New concept proposal

Lab Analyzer

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Dataset release	2022.1	**Consulted expert**	Alexander Leichtle

1 Rationale

Information about the analyzer, namely all devices used to analyze biosamples in a laboratory, is crucial for the interpretation of certain laboratory test results such as the tumor marker Prostate-specific antigen (PSA). Therefore, both information about the analyzer instrument (or device) and the analyzer testkit are important for personalized health research and should be defined in the SPHN Dataset. It allows assessment of comparability of lab test results across institutions and over time. The information about the analyzer is not included in the LOINC code that identifies the laboratory test, therefore separate concepts must be provided to capture this information. Further, the lab analyzer concept will facilitate the (future) implementation of genomic concepts (e.g., sequencing devices, library preparation kits) to the SPHN Dataset.

The document contains 3 proposals that have been discussed during concept development. Proposal C has been selected and integrated into the SPHN Dataset release 2022.1.

2 Comparison to other standards/data models

2.1 HL7 FHIR

Laboratory test results in FHIR are represented in the resource *Observation*. The resource contains an element called *device* which can hold up to one (0..1) measurement device. In addition, FHIR defines a resource Device with the following description: “A type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device.” One of the properties of this resource is the udiCarrier which refers to the Unique Device Identifier (UDI) barcode string.

2.2 LOINC

In LOINC, the analyzer device and the analyzer testkit are not represented.

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Personalized Health Informatics Group (PHI)
Elisabethenstrasse 43
CH-4051 Basel

2.3 UMLS

In the UMLS Metathesaurus, three definitions are available for the concept *Analyzer, device* with UMLS Concept Unique Identifier (CUI): C0179038:

> Instruments to separate or break up any whole into its parts, to find out their nature, proportion, function, or relationship. Most analyzers are used in the clinical field for in vitro analysis in the laboratory and/or at the point of care; some others are capable of physiologic or technical parameter analysis. These instruments are not designed to take continuous records (i.e., monitor) of the parameters that are measured or determined in their analysis. **(UMD)**

> Any component designed to perform an analysis. **(NCI)**

> Any device designed to perform an analysis. **(NCI)**

In the UMLS Metathesaurus, there is a definition for test kit with CUI: C1272835:

> A packaged system consisting of the main component materials necessary to perform one or more designated diagnostic tests or procedures. **(NCI)**

3 Proposal A

3.1 Concept information

3.1.1 Lab Analyzer

Concept name	Description	Type	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Analyzer	laboratory analyzer used to assess medical laboratory samples			
device	device used to assess medical laboratory samples	Lab Analyzer Device		
testkit	test kit used to assess medical laboratory samples	Lab Analyzer Testkit		

3.1.2 Lab Analyzer Device

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Analyzer Device	instrument used to assess medical laboratory samples	Medical Device			80617005 | Analyzer, device (physical object)	
type identifier	code, name, coding system and version describing the type of laboratory analyzer device	Code	GMDN, EMDN			66464-9 Medical device type [PhenX]
product identifier	code, name, coding system and version of the unique device identifier (UDI) of the laboratory analyzer device to identify its model and manufacturer	Code	UDI-DI from GUDID (UDI-DI from EUDAMED in the future)			

3.1.3 Lab Analyzer Testkit

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Analyzer Testkit	test kit used to assess medical laboratory samples	Medical Device				
type identifier	code, name, coding system and version describing the type of laboratory analyzer test kit	Code	GMDN, EMDN			66464-9 Medical device type [PhenX]
product identifier	code, name, coding system and version of the unique device identifier (UDI) of the laboratory analyzer test kit to identify its model and manufacturer	Code	UDI-DI from GUDID (UDI-DI from EUDAMED in the future)			

3.2 Impact on the SPHN Dataset

3.2.1 Three new concepts

Three new concepts would need to be added to the SPHN Dataset: *Lab Analyzer, Lab Analyzer Device* and *Lab Analyzer Testkit*.

3.2.2 Change in Lab Result

To link the analyzer information to the lab result, the concept *Lab Result* would need to be extended by a composedOf *lab analyzer*.

