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Health informatics — Re-usable component strategy for use case development

Informatique de santé — Stratégie de composants réutilisables pour le développement de cas pratiques

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This document is based in part on ISO/TR 21089 and ISO/HL7 10781.

Introduction

Use cases are often utilized to establish key objectives and requirements for software design and development, system testing, certification and implementation. This document offers a methodology for use case development that discovers common components of use case scenarios, then establishes a component catalogue for subsequent re-use and re-purposing of those components in new use case scenarios. The methodology establishes re-use as a key foundation for consistent infrastructure and build-out of software application systems in healthcare (and potentially other industries). Re-use of requirements often leads to re-use of software solutions (to those requirements). The methodology leads to uniformity in, and optimization of, requirement specification, standards and implementation guidance, software development, testing and certification and ultimately implementation. The methodology establishes the basis for requirements traceability, at each progression step, and end-to-end (use case to implementation).

Health informatics — Re-usable component strategy for use case development

1 Scope

This document specifies a use case development methodology, facilitated by a dynamic catalogue of re-usable components. Use cases are a basic tool in describing requirements for health and healthcare settings, service provision, information technology and software products. Use case development often follows a uniform template with components such as actors, roles, scenarios, event steps, actions, data objects/elements and requirements statements. This document includes a basic use case template and the methods of component identification, capture, cataloguing and re-use. This document also includes guidance for software designed to implement the methodology in the form of a use case authoring tool.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
action
activity or task performed by an entity at a given point in time

Note 1 to entry: A use case event is comprised of one or more actions occurring in sequence.

Note 2 to entry: It can also be defined as an element of an event (step) that a user performs during a procedure (see ISO/IEC 26514).

3.2
actor
health professional, healthcare employee, patient/consumer, sponsored healthcare provider, healthcare organisation, subject of care, device, system or application that acts (performs a role) in a health related communication or service

[SOURCE: ISO 17090-1:2013, 3.1.3, modified]

3.3
assumption
condition that is accepted as true

Note 1 to entry: It can also be defined as factors that, for planning purposes, are considered to be true, real, or certain without proof or demonstration (see ISO/IEC/IEEE 24765) or a statement that describes the expected behaviours of a system or actors who will use the system (see Reference [20]).

3.4
data element
data concept represented by a specific value domain and that describes a single atomic property about an object class

[SOURCE: ISO 14817-1:2015, 4.17, modified - Note 1 to entry deleted]

3.5
data object
collection of data that has a natural grouping and may be identified as a complete entity

Note 1 to entry: It can also be defined as a collection (set) of logically related data elements, e.g. "patient vital signs typically comprise heart rate, respiration rate, temperature and blood pressure".

[SOURCE: ISO/TS 27790:2009, 3.20, modified - Note 1 to entry has been added]

3.6
electronic health record
repository of information regarding the health of a subject of care, in computer processable form

Note 1 to entry: It can also be defined as comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual (ASTM 1769) or information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model (ISO 18308).

[SOURCE: ISO 13606-2:2008, 4.7, modified - Note 1 to entry replaced]

3.7
event
performance of a specified set of functions or operations

Note 1 to entry: It can also be defined as a health care interaction that involves a patient and that may be delivered by a health care provider or be provided as a service[21].

[SOURCE: ISO/IEC 23006-2:2016, 3.1.6, modified - Note 1 to entry has been added]

3.8
entity
legal (e.g. a corporation, labour union, state or nation) or natural person or system (e.g. device, software)

[SOURCE: ISO 15782-1:2009, 3.35, modified - text has been added to the definition and the example has been deleted]

3.9
health/care
health and/or healthcare

EXAMPLE Health/care providers support individual health and provide healthcare services.

3.10
initiative
collaboration of business/clinical experts to develop one or more use cases

3.11
pre-condition
condition which must be true prior to undertaking use case action(s)

3.12
post-condition
condition which must be true after undertaking use case action(s)

3.13
requirement
requirement statement
declaration of necessary condition(s)

Note 1 to entry: "specified requirement" is a need or expectation that is stated (*requirements are intended to define some feature of a real implementation and offer the possibility of testing)* (see ISO/IEC 17007:2009, 3.4).

3.14
re-usable component
element of the use case description that can be excerpted, labelled, catalogued and retained (in a persistent file) for selection and inclusion in a future use case or scenario

3.15
scenario
sequence of event (steps) necessary to complete a business/clinical process

Note 1 to entry: It can also be defined as a description of high level business activities defining process and requirements (see ISO/IEC 19501:2005).

3.16
subject of care
one or more persons scheduled to receive, receiving, or having received a health service

Note 1 to entry: It can also be defined as any person who uses, or is a potential user of, a health care service (see ISO/TS 22220:2011).

[SOURCE: ISO 18308:2011, 3.47, modified - definition has been amended and Note 1 to entry added]

3.17
use case
set of scenarios which address a particular business/clinical domain or topic

Note 1 to entry: It can also be defined as a specification of interactions between external actors and the system to attain particular goals (technopedia.com) or methodology used in system analysis to identify, clarify, and organize system requirements (whatis.com).

3.18
user story
simple narrative illustrating the user goals that a software function will satisfy

[SOURCE: ISO/IEC/IEEE 26515:2011, 4.16]

4 Symbols and abbreviated terms

EHR	electronic health record
EHR-S	electronic health record system
HIT	health information technology
SKMT	ISO TC215 Standards Knowledge Management Tool
SME	subject matter expert
UCR	use case requirements
UCA	use case analyst
UCAT	use case authoring tool

5 Objectives for the re-usable component strategy

The re-usable component strategy (for use case development) is based on the following objectives.

a) To formalize a process of identifying and cataloguing common use case components and patterns of re-use from developing use cases.

b) To save new resource investment by allowing business requirements analysts to quickly identify and re-use catalogued use case components already specified or to add new ones, when appropriate.

c) To formalize a process of identifying and cataloguing implementable software modules and data objects, either commercial or open source, which implement various aspects of required use case-identified software functionality, data/record management and exchange.

d) To save new resource investment by allowing software developers to readily identify and re-use catalogued software modules and data objects in their solutions.

e) To facilitate and promote uniformity in requirement specification, standards and implementation guidance.

f) To lay the foundation for uniform and consistent information infrastructure and build-out.

g) To ensure requirements traceability step-by-step and end-to-end (use case to implementation).

