DELIVERABLE

Project Acronym: **ASSESS CT**
Grant Agreement number: **643818**
Project Title: **Assessing SNOMED CT for Large Scale eHealth Deployments in the EU**

**WP1 D1.1 Set-up of Focus Groups and Delphi study**

Revision: 1.0

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<th>PP Restricted to other programme participants (including the Commission Services)</th>
<th>RE Restricted to a group specified by the consortium (including the Commission Services)</th>
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## Revision History

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<td>13/03/2015</td>
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<td>HL7 Foundation</td>
<td>First Outline</td>
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<tr>
<td>0.2</td>
<td>29/04/2015</td>
<td>G.Cangioli</td>
<td>HL7 Foundation</td>
<td>Almost complete draft (§ 4 to be completed)</td>
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<tr>
<td>0.3</td>
<td>30/04/2015</td>
<td>G.Cangioli; C. Chronaki; D. Karlsson; R. Fathollah</td>
<td>HL7 Foundation; LIU UvNied</td>
<td>Complete Draft. Revision of Countries Information</td>
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<tr>
<td>0.4</td>
<td>30/04/2015</td>
<td>C. Chronaki</td>
<td>HL7 Foundation</td>
<td>Extended the Executive Summary Minor corrections</td>
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<tr>
<td>0.5</td>
<td>08/05/2015</td>
<td>G.Cangioli; D. Kalra; M.C. Jaulent; V. Kalliokuusi</td>
<td>HL7 Foundation</td>
<td>First Internal Review. Revised French and Finnish Information</td>
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<tr>
<td>0.9</td>
<td>10/06/2015</td>
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<td>Included report of the first revision workshop. Updated survey information. Included Assessment of annex II of the EU standardization regulation. Moved to annexes the Focus Group guidelines. Updated the executive summary.</td>
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<tr>
<td>1.0</td>
<td>11/06/2015</td>
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<td>HL7 Foundation; Eurorec</td>
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<td>21/11/2016</td>
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Date of delivery

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Status

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Abstract (for dissemination)

This document presents the methodology adopted for setting up the Focus Groups and the Delphi Study (including stakeholders/experts engagement) and the preliminary surveys developed to enable the realization of an intermediate report about the usage of terminologies in Europe (and beyond), with a special focus on SNOMED CT.
Keywords | Focus Groups, Delphi Study, Survey
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**Statement of originality**
This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.
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Executive Summary

“Current Use of SNOMED CT” runs parallel to other streams of work in ASSESS CT to obtain background information on the current extent of adoption of SNOMED CT (SCT) and other international terminology systems, and the experiences of use across Europe and in selected countries outside Europe. In our effort to understand the way and the extent to which SCT is used, several different instruments were deployed: questionnaires, focus groups, interviews, and Delphi studies.

Besides information on use of SCT, ASSESS CT is concerned with collecting information on the current and emerging policies of IHTSDO including cooperation with other SDOs and their local chapters, user groups, or affiliates.

Deliverable D1.1 details the methodology used in data collection and analysis for using focus groups and the Delphi method. Additionally, D1.1 aims to provide preliminary results on the data collected and results of assessment against the criteria defined in Annex II of the Regulation (EU) No 1025/2012.

The first version of D1.1 was released on April 30th. This revised and final public version includes information from the ASSESS-CT Validation Workshop on May 22, 2015, includes updated results from the country overview and stakeholder questionnaires and background on focus groups and a first assessment of Annex II requirements.

Member state focus groups

Up-to-date, June 2015, eight country focus groups have been established. In addition, a discussion group with the US was established and had its first meeting. The 8 EU member states include 4 members of IHTSDO (Belgium, Denmark/Sweden, Netherlands) Portugal and 4 non-members (Croatia, Finland, France, Germany). The eHealth Governance initiative was the first to review the use of SNOMED CT across the European Union¹. This information formed the basis of our work, is updated within the ASSESS CT project, with input from discussions, workshops, interviews, questionnaires, as well as country focus groups. Belgium is a multi-language country, member of IHTSDO, in which introduction of SCT is a multi-annual project, currently on-hold, focusing on usability aspects. Denmark, an IHTSDO country with small scale local SCT implementations, started translation of SCT in 2004. Sweden, founding member of IHTSDO, has a full translation of SCT with very few synonyms. Denmark and Sweden conduct a joint cross-border focus group. Portugal, a recent member of IHTSDO, plans to roll-out SCT nationwide and is keen to share experience, opinions, and best practices with other countries. The Netherlands, an IHTSDO country, has adopted SCT for various local projects based on specific use cases such as Ophthalmology applications that started to use SCT for Clinical Findings.

From the non-IHTSDO countries, Croatia is interested in evaluating SCT for eHealth Innovation in specific use case pilots such as injuries management and oncology. Finland, a bilingual (Finish and Swedish) country, has long experience with national information services for eHealth (e.g. e-prescription and patient data repository) and TNL, the National Finish Code Service, publishes over 300 code sets from national and international classifications. Germany has long experience with terminology management (DIMDI) and is in the process of accelerating roll-out of national eHealth policies with Federal Ministry of Health promoting an “eHealth Law” that also highlights the importance of interoperability with regards to interchanging health data nationally and cross-border. France adopted SNOMED CT 3.5, an early SCT version in 2003. In France, there is general interest on SCT as a core clinical terminology, but also different opinions about the opportunity of adopting SCT and as a result the ASSESS CT focus group is important in facilitating also the national discussion

on SCT, while research teams involved in EU projects using SCT wish to disseminate research results at the national level.

The aim of the ASSESS CT country focus groups is to solicit European Views on current and future use of terminology in the health care sector with special focus on the use of SNOMED CT. Four themes where selected to underpin all country focus or discussion groups:

- Current use of terminology
- Barriers for extended terminology adoption and use
- Enabling factors for extended terminology adoption and use
- Recommendations

So far 6 out of the 8 countries have had at least one focus group meeting. Most updated information on focus groups appears in table below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Facilitator</th>
<th>Progress Status</th>
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<tr>
<td>Belgium</td>
<td>Hans van Belleghem</td>
<td>The meeting is scheduled for June 24th.</td>
</tr>
<tr>
<td>Croatia</td>
<td>Vesna Kronstein &amp; Zlatko Boni</td>
<td>Preparatory meeting on 2015, April 23rd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Focus Group meeting was held on 2015, April 30th.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Kirstine Rosenbeck Gøeg</td>
<td>Focus group meeting was held on 2015, April 27th, with a common DK-SE evaluation session.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Daniel Karlsson</td>
<td>Focus group meeting was held on 2015, April 27th, with a common DK-SE evaluation session.</td>
</tr>
<tr>
<td>Finland</td>
<td>Päivi Hämäläinen, THL</td>
<td>Invited about 12 experts. Focus Group meetings were held on 2015, May 5th and May 26th.</td>
</tr>
<tr>
<td>France</td>
<td>Marie-Christine Jaulent PhD : INSERM</td>
<td>Established a core team with 8 people and the facilitator.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Organized already call conferences and meetings. (First call on 2015, March 19th and introductory meeting on 2015, March 30th). The focus group members are now identified. First meeting was held on 2015, May 4th.</td>
</tr>
<tr>
<td>Germany</td>
<td>Sylvia Thun</td>
<td>An introductory Focus Group meeting was held on 2015, March 1st and a second one on 2015, June 9th.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Hans van Belleghem</td>
<td>Focus group meeting was held on 2015, May 13th.</td>
</tr>
<tr>
<td>Portugal</td>
<td>Anabela Santos (to be confirmed)</td>
<td>The meeting will be organized by mid of July 2015.</td>
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Preliminary results from focus groups were presented as anecdotal evidence at the validation workshop on May 22, 2015. Updated Results of the country focus groups will be presented in D1.2, along with the country overview questionnaires and literature research.

**Stakeholder registry**

A stakeholder registry for the realization of the Delphi study has been implemented with a target to include 300 stakeholders in different roles (decision makers, terminology experts/authorities, industry, users) covering 75% of the European Union member states. ASSESS CT also identified the members of the eHealth stakeholders group as a target group not only engagement, but also for dissemination. At this time, in addition to members of the eHealth stakeholders group and country specific focus group members, another 194 stakeholders have been identified: 122 gave their consent in being inserted in the stakeholder registry through the all stakeholder questionnaire form; 10 answering the country overview questionnaire form; 45 (on a total of 53 registrations) registered in the ASSESS CT Validation workshop.

**Questionnaires**

Two questionnaires, one for general stakeholders and a country overview questionnaire, have been developed and tested, before being applied to the wide population. 133
responses were received by June 10, 2015. To achieve a balanced representation the ground rules were established: (a) at least 10 stakeholders (b) representative of these categories: CMO/CIO/Public Officer, health care professionals, terminology authority & implementers, eHealth industry.

At the time of this writing the figure below shows current coverage of member states with stakeholder questionnaires.

At the time of this writing we still anticipate a response from Spain, Poland, Bulgaria, Hungary, Switzerland, Czech Republic, Slovakia, Greece, Slovenia, Turkey, while countries that have yet to be contacted are: Ireland, Luxembourg, Latvia, Cyprus, Lithuania, and Norway. The figure will be updated as additional questionnaires arrive to reach the objective of 21 Members states (75% of the 28 Member States).

**Stakeholder responses to the Questionnaire**

A stakeholder question asking “how do you score the use of SNOMED CT in their country” yielded the not so surprising response:
The normalized distribution of answers within individual member states is as follows:

When we assign a numeric score 0 (not used) to 4 (widely used) to each class and calculating the arithmetic mean for each member state, we see that member states can be easily placed in three groups: Group 1: UK; Group 2: Sweden, Malta, Netherlands, Denmark, Finland; Group 3: Germany, France, Estonia, Austria, Italy, Belgium and Croatia. Most of the Member States in Groups 1 and 2 are IHTSDO Member countries.

Around half the stakeholders indicated that currently, SCT has limited use in their country. The reported benefits appear to be reduced costs for data exchange and secondary uses (but this needs to be clarified). In cross-border patient data exchange, several limitations of current terminologies where reported: lack of common terminologies; need to combine several terminologies; issues with mapping to local terminologies; issues with licensing terminologies; need for translations that do not exist yet; lack of structured/coded information at the source; Inadequate terminology strategies and policies. It was also noted that tools are needed to hide the complexity of SCT from end users. National governance is considered an important success factor for the deployment of clinical terminologies.

An equally important question concerns knowledge and perception about “whether SCT is suitable for the cross-border exchange of health information”. The large majority indicated that SCT is a good candidate for cross-border exchange under specific conditions and caveat.
The main benefits experienced from SCT seem to be realized by developers of solutions and research communities, rather than the end users. The acceptance by end users appears to be a challenge.

With regard to other international terminologies, and national legacy ones, there will be costs of migration. End-user acceptance issues seem to be present for other terminologies, not just for SCT. There can also be challenges with local terminologies: they are not always complete and might not be sustainable.

Particularly interesting were the preferred way of using coded values and in particular SCT, shown below.

Most respondents favored the direct selection of terms by clinicians during data entry, and not post-hoc clinical coding. It was recognised that SCT is the most complete solution for cross-border patient information flows.

In conclusion, based on these preliminary results, the current use and experience on SCT appears low. Any future European intent to adopt SCT as a core clinical terminology would seem to require complementary national policies and greater clarity on managing the licensing costs.
The available results from the studies reported in this deliverable were presented to a multi-stakeholder workshop held in Brussels on 22nd May 2015. There was general endorsement of the early results of the surveys. However, it was noted and supported by many participants that terminology systems cannot be assessed for suitability except in the context of specific use cases that dictate the purpose for which “fitness for purpose” can be assessed. The project was recommended to define a set of use cases for which a terminology system would be most needed and might deliver greatest value.
1 Aim and Scope

The scope of deliverable D1.1 is to describe the methodology adopted for setting up the Focus Groups and the Delphi Study (including stakeholders/experts engagement) and the preliminary surveys developed to enable the realization of an intermediate report about the usage of terminologies in Europe (and beyond), with a special focus on SCT.

The goal of work package 1 “Current Use of SNOMED CT” is to build a solid background of common knowledge about the usage of terminologies in Europe with a special focus on SCT.

This goal is expanded in several objectives:

- Collect information about the past, current and future usage of SNOMED CT in Europe at all the involved levels (Cross-Borders/National/Regional); with a view also to non-EU experiences.
- Collect information about current and future possible policies of IHTSDO, including cooperation with other SDOs, and about the usage of SNOMED CT within other standards
- Assess whether SNOMED CT satisfies the criteria listed in annex II of the EU standardization regulation
- Identify - among those realized - appropriate use cases suitable for performing an evidence-based assessment;
- Provide an overview of the commonly recognized advantages and drawbacks of SNOMED CT.
## 2 Glossary

<table>
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<th>Acronym</th>
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<td>SCT</td>
<td>SNOMED CT</td>
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<tr>
<td>SDO</td>
<td>Standard Development Organization</td>
</tr>
<tr>
<td>IHTSDO</td>
<td>International Health Terminology Standards Development Organisation</td>
</tr>
<tr>
<td>MS</td>
<td>Member State</td>
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<tr>
<td>eHGI</td>
<td>eHealth Governance Initiative</td>
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<tr>
<td>WP</td>
<td>Work Package</td>
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<td>BMM</td>
<td>Business Motivation Model</td>
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<td>DOW</td>
<td>Description of Work</td>
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3 Introduction

ASSESS CT will collect and elaborate information about past and current use and, where applicable, about future prospects for the usage of terminologies with a focus on SCT. This will be performed covering most of the 28 Member States (MS) of the European Union building on the informative and relevant eHGI information paper\(^2\).