Currently released version of concept *Lab Result*

SPHN Dataset version: 2021.1

Unique concept ID: 0000000341

Concept name	Description	Type	Standard	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Result	laboratory analysis transmitted			118246004 |Laboratory test finding (navigational concept)|	
unstructured lab result	comments up to full report	string			
lab test	code of the lab test	Code	LOINC	15220000 |Laboratory test (procedure)|	
biosample	any material sample taken from a biological entity for testing, diagnostic, propagation, treatment or research purposes	Biosample			
analysis datetime	datetime the analysis takes place	temporal			45353-0 Date of analysis of unspecified specimen
value	result of the laboratory test	string			
unit	unit of the result	Unit			
normal range	normal range for population	string		260395002 |Normal range (qualifier value)|	19146-0 Reference lab test results

Proposed extension of the concept *Lab Result*

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Result	laboratory analysis transmitted				118246004 |Laboratory test finding (navigational concept)|	
...	...	...				
lab analyzer	laboratory analyzer used to assess the biosample	Lab Analyzer				

3.2.3 Change in Medical Device

The concept *Medical Device* would need to be adapted in a way that it can hold a type *identifier* and a *product identifier*.

Currently released version of the concept *Medical Device*

SPHN Dataset version: 2021.1

Unique concept ID: 0000000456

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not limited to, implants, instruments, devices, in vitro diagnostics				49062001 |Device (physical object)|	66464-9 Medical device type [PhenX]
Code	code, name, coding system and version used to describe the medical device	Code	SNOMED CT	child of : 272181003 | Clinical equipment and/or device (physical object) |		

Proposed adaptation of the concept *Medical Device*

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not limited to, implants, instruments, devices, in vitro diagnostics				49062001 |Device (physical object)|	
type identifier	code, name, coding system and version used to describe the medical device type	Code	SNOMED CT or other	For SNOMED CT child of : 272181003 | Clinical equipment and/or device (physical object) |		66464-9 Medical device type [PhenX]
product identifier	code, name, coding system and version used to describe the medical device product	Code				

3.3 Pros and cons

Advantages

- Testkit and analyzer are defined separately and can be extended with additional composedOfs (properties) on demand in the future
- Testkit and analyser can be reused in any future concepts separately depending on what information is needed
- It is possible to represent an analysis where several test kits are used in parallel for a single read out (also possible with proposal B)

Disadvantages

- Lab Analyzer Device and Lab Analyzer Testkit have the same composedOfs connected to the same standards, and the difference between the two does not become apparent with regards to the machine readable definition

4 Proposal B

4.1 Concept information

4.1.1 New concept Lab Analyzer

The prerequisite of this proposal is to modify the concept *Medical Device* as outlined in chapter 3.2.3.

Concept or concept compositions or inherited	Concept name	Description	Type	Standard	Additional Information
concept	**Lab Analyzer**	laboratory analyzer used to assess medical laboratory samples	Medical Device		
inherited	type identifier	code, name, coding system and version used to describe the lab analyzer type	Code	GMDN, EMDN	
inherited	product identifier	code, name, coding system and version used to describe the lab analyzer product	Code	UDI-DI from GUDID, or other	UDI-DI from EUDAMED in the future

4.2 Impact on the SPHN Dataset

4.2.1 Change in Lab Result

Proposed extension of the concept *Lab Result*

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Lab Result	laboratory analysis transmitted				118246004 |Laboratory test finding (navigational concept)|	
…	…	…				
device	laboratory analyzer used to assess the biosample used in this lab test	Lab Analyzer				
testkit	testkit used to assess the biosample used in this lab test	Lab Analyzer				

4.3 Pros and Cons

Advantages

- Instead of three new concepts only one new concept needs to be defined in the SPHN Dataset
- less nodes in the graph to consider for the same information

Disadvantages

- Limited extensibility of analyzer device and analyzer testkit in case additional pieces of information need to be added later on to only the analyzer device or to only the analyzer testkit