6 Use case basics

6.1 General

In healthcare, use cases typically describe scenarios involving patient flows (with the patient as an actor), provider/work flows (with provider(s) as actor(s)) and information flows [with systems or devices as actor(s)]. Use cases resolve to actors taking actions in sequence, as a progression of steps. EHR (or other) systems capture record entries resulting from actions taken, as persistent evidence of their occurrence.

6.2 Use case scenarios, events and actions

A use case has (is specified in terms of) one or more scenarios. Each scenario has (is specified in terms of) one or more events (in step-wise sequence) to support individual health and to provide healthcare. Each event/event step has (is specified in terms of) one or more actions (in step-wise sequence).

6.3 Use case actors

Use cases have business and clinical actors, as individuals or organizations acting in roles (e.g. performer, assistant, observer, author, scribe, attester). Use cases have technical actors, as systems and devices, also acting in roles (e.g. originator, sender or receiver).

7 Use case component candidates

7.1 General

Use case components are a vital part of a typical use case narrative, but don't necessarily include all elements (e.g. all sections of the use case requirements template). As specified in this document, use case components candidates have four distinctions, in arbitrary order: 1) identify-ability, 2) catalogue-ability, 3) commonality and potential for re-use, 4) computability.

7.2 Identify-ability

The use case component is consistently evident (identifiable) in the use case scenario or narrative. (Clause 10).

7.3 Catalogue-ability

The use case component is readily captured and retained as entry in a catalogue or registry, allowing it to be queried and selected then re-used or re-purposed in subsequent use cases.

7.4 Commonality

The use case component is evident in existing use case scenarios and has a significant potential for re-use in new or revised scenarios. Note that re-use often extends to the solution and thus, once a requirement has a designated software or dataset solution re-selecting that same component in a new use case or scenario offers potential for re-use of the same solution.

7.5 Computability

The use case component has characteristics which may be computable and thus may be implemented as standard software modules and/or data constructs.

8 Use case components

8.1 General

Based on distinctions identified in Clause 7 and review of the use case template in Clause 10, four basic categories of use case components are evident: 1) requirements, 2) actors and roles, 3) scenarios, events and actions, 4) data objects and elements.

8.2 Requirements

Use case requirements are statements of necessary conditions, which must be determined "true" to satisfy fulfilment. Use case requirements may be offered as proof statements and/or conformance criteria. (See examples in Tables 6 and 7.)

a) Requirements state necessary conditions which occur before, during and/or after each use case scenario.

b) Requirements may take the form of assumptions (10.5), pre-conditions (10.6), post conditions (10.7) or system functional requirements (10.13.3).

c) Requirements may be applicable (and accountable) to particular actors, at specific event steps or actions.

d) As a result, discrete requirements may be fulfilled by, and are thus traceable to, particular use case actors and actions.

e) Requirements are typically stated as SHALL (required), SHOULD (preferred) or MAY (optional).

f) Common requirements statements are catalogued as *re-usable components*.

8.3 Actors and roles

In the use case requirements template (Clause 10), use case actors are enumerated (10.8) and shown taking/performing actions in scenario events (10.10). (See examples in Table 8.)

a) Actors are individuals or organizations whose actions are often facilitated by EHR or other system software.

b) Actors (in roles) perform (and are typically accountable for) use case actions.

c) In separate actions, an actor may play a different role.

d) Actors may fulfil established requirements by performing specific actions (showing requirements traceability).

e) Common actors and roles are catalogued as *re-usable components.*

8.4 Scenarios, events and actions

In the use case requirements template, use case scenarios, events and actions are specified in 10.10. (See examples in Tables 10 and 11.)

a) Scenarios are comprised of discrete event steps in a typical sequence.

b) Scenarios have a base flow and may have one or more alternate flows.

c) Event steps are broken into discrete action(s) taken.

d) Actions are taken/performed by actor(s) in role(s).

e) Actors and actions may invoke EHR or other system functions.

f) Actions may be auditable at each occurrence.

g) Actions may be attestable (with signature).

h) Events and actions have discrete data inputs and outputs.

i) Inputs and outputs may be specified in terms of required data objects and elements (8.5).

j) Common actions are catalogued as *re-usable components.*

8.5 Data objects and elements

In the use case requirements template (Clause 10), data requirements are specified in 10.15. (See examples in Table 11.)

a) Data requirements resolve to data objects and elements essential to undertake events and actions in use case scenarios.

b) Data requirements typically include data objects and elements specified as, data/record inputs to and/or outputs from, use case events and actions.

c) Common data objects and elements are catalogued as *re-usable components.*

9 Use case scenarios

9.1 General

Use case scenarios describe a typical health/care work flow interwoven with patient, provider/practitioner and information flows. Use case scenarios describe a sequence of event steps with actors taking actions.

9.2 Events and event steps

Regarding events and event steps

a) Each event step comprises one or more action(s) taken.

b) Each event step is initiated by an actor performing [taking action(s)] in a role.

c) Each event step has inputs and outputs.

d) Inputs include data/records required to take/initiate action(s).

e) Outputs are new data/records produced by action(s) taken/performed.

Events and event steps may be *re-usable components*.

9.3 Actors and roles

Each event step is initiated by an actor performing in a particular role. Actors and roles are *re-usable components.*

9.4 Actions taken

Each action is a discrete task, operation or process initiated or performed by an actor. Each action may have inputs and outputs. An action may be designated as auditable (at run-time). An action may be designated as attestable with signature (at run-time). An action may invoke one or more EHR (or other) system functions. Actions are *re-usable components.*

NOTE See ISO/HL7 10781 and ISO/HL7 16527.

