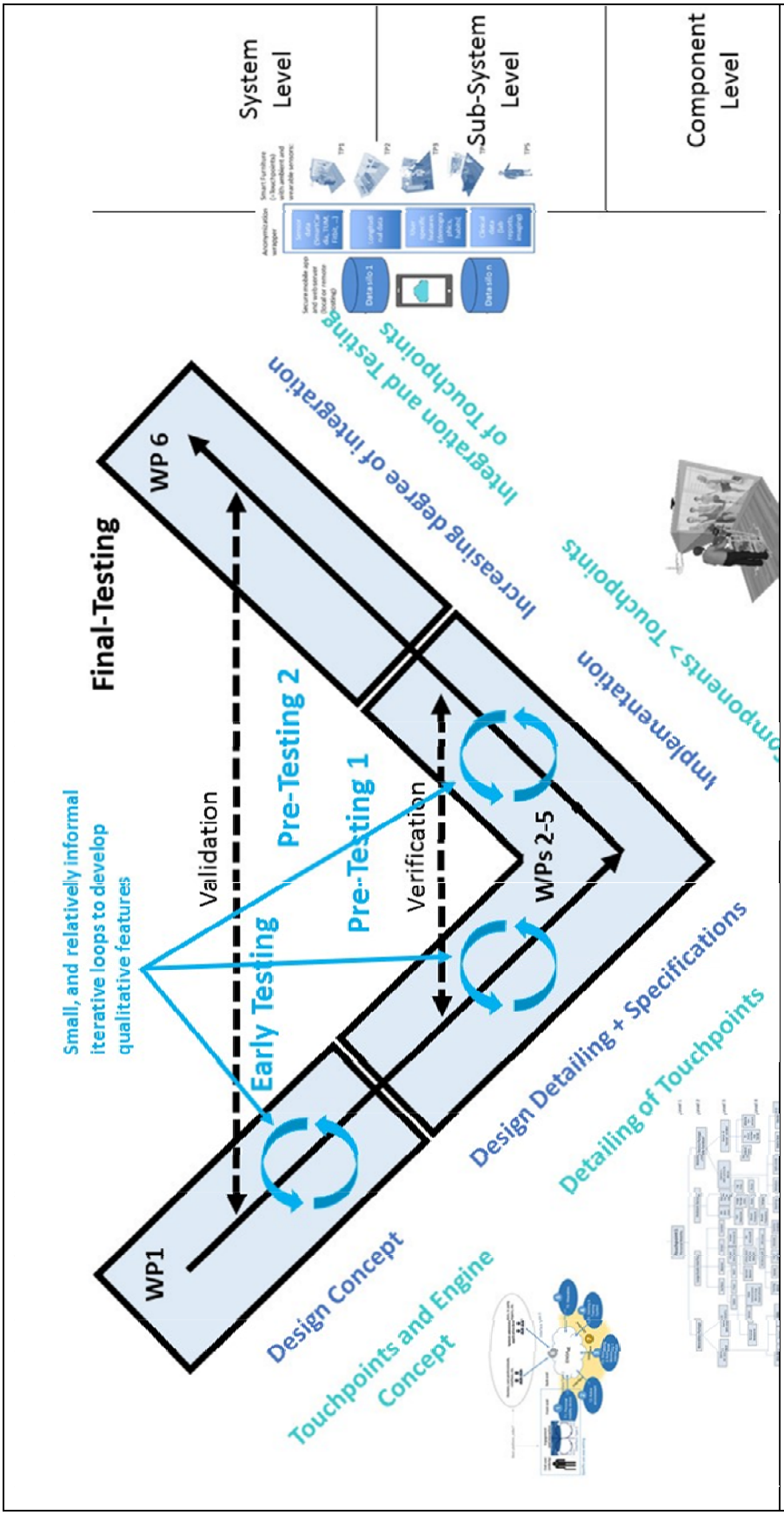

Figure 2-8: REACH flexibly utilizes and combines elements of the (1) V-Model approach, (2) Agile Management, and the (3) NASA systems engineering approach

Color code:

- **V-Model**
- **Agile Project Management**
- **NASA Systems Engineering Guideline**
- **REACH's Touchpoints and Engine Concept**

2.4 Best practice guidelines

Based on REACH's system integration management approach presented in the previous section (**Section 2.3**), as set of best practice guidelines was formulated that shall guide the design, detailing, interface conception, implementation and integration activities in REACH. **WP6.1** as a task that continues throughout the projects duration will facilitate and oversee the use of the in this section outlined practices by individual work teams (e.g. Touchpoint work teams) or development partners. The tools and methods provided (e.g. interface identification method; Product Breakdown Structure, assessment of Integration Readiness Levels) will be used by the (Touchpoints/Engine) implementation work teams as a common system detailing tools; the T6.1 participants will facilitate this process.

2.4.1 Clarify scenarios and testing plan

To allow a target oriented development of components, sub-systems and systems (e.g. Touchpoints) that consider the limited resources REACH has at hand, it is necessary that prior to implementation, the testing/validation/demonstration goals with regard to the key REACH aspects (1) early detection, (2) motivational techniques, and (3) interventions are specified. As reach is and experimental research project rather than a real product development project, it is pertinent that these testing/demonstration goals equal to the actual product to be achieved by reach's development and implementation activities. Therefore, for each Touchpoint (**Chapter 4**) separate testing instances were created and each of this testing instances represents a separate trial with an own hypothesis, own outcome measures, and an instance specific trial design. The development team of each Touchpoint can now during the implementation phase react on this testing requirements and e.g. select sensors or mechanical components in accordance with the foreseen testing plans and hypotheses (a first draft for detailed plans for each Touchpoint that consider the planned testing instances was presented in **Deliverable T1.4/D4, Chapter 3**).

2.4.2 Detail specifications

The word specification originates from the Latin word "specificatio" referring to a detailed listing of items. In systems engineering a specification refers to an exact and detailed statement with regard to the system (or its components) in question. Basically, two major categories of specifications can be distinguished:

1. Performance specifications: e.g. specification of certain requirements the system must meet)

2. Technical specifications: detailed technical description of a system part of interface).

Performance specification are rather a component of the design and planning phase whereas technical specifications are rather a component of the implementation process. As per the NASA systems engineering guideline (see also **Section 2.3.3**) the detailing of specifications regarding the system and its components and the resulting interfaces shall be a continuous and systematic process throughout the project. Specifications must get more detailed and concert the more a project progresses from conception/design to implementation and integration. Regarding REACH it is pertinent that the specifications for

(1) the 5 Touchpoints, (2) the Engine, and (3) the resulting interfaces are subject of such a continuous detailing process. The approach and roadmap for this specification detailing was presented in **Deliverable T1.4/D4**, **Chapter 5**; detailing will be done based on the REACH system architecture high-level description (**Deliverable T1.4/D4**, **Section 5.3.1).**

The level of detailing of certain specifications should be well defined. Too detailed specifications are impractical and my hinder the innovation process.

2.4.3 Systematic identification and analysis of interfaces

The systematic identification and analysis of interfaces form early design stages on is key for a successful and time and resource efficient system integration. When system integration fails due to interface issues in an iteration loop the design of the interface and sometimes even the conception or the design of the components themselves have to be changed. In REACH therefore two approaches shall be used in parallel as a tool for identification and analysis of interfaces: the Product Breakdown Structure (PBS) and the Level-vs-System Matrix. The Product Breakdown Structure (PBS) approach was previously outlined already in **Section 2.2**. The Level-vs.-System Matrix approach is outlined in **Figure** 2-9 - **Figure 2-12**. It can be used to systematically identify (1) horizontal interfaces, (2) vertical interfaces, and (3) spaghetti interfaces.

As per **Deliverable T1.4/D4** (Chapter 5) the REACH system architecture distinguishes between three major types of interfaces:

1. Interface Type 1**:** refers to the human-system interfaces including all technologies and techniques that facilitate engagement, activation, and motivation. These interfaces are strongly bound to or inherent elements of the Touchpoints.
2. Interface Type 2**:** refers to system-system interfaces between “Touchpoints” and the ICT-system “Engine” such as APIs that allow to register devices to the Engine for managing a bidirectional data and information flows.
3. Interface Type 3: refers to “b to b” interfaces between the Engine and non-end users such as care professionals, doctors, administrators, and 3dr-party application developers, etc.

These three types of interfaces can be identified and modeled by the Level-vs.-System Matrix approach.

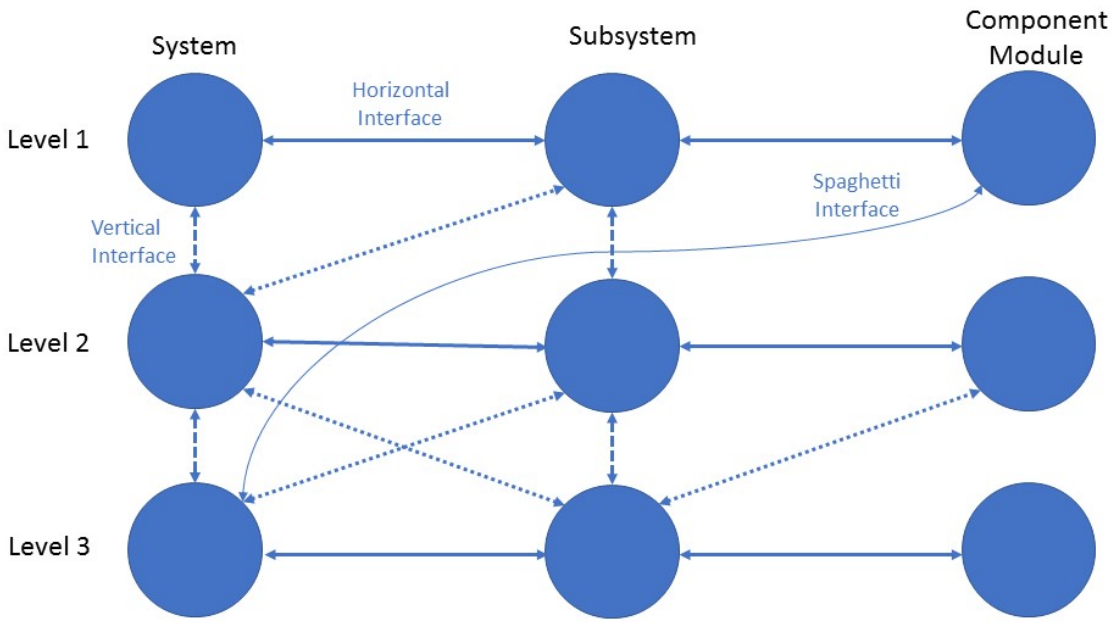

Figure 2-9: Level-vs-System Matrix general approach. The Level-vs.-System Matrix can be used to systematically identify (1) horizontal interfaces, (2) vertical interfaces, and (3) spaghetti interfaces.