5 Proposal C

5.1 Concept information

5.1.1 Lab Analyzer

Same new *Lab Analyzer* concept definition as in proposal B:

Concept name	Description	Type	Standard	Additional information
Lab Analyzer	laboratory analyzer used to assess medical laboratory samples	Medical Device		
type identifier	code, name, coding system and version used to describe the lab analyzer type	Code	GMDN, EMDN	
product identifier	code, name, coding system and version used to describe the lab analyzer product	Code	UDI-DI from GUDID, or other	UDI-DI from EUDAMED in the future

5.2 Impact on the SPHN Dataset

5.2.1 Change in Lab Result

Currently released version of the concept Lab Result

Concept name	Description	Type	Standard	Meaning binding SNOMED CT	Meaning binding LOINC	Additional information
Lab Result	laboratory analysis transmitted			118246004 |Laboratory test finding (navigational concept)|		
unstructured lab result	comments up to full report	string				
lab test	code of the lab test	Code	LOINC			use for standard laboratory tests (not for microbiology or pathology)
…	…	…				

Proposed adaptation of the concept Lab Result

Concept name	Description	Type	Standard	Meaning binding SNOMED CT	Meaning binding LOINC	Additional information
Lab Result	laboratory analysis transmitted			118246004 |Laboratory test finding (navigational concept)|		
unstructured lab result	comments up to full report	string				
lab test	lab test information including information elements provided by LOINC, instrument and test kit	Lab Test				use for standard laboratory tests (not for microbiology or pathology)
…	…	…				

Please refer to the “New Concept Proposal” for *Lab Test* for further information on this concept.

5.3 Pros and Cons

Advantages

- Instead of three new concepts (proposal A) only two new concepts need to be defined in the SPHN Dataset (*Analyzer* and *Lab Test*)
- Creating the new *Lab Test* concept allows adapting the existing composedOf code in the *Lab Result* concept instead of adding two new composedOfs (proposal B)

Disadvantages

- No opportunity to define properties that are only relevant to analyzer device or analyzer testkit later on (both are considered to be of type Lab Analyzer and the distinction between the two is represented in the *Lab Test* concept)

6 Discussion

Lab analyzer devices and lab analyzer testkits are in-vitro diagnostic devices (IVDs) which fall under the Medical Device Regulation (MDR) and therefore one can say that a Lab Analyzer Device is-a Medical Device and a Lab Analyzer Testkit is-a Medical Device. In both alternative proposals (A and B), the concept *Medical Device* is re-used for both concepts and with that the SPHN semantic strategy principle of re-use would be fulfilled. We can assume that for each medical device under the MDR there is a type identifier and a product identifier which supports the proposal to adapt the *Medical Device* concept in a way that both features are represented as shown above.

Lab analyzer devices are different from lab analyzer testkits. A lab analyzer device is a machine and can be used for different types of analyses depending on the testkit used. A machine can be used together with testkits from different manufacturers. Testkits are consumables with relatively frequent updated versions whereas analyser devices are devices with a long lifetime and therefore, a low turnover in the clinical setting. However, in the definitions from UMLS, the difference between the two does not become apparent and in the proposals presented in this document, they do not differ from each other. Both hold a type identifier and a product identifier from exactly the same semantic standard(s). The separation between type and product is essential so that the appropriate standards can be connected: a nomenclature such as GMDN connects to the analyzer type and a product identifier system like GUDID connects to the analyzer product. Using unique identifiers from international nomenclatures (EMDN, GMDN) and worldwide device identification systems (GUDID, EUDAMED) supports interoperability in multi-centre projects. The European Database EUDAMED for identification of Medical Devices in Europe is not ready yet, and we have to temporarily work with a resource (GUDID) which might not contain all medical device products used in

Switzerland. As soon as EUDAMED is established as the database for Medical Device information in Europe it should be used as the source of information about analyzer devices and analyser testkits. As a workaround, it is possible for projects to create project-specific codes to uniquely identify a medical device, for products not included in the GUDID.