For each MS, we will extend our knowledge of how terminologies are managed, investigating aspects surrounding the use of clinical terminologies including how semantic interoperability issues have been addressed including national policies and guidelines, terminology infrastructures services, type and cost of licence, cost for maintaining a national terminology, timelines, and milestones of adoption, as well as lessons learned, expectations, perceptions, and beliefs. Those, and all the other aspects documented in the reports, will be investigated collecting the **concrete facts** (experiences, evidences) that support the opinions expressed.

A list of best practices and pitfalls in the usage of SCT pointing to the relevant merits and faults, will be gathered for the European IHTSDO members countries; the reasons for non-adoption and the relevant merits and faults in using alternative terminologies will be collected for the MS that are not IHTSDO Members. Experience and lessons learned on the usage of terminologies beyond Europe (e.g. US) and in extra-European cross-borders context (e.g. EU/US) will be analysed as well.

Therefore, even if this WP is focused on the usage of SCT, the instruments have been designed for collecting experiences and facts enabling the assessment of all the three identified scenarios:

- **ADOPT**: use of SNOMED CT on an EU-wide scale
- **ALTERNATIVE**: use of other terminologies on an EU-wide scale
- **ABSTAIN**: do nothing at the EU level for the development of a semantic interoperability framework for the cross borders healthcare (not limited to the exchange of data).

Survey tools, used to apply the Delphi method, will be complemented by a focused literature research, the collection of non-published evidence and studies and selectively expert focus groups. Besides scientific literature related to SCT, grey literature, IHTSDO projects material, anecdotal evidence and innovative approaches will be considered as well. Hence, in all cases the most appropriate means (focus group, literature/evidence review, questionnaires, structured interviews, and Delphi study) will be selected depending on the purpose of each specific activity and on the type of the target population selected as described in the following sections. Within this context this deliverable (D1.1) will:

1. Provide a general description of the methodology adopted for achieving the WP1 objectives (Section 4)
2. Describe how the Focus Groups (section 5) and the Delphi Study (section 6) including stakeholders/experts engagement have been set up.
3. Document the surveys that have been developed to enable the realization of the intermediate report presenting preliminary results (section 7)
4. Report about the EU / US discussion group (section 8)
5. Summarize the first assessment concerning whether SNOMED CT satisfies the requirements for the Identification of ICT Technical Specifications of the EU standardization regulation, annex II\(^3\) (section 9)

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4 Methodology

This section provides a general description of the methodology adopted for achieving the WP1 objectives, using where appropriate the BPMN⁴ and the BMM⁵ formalism.

4.1 General Approach

The main goal of this project is to “investigate the fitness of the international clinical terminology SCT as a potential standard for EU-wide eHealth deployments”.

This goal includes a number of WP specific goals described in the Description of Work (DOW) (see that document for further details), some of them identified as Key Objectives (in yellow in the figure). The investigation needs to consider the goal of comparing the SNOMED CT adoption scenario (ADOPT) with (a) defining a semantic interoperability framework without SNOMED CT (ALTERNATIVE) and (b) doing nothing at the EU level (ABSTAIN).

The goal specified for WP1 is that to “Build a solid background of common knowledge about the usage of terminologies in Europe with a special focus on SNOMED CT”, having as “key objectives” (in the sense defined in the Description of Work) to:

- Investigate the use of SCT across the EU.
- Assess if SCT satisfies the requirements for the Identification of ICT Technical Specifications of the EU standardization regulation, annex II.

The WP1 goal has been therefore amplified in the following objectives:

1. Collect information about the past, current and future use of SCT in Europe at all the involved levels (Cross-Borders/National/Regional); with a view also to non-EU experience.
2. Collect information about current and future possible policies of IHTSDO, including cooperation with other SDOs, and about the use of SCT within other standards
3. Assess if SCT satisfies the requirements for the Identification of ICT Technical Specifications of the EU standardization regulation, annex II.
4. Identify - among those realized - appropriate use cases suitable for performing an evidence-based assessment;
5. Provide an overview of the commonly recognized advantages and drawbacks of SCT

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⁵ Business Motivation Model Version 1.2 http://www.omg.org/spec/BMM/
The strategies agreed for achieving the identified goal are as follows:

- **Trigger, encourage, and support Rich Policy Dialogues and Mutual Learning exercises** to promote semantic interoperability in Europe, preparing the ground for large scale eHealth deployment in the context of the Connected Europe Facility (CEF).

- **Enforce the Stakeholders Involvement.** Even if the project includes in both the consortium and in the Expert Panel the spectrum of expert organizations and individuals, the involvements of different types of stakeholders (decision/policy makers; terminology experts; users (clinicians, industry),...) is a key factor for the success of the project. To counteract the possible risk of low involvement, the project reserved an extensive budget to guarantee availability, incentives, and commitment of external experts.

- In order to assure a right balance between the achievement of the business goals, typically assured by a top-down approach, and the input derived from stakeholder experience a "**meet-in-the-middle**" approach has been adopted.

- **Learn to Adapt (Agile).** Considering the variability of the influencing factors, the large number of dimensions, elements and facts to be considered and the breadth of the objectives, an agile methodology has been adopted, in order to timely react to the input coming from investigation, the suggestions of stakeholders (including Joint Action representatives, European Commission, other PHC-34 projects,..), and the lessons learned during the project itself.

- **Continuous Monitoring of results and indicators.** Any kind of adaptive / agile methodology shall rely on objective evidence. A continuous monitoring of the initiated tasks is therefore required for measuring the (in progress) achieved result indicators in term of defined measures (e.g. country coverage) and identified objectives and goal (e.g. Does the information collected answer the expected questions?).

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6 For example it was initially planned to deliver three types of questionnaires: one general for all the stakeholders; one for getting data about countries and one more specific for the experts. During the design phase of this last questionnaire the relevant topics to be addressed progressively increased in number and type. Reviewing the results of the pilot phase, initially, it was agreed to refactor this questionnaire as a structured interview, but proceeding with the analysis it has been decided to wait for the initial results from Focus Groups, the first Workshop and the preliminary questionnaires to have more information for selecting the really relevant questions and identify the most appropriate mean (a single structured interview; several more focused questionnaires; a combination of both).
**Employ multiple instruments.** Several different means (Focus Groups, Questionnaires, Structured / Unstructured Interviews, Workshop, literature review …) will be employed to realize the ASSESS CT goals.

![Figure 3 Multiple instruments approaches, as presented in the deliverable.](image)

- **Staged Approach.** Considering the large number of possible target countries, the different level of engagement, the large variability of the stakeholder involved and their responsiveness, it has been chosen to adopt a staged approach in order to be able to elaborate information without interrupting the global process. In practice for each selected surveys have been defined intermediate milestones associated to partial set of target population chosen basing on the actual maturity of the process; those partial results can be therefore elaborated for getting information, monitoring the process and defining/adapting the next steps without waiting that the full survey will be completed. Results can be then integrated in a following stage when new tasks have been completed. Just for example purpose if questionnaire results are available only for a subset of the 28 potential countries those will be elaborated – even if not completed - in order to have enough inputs for better design the questionnaires / interviews directed to experts.
As previously described several different means have been identified for implementing the multiple instruments strategy. Those instruments have been selected for better adapting the investigation to the type of data to be captured (perception and beliefs, quantifiable measures, facilitation of open discussion, evidences and facts...) and the target involved. Figure 5 shows the identified means and the following table summarizes what they are used for. More details will be provided in the following sections.

<table>
<thead>
<tr>
<th>Mean</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country-based Focus Group</strong></td>
<td>Focus Group will help the project to capture stakeholders’ reflections on why they experienced something, which factors influenced something, what would lead to better results in the future, how and why the views of participants differ.</td>
</tr>
<tr>
<td><strong>Delphi Method</strong></td>
<td>The Delphi method is particularly effective in developing a full range of alternatives, exploring or exposing underlying assumptions, and building consensus involving a wide set of experts.</td>
</tr>
<tr>
<td><strong>On-line Questionnaires</strong></td>
<td>On-line questionnaires are used to collect from a wide audience information about a set of questions phrased in exactly the same way. Hence, they facilitate the comparison of results and provide the possibility to deliver structured and coded questions that enable the collection of quantifiable results.</td>
</tr>
<tr>
<td><strong>Literature Review</strong></td>
<td>The scope of literature review is to provide a comprehensive and up-to-date overview of the principal research about the topic being studied (in this context the experiences, evidences and drawbacks in the usage of SCT). Thus, literature research mainly focuses on the use of SCT, and will be supplemented with anecdotal evidence and grey literature.</td>
</tr>
</tbody>
</table>
| **Interview**               | Interviews are mainly used for collecting experiences of stakeholders and involve social interaction that allows the interviewer and interviewee to create
Mean Purpose
---
knowledge. Interviews may be structured, semi-structured or unstructured interviewed depending on the need of privileging the comparability of results or the flexibility of the investigation.

Workshop
Workshops enable active engagement of selected experts representing different kind of stakeholders (regulatory and competent European and national authorities, vendors, SDOs, healthcare professionals and/or other stakeholders) maximising communication outreach and minimising economic effort. This includes sharing and validation of the methodologies applied and of the results obtained as well as elaboration of input for better definition of goals and means used.

Weekly WP1 meeting were scheduled for allowing the project to continuously monitor the investigation and apply the “Learn to Adapt” approach.

The described surveys will be organized in three main phases:

- A first phase (preliminary investigation) in which the objectives are consolidated, the methodology is discussed and agreed in the project team and the first surveys are launched. This phase concludes after the 1st validation workshop and it will be concluded with the production of the intermediate report (D1.1).

- A second phase (in depth study) in which based on the results of consultations and of the preliminary studies, as well as lessons learned, more specific investigations will be realized (e.g. interview with experts for analysing more in deep specific questions, or discussing about relevant experiences and facts). In this phase, the results of the intermediate report (D1.1) will be integrated with new evidence and information, and an updated intermediate report will be produced (D1.2).

- A final revision phase will be therefore accomplished for discussing all the results gathered, refine where needed the conclusion and support the identification of recommendations. This phase will include the Final Workshop and will end with the delivering of the “Current and Future use of SNOMED CT” deliverable (D1.3).

**Figure 6 Plan Overview**

![Plan Overview Diagram](image)

Figure 7 provides an overview of the Preliminary Investigation phase.
As the group agreed about the overall methodology, and the first tasks realized were:

1. The creation of a candidate stakeholder registry, from which the questionnaire target population was selected according to the criteria defined and countries correspondents were identified starting from the countries associated with consortium partners
2. The design, piloting, and delivering of the questionnaires
3. The activation of focus groups, including the definition of guidelines for their realization.

Focus group and questionnaires related activities are now well in progress. More details about those tasks are provided in the dedicated sections.

4.2 Delphi Study

The Delphi method\(^7\) is one of the most widely used and accepted methods in needs assessment and policy design for gathering data from experts, designed as a group communication process aiming at convergence of opinions and eventually reaching consensus. The Delphi method has proved particularly effective in developing a full range of alternatives, exploring or exposing underlying assumptions, and building consensus. In applying the Delphi method a series of questionnaires are designed and offered to participating experts and thought leaders in a blind review.

In a sense, the Delphi method is primarily used for validating the results more than for collecting data. The multiple iterations are the means to converge and achieve consensus. The results of each iteration of the Delphi method will be used in the focus group meetings to elicit further insights. Initially, we proposed that the participants to the Delphi method include

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members of the eHealth stakeholders group. As the project execution proceeded, additional stakeholders suggested by partners, MS representatives and other stakeholders were also approached.

The means used for collecting stakeholders/ experts contributions (questionnaires, interviews, on line surveys, workshops, etc.) and the scope of their involvement may change depending on the task considered; as well as the type of experts/stakeholders involved.

The first expert round was realized organizing the Validation Workshop initially planned for Month 3, scheduled for May 22 in Brussels and through other specific actions (interviews, survey and focus groups). For the second expert round, a policy workshop is foreseen on month 10 and a report review by external experts. The participants to the Delphi method include members/representatives of organizations similar to those included in the eHealth stakeholders group and other eHealth stakeholders.