9.5 Inputs and outputs

Each event and action has specified data as inputs to or outputs from specified functions and processes. Inputs and outputs resolve to data requirements in the form of data objects and elements. Data objects and elements are *re-usable components* and may be drawn from a formalized information model.

NOTE See Reference [18].

10 Use case requirements template

10.1 Preface and introduction

The preface and introduction explains the purpose of use case development. A use case focuses on a topic area for software development, typically with the intent to promote consistency and uniformity. A new scenario might fit within an existing use case or might be better included in a new use case. This may be a subjective decision. Format is paragraph(s).

10.2 Initiative overview

10.2.1 General

The initiative overview articulates the overarching subject area(s), business case(s) and issues that the initiative aims to address. The initiative's goal is generally at a higher level than those of the use case and are distinguished as such in this section. When an initiative has multiple use cases, this initiative overview should be consistent for each use case. A recommended starting point for this content is the project charter and related research collected during the pre-development phase. Format is paragraph(s).

10.2.2 Initiative challenge statement

The initiative challenge statement states the current challenge or problem, on a healthcare industry level, that the initiative seeks to address. Related issues should be included within this clause, with the exception of risks, which are outlined later in the use case. Format is paragraph(s).

10.3 Use case scope

10.3.1 General

This section describes the scope of the use case. Most use cases in healthcare informatics focus on information processes and flows, step-wise and integral to health care/business processes, often tightly interwoven with patient flows and provider/practitioner work flows. The scope statement outlines flows and processes pertinent to this use case. If there are multiple use cases within the same Initiative, this section can be used to explain how the scope of this use case relates to the others. Subclauses 10.4.2 to 10.4.4 further define scope at a more granular level. Diagrams and other supplemental data/examples often help to provide context and clarify the basis for the use case. Format is paragraph(s), with optional diagrams.

10.3.2 Background

The background section goes into more detail than the initiative overview to describe the relevance of the use case in terms of gaps and misalignments in health care/business flows and processes. Also describe key policy and/or regulatory issues as well as dependencies that may impact the use case. Format is paragraph(s).

10.3.3 In scope

The in scope section offers the opportunity to further define and refine the scope, adding details. The section can further elaborate how health/care data/records are captured, retained and conveyed in in a particular business context. It can describe exchange transactions and data content to be included. It can describe specific aspects that need to be in place to enable the information to be sent, received and understood the same at both ends of the transmission. Format is bulleted list.

10.3.4 Out of scope

This section indicates what is out of scope for the use case. This section may highlight dependencies on the feasibility, implement-ability, and usability that result in limitations of the use case. It is not intended to be an exhaustive enumeration of all possibilities. At a higher level, that which is not declared "In Scope", is by definition, "Out of Scope". Format is bulleted list.

10.3.5 Stakeholders

The stakeholder section identifies particular individuals and organizations that are potentially affected by content of the use case. It is not intended to be an exhaustive enumeration but rather focus on those with most direct impact. Format is a table of identified communities (see Table 1).

Table 1 — Stakeholders (example)

Stakeholder	Working definition
Patient	Healthcare consumers who are recipients of healthcare services and products.
Health Care Provider	A person or organization that's licensed to offer healthcare services.

10.4 Value statement

The value statement provides a high level description of values and/or anticipated benefits of this use case to the healthcare community. This section also identifies anticipated outcomes and metrics that will be used to assess success factors. Format is paragraph(s) followed by a bulleted list of values/benefits.

10.5 Use case assumptions

This section describes use case assumptions or those characteristics, functions or processes needed to establish the circumstances within which use case requirements are properly met or realized (e.g. an encompassing privacy and security framework). These points may be more functional in nature and may be stated in terms of broad overarching concepts of the Initiative. Success metrics for software design, development, testing, certification and implementation may include criteria based on use case assumptions. Format is bulleted list. Assumptions are *re-usable components* (as requirements statements). (See examples in Tables 6 and 7.)

10.6 Pre-conditions

This section describes use case pre-conditions or the state of the health/care environment or system that must be true before use case operations, processes, activities or tasks can be executed. Success metrics for software design, development, testing, certification and implementation may include criteria based on pre-conditions. Format is bulleted list. Pre-conditions are *re-usable components* (as requirements statements). (See examples in Tables 6 and 7.)

10.7 Post-conditions

This section describes use case Post-Conditions or the state of the health/care environment or system that will be true after successful execution of use case operations, processes, activities and tasks. Success metrics for software design, development, testing, certification and implementation may include criteria based on Post-Conditions. Format is bulleted list. Post-Conditions are *re-usable components* (as requirements statements). (See examples in Tables 6 and 7.)

10.8 Actors and roles

This section describes business actor(s) who participate (play a role) in use case scenarios, events and actions (see Table 2). A Business actor (person or organization) typically uses an EHR or other system to perform/fulfil health/care functions and processes including information interchange. Format is a table of business actors and related roles. Actors and roles are *re-usable components*. (See examples in Table 8.)

Table 2 — Actors and roles (example)

Actor	System	Role
Primary Care Physician	EHR System	Sender
Specialist	EHR System	Receiver

10.9 Use case diagram

This section describes the use case conceptually as a use case diagram. The diagram offers an overview use case scenarios as described in user stories and shows interactions between business actors and EHR or other systems. This section includes a use case diagram and, if applicable, a context diagram (examples are shown below in Figures 1 and 2). The context diagram uses inputs and outputs to provide a pictorial representation of the environment. Format is graphic diagram(s).

