TRILLIUM II
Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

WP2

D2.3 v2017-12-30 Medications and Medical devices: data sets, information structures, value sets, & tools-WP2-T2.2-PHAST

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| Publishable summary:           | Trillium-II scales up the EU/US cooperation initiated with Trillium Bridge, to advance adoption of the International Patient Summary supported by broadly and consistently implemented standards. Work Package 2 defines the contents, which are required in the International Patient Summary for emergency and unplanned care, and builds the standardized components, assets and tools needed for this purpose.

The *Medications* component of a Patient Summary lists the patient’s current medications that a new healthcare professional needs to be aware of in order to provide appropriate care to the patient.

The *Medical Devices* component of a Patient Summary lists the medical devices implanted on or used by the patient that are of clinical significance to any new healthcare professional delivering care to the patient.

The two components use the base standard FHIR STU3 and a number of reference terminologies to represent in a meaningful way medications and devices.

The *Medications* component also takes into account the ISO IDMP standard set, using the IDMP attributes suitable for representing medications in the International Patient Summary. Among these are substances, administrable dose forms, strengths, routes of administration. The component also sets the attributes to express the IDMP identifiers when these become available.

The *Medical Devices* component takes into account the unique device identification system (UDI) established by the FDA and also adopted by the recent European Medical Device and IVD Regulations.

This D2.3 deliverable specifies the interoperable FHIR artefacts that represent each of the two components *Medication* and *Medical Devices* in an international patient summary. These artefacts include machine-processable FHIR resource profiles, as well as the FHIR ValueSet resources, which select the standardized vocabularies supporting the content. In addition, the deliverable provides examples for each of the two components. All these artefacts are accessible on line and the deliverable provides the links.

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<td>François Macary, FR: <a href="mailto:francois.macary@phast.fr">francois.macary@phast.fr</a></td>
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Statement of originality

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<td>Added 2 profiles of “List” resource 7.3 Value sets Processing of Giorgio’s additional comments Update of datasets, scenarios, resource profiles</td>
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<td>Added a core scenario on each dataset Added dosage instructions in structured way Change two concept names: Statement Source -&gt; Source of Information ; Statement Date -&gt; Assertion Date Added an extension to DeviceUseStatement FHIR resource to carry “none used” and “unknown usage of devices” as a code. Complemented the value sets Added 3 examples</td>
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<td>Update post final review within WP2 - suppress “ingredients” plural in Med dataset - corrections to some cardinalities - replace all “M” with “R” - all lower cases for FHIR profiles’ names - added references to available mappings for both contents - added examples of mappings (6.1.2.6) - Glossary</td>
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<td>Alexander Berler</td>
<td>Gnomon</td>
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Executive summary

Trillium-II scales up the EU/US cooperation initiated with Trillium Bridge, to advance adoption of the International Patient Summary supported by broadly and consistently implemented standards. Work Package 2 defines the contents, which are required in the International Patient Summary for emergency and unplanned care, and builds the standardized components, assets and tools needed for this purpose.

In this Work Package, task 2.2 produces the “Medications” and the “Medical Devices” components of the International Patient Summary. This document – “D2.3: Medications and Medical Devices components for the patient summary” is the main deliverable from this task.

The Medications component of a Patient Summary lists the patient’s current medications that a new healthcare professional needs to be aware of in order to provide appropriate care to the patient.

The Medical Devices component of a Patient Summary lists the medical devices implanted on or used by the patient that are of clinical significance to any new healthcare professional delivering care to the patient.

The two components use the base standard FHIR STU3 and a number of reference terminologies to represent in a meaningful way medications and devices.

The Medications component also takes into account the ISO IDMP standard set, using the IDMP attributes suitable for representing medications in the International Patient Summary. Among these are substances, administrable dose forms, strengths, routes of administration. The component also sets the attributes to express the IDMP identifiers when these become available.

The Medical Devices component takes into account the unique device identification system (UDI) established by the FDA and also adopted by the recent European Medical Device and IVD Regulations.

This D2.3 deliverable specifies the interoperable FHIR artefacts that represent each of the two components Medication and Medical Devices in an international patient summary. These artefacts include machine-processable FHIR resource profiles, as well as the FHIR ValueSet resources, which select the standardized vocabularies supporting the content. In addition, the deliverable provides examples for each of the two components. All these artefacts are accessible on line and the deliverable provides the links.
1 Introduction

Work Package 2 of the Trillium II project covers the baseline use case of emergency and unplanned care, and builds the standardized components, assets and tools needed for this purpose.

Within this Work Package, Task 2.2 defines the conditions and scope of integration into international patient summaries of statements about the medications used by the patient, as well as about the devices implanted on or used by the patient. The task builds the standardized component which carries these two kinds of contents, enabling care providers to view them and to integrate them into their own EHR systems.

Thus, the task builds two content components for the Patient Summary:

- **Medications**: lists the drugs prescribed or dispensed or administered to the patient, or consumed by the patient, and considered as relevant for the attention of new care providers met by the patient during future unplanned care.
- **Medical Devices**: lists the medical devices implanted on or used by the patient, and considered as relevant for the attention of new care providers met by the patient during future unplanned care.

The first component “**Medications**” is a list of medication statements. Each statement describes a medication prescribed, dispensed, administered or taken, with start date and possibly stop date, and additional details about the posology. Each statement includes its own source such as a physician, a caregiver, the patient, a next of kin, or another informer.

The second component “**Medical Devices**” is a list of device use statements. Per a decision made jointly by WP2 and WP3 leaderships during a joint meeting in Brussels on October 4th, 2017, the second component has had its scope extended from “**Implanted devices**” to “**Medical devices implanted on or used by the patient**”. In fact, if all implants are expected to appear in the patient summary, it is obviously not the case of all medical devices that the patient may be using externally. Gauzes, pads, scales, bandages … used on an ad hoc basis by a person are of no interest in the patient summary. However, the knowledge about some specific medical devices used externally on a recurring basis by the patient may be useful to the practitioner discovering this patient during unplanned care. For instance, the nightly use of a continuous positive airway pressure device, or the daily use of a urinary probe, are facts worth to be brought to the attention of new care providers encountered by the patient. Hence the decision to extend the scope of this second component, to those of the medical devices externally used by the patient, that directly influence the patient health status and may have a significant impact on future unplanned care provided to the patient.

This document – “D2.3: Medications and Medical Devices components for the patient summary” is the main deliverable from this task. The other deliverables of the task are annexed to it: machine-processable artefacts, such as profiles of resources from the HL7 FHIR standard, semantic value sets based on reference terminologies, coded examples.
2 Dependencies upon Other Trillium II Deliverables

2.1 D2.1 Patient Summary services: Gap analysis

Based on an inventory and a review of patient summary initiatives in Europe and in the US, this deliverable provides an assessment of the topics typically expected in a patient summary, as well as an inspection of the details of each topic. It also draws some open issues regarding some of the topics, to be solved downstream by the content deliverables. As such, D2.1 is an input to task 2.3 in terms of scope, high-level requirements and information model regarding the two topics “Medications” and “Medical Devices”.

D2.1 has identified three open issues regarding the Medications topic, to be further analyzed and closed by the current D2.3 deliverable:

a) Should the Patient Summary also include historical medications (recently taken, but no longer part of the medication therapy)?

b) Should the Patient Summary limit its Medication content to prescribed medications (represented by medication prescriptions rather than medication statements), in contrast to all known medications (including over-the-counter and self-administered)?

c) Should the Patient Summary capture the situation where a medication part of the patient current treatment, is not taken and the reason for not taking it?

These three issues are addressed and closed in chapter 6 of the current deliverable.

Regarding the “Medical Devices” topic, although D2.1 reports that current existing patient summary initiatives generally limit the scope of this content to implanted devices, this D2.3 deliverable extends this scope to those non-implant medical devices, which are used by the patient on a recurring basis, and whose awareness by a new care provider met by the patient for unplanned care, might influence his or her decisions. The origin of this choice is exposed in the Introduction of this deliverable.

The outcome of D2.1 are key input to the content of chapters 6 and 7 of the current deliverable.

2.2 D2.2 Configuration Canvas for Patient Summary Component Libraries

D2.2 provides the template for all content deliverables, including this D2.3 deliverable.