4.3 Country-based Focus Groups

A focus group is a small group led through an open discussion by a skilled moderator. The dimension of the group needs to be such to generate rich discussion without leaving out any of the participants. Success of the focus group depends very much on the skills of the facilitator in nurturing discussions in an open and spontaneous format, generating a maximum number of different ideas and opinions from as many different people as possible. Focus groups are well suited for those situations where listening to the opinion of others helps form thoughts and opinions, revealing a wealth of detailed information and insight. Focus groups go a step beyond surveys and questionnaires in an effort to understand things at a deeper level. Focus groups can help produce qualitative data with focus on preferences and beliefs. While reviews, interviews and questionnaires might help us to answer What experiences stakeholders might have, the focus groups (and interviews) help us to get stakeholders to reflect on why they experience something, which factors influenced something, what would lead to better results in the future, how and why does participants view differ.

Focus groups aim at a discussion instead of on individual responses to formal questions, and produce qualitative data (preferences and beliefs) that may or may not be representative.

Group session concentrates on gathering opinions, beliefs, and attitudes about issues of relevant to the aim. It also helps test one’s assumption, encourage discussion, build excitement, and learn about a topic or issue.

Focus groups are structured around a set of carefully prepared questions which move from the general to the specific. Discussion should be such that in stimulates and influences the thinking and sharing of ideas, so that participants may event change their thoughts and ideas in the course of the focus group proceedings.

4.4 Questionnaires and Interviews

Questionnaires and interviews are used to get information from individuals and in many occasions aggregate responses to get more data.

Questionnaire allows each respondent to receive the same set of questions phrased in exactly the same way. Questionnaires may, therefore, yield data more comparable than information obtained through an interview. Moreover when questions are structured and coded standardisable and comparable results can be obtained

In the context of this project interviews and questionnaires might help to answer which experiences stakeholders might have.
5 Set-up of Focus Groups

Section 4.3 Country-based Focus Groups described the purpose of the Country-based Focus Groups in the context of this project.

Special effort has been invested in defining the focus group and its questions, recruiting and preparing the participants, conducting the focus group with a skilled knowledgeable moderator, analysing the data and carrying out mutual learning exercises with participation of multiple focus groups.

This section describes how this has been realized and reports on the current progress status of their activities.

5.1 Selection Criteria and Engagement

The selection criteria adopted for selecting the countries in which to establish Focus Groups takes in account competing needs:

- Have a wide coverage (in that case it might be preferable that countries will be selected among those that are not strongly represented already in the project);
- Have committed groups (in that case having people that are engaged in the project may help)
- Have a balanced representation of countries and experts involved (IHTSDO member/non-member; positive/skeptical, decision makers, etc.)
- Assure the participation of qualified people in the groups
- Focus the efforts (even if in principle interesting it would not be reasonable in term of cost/effectiveness to extend Focus Groups to a very large number of countries. A minimum number of 7 countries was however identified in the DoW).

After a first analysis within the project team, and based on the above mentioned requirements, a first set of candidate MS have been selected and contacted for evaluating the possibility of establishing a Focus Group. Considering the commitment and added value for the capture of timely and meaningful information the initial set of MS has been chosen among the project members.

The following table summarizes the main characteristics of each candidate country.

<table>
<thead>
<tr>
<th>Country</th>
<th>IHTSDO Member</th>
<th>Main Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>Belgium is a multi-language country, involved in a multi-year project for the introduction of SNOMED CT at the National Level with a particular attention to usability aspects. The national project is almost completed, but currently on hold.</td>
</tr>
<tr>
<td>Croatia</td>
<td>No</td>
<td>Interest in getting information about SNOMED CT for evaluating the adoption of this terminology for piloting. As “new” EU member, it is keen to introduce eHealth innovation. Experts expressed a strong interest on SNOMED CT: two use cases identified injuries management and oncology treatments.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes</td>
<td>Long experience with SNOMED CT (translation of core concepts started on 2004). Few local pilot and several national projects. National projects: National register for microbiology, Common language for home care nursing documentation and a national project on using SNOMED CT as national terminology for pharmaceuticals. Local projects: A big EHR-implementation (EPIC) in Denmark, the Capital Region and Region Zealand use SNOMED CT as their core terminology foundation.</td>
</tr>
<tr>
<td>Country</td>
<td>IHTSDO Member</td>
<td>Main Characteristics</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sweden</td>
<td>Yes</td>
<td>Founding member of IHTSDO in 2007. Full translation of SNOMED CT exists with at least one Swedish term per SNOMED CT concept. Swedish synonyms are so far, few. Sweden has a long history of classification-based coding of health data and the international classifications (or Swedish versions thereof) play an important role in many national eHealth projects. Current national projects often combine the use of SNOMED CT with the use of other national terminologies and/or classifications. Examples of projects where standardized terminologies are used are national health registries, antibiotic use follow up, national guidelines, as well as regional projects aiming at structured health records.</td>
</tr>
<tr>
<td>Finland</td>
<td>No</td>
<td>Finland is a bilingual country with Finnish and Swedish as the official languages. Long experience of building national information services for eHealth (e.g. e-prescription and patient data repository). Standardized information structures with over 300 code sets, including both national and international classifications, are currently published and shared via the THL National Code Service. Topical interest in analyzing the possibilities of adopting SNOMED CT in Finland and in learning about the use cases of other EU countries.</td>
</tr>
<tr>
<td>France</td>
<td>No</td>
<td>Adopted SNOMED CT 3.5. General interest on this terminology. There are different opinions in the country about the opportunity of the adoption of SNOMED-CT. The Focus Group is considered important for facilitating also the national discussion about SNOMED CT. Research teams are involved in European projects using SNOMED CT and are interested in the output of the ASSESS-CT project (how to disseminate the results from research at the national level).</td>
</tr>
<tr>
<td>Germany</td>
<td>No</td>
<td>Strong experience with legal terminology management (DIMDI). Biggest healthcare system in Europe due to its large population. In the process of accelerating the national eHealth policies: Federal Ministry of Health is promoting an “eHealth Law” that also highlights the importance of interoperability with regards to interchanging health data nationally but also across the border. The planned law is equipped with rewards and sanctions. High usage of Electronic Health Records.</td>
</tr>
<tr>
<td>Netherland</td>
<td>Yes</td>
<td>SNOMED CT adopted for various local and a national project (e.g. Diagnosis for Hospitals) based on specific use cases (first Ophthalmology applications started to use SNOMED CT for Clinical Findings.).</td>
</tr>
<tr>
<td>Portugal</td>
<td>Yes</td>
<td>Recent member of IHTSDO. It’s going to introducing SNOMED CT keen to share experiences and opinions with other countries.</td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td>The introduction of SNOMED CT started several years ago (around 2011), committed to use it at the National Level (Medicines catalog, Patient Summary, minimum dataset of clinical documents, etc.)</td>
</tr>
</tbody>
</table>
The number of projects that use some form of SNOMED CT are innumerable, some in England which are national strategic initiatives and have been in live use for some years – e.g. Electronic Prescription Service, Summary Care Record and Choose and Book (referrals from primary care). All of these have subsequent phases which will extend the usage of SNOMED CT. As the UK has been working with SNOMED for some years, there is also a number of projects that are led outside of the National Release Center (NRC) and the NRC provides advice as and when requested. Internationally, the UK provided input into the collaboration on harmonization of Medical Device nomenclature (GMDN) with SNOMED CT. Output is expected to inform the basis for the UK medical device extension to support prescribing, recording, and analysis of secondary care devices.

Strongly involved in EU projects. There is an established (and evolving) national program for eHealth (ELGA).

Involved through the Lombardy Region in epsOS and other related projects. A National Program for the realization of interoperable Regional EHR-S is in progress, the terminology management is a priority topic.

Asking for the identification of possible members that represent several categories and that may contribute (where applicable) on bringing experiences / knowledge on the Adopt and /or the Abstain, Alternative scenarios.

Table 2 Suggested Focus Group composition

<table>
<thead>
<tr>
<th>Categories</th>
<th>Adopt</th>
<th>Abstain/Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Termination Standardization Org. Representatives e.g. SNOMED CT, ICD10...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy makers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vendors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional Health Terminologist/terminology implementers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For supporting the evaluation of the possibility of creating a Focus Group a guideline document was created providing general concepts and methodologies about Focus Groups (what they are useful for, how to organize them, the role of facilitator, how to manage a focus group,....); and more in detail about the aim, the questions to be discussed and how to assure harmonized and comparable results among the different country focus groups of this project. A summary of those contents is provided in § 5.2 Focus Group Guidelines, the complete guideline is attached in in “Appendix 2: Focus Group Guidelines”.

All the candidate Member States have been contacted. Belgium, Croatia, Denmark, Sweden, Finland, France, Germany, Netherland and Portugal gave their availability for establishing in this phase country-based Focus Groups. The other ones demonstrated interest on cooperating with the project, but they were unable to take any commitment at this time, investigating the possibility of establishing Focus Groups in a second stage.

The following table summarizes for each Member State that agreed on creating Focus groups, the progress status at the time of the delivering of this document (June 10, 2015).
<table>
<thead>
<tr>
<th>Country</th>
<th>Facilitator</th>
<th>Progress Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Hans van Belleghem</td>
<td>The meeting is scheduled for June 24th.</td>
</tr>
<tr>
<td>Croatia</td>
<td>Vesna Kronstein, Kufrin and Zlatko Boni</td>
<td>Preparatory meeting on 2015, April 23rd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Focus Group has been hold on 2015, April 30th.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Kirstine Rosenbeck Gøeg</td>
<td>Focus group held on 2015, April 27th with a common DK-SE evaluation session.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Daniel Karlsson</td>
<td>Focus group held on 2015, April 27th with a common DK-SE evaluation session.</td>
</tr>
<tr>
<td>Finland</td>
<td>Päivi Hämäläinen, THL</td>
<td>Invited about 12 experts. FG sessions held on 2015, May 5th and May 26th.</td>
</tr>
<tr>
<td>France</td>
<td>Marie-Christine Jaulent PhD : INSERM</td>
<td>Established a core team with 8 people and the facilitator.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Organized already call conferences and meetings. (First call on 2015, March 19th and introductory meeting on 2015, March 30th). The focus group members are now identified. First meeting on 2015 May 4th.</td>
</tr>
<tr>
<td>Germany</td>
<td>Sylvia Thun</td>
<td>Introductory meeting held on 2015, March 1st, a second one on 2015, June 9th.</td>
</tr>
<tr>
<td>Netherland</td>
<td>Hans van Belleghem</td>
<td>Focus group held on 2015, May 13th.</td>
</tr>
<tr>
<td>Portugal</td>
<td>Anabela Santos (to be confirmed)</td>
<td>The meeting will be organized by mid of July.</td>
</tr>
</tbody>
</table>

The following sub paragraphs briefly document the input collected from each member state in the preparatory phase about the questions they would like to discuss; the selection criteria for the focus group members; the identified challenges and other notes.

The information captured has been socialized in the team and used as input for the definition of the Focus Group Activity, that have been therefore harmonized in the Focus Group Guidelines (see Appendix 2: Focus Group Guidelines).

## 5.1.1 Belgium

### Suggested Selection Criteria

- Involve clinicians that have been actually part of the development of the terminology.
- Privilege informed stakeholders more than try to achieve “just” a wide representation
- Challenges
- To be able to involve the experts after the Belgian project has been put on hold.

### Suggested Topic/Questions

- Focus in usability, including tools and interfaces needed for making SCT usable
- Challenges
- Define very precise objectives and questions
- How SCT could be the semantic integrator for also other use (Link with registries)
- Use cases for which we can see priority in adopting SCT
- How SCT can solve the issues of mapping (export to other classification systems). Availability of official mappings.
<table>
<thead>
<tr>
<th>Other Notes</th>
<th>Member of IHTSDO, there is a national License. National Refset for most of the use cases (global approach). Other refset derived from the national subset ICD-10 used for DRG, is still the main classification system used in Belgium. Mapping SCT to ICD-10-CM is a good driver for pushing the adoption of SCT Two roadmaps one is the ICD-10-CM and one is SCT 3 national languages: translation is needed Plan gather: those working in the resources (clinicians hospital and ambulatory) (80%) Newcomers: people trying to implement SCT (hospital level) Develop a methodology for doing this: e.g. only pre-coordinated or also post-coordinated. Selection and translation of concepts. Domains: pharma procedures, etc. The project is done at 80% (not yet validated). Hospitals want to use it.</th>
</tr>
</thead>
</table>

### 5.1.2 Croatia

<table>
<thead>
<tr>
<th>Suggested Selection Criteria</th>
<th>Contacted all the stakeholders (familiar with SCT): Public Health experts, decision makers, clinicians, researchers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Topic/Questions</td>
<td>Used ICD-10, what could be the impact of using SCT? Pros and Cons of SCT from the Croatian Perspective Challenge: Actual knowledge about SCT by the Focus group participants is low, even though they have however experience with other terminologies.</td>
</tr>
<tr>
<td>Other Notes</td>
<td>SCT is not used in Croatia. Opportunity to get in touch with other organizations and learn from them.</td>
</tr>
</tbody>
</table>

### 5.1.3 Denmark

The preliminary analysis about Focus Groups has been jointly accomplished by Denmark and Sweden. Most of the items included in the Danish table are applicable to Sweden.