	System	Sub-System	Interfaces
Societal Level	• Health Care System	• Hospital • Rehabilitation • Living	• Funding • Legal Framework
Medical Level	• Medical Care	• Doctor • Medical Assist Systems	• Scientific Exchange • Medication • Instruction
Technical Level	• General Assist System • Data Exchange • Mechanical Fit	• Touchpoints • Engine	• Data Exchange • Mechanical Fit

Figure 2-10: Level-vs-System Matrix. Exemplary definition of levels and systems

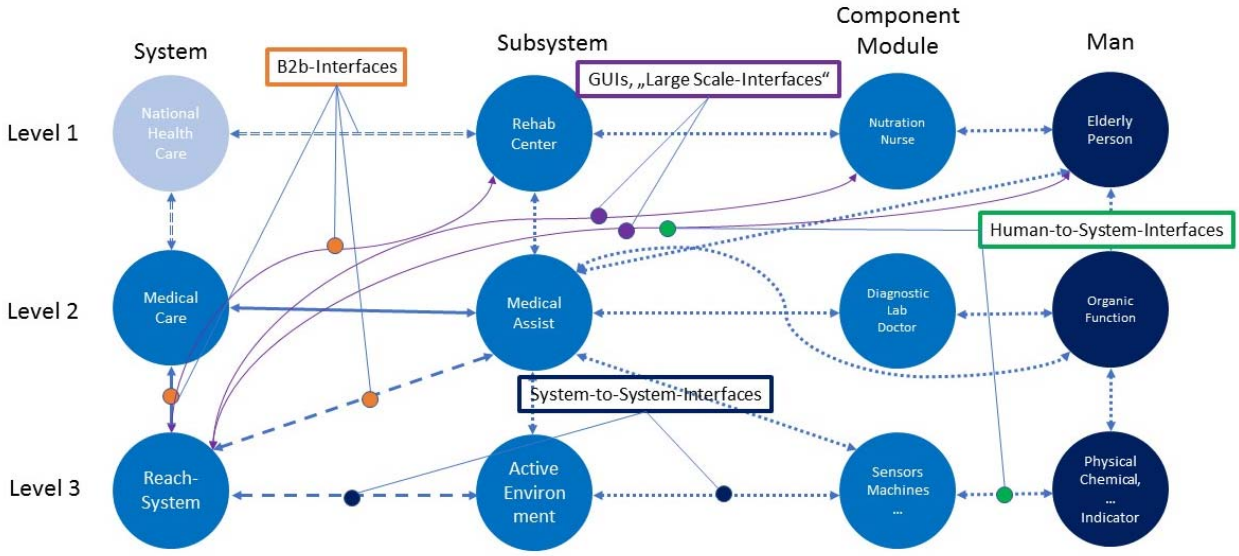

Figure 2-11: Level-vs-System Matrix used in the REACH context to identify various interfaces related to the REACH Engine

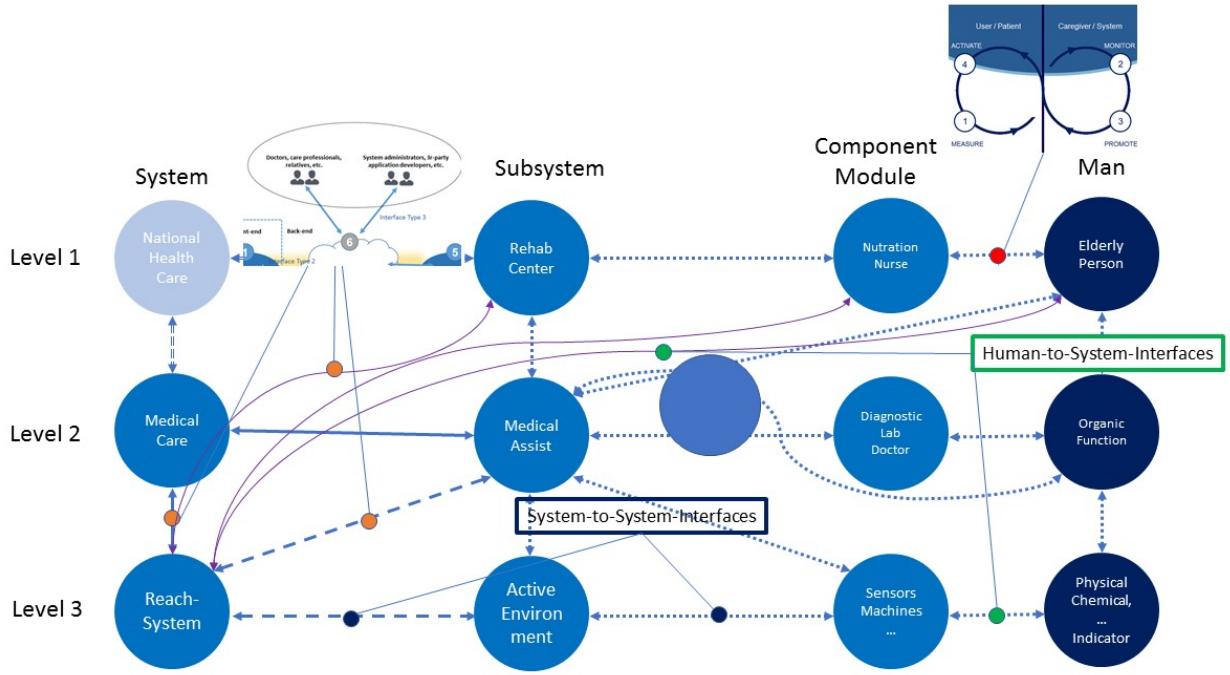

Figure 2-12: Level-vs-System Matrix used in the REACH context to identify various interfaces related to the REACH Engine

2.4.4 Review and improvement of the modular system in order to reduce and or generalize interfaces

According to Milgrom and Roberts (**Baldwin & Clark, 2000**) it is pertinent that the composition and modular structure of systems is optimized regarding the interfaces. In really “modular” systems, the interdependencies between modules and the interfaces between modules are minimized. This reduces the complexity of the integration process and allows for a more independent, parallelized development of the individual system modules. With

regard to REACH it is important interfaces between the Touchpoint and he Engine are minimized/optimized as well as the interfaces between major components within each Touchpoint. Tools that can be used to optimize modular structure of and interdependencies and interfaces are the Product Breakdown Structure (PBS; see also **Section 3.2**) and the Design Structure Matrix (DSM; see for example, (**DSMweb.org, n.d**.)). Furthermore, modularity is of particular importance in the context of the REACH Touchpoints' life cycles, since they combine elements different life-cycles (mechanical parts, sensors, software, etc.) and both the chosen interfaces and the allocation in the Touchpoint determine if and to what extent adaptability throughout the life-cycle is accomplishable.

2.4.5 Definition of cross-compatibility specifications

Cross compatibility specifications must bet set up to guarantee a flexibility in the combination of components or systems within REACH (e.g. the combination of certain Touchpoints for a certain scenario, patient journey, or use case setting) as well as to guarantee that the resulting systems of systems are compatible with the environment (e.g. existing care processes, ICT, and data recording systems in a specific use case setting).

1. System architecture specifications: High-level system architecture specifications were set up in **Deliverable T1.4/D4 (Chapter 5)** clarifying the relations, interfaces, and the modular structure of the individual Touchpoints and their sub-systems and components with the Engine and the use cases to which. As per the NASA system engineering guideline these specifications (**Section 2.4.2**) will now be gradually detailed and guide technology selection and implementation.

2. Interface specifications: besides the system architecture, and the design of individual components or systems, interfaces play a key role in guaranteeing cross-compatibility. In **Deliverable T1.4/D4 (Sections 5.5.1 – 5.5.3)** initial specifications/requirements for 1) human-system interface (e.g. regarding intuitiveness, scalable GUI, gesture control), 2) system-system interface (transmission protocols, message brokers, scrips), and 3) B2B interfaces (GUI for professionals, developer GUI) were provided. In the implementation phase The Touchpoints and Engine work teams must detail these initial specifications and select suitable interface technologies, protocols, and standards.

3. Sensing and data analytics process specifications: In REACH test with various types of sensors will be conducted in a variety of use case settings in different countries and under the control of different study leaders. In order to be able to exploit the resulting data sets efficiently by using data analytics algorithms, these data sets and the process of creating them must follow certain specifications. The analysis of sensor measurements can only work well if there is a clear specification of all the relevant context parameters of the sensing process. Algorithms usually need to be fed with accurate and well understood historic time series data. These data need to be labelled with the time points when interesting events happened. And those time points should be very precise. If one can provide such data to the algorithms for training, the resulting classifiers will eventually be able to associate characteristic patterns of sensor measurements with the activity classes. The requirements for the specifications were identified and categorizes in **Deliverable T1.4/D4 (Section 5.6)** into 1) sensor specifications, 2) scenario specifications, 3) annotations specifications,

and 4) data format specifications. The detailing of this specifications will be accomplished jointly by the now starting **WPs 2** (sensing) and **WP3** (data analytics). The detailed list of specifications will be distributed then to all use case settings and the testing coordination partners.

4. Standards related to interfaces and interoperability: The application of standards both for the development of sub-systems/systems and interfaces is an important facilitator for ensuring cross-compatibility, Standards embed best practices and provide usually a common denominator among researchers and developers in a field. The adherence to an incorporation of standards at best avoids a lengthy and iterative interface development and integration process. Of particular interest with regard to system integration in REAC are standards related to interfaces and interoperability, such as ISO/TR 16056-1:2004 (Health informatics - Interoperability of telehealth systems and networks - Part 1: Introduction and definitions) or IEEE 11073-10101*ISO/IEEE 11073-10101(Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature). For a detailed overview over interface/interoperability related standards relevant in the context of REACH, see **Chapter 3**.

2.4.6 Tracking of technology and integration readiness levels

In REACH, scales bound to Technology Readiness Levels (TRLs), Integration Readiness Levels (IRLs): System Readiness Levels (SRLs) will be used to track the progress and maturity of the developments and integration of the work of the various working groups (e.g. working groups around Touchpoints). The method suggested by (**Sauser, et al., 2006**) is applied in which the SRL is determined based on the TRLs and IRLs determined for the components of the system in question.

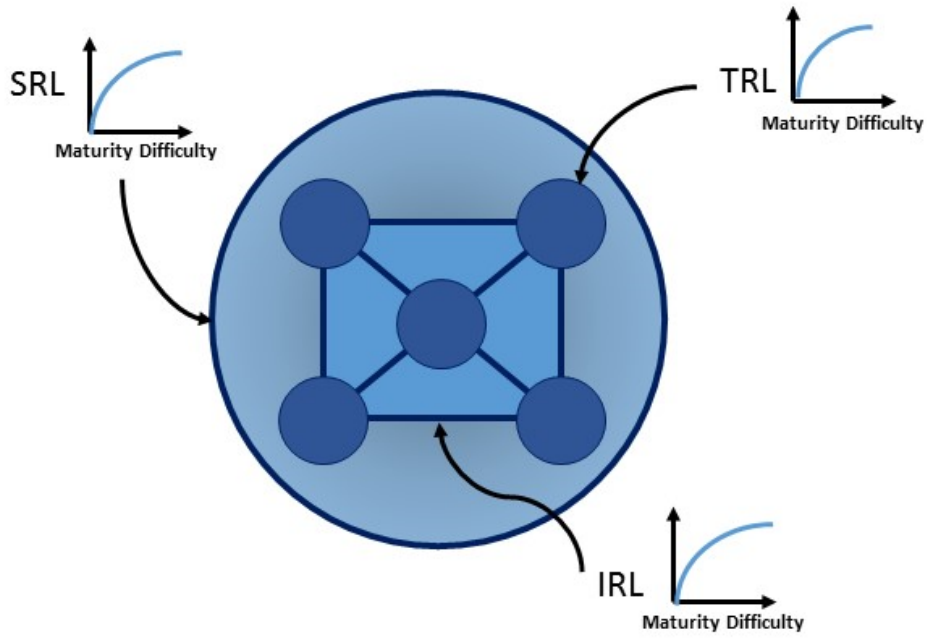

Figure 2-13: TRL-SRL-IRL Interrelation according to Sauser et al. (2006)

Technology Readiness Levels (TRLs): TRLs are used to characterize the maturity of a certain technology or component of a system.

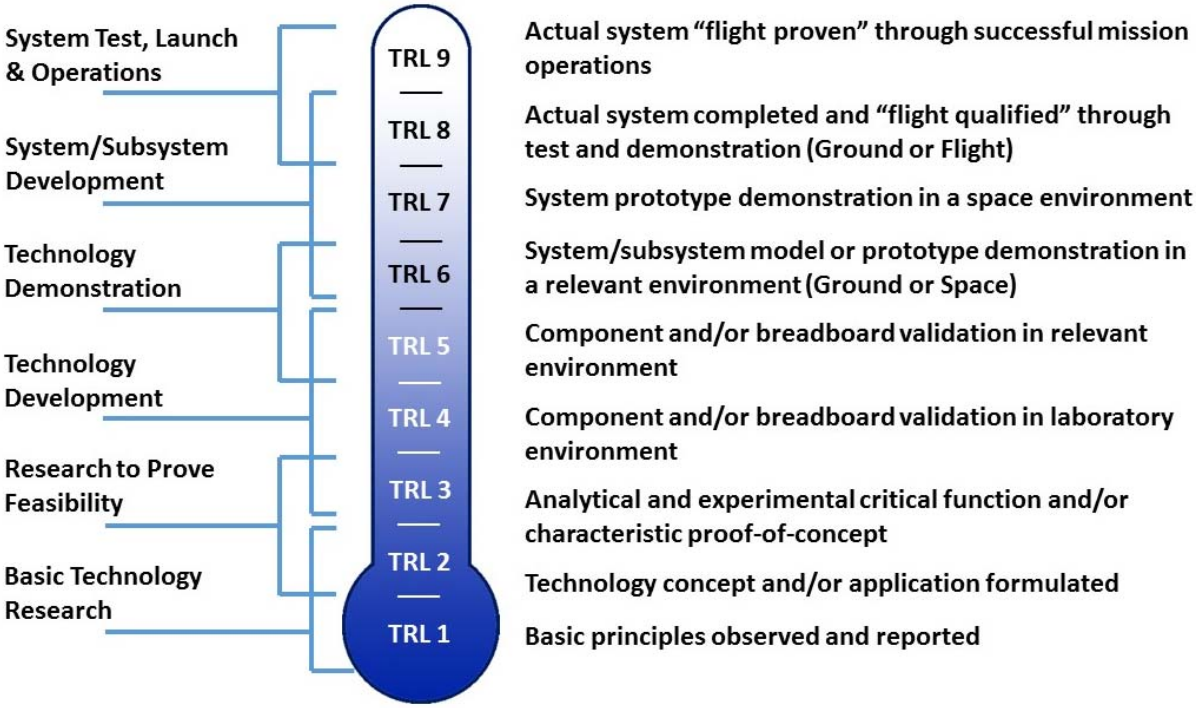

Figure 2-14: TRLs according to NASA standard for hardware/product development (after NASA, 2012)

Integration Readiness Levels (IRLs): Integration Readiness Levels determine the degree of maturity of an interface and/ or an integration procedure.