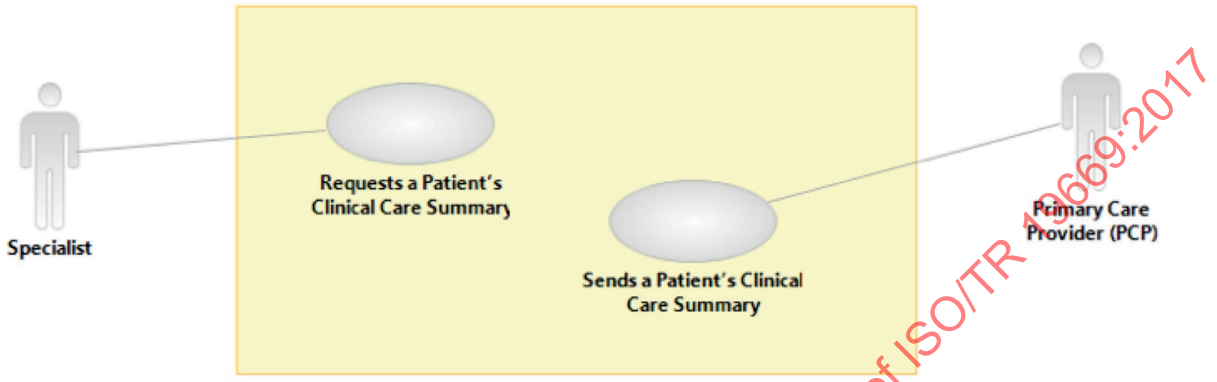

Figure 1 — Use case diagram (example)

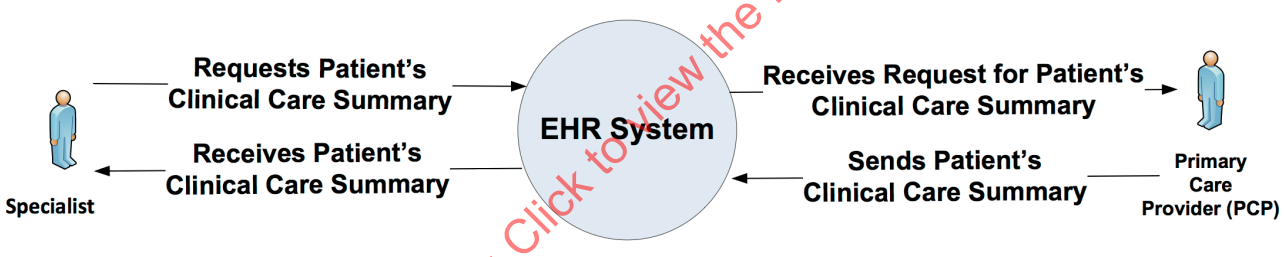

Figure 2 — Context diagram (example)

10.10 Use case scenario(s)

This section describes health/care actors, interactions, actions and requirements in the form of a use case scenario. It offers a prototypical sequence of interactions in a business or clinical collaboration or an application context. Use case scenarios may describe different paths (actors, sequences, steps) to achieve the same purpose or may cascade: first sequence, second sequence, etc. A scenario may include one or more user stories, each with an activity diagram, base flow table and alternative flow table (if applicable). Format is paragraph(s).

EXAMPLE Specialist requests patient information from Primary Care Provider (PCP).

10.11 User story

User stories describe the interaction between various actors of the use case. User stories also describe key patient, provider (work) and information flows. These interactions are further described in subsequent sections. User stories are often used to provide clinical context. Format is paragraph(s).

EXAMPLE A specialist receives a referral and requires more information to treat the patient properly at the point of care. Using an EHR System, the specialist sends a request to the PCP for the patient's clinical care summary. The PCP successfully receives the requests, understands the requests, and sends the patient's clinical care summary back to the specialist via the EHR System. The specialist successfully receives the patient information, understands it, and makes an informed decision that can provide better quality of care to the patient.

10.12 Activity diagram

An activity (or behaviour) diagram is a special form of a state transition diagram in which all or most of the states are action states. An action state represents the fulfilment of associated responsibilities in response to the information received from the previous step. The activity diagram (Figure 3) illustrates the use case flows graphically, and represents the events/actions and the flow of information between the actors.