We are aware that providing the analyzer information on a routine basis requires resources on the data provider side and an appropriate data flow need to be defined and implemented.

7 Examples

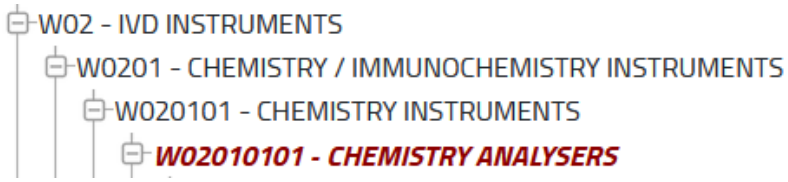
7.1 Lab Analyzer Instrument : Cobas 8000 (module c 702) analyser

Type identifier: GMDN code: 56676 (name : Multiple clinical chemistry analyser IVD, laboratory, automated)

EMDN code: W02010101 (name : CHEMISTRY ANALYSERS)

Product identifier: GUDID code: 04015630930845

The **GMDN** provides definitions. For the example outlined above (code: 56676), the definition reads: “An electrically-powered laboratory instrument intended to be used for the qualitative and/or quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and/or cardiac function test analytes. The analyser typically requires analyte specific test kits or reagents, using one or more technologies which may include microfluidics, electrometry, spectrophotometry, fluorimetry, radiometry and/or chemiluminescence. The device operates with minimal technician involvement and complete automation of all procedural steps.”. Whereas **EMDN** provides a hierarchy of devices:



The GUDID code refers to product information accessible via a persistent URL (URI).

URI: https://accessgudid.nlm.nih.gov/devices/04015630930845

Brand name: cobas 8000 c 702 Module

Catalog Number: 6473245001

Company Name: Roche Diagnostics GmbH.

7.2 Lab Analyzer Test kit : Roche ALTPM testkit

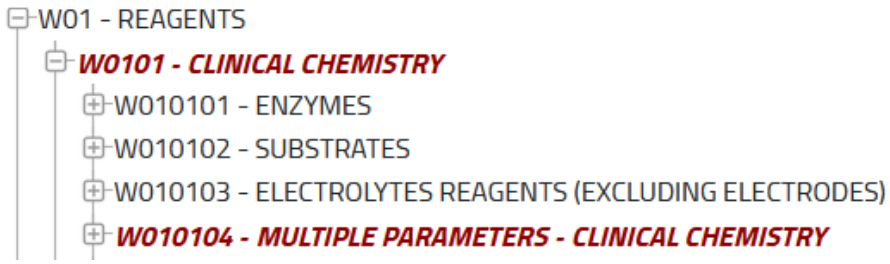
The RocheALTPM testkit is used to measure Alanine aminotransferase activity.

Type identifier: GMDN code: 52923 (name : Alanine aminotransferase (ALT) IVD, kit, enzyme spectrophotometry)

EMDN code: W0101 (name : CLINICAL CHEMISTRY)

Product identifier: GUDID code: 04015630927425

The **GMDN** provides definitions. For the example outlined above (code: 52923), the definition reads: “A collection of reagents and other associated materials intended to be used for the quantitative measurement of alanine aminotransferase (ALT) in a clinical specimen, using an enzyme spectrophotometry method.”. Whereas **EMDN** provides a hierarchy of test kits:



The GUDID code refers to product information accessible via a persistent URL (URI).

URI: https://accessgudid.nlm.nih.gov/devices/04015630927425

Brand name: Alanine Aminotransferase / Aspartate Aminotransferase acc. to IFCC with PYP

Catalog Number: 5531462190

Company Name: Roche Diagnostics GmbH.

8 Glossary

DI	Device Identifier
EMDN	European Medical Device Nomenclature (will be used in EUDAMED)
EUDAMED	European database on medical devices to be set up under Regulation (EU) 2017/745 and Regulation (EU) 2017/746
GMDN	Global Medical Device Nomenclature (from Global Medical Device Nomenclature Agency, used in GUDID)
GUDID	Global Unique Device Identification Database (administered by the FDA)
UDI	Unique Device Identification