Table 2-1: IRLs according to Sauser et al. (2006). (Image: adopted from Sauser et al., 2006)

IRL	Definition
7	The integration of technologies has been verified and validated with sufficient detail to be actionable.
6	The integration technologies can accept, translate, and structure information for its intended application.
5	There is sufficient control between technologies necessary to establish, manage, and terminate the integration.
4	There is sufficient detail in the quality and assurance of the integration between technologies.
3	There is compatibility (i.e. common language) between technologies to orderly and efficiently integrate and interact.
2	There is some level of specificity to characterize the interaction (i.e. ability to influence) between technologies through their interface.
1	An interface (i.e. physical connection) between technologies has been identified with sufficient detail to allow characterization of the relationship.

System Readiness Levels (SRLs): System Readiness Levels determine the degree of maturity of the whole system with a special focus on the readiness of both sub-systems and interfaces.

Table 2-2: SRLs according to US Department of Defense and Sauser et al. (2006). (Image: adopted from Sauser et al., 2006)

SRL	Name	Definition
5	Operations & Support	Execute a support program that meets operational support performance requirements and sustains the system in the most cost-effective manor over its total life cycle.
4	Production & Development	Achieve operational capability that satisfies mission needs.
3	System Development & Demonstration	Develop a system or increment of capability; reduce integration and manufacturing risk; ensure operational supportability; reduce logistics footprint; implement human systems integration; design for producibility; ensure affordability and protection of critical program information; and demonstrate system integration, interoperability, safety, and utility.
2	Technology Development	Reduce technology risks and determine appropriate set of technologies to integrate into a full system.
1	Concept Refinement	Refine initial concept. Develop system/technology development strategy.

2.5 Cross-compatibility with Philip's HSDP (and other platform systems)

As outlined in **Deliverable T1.4/D4 (Appendix 4)** the REACH partners analyzed in detail a variety of proprietary and non-proprietary, open source platforms for which the consortium sees the possibility to host parts of the in REACH developed technologies and techniques, and to which it in general considers to establish cross-compatibility links.

Following platforms were considered in terms of the establishment of cross-compatibility links:

1) DHIS2 open source framework
2) Pryv Middleware
3) REACH adapted version of Smart Cardia's platform solution
4) Philips Health Suite Digital Platform

The analysis clarified for each of the analyzed platforms the following performance items:

1) Certification/ compliance: medical ethics compliance, data protection compliance
2) Data warehouse: access control, logging, data segregation, APIs, etc.
3) Data anonymity: e.g. pseudo-anonymization administration, K-Anonymity realization, etc.
4) Functionality of a time series data base: e.g. allow for easy retrieval of data for specific time points across different data channels
5) Support for user interaction: e.g. enables push notification system allowing for feedback/communication with the end user?
6) Categorization of technical system: data live feed from sensors, data management possible, etc.

To establish a solid base in the EU in health care ICT-platforms, as part of ongoing work in **WPs 2** (sensing), **WP3** (data analytics), and **WP6** (standards and system integration support) it was discussed, whether it is better to establish for REACH technologies and techniques (Touchpoints, sensors, motivational strategies, analytics algorithms, etc.) cross-compatibility protocols only with Philips HSDP or alternatively with a variety of platforms to demonstrate their viability. To be able to really strengthen Europe's support in the health care ICT market, the consortium sees it as necessary to demonstrate principal cross-

compatibility with a variety of platforms, given the fact that several REACH partners are working on (and plan to introduce) their own platforms in future (e.g. Smart Cardia, ArjoHuntleich, Alreh Medical). As outlined in Deliverable **T1.4/D4** (**Section 5.4.1**), REACH will demonstrate cross compatibility in earlier project phases with SC's platform and in later project phases with Philip's HSDP. Therefore, REACH's ICT core (linked to which various Touchpoints and Engine functionalities can be demonstrated) will in a first step be implemented as an ad-hoc, Smart Cardia based research version that allows to centrally manage and store all data gathering activities and in later project phases cross links to Philip's proprietary HSDP will be created.

Figure 2-15 shows that REACH develops a pool of technologies and techniques that shall be exploitable in general for a variety of project internal and project external platforms. Primary demonstration cases in REACH will be the Platforms of Philips and SC. **Figure** 2-16, shows, that APIs will serve as the primary interface and mediator between a specific platform and the REACH devices and items such as Touchpoints, sensors, and existing data bases. APIs are specific for a certain platform and may come, for example, in the form of predefined programming elements, libraries, or message brokers. In order to allow REACH devices and items to be cross compatible with (or better: efficiently adaptable to) several platforms the device control element shall be split API adapted communication software module and a generic device task execution software.

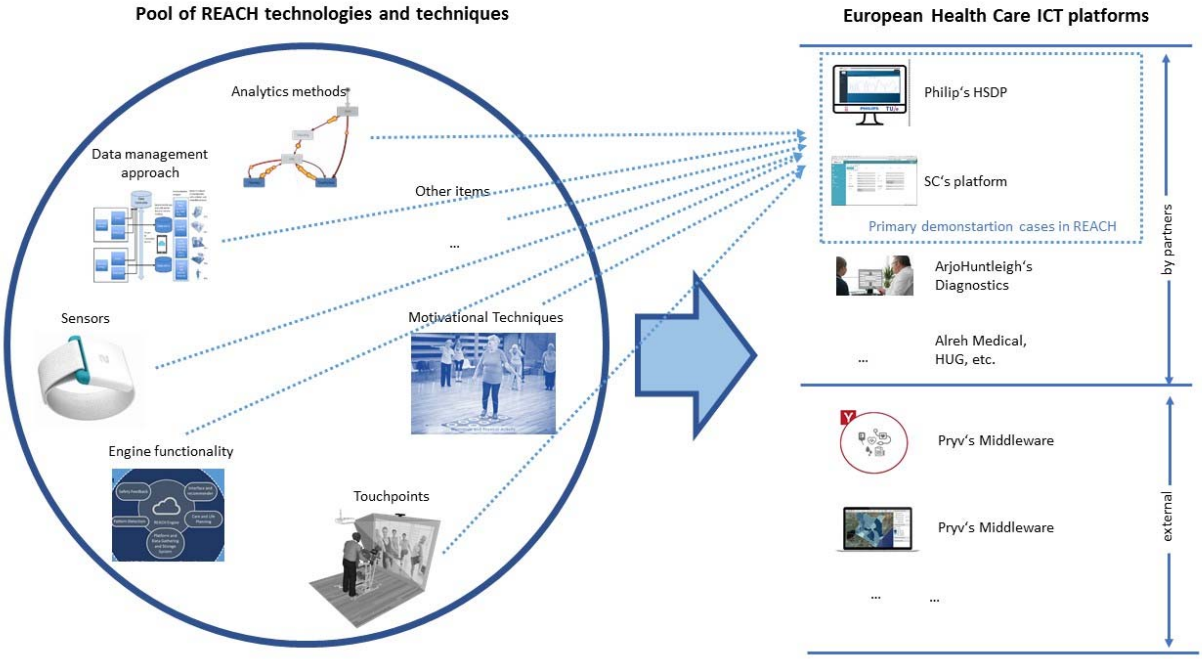

Figure 2-15: REACH develops a pool of technologies and techniques that shall be exploitable in general for a variety of project internal and project external platforms. Primary demonstration cases in REACH will be the Platforms of Philips and SC

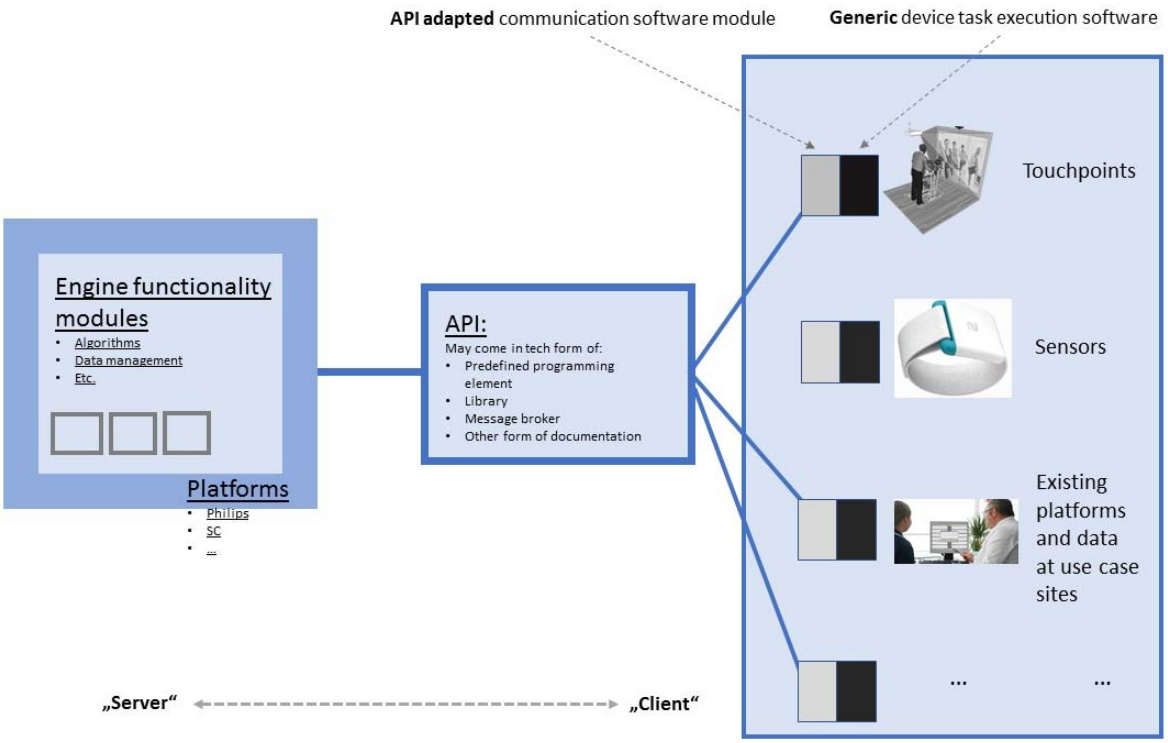

Figure 2-16: APIs will serve as the primary interface and mediator between a specific platform and the REACH devices and items such as Touchpoints. In order to allow REACH devices and items to be efficiently adaptable to several platforms the device control element

3 Standardization: identification and analysis of applicable standards with regard to the implementation of the Touchpoint/Engine concept

A standard is a consensus based document that is approved by a recognized body. It provides for common and repeated use, rules, guidelines or characteristics for activities or their results aimed to reflect the state of the art. It should be based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits. (**DIN, 2012**) Standardization activities are considered in REACH to transfer relevant research results into standardization and make correspondent results publicly available even after the research project terminates.

3.1 Standardization landscape and European policy

Standardization landscape comprises of organizations responsible of standardization activities conducted on national, European as well as international level (see **Figure 3-1**).