D2.2 is also an input to this deliverable in terms of technical framework and production environment. In particular, D2.2 selects the framework of tools to be used to produce the component library and sets up the orchestration of these tools along the various steps of this production.

D2.2 also provides conventions common to all content deliverables, about conformance clauses, cardinalities, as well as naming and identification conventions. These conventions are applied in chapters 6 and 7 of the current deliverable.

3 External Sources Considered

3.1 HL7 International/CEN TC251 International Patient Summary (IPS)

3.1.1 Artefacts produced by IPS for Medications and Medical Devices

IPS is the most recent source of thoughts for incorporating medication lists and medical device lists into patient summaries.
The artefacts of the IPS project that are used as input to this deliverable are listed in the table below:

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<tr>
<th>Artefacts</th>
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<th>Medical Devices</th>
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<td>Dataset</td>
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<td>“IPS Medication Summary Section”</td>
<td>“IPS Medical Devices Section”</td>
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<td>Entry-level templates</td>
<td>“IPS Medication Entry”</td>
<td>“IPS Medical Device”</td>
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<tr>
<td>Subordinate templates for entries</td>
<td>“IPS Manufactured Product”, “IPS Subordinate SubstanceAdministration”</td>
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Table 1: IPS artefacts used as input to D2.3

3.1.2 Comparison of scopes between IPS and Trillium II for Medications
The “IPS Medication Summary Section” may document current medications as well as past medications. This section contains a list of medication statements, which can represent prescribed medications, dispensed medications or administered medications, or medications over the counter. Each item of the list may include more or less structured details about the product, substances, strength, dose form, route, posology, when these details are available and reliable from the source of the medication statement.

The “Medication” scope of this D2.3 deliverable covers the scope of the “Medication” content of the IPS project.

3.1.3 Comparison of scopes between IPS and Trillium II for Medical Devices
The “IPS Medical Devices section” does not limit its content to implanted devices. It addresses implanted and external medical devices that the patient health status depends on. However, the corresponding entry content of IPS is basically focused on devices, and has limited capability for indicating how, where and why the device is actually used. In particular, for implants, the IPS entry content does not provide any precision on the implantation of the device on the patient (where, how, why).

Unlike what it is in IPS, the “Medical Devices” content of D2.3 is structured as a list of device use statements, describing the usage of each medical device before describing the device itself. Thus, the scope of D2.3 for medical devices is broader than the scope of IPS. In particular, D2.3 enables to capture the target anatomic location for an implanted device, and the reason why a device is used or implanted.

3.2 HL7 DAM for UDI Implementation Guidance – Informative Ballot September 2017
Among other things, the HL7 DAM for UDI Implementation Guidance provides the guidance for implementing the unique device identifier (UDI) of a medical device in the FHIR standard. The current deliverable follows the recommendations of this document.
4 Base Standards

4.1 FHIR

FHIR is the base-standard chosen by the Trillium II project for the representation and structuration of the content of International Patient Summary.

This D2.3 deliverable builds Profiles on these Resources from the FHIR standard:

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</tr>
<tr>
<td>Device</td>
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<td>x</td>
</tr>
</tbody>
</table>

Table 2: FHIR resources profiled by D2.3

In addition, the deliverable uses profiles, which are common to all content deliverables for the following resources: Encounter, Organization, Patient, Practitioner, RelatedPerson.

4.2 ISO IDMP Standards Set

The purpose of the ISO “Identification of Medicinal Products” (IDMP) set of standards is to facilitate the reliable exchange of medicinal product information in a robust and consistent manner in the regulatory space (clinical trials, regulatory submissions, pharmacovigilance ...).

The European project OpenMedicine [http://www.open-medicine.eu] has recognized that the IDMP standards may become also useful beyond the regulatory space, for the description and identification of medications in the clinical space and for exchange of information across these two spaces.

This set of standards will be complemented in the future by robust identifiers assigned to the products, in particular the Pharmaceutical Product Identifiers (PhPIDs), which are independent of market authorizations granted to products, and therefore useful in the context of cross-jurisdictional patient summaries. However, these identifiers are not available yet.

The Medications content of this D2.3 deliverable takes into account relevant IDMP attributes suitable for representing medications in the International Patient Summary. Among these are substances, administrable dose forms, strengths, routes of administration.

The Medications content of this deliverable specifies the standardized elements that will carry the IDMP PHPIDs when these identifiers become available.

4.3 Unique Device Identifier (UDI)

The US FDA has established a unique device identification system (UDI) to adequately identify medical devices through their distribution and use. This system is already mandatory for implantable, life-supporting or life-sustaining devices of all classes, since 2015. It will progressively be extended to all classes of medical devices. The European Medical Device and IVD Regulations published on May 5th 2017 has adopted the same UDI system, and mandates its usage in the coming years, more or less shortly depending on the device class.

The components of UDI are the mandatory Device Identifier (UDI-DI), and the following individual Production identifiers (UDI-PI):
Deliverable 2.3: Medications and Medical Devices: data sets, information structures, value sets, & tools

- lot or batch number,
- serial number,
- manufacturing date,
- expiration date,
- distinct identification code.

The Device Identifier is the primary identifier of a device model. It is a unique key to access the properties of the device (safety information, brand name, device type, model number, manufacturer ...) recorded in a UDI database such as the GUDID in the US or EUDAMED in Europe.

The Medical Devices content of this D2.3 deliverable takes into account the UDI system and specifies the element carrying the Device Identifier and those carrying the Production Identifiers.

4.4 Reference Terminologies for Value Sets

The Trillium II project has chosen a number of international reference terminologies to carry the semantic of the content of the International Patient Summary.

This deliverable uses these reference terminologies for these main purposes:

- LOINC: identification of clinical and physiological observations.
- SNOMED CT: identification of anatomy, procedures, clinical findings, substances for medications.
- EDQM Standard Terms: identification of dose forms and routes of administration.
- UCUM: units of measure for quantitative results of observations (imposed by IDMP).
- HL7 Vocabularies: small additional value sets for various attributes.
- GMDN: Identification of medical devices.
- IDMP: Pharmaceutical Product Identifiers when these become available.

5 Tools

This section builds on top of section 3 “Orchestration of tools” of deliverable D2.2, and derives the choices made to the actual content of D2.3: medications and implanted devices.

5.1 ART-DECOR for Dataset, Associated Semantics, Value Sets and Mappings

The tool ART-DECOR is used to define the two contents Medications and Implanted Devices of the patient summary and to capture the related business requirements. The features of the tool used for these steps are:

- “dataset”: to build the reference model and underlying concepts;
- “scenario”: to describe the dynamic usage of each content in the context of the “unplanned care” general scenario; scenario is a layer on the dataset, and provides the cardinalities and conformance clauses.
- “value sets”: to select the semantics associated with coded concepts of each of these contents.

Art-decor is used again downstream to map the FHIR profiles registered in Simplifier.net back to the datasets in Art-decor, and to the associated value sets.

5.2 Forge for profiling FHIR Resource

Forge authoring tool is used to transpose the information model into a set of related FHIR resource profiles.

5.3 Simplifier.net for storage of Profiles and assembly of Implementation Guide

The Simplifier.net registry is used to publish the FHIR resource profiles, and to assemble the set of FHIR resource profiles together with server capabilities, into a FHIR implementation guide.
6 Information Model

6.1 Medications

6.1.1 Guidelines for including Statements on Medications in a Patient Summary

Focus on current medications:

As established by the overall topic matrix annexed to deliverable D2.1, the medications expected to be found in the International Patient Summary are the active medications, that is the medications prescribed to or taken by the patient at the time the patient summary is built. Each medication statement should provide the period of treatment planned for the medication, with start date and intended stop date. It may happen that when the patient summary is viewed downstream, some of the stop dates may have been passed, and therefore the associated medications have become historical medications. Nonetheless, the focus of the patient summary is on currently prescribed, or dispensed, or taken medications.

Medications prescribed, dispensed, or self-administered:

Depending upon the organization of the patient’s home country, the information about medications can be captured from prescriptions or dispenses, or self-statements made by the patient or by another informant, or from any combination of these sources. Therefore, the Medications content of the International Patient Summary must be able to capture medication statements of these various kinds, and to qualify the source of information for each of these statements.