<table>
<thead>
<tr>
<th>Suggested Selection Criteria</th>
<th>Inclusion criteria: Participants would be selected to be able to make reasonably well-informed contributions, thus &quot;just clinicians&quot; are not on the list. • Personal network, including extended network e.g. using LinkedIn • Members of national medical informatics association • Members of national SNOMED CT implementation network • SNOMED CT licensees • SNOMED CT implementation project participants • National terminology conference participants • Projects which have opted to use other terminologies, e.g. the classifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder categories</td>
<td>Adopt</td>
</tr>
<tr>
<td>(NRC) National terminology Standardization Organisation representatives e.g. SCT, ICD10, ICF, ICPC, etc.</td>
<td>National Health-IT representatives: n1, n2 or n3 (Argument: n1, n2 or n3 are all NRC representatives and eHealth authority employees so both NRC and Policy makers)</td>
</tr>
</tbody>
</table>
Policy makers

Project leader, Local Government Denmark p1,
(Argument: Local Government Denmark, a central organization for municipalities. P1 has been project leader of a national project that aims at utilizing SCT, among others, for home nursing documentation)

Medcom representative: p2
(Medcom is responsible for the extensive Danish messaging framework, but they have not applied SCT in their standards, whereas ICD10 codes and ICPC codes are applied as valid values for some fields)

Stakeholder categories

<table>
<thead>
<tr>
<th>Stakeholder categories</th>
<th>Adopt</th>
<th>Abstain/Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vendors</td>
<td>Vendors that have adopted or plan to adopt SCT: v1, v2, v3 (Argument: v1 has a terminology management system including SCT, v2 works together with EPIC to implement EHRs in a large part of Denmark where SCT is implemented to some degree, v3 work together with v1 to be able to deliver terminology services in their system)</td>
<td>Vendors that have not adopted SCT V4 (V4 has terminology management in their systems, SCT has been discussed in the organization, HL7 standards are applied, but no SCT adoption)</td>
</tr>
</tbody>
</table>
| Regional Health Terminologist/terminology implementers      | Regional implementers: r1 and r2
Argument: r1 is involved in the EPIC implementation project
R2 works with terminology standardization in a Danish region, where SCT has been considered | Regional implementers r3 and r4:
(EHR implementers in two Danish regions. They both know what SCT is, but it has not been applied in their implementations) |
| Other                                                       | o1 and o2 (very knowledgeable individuals which have earlier been involved in the decision of being member of IHTSDO and translating SNOMED CT) | |

Proposed Aim: European views on current and future terminology use in the health care sector, with special focus on the role of SNOMED CT

Examples of focus Interview questions:

- Pros and cons: Terminologies in use today
- What are the benefits of terminologies in use today?
- What the the shortcomings of terminologies in use today?
- Pros and cons: SNOMED CT
- What are the benefits of SNOMED CT usage?
- Which factors are barriers to SNOMED CT usage?
- Future terminology usage
- What would an ideal situation be in terms of use of terminologies in the health sector?
- Which support functions are needed to realize benefits?
- Who is responsible for realizing the benefits?
- Specifically: Which role could EU have?
### Suggested Selection Criteria

- **main focus will be on medical experts (both users and those involved in classification work)**
- a few IT vendors will be invited
- policy makers, representatives of various authorities and municipalities
- representatives of national registries

Members were identified through co-operation networks and various expert groups, especially those involved in national code service processes and national and international classification activities.

### Suggested Topic/Questions

- what possibilities are seen for the utilization of SCT in structured health records in Finland and in the Finnish centralized patient archive
- Who will be the presumed users of SCT?
- Do we need use-cases and use-case analysis?
- Would SCT be implemented in certain specialties only and what would be its coverage in different specialties? Which are the main specialties that could implement SCT?
- Should we aim for a full implementation of SCT or just parts of it?
- Should the implementation of SCT be planned in phases? What would be the best approach in Finland?
- Local and national implementation of SCT versus international needs (semantic interoperability and cross-border data exchange) – what would be the balance between these different approaches in the implementation strategy?
- What facilities are needed for the utilization of SCT?
- What resources needed for the implementation of SCT?

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Which type of stakeholders are we aiming for?

Represent: “countries that use SCT” vs. “diversity in how terminology management is handled”.

**Suggestion:** Invite participants that reflect the diversity of terminology management at local, regional, national level for example:

**Alternative:** Choose use case e.g. "Regional terminology management" or "communication of discharge summaries" and invite focus groups based on the use cases.

Main challenges

- Determine final aim and interview guide

Study quality:

- Focus groups should be somehow uniformly run, how is that achieved? And how are results from focus groups interpreted and compared?
- How do we ensure validity? E.g. the terminology-information model boundary is (close to) fully arbitrary. What are we covering by looking solely at "terminology"? How informed will opinions/recommendations be?

Are we to transcribe the discussions, translate them to English, and do the coding of the results on the European level? OR, are we coding the transcripts in each country? If so, how do we ensure consistent coding? Do we e.g. use a common set of codes? Coding triangulation? Are results of survey used in the focus group analysis (data triangulation)?

Danish-Swedish evaluation session will allow dissemination of results just after the session and allow stakeholders to share experiences with their Scandinavian colleges.

### 5.1.4 Finland
- Who would be responsible for organizing the implementation in Finland?
  Possible challenges to be discussed:
  - SCT’s relation to existing classifications already use in Finland?
  - Finnish translations needed (all or part of SCT, which parts?)
  - Can we implement some parts of SCT in English?
  - costs of the license and the implementation
  - challenges in organizing the focus group activities in Finland: mainly schedule and work load challenges

### 5.1.5 France

The main criteria were to select people being well informed on SCT and covering as much as possible the different categories: Public Health experts, decision makers, clinicians, researchers.

The personal network of the facilitator was used to identify the focus group members. Two criteria were particularly important:

- The familiarity of the members with SCT
- A good balance between the current opinions in France regarding the adoption of SCT

Six persons were first invited to be part of the Focus Group. After a first meeting where the optimal coverage of the focus group was discussed, the group was extended to 8 persons.

Focus group members:

- Stefan Darmoni MD, PhD : Director of CISMeF (Catalog and Index of French-language Health Internet Resources)
- Christel Daniel MD, PhD : Responsible of the AP-HP team in charge of the referentials and the clinical information treatment for research- responsible for the semantic interoperability Platform in a European project involving a French hospital
- Philippe Manet : ANAP (National Agency for healthcare structures performance)
- Michèle Thonnet PhD : Ministry of Health, EPSOS project
- Rémy Choquet PhD: Operational Director at National Database for Rare Diseases, previously responsible of an interoperability Platform in a European project involving the HEGP hospital in France
- Jean Charlet, Researcher APHP, long experience in termino-ontology building and alignments
- François Macary, Responsible of the semantic interoperability topic at ASIP Santé – Author in 2015 of a report about use of terminology in healthcare including SCT
- Florence Amardeilh, research director in the MONDECA company

A first proposition of 7 questions has been set. There are in relation with the 5 themes presented in section 5.3. This proposition will be refined in the future:

1. What is the current state in France in terms of terminologies use? (Since France is not an IHTSDO member, the current state reflects the ALTERNATIVE or ABSTAIN scenarios)
2. What are the success stories (the working current use cases)?
3. What are the priority use cases for the country? What are the Strengths
and Weaknesses of the current use of terminologies according to the set of use cases to be covered?

4. Do you think there is a need of new terminologies, (such as SCT) or do you think there is a need to improve (extend) the implementation of current terminologies (reference and local)?

5. What are the main barriers you identify for adopting international terminologies (eventually new ones) rather than local ones? (ALTERNATE versus ABSTAIN scenario)

6. What are the main barriers (and fears) for adopting SCT as a facilitator for integration and interoperability? Do you think the SCT can be used as “reference” terminology for clinical terms?

7. What will be the facilitators to overcome the barriers? What will be the different steps and the local challenges? Is that an option in the current situation (already existing facilitators)?

8. What would you recommend as the next steps in terminology adoption and usage (at the level of the country and the EU)? Who is responsible of the enabling factors (at the level of the country and the EU)?

Other Notes
Non Member of IHTSDO
Use of SCT V3.5 which has been translated in French

5.1.6 Germany

Cover as possible those roles:

- National terminology experts
- Representatives of SDOs (HL7, IHE, DIN etc.)
- Representatives of assigned eHealth Competence Centers (gematik)
- Representatives of Health Care Authorities
  - Ministry of health
  - DIMDI, RKI, BfArM
  - Selbstverwaltung (insurance companies, hospital associations, …)
  - Scientists (eHealth, Medical informatics)
  - Representatives of business companies (Health Care IT)

Members:

- Dr. Christof Gessner gematik
- Dr. med. Kai U. Heitmann hl7
- Zain Elabdin
- Tarik Idris
- Dr. Jörg Caumanns, Fokus
- Dr. Frank Oemig, AGFA
- Klaus Urban
- Daniel Flemming
- Stefanie Weber DIMDI
- Bernd Schütze
### How members have been identified:
- Personal contacts
- Insider concerning the German eHealth-field
- Common known decision makers in the German Health Care Environment
- Search within terminological groups (TMF, DIMDI, HL7 (TC Terminologien), IHE)

### Suggested Topic/Questions
- What may be the main obstacles for adopting SCT in your country?
- What may be the main obstacles for joining the IHTSDO?
- What benefit do you rank highest in the adoption of SCT?
- What kind of incentives (by the state) would be needed to implement SCT in your country?
- What do you expect from the IHTSDO to make the use of SCT and the IHTSDO membership more attractive for a nation?

### Identified Challenges to be discussed
- Licence
- No interest in SCT because of other challenges: Security, Messaging
- Teaching
- Implementing
- Politics (no need, because vendors want to stick to their own terminology)
- TermInfo problem

### 5.1.7 Portugal

| Suggested Selection Criteria | Portugal has been involved in a second stage so it didn't participate to the discussion about selection criteria and topic |
| Suggested Topic/Questions | Portugal has been involved in a second stage so it didn’t participate to the discussion about selection criteria and topic |

### 5.1.8 Netherlands

| Suggested Selection Criteria | Selection will be made according to the classification identified in WP3 In particular candidates are (Stakeholder name, with Snomed CT licence ?) |
| Patients | NPCF No |
| Academic Hospital | Prog Reg ad Bron No; VUMC Yes; Radboud No |
| General Hospital | Amphia Via Epic; Isala kliniek Yes |
| Policy Makers | VWS Yes; ZIN Yes; NZA No; IPZ No; Nictiz Yes |
| Software vendors | Epic Yes; Nexus AG Yes; Chipsoft Yes |
5.1.9 Sweden

The preliminary analysis about Focus Groups has been jointly accomplished by Denmark and Sweden. Most of the items included in the Danish table are applicable to Sweden.

Facilitator | Daniel Karlsson
---|---
Suggested Selection Criteria | See Denmark
  Invitations to participants included representatives from:
  - The Swedish department of health
  - The Swedish SNOMED CT National Release Center
  - The release center for national classifications
  - Regional projects implementing standard terminologies and classifications
  - National projects implementing standard terminologies and classifications
  - Health IT vendors and/or consultants
  - Health professionals societies

5.2 Focus Group Guidelines

This section provides a synthesis of the main elements included in the Focus Group Guidelines document, included as appendix to this deliverable.

The Focus Group instrument has been selected in ASSESS CT for the purpose of producing qualitative data with focus on preferences, perceptions, and beliefs. In fact, focus groups (but also interviews) will help the project to capture stakeholder reflections on why they experienced something, which factors influenced something, what would lead to better results in the future, how and why the views of participants differ. Where instead, reviews, interviews and questionnaires might help the project to answer about what experience stakeholders have.

The composition of the focus group should balance different types of stakeholders and enable the collection of different perspectives concerning the ADOPT/ABSTAIN/ALTERNATIVE scenarios. See on this purpose: Table 2 Suggested Focus Group composition.

The agreed aim of the ASSESS CT Focus Group is to collect:

*European views on current and future terminology use in the health care sector, with special focus on the role of SNOMED CT.*
To develop this subject a set of common themes has been agreed, in order to have comparable results from the focus group. However for capturing countries specificity it has been allowed each country to extend those topics with specific questions, and/or introduce limited number country-specific topics. As common approach, facilitators have been asked to keep track on how many members of the focus group agree with the conclusions and ask for details on why they do not agree.

5.2.1 Theme 1: Current terminology usage
The purpose of this theme is to gather from focus group members the perceived strengths and weaknesses of the current situation with regards to usage of clinical terminology. The role of the facilitator is to make focus group members discuss, which strengths and weaknesses are the most prominent, and to conclude upon this at the end of the session. Examples of questions:

- Which terminology systems are being used now?
- To what extend are they useful?
  - (Strengths) In what situations/for what use cases are they useful?
  - (Weaknesses) In what situations/for what use cases are they not useful?

5.2.2 Theme 2: Benefits of adopting new terminologies
The purpose of this theme is to gather the FG members’ attitude towards adopting more international terminologies than what are implemented now. The role of the facilitator is to make focus group members discuss what is actually the benefit of adopting something new? Vs. what could already be done if implementation of current terminologies were handled differently? Upon the end of the session, it should be concluded what benefits FG members’ see in adopting new terminologies.