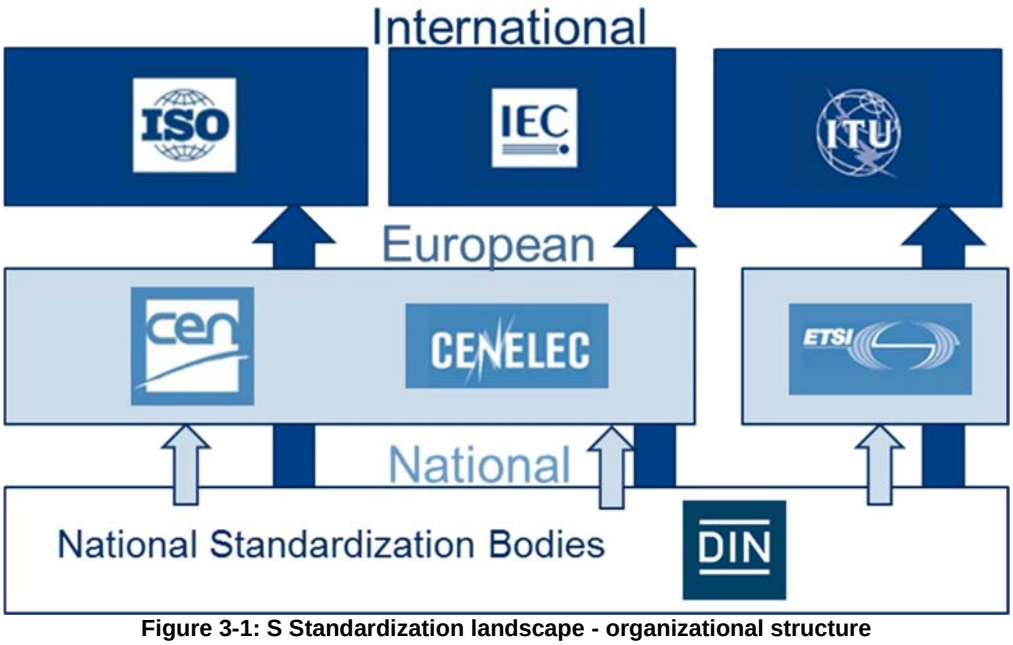

Figure 3-1: S Standardization landscape - organizational structure

Currently industry-related fora and consortia, that are not represented by national standardization bodies, CEN or ISO, have to be considered as well when mentioning the standardization landscape.

3.1.1 European standardization

The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) as well as the European Telecommunication Standards Institute (ETSI) carryout the standardization work on European level. Common standards applied across the whole of the European single market ensures protection of consumers and interoperability of products, encourage innovation and technological

development. CEN and CENELEC provide the platform for European standardization. **(CEN, 2017**)

The European standardization organizations CEN and CENELEC associate national standards bodies according to Belgian law. Members of CEN and CENELEC are first and foremost the national standards organizations of EU and EFTA member states, and the national standards organizations of other countries intending to become members of the EU or EFTA. CEN/CENELEC organs such as the General Assembly, Administrative and Technical Boards and Technical Committees are open to all members, and include national delegations presenting agreed positions. European organizations which represent a particular sector may have observer status. In addition to the full members, there are also affiliated standards bodies and associate organizations.

In 1988, ETSI developed from the standardization activities of the European Conference of Postal and Telecommunications Administrations. It does not involve national delegates, its members being stakeholders from industry, organizations and government. (**Hartlieb, 2009**) On European level different standardization documents are available. Each of this represents a different level of consensus. The European Standard (EN) is a technical document reflecting the current state of technology and knowledge and designed to be used as rule, guideline or definition. **(CEN, 2017**) While developed, the standstill policy comes into force. This means that during work on a European standard and after its publication, CEN/CENELEC Members agree not to publish national standards which are not in line with it. This is done to prevent any situation occurring during the preparation or after publication of a standard which could impair or undermine harmonization. National standards which are in conflict or duplicate EN standards should be withdrawn as an EN automatically becomes a national standard.

One special type of EN is the mandated European standard (harmonized EN), which is applied in the context of the New Legislative Framework (a.k.a. New Approach) and developed on the basis of a mandate from the European Commission to set out the Essential Requirements for the product or service that are specified in an EC Directive. These Essential Requirements deal in particular with the health and safety of users and other fundamental matters. It has no special designation, except from a note in the foreword of the standard.Other products of European standardization include European Technical Specifications (CEN/TS) which aim to aid market development and growth for products or methods that are still in the development and/or trial phase, and European Technical Reports (CEN/TR) which provide specifications of a recommendatory and explanatory nature. Special specifications, which are developed with the rapid consensus of expert stakeholders (no full consensus needed), can be found in CEN Workshop Agreements (CWA). All document types differ in their development procedures and binding forces. (**Hartlieb, 2009**)

Relevant CEN/TCs

The following Technical committees are the most relevant ones to be considered in context of active and healthy ageing:

- CEN Healthcare Services Focus Group
- CEN/TC 3 Quality management and corresponding general aspects for medical devices
- CEN/TC 122 Ergonomics

- CEN/C 206 Biological and clinical evaluation of medical devices
- CEN/TC 251 Health informatics
- CEN/TC 293 Assistive products for persons with disability
- CEN/TC 362 Healthcare services – Quality management systems
- CEN/TC 431 Service Chain for Social Care Alarms
- CEN/TC 449 Quality of care for older people
- CEN/TC 450 Patient involvement in person-centered care
- CEN-CENELEC Joint Working Group 5 – Design for All
- CEN/TC 224/WG 6 User interface
- CEN Healthcare Services Focus Group

3.1.2 International standardization

The International Organization for Standardization (ISO) (**ISO, 2017**) as well as the International Electrotechnical Commission (IEC) (**IEC, 2017**) are the responsible standardization organizations on global level. The United Nations specialized agency in terms of information and telecommunication technologies is the International Telecommunications Union (ITU) (**ITU, 2017**). ISO, IEC and ITU established the WSC - The World Standards Cooperation in 2001, in order to strengthen and advance their voluntary consensus-based international standards systems **(World standards cooperation, 2017**). Currently 163 national standards bodies are members in ISO (**ISO, 2017**). This means “Codes of practices” have to be established in order to allow a smooth operation of the standardization process on international as well as on European level. Therefore l the Vienna and Dresden Agreements have been concluded. Those agreements between CEN and ISO (Vienna), CENELEC and IEC (Dresden) got the objective, to carry out work at one level of standardization (where possible), and use parallel voting procedures to achieve simultaneous adoption as ISO/IEC and EN standards.

Relevant ISO/TCs and IEC/TCs

Ageing societies is considered a most relevant future topic in international standardization landscape. (**ISO, 2017, p. 1 ff**). An ISO Technical Management Board strategic advisory group on ageing societies (ISO/TMBG/SAG on Ageing Societies) has been established that aims to inform the future ISO work in supporting the demographic transition **(ISO, 2017**). Furthermore some relevant Technical Committees (**ISO, 2017**) in terms of assistive technologies, enhancement of elderly people, ageing societies, active and customized healthcare for elderly people have to be mentioned, such as:

- ISO/IEC JTC 1 Information technology
- ISO/TC 83 Sports and other recreational facilities and equipment
- ISO/TC 136 Furniture
- ISO/TC 159 Ergonomics
- ISO/TC 173 Assistive products for persons with disability
- ISO/TC 194 Biological and clinical evaluation of medical devices
- ISO/TC 210 Quality management and corresponding general aspects for medical devices
- ISO/TC 215 Health informatics
- ISO/TC 304 Healthcare administration
- ISO/COPOLCO Committee on consumer policy

Besides these committees listed IEC Technical committees exist that are relevant in context of Reach:

- IEC/TC 100 Audio, video and multimedia systems and equipment – TA 16 Active Assisted Living (AAL), accessibility and user interfaces
  IEC SyC AAL Active Assistive Living

3.1.3 National standardization bodies

German Institute for Standardization (DIN), British Standards Institute (BSI) and Nederlandse Norm (NEN) are national standardization organizations of whom different exist on national level. In Europe each member state is represented by a national standardization body within CEN (**CEN, 2017**). Nevertheless each national standardization body develops national standards as far as no EN standards exist on a particular scope. In some situations where more requirements suiting to specific needs of the member state are needed, it is possible to complement EN standards with additional national standards.

3.1.4 European policy

European directives are restricted to determine protection objectives which are formulated as fundamental requirements. The directive refers to European standards in order to fulfil those requirements (**Hartlieb, 2009, p. 81**). In this context European Commission requests CEN and CENELEC to develop European Standards to support legislation. This specific "standardization request" or "mandates" appear in a number of areas, amongst others healthcare. (**CEN, 2017**) Mandated standards are called "Harmonized standards". Their titles and references are published in the "Official Journal of the European Union" (**CEN, 2017**). The current lists of harmonized standards published are available on a dedicated website of the European Commission.

3.1.4.1 Medical devices

CEN and CENELEC were mandated by the European Commission to support legislation in the field of medical equipment according to Directive 93/42/EEC on Medical Devices **(EC, 1993**), Directive 90/385/EEC on Active Implantable Medical Devices (**EC, 1990**) as well as Directive 98/79/EC on In vitro Diagnostic Medical Devices (**EC, 1998**) (**CEN, 2017**). In 2012, a package of measures on innovation in health has been adopted by the European Commission. The aim of this package has been for instance to revise existing legislation on medical devices and to replace Directive 90/385/EEC and 93/42/EEC by a Regulation on medical devices. All kinds of medical devices have been affected by the revisions. The Council and the European Parliament agreed on a final text of the proposed regulation in June 2016 (**Council and European Parliament, 2016**). Final formal adaption is expected during first half of 2017 (**EC, 2016**).

- Mandates:
  Four mandates from European Commission to CEN and CENELEC are currently ongoing:

- M/023 (1993) Standardization mandate to CEN/CENELEC concerning the development of European Standards relating to medical devices (complemented by M/295)
- M/295 (1999) Standardization mandate to CEN/CENELEC concerning the development of European Standards relating to medical devices
- M/252 (1997) Standardization mandate to CEN/CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices
- M/467 (2010) Standardization mandate addressed to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children on medical cost (**CEN, n.d.**) (**CEN, 2017**).

3.1.4.2 E-health

- EU Directive 93/42/EEC on Medical Devices (**EC, 2017**), Directive 2007/47/EC: It does not cover explicitly standalone health software (**CEN, 2017**). Directive 2007/47/EC (amendment of Directive 93/42/EEC) states "[…] It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device […]" (**EC, 2007**). CEN/TC 251 Health informatics established a group of experts on "Software as a medical devices" (SAMD) that contributed to the development of EU Guideline document MDDEV 2.1/6. "Guidelines on the qualification and classification of standalone software use in healthcare within the regulatory framework of medical devices" (**CEN, 2017**).

- Mandate: M/403 (2007) Standardization mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth

As response to M/403 the "eHealth-INTEROP report" provided a set of recommendations related to interoperability in the Health informatics domain (**e-health Interop, 2016**).

3.2 Methodology for the research and analysis of existing standards

The basis for the research on relevant standards in the REACH context was a set of keywords grouped in different clusters. In the project context different products and applications can be developed. To provide information for each of the possible research outcomes an extensive list of keywords has been gathered and clustered in cooperation with the project partners. A complete list of keywords can be found in the **Appendix 1**. These keywords have been used to perform the standards research within the DIN standards data base PERINORM. Beside the standards of European national organizations like e. g. DIN, NEN or BSI and Non-European national standardization organizations e. g. from Brazil, USA or South Africa, the database also includes standards from the European organizations CEN, CENELEC, ETSI and international organizations such as ISO, IEC and ITU. Regulations, technical documents and reports on these levels have been considered for the analysis. In case of national standards it has to be stated that due to language barriers mostly those providing at least an English title have been considered. PERINORM presents large amounts of standards when entering popular keywords like "service". In this case

several keywords were combined. Another measure to reduce search entries was to filter according to suggested categories.

In order to reduce the still large amount of standards from the initial search, refinement was carried out. The keywords were assigned to the touchpoint and engine concepts developed in **Task 1.4** to focus the search for relevant standards according to expected outcomes. Duplicates were not removed to allow filtering according to keywords within each spreadsheet. The standards were then analyzed per touchpoint or engine concept. First, DIN suggested most important standards within each touchpoint or engine cluster. Afterwards, the respective touchpoint or engine leaders evaluated the suggested standards regarding their relevance for the different touchpoint and engine concepts. This process led to a number of most important standards per touchpoint and engine concept provided in **Chapter 3.3**. The provided list of standards will be updated in the course of the project. Within the REACH project **WP6** as well as **WP8** will deal with standardization activities. Therefore, the upcoming work packages are going to consider this report as a basis and trying to refine conclusion and suggestions in context of standardization needs and activities. The knowledge of existing standards will help to develop products and services along with the status quo.

