TRILLIUM II

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

WP7

D7.5 v2018-12-11 Outlook on licensing and deployment of information structures, tools, and associated value sets for patient summary components-WP7-ADI

11 December 2018

Project title: Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary
Grant Agreement: 727745
Call identifier: H2020-SC1-2016-CNECT

Dissemination level: Public

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 727745

Deliverable description

Number and name of deliverable:	D7.5 v2018-12-11 Outlook on licensing and deployment of information structures, tools, and associated value sets for patient summary components-WP7-ADI				
Publishable summary:	This is the project's examination of the challenges that will be necessary to overcome to utilise the necessary components in the delivery of the International Patient summary				
Status:	Final	Version:	1.0	Last update:	11.12.2018
Deadline:	31.12.2018 (M24)				
Actual delivery:	11.12.2018 (M24)				
Lead beneficiary:	ADI				
Contact:	Charles.lowe@dhaca.org.uk				
Contributors:	Giorgio Cangioli, Rainer Thiel, Marcell Melgara, Jane Millar (SNOMED International), Mie Matthiesen, Shirin Golyardi				
Editor:	Charles Lowe				

Statement of originality

Change History

Version	Date	Author	Organisation	Description
Draft	04-12-2018	Charles Lowe	ADI Ltd.	After discussions at Copenhagen PEC
Draft	10-12-2018	Shirin Golyardi	NEN	Clarification on European standards
Final	10-12-2018	Charles Lowe	ADI Ltd.	After WP7, SNOMED consultation & PEC review
Final for submission	11-12-2018	Mie H. Matthiesen	MedCom	Editorial corrections

Table of Contents

Introduction and Executive summary

The purpose of this document is to review each of the licensing arrangements for each of the information structures, tools and related data sets used in Trillium II to identify any issues that may prevent widespread adoption of the International Patient Summary (IPS).

After exhaustive review, no licence-related impediments to IPS rollout were identified: those structures, such as SNOMED CT, that require licences, have been given them free of charge (with limitations). However two large EU Member States are currently not SNOMED member countries. If this situation continues it may hinder widespread adoption of the IPS.

This will be a living document – as the project progresses, greater detail may emerge of additional items requiring inclusion.

1. Existing Information structures & value sets

1.01 SNOMED CT

SNOMED CT is the principal clinical terminology database

SNOMED CT is the principal product of SNOMED International.

Licensing is detailed here[1], Specifically regarding the IPS Jane Millar, Collaboration Lead at SNOMED, has kindly confirmed that:

- *SNOMED International is prepared to provide to Europe a list of SNOMED Codes and corresponding descriptions (human words) for use freely in Europe across both Member and non-Member countries to support EU implementation of the Patient Summary. The offer does not include relationships.*
- *This set will be based on the set developed by HL7 International in order to support interoperability but SNOMED International will work with the EU IPS team to confirm the use case and identify any additional content that Europe propose in support of cross border care.*
- *SNOMED International will manage the set and its distribution, and provide a mechanism for feedback and updating as the set goes in to use.*

If the hierarchical aspects of SNOMED CT are used, they do require an additional licence. If using and/or deploying SNOMED CT in a non-Member country/territory, licences are applied for through the Member Licensing & Distribution Service (MLDS). If deploying SNOMED CT in a Member country, usage should be registered with the National Release Center (NRC) of that country (unless that country has MLDS access, when it should instead be used).

A list of the member countries[2] is shown here. This currently[3] includes two thirds of all EU Member States (Belgium, Cyprus, Czech Republic, Denmark, Estonia, Ireland, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden & United Kingdom) plus Iceland, Norway & Switzerland. Other large countries that are members include Australia, Brazil, Canada, HongKong China, India and the United States. However two large EU Member States, France and Germany, are not member countries and are understood to have issues with SNOMED CT International; unless resolved this may impact widespread adoption of the IPS.