Examples of questions:

- For which use cases do you see benefits in extending the use of international terminologies?
  - Specifically: For which use cases do you see benefits in using SCT?
- What would an ideal situation be in terms of use of terminologies in the health sector?
  - What would characterize terminologies that live up to these requirements?

5.2.3 Theme 3: Barriers for extended terminology adoption and use
The purpose of this theme is to gather the FG members’ opinions about which barriers are stopping the adoption or use of international terminologies. When addressing barriers, we study which barriers FG members consider to be important, but also whether they think these factors are currently present. The role of the facilitator is to make focus group members discuss what is stopping them from adopting and promoting the use of international terminologies. The facilitator has to make sure that both SCT and alternative terminologies are discussed. Upon the end of the session, it should be concluded what barriers FG members’ consider most prominent when adopting or considering extended use of international terminologies.

Examples of questions:

- What are the reasons why international terminologies are not adopted and used more extensively? (Alternative formulation: What are the barriers to adoption and use of international terminologies?)
• What are the barriers in your organizational context? (Alternative formulation: To what extend do the barriers currently exist in your organization?)

• Discuss the importance of the barriers when looking beyond your own organization e.g. seeing your countries development as a whole.

• How can the barriers be overcome? (Transition to the next theme, maybe leave out here)

5.2.4 Theme 4: Enabling factors for extended terminology adoption and use

The purpose of this theme is to gather the FG members’ opinions about which enabling factors could promote the adoption and use of international terminologies. When addressing enabling factors, we study which barriers FG members consider to be important, but also whether they think these factors are currently present. The role of the facilitator is to make focus group members discuss what is helping them in adopting and promoting the use of international terminologies. The facilitator has to make sure that both SCT and alternative terminologies are discussed. Upon the end of the session it should be concluded what enabling factors FG members’ consider most prominent when adopting or using international terminologies.

Examples of questions:

• What enables adoption and use of international terminologies?

• What enabling factors are already in place?

• Which enabling factors are missing?

• Discuss the importance of the enabling factors when looking beyond your own organization e.g. seeing your countries development as a whole.

5.2.5 Theme 5: Recommendations

The purpose of this theme is to make the FG members’ reflect upon how to take action based on the information they have shared in themes 1-4. What should be the strategic goal, and who is responsible for reaching that? The facilitator has to make sure that both SCT and alternative terminologies are discussed, and that different organizational levels are considered. Upon the end of the session it should be concluded what could be feasible strategic goals and who should be responsible. Note that consensus is based on “feasibility” rather than “importance”, because we want the strategic direction to be realistic.

Examples of questions:

• What would you recommend as the next steps in terminology adoption and usage?
  o In your organization?
  o In your country?
  o At EU level?

• Which enabling factors would you suggest to support these steps?

• Who is responsible for these enablers?
  o In your organization?
  o In your country?
  o At EU level?
6 Set up of Delphi Study

Section 4.2 Delphi Study describes the reason for adopting the Delphi Study in the context of this project. This section describes how they have been set up.

In recruiting the participants in Member States, ASSESS CT has join forces with key European organisations to identify the institutions and the thought leaders that can best serve the objectives of ASSESS CT in recommending an incremental and sustainable solution for semantic interoperability in Europe. Additional contacts were provided by EXPAND (following upon epSOS) in regards to the Terminology responsible contact in each Member State.

6.1 Stakeholder registry

The first step for the realization of the Delphi Study has been the activation of a process for realizing a stakeholder registry, having a target of at least 300 stakeholders.

This selection process has been done considering the following precepts, in order to avoid (or reduce as possible) biased results due to the selection of specific target populations only, e.g. per country, per type (e.g. IHTSDO member/non-member), per opinion on specific topic (e.g. SNOMED enthusiastic vs. skeptical):

- Assure a balanced coverage of different types of stakeholders (DOW measure: at least one for each of the 4 categories identified in the DOW CMO / CIO / Public Officer; Terminology authorities & implementers; eHealth industry; Health care professionals)
- Assure a wide geographical coverage (DOW measure: 75% EU countries) including also those countries that are not already strongly represented in the project. This will also assure a balanced presence of IHTSDO member/non-member countries.
- Assure a sufficient number of contributors in order to get statistically meaningful results both at the global, both at the country level.
- Avoid decreasing the quality of the contributions in favor of a numeric increment of stakeholders. It has been preferred to have less, but qualified contributors.

Those principles were enforced in the selection guidelines prepared for the different types of surveys realized and applied “cum grano salis” on dependence on the type of investigation considered.

As declared in the scope of the stakeholder questionnaire (see the dedicated section) this survey was also used to profile the respondents and facilitate the selection of suitable targets for the following surveys in line with the agreed precepts.

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8 More than 350 stakeholders have been finally involved covering 24 European countries (Austria; Belgium; Bulgaria; Croatia; Czech Republic; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Italy; Luxembourg; Malta; Netherlands; Norway; Portugal; Slovakia; Slovenia; Spain; Sweden; Switzerland; United Kingdom); and 8 Non-EU countries (Australia, Canada; India; Israel; Malaysia; New Zealand; U.S.; Uruguay).

9 “Qualified” here is not a synonymous of terminology expert / authority, but indicates any person that per role or expertise may provide reliable opinions / perceptions about terminologies: for example as skilled user (Health Professional, Industry); as terminology decision maker; as involved in relevant national eHealth projects; as involved in terminology content and/or service management; and so on...

10 See for example for questionnaires § 7.2.1 - Targets selection and engagement and § 7.3.1 - Targets selection and engagement; or for the focus groups Appendix 2: Focus Group Guidelines.

11 For example a limited number of experts was invited to the EU –US focus group trying to balance “SNOMED CT proud” users (e.g. Kaiser Permanente) and other experts strongly involved in WHO ICD-11. Similar approaches were followed for the expert review meetings considering the involvement of vendors, decision makers, and terminology experts with different viewpoints.
The results collected reasonable confirmed a good achievement of the identified goals in term of balance:

- all the quality criteria defined in the DOW in term of coverage and distribution have been reached;
- The presence of different viewpoints is clearly evidenced by the results of the investigations (see expert meeting minutes; questionnaires and Focus Group results) from which is easy to identify little groups of enthusiasts and detractors and a wide range of “conditional Yes”. The extent and the kind of conditions vary among the different stakeholders, making in some case the "Yes" closer to a "No" (e.g. "Yes it was freely available").
- Focus group composition respected the principles agreed: so that the focus group set-up in France included a good representation of that created by ASIP Santé for the national survey on terminologies; and the one created in Germany had seven with a positive view on the adoption of SNOMED CT; four with a negative view and five neutral.

The process was realized in two main steps: initially a set of candidate stakeholders was identified with the involvement of the project members and of the pre-identified experts; after this preparatory phase, for each type of investigation performed, a selection was accomplished and the stakeholders engaged. The means used to collect those data are described below.

As a first group, the project identified the EU eHealth stakeholder group (as participants to the Delphi method and target group to receive press releases and newsletter).

<table>
<thead>
<tr>
<th>eHealth Stakeholder Group</th>
<th>Participant</th>
<th>Target Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Association of Hospital Pharmacists (EAHP)</td>
<td>Leonidas TZIMIS</td>
<td>Pharma</td>
</tr>
<tr>
<td>Association of EU Self-Medication Industry (AESGP)</td>
<td>Roger SCARLETT-SMITH</td>
<td>Pharma</td>
</tr>
<tr>
<td>European Association of Pharma Wholesalers (GIRP)</td>
<td>Ulrich SCHÄFER</td>
<td>Pharma</td>
</tr>
<tr>
<td>Pharmaceutical Group of the European Union (PGEU)</td>
<td>Jurate SVARCAITE</td>
<td>Pharma</td>
</tr>
<tr>
<td>Standing Committee of European Doctors (CPME)</td>
<td>Michael WILKS</td>
<td>Healthcare professionals</td>
</tr>
<tr>
<td>European Union of Medical Specialists (UEMS)</td>
<td>Cillian TWOMEI</td>
<td>Healthcare professionals</td>
</tr>
<tr>
<td>Council of European Dentists (CED)</td>
<td>Piret VALI</td>
<td>Healthcare professionals</td>
</tr>
<tr>
<td>UKCHIP - EuroRec</td>
<td>Jean ROBERTS</td>
<td>Healthcare professionals</td>
</tr>
<tr>
<td>European Union of Private Hospitals (UEHP)</td>
<td>Jose Carlos NASCIMENTO</td>
<td>Healthcare providers</td>
</tr>
<tr>
<td>European Hospital and Healthcare Federation (HOPE)</td>
<td>Pascal GAREL</td>
<td>Healthcare providers</td>
</tr>
<tr>
<td>European Federation of Nurses (EFN)</td>
<td>Paul DE RAEEVE</td>
<td>Nurses</td>
</tr>
<tr>
<td>European Patients' Forum (EPF)</td>
<td>Liuska SANNA</td>
<td>Patients</td>
</tr>
<tr>
<td>AGE Platform Europe (AGE)</td>
<td>Anne-Sophie PARENT</td>
<td>Patients</td>
</tr>
<tr>
<td>European Consumers Organisation (BEUC)</td>
<td>Ilaria PASSARANI</td>
<td>Patients</td>
</tr>
<tr>
<td>European Health Telematics Association (EHTEL)</td>
<td>George CROOKS</td>
<td>Healthcare providers, etc</td>
</tr>
<tr>
<td>European Public Health Alliance (EPHA)</td>
<td>Monika KOSINKA</td>
<td>Professionals, Patients,</td>
</tr>
<tr>
<td>European Connected Health Alliance (ECHA)</td>
<td>Brian O'CONNOR</td>
<td>Industry, Research</td>
</tr>
<tr>
<td>European Health Management Association (EHMA)</td>
<td>Jenni BRENNER</td>
<td>Healthcare providers, Healthcare</td>
</tr>
<tr>
<td>European Regional and Local Health</td>
<td>Alan BARRELL</td>
<td>Regional/local healthcare</td>
</tr>
</tbody>
</table>
The selected stakeholder was included in the registry that has been kept continuously updated during the whole project lifecycle.

At the date of the first delivering of this document, beside the 28 people mentioned above (eHealth stakeholder group) other 194 stakeholders have been identified as of June 10, 2015.

- 122 gave their consent in being inserted in the stakeholder registry through the all stakeholder questionnaire form
- 10 answering the country overview questionnaire form
- 45 (on a total of 53 registrations) registering to the 1st workshop
- 17 through direct contacts

The following Figure shows the distribution of stakeholders per country.
The following figures provide an overview of types of stakeholders that gave their consent in being inserted in the stakeholder registry through the questionnaire form:

- per role in healthcare (Figure 10)
- per type of involvement with terminologies (Figure 11)

**Figure 9 Registered Stakeholders per Country**

**Figure 10 Registered Stakeholders roles in healthcare (questionnaire)**

Note most of the role classified as “other” could be often reclassified to one of the existing classes (some example: “Strategic Adviser”; “Information specialist”; “presidency of TC215 at Croatian Organization for Standardization”; “biobank development”; “Policy advisor”; “member of groups who makes decisions about documentation” ; “Quality assessing ICT products”; “Business developer responsible for helping to profile”; “configure and harmonise terms used within ICT products deployed in my local environment, who also takes part in moving my organization towards structured and standardized EHR content”; “Director of several healthcareIT businesses”;….)
Some example of “Other” are: I consult on cost benefits and feasibility; Translation of terminologies; I participate in specifying EHR system requirements and improvements, and in developing strategies for health record content management within my organisation for the purpose of attaining a higher level of standardization and structure.; I manage a company that undertakes health data transformation; I'm involved in WHO and IHTSDO activities.
6.2 1st Revision Workshop

6.2.1 General description and agenda

On Friday, 22nd May 2015 (08:30-17:30h) took place in Brussels the First Expert Workshop of the ASSESS CT project at the Federal Public Service (FPS) Health, Food Chain Safety and Environment, Eurostation II, Place Victor Horta, 40.

53 stakeholders attended this workshop, covering different roles and countries (see Figure 12). This includes also an IHTSDO representative as observer, and three representatives from the European Commission.

The scope of this workshop have been to present the project, socialize the approach followed by the different work packages and the preliminary results; stimulate the discussion about the treated themes and collect feedback about the work done and the next steps.

A brief background document was shared in advance with the registered stakeholders in order to help them to prepare for the workshop discussions.