Qualified medication statements:

Each medication statement is about one medication. This statement must be able to specify who made it and when, as well as what period is intended for taking this medication. And it must be able to express how the medication is taken or expected to be taken: dose, route, method, site, timing specifications.

“Reason for taking” left out of a patient summary for future unplanned care:

The patient summary built to support unplanned care, provides synthetic information needed by any new care provider met by the patient in this context. Among other things, such a care provider needs to be aware of the current medications taken by the patient, as well as of the patient’s current health problems. It is most likely that medications of the current medication list have a “reason for taking”, which is related to some problems of the current problem list. However, the detail of these relationships is not of primary interest to the new care provider met by the patient for unplanned care. Thus, the reason for taking a medication is left out of the Medications content of the patient summary.

“Reason not taken” left out of a patient summary for future unplanned care:

It may happen that a medication of the list is temporarily not taken by the patient at the moment a new care provider meets him or her. The chances that such a situation be registered into the information system authoring the patient summary are low. Even lower are the chances that the reason for not taking the medication be registered. For instance, it may simply happen that the patient has used up his or her supply of this drug and has not found yet a pharmacy able to refill the prescription with a new dispense. These considerations lead to leave out of scope of the patient summary the reason why a medication is temporarily not taken.
6.1.2 Medications Dataset for a Patient Summary

6.1.2.1 Rationale for Building the Dataset

The Medications component of the International Patient Summary is a list of qualified statements, each of which describing a medication prescribed for/dispensed to/taken by the patient during a period. The statement includes the available details about the medication (reason, dosage, ...).

Alternatively, the list may be limited to a single statement expressing “no medication in use” or to a single statement expressing that “no information is available about the patient’s medications”.

The dataset exists in two flavors:

- **A core dataset** limited to the minimal concepts, which should be systematically presented at first intent to the reader of a patient summary.
- **A comprehensive dataset**, which includes all detailed concepts potentially useful for the Medications content of a patient summary, but not necessarily presented at first intent.

6.1.2.2 Overview of the Dataset

The figure below shows the tree structure of the comprehensive Medications dataset. Optionality/cardinalities of each concept are not shown on this high-level view.

Most concepts are optional. For instance, a medication statement need not provide the ingredients of the drug nor the dosage instructions. The medication may be identified per se with a global identifier and a global name including substances and strengths, in which case listing its ingredients is redundant. Also, the IDMP set of identifiers, which are intended for future use when these identifiers become available, are not detailed on this high-level view.

The top element “Medications” represents a homogeneous list of Medication Statements.

A statement about a medication is qualified with:

- a source of information for this statement (practitioner, patient, related ...),
- an assertion date (date the statement was made),
- a status about the medication use (current, completed, intended, on hold ...)

The next sections of this document provide the conformance constraints and the cardinalities for each concept, successively in the two flavors of the dataset – core dataset and comprehensive dataset.
6.1.2.3  **Detailed View of the Core Medications Dataset**

The table below details the structure of the core *Medications* dataset in the general “unplanned care” scenario. The underlying tree structure is the one presented on Figure 1, above. The core dataset is limited to the minimal set of concepts, which should be systematically presented at first intent to the reader of a patient summary. Conformance, cardinalities and datatypes appearing in the figure below, follow the conventions set in deliverable D2.2. Concepts, which are not leaves of the tree structure appear in bold style.

---

*Figure 1: High-level View of the Comprehensive Medications dataset*
### Deliverable 2.3: Medications and Medical Devices: data sets, information structures, value sets, & tools

<table>
<thead>
<tr>
<th>Medications 1..1 R</th>
<th>1</th>
</tr>
</thead>
</table>

**Medications Statement 1..* R | 8**

A statement about one medication prescribed to, or dispensed to, or taken by the patient, specifying the date/time or period for taking this medication, qualifying the statement itself, and capturing the details available about this medication. Alternatively, the statement may express "No information available about the patient’s medications" or "The patient is not using any medication". In these two cases the statement SHALL be the only one in the Medications content of the patient summary.

**Medication Category (Code) 0..1 C | 3**

The item is used when the only information available about the medication taken by the patient is a rough category (e.g. anticoagulant, antibiotic) without any further detail available. It is exclusive of "Medications Use Unknown", "No Medication in Use" and "Medication".

- 1..1 R: if "Medications Use Unknown" and "Medication" and "No Medications in Use" not present
- 0..0 NP Else

**No Medications in Use (Code) 0..1 C | 176**

This item indicates that the patient does not take any medication. It is exclusive of "Medication Category", "Medications Use Unknown" and "Medication".

- 1..1 R: if "Medications Use Unknown" and "Medication Category" and "Medication" not present
- 0..0 NP Else

**Medications Use Unknown (No information available on medications use) (Code) 0..1 C | 175**

This item indicates that no information is available about whether the patient takes medications or not. The item is exclusive of "Medication Category", "Medication", "No Medication in Use"

- 1..1 R: if "No Medications in Use" and "Medication Category" and "Medication" not present
- 0..0 NP Else

**Medication 0..1 C | 11**

This group of items enables to provide full details about one medication taken by the patient. It is exclusive of the elements "Medication Category", "No Medication in Use" and "Medications Use Unknown"

- 1..1 R: if "Medications Use Unknown" and "Medication Category" and "No Medications in Use" not present
- 0..0 NP Else
Table 3: Detailed Description of the Medications Core Dataset

6.1.2.4 Detailed View of the Comprehensive Medications Dataset

The table below details the structure of the comprehensive Medications dataset in the general “unplanned care” scenario. The underlying tree structure is the one presented on Figure 1, above. The comprehensive dataset adds to the core dataset, all the concepts that might potentially be useful in some cases in a patient summary, and for this reason need to be accessible to the reader, but are not necessarily presented to the reader at first intent.

Conformance, cardinalities and datatypes follow the conventions set in deliverable D2.2.

Concepts, which are not leaves of the tree structure appear in bold style.

---

<table>
<thead>
<tr>
<th>Field</th>
<th>Cardinality</th>
<th>Datatype</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product and Strength Common Name</td>
<td>0..1 R</td>
<td>String</td>
</tr>
<tr>
<td>Non-proprietary name of the pharmaceutical product including the strength of each ingredient. This name is associated with the PhPID_L2 IDMP identifier if it exists.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredient</td>
<td>0..* C</td>
<td></td>
</tr>
<tr>
<td>1..* R: if &quot;Product and Strength Common Name&quot; is not present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0..* Else</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance (Code)</td>
<td>0..1 R</td>
<td>Code</td>
</tr>
<tr>
<td>A codeable concept representing the substance used as ingredient in the medication. The substance may be coded or represented in textual format.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength (Quantity)</td>
<td>0..1 R</td>
<td>Quantity</td>
</tr>
<tr>
<td>Strength of the substance in the composition of the product expressed as a ratio or in textual format.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Period of Medication Use</td>
<td>0..1 R</td>
<td></td>
</tr>
<tr>
<td>The period when the medication is taken. It includes a start date and a stop date. If the stop date is missing, it means that the medication treatment is ongoing, with no stop date assigned. If the start date is missing, it means that it is not known. In case of a single take, start date and stop date are equal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start (Date+time)</td>
<td>0..1 R</td>
<td></td>
</tr>
<tr>
<td>Start date/time of the product usage. Is in the past for active use, and in the future for intended use.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop (Date+time)</td>
<td>0..1 R</td>
<td></td>
</tr>
<tr>
<td>Stop date for the treatment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Deliverable 2.3: Medications and Medical Devices: data sets, information structures, value sets, & tools**

---

**Medications 1..1 R 1**

*Medications*

**Medication Statement 1..* R 8**

A statement about one medication prescribed to, or dispensed to, or taken by the patient, specifying the date/time or period for taking this medication, qualifying the statement itself, and capturing the details available about this medication. Alternatively, the statement may express "No information available about the patient's medications" or "The patient is not using any medication". In these two cases the statement SHALL be the only one in the Medications content of the patient summary.

**Source of Information (Collection of data) 0..1 R 9**

The person (practitioner, patient, related person) or organization (hospital, care center, ...) providing this statement

**Assertion Date (Date+time) 1..1 R 10**

The date/time the statement was made

**Status (Code) 1..1 R 13**

The status of the product usage:
The only values that make sense in the context of a patient summary are those below:
- active: product is in current use
- intended: usage is planned in the near future
- on-hold: usage temporarily halted, but is expected to resume later

- active
- intended
- on-hold

**Statement Note (Text) 0..* R 2**

*Further textual information about the statement*

**Medication Category (Code) 0..1 C 3**

The item is used when the only information available about the medication taken by the patient is a rough category (e.g. anticoagulant, antibiotic) without any further detail available. It is exclusive of "Medications Use Unknown", "No Medication in Use" and "Medication".