3.3 Results of the analysis of existing standards

In collaboration with the project partners around 100 keywords were collected and structured in the following clusters:

- Equipment
- Services
- Health Care Platforms
- Testing and Data Collection
- Early/Preemptive Intervention
- Other.

The gathering of relevant keywords was performed in autumn 2016 in the context of **Task 6.1**. A complete list of keywords can be found in the **Appendix 1** (**Section 6.1.2**). Based on these keywords an extensive standards research was conducted. More than 960 standards were identified in the context of the interdisciplinary research and development performed in the REACH research project. This first overview of standards was finalized in February 2017. During the standard research some keywords delivered no search results.

These keywords are:

- Early/preemptive intervention
- Motivation
- Gamification
- GET / POST requests
- Home appliance
- Design for all
- Distance walked
- Fluid intake
- Skin conductance
- Skin humidity
- Weight

- Height
- Thoracic fluid level.

Technologies and services in the context of Ageing Societies can be identified that are not yet developed or standardized by analyzing these keywords. This information gives a hint on which areas are well suited for further research and development activities. During the PERINORM research, the list of entries presented per keyword was filtered. Entries were mostly filtered according to the categories home related services, selected IT applications and medicine. These product or service categories are close to the innovations that are expected to be developed within REACH.

The next step was to align the keywords to the touchpoint and engine concepts for structuring and plainer consultation. The following lists present the most important standards per touchpoint and engine concepts. The number of relevant standards is roughly between 10 and 40 standards per concept. The extensive list of standards is provided in the **Appendix 1**.

3.3.1 Touchpoint 1: Mobility

Document No.	Title	Date of publication	Author
IEC/TR 62678*CEI/TR 62678	Audio, video and multimedia systems and equipment - Activities and considerations related to accessibility and usability	2010-10-00	IEC/TC 100 Sound, vision and multimedia systems and equipment
ISO 11156	Packaging - Accessible design - General requirements	2011-07-00	ISO/TC 122 Packaging*
ISO/IEC TR 19766	Information technology - Guidelines for the design of icons and symbols accessible to all users, including the elderly and persons with disabilities	2007-06-00	ISO/IEC JTC 1/SC 35 User interfaces*ISO/CEI JTC 1/SC 35 Interfaces utilisateur
ISO/IEC 29136	Information technology - User interfaces - Accessibility of personal computer hardware	2012-05-00	ISO/IEC JTC 1/SC 35 User interfaces*ISO/CEI JTC 1/SC 35 Interfaces utilisateur
ANSI/CTA 2056	Physical Activity Monitoring for Fitness Wearables Step Counting	2016-00-00	American National Standards Institute (ANSI)*American National Standards Institute
IEEE 11073-00103	Health Informatics - Personal health device communication - Part 00103: Overview	2012-00-00	IEEE Engineering in Medicine and Biology Society
DIN SPEC 91280	Ambient Assisted Living (AAL) - Classification of Ambient Assistant Living services in the home environment and immediate vicinity of the home	2012-09-00	DIN SPEC (PAS, CWA)
IEEE 2700	IEEE Standard for Sensor Performance Parameter Definitions	2014-00-00	IEEE Electron Devices Society
FprEN 15224	Quality management systems - EN ISO 9001:2015 for healthcare	2016-10-00	CEN/TC 362 Healthcare services - Quality management systems
EN ISO 9241-161	Ergonomics of human-system interaction - Part 161: Guidance on visual user-interface elements (ISO 9241-161:2016)	2016-03-00	CEN/TC 122 Ergonomie*CEN/TC 122 Ergonomics
EN ISO 9241-420	Ergonomics of human-system interaction - Part 420: Selection of physical input devices (ISO 9241-420:2011)	2011-07-00	CEN/TC 122 Ergonomie*CEN/TC 122 Ergonomics

IEC 62366-1 Corrigendum 1*CEI 62366-1 Corrigendum 1	Medical devices - Part 1: Application of usability engineering to medical devices; Corrigendum 1	2016-07-00	IEC/SC 62A Common aspects of electrical equipment used in medical practice
ISO 11199-2	Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators	2005-04-00	ISO/TC 173 Assistive products for persons with disability
ISO/DIS 9241-333	Ergonomics of human-system interaction - Part 333: Stereoscopic displays using glasses	2016-03-00	ISO/TC 159 Ergonomics
ISO/DIS 9241-960	Ergonomics of human-system interaction - Part 960: Framework and guidance for gesture interactions	2015-08-00	ISO/TC 159 Ergonomics
ISO/IEC TR 15440	Information technology - Future keyboards and other input devices and entry methods	2016-02-00	ISO/IEC JTC 1/SC 35 User interfaces
15/30302181 DC	BS ISO/IEC 18305. Information technology. Real time locating systems. Test and evaluation of localization and tracking systems	2015-09-10	IST/34
ISO/IEC DIS 18305	Information technology - Real time locating systems - Test and evaluation of localization and tracking systems	2015-09-00	ISO/IEC JTC 1/SC 31 Automatische Identifikation und Datenerfassungsverfahren*ISO/IEC JTC 1/SC 31*ISO/CEI JTC 1/SC 31
ISO/DIS 80601-2-61	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	2016-10-00	ISO/TC 121 Anaesthetic and respiratory equipment
IEEE 1708	IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices	2014-00-00	IEEE Engineering in Medicine and Biology Society
EN 60601-1-6/A1	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010/A1:2013)	2015-05-00	CLC/TC 62 Electrical equipment in medical practice
JIS S 0012	Guidelines for all people including elderly and people with disabilities - Usability of consumer products	2000-11-20	Technical committee for older persons and persons with disabilities
JIS S 0012/ERRATUM 1	Guidelines for all people including elderly and people with disabilities - Usability of consumer products (Erratum 1)	2001-00-00	Technical Committee on Consumer Life Products
JIS X 8341-3	Guidelines for older persons and persons with disabilities - Information and communications equipment, software and services - Part 3: Web content	2016-03-22	Technical Committee on Information Technology
EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)	2015-04-00	CLC/TC 62 Electrical equipment in medical practice
EN 62366-1/AC	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015); Corrigendum	2015-12-00	CLC/TC 62 Electrical equipment in medical practice
IEC 62366	Medical devices - Application of usability engineering to medical devices	2007-10-00	ISO/TC 210 Quality management and corresponding general aspects for medical devices

IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02-00	ISO/TC 210 Quality management and corresponding general aspects for medical devices
IEC/TR 62366-2	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	2016-04-00	ISO/TC 210 Quality management and corresponding general aspects for medical devices
FprEN ISO 11073-10441	Health informatics - Personal health device communication - Part 10441: Device specialization - Cardiovascular fitness and activity monitor (ISO/IEEE 11073-10441:2015)	2016-09-00	CEN/TC 251 Health informatics
VDE-AR-E 2757-2	Service Staying at Home - Requirements for suppliers of combined services	2011-08-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
ETSI TS 103378 V 1.1.1	Smart Body Area Networks (SmartBAN) Unified data representation formats, semantic and open data model	2015-12-00	ETSI/SmartBAN
DSF M303545	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO/DIS 17664:2016)		S-259
NEMA HN 1	Manufacturer Disclosure Statement for Medical Device Security	2013-00-00	NEMA National Electrical Manufacturers Association
IEC 82304-1*CEI 82304-1	Health software - Part 1: General requirements for product safety	2016-10-00	IEC/SC 62A Common aspects of electrical equipment used in medical practice
NPR-ISO/TR 16056-2:2004 en	Health informatics - Interoperability of telehealth systems and networks - Part 2: Real-time systems	2004-07-01	303006: Informatievoorziening in de zorg

3.3.2 Touchpoint 2: Active

Document No.	Title	Date of publication	Author
EN ISO 11073-10471	Health Informatics - Personal health device communication - Part 10471: Device specialization - Independent living activity hub (ISO/IEEE 11073-10471:2010)	2011-03-00	CEN/TC 251 Health informatics
IEEE 11073-00103	Health Informatics - Personal health device communication - Part 00103: Overview	2012-00-00	IEEE Engineering in Medicine and Biology Society
ISO/IEEE 11073-10471	Health informatics - Point-of-care medical device communication - Part 10471: Device specialization - Independant living activity hub	2010-05-00	CEN/TC 215 Health informatics
EN ISO 12967-2	Health informatics - Service architecture - Part 2: Information viewpoint (ISO 12967-2:2009)	2011-03-00	CEN/TC 251 Health informatics
EN ISO 21090	Health Informatics - Harmonized data types for information interchange (ISO 21090:2011)	2011-02-00	CEN/TC 251 Health informatics
EN ISO 21549-2	Health informatics - Patient healthcard data - Part 2: Common objects (ISO 21549-2:2014)	2014-02-00	CEN/TC 251 Health informatics

FprEN 15224	Quality management systems - EN ISO 9001:2015 for healthcare	2016-10-00	CEN/TC 362 Healthcare services - Quality management systems
CEN ISO/TR 9241-308	Ergonomics of human-system interaction - Part 308: Surface-conduction electron-emitter displays (SED) (ISO/TR 9241-308:2008)	2015-12-00	CEN/TC 122 Ergonomics
CEN ISO/TR 9241-309	Ergonomics of human-system interaction - Part 309: Organic light-emitting diode (OLED) displays (ISO/TR 9241-309:2008)	2015-12-00	CEN/TC 122 Ergonomics
CEN ISO/TR 9241-310	Ergonomics of human-system interaction - Part 310: Visibility, aesthetics and ergonomics of pixel defects (ISO/TR 9241-310:2010)	2015-12-00	CEN/TC 122 Ergonomics
CEN ISO/TR 9241-331	Ergonomics of human-system interaction - Part 331: Optical characteristics of autostereoscopic displays (ISO/TR 9241-331:2012)	2013-09-00	CEN/TC 122 Ergonomics
CEN ISO/TS 9241-411	Ergonomics of human-system interaction - Part 411: Evaluation methods for the design of physical input devices (ISO/TS 9241-411:2012)	2014-08-00	CEN/TC 122 Ergonomics
EN 12183	Manual wheelchairs - Requirements and test methods	2014-03-00	CEN/TC 293 Assistive products for persons with disability
EN 12520	Furniture - Strength, durability and safety - Requirements for domestic seating	2015-12-00	CEN/TC 207 Furniture
EN ISO 11199-2	Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators (ISO 11199-2:2005)	2005-04-00	CEN/TC 293 Assistive products for persons with disability
EN ISO 11199-3	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables (ISO 11199-3:2005)	2005-04-00	CEN/TC 293 Assistive products for persons with disability
EN ISO 9241-110	Ergonomics of human-system interaction - Part 110: Dialogue principles (ISO 9241-110:2006)	2006-04-00	CEN European Committee for Standardization
EN ISO 9241-151	Ergonomics of human-system interaction - Part 151: Guidance on World Wide Web user interfaces (ISO 9241-151:2008)	2008-05-00	CEN/TC 122 Ergonomie*CEN/TC 122 Ergonomics
EN ISO 9241-154	Ergonomics of human-system interaction - Part 154: Interactive voice response (IVR) applications (ISO 9241-154:2013)	2013-02-00	CEN/TC 122 Ergonomie*CEN/TC 122 Ergonomics
EN ISO 9241-161	Ergonomics of human-system interaction - Part 161: Guidance on visual user-interface elements (ISO 9241-161:2016)	2016-03-00	CEN/TC 122 Ergonomie*CEN/TC 122 Ergonomics
ISO 11334-1	Assistive products for walking manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches	2007-02-00	ISO/TC 173 Assistive products for persons with disability
ISO/DIS 9241-960	Ergonomics of human-system interaction - Part 960: Framework and guidance for gesture interactions	2015-08-00	ISO/TC 159 Ergonomie*ISO/TC 159 Ergonomics
ISO/IEC TR 15440	Information technology - Future keyboards and other input devices and entry methods	2016-02-00	ISO/IEC JTC 1/SC 35 User interfaces

prEN ISO 9241-11	Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts (ISO/DIS 9241-11:2016)	2016-12-00	CEN/TC 122 Ergonomics
CTA-2052.1	Definitions and Characteristics for Wearable Sleep Monitors	2016-09-00	EIA Electronic Industries Alliance
ISO/IEEE 11073-10441	Health informatics - Personal health device communication - Part 10441: Device specialization - Cardiovascular fitness and activity monitor	2015-03-00	ISO/TC 215 Health informatics
EN 50491-3	General requirements for Home and Building Electronic Systems (HBES) and Building Automation and Control Systems (BACS) - Part 3: Electrical safety requirements	2009-07-00	CLC/TC 205 Home and Building Electronic Systems (HBES)
VDE-AR-E 2757-6-2	Ambient Assisted Living (AAL) - Conceptualisation of integration profiles	2015-02-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-4	Staying at home service - Quality criteria for providers, services and products of Ambient Assisted Living (AAL)	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-8	Ambient Assisted Living (AAL) - Process support for the technical implementation of assistant systems (ambient assisted technology) in homes and residential buildings	2014-12-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-3	Staying at Home service - Criteria for the selection and installation of AAL components	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
EN 15251	Indoor environmental input parameters for design and assessment of energy performance of buildings addressing indoor air quality, thermal environment, lighting and acoustics	2007-05-00	CEN/TC 156 Ventilation for buildings
IEC/TR 80001-2-8	Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	2016-05-00	ISO/TC 215 Health informatics
CWA 50487/AC	SmartHouse code of practice	2006-01-00	CLC/TC 205 Home and Building Electronic Systems (HBES)
IEC/TR 62678*CEI/TR 62678	Audio, video and multimedia systems and equipment - Activities and considerations related to accessibility and usability	2010-10-00	IEC/TC 100 Sound, vision and multimedia systems and equipment
IEC 82304-1*CEI 82304-1	Health software - Part 1: General requirements for product safety	2016-10-00	IEC/SC 62A Common aspects of electrical equipment used in medical practice