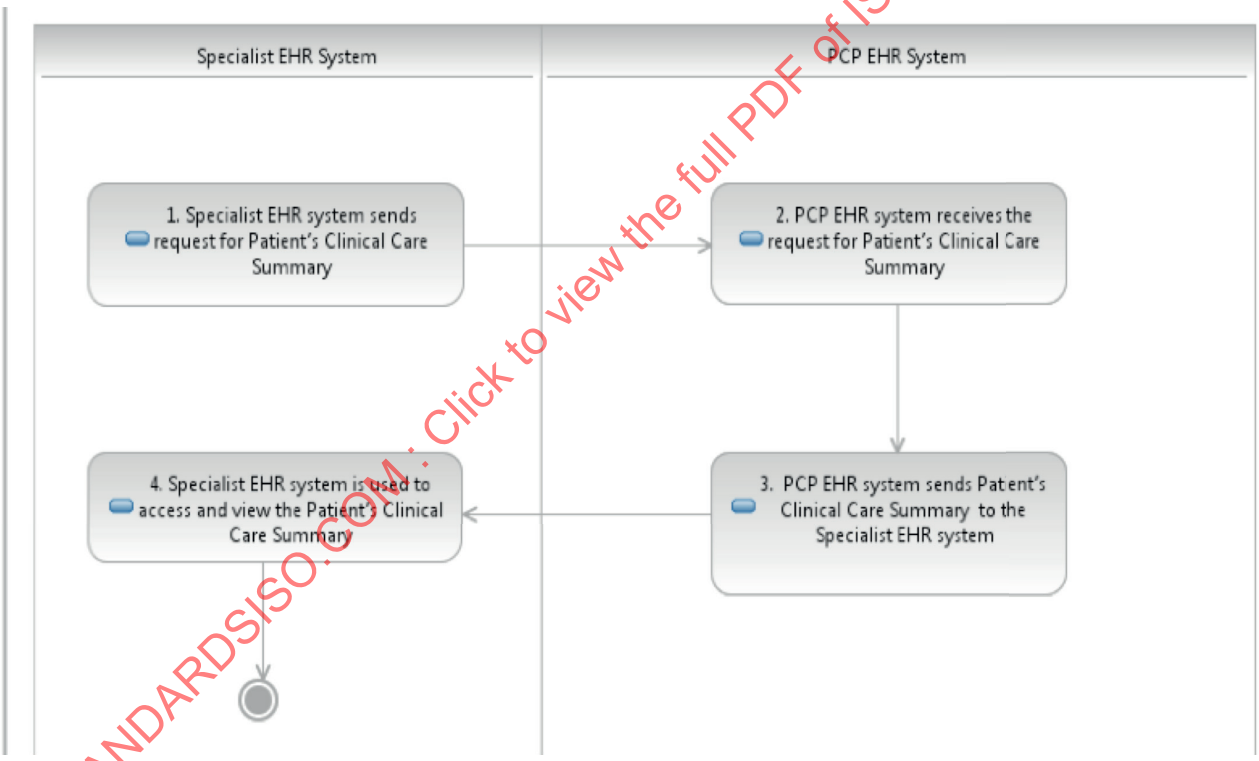

Figure 3 — Activity diagram (example)

10.13 Flow

10.13.1 Base flow

The base flow describes step by step use case events and actions within a use case scenario (see Table 3). Each row is an event step and includes the actor, the role played by the actor, event description, inputs (records/data required to undertake the event) and outputs (records/data resulting from event), and discrete actions taken. Format is a table. Actors, roles, use case scenarios, events and actions are *re-usable components.* (See examples in Table 9.)

Table 3 — Base flow with event steps (example)

Step	Actor	Event/description	Inputs	Outputs	Action(s)
Transitions of Care (TOC) – Transitions of Care – Scenario 1A – Exchange of discharge summary to support transfer of care					
Pre	**EHR System(s)**	**Reference/Set consistent time**			**Reference consistent time**
1	Provider	Trigger generation of discharge summary for Patient A	START	Discharge instructions	Identify patient, provider, EHR system
					Originate/attest/retain – discharge summary
					Set data access permissions
2	Hospital EHR system	Send discharge summary to PCP's EHR system or other provider EHR system	Discharge instructions	Discharge instructions	Transmit – discharge summary
3	PCP or other provider EHR system	Receive discharge summary	Discharge instructions	Discharge instructions	Identify (EHR) system
					Receive/retain – discharge summary
4	Provider	Trigger generation of discharge summary for Patient A	Discharge summary	Discharge summary	Identify patient, provider, EHR system
					Originate/attest/retain – discharge summary + instructions
					Set data access permissions
5	Hospital EHR system	Send discharge summary to PCP's EHR system or other provider organization	Discharge summary	Discharge summary	Transmit – discharge summary + instructions
6	PCP or other provider EHR system	Receive discharge summary	Discharge summary	Discharge summary	Identify (EHR) system
					Receive/retain – discharge summary + instructions
7	Provider	View discharge summary/ instructions	Discharge summary	END	Identify/authenticate provider
					Check user data access permission
					Access/view – discharge summary + instructions

10.13.2 Alternate flow

The alternate flow is optional and describes alternate step by step use case event steps and actions. An alternative flow might be offered in contrast (or as an option to) the base flow or might be better included in a new scenario. This may be a subjective decision. For example, alternative flows might be used to capture error messages returned if data is unavailable or not permitted to be shared. Format is a table structured as per base flow (in the previous section). (See examples in Table 9.)

10.13.3 Functional requirements

The functional requirements section identifies the capabilities a system must have in order to enable functionalities described in the user story (see 10.11), base and alternate flows (see 10.13.1 and 10.13.2). This section provides a detailed breakdown of requirements in terms of intended functional behaviours of the application systems involved in the capture, verification, attestation, retention, management and exchange of health data/records. Functional requirements include information interchange requirements, system requirements and dataset requirements as specified in 10.13.4, 10.13.5 and 10.15. Format is paragraph(s). Functional requirements are *re-usable components* (as requirements statements). (See examples in Tables 6 and 7.)

10.13.4 Information interchange requirements

The information interchange requirements section identifies system to system interchanges described in the user story (10.11), base and alternate flows (10.13). Format is a table (see Table 4).

Table 4 — Information interchange requirements (example)

Initiating system	Action	Information interchange	Action	Receiving system
	Send		Receive	
	Send		Receive	

10.13.5 System requirements

The system requirements section lists system capabilities to support functionalities (behaviours) described in the user story (10.11), base and alternate flows (10.13), including work and information flows and data/record interchange. Format is a table. (See examples in Tables 6 and 7.)

10.13.6 Sequence diagram

The sequence diagram (Figure 4) shows interactions in the sequential order that they occur. This representation can make it easy to demonstrate how separate components interact in sequence. Horizontal lines are used to identify the specific activity between the systems.