- 1..1 R: if "Medication", "No Medication in Use" and "Medication Use Unknown" not present
- 0..0 NP Else

**No Medications in Use (Code) 0..1 C 176**

This item indicates that the patient does not take any medication. It is exclusive of "Medication Category", "Medications Use Unknown" and "Medication".

- 1..1 R: If "Medication Category", "Medications Use Unknown", "Medication" not present
Deliverable 2.3: Medications and Medical Devices: data sets, information structures, value sets, & tools

○ 0..0 NP Else

Medications Use Unknown (No information available on medications use) (Code) 0..1 C 175

This item indicates that no information is available about whether the patient takes medications or not. The item is exclusive of "Medication Category", "Medication", "No Medication in Use"

○ 1..1 R: If "Medication Category", "No Medications in Use", "Medication" not present
○ 0..0 NP Else

Medication 0..1 C 11

This group of items enables to provide full details about one medication taken by the patient. It is exclusive of the elements "Medication Category", "No Medication in Use" and "Medications Use Unknown"

○ 1..1 R: if "Medication Category", "Medications Use Unknown", "No Medications in Use" are not present
○ 0..0 NP Else

ATC Class (Count) 0..1 R 180

Anatomic Therapeutic Chemical (ATC) Class of medication as defined by the World Health Organization (WHO)

Product Identifier (Code) 0..* R 12

A codeable concept representing the medication taken

IDMP Identifiers 0..1 R 177

This group holds the IDMP identifiers: MPID, PhPIDs, PCID.

MPID(Medicinal Product Identifier) (Identifier) 0..1 R 178

This element is the medicinal product identifier within the set of IDMP identifiers

PhPID Set 0..1 R 14

This group holds the set of pharmaceutical product identifiers within the IDMP set of identifiers.

PhPID Sub L1 (Identifier) 0..1 R 15

PhPID Active Substance Stratum Level 1. It identifies the substance(s) in the medication product

PhPID Sub L2 (Identifier) 0..1 R 16

PhPID Active Substance Stratum Level 2. It identifies Substance Term(s), Strength and Reference Strength
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PhPID Sub L3 (Identifier) 0..1 17

PhPID Active Substance Stratum Level 3.
It identifies substance(s) and administrable dose form

PhPID Sub L4 (Identifier) 0..1 R 18

PhPID Active Substance Stratum Level 4.
It identifies Substance(s) Term, Strength, Reference Strength and Administrable Dose Form

PCID(Packaged Medicinal Product Identifier) (Count) 0..1 R 179

This element holds the identifier of the packaged medicinal product authorized for usage in a regulated market.

Product non-proprietary Name (String) 0..1 R 24

International non-proprietary name of a pharmaceutical product, granted by the World Health Organization (WHO), or, if one does not exist, a non-proprietary name recommended by the jurisdiction regulating the market within which this medication is used.
This name does not include strength nor dose form. It is associated with the PhPID_L1 identifier if it exists.

Product and Strength Common Name (String) 0..1 R 181

Non-proprietary name of the pharmaceutical product including the strength of each ingredient.
This name is associated with the PhPID_L2 IDMP identifier if it exists.

Virtual Medicinal Product Name (String) 0..1 R 182

Non-proprietary name of a pharmaceutical product, including name of substance(s), strength(s) and dose form.
This name is associated with the PhPID_L4 identifier when it exists.

Branded Packaged Product Name (String) 0..1 R 25

Branded name of a packaged product authorized to a market by a regulatory agency

Dose Form (Code) 0..1 R 26

Pharmaceutical dose form of the medication. It can refer to the administered dose form or to the manufactured dose form.

Ingredient 0..* C 28

- 1..* R: if "Product and Strength Common Name" is not present
- 0..* Else

Substance (Code) 1..1 R 29
A codeable concept representing the substance used as ingredient in the medication. The substance may be coded or represented in textual format.

**Strength (Quantity) 0..1 R 30**

Strength of the substance in the composition of the product expressed as a ratio or in textual format.

**Period of Medication Use 0..1 R 19**

The period when the medication is taken. It includes a start date and a stop date. If the stop date is missing, it means that the medication treatment is ongoing, with no stop date assigned. If the start date is missing, it means that it is not known. In case of a single take, start date and stop date are equal.

**Start (Date+time) 0..1 R 21**

Start date/time of the product usage. Is in the past for active use, and in the future for intended use.

**Stop (Date+time) 0..1 R 22**

Stop date for the treatment.

**Dosage Instruction 0..* C 33**

Instructions for medication intake (frequency, conditions, preparation ...)

- 0..* : if Medication is present
- 0..0 NP Else

**Dose (Quantity) 0..1 R 34**

Number of units of dose form per intake

**Route (Code) 0..1 R 37**

Route of administration

**Timing Instructions (String) 0..1 R 38**

Frequency, association with specific events ...

**Maximum Dose per Period (Quantity) 0..1 R 35**

The maximum quantity to be taken over a period of time (day, week, 6 hours, ...). It is expressed as a ratio

---

**Table 4: Detailed Description of the Medications Comprehensive Dataset**

---
6.1.2.5 Associated Semantics

The table below lists the semantics for the codeable items of the dataset.

<table>
<thead>
<tr>
<th>Item</th>
<th>Value set / open semantics</th>
<th>Source</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>Medication Statement Statuses</td>
<td>FHIR</td>
<td><a href="http://hl7.org/fhir/codesystem-medication-statement-status.html">http://hl7.org/fhir/codesystem-medication-statement-status.html</a> limited to these values: active, intended, on-hold</td>
</tr>
<tr>
<td>No Medications in Use</td>
<td>Absent or Unknown Medication</td>
<td>HL7 IPS</td>
<td></td>
</tr>
<tr>
<td>Medications Use Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Category</td>
<td>Code representing a coarse category of drug in an international (e.g. SNOMED CT) or in a national code system</td>
<td>multiple</td>
<td></td>
</tr>
<tr>
<td>ATC Class</td>
<td>WHO ATC classification</td>
<td>WHO</td>
<td></td>
</tr>
<tr>
<td>Product Identifier</td>
<td>Code representing a drug in an international (e.g. SNOMED CT) or in a national code system</td>
<td>multiple</td>
<td></td>
</tr>
<tr>
<td>Mpid</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Phpid Sub L1</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Phpid Sub L2</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Phpid Sub L3</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Phpid Sub L4</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Pcid</td>
<td>To be defined in the future</td>
<td>IDMP</td>
<td></td>
</tr>
<tr>
<td>Dose Form</td>
<td>Pharmaceutical Dose Forms</td>
<td>EDQM</td>
<td><a href="https://standardterms.edqm.eu">https://standardterms.edqm.eu</a></td>
</tr>
<tr>
<td>Substance</td>
<td>Medicament substances</td>
<td>SNOMED CT</td>
<td>[&lt;&lt; 410942007</td>
</tr>
<tr>
<td>Route</td>
<td>Routes and Methods of Administration</td>
<td>EDQM</td>
<td><a href="https://standardterms.edqm.eu">https://standardterms.edqm.eu</a></td>
</tr>
</tbody>
</table>

Table 5: Semantics for Medications Dataset

6.1.2.6 Examples of Mappings

Some of the concepts of the Medications content are covered by more than one coded vocabulary, some of these vocabularies being defined globally (e.g. SNOMED CT), while other vocabularies address a continent (e.g. EDQM standard terms), or a single country like the “UCD” code system for drugs in France or dm+d for drugs in the UK. Mappings from one code system to another are needed to enable translation of the coded data of the Medications content of the patient summary. Below are some examples of such mappings:

- SNOMED CT to EDQM simple map (for dose forms and routes)
- Phast IOdc mapping from the French drug code system to SNOMED CT substances
6.2 Medical Devices

6.2.1 Guidelines for Describing Medical Devices Implanted or Used in a Patient Summary

All implants currently on the patient, or planned to be implanted, or recently explanted:

The patient summary includes all devices implanted or planned to be implanted on the patient. Any care provider met by the patient in the context of unplanned care, will need to be aware of these implants to provide accurate care.