Note that use of SNOMED CT in the IPS is currently preferred though not imposed (see also the H2020 Coordination and Support Action ASSESS CT - Assessing SNOMED CT for Large Scale eHealth Deployments in the EU[4]); when the subset referred to above that is specifically for IPS usage is published, usage will become mandatory.

1.02 ICD-10 and ICD-11

ICD-10/11 is used for statistical reporting of clinical conditions.

[1] https://www.snomed.org/snomed-ct/get-snomed-ct/

[2] 36 on 4-Dec-2018

[3] On 4-Dec-2018

[4] http://www.assess-ct.eu/

ICD-11 is the current version of the International Classification of Diseases, produced by the World Health Organisation (WHO). There are 194 Member States of the WHO

Licensing of ICD-11 and its predecessors is covered here[5]. The principal considerations are:

Licensing WHO classifications for commercial use

WHO is able to issue commercial licences to companies wishing to incorporate and distribute WHO classifications in their software products for sale to customers in certain countries.

- The licence is non-exclusive, non-transferable and time limited.

- The licence authorizes the use of the codes and descriptions in a product that will be distributed to customers in specific countries.

- Licensees are not permitted to modify, translate or amend the codes or descriptions of the classification in any way.

- There should be no suggestion of endorsement of the product or the company by WHO.

Companies wishing to obtain a commercial licence are asked to complete this form[6] so that the proposed use of the classifications and the type of product are evaluated.

Licensing WHO classifications for internal use within your organization

WHO is able to issue internal licences to organizations wishing to incorporate WHO classifications into their internal information systems for use by employees for use for administrative purposes eg. health records management.

Companies wishing to obtain an internal licence are asked to provide the following information and send this to licensing@who.int

- Name and address of organization.
- Name and job title of person signing the licence.
- Name of the organization's information system in which ICD-10 will be incorporated
- A short summary of the intended use of WHO classifications within your organisation's information systems. Please include a selection of screen shots from the product that illustrate how WHO classifications is used in the product. This information will not be used by WHO for any purpose other than compiling data on the use of WHO classifications and shall not be transmitted outside of WHO.
- Number of concurrent users accessing WHO classifications within the organization.

Licensing WHO classifications for non-commercial use

If an organization is planning to use WHO classifications for non-commercial or research purposes, then it may qualify for a licence for non-commercial research use. Register for non-commercial use is here[7].

Mappings

For completeness, SNOMED CT to ICD-X mappings exist – more information is here[8].

[5] http://www.who.int/about/licensing/Internettext_FAQ.pdf

[6] http://www.who.int/about/licensing/licence_request_form/en/index.html

[7] http://www.who.int/classifications/apps/icd/ClassificationDownload

1.03 HL7 – FHIR

HL7 – FHIR is the system used for representing data in the IPS.

A summary of the licence terms is here, however note that V3, which includes IPS-related data representation, is not yet covered by the standard terms.

There are many different categories of membership of HL7 depending on role of the organisation/ individual. Membership confers rights to reproduce and use the protocols produced. Non-members may purchase protocol specifications from HL7 or may otherwise gain access to protocol specifications through HL7 licensed channels. Registration and acceptance of HL7's IP Policy for Specified Material is required if said material is to be used other than on a read-only basis for the sole purpose of the personal edification of the nonmember. Nonmembers are expressly prohibited from reproducing or distributing any HL7 protocol specification.

1.04 LOINC

LOINC[9] is the universal standard for identifying health measurements and observations, and document ontologies. "Reference labs, healthcare organizations, U.S. federal agencies, insurance companies, software vendors, in vitro diagnostic testing companies, and more than 71,800 registered users from 174 countries use LOINC to move data seamlessly between systems."

Regenstrief Institute distributes LOINC free of charge. In obtaining and using LOINC, users agree to the terms-of-use that are outlined here[10]. No extra approval from Regenstrief Institute is necessary for use consistent with these terms.

1.05 UCUM

UCUM[11], also overseen by the Regenstrief Institute, is the Unified Code for Units of Measure. It is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units.