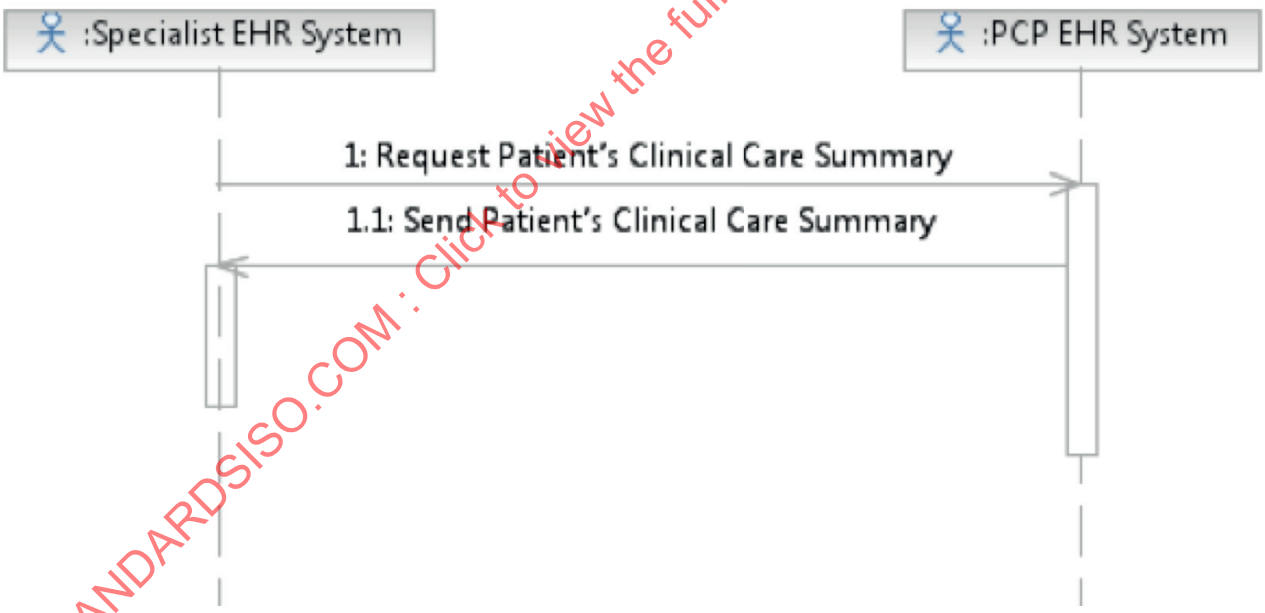

Figure 4 — Sequence diagram (example)

10.14 Risks, issues and obstacles

The risks, issues and obstacles section describes any concerns that might interfere with meeting the requirements of the use case. Format is paragraph(s) with a bulleted list.

10.15 Dataset requirements

The dataset requirements section describes data objects and elements that are required (or optional) in the course of each use case scenario (see Table 5). The designation of required versus optional may occur at a later stage of development (after use case requirements are specified). However it is

important that these dataset requirements be as fully specified as possible. Each data element specified is necessary for some aspect of the use case but does not specify exactly how they may be used together. Each data element set may contain multiple data elements unless otherwise stated. Data elements should be specified at their most granular level. For example, if it is necessary to specify a mailing code, do not use the less specific data object 'address'. For coded data elements it is important to specify the base standard from which they are chosen, e.g., a specific vocabulary, coding or classification scheme, and the organization who maintains these schemes. Format is a table including sections for each data objects followed by columns for data element name, description/definition, sample representation and source vocabulary. Data objects and elements are *re-usable components.* (See examples in Table 11.)

Table 5 — Dataset requirements (example)

Data element	Element description	Sample representation	Terminology
<data object name/description>			
<data element name>	<data element description>		

11 Methodology for component capture, cataloguing and re-use

11.1 General

As noted in Clause 8, use cases components are a) requirements, b) actors and roles, c) scenarios, events and actions, d) data objects and elements. Depending on the situation, certain use case components may be optional.

11.2 Component — Requirements

Common use case requirements are derived from, or re-used as, assumptions, pre- and post-conditions, and system functional requirements.

11.3 Derivation of common requirements from existing use case template

11.3.1 General

Capture each assumption, pre- and post-condition (from 10.5 to 10.7), and system functional requirements (from 10.13.5) in the existing (completed) use case template. Format each as: <actor> <SHALL/SHOULD/MAY> <verb> <requirement statement>. Check catalog for existing same or closely matching requirement. If new, determine if requirement is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

NOTE 1 Actors may vary depending on specific application of a requirement within a use case scenario.

NOTE 2 Required-ness (SHALL/SHOULD/MAY) may vary depending on use case scenario.

11.3.2 Re-use of common requirements in new use case scenario

When considering a new use case assumption, pre- or post-condition, or system functional requirement, search/review catalog for desired requirement component. If found, select for inclusion in new use case scenario, specifying actors to whom applicable and required-ness (SHALL/SHOULD/MAY). If not found, add new requirement to use case scenario then determine if the new requirement is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

Table 6 — Common requirements (first example)

ID [Rxxx]	Who [Typical actor]	SHALL SHOULD MAY	Requirements derived from Assumptions, Pre/Post Conditions
R1-R16	At the point of data origination and/or retention…		Baseline Requirements for Data at Rest
R1	The System…	SHALL	Capture and maintain HR Entries documenting actions taken.
R2			Manage and protect patient HR at rest.
R3			Manage patient identity.
R4			Identify patient as subject of care.
R5			Identify patient when subject of HR Entry.
R6			Identify patient when author of HR Entry.
R7			Manage patient data access consents and permissions.
R8			Manage provider identity: individual and organization.
R9			Identify provider of healthcare.
R10			Identify provider when subject of HR Entry.
R11			Identify provider (or other system user) when author of HR Entry.
R12			Manage lifecycle and version audit for HR entries, including: origination, verification, attestation, amendment, view/access, retention.
R13			Manage provenance details for HR Entries, including: • Who - patient - individual • Who - provider - individual and/or organization • Who - author of HR Entry • What - action taken • When - date, time, duration of action • When - date, time of authorship • Where - location, system, network address, device
R14			Identify system (as source or receiving EHRS/PHRS).
R15			Manage user access to system resources, including PHI and HR Entries.
R16			Manage data de-identification and/or aliasing as necessary.
R17			Manage data re-identification as necessary.
R1.1-R16.1	At the point of data exchange…		Corresponding Baseline Requirements for Data in Motion
R1.1			Identify HR information corresponding to actions taken in exchange instances.
R2.1			Protect Patient HR information in transit (during exchange).
R4.1			Identify patient as subject of care in exchange instances.
R5.1			Identify patient when subject of HR information in exchange instances.
R6.1			Identify patient when author of HR information in exchange instances.