3.3.3 Touchpoint 3: Monitoring

Document No.	Title	Date of publication	Author

ISO/IEC TR 19766	Information technology - Guidelines for the design of icons and symbols accessible to all users, including the elderly and persons with disabilities	2007-06-00	ISO/IEC JTC 1/SC 35 User interfaces
EN ISO 9241-110	Ergonomics of human-system interaction - Part 110: Dialogue principles (ISO 9241-110:2006)	2006-04-00	CEN European Committee for Standardization
EN ISO 9241-151	Ergonomics of human-system interaction - Part 151: Guidance on World Wide Web user interfaces (ISO 9241-151:2008)	2008-05-00	CEN/TC 122 Ergonomics
EN ISO 9241-154	Ergonomics of human-system interaction - Part 154: Interactive voice response (IVR) applications (ISO 9241-154:2013)	2013-02-00	CEN/TC 122 Ergonomics
EN ISO 9241-161	Ergonomics of human-system interaction - Part 161: Guidance on visual user-interface elements (ISO 9241-161:2016)	2016-03-00	CEN/TC 122 Ergonomics
EN ISO 9241-20	Ergonomics of human-system interaction - Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services (ISO 9241-20:2008)	2009-01-00	CEN/TC 122 Ergonomics
EN ISO 9241-300	Ergonomics of human-system interaction - Part 300: Introduction to electronic visual display requirements (ISO 9241-300:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-302	Ergonomics of human-system interaction - Part 302: Terminology for electronic visual displays (ISO 9241-302:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-303	Ergonomics of human-system interaction - Part 303: Requirements for electronic visual displays (ISO 9241-303:2011)	2011-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-304	Ergonomics of human-system interaction - Part 304: User performance test methods for electronic visual displays (ISO 9241-304:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-305	Ergonomics of human-system interaction - Part 305: Optical laboratory test methods for electronic visual displays (ISO 9241-305:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-306	Ergonomics of human-system interaction - Part 306: Field assessment methods for electronic visual displays (ISO 9241-306:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-307	Ergonomics of human-system interaction - Part 307: Analysis and compliance test methods for electronic visual displays (ISO 9241-307:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-391	Ergonomics of human-system interaction - Part 391: Requirements, analysis and compliance test methods for the reduction of photosensitive seizures (ISO 9241-391:2016)	2016-03-00	CEN/TC 122 Ergonomics
EN ISO 9241-400	Ergonomics of human-system interaction - Part 400: Principles and requirements for	2007-02-00	CEN/TC 122 Ergonomics

	physical input devices (ISO 9241-400:2007)		
EN ISO 9241-410	Ergonomics of human-system interaction - Part 410: Design criteria for physical input devices (ISO 9241-410:2008)	2008-02-00	CEN/TC 122 Ergonomics
EN ISO 9241-410/A1	Ergonomics of human-system interaction - Part 410: Design criteria for physical input devices (ISO 9241-410:2008/AMD 1:2012)	2012-07-00	CEN/TC 122 Ergonomics
EN ISO 9241-420	Ergonomics of human-system interaction - Part 420: Selection of physical input devices (ISO 9241-420:2011)	2011-07-00	CEN/TC 122 Ergonomics
EN ISO 9241-5	Ergonomic requirements for office work with visual display terminals (VDTs) - Part 5: Workstation layout and postural requirements (ISO 9241-5:1998)	1999-03-00	CEN European Committee for Standardization
EN ISO 9241-910	Ergonomics of human-system interaction - Part 910: Framework for tactile and haptic interaction (ISO 9241-910:2011)	2011-07-00	CEN/TC 122 Ergonomics
EN ISO 9241-920	Ergonomics of human-system interaction - Part 920: Guidance on tactile and haptic interactions (ISO 9241-920:2009)	2016-07-00	CEN/TC 122 Ergonomics
ISO/DIS 9241-960	Ergonomics of human-system interaction - Part 960: Framework and guidance for gesture interactions	2015-08-00	ISO/TC 159 Ergonomics
NEN-ISO 16391:2002 en	Aids for ostomy and incontinence - Irrigation sets - Requirements and test methods	2002-11-01	301088: Coordinatie technologie gehandicapten en ouderen
IEC 100/2730/CDV*CEI 100/2730/CDV*IEC 62481-1-1*CEI 62481-1-1	Digital living network alliance (DLNA) home networked device interoperability guidelines - Part 1-1: Architecture and protocols	2016-09-00	IEC/TC 100 Sound, vision and multimedia systems and equipment
DIN EN ISO 12967-1	Health informatics - Service architecture - Part 1: Enterprise viewpoint (ISO 12967-1:2009); English version EN ISO 12967-1:2011	2011-06-00	DIN-Normenausschuss Medizin (NAMed)*Medical Standards Committee
PD ISO/TR 16056-1:2004	Health informatics. Interoperability of telehealth systems and networks. Introduction and definitions	14.02.2005	IST/35
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015)	2015-05-00	CLC/TC 62 Electrical equipment in medical practice
SAE AIR 6552/3	Network End-to-End Data Link Evaluation System Transceiver Health Monitoring	2016-05-17	Society of Automotive Engineers, Inc.
DS/EN 50491-1	General requirements for Home and Building Electronic Systems (HBES) and Building Automation and Control Systems (BACS) - Part 1: General requirements	27.11.2014	S-705
EN ISO 11073-10101	Health informatics - Point-of-care medical device communication - Part 10101:	2005-08-00	CEN/TC 251 Health informatics

	Nomenclature (ISO/IEEE 11073-10101:2004)		
EN ISO 11073-10101/FprA1	Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature - Amendment 1: Additional definitions (ISO/IEEE 11073-10101:2004/FDAmd 1:2016)	2016-08-00	CEN/TC 251 Health informatics

3.3.4 Touchpoint 4: Gaming

Document No.	Title	Date of publication	Author
ANSI/CTA 2056	Physical Activity Monitoring for Fitness Wearables Step Counting	2016-00-00	American National Standards Institute (ANSI)*American National Standards Institute
EN ISO 11073-10471	Health Informatics - Personal health device communication - Part 10471: Device specialization - Independent living activity hub (ISO/IEEE 11073-10471:2010)	2011-03-00	CEN/TC 251 Health informatics
EN ISO 9241-300	Ergonomics of human-system interaction - Part 300: Introduction to electronic visual display requirements (ISO 9241-300:2008)	2008-11-00	CEN/TC 122 Ergonomics
EN ISO 9241-410	Ergonomics of human-system interaction - Part 410: Design criteria for physical input devices (ISO 9241-410:2008)	2008-02-00	CEN/TC 122 Ergonomics
EN ISO 9241-410/A1	Ergonomics of human-system interaction - Part 410: Design criteria for physical input devices (ISO 9241-410:2008/AMD 1:2012)	2012-07-00	CEN/TC 122 Ergonomics
EN ISO 9241-420	Ergonomics of human-system interaction - Part 420: Selection of physical input devices (ISO 9241-420:2011)	2011-07-00	CEN/TC 122 Ergonomics
EN ISO 9241-5	Ergonomic requirements for office work with visual display terminals (VDTs) - Part 5: Workstation layout and postural requirements (ISO 9241-5:1998)	1999-03-00	CEN European Committee for Standardization
EN 62481-1:2014-06 E*EN 62481-1	Digital living network alliance (DLNA) home networked device interoperability guidelines -- Part 1: Architecture and protocols	2014-06-05	KT 103
ISO/DIS 9241-11	Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts	2015-11-00	CEN/TC 159 Ergonomics
EN 60601-1-6	Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)	2010-04-00	CLC/TC 62 Electrical equipment in medical practice
JIS S 0012	Guidelines for all people including elderly and people with disabilities - Usability of consumer products	2000-11-20	Technical committee for older persons and persons with disabilities

JIS S 0012/ERRATUM 1	Guidelines for all people including elderly and people with disabilities - Usability of consumer products (Erratum 1)	2001-00-00	Technical Committee on Consumer Life Products

3.3.5 Touchpoint 5: Wearables

Document No.	Title	Date of publication	Author
EN ISO 11073-10471	Health Informatics - Personal health device communication - Part 10471: Device specialization - Independent living activity hub (ISO/IEEE 11073-10471:2010)	2011-03-00	CEN/TC 251 Health informatics
IEEE 11073-00103	Health Informatics - Personal health device communication - Part 00103: Overview	2012-00-00	IEEE Engineering in Medicine and Biology Society
ISO/IEEE 11073-10471	Health informatics - Point-of-care medical device communication - Part 10471: Device specialization - Independant living activity hub	2010-05-00	ISO/TC 215 Health informatics
ISO/TS 25237	Health informatics - Pseudonymization	2008-12-00	ISO/TC 215 Health informatics
ISO 22857	Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health data	2013-12-00	ISO/TC 215 Health informatics
ISO/FDIS 25237	Health informatics - Pseudonymization	2016-09-00	ISO/TC 215 Health informatics
ETSI TR 102764 V 1.1.1	eHEALTH - Architecture - Analysis of user service models, technologies and applications supporting eHealth	2009-02-00	ETSI/eHEALTH
PD CR 13694:1999*CR 13694:1999	Health informatics. Safety and security related software quality standards for healthcare (SSQS)	1999-11-15	IST/35
EN 15224	Health care services - Quality management systems - Requirements based on EN ISO 9001:2008	2012-10-00	CEN/TC 362 Healthcare services - Quality management systems
ISO/IEEE 11073-10441	Health informatics - Personal health device communication - Part 10441: Device specialization - Cardiovascular fitness and activity monitor	2015-03-00	ISO/TC 215 Health informatics
NPR-ISO/TR 14292:2012 en	Health informatics - Personal health records - Definition, scope and context	2012-04-01	303006: Informatievoorziening in de zorg
EN ISO 11073-10404	Health informatics - Personal health device communication - Part 10404: Device specialization - Pulse oximeter (ISO/IEEE 11073-10404:2010)	2011-03-00	CEN/TC 251 Health informatics
ANSI/AAMI/ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016-00-00	American National Standards Institute (ANSI)*American National Standards Institute
ANSI/IEEE 11073-10404	Standard for Health Informatics - Personal Health Device Communication - Device Specialization - Pulse Oximeter	2008-00-00	American National Standards Institute (ANSI)*American National Standards Institute