In some cases, the knowledge about recently explanted devices may also be of interest. Conversely, medical devices, which the patient bore in the past, are of no interest to the patient summary.

Medical devices used externally that impact further care provision to the patient:

The patient summary selects those medical devices externally used by the patient, currently on a regular basis that directly influence the patient health status and may have a significant impact on future unplanned care provided to the patient.

6.2.2 Medical Devices Dataset for a Patient Summary

6.2.2.1 Rationale for Building the Dataset

The Medical Devices content of the patient summary is a list of qualified statements about medical device usage. Each statement describes the use of an implant or the use of an external medical device.

Alternatively, the list may be limited to a single statement expressing “no information available about the patient’s medical devices” or “no medical device implanted nor externally used”.

The reason for use/implant of a medical device can be expressed briefly as a concept expressing a disorder, symptom, complaint, or any other finding. If more detail is needed about the health problem addressed by the medical device, the full description about this current problem is assumed to be part of the Problems component of the patient summary.

The dataset exists in two flavors:

- A core dataset limited to the minimal concepts, which should be systematically presented at first intent to the reader of a patient summary.
- A comprehensive dataset, which includes all detailed concepts potentially useful for the Medical Devices content of a patient summary, but not necessarily presented at first intent.

6.2.2.2 Overview of the Dataset

The figure below shows the general shape of the comprehensive Medical Devices dataset. Optionality/cardinalities of the items are not shown on this high-level view.

The top element “Medical Devices” represents the concept of homogeneous list of Device Use Statements.

A statement about a medical device is qualified with:

- a source of information for this statement (practitioner, patient, related ...),
- an assertion date (date the statement was made),
- a status about the device use (current, past, intended)

The statement declares the period of use of the device. In the case of an implant, the start date represents the date the device was or will be activated on the patient. Activation of an implant in most cases coincides
with the date of implantation, but in some case, it may take place later. The stop date represents the date the device was or will be inactivated/explanted.

The statement includes reasons for use of the device, as simple codeable concepts expressing findings or health problems. Whenever a more comprehensive description of the problem is needed, the problem is included in the Problems component of the patient summary.

The statement expresses the body site targeted by the external device or where the device is implanted.

The next sections of this document provide the conformance constraints and the cardinalities for each concept, successively in the two flavors of the dataset – core dataset and comprehensive dataset.

Figure 2: High-level view of the Medical Devices dataset

6.2.2.3 Detailed View of the Core Medical Devices Dataset
The table below details the structure of the Medical Devices core dataset in the context of the unplanned care scenario. The underlying tree structure is the one presented on Figure 2.
The core dataset is limited to the minimal set of concepts, which should be systematically presented at first intent to the reader of a patient summary.

Conformance, cardinalities and datatypes follow the conventions set in deliverable D2.2.

Concept names in the tree structure appear in bold style, except for the leaf concepts.

**Medical Devices 1..1 R 1**

This dataset lists the medical devices implanted on or used externally by the patient, and considered as relevant for the attention of new care providers met by the patient during future unplanned care.

If all implants are expected to appear in the patient summary, it is obviously not the case of all medical devices that the patient may be using externally. Gauzes, pads, scales, bandages ... used on an ad hoc basis by a person are of no interest in the patient summary. However, the knowledge about some specific medical devices used externally on a recurring basis (such as a urinary probe or a continuous positive airway pressure device) by the patient may be useful to the practitioner discovering this patient during unplanned care.

**Device Use Statement 1..* R 2**

A statement about one medical device implanted on or use externally by the patient. Implants that were recently explanted from the patient as well as those that are planned to be implanted on the patient may also be captured in this dataset. Alternatively, the statement may express "No information available about the patient’s devices" or "The patient is not using any medical device". In these two cases the statement SHALL be the only one in the Medical Devices content of the patient summary.

**Statement Note (Text) 0..1 R 14**

Further textual information about the statement

**No Device or Implant (Code) 0..1 C 184**

The patient has no implant and is not using any particular medical device

- 1..1 R: if "Device" and "Patient Devices Unknown" are not present
- 0..0 NP Else

**Patient Devices Unknown (Code) 0..1 C 185**

No information available about the patient's devices or implants.

- 1..1 R: if "No Device or Implant" and "Device" are not present
- 0..0 NP Else

**Device 0..1 C 13**

The device implanted or externally used by the patient.

- 1..1 R: if "No Device or Implant" and "Patient Devices Unknown" are not present
- 0..0 NP Else
Deliverable 2.3: Medications and Medical Devices: data sets, information structures, value sets, & tools

Table 6: Detailed Description of the Medical Devices Core Dataset

6.2.2.4 Detailed View of the Comprehensive Medical Devices Dataset

The table below details the structure of the Medical Devices comprehensive dataset in the context of the unplanned care scenario. The underlying tree structure is the one presented on Figure 2.

The comprehensive dataset adds to the core dataset, all the concepts that might potentially be useful in some cases in a patient summary, and for this reason need to be accessible to the reader, but are not necessarily presented to the reader at first intent.

Conformance, cardinalities and datatypes follow the conventions set in deliverable D2.2. Concept names in the tree structure appear in bold style, except for the leaf concepts.

Medical Devices 1..1 R

This dataset lists the medical devices implanted on or used externally by the patient, and considered as relevant for the attention of new care providers met by the patient during future unplanned care.

If all implants are expected to appear in the patient summary, it is obviously not the case of all medical devices that the patient may be using externally. Gauzes, pads, scales, bandages ... used on an ad hoc basis by a person are of no interest in the patient summary. However, the knowledge about some specific medical devices used externally on a recurring basis (such as a urinary probe or a continuous positive airway pressure device) by the patient may be useful to the practitioner discovering this patient during unplanned care.

Device Use Statement 1..* R

A statement about one medical device implanted on or use externally by the patient. Implants that were recently explanted from the patient as well as those that are planned to be implanted on the patient may also be captured in this dataset. Alternatively, the statement may express “No information available about the patient’s devices” or
"The patient is not using any medical device". In these two cases the statement SHALL be the only one in the Medical Devices content of the patient summary.

Source of Information (Collection of data) 1..1 R 4

The person (practitioner, patient, related person) or organization (hospital, care center, ...) providing this statement

Assertion Date (Date+time) 1..1 R 5

The date/time the statement was made

Device Use Status (Code) 0..1 R 183

This item expresses whether the device is currently used or if this usage happened in the past or is intended for the future.

Statement Note (Text) 0..* R 14

Further textual information about the statement

No Device or Implant (Code) 0..1 C 184

The patient has no implant and is not using any particular medical device

  - 1..1 R: if "Device" and "Patient Devices Unknown" are not present
  - 0..0 NP Else

Patient Devices Unknown (Code) 0..1 C 185

No information available about the patient's devices or implants.

  - 1..1 R: if "No Device or Implant" and "Device" are not present
  - 0..0 NP Else

Device 0..1 C 13

The device implanted or externally used by the patient.

  - 1..1 R: if "No Device or Implant" and "Patient Devices Unknown" are not present
  - 0..0 NP Else

Serial Number (Identifier) 0..1 R 26

Serial number of the device

UDI 0..1 R 16

Unique Device Identifier

  Device Identifier (Identifier) 0..1 R 17
The mandatory part of the UDI

The Device Identifier is the primary identifier of a device model. It is a unique key to access the properties of the device (safety information, brand name, device type, model number, manufacturer ...) recorded in a UDI database such as the GUDID in the US or EUDAMED in Europe.

Human Readable Barcode (String) 0..1 R 18

*Human Readable Form (HRF) of the UDI barcode*

Machine Readable Barcode (Binary) 0..1 R 19

*UDI machine readable form of the barcode*

Automatic Identification and Data Capture (AIDC)

Device Category (Code) 1..1 R 31

*Category or class of device*

Manufacturer (String) 0..1 R 21

*Manufacturer of the device*

Lot Number (String) 0..1 R 22

*Lot number of the device*

Manufacture Date (Date) 0..1 R 23

*Fabrication date of the device*

Expiration Date (Date) 0..1 R 24

*Date of expiration of the device*

Model (String) 0..1 R 25

*Model of the device*

**Owner 0..1 R 27**

*Organization responsible for the device*

Name (String) 0..1 R 28

*Name of the organization responsible for the device*

Contact (Collection of data) 0..1 R 29

*Contact of the person or organization responsible for the device*
### Period of Use 0..1 R

The period of use of the device. It includes a start date and a stop date. If the stop date is missing, it means that the device is implanted or used with no stop date assigned. If the start date is missing, it means that it is not known.