Table 6 *(continued)*

ID [Rxxx]	Who [Typical actor]	SHALL SHOULD MAY	Requirements derived from Assumptions, Pre/Post Conditions
R7.1	The System…	SHALL	Convey patient data access consents and permissions along with and corresponding to patient HR information exchanged.
R9.1			Identify provider of healthcare in exchange instances.
R10.1			Identify provider when subject of HR information in exchange instances.
R11.1			Identify provider (or other system user) when author of HR information in exchange instances.
R12.1			Include lifecycle and audit of HR information in exchange instances.
R13.1			Include provenance of HR information in exchange instances.
R14.1			Identify system in exchange instances (as source or receiving EHRS, PHRS or Intermediary).
R16.1			Exchange de-identified HR information as necessary.

Table 7 — Common requirements (another example)

ID [Rxxx]	Who [Typical actor]	SHALL SHOULD MAY	Requirements derived from Assumptions, Pre/Post Conditions
R101	1. Individual (provider) 2. Organization (provider)	SHALL	1. Be a clinician in a care delivery setting; OR 2. Be a Provider organization.
R102	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider)	SHALL	1. Be capable of producing a structured summary document using C32/CCD and/or CCR standards [with] properly coded data elements; AND 2. Be capable of exchanging [a summary document] with another EHR system or PHR system.
R103	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider)	SHALL	Be capable of ensuring that content of the Summary Record (as exchanged) maintains its fidelity to source, as well as assured identity, provenance, completeness, audit/traceability, full context, along with permissions and qualifications.
R104	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider) 4. Network	SHALL	Enable consistent, appropriate, and accurate information exchange across clinician systems, data repositories and locator services, including but not limited to:
R105			Implement methods to identify and authenticate users;
R106			Implement methods to identify and determine providers of care;
R107			Implement methods to enforce data access authorization policies.
R108	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider)	SHALL	Implement security and privacy policies to support acceptable levels of patient privacy and security; i.e., HIPAA, HITECH and EHR certification criteria.

Table 7 *(continued)*

ID [Rxxx]	Who [Typical actor]	SHALL SHOULD MAY	Requirements derived from Assumptions, Pre/Post Conditions
R109	Individual (patient)	SHALL	Has and use a PHR.
R110	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider)	SHALL	Enable data transmission via Health Information Exchanges – as data may be transmitted to multiple HIEs and providers.
R111	1. Individual (provider) 2. Organization (provider) 3. EHR System (provider) 4. PHR System (patient)	SHALL	Ensure Summary Record maintains its fidelity to source, assured identity, provenance, completeness, audit/ traceability, full context, along with permissions and qualifications-both as a pre-condition of transmittal/disclosure (source/sending EHRs/PHR

11.4 Component – Actors/roles

11.4.1 General

Common actors and roles are derived from, or re-used in, use case scenario event steps.

11.4.2 Derivation of common actors/roles from existing use case template

Capture each actor/role from the existing (completed) use case template (10.12). Check catalog for existing same or closely matching actor/role. If new, determine if actor/role is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

11.4.3 Re-use of common actors/roles in new use case scenario

When considering a new actor/role, review catalog for desired actor/role component. If found, select for inclusion in new use case scenario. If not found, add new actor/role to use case and scenario then determine if the new actor/role is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

Table 8 — Common actors/roles (example)

Actor	Role	Participation
Individual	Patient	• Subject of care • Subject of health record
Individual	Provider	• Performer • Author of data/record content • Verifier, Attester
Organization	Provider	Accountable Care Organization
System, device or software		• Capturer of data/record content • Retainer of health record • Transmitter • Receiver

11.5 Component — Scenarios

11.5.1 General

Common scenario(s) are derived from, or re-used in, use cases.

11.5.2 Derivation of scenarios from existing use case template

Capture each scenario from the existing (completed) use case template (10.12). Check catalog for existing same or closely matching scenario. If new, determine if scenario is likely to be re-used in future use cases and if so, add as new Core component candidate.

11.5.3 Re-use of common scenarios in new use case

When considering a new scenario, review catalog for desired scenario component. If found, select for inclusion in new use case. If not found, add new scenario to use case then determine if the new scenario is likely to be re-used in future use cases and if so, add as new core component candidate.

11.6 Component — Events

11.6.1 General

Common events(s) are derived from, or re-used in, use case scenarios.

11.6.2 Derivation of events from existing use case template

Capture each event from the existing (completed) use case template (10.12). Check catalog for existing same or closely matching event. If new, determine if event is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

11.6.3 Re-use of common events in new use case scenario

When considering a new event, review catalog for desired event component. If found, select for inclusion in new use case scenario. If not found, add new event to use case scenario then determine if the new event is likely to be re-used in future use case scenarios and if so, add as new core component candidate.

Table 9 — Common scenarios and events (example)

	Actor	Event/description	Inputs	Outputs	Sample action(s)
Transitions of Care - scenario 1A - Exchange of Discharge Summary to Support Transfer of Patient Information from One Provider to Another Provider					
Pre	EHR System(s)	Reference/Set Consistent Time			Reference Consistent Time
1	Provider	Trigger Generation of Discharge Summary for Patient A	START	Discharge Instructions	Identify Patient, Provider, EHR System
					Originate/Attest/Retain - Discharge Summary
					Set Data Access Permissions
2	Hospital EHR System	Send Discharge summary to PCP's EHR System or other Provider EHR System	Discharge Instructions	Discharge Instructions	Transmit - Discharge Summary
3	PCP or other Provider EHR System	Receive Discharge Summary	Discharge Instructions	Discharge Instructions	Identify (EHR) System
					Receive/Retain - Discharge Summary
4	Provider	Trigger Generation of Discharge Summary for Patient A	Discharge Summary	Discharge Summary	Identify Patient, Provider, EHR System
					Originate/Attest/Retain - Discharge Summary + Instructions
					Set Data Access Permissions