3.3.6 Engine 1: Safety

Document No.	Title	Date of publication	Author
ISO/TS 25237	Health informatics - Pseudonymization	2008-12-00	ISO/TC 215 Health informatics
ISO/TS 29585	Health informatics - Deployment of a clinical data warehouse	2010-05-00	ISO/TC 215 Health informatics
ISO 22857	Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health data	2013-12-00	ISO/TC 215 Health informatics
DIN EN 14485	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive; German version EN 14485:2003, text in English	2004-03-00	DIN-Normenausschuss Medizin (NAMed)*Medical Standards Committee
ISO/TR 17791	Health informatics - Guidance on standards for enabling safety in health software	2013-12-00	ISO/TC 215 Health informatics
EN ISO 11073-20601	Health informatics - Personal health device communication - Part 20601: Application profile - Optimized exchange protocol (ISO/IEEE 11073-20601:2016, including Cor 1:2016)	2016-08-00	CEN/TC 251 Health informatics
ISO/IEC 24767-2	Information technology - Home network security - Part 2: Internal security services: Secure Communication Protocol for Middleware (SCPM)	2009-01-00	ISO/IEC JTC 1/SC 25
PAS 1011	VCS Communication concepts for the health service	2001-03-00	Verband Deutscher Arztpraxis-Sofware-Hersteller e. V.
ETSI TS 101323 V 1.2.3	Telecommunications and Internet Protocol Harmonization Over Networks (TIPHON) - Interoperable security profiles	1999-07-00	ETSI/TIPHON 3
ASTM E 1986	Standard Guide for Information Access Privileges to Health Information	2009-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
ASTM E 2147	Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems	2001-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
ETSI TR 102764 V 1.1.1	eHEALTH - Architecture - Analysis of user service models, technologies and applications supporting eHealth	2009-02-00	ETSI/eHEALTH
ASTM E 1869	Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records	2004-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
ASTM E 1986	Standard Guide for Information Access Privileges to Health Information	2009-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
ASTM E 2369	Standard Specification for Continuity of Care Record (CCR)	2012-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
EN 62481-3	Digital living network alliance (DLNA) home networked device interoperability	2014-03-00	CENELEC European Committee for Electrotechnical Standardization

	guidelines - Part 3: Link protection (IEC 62481-3:2013)		
DIN EN ISO 25237	Health informatics - Pseudonymisation (ISO/DIS 25237:2015); German and English version prEN ISO 25237:2015	2015-10-00	DIN-Normenausschuss Medizin (NAMed)*Medical Standards Committee
ITU-T X.1528	Common platform enumeration	2012-09-00	ITU International Telecommunication Union

3.3.7 Engine 2: Pattern Detection

Document No.	Title	Date of publication	Author
ISO/IEC 13066-1	Information technology - Interoperability with assistive technology (AT) - Part 1: Requirements and recommendations for interoperability	2011-05-00	ISO/IEC JTC 1/SC 35 User interfaces
ISO/IEC TR 13066-3	Information technology - Interoperability with assistive technology (AT) - Part 3: IAccessible2 accessibility application programming interface (API)	2012-09-00	ISO/IEC JTC 1/SC 35 User interfaces
ITU-T Y Supplement 40	Big data standardization roadmap	2016-07-00	ITU International Telecommunication Union
ITU-T Y.3600	Big data - cloud computing based requirements and capabilities	2015-11-00	ITU International Telecommunication Union
ITU-T H.813	Interoperability design guidelines for personal health systems: Health record network (HRN) interface	2015-11-00	ITU International Telecommunication Union
ANSI/ASTM E 1744	Practice for View of Emergency Medical Care in the Electronic Health Record	2005-00-00	American National Standards Institute (ANSI)*American National Standards Institute
ISO 18308	Health informatics - Requirements for an electronic health record architecture	2011-04-00	ISO/TC 215 Health informatics
ASTM E 1986	Standard Guide for Information Access Privileges to Health Information	2009-00-00	American Society for Testing and Materials (ASTM)*American Society for Testing and Materials
CEN ISO/TS 14441:en	Health informatics. Security and privacy requirements of EHR systems for use in conformity assessment (ISO/TS 14441:2013)	07.03.2014	
ABNT ISO/TR 20514	Health informatics - Electronic health record - Definition, scope and context	23.06.2008	ABNT/CEE-78 Informatics in healthcare
SFS-ISO/TS 21547	Health informatics -- Security requirements for archiving of electronic health records -- Principles	31.08.2012	

3.3.8 Engine 3: Interface and Recommendation

Document No.	Title	Date of publication	Author
ISO/IEC 13066-1	Information technology - Interoperability with assistive technology (AT) - Part 1:	2011-05-00	ISO/IEC JTC 1/SC 35 User interfaces

	Requirements and recommendations for interoperability		
ISO/IEC TR 13066-3	Information technology - Interoperability with assistive technology (AT) - Part 3: IAccessible2 accessibility application programming interface (API)	2012-09-00	ISO/IEC JTC 1/SC 35 User interfaces
ISO/IEC TR 13066-4	Information technology - Interoperability with assistive technology (AT) - Part 4: Linux/UNIX graphical environments accessibility API	2015-11-00	ISO/IEC JTC 1/SC 35 User interfaces
ISO/IEC TR 13066-6	Information technology - Interoperability with Assistive Technology (AT) - Part 6: Java accessibility application programming interface (API)	2014-07-00	ISO/IEC JTC 1/SC 35 User interfaces
IEC 82304-1*CEI 82304-1	Health software - Part 1: General requirements for product safety	2016-10-00	IEC/SC 62A Common aspects of electrical equipment used in medical practice
DIN SPEC 91222	Information technology - Platform and programming language independent interoperability	2010-11-00	DIN-Normenausschuss Informationstechnik und Anwendungen (NIA)*Information Technology and selected IT Applications Standards Committee
IEEE 11073-10101*ISO/IEEE 11073-10101	Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature	2004-00-00	IEEE Engineering in Medicine and Biology Society
EN ISO 27799	Health informatics - Information security management in health using ISO/IEC 27002 (ISO 27799:2016)	2016-08-00	CEN/TC 251 Health informatics
ISO/IEC 40500	Information technology - W3C Web Content Accessibility Guidelines (WCAG) 2.0	2012-10-00	ISO/IEC JTC 1 ISO/IEC Joint Technical Commitee for Information Technology
ISO/IEC DIS 30113-11	Information technology - Gesture-based interfaces across devices and methods - Part 11: Single-point gestures for common system actions	2016-04-00	ISO/IEC JTC 1/SC 35 User interfaces
ISO/IEC DIS 20382-1	Information technology - User interfaces - Face-to-face speech translation - Part 1: User interface	2016-10-00	ISO/IEC JTC 1/SC 35 User interfaces
ISO/IEC DIS 20382-2	Information technology - User interface - Face-to-face speech translation - Part 2: System architecture and functional components	2016-10-00	ISO/IEC JTC 1/SC 35 User interfaces
NPR-ISO/TR 16056-1:2004 en	Health informatics - Interoperability of telehealth systems and networks - Part 1: Introduction and definitions	2004-07-01	303006: Informatievoorziening in de zorg
NPR-ISO/TR 16056-2:2004 en	Health informatics - Interoperability of telehealth systems and networks - Part 2: Real-time systems	2004-07-01	303006: Informatievoorziening in de zorg

3.3.9 Engine 4: Care and Life

Document No.	Title	Date of publication	Author

VDE-AR-E 2757-3	Staying at Home service - Criteria for the selection and installation of AAL components	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-4	Staying at home service - Quality criteria for providers, services and products of Ambient Assisted Living (AAL)	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-2	Service Staying at Home - Requirements for suppliers of combined services	2011-08-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-3	Staying at Home service - Criteria for the selection and installation of AAL components	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
VDE-AR-E 2757-4	Staying at home service - Quality criteria for providers, services and products of Ambient Assisted Living (AAL)	2012-01-00	German Commission for Electrical, Electronic and Information Technologies of DIN and VDE
DIN SPEC 77002	Ambient Assisted Living (AAL) - Requirements for AAL services	2013-04-00	DIN-Normenausschuss Dienstleistungen (NADL)*Services Standards Committee
PD CEN/TR 15253:2005 en	Health informatics - Quality of service requirements for health information interchange	01.12.2005	303006: Informatievoorziening in de zorg
OENORM EN 15224	Health care services - Quality management systems - Requirements based on EN ISO 9001:2008	01.12.2012	ASI/Komitee 250 Qualitaetsmanagement in Einrichtungen des Gesundheitswesens
JIS B 8445	Robots and robotic devices - Safety requirements for personal care robots	20.04.2016	Industrial Machinery
PAS 800:2010	Use of Dementia Care Mapping for improved person-centred care in a care provider organization. Guide	29.01.2010	
UNI 11010:2016	Health care and social services - Services for living and for social inclusion of people with disabilities - Service requirements	30.08.2016	UNI/CT 040/GL 17 Servizi socio-sanitari e servizi sociali*UNI/CT 040 Services
IWA 18	Framework for integrated community-based life-long health and care services in aged societies	2016-06-00	ISO/TMB Joint Technical Coordination Group

3.3.10 Engine 5: Platform and Data

Document No.	Title	Date of publication	Author
ISO/IEC 9066-2	Information processing systems; text communication; reliable transfer; part 2: protocol specification	1989-11-00	ISO/IEC JTC 1 ISO/IEC Joint Technical Commitee for Information Technology
ISO/IEC 9072-2	Information processing systems; text communication; remote operations; part 2: protocol specification	1989-11-00	ISO/IEC JTC 1 ISO/IEC Joint Technical Commitee for Information Technology
EN ISO 11073-20601	Health informatics - Personal health device communication - Part 20601: Application profile - Optimized exchange protocol (ISO/IEEE 11073-20601:2016, including Cor 1:2016)	2016-08-00	CEN/TC 251 Health informatics

EN 62481-1	Digital living network alliance (DLNA) home networked device interoperability guidelines - Part 1: Architecture and protocols (IEC 62481-1:2013)	2014-04-00	CENELEC European Committee for Electrotechnical Standardization
ITU-T Y.3600	Big data - cloud computing based requirements and capabilities	2015-11-00	ITU International Telecommunication Union
ISO/TS 25237	Health informatics - Pseudonymization	2008-12-00	ISO/TC 215 Health informatics
DIN ISO/IEC 27009	Information technology - Security techniques - Sector-specific application of ISO/IEC 27001 - Requirements (ISO/IEC 27009:2016)	2016-11-00	Information Technology and selected IT Applications Standards Committee
ASTM E 1986	Standard Guide for Information Access Privileges to Health Information	2009-00-00	American Society for Testing and Materials (ASTM)
ASTM E 1869	Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records	2004-00-00	American Society for Testing and Materials (ASTM)
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)	2011-10-00	CEN/TC 258 Clinical investigation of medical devices
NPR-ISO/TS 22220:2011 en	Health informatics - Identification of subjects of health care	01.12.2011	303006: Informatievoorziening in de zorg

4 Initial testing plan (verification and validation)

In this chapter the testing approach was decomposed and an initial testing plan is set up. **Section 4.1** shows how the 4 test phases are relate to the V-Model phases. A set of testing dimensions (**Section 4.2**) are developed which shall manage the design and execution of test. For each Touchpoint separate testing instances were created and each of this testing instances represents a separate trial with an own hypothesis, own outcome measures, and an instance specific trial design (**Section 4.3**).

4.1 Testing plan and the V-Model approach

Following the outcomes of **Deliverable T1.4/D4** (detailing of the system architecture and the Touchpoints/Engine concept) and the in the present deliverable in **Chapter 2** clarified systems engineering approach, the testing approach could be decomposed and an initial testing plan was set up. **Table 4-1** shows how the 4 test phases relate to the V-Model phases; **Figure 2-8** in **Section 2.3.4** outlines this relation in a graphical form.