The agenda (see tables below) foresaw an initial general introduction and a set of sessions focusing on the different ASSESS CT Workpackages in which presentation and discussions sessions have been alternated.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00-08:30</td>
<td><strong>Arrival and registration</strong></td>
<td></td>
</tr>
<tr>
<td>08:30-08:50</td>
<td><strong>Introduction, objectives, expected outcomes</strong></td>
<td><em>Sylvia Thun, Veli Stroetmann</em></td>
</tr>
<tr>
<td>08:50-09:10</td>
<td><strong>eHealth Joint Action &amp; semantic interoperability</strong></td>
<td><em>Luc Nicolas</em></td>
</tr>
<tr>
<td></td>
<td><strong>Current use of clinical terminologies / SNOMED CT</strong></td>
<td></td>
</tr>
<tr>
<td>09:10-09:40</td>
<td><strong>State-of-the art in adoption of clinical terminologies: benefits and challenges - initial results from national surveys across Europe</strong></td>
<td><em>Giorgio Cangioli, Catherine Chronaki</em></td>
</tr>
<tr>
<td>09:40-10:10</td>
<td><strong>National focus group reports</strong></td>
<td><em>Kirstine Rosenbeck Gøeg, Daniel Karlsson</em></td>
</tr>
<tr>
<td>10:10-10:40</td>
<td><strong>Coffee break</strong></td>
<td></td>
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<tr>
<td>10:40-11:40</td>
<td><strong>Discussion</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>Three scenarios</strong>: <strong>ADOPT</strong> (SNOMED CT as a potential standard for EU-wide eHealth deployments), <strong>ALTERNATIVE</strong> (EU-wide semantic interoperability framework without SNOMED CT), <strong>ABSTAIN</strong> (from action at EU level)</td>
<td><em>Moderator: Anne Randorff Højen</em></td>
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### Building new evidence

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>11:40-12:10</td>
<td><strong>Assessing “fitness for purpose” - three use cases:</strong></td>
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<tr>
<td></td>
<td>- Measuring fitness of clinical terminologies against real clinical data (<em>Stefan Schulz</em>)</td>
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<td></td>
<td>- Using clinical terminologies for semantic annotation of clinical narratives using language technology (<em>Kornél Markó</em>)</td>
</tr>
<tr>
<td></td>
<td>- Binding clinical terminologies to structured patient summaries (<em>Daniel Karlsson</em>)</td>
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<tr>
<td>12:10-12:50</td>
<td>Discussion</td>
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<td></td>
<td><em>Moderator: Ronald Cornet</em></td>
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<tr>
<td>12:50-13:30</td>
<td>Lunch break</td>
</tr>
<tr>
<td>13:30-13:45</td>
<td><strong>Impact assessment, socio-economic stakeholder analysis</strong></td>
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<tr>
<td></td>
<td><strong>A cost-benefit framework for assessing the impact of SNOMED CT</strong></td>
</tr>
<tr>
<td></td>
<td><em>Rainer Thiel</em></td>
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<tr>
<td>13:45-14:10</td>
<td><strong>Individual work on impact indicator rating</strong></td>
</tr>
<tr>
<td>14:10-15:10</td>
<td><strong>Indicator evaluation break out groups</strong></td>
</tr>
<tr>
<td></td>
<td><em>(Facilitators /rapporteurs from WP3 core team)</em></td>
</tr>
<tr>
<td>15:10-15:40</td>
<td><strong>Coffee break</strong></td>
</tr>
<tr>
<td>15:40-16:00</td>
<td><strong>Results from break out groups</strong></td>
</tr>
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</table>

### Policy guidance and recommendations

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>16:00-17:15</td>
<td><strong>eHealth Joint Action &amp; Semantic Interoperability</strong></td>
</tr>
<tr>
<td></td>
<td><em>Luc Nicholas</em></td>
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<tr>
<td></td>
<td><strong>Preparing evidenced recommendations for decision makers</strong></td>
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<tr>
<td></td>
<td><em>Dipak Kalra</em></td>
</tr>
<tr>
<td></td>
<td><strong>The eHealth Network perspective</strong></td>
</tr>
<tr>
<td></td>
<td><em>Michèle Thonnet</em></td>
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<tr>
<td></td>
<td><strong>Codification for Cross Border exchange in the EU? The example for rare diseases</strong></td>
</tr>
<tr>
<td></td>
<td><em>(Rème Choquet)</em></td>
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<tr>
<td></td>
<td><strong>Discussion</strong></td>
</tr>
<tr>
<td></td>
<td><em>(incl. interaction with the Joint Action and interoperability Support Actions)</em></td>
</tr>
<tr>
<td></td>
<td><em>Moderator: Dipak Kalra</em></td>
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<tr>
<td>17:15-17:30</td>
<td><strong>Next steps</strong></td>
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<tr>
<td></td>
<td><em>Veli Stroetmann, Sylvia Thun</em></td>
</tr>
</tbody>
</table>

In the following section are summarized the presentations done for this Workpackage and the main feedback and comments received.
6.2.2 Workpackage 1 – Current use of clinical terminologies / SNOMED CT

State-of-the-art in adoption of clinical terminologies: benefits and challenges – initial results from national surveys across Europe

Giorgio Cangioli provided an overview of the WP1 including the goals, the means adopted and its initial results. This presentation covered also the EU-US discussion group and the two questionnaires.

For what concern the “all stakeholder” questionnaires results about the coverage in terms of countries (124 responses from 12 countries at that time12), kinds of stakeholders and involvement in cross-border projects (about the 30%) was provided. The main limitations of current terminologies in support of cross-border patient data exchange and the most favored proposed solutions were presented. The perceived and the experienced benefits and challenges/issues was described for SCT and for other international terminologies including local terminologies.

Most respondents favored aiming for the direct selection of terms by clinicians during data entry, and not post-hoc clinical coding. It was recognised that SCT is the most complete solution for cross-border patient information flows.

He reflected, in conclusion, that a European commitment to SCT is necessary for its adoption, including managing the licensing costs.

For the details about the content presented please refer to the dedicated sections § 7 “Questionnaires” and § 8 “The EU US Discussion Group” in this deliverable.

National focus group reports

Daniel Karlsson introduced the choice of a focus group methodology to tap into expert knowledge in different countries. Daniel stressed that country based expert focus groups are being conducted, to help inform the three scenarios recognizing that these are expert opinions, not quantitative facts. The groups are all being run to common guidelines, with comparable kinds of expertise and experience, and covering the same core themes. Six groups have so far been held, others are in preparation. He noted that the data are still being analyzed and presented some preliminary findings from SE and DK.

Discussion about the first two presentations

In the context of the SE and DK focus groups:

- a Danish expert commented on the benefits of being able to share the meaning of laboratory test results between healthcare organizations (currently using an international terminology system).

- A Swedish expert proposed that terminologies would be valuable where the requirements are already clear and where there are working systems e.g. for quality registers.

A British expert noted the emphasis in this opinion on value from population data (registries), whereas the questionnaire survey presented emphasized the value for patients.

A French expert voiced the importance of assessing the contribution of a terminology (or other standard) for specific use cases: assessments that do not start by specifying the use case are a waste of time.

The importance of starting from use cases was reinforced by a Dutch expert.

Veli Stroetmann made clear that the project is guided by use cases, but that this aspect of the introduction was not stressed enough, in the interest of using the time to present progress.

12 Now 133 for 13 countries, but still below the 75% score.
A Danish expert stressed that terminologies should not be used beyond the scope of their purpose, as has occurred in the reported use of a Danish procedure classification system. The British expert (on the management board of IHTSDO) pointed out that he understood that the workshop was exploring if SCT was the answer, but he was not certain to have heard the question.

Discussion 1: Three scenarios (ADOPT, ALTERNATIVE, ABSTAIN)

Anne Randorff Højen reminded the audience of the three scenarios that scope the whole project: Adopt, Alternative, Abstain. These are three options, at a European level.

- Adopt needs to be informed by experiences of SCT adoption so far across Europe and beyond. This includes a multi-linguistic perspective. Costs and benefits have to be taken into account.
- If an alternative, what other terminologies would we recommend? What experiences have been gained with these other terminologies: are any of them suitable as a preferred European standard, are they multi-lingual and cost-effective to adopt?
- Abstain is harder to define.

What is to be gained from cross-border exchange, as the main use case for adoption a European terminology system? (How does this justify the cost?)

If we wish to adopt SCT as a pan-European standard, what use cases are in scope or out of scope? What is the expected outcome? She asserted that the first quote supported the adopt scenario.

The main feedbacks / comments provided during the discussion have been the following:

- move the discussion from a pure theoretical view to real usage across countries (e.g. cancer registries), looking at the existing success stories in several countries.
- Need to clarify the generic statement about adopting SNOMED CT at a European: who it to adopt it (e.g. the multi-stakeholder platform?) and for what purposes: in projects?
  - On that point, Veli Stroetmann emphasized that there are important key words in the scenario choice: the choice is for the "core" terminology, not the exclusive one. However, the term "core" is not well defined. We have to contribute to a European interoperability framework with SNOMED CT as the core terminology, for cross-border care. It is in addition expected to solve national and regional interoperability problems too.
- Good quality healthcare and documentation, under increasing time pressures, is achieved only through more structured data entry and adopting terminology systems. SCT is one (for sure a good) of the possible choices. Maybe not to be used immediately where there are existing solutions, but it can be used in situations where there are no existing terminology systems. Cross-border and cross-organizational sharing will benefit by using the same terms.
- SCT is not complete for clinical use - with a real experience stroke care data it was found that less than half of the terms needed were missing. The terms (words) are just part of interoperability: also the field name and the information models need to be standardized.
- It is important not to reverse the order between cross-borders and national use: it cannot be supposed to have nicely coded data for cross-border exchange if the quality of local data is "poor".
- Even if the target are the Member States there is in any case an added value, since they can work together to remove barriers and reduce costs.
- Depending on the scope several different terminology are (and can be) used. EMA and ECDC are collecting clinical trials data and infection outbreak data using completely
different terminology systems. SCT must not be considered a panacea for any usage: its adoption has to be use case specific.

- Cross-border exchange should not be limited to patient data, but could also be used for the measurement of quality of care.
- SCT should also be considered a language for the development of future innovative solutions. Technology may be the demanding force for a universal (clinical) language in Europe.
- The idea of a single terminology that solves all the needs is a vision that cannot be applied today (even if we can probably agree that the vision is right). So the suggestion is to try to solve the delivery needs identifying for example what are the “five” data items that could be used to deliver some value today (e.g. problems).
- SCT cannot be used alone: e.g. radiology procedure orders cannot be represented in SCT. A strategy to reach a common language vision for Europe is needed. On that purpose it was wondered if to enrich terms through national extensions, that gradually become internationalized could be a solution; and how many terminologies (SDOs) allow for that.
- All the scenarios will need a mechanism for extensions. Radiology is an example domain that may need an extension, which is a different dimension from a national extension. epSOS found that only a small number of terms were needed for its use cases.
- Debates about sufficient content are going on for a decade: SCT does not have the whole content, but can it be the backbone onto which other terminologies can build, crowding sourcing can enrich etc.
- An important item to be consider in the choice of terminology is not only the content, but also its maintainability (epSOS adopted this criterion in its selection).

Some discussions about the usage of “core” terminology took place concerns about this term were risen since it gives the wrong message to the politicians that adopting a core is a sufficient solution for all the needs. No one terminology could be at that time the centre of the world”. It was suggested to consider SCT “a” core rather than “the” core. (note the word Core comes from the call text).

The discussion shifted to the alternative scenario. Denmark has found that alternative classifications cannot easily be extended to additional use cases, so if SCT is not adopted, can other terminologies meet the need?

These are the main comments collected:

- Even if SCT is adopted, there is in any case the need of having alternatives for billing, reporting, comparisons etc.
- many existing classifications cannot be used for new purposes - many were built for purely statistical purposes and therefore cannot be often used for clinical documentation (except perhaps in niche areas).
- Concern was expressed about the ambition of this one year project.
- It was questioned if Alternative is really competing with Adopt, and if Abstain is really just another kind of Alternative.
7 Questionnaires

Section 7 Questionnaires and Interviews describes the reasons and the ways these instruments are used in ASSESS CT. 
This section describes how questionnaire have been designed, how the target population was selected and contacted, and how the questionnaire have been delivered. It includes also a brief update about the progress status and very preliminary results.

7.1 Introduction

The delivering of questionnaire has been one of the primary instruments adopted in the preliminary investigation phase (see 4.1 General Approach for detail about the methodology adopted). This instrument has been used to reach with relative ease, a large number of stakeholders and to capture preliminary feedback about knowledge, perceptions and facts around the use of clinical terminologies (with a focus on SCT); it has been also used to profile the stakeholders to be included in the stakeholder registry (when consent is provided); and finally to capture from a selected number of Member States/Regions representatives information about the usage of terminologies in those countries.

Those goals have been realized through two distinct questionnaires, labeled as:
- the “all stakeholder” questionnaire describe in § 7.2
- the Country overview questionnaire described in § 7.3

For both of the same process has been followed:

1. the questionnaire objectives were identified, refined and agreed
2. based on those objectives, and considering the target population involved, a first set of questions were drafted, shared and discussed in the WP1 team considering the contributions from the other WPs and the external experts
3. The content of questionnaire was consolidated and the on-line questionnaire was implemented
4. The on-line questionnaire was reviewed and tested/piloted by WP1 members
5. The on-line questionnaire was refined and distributed.

For the implementation of the on-line questionnaire several tools were analysed and proved (Limesurvey, SurveyMonkey, Qualtrics, Google Form) evaluating costs, user friendliness, simplicity of use, data processing capabilities (including data export). The Limesurvey has been therefore selected and an ASSESS CT environment was created (http://assessct.limequery.org).