**Start (Date+time) 0..1 R**

Start date/time of the product usage. Is in the past for active use, and in the future for intended use.

**Stop (Date+time) 0..1 R**

Date (in the past, present or future) for the end of use of the product.

**Reason for Use (Code) 0..1 R**

The reason why the device is implanted (or externally used).

**Body Site (Code) 0..1 R**

Body site targeted

### Table 7: Detailed Description of the Medical Devices Comprehensive Dataset

<table>
<thead>
<tr>
<th>Item</th>
<th>Value set / open semantics</th>
<th>Source</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>medication-statement-status</td>
<td>FHIR</td>
<td>A subset of <a href="http://hl7.org/fhir/codesystem-medications-statement-status.html">http://hl7.org/fhir/codesystem-medications-statement-status.html</a> limited to these values: active, intended, on-hold,</td>
</tr>
<tr>
<td>No Device or Implant</td>
<td>Absent or unknown devices</td>
<td>Trillium-2</td>
<td></td>
</tr>
<tr>
<td>Patient Devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Category</td>
<td>Code representing a category or class of device in an international (e.g. SNOMED CT or GMDN) or in a national code system</td>
<td>multiple</td>
<td></td>
</tr>
<tr>
<td>Reason for Use</td>
<td>condition-code (FHIR)</td>
<td>SNOMED CT</td>
<td>&lt;&lt;&lt; 404684003</td>
</tr>
<tr>
<td>Body Site</td>
<td>approach-site-codes (FHIR)</td>
<td>SNOMED CT</td>
<td>&lt;&lt;&lt; 91723000</td>
</tr>
</tbody>
</table>

### 6.2.2.5 Associated Semantics

The table below lists the semantics for the codeable items of the dataset.

### Table 8: Semantics for Medical Devices Dataset
7 Technical Specification

7.1 Implementation of the datasets in the FHIR Standard

7.1.1 Common choices

The Medications dataset is implemented by a list of MedicationStatement resources. This list is constructed as a list of entry elements from the “Medications” section of the Composition resource holding the whole patient summary. The Medical Devices dataset is implemented by a list of DeviceUseStatement resources. This list is constructed as a list of entry elements from the “Medical Devices” section of the Composition resource holding the whole patient summary. The subject of both MedicationStatement and DeviceUseStatement resources is a reference to the Patient resource introduced by the Composition resource holding the whole patient summary for this person.

A device used is described by a Device resource. A medication used is described by a Medication resource unless it is only known by its coarse category such as “anticoagulant” or “antibiotic”, in which case it may be embedded in the MedicationStatement resource.

Figure 3: Implementation of the two datasets with FHIR resources, general case

In case the patient uses no medication or no medical device the corresponding section has a single entry referencing a statement resource expressing “no device/implant in use” or “no medication in use”. Similarly, in case no information is available about the patient medications or about the patient medical devices the corresponding section has a single entry referencing a statement resource expressing “patient’s medications use unknown” or “patient’s devices/implant unknown”.

Figure 4: Implementation of the two datasets with FHIR, cases “none in use” and “unknown”
7.1.2 Representing Multiple Names and Codes for a Medication

The concept representing a medication may have various names and identifiers, each expressed in a particular system (INN, IDMP MPID, PhPID Sub L1, PhPID Sub L4, PCID, branded names authorized by a regulatory jurisdiction, SNOMED CT ...). All these names and identifiers are populated in the Medication.code element of type CodeableConcept. Each present name uses a distinct “coding” sub-element of the CodeableConcept datatype. The name may stand alone, like the non-proprietary name defined by WHO INN, or may be accompanied by the code representing it in the same system.

![Diagram of representing multiple names and codes for a medication.](image)

*Figure 5: Representing Multiple Names and Codes for a Medication*
### 7.1.3 FHIR Resources for the Medications Dataset

The table below maps the Medications dataset to the set of FHIR STU3 resources profiled to represent this dataset, and summarizes in its rightmost column the constraints applied by the profiles.

<table>
<thead>
<tr>
<th>Dataset item</th>
<th>FHIR Resource / Datatype</th>
<th>Date element</th>
<th>Profiling constraints / extensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications</td>
<td>List</td>
<td></td>
<td>Bound to MedicationStatement</td>
</tr>
<tr>
<td></td>
<td>MedicationStatement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Statement Source</td>
<td>MedicationStatement</td>
<td>informationSource</td>
<td>Min = 1</td>
</tr>
<tr>
<td>- Statement Date</td>
<td>MedicationStatement</td>
<td>dateAsserted</td>
<td>Min = 1</td>
</tr>
<tr>
<td>- Status(1)</td>
<td>MedicationStatement</td>
<td>status</td>
<td>value set: active</td>
</tr>
<tr>
<td>- Statement Note</td>
<td>MedicationStatement</td>
<td>note</td>
<td></td>
</tr>
<tr>
<td>- Medication Category</td>
<td>MedicationStatement</td>
<td>medicationCodeableConcept</td>
<td></td>
</tr>
<tr>
<td>- No Medication in Use</td>
<td>MedicationStatement</td>
<td>medicationCodeableConcept</td>
<td></td>
</tr>
<tr>
<td>- Medications Use Unknown</td>
<td>MedicationStatement</td>
<td>medicationCodeableConcept</td>
<td></td>
</tr>
<tr>
<td>- Medication</td>
<td>MedicationStatement</td>
<td>medicationReference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ATC Class</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- Product Identifier</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- IDMP Identifiers</td>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- - MPID</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- - PhPID Set</td>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- - - PhPID L1</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- - - PhPID L2</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- - - PhPID L3</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- - - PhPID L4</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- - - PCID</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- Product non-proprietary Name</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding</td>
</tr>
<tr>
<td>- Product and Strength</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding per system of representation (dm+d, RxNorm, …)</td>
</tr>
<tr>
<td>Common Name</td>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Virtual Medicinal Product Name</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding per system of representation (SNOMED CT, RxNorm, dm+d, other jurisdictional coding schemes …)</td>
</tr>
<tr>
<td>- Branded Packaged Product Name</td>
<td>Medication</td>
<td>code</td>
<td>One slice of CodeableConcept.coding per jurisdictional system of representation of branded product</td>
</tr>
<tr>
<td>- Dose Form</td>
<td>Medication</td>
<td>form</td>
<td></td>
</tr>
<tr>
<td>- Ingredients</td>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ingredient</td>
<td>Medication</td>
<td>ingredient</td>
<td></td>
</tr>
<tr>
<td>- - Substance</td>
<td>Medication</td>
<td>itemCodeableConcept</td>
<td></td>
</tr>
<tr>
<td>- - Strength</td>
<td>Medication</td>
<td>amount</td>
<td></td>
</tr>
<tr>
<td>- Period of Medication Take</td>
<td>MedicationStatement</td>
<td>effectivePeriod</td>
<td>Conditional (M/X)</td>
</tr>
<tr>
<td>- - Start</td>
<td>Period</td>
<td>start</td>
<td></td>
</tr>
<tr>
<td>- - Stop</td>
<td>Period</td>
<td>end</td>
<td></td>
</tr>
<tr>
<td>- Dosage Instruction</td>
<td>MedicationStatement</td>
<td>dosage</td>
<td>Conditional (R/X)</td>
</tr>
<tr>
<td>Dosage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Dose</td>
<td>Dosage</td>
<td>doseQuantity</td>
<td></td>
</tr>
<tr>
<td>- Route</td>
<td>Dosage</td>
<td>route</td>
<td></td>
</tr>
<tr>
<td>- Timing Instructions</td>
<td>Dosage</td>
<td>timing</td>
<td></td>
</tr>
<tr>
<td>- Maximum Dose per Period</td>
<td>Dosage</td>
<td>maxDosePerPeriod</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: FHIR STU3 resources mapped to and constrained by the Medications dataset
7.1.4 FHIR Resources for the Medical Devices Dataset

The table below maps the Medical Devices dataset to the set of FHIR STU3 resources profiled to represent this dataset, and summarizes in its rightmost column the constraints applied to the data elements of these resources.