Table 4-1: The four major trial phases

Trial phase	Locations	Trial details	Relation to V-Model
Test Period 1: Early testing (year 1)	HUG, ZZ, Lyngby, SK	Testing of existing sensors/equipment, more explanatory, duration ranging from several hours up to eight weeks.	Concept and design phase, element of "agile management", provides requirements and qualitative inputs.
Test Period 2: Pre-testing 1 (end of year 2)	Academic labs of TUM, TU/e, EPFL, and DTU	Evaluate the selected technologies developed in REACH in labs of academic partners, simulating care environments – short duration test/several days.	Design and early implementation phase, element of "agile management", provides inputs on qualitative features and usability
Test Period 3: Pre-testing 2 (year 3)	HUG, Schön Klinik, Zuidzorg, and Lyngby	Evaluate some selected technologies in real world environments – short duration test/1-3 weeks.	Technology verification
Test Period 4: Final testing / demonstration (year 4)	Unstructured, real-world environment at Lyngby	Evaluate some selected technologies in real world environments – longer duration test/more than 3 weeks.	Technology validation

4.2 Testing dimensions definitions

In an in-person meeting of the WP6 participants, following testing dimensions were developed which shall govern the design and execution of test in test periods 2, 3, and 4:

1. Components/sub-systems/system dimension: e.g. first test involve only selected "components" later pre-tests involve a more comprehensive REACH "system". The final demo may focus only on technological core aspects and the by then most robust technologies in order to guarantee that a relative long duration of the study can be accomplished with the given resources
2. Test duration dimension: duration or depth of technology of tests will be increased from period to period

3. Evaluation strategy dimension: test in the beginning are more formative (provide feedback to the developers how to design improve the system) and more summative (evaluate if system is feasible/effective/has desired outcome/impact/etc.) in the end
4. Type/structure dimension: the strength of the tests and the study methods applied (qualitative/quantitative) during the study will vary according to the specific objectives and constraints.
5. Strength dimension: One of the important dimensions is the strength of a test, but this is not necessarily the most important one (relevance, generalizability) and if we use the usual Cochrane hierarchy (metareview, randomized controlled trial, cohort-study, case study) does not capture degrees of strength of qualitative studies.

4.3 Initial testing plan for each Touchpoint

As outlined in **Deliverable T1.4/D4** with the detailing of the Touchpoints/Engine concept and the detailing of motivational techniques and sensing/analytics aspects in **Deliverable D1.2/D2**, it was also possible to "decompose" the testing approach into manageable parts. With the overall system architecture detailed and the first early trials completed, it becomes obvious that it is impractical to test each Touchpoint with regard to its complex, subsequent chain of early detection, motivational techniques, and programmed interventions in a single trial. For this unrealistically large and long trials would be required which are beyond the scope and resources of the project. Instead, following **Review Recommendations R2-4**, a decomposition of the "testing problem" is suggested. For each Touchpoint separate testing parts/instances were created and each of this testing instances represents a separate trial with an own hypothesis, own outcome measures, and an instance specific trial design. **Table 4-2** shows the general concept for decomposition of testing approach, and **Table 4-3** shows an initial detailing of testing approach decomposition scheme based on the Touchpoint detailing presented in **Chapter 3**.

Table 4-2: Concept for decomposition of testing approach

Touchpoint		Testing Instances		
Name	Theme	Early Detection	Motivational Techniques	Programmed Interventions
TP1 Personal Mobility Device	Frailty and risk of falls	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…
TP2 Active Environment	Mobility	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…
TP3 Socializing and Nutrition	Social interaction and nutrition	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…
TP4 Gaming and Training	General physical and cognitive ability	• Hypothesis:…	• Hypothesis:…	• Hypothesis:…

		• Outcome measures: • Study Design:…	• Outcome measures: • Study Design:…	• Outcome measures: • Study Design:…
TP5 Wearables	General physical and cognitive ability	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…	• Hypothesis:… • Outcome measures: • Study Design:…

Table 4-3: Initial detailing of testing approach decomposition scheme

Touchpoint		Testing Instances		
Name	Theme	Early Detection	Motivational Techniques	Programmed Interventions
TP1 Personal Mobility Device	Frailty and risk of falls	signs of frailty person under risk of falls Evolutionary approach: early detection will be done only with the sensors; when then risks of falls or signs of frailty are detected the mobility device comes in as a safe activation and training device. The mobility device optimally follows (and can modularly be adapted to) the person throughout the patient journey through different care stages.	Goal must be to motivate the elderly (e.g. through gamification) to use the equipment to train a) themselves, b) or in a community (e.g. a ZZ), or c) together with care personnel in an institution to achieve a better level of mobility. At best, this results in an improved mobility, e.g. in terms of distances walked (also without using the equipment).	The mobility device functions as a kind of medical home or indoor fitness device. A screen and motion sensor allows for an interactive scenario where the users can play games or follow mobility training instructions. Like in a fitness device in a fitness studio, our device should contain some basic (and modularly separable) physiological sensors on board that allow to monitor the training progress and outcomes.
TP2 Active Environment	Mobility	Early detect and prevent decrease of (micro) mobility in a care environment. Therefore measure/monitor performance levels: positioning problems, balance/falls. Measure/monitor mood: Track mood based on the physiological measurement + track mood by clinical	Engage in activity in patient and therapy rooms. Motivate to participate in and adhere to therapies/scheduled trainings/interventions and.	A combination and integration of "furniture" components (bed + bed periphery + mobility device (iStander) + toileting support) to a seamless in-house "transfer and mobility chain" should facilitate a significant increase of mobility in the patient room.

		professionals e.g. by depression questionnaire (and correlate/match both).		Both the personal mobility device (TP1) and the Playware tiles based "gaming and training" system (TP4) may later on be used as additional interventions.
TP3 Socializing and Nutrition	Social interaction and nutrition	Physical activity in relation to eating habits. Inputs my come from self-reporting, doctor assessments, sensors, and/or other Touchpoints.	Find out what motivates specific elderly to eat what they should eat, stick to eating recommendations, etc. Develop motivational strategies that facilitate the physical activity levels within the context of socializing and nutritional intake. Measures: measure impact of socializing, measure improvement in terms nutritional intake.	Personal advice on food intake in combination with physical activity recommendation. The food nutrition, recipes, recommendations should make them active (go shopping to get ingredients, meet with others to cook, etc.). Facilitation of socializing and nutritional intake should enhance the physical activity level.
TP4 Gaming and Training	General physical and cognitive ability	Changes in physical activity > infer from these changes in physical ability. Use of Philip's back end server (dashboard) to explore the by DTU collected data sets to identify what (probably signals or trends) to early detect. Playware tiles themselves and/or sensors may be used as early detection tools.	Playware tiles are seen as a tool/means to explore and test a variety behavior change tactics. Produce knowledge about what training and gaming can mean as an activity promoter.	Playware tile themselves (plus associated games and training procedures) may be seen as an intervention. In case the tiles themselves are rather used as a detection means, additional services (e.g. by care professionals, etc.) may be seen as intervention. At ZZ/Tu/e: make use of an RTC trial to draw conclusions about effects of engagement/training.
TP5 Wearables	General physical and cognitive ability	Detect changes in activity, i.e. deviations from normal activity; this has two dimensions:	Development of approaches for wearables that enhance willingness	Development of clustering algorithms to identify intra-personal behavior

		Micro changes: changes in micro activity patterns (within hours or minutes) Macro changes: variations cross days/weeks	and adherence to wearing them. In that context: find the right balance between perceived safety gains and privacy aspects/ concerns	patterns and infer from this intervention profiles. In that context the success of a variety of interventions (i.e. intervention alternatives and/or motivational techniques) for specific persons or cohorts shall be predicted. Feedback of information/recommendations/interventions through a) (Interfaces) on the wearables and b) other Touchpoints (and/or services tied to them)

4.4 Relation between testing plan and system integration activities:

Prior to each trial phase (i.e. prior to trial phases 2, 3, and 4) parts of the REACH system have to be integrated to mock-ups or prototypes that allow to test one or several of the in **Section 4.2** specified testing instances. Prior to each integration, the tools and best practice guidelines outlined in **Section 2.4** will be used to determine the system readiness state and possibly associated risks. **Task 6.2** (pre-integration to mock-ups) will facilitate an efficient technology/components selection and integration process prior to testing phases 2 and 3. **Task 6.6** (final integration to demonstrators) will do so for the larger testing phases at the end of the project. Whereas the first tests involve only selected “components” (e.g. integration of parts of a Touchpoint or testing of a single complete Touchpoint) later pre-tests involve a more comprehensive REACH “system” and the combination and integration cross Touchpoints.

5 Conclusion and Roadmap

WP6 is closely linked to the system architecture (e.g. Touchpoint/Engine concept) developed in **WP1** (see **Deliverable T1.4/D4),** provides tools and methods to facilitate and coordinate integration and verification/validation, and thus complements the actual implementation activities carried out in smaller teams in the development work packages **WP2**-**WP5**. In **WP6**, **T6.1** is concerned with the overall methods, best practices, standards, and coordination/planning of system integration activities, tasks **T6.2** (pre-integration to mock-up) and **T6.6** (final integration to demonstrators/prototypes) focus on the actual integration work. Actual integration work systematically always starts before a testing phase (**T6.3**: Pre-testing; **T6.4**: Pre-testing 2; **T6.7**: Final-testing). Within the testing tasks phases in **WP6**, both technology partners (e.g. for Touchpoint deployment) and the use case settings have resources allocated, to be able to jointly plan, design, conduct, and interpret the studies and test to be conducted. **T6.8** states a relatively long phase at the end of the project in which the developments and test should be reviewed and the overall system should be optimized. **Table 5-1** provides a roadmap for **WP6** and outlines and details the activities to be carried out.

Table 5-1: Roadmap for WP6

Project Month	Phase	Task	Status
M1-M14	T6.1a: System integration general method and standards, general testing strategy	• Detailing of system integration strategy and plan • Provision of systems engineering tools and best practices • Standards research • General testing strategy and decomposition of testing problem into several testing instances • Early trials	completed
M15-M21	T6.1a: Detailing testing plan, detailing of system integration specifications	• Detailing of the testing plan and set up of test plans and hypothesizes for test items (Touchpoints, etc.) • Consider early testing, motivational techniques, and programmed interventions • Hold a work-shop with external experts and advisory board members to clarify testing hypotheses and “what to early detect” • Detailing of specifications of interfaces, interoperability, etc. • Early trials	ongoing
M22-M26	T6.2: Pre-integration 1	• Integration of selected components to systems (i.e. Touchpoints)	pending
M22-M26	T6.3: Pre-Testing 1	• Verification: functional testing (including usability testing) of systems (i.e. Touchpoints)	pending
M27-M33	T6.4: Pre-Testing 2	• Validation 1: Testing of selected Touchpoints in real world environments	pending

M27-M33	T6.5: Optimization 1	• Review of system architecture and systems integration aspects • Detailing and re-design based on outcomes of T6.3 and T6.4	pending
M32-M36	T6.6: Integration 2	• Integration of selected systems to systems of systems (e.g. selected combination of Touchpoints/Engine) • Functional testing of the resulting system of systems	pending
M34-M40	T6.7: Final-Testing	• Validation 2: testing of and use case adapted system of systems in a naturalistic environment (primarily in Lyngby)	pending
M41-M48	T6.8: Optimization 2	• Review of system architecture and systems integration aspects • Detailing and re-design based on outcomes of T6.3 and T6.4 • Further testing if relevant	pending

REACH flexibly utilizes and combines elements of the (1) V-Model approach, (2) Agile Management, and the (3) NASA systems engineering approach. With regard to REACH as a System of Systems (**Section 2.2**) and the REACH system architecture specified in **Deliverable T1.4/D4**, a key aspect of our system integration approach is to give the Touchpoints and Engine work teams as much freedom as possible with regard to the Touchpoint-internal design and composition (and thus see them as “real” modules as defined in **Section 2.2.4**), but on the other hand require a commitment for clearly defined interfaces to other parts of REACH an date REACH environment (including its users and other stakeholders).

T6.1 is a task that continues and therefore the partners have not yet used all the allocated resources. Beyond this deliverable report, **T6.1** (as a task that continues up to project Month 48) will facilitate the uptake of the introduced guidelines, the subsequent detailing of interfaces and specifications by the implementation work teams (e.g. the Touchpoints/Engine associated work teams), and the monitoring of the technology maturation and integration processes. The tools and methods provided (e.g. interface identification method; Product Breakdown Structure, assessment of Integration Readiness Levels) will be used by the (Touchpoints/Engine) implementation work teams as a common system detailing tools; the **T6.1** participants will facilitate this process. The outcome of this facilitation work will be laid down as updates to this deliverable report.

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6 Appendix

6.1 Appendix 1: Standards research in full length

The following appendices of this deliverable were considered as confidential and therefore were integrated as “Appendix 8” into the linked Deliverable T1.4/D4 (confidential deliverable).

6.1.1 Overview

6.1.2 Keywords

6.1.3 TP1 Mobility

6.1.4 TP2 Active Environment

6.1.5 TP3 Monitoring

6.1.6 TP4 Gaming

6.1.7 TP5 Wearables

6.1.8 E1 Safety

6.1.9 E2 Pattern Detection

6.1.10 E3 Interf. + Rec.

6.1.11 E4 Care and Life

6.1.12 E5 Platform and Data

6.1.13 Abbreviations

6.1.14 List of ICS fields