7.2 All stakeholders Questionnaire

The “all stakeholders” questionnaire has been conceived for these goals:

- Profile the stakeholders
- Get an overview of the knowledge/perceptions of the interviewed persons about clinical terminologies and their use
- Capture preliminary feedbacks about facts and experiences around the usage of clinical terminologies (with a focus on SCT)
- Facilitate the selection of suitable targets and the design of the following survey phases.

Specific targets selection criteria (hereafter described) were identified for achieving those goals. The team convened however that the approach to be followed for identifying and contacting those targets, the choice of involving specific targets in one or more than one ASSESS CT questionnaires, and other related choices were strictly country dependent. We assume in fact that each country representative is in the best position for evaluating what the
most suitable solution for his/her country, knowing – presumably – better than any other project member the characteristic of the identified contacts, the culture of his/her country, any enabling factor or barrier for the success of this survey.

The online questionnaire has been published in the following link:
http://assessct.limequery.org/index.php/749973

7.2.1 Targets selection and engagement

Basing on the above mentioned goals and on the measures defined in the DoW the selection shall:

- Assure a balanced coverage of different types of stakeholders (DOW measure: at least one for each of the 4 categories identified in the DOW CMO / CIO / Public Officer; Terminology authorities & implementers (> contacts epSOS); eHealth industry; Health care professionals)
- Assure a wide geographical coverage (DOW measure: 75% EU countries)
- Assure a sufficient number of responses in order to get statistically meaningful results both at the global, both at the country level.
- Avoid decreasing the quality of the responses in favour of a numeric increment: is better to have fewer qualified targets than more not adequate.
- Avoid biased results due to the selection of only specific targets population (per country, per type, per opinion on specific topic).

Hence, the rules for selection suggested to country representatives are the following:

1. At least 10 stakeholders
2. At least one for each of those categories
   - CMO / CIO / Public Officer
   - Healthcare Professionals
   - Terminology authority & implementer
   - eHealth Industry (EHR System Vendors; Medical Device Vendors; ICT Infrastructure Vendors; Industry Associations; Pharma)
3. Following the stakeholders WP3 classification would be nice to have at least one for each of the following classes, where applicable and suitable for that country:
   - Healthcare Provider Organizations (Hospitals, GP practices, etc.; Healthcare managers & Administrators)
   - National Decision Makers (Health ministries; Public health bodies; National & regional healthcare authorities)
   - Payers (Private (insurers, employers, patients); Public (government, commissioners)
   - Standards Development Organisations
   - Research

for this questionnaire “qualified” is not a synonymous of terminology expert / authority, but indicates any person that per role or expertise may provide reliable opinions / perceptions about terminologies: for example as skilled user (Health Professional, Industry); as terminology decision maker; as involved in relevant national eHealth projects; as involved in terminology content and/or service management; and so on …

Note that one target may play more than one role.

Note role hereafter described may belong to one or more of the previously mentioned categories.
7.2.2 Progress Status
At the time of the delivering of this document 133 responses coming from 13 countries have been collected, so distributed:

Figure 13 Completed Responses per Country (all stakeholders quest.)

Portugal will deliver the questionnaire during the first meeting of the Focus Group.
Other Countries (Spain, Poland, Bulgaria, Hungary, Switzerland, Czech Republic, Slovakia, Greece, Slovenia, and Turkey) have been contacted as well, but no questionnaire responses have been received so far.
A complete report of the first stage, including all the questionnaires received by June 10, will be reported in D1.2. Additional responses received after that date, hopefully including all the missing countries, will be integrated in a second stage.
The following section reports some preliminary processing results covering most of the questions included in the questionnaires, as shared also during the first revision workshop.

7.2.3 Preliminary results
General information about the geographical coverage and the stakeholder profiles have been provided in the previous sections. See for example:
- Figure 13 for the country coverage
- Figure 10 for the roles in healthcare
- Figure 11 for the type of involvement with terminology of the interviewed.
A good coverage for all the identified roles has been achieved, with a little prevalence of Health care and ICT professionals and a minor, but still significant number of members of advocacy groups.
A relatively high percentage of those interviewed declared to have been involved in cross-border healthcare activities (just under the 30%): mostly of them through EU funded projects
like epSOS, Trillium Bridge, SHN, PARENT JA, EHR4CR, EXPAND, but experience are not limited to those projects (e.g. INTERREG Italy-Slovenjia "Patient without borders").

**Figure 14 Have you been involved in cross-border healthcare activities (e.g. pilot projects)?**

The main limitations of current terminologies in supporting cross-border patient data exchange were reported in response to the following question.

**From your knowledge and experience of the cross-border exchange of patient data, what are the main limitations or problems with the currently available terminologies?**

These limitations were identified in:

- Lack of **common** terminologies
- Need to **combine** several terminologies
- Issues with **Mapping** to local terminologies
- Issues with **Licensing** terminologies
- Need for **translations** that do not exist yet
- Lack of **good quality structured and coded** data in the source EHR systems
- Inadequate terminology **strategies and policies**

The most favored proposed solution for overcoming those problems was the adoption of a centralised European terminology ("Adoption of a **centrally curated reference terminology** that allows decentralized, customized country and enterprise extensions by all countries involved in the cross-border exchange"), for which SCT may be the best solution. This was combined with reduction of license cost barriers and the agreement on common legislation at the EU level on exchange of (health) data across national borders.

Globally it can be asserted that more than half of respondents claimed that in their country there is a very limited usage of SCT.
Figure 15 How could you score the current usage of SNOMED CT in your country?

The following figures show the same response distributing the answer per country, normalized (Figure 16) and as a mean score (Figure 17).

Figure 16 How could you score the current usage of SNOMED CT in your country?
[Normalized distribution]

The score has been calculated assigning an integer from 0 (not used) to 4 (widely used) to each class and calculating the arithmetic mean.

Figure 17 How could you score the current usage of SNOMED CT in your country?
[Mean score]

As expected, very limited use of SCT is reported by the non-IHTSDO member countries, limited use for Denmark, Netherlands, Malta and Sweden; and the highest score for England.
Moving to the questions about beliefs and experiences about the benefits and the challenges associated to SCT and other international and local terminologies the following figure summarizes the relevant considerations.

**What would you personally believe to be the main benefits of using SNOMED CT in your organization?**

Less than the 5% believes that there are no benefits (this percentage is almost recurring in all the questions related to SNOMED CT). Some of the reported perceived benefits were:

- interoperability; detailed medical knowledge; cost reduction
- Access to a granular detailed terminology system covering many areas of healthcare essential to structured EHR content.
- facilitate the “data export/reporting”, the “data integration between different organisations” and “the non-redundant data capture”
- Improve the “coding and the code decision support, the data extraction for research, statistics”
- Improve the “quality of data” reducing errors

**What would you personally believe to be the possible risks, constraints or challenges with adopting SNOMED CT in your organisation?**

Less than the 10% of respondents didn’t indicate any specific issue.

The main classes of problems identified have been:

- High costs (terminology license, software licenses, training, EHR-S implementation, translation)
- Quality and consistency issue
- Complexity
- huge learning curve
- end-users acceptance
- bridging with billing code systems
- low EHR-S maturity
- lack of supporting policies (including resources (maps, value sets...) availability and countries commitment).

Some example quotes:

- “I somewhat believed that an Italian translation could be useful, it is unlikely we are able to sustain its translation in time, due to the absence of policies and long term choices, so better to concentrate on subsets or also interface terminologies.”
- “No real benefits until there is a critical mass of implementation.”
- “the challenge is making such a complex terminology usable for clinicians.”
- “Underestimation of the amount of work to get it into production software across IT-boundaries and overestimation of the benefits, SNOMED CT is no "golden bullet" that solves everything by itself.”
- “Huge expenditure of technical, financial, timely and personal resources needed to implement the national SNOMED CT agency”
- “A real success of adopting SNOMED CT in one organization depends mainly on the national adoption together with lots of accompanying measures like providing secondary resources, e.g. mappings to ICD-10, OPS, etc.; indexed Value Sets like VSAC in USA, indexed knowledge sources like dm+d in UK; etc.”
• “Regarding the necessary version management this is very, very complex and costly.”

• “Different to most existing terminologies pre- and post-coordinated SNOMED CT codes and code expressions are complex and can be evaluated not just by simple SQL-Queries but by sophisticated "structural" or "logical" evaluations.”

• “Suppliers of clinical software and developers of communication interfaces (e.g. HL7 V2) face a huge and costly challenge.”

• “Due to a weak national governance most actors in healthcare delivery, healthcare industry etc. have a "wait-and-see" attitude. They are not convinced to make profit of using a standard terminology like SNOMED CT as almost nobody (who has to pay for it) is asking for it.”

• “The few "success stories" are limited to few projects in English speaking countries. Apart from theoretical projects it is not clear what are the practical outcomes of adopting SNOMED CT by the existing member states.”

What benefits you have already experienced in your own organization through the use of SNOMED CT?

Coherently with the low usage of SCT more than 50 % of interviewed asserted that they have no direct experiences with SCT in their organizations.

The main benefits experienced seem to be realised by developers of solutions and research communities, rather than the end users.

For example, consider the following comments, and concerns: “the possibility of an ontological classification of concepts; the usage of SNOMED CT for tagging artefacts; use as an interlingua: providing a single target language for Summary Care Record.”

Other benefits experiences are the coverage of several medical domains and a better understanding of the medical concepts.

Have you already experienced or observed any challenges with using SNOMED CT in your organisation?

For what concern the challenges experienced the main ones have been the complexity in learning and using it (“Post-coordination; teaching; implementing in CDA/FHIR”), in "understanding the added value" and the license and implementation costs (“Annual fees are high; even higher are the costs of the initial implementation of SNOMED within the country.”)

Have you already experienced or observed any challenges with using other international terminologies in your organisation? / Have you already experienced or observed any challenges with using local terminologies in your organisation?

Responses identified that with regard to other international terminologies, and national ones, there will be costs of migration. End user acceptance issues seem to be present for other terminologies, not just SNOCT. There can also be challenges with local terminologies: they are not always complete and might not be sustainable.

Some example quotes follow:

• “The classifications ICD-10 and ICF are not granular enough for documentation of individual health data. But since they are already implemented in Swedish health care systems, there is resistance to using SNOMED CT instead.”

• “Social and cultural resistance by healthcare professionals”

• “Significant costs associated with constructing and maintaining crossmaps between different local terminologies”

• “The maintenance of local terminologies that are not national is unsustainable.”
Which are practical approaches to coding clinical facts about a patient with SNOMED CT?

Most respondents favored the direct selection of terms by clinicians during data entry, and not post-hoc clinical coding.

Figure 18 Which are practical approaches to coding clinical facts about a patient with SNOMED CT?

According to your knowledge and perception do you think that SNOMED CT should be used for the exchange of health and social data cross-borders?

It is interesting to note that although the score about the usage of SCT is relatively low, the large majority of replies indicates SCT as a suggested candidate for the exchange of health and social data cross-border having a good coverage of most of the medical domains and being “the only broadly available terminology that can (when translated) overcome the language barriers”. This positive answer should however be read under well specified conditions and with identified caveats. Like the fact that it might be one of the terminologies used, the answer may refer to specific use cases, the need in any case to support mapping with other terminologies (including legacy local terminologies), and other challenges identified by the previous questions (license cost, complexity, etc)

Figure 19 According to your knowledge and perception do you think that SNOMED CT should be used for the exchange of health and social data cross-border?
7.3 Country Overview

The goal of this questionnaire is to

- Capture synthetic information about use or non-use of SCT and other terminologies within the European Member States.
- Have an updated and geographically wider overview about the use or non-use of SCT and other terminologies for the large majority of the European Member States, and possibly for a subset of regions/subdivisions where those regions/subdivisions have a relevant autonomy in the national Health Policies.

This questionnaire is based on the questionnaire created for the eHealth Network survey (“MAKING USE OF SNOMED CT: KEY QUESTIONS and STATUS as of SEPTEMBER 2013”) extending its scope also to the non IHTSDO member countries.

The same considerations about the target selection and engagement made for the all stakeholder questionnaire applies this one (see above for details).

The on-line questionnaire has been published in the following link: http://assessct.limequery.org/index.php/138583

7.3.1 Targets selection and engagement

The expectation for this questionnaire is to realize one single record per country, with sub-national (e.g. regional) information where applies.

For doing that a project contact point per country is supposed to be identified, leaving to him/her the choice to:

- act as data collector interacting with the national/subdivisional experts, and filling one single questionnaire; or
- identify the appropriate experts to be involved in this questionnaire.

7.3.2 Progress Status

At the time of the delivering of this document, questionnaire responses from 10 Member States have been collected: Austria; Belgium; Croatia; Estonia; Finland; Germany; Malta; Netherlands; Slovakia; Sweden.

A meeting was organized with UK representatives for collecting the information about the questionnaire, a draft response has been agreed and it is under validation.

Portugal will complete the questionnaire during the first meeting of the Focus Group.

A complete report of the first stage, including all the questionnaires received by end of June will be reported in D 1.2.