<table>
<thead>
<tr>
<th>Dataset item</th>
<th>FHIR Resource / Datatype</th>
<th>Date element</th>
<th>Profiling constraints / extensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td>List</td>
<td></td>
<td>A list of one or more DeviceUseStatement resources</td>
</tr>
<tr>
<td>- Device Use Statement</td>
<td>DeviceUseStatement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Statement Source</td>
<td>DeviceUseStatement</td>
<td>source</td>
<td></td>
</tr>
<tr>
<td>- Statement Date</td>
<td>DeviceUseStatement</td>
<td>recordedOn</td>
<td>Min = 1</td>
</tr>
<tr>
<td>- Statement Status</td>
<td>DeviceUseStatement</td>
<td>status</td>
<td>value set: active</td>
</tr>
<tr>
<td>- Statement Note</td>
<td>DeviceUseStatement</td>
<td>note</td>
<td></td>
</tr>
<tr>
<td>- No Device or Implant</td>
<td>DeviceUseStatement</td>
<td>unknownOrNone</td>
<td>Extension to DeviceUseStatement introducing a CodeableConcept to carry one of these two meanings</td>
</tr>
<tr>
<td>- Patient Devices Unknown</td>
<td>DeviceUseStatement</td>
<td>unknownOrNone</td>
<td></td>
</tr>
<tr>
<td>- Device</td>
<td>DeviceUseStatement</td>
<td>device</td>
<td>A literal &quot;reference&quot; to a Device resource or a simple &quot;display&quot; narrative text representing the device by a string if no other detail is available about this device.</td>
</tr>
<tr>
<td>- - Serial Number</td>
<td>Device</td>
<td>identifier</td>
<td>Identifier.type = &quot;SNO&quot;</td>
</tr>
<tr>
<td>- - UDI</td>
<td>Device</td>
<td>udi</td>
<td></td>
</tr>
<tr>
<td>- - - Device Identifier</td>
<td>Device</td>
<td>deviceIdentifier</td>
<td></td>
</tr>
<tr>
<td>- - - Human Readable Barcode</td>
<td>Device</td>
<td>carrierHRF</td>
<td></td>
</tr>
<tr>
<td>- - - - Machine Readable Barcode</td>
<td>Device</td>
<td>carrierAIDC</td>
<td></td>
</tr>
<tr>
<td>- - Device Category</td>
<td>Device</td>
<td>type</td>
<td></td>
</tr>
<tr>
<td>- - Manufacturer</td>
<td>Device</td>
<td>manufacturer</td>
<td></td>
</tr>
<tr>
<td>- - Lot Number</td>
<td>Device</td>
<td>lotNumber</td>
<td></td>
</tr>
<tr>
<td>- - Manufacture Date</td>
<td>Device</td>
<td>manufactureDate</td>
<td></td>
</tr>
<tr>
<td>- - - Expiration Date</td>
<td>Device</td>
<td>expirationDate</td>
<td></td>
</tr>
<tr>
<td>- - - Model</td>
<td>Device</td>
<td>model</td>
<td></td>
</tr>
<tr>
<td>- - - Owner</td>
<td>Device</td>
<td>owner -&gt; Organization</td>
<td></td>
</tr>
<tr>
<td>- - - - Name</td>
<td>Organization</td>
<td>name</td>
<td></td>
</tr>
<tr>
<td>- - - - Contact</td>
<td>Device</td>
<td>contact</td>
<td></td>
</tr>
<tr>
<td>- - - Period of Use</td>
<td>DeviceUseStatement</td>
<td>whenUsed</td>
<td>Min = 1</td>
</tr>
<tr>
<td>- - - - Start</td>
<td>Period</td>
<td>start</td>
<td></td>
</tr>
<tr>
<td>- - - - Stop</td>
<td>Period</td>
<td>end</td>
<td></td>
</tr>
<tr>
<td>- - - Reason for Use</td>
<td>DeviceUseStatement</td>
<td>indication</td>
<td></td>
</tr>
<tr>
<td>- - - Body Site</td>
<td>DeviceUseStatement</td>
<td>bodySite</td>
<td></td>
</tr>
</tbody>
</table>

Table 10: FHIR STU3 resources mapped to and constrained by the Medical Devices dataset
7.2 FHIR Resource Profiles
The table below references the resource profiles built on FHIR STU3 by this deliverable.

<table>
<thead>
<tr>
<th>FHIR STU3 resource</th>
<th>Access to online specification</th>
<th>Canonical uri</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td><a href="https://simplifier.net/TrilliumII/Medication-uv-trillium2">https://simplifier.net/TrilliumII/Medication-uv-trillium2</a></td>
<td><a href="http://trilliumbridge.eu/fhir/StructureDefinition/medication-uv-trillium2">http://trilliumbridge.eu/fhir/StructureDefinition/medication-uv-trillium2</a></td>
</tr>
<tr>
<td>Extension to DeviceUseStatement</td>
<td><a href="https://simplifier.net/TrilliumII/UnknownOrNoDevice-uv-trillium2">https://simplifier.net/TrilliumII/UnknownOrNoDevice-uv-trillium2</a></td>
<td><a href="http://trilliumbridge.eu/fhir/StructureDefinition/unknownornodevice-uv-trillium2">http://trilliumbridge.eu/fhir/StructureDefinition/unknownornodevice-uv-trillium2</a></td>
</tr>
</tbody>
</table>

Table 11: Resource profiles and extensions built on FHIR STU3 by D2.3

7.3 Value Sets
The value sets are built and managed in ART-DECOR. The lists below provide the direct links to the value sets on the ART-DECOR platform as well as the canonical url of the ValueSet resources.

7.3.1 Value Sets for the Medications Component

<table>
<thead>
<tr>
<th>Name</th>
<th>ValueSet Resource</th>
<th>ART-DÉCOR Value Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent or Unknown Medications</td>
<td><a href="http://trilliumbridge.eu/fhir/ValueSet/absent-or-unknown-medications">http://trilliumbridge.eu/fhir/ValueSet/absent-or-unknown-medications</a></td>
<td>2.16.840.1.113883.11.22.15 Absent or Unknown Medication</td>
</tr>
<tr>
<td>Pharmaceutical Dose Forms</td>
<td><a href="http://trilliumbridge.eu/fhir/ValueSet/medicine-dose-form">http://trilliumbridge.eu/fhir/ValueSet/medicine-dose-form</a></td>
<td>2.16.840.1.113883.11.22.25 Medicine Doseform</td>
</tr>
<tr>
<td>Routes and Methods of Administration</td>
<td><a href="http://trilliumbridge.eu/fhir/ValueSet/medicine-route-of-administration">http://trilliumbridge.eu/fhir/ValueSet/medicine-route-of-administration</a></td>
<td>2.16.840.1.113883.11.22.33 Medicine Route of Administration</td>
</tr>
<tr>
<td>Medicament substances</td>
<td><a href="http://trilliumbridge.eu/fhir/ValueSet/medicine-active-substance">http://trilliumbridge.eu/fhir/ValueSet/medicine-active-substance</a></td>
<td>2.16.840.1.113883.11.22.32 Medicine Active Substances</td>
</tr>
<tr>
<td>ATC Classes</td>
<td><a href="http://trilliumbridge.eu/fhir/ValueSet/who-atc">http://trilliumbridge.eu/fhir/ValueSet/who-atc</a></td>
<td>2.16.840.1.113883.11.22.29 WHO ATC</td>
</tr>
</tbody>
</table>

Table 12: Value Sets for the Medication Component

7.3.2 Value Sets for the Medical Devices Component

<table>
<thead>
<tr>
<th>Name</th>
<th>ValueSet Resource</th>
<th>ART-DÉCOR Value Set</th>
</tr>
</thead>
</table>
Table 13: Value Sets for the Medical Devices Component