It is also free to use.

1.06 ATC

The ATC[12] is a classification system provided by WHO for active medical substances which are classified in a hierarchy with five different levels. Medicinal products are classified according to the main therapeutic use of the principal active ingredient.

Related to the ATC is the Defined Daily Dose[13] (DDD) also provided by WHO which is self-expalantory.

Both are free to use.

---

[8] https://www.snomed.org/snomed-ct/mapping-to-other-terminologies/existing-mappings

[9] https://loinc.org/

[10] https://loinc.org/license

[11] http://unitsofmeasure.org/trac

[12] https://www.whocc.no/atc/structure_and_principles/

[13] https://www.whocc.no/ddd/definition_and_general_considera/

1.07 ISO 3166

ISO 3166[14] is a standard published by the International Organization for Standardization (ISO) that defines codes for the names of countries, dependent territories, special areas of geographical interest, and their principal subdivisions (e.g., provinces or states).

The standard can be purchased from each country's standards institute or from the ISO store, though it is free to use the codes.

1.08 ISO 639 and BCP47

ISO 639[15] is the International Standard for language codes. The purpose of ISO 639 is to establish internationally recognised codes (either 2, 3, or 4 letters long) for the representation of languages or language families.

The standard can be purchased from each country's standards institute or from the ISO store, though it is free to use the codes.

BCP47[16] is an IETF code that escribes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object

1.09 ISCO

The Internal Standard of Classification for Organisations (ISCO[17]) is a tool for organizing occupations into a clearly defined set of groups according to the tasks and duties undertaken in each occupation.

It is managed by the International Labour Organisation (ILO) which allows free usage.

1.10 EDQM

The European Directorate for the Quality of Medicine[18] (EDQM) is a leading organisation that protects public health by enabling the development, supporting the implementation, and monitoring the application of quality standards for safe medicines and their safe use which are recognised as a scientific benchmark and applied world-wide. The guidance and standards developed by the EDQM in the areas of blood transfusion, organ, cell and tissue transplantation and consumer health issues are widely used and highly regarded.

The EDQM has an extensive standards store that also includes a range of WHO standards (international Standards for Antibiotics (ISA) and International Chemical Reference Substances (ICRS)). Usage of the resultant codes is free.

1.11 GMDN

The Global Medical Device Nomenclature[19] (GMDN) is used to identify medical devices. It comprises a list of generic names used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

[14] https://www.iso.org/iso-3166-country-codes.html

[15] https://www.iso.org/iso-639-language-codes.html

[16] https://tools.ietf.org/html/bcp47

[17] http://www.ilo.org/public/english/bureau/stat/isco/

[18] https://www.edqm.eu/

[19] https://www.gmdnagency.org/

The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety. Membership costs are dependent on size and function and enable provision of appropriate codes which can then be freely exchanged.

According to the website it is now used by over 70 national medical device regulators to support their activity.

2. Future Implementations

2.01 ISO IDMP

The European Medicines Agency (EMA) is in the process of implementing the standards developed by the International Organization for Standardisation (ISO) for the identification of medicinal products (IDMP[20]). These will cover the four domains of master data[21] in pharmaceutical regulatory processes: substance, product, organisation and referential (SPOR) master data. These 5 standards have been developed in cooperation with the European Standardisation organisation (CEN) after which they have been referenced to in the applicable Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26).

The five standards provide data elements and structures to uniquely identify and exchange information on:

- substances (EN-ISO 11238[22]);
- pharmaceutical dose forms, units of presentation, routes of administration and packaging (EN-ISO 11239[23]):
- units of measurement (EN-ISO 11240[24]);
- regulated pharmaceutical product information (EN-ISO 11616[25]);
- regulated medicinal product information (EN-ISO 11615[26]).

[20] https://www.ema.europa.eu/en/glossary/medicinal-product

[21] https://www.ema.europa.eu/en/glossary/master-data

[22] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55031

[23] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55032

[24] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55033

[25] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55035

[26] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55034