Additional responses received after that date, hopefully including all the missing countries, will be integrated in a second stage.
8  The EU US Discussion Group

On 2015, March 23th, in conjunction with the Trillium Bridge Workshop, a meeting with US representatives has been organized in Brussels.

The objective of this meeting was that of gathering expert opinion regarding

1. The current use of SNOMED CT in the US
2. The lessons that Europe can take from their experiences
3. The potential for EU-US collaboration

The US participants were:

- **Christopher Chute**: M.D., Dr. P.H., John Hopkins (Chair, ICD-11 Revision Steering Group, World Health Organization, Geneva, 2010-2015; Chair, International Organization for Standardization (ISO) TC215 on Health Informatics, 2010-2015; Member, Health Level Seven Advisory Council)
- **Jamie Ferguson**: Vice President, Health Information Technology Strategy and Policy Fellow, Institute for Health Policy
- **Virginia Riehl**: Health Care Management Consultant to the ONC (http://www.virginiariehl.com)
- **James Case**, PhD Health Programs Specialist; National Institutes of Health / National Library of Medicine, responsible for SNOMED CT. Member of the HL7 International Board.
- **Elaine A. Blechman**, President at Prosocial Applications, Inc. Professor Emeritus, University of Colorado, Boulder

For the ASSESS CT project attended/participated:

- **Veli Stroetmann**, Empirica;
- **Dipak Kalra**, EuroRec;
- **Luc Nicolas**, Federal Public Service Public Health, Belgium
- **Giorgio Cangioli**, HL7 Foundation
- **Catherine Chronaki**, HL7 Foundation
- **Henrique Manuel Gil Martins**, SPMS Portugal

A set of questions were shared in advance to share the themes of interest and discussed in an unstructured way during the meeting, under the coordination of Veli Stroetmann:

1. What is SNOMED CT mainly used for in the US today and what are the benefits for those that use it?
2. What were the main challenges of adopting SNOMED CT in the US and how they were overcome?
3. What have been to date the most important enabling factors (incentives, education, usability, tools, resources (maps)) in the US and why?
4. What are the current challenges of adopting SNOMED CT in the US?
5. If were able to change the past, what policies (education, maintenance, distribution) would you adopt to reap the benefits of SNOMED CT?
6. What are the initiatives that you would suggest be adopted as part of the Trans-Atlantic collaboration?
7. What would be your advice to EU Commission and EU member states for developing a terminology strategy for healthcare in Europe (short, medium and long term)?

Hereafter a summary of the main points discussed:
Premising that no one was entitled to speak on behalf of “US”, each US representative introduced how terminology (and in particular SNOMED CT) were used in their organization.

The US scenario is very fragmented, the vision that all the patient information can be annotated with SCT is not applied in all the US. This is due to the preexistence of “legacy” value sets and the absence of financial incentives to facilitating the adoption. As a result, the usage in hospitals is still lower than in academic environments.

The main use of SCT in US is mainly for supporting the Meaningful Use, even if it is not really actively used for the cross-organization communications. Maybe it will be used more broadly with the Meaningful Use phase 3.

For what concern the organization represented in the meeting, Kaiser Permanente is a large integrated Healthcare Provider Organization with about 25000 Physicians, using SCT in its EHR-S for about 55 Millions of records for describing any information about the patient that can be coded in the EHR. The 98% of the inpatient records are coded in SCT. ICD-10 is mainly related to administrative and financial usage.

Kaiser Permanente makes usage of the SCT description logic and of the inferences (associations) not only limited to the hierarchical relationship. (Coded) Information is captured (and displayed) using interface terms. Interface terms – based on SCT - have been defined for being used by clinicians, but also for patient (patient friendly display Name).

Physicians are not forced to use SCT (they can use free text), but they have tools for automatically getting the SCT codes and facilitating their job.

Moreover they are allowed to ask for new pre-coordinated concepts, developing clinician-specific synonyms. Those local extensions are handled as formal SCT extensions. This solution, even if it requires strong investments appears to be the most efficient. For evaluating the actual need of those concepts, Kaiser Permanente (KP) calculates the frequency distribution of about 350 000 codes (most of them have a frequency less than 5%). This local terminology is made public available.

The role of NLM in maintaining the extensions is considered an added value allowing reducing divergence.

The need of coding for reimbursement is low in KP, however when needed they use mappings defined in partnership with NLM (National Library of Medicine). Kaiser Permanente uses about 180.000 codes for problems, also procedures (including Labs) are in SNOMED CT.

Mayo Clinic is an Academic Organization smaller than Kaiser Permanente. SNOMED CT is used only for coding the problems in the problem list for the Meaningful Use Purposes. For this use case a mapping with the legacy terminologies used has been done.

It was pointed out how SNOMED CT may create some problems when handling residual categories (e.g. other, unspecified) unless to use the parent concept.

Mayo is considering for the future ICD 11, that will allow for post coordination with classification, and will share a common ontology layer with SNOMED CT.

NLM is not a terminology user but provides services for terminologies. It is the US IHTSDO Release Center, it acts as National Value Set Authority (create contents and value sets for supporting the MU) and provides mappings for SNOMED CT and ICD-10-CM.

The role of NLM is essential in facilitating the use of SNOMED CT, since you cannot use it just “as it is”: NLM provides an open value sets library, creates tools managing them and assuring the integrity along the code system versions.

**The presence of such authority at the US level is an enabling factor that also EU should consider.**

The discussion then moved to the issue of post vs pre-coordination: it was pointed out that usually clinicians prefer pre-coordination, where researchers want instead post-coordination. The usage of post-coordination requires however a bigger learning curve, since users need to have a full knowledge of the description logic. Moreover in the balancing between these
two choices, the amount of information that the human being is able to get when it get a “complex” concept (cognitive learning) needs to be taken into account.

Most EHR-S cannot support the complexity of the description logic of SCT, in general when supporting only the post-coordination is considered. However in these last years, thanks to the Meaningful Use program, Vendor products are more robust in term of capability of handling SCT.

The discussion group participants convened on the fact that **SNOMED CT has no actual alternative if an unambiguous common language is needed**. This however does not exclude the problem of the mapping, since it is still needed to map with the interface terms at the source and at the destination.
9 Assessment of Annex II: Requirements for the Identification of ICT Technical Specifications

This section summarizes the results of the first assessment about the capability of SNOMED CT to satisfy the requirements for the Identification of ICT Technical Specifications of the EU standardization regulation, annex II\(^\text{16}\).

This assessment may be subject to further revisions according to additional evidences and information collected during the project lifecycle.

The referred norm and a more detail report of this assessment is attached at this deliverable in Appendix 3: Regulation (EU) No 1025/2012 Annex II Assessment.

This first assessment has been made considering as targets both the Technical Specifications delivered by IHTSDO related to the SNOMED CT terminology (e.g. http://snomed.org/compgrammar.pdf) and the terminology itself as standardization product (“Standardisation can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in product or services markets….” from the Regulation (Eu) No 1025/2012).

Based on that we can assert that the four criteria defined by annex II are satisfied with the following caveats:

**Criterion 1:** the second part of the criterion assert “…implementations do not hamper interoperability with the implementations of existing European or international standards”.

The concept of hamper may be interpreted in a more restrictive or in a wider sense, and the implementations of existing standards may refer to very different things varying from other terminologies, service specifications or data models. Considering this criterion in a very restricted way, it is evident that implementations based on other international terminologies may be affected by the adoption of SNOMED CT, as well as the use of SNOMED CT (above all when used as post-coordinate) may interfere with data model implementations. However, several initiatives for improving the coexistence with other standards and mitigate the barriers have been taken by IHTSDO with the cooperation of other SDOs (for example the agreements with LOINC, HL7, WHO (ICD-11), etc.). For that reason we consider this criterion as satisfied.

**Criterion 2:** “…as they do not conflict with European standards,…”.

For evaluating this criterion, it has been considered the definition of European Standards as provided in the point (4) of this norm (“European standards are adopted by the European standardisation organisations, namely CEN, Cenelec and ETSI.”). Based on that, at this stage of the investigation, no potentially conflicting standards have been identified.

**Criterion 4, point (b):** “specifications are publicly available for implementation and use on reasonable terms (including a reasonable fee or free of charge)”

The concept of “reasonable” is very subjective and difficult to quantify: very different opinions can be collected about this point, as pointed out also by the questionnaire results. The evaluation if the SNOMED CT fee is “reasonable” may also strongly depends on the purpose, the context and the extension of use. For example: country versus organization-wide license, operation versus research; and so on.

In this first assessment we consider this criterion satisfied, considering also the result of criterion 1 about market acceptance, assuming that if there is a Market Acceptance it (partially) implies also the fee is considered reasonable.

Additional information about the actual value chain on using SNOMED CT that can be derived from the WP3 activity may help to better quantify this criterion.

**Criterion 4, point (e.i):** “…specifications whenever possible are performance oriented rather than based on design or descriptive characteristics…”

There is not at this stage of assessment a definitive position on how this sub-criterion applies to SNOMED CT. For the time being the performance orientation has been interpreted in term of domain coverage, maintainability, extendibility, responsiveness, etc. All those properties are taken in account in the standards development and decision-making processes of SNOMED CT.
10    Appendix 1: Questionnaires

10.1 All stakeholder questionnaire

10.2 Country overview
11 Appendix 2: Focus Group Guidelines
12 Appendix 3: Regulation (EU) No 1025/2012 Annex II Assessment

12.1 Regulation (EU) No 1025/2012 of The European Parliament and of the Council on European Standardization

12.2 Assessment Details

12.2.1 Foreword

The REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardisation, covers “various issues, such as standardization of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential”

The assessment of SNOMED CT against the criteria listed in the ANNEX II of the above mentioned regulation considers both the SNOMED CT terminology as a standardization product and the technical specifications (e.g. http://snomed.org/compgrammar.pdf) associated to that terminology.

12.2.2 Criterion 1

Description:
The technical specifications have market acceptance and their implementations do not hamper interoperability with the implementations of existing European or international standards.

Market acceptance can be demonstrated by operational examples of compliant implementations from different vendors.

Satisfied: Yes, see notes

Notes:
SNOMED CT have market acceptance being implemented by several European and Non-European countries and organizations and used by many vendors.

Concerning however the sub-criterion of “do not hamper interoperability” is not so easy to provide a definitive assertion considering that the concept of “hampering” may be interpreted in a restrictive or in a wide-sense and that the implementations of existing standards may refer to very different things varying from other terminologies, service specifications or data model. Considering this criterion in a very restricted way, it is evident that implementations based on other international terminologies may be affected by the adoption of SNOMED CT, as well as the usage of SNOMED CT (above all when use as post-coordinate) may impact with some data model implementation. However several initiatives for improving the coexistence with other standards and mitigate the barriers have been taken by IHTSDO with
the cooperation of other SDOs (for example the agreements with LOINC, HL7, WHO (ICD-11), etc.). For that reason we consider this criterion as satisfied.

12.2.3 Criterion 2

Description:
The technical specifications are coherent as they do not conflict with European standards, that is to say they cover domains where the adoption of new European standards is not foreseen within a reasonable period, where existing standards have not gained market uptake or where these standards have become obsolete, and where the transposition of the technical specifications into European standardisation deliverables is not foreseen within a reasonable period.

Satisfied: Yes, see notes

Notes:
For evaluating this criterion it has been considered the definition of European Standards as provided in the point (4) of this norm ("European standards are adopted by the European standardisation organisations, namely CEN, Cenelec and ETSI."). Based on that at this stage of the investigation no potentially conflicting standards have been identified.

12.2.4 Criterion 3

Description:
The technical specifications were developed by a non-profit making organisation which is a professional society, industry or trade association or any other membership organisation that within its area of expertise develops ICT technical specifications and which is not a European standardisation organisation, national or international standardisation body, through processes which fulfil the following criteria:

a) openness: the technical specifications were developed on the basis of open decision-making accessible to all interested parties in the market or markets affected by those technical specifications;

b) consensus: the decision-making process was collaborative and consensus based and did not favour any particular stakeholder. Consensus means a general agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Consensus does not imply unanimity;

c) transparency:

i. all information concerning technical discussions and decision making was archived and identified;

ii. information on new standardisation activities was publicly and widely announced through suitable and accessible means;

iii. participation of all relevant categories of interested parties was sought with a view to achieving balance;

iv. consideration and response were given to comments by interested parties.

Satisfied: YES

Notes: IHTSDO adopts a robust and responsive standards development and approval process that meets the needs of its Members and other users of SNOMED CT, capable of a rigorous standards development by consensus building or commission and that applies the fundamental principles of openness, fairness, and transparency in standards development and decision-making processes (see “Maintenance and Review of IHTSDO Technical Reports, Guidelines and Standards” Guideline)
12.2.5 Criterion 4

Description: The technical specifications meet the following requirements: (see criteria 4.a, 4.b and 4.c)

Criterion 4.a

Description: (a) maintenance: ongoing support and maintenance of published specifications are guaranteed over a long period;

Satisfied: YES

Notes: SNOMED CT is periodically updated and published and the complete history (including the changes applied) made accessible for a long