<table>
<thead>
<tr>
<th>Name</th>
<th>ValueSet Resource</th>
<th>ART-DÉCOR Value Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent or Unknown Patient Devices</td>
<td><a href="http://trilliubridge.eu/fhir/ValueSet/absent-or-unknown-devices">http://trilliubridge.eu/fhir/ValueSet/absent-or-unknown-devices</a></td>
<td>2.16.840.1.113883.3.1937.777.19.11.5 Absent Or Unknown Patient Devices</td>
</tr>
<tr>
<td>Device Categories</td>
<td><a href="http://hl7.org/fhir/ValueSet/device-kind">http://hl7.org/fhir/ValueSet/device-kind</a></td>
<td>SNOMED CT: descendants of 49062001 [Device (physical object)]</td>
</tr>
<tr>
<td>Body Sites</td>
<td><a href="http://hl7.org/fhir/ValueSet/body-site">http://hl7.org/fhir/ValueSet/body-site</a></td>
<td>SNOMED CT: descendants of 442083009 [Anatomical or acquired body structure (body structure)]</td>
</tr>
<tr>
<td>Reasons For Use</td>
<td><a href="http://trilliubridge.eu/fhir/ValueSet/reason-for-use">http://trilliubridge.eu/fhir/ValueSet/reason-for-use</a></td>
<td>SNOMED CT: descendants of 404684003 [Clinical finding (finding)]</td>
</tr>
</tbody>
</table>

8 Examples

The examples built in this D2.3 deliverable are individual statements (about medication or medical device use). Full examples of international patient summaries including lists of statements for each kind of content will be built by deliverable D2.7 “Patient Summary Orchestration”, using the Composition resource.

The examples below can be retrieved manually using a REST client like “POSTMAN”, for instance.

8.1 Medications

8.1.1 Acetaminophen 500 mg oral tablet – one tablet three times a day – over the counter

This example uses:
- one resource MedicationStatement, the patient being the source of the statement (http://vonk.furore.com/MedicationStatement/TrilliumII-examples-MedicationStatement-01),

8.1.2 Anticoagulant

This example states a coarse category of medication, relying on a single MedicationStatement resource (http://vonk.furore.com/MedicationStatement/TrilliumII-examples-MedicationStatement-02)

8.2 Medical Devices

8.2.1 Implanted cardiac pace maker - stated by a hospital

This example uses:
- one resource DeviceUseStatement (http://vonk.furore.com/DeviceUseStatement/TrilliumII-examples-DeviceUseStatement-01) with a statement made by a hospital,
- one resource Device (http://vonk.furore.com/Device/TrilliumII-examples-Device-01) identifying this implant.
9 Open & Closed Issues

9.1 Representing “no product used” or “no info available on product usage” in FHIR STU3

Medical Devices and Medications contents are lists of statements about medications or devices used by the patient.

When the patient does not use any medical device, the device statement list is limited to a single statement expressing “no device or implant”. When no information is available about devices used by the patient the list is limited to a single statement expressing “patient devices unknown”.

Similarly, when the patient does not take any medication, the medication statement list is limited to a single statement expressing “no medication in use”. When no information is available about medications taken by the patient the list is limited to a single statement expressing “medications use unknown”.

The MedicationStatement resource offers a choice structure medication[x] to either reference a Medication resource or simply provide a codeable concept. The codeable concept may identify the medication concerned by the statement. It may also be used to carry one or the other of the two meanings “no medication in use” and “medications use unknown”. This is the solution chosen by this specification.

The DeviceUseStatement resource has a mandatory device element in STU3, defined as a Reference(Device). It does not provide the same choice structure as the MedicationStatement resource. DeviceUseStatement is expected to evolve in FHIR R4 so as to be harmonized with MedicationStatement. Nevertheless, in STU3, it is not possible to represent the meanings “no device or implant” or “patient devices unknown” with the same kind of construct as for MedicationStatement. The solution to express these two meanings with STU3 uses a codeable concept built in an extension “UnknownOrNoDevice” to the DeviceUseStatement resource. In this situation, the element “display” of Reference(Device) also carries the same meaning as a string and the “reference” and “identifier” elements of Reference are empty.

Issue closed on December 11, 2017

9.2 Assign systems to all medications standardized representations, coded and non-coded

A medication may be represented by names and codes at various levels of granularity, by local jurisdictions authorizing this medication to be marketed, or by reference vocabularies coded (such as SNOMED CT, RxNorm, WHO ATC) or not (such as WHO INN).

The project needs to assign systems (urn) to all these vocabularies, including all the national official vocabularies used to code medications.

Then, each slice of Medication.code will be assigned to one of these systems.

A registration process has to be set in place to record new code systems representing medications as the International Patient Summary is deployed in new jurisdiction.

Issue closed on December 11, 2017
10 Recommendations

10.1 Registration Process for Code Systems
A registration process has to be set in place to record new code systems representing medications as the International Patient Summary is deployed in new jurisdiction. This process will frame cooperation of the Trillium II project team with international SDOs as well as with national jurisdictions.

10.2 Evolution of the FHIR Standard
This deliverable triggered change request #14142 to the FHIR standard, asking for a better alignment of DeviceUseStatement resource with MedicationStatement.

11 Index of Value Sets
See section 7.3.
12 Glossary

<table>
<thead>
<tr>
<th>Abreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART-DECOR</td>
<td>Advanced Requirement Tooling – Data Elements, Codes, OIDs and Rules</td>
</tr>
<tr>
<td>ATC</td>
<td>Anatomical Therapeutic Chemical classification of drugs from WHO</td>
</tr>
<tr>
<td>CEN TC 251</td>
<td>Comité Européen de Normalisation – Technical Committee of Health Informatics</td>
</tr>
<tr>
<td>DAM</td>
<td>Domain Analysis Model – One of HL7 International products</td>
</tr>
<tr>
<td>EDQM</td>
<td>The European Directorate for the Quality of Medicines and HealthCare</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (US)</td>
</tr>
<tr>
<td>FHIR</td>
<td>Fast Healthcare Interoperability Resource – Standard from HL7</td>
</tr>
<tr>
<td>GMDN</td>
<td>Global Medical Device Nomenclature – maintained by the GMDN Agency</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level Seven - organization developing standards for interoperability in healthcare</td>
</tr>
<tr>
<td>IDMP</td>
<td>Identification of Medicinal Products – Set of standards from ISO/TC 215</td>
</tr>
<tr>
<td>INN</td>
<td>International Nonproprietary Names – Naming system from WHO</td>
</tr>
<tr>
<td>IPS</td>
<td>International Patient Summary – Project of HL7 International and CEN TC 251</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>ISO/TC 215</td>
<td>Health Informatics Technical Committee of ISO</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostic (a kind of medical device operating on in vitro biologic specimens)</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical Observation Identifier Names and Codes – reference terminology</td>
</tr>
<tr>
<td>MPID</td>
<td>Medicinal Product Identifier – for the IDMP standard set</td>
</tr>
<tr>
<td>OID</td>
<td>Object Identifiers, which are universal by construction</td>
</tr>
<tr>
<td>PCID</td>
<td>Packaged Medicinal Product Identifier – for the IDMP standard set</td>
</tr>
<tr>
<td>PhPID Set</td>
<td>Set of Pharmaceutical Product Identifiers – for the IDMP standard set</td>
</tr>
<tr>
<td>PhPID SUB_L1</td>
<td>PHPID Active Substance Stratum Level 1: product containing substance(s)</td>
</tr>
<tr>
<td>PhPID SUB_L2</td>
<td>PHPID Active Substance Stratum Level 2: product containing substance(s) + strength</td>
</tr>
<tr>
<td>PhPID SUB_L3</td>
<td>PHPID Active Substance Stratum Level 3: product containing substance(s) + administrable dose form</td>
</tr>
<tr>
<td>PhPID SUB_L4</td>
<td>PHPID Active Substance Stratum Level 4: product containing substance(s) + strength + administrable dose form</td>
</tr>
<tr>
<td>SNOMED CT</td>
<td>Systematized Nomenclature of Medicine Clinical Terms – reference terminology</td>
</tr>
<tr>
<td>STU3</td>
<td>Standard for Trial Use release 3 of the FHIR standard</td>
</tr>
<tr>
<td>UCUM</td>
<td>The Unified Code for Units of Measure – code system</td>
</tr>
<tr>
<td>UDI</td>
<td>Unique Device Identification system defined by the FDA</td>
</tr>
<tr>
<td>WHO</td>
<td>The World Health Organization</td>
</tr>
</tbody>
</table>