Table 9 *(continued)*

	Actor	Event/description	Inputs	Outputs	Sample action(s)
Transitions of Care - scenario 1A - Exchange of Discharge Summary to Support Transfer of Patient Information from One Provider to Another Provider					
Pre	EHR System(s)	Reference/Set Consistent Time			Reference Consistent Time
5	Hospital EHR System	Send Discharge summary to PCP's EHR System or other Provider Organization	Discharge Summary	Discharge Summary	Transmit - Discharge Summary + Instructions
6	PCP or other Provider EHR System	Receive Discharge Summary	Discharge Summary	Discharge Summary	Identify (EHR) System
					Receive/Retain - Discharge Summary + Instructions
7	Provider	View Discharge Summary/Instructions	Discharge Summary	END	Identify, Authenticate Provider
					Check User Data Access Permissions
					Access/View - Discharge Summary + Instructions
Transitions of care - scenario 1B - Exchange of clinical summaries to support closed loop referral of patient from one provider to another					
Pre	EHR System(s)	Reference/Set Consistent Time			Reference Consistent Time
1	Provider	Trigger Generation of Consultation Request Clinical Summary for Patient A	START	Generated Consultation Request Clinical Summary	Identify Patient, Provider, EHR System
					Originate/Attest/Retain - Clinical Summary
					Verify - Clinical Summary
					Set Data Access Permissions
2	PCP EHR System	Send Consultation Request Clinical Summary to specialist's EHR System	Consultation Request Clinical Summary	Consultation Request Clinical Summary	Transmit - Clinical Summary
3	Specialist EHR System	Receive Consultation Request Clinical Summary from PCP's EHR System	Consultation Request Clinical Summary	Consultation Request Clinical Summary	Identify (EHR) System
					Receive/Retain - Clinical Summary
4	Provider	View Consultation Request Clinical Summary in specialist's EHR System	Consultation Request Clinical Summary	END	Identify Provider
					Check User Data Access Permissions
					Access/View - Clinical Summary
5	Provider	Trigger Generation of Consultation Summary for patient A	START	Generated Consultation Summary	Identify Patient, Provider EHR System
					Originate/Attest/Retain - Consultation Summary
6	Specialist EHR System	Send Consultation Summary to PCP's EHR System	Consultation Summary	Consultation Summary	Transmit - Consultation Summary
7	PCP EHR System	Receive Consultation Summary from specialist's EHR System	Consultation Summary	Consultation Summary	Identify (EHR) System
					Receive/Retain - Consultation Summary

Table 9 *(continued)*

	Actor	Event/description	Inputs	Outputs	Sample action(s)
Transitions of Care - scenario 1A - Exchange of Discharge Summary to Support Transfer of Patient Information from One Provider to Another Provider					
Pre	EHR System(s)	Reference/Set Consistent Time			Reference Consistent Time
8	Provider	View Consultation Summary in PCP's EHR System	Consultation Summary	END	Identify, Authenticate Provider
					Check User Data Access Permissions
					Access/View – Consultation Summary

11.7 Component — Actions

11.7.1 General

Common action(s) are derived from, or re-used in, use case scenario event steps.

11.7.2 Derivation of actions from existing use case template

Capture each action from the existing (completed) use case template (10.12). Check catalog for existing same or closely matching action. If new, determine if action is likely to be re-used in future use case scenario event Steps and if so, add as new core component candidate.

11.7.3 Re-use of common actions in new use case scenario event steps

When considering a new action (see Table 10), review catalog for desired action component. If found, select for inclusion in new use case scenario event step. If not found, add new action to use case scenario event step then determine if the new action is likely to be re-used in future use case scenario events and if so, add as new core component candidate.

Table 10 — Common actions (example)

Action category	Action ID	Action
Identity	A.ID.1	Identify, Authenticate Individual Patient
	A.ID.2	Select Individual Patient
	A.ID.3	Identify, Authenticate Provider
	A.ID.4	Select Provider
	A.ID.5	Identify System
	A.ID.6	Validate Identity Certificate
Consistent Time	A.TIME	Reference Current Time
Data Access Permissions	A.PERMIT.1	Set Data Access Permissions, including Patient Consent
	A.PERMIT.2	Determine/designate Scope of Data Access Permissions
Access Control	A.ACCESS.1	Check User Data Access Permissions
	A.ACCESS.2	Access/View Record, Document or Message
Audit	A.AUDIT	Audit action and/or Record action
Query	A.QUERY	Query
Encrypt	A.ENCRYPT	Encrypt Record or Exchange Content
De-Crypt	A.DECRYPT	Decrypt Record or Exchange Content
Signature	A.SIGN	Apply Signature

Table 10 *(continued)*

Action category	Action ID	Action
Exchange	A.XFER.1	Transmit Record, Document or Message
	A.XFER.2	Receive Record, Document or Message
Acknowledgement	A.ACK	Acknowledgement
Record Lifecycle	A.REC.1	Originate
	A.REC.2	Retain
	A.REC.3	Verify
	A.REC.4	Attest
	A.REC.5	Amend
	A.REC.6	De-Identify or Alias
	A.REC.7	Re-Identify
	A.REC.8	Extract
	A.REC.9	Translate
	A.REC.10	Output/Report
	A.ACCESS.2	Access/View
	A.ENCRYPT	Encrypt
	A.DECRYPT	Decrypt
	A.XFER.1	Transmit, Disclose
	A.XFER.2	Receive

11.8 Component — Data objects/elements

11.8.1 General

Each data object is comprised of data object(s) and elements are derived from, or re-used in, use case data requirements.

11.8.2 Derivation of data objects/elements from existing use case template

Capture each data object/element from the existing (completed) use case template (Section 10.x). Check catalog for existing same or closely matching data object/element. If new, determine if data object/element is likely to be re-used in future use case data rRequirements and if so, add as new core component candidate.

11.8.3 Re-use of common data objects/elements in new use case data requirements

When considering a new data object/element, review catalog for desired data object/element component (see Table 11). If found, select for inclusion in new use case scenario data requirement. If not found, add new data object element to use case scenario data requirements then determine if the new data object is likely to be re-used in future use case data requirements and if so, add as new core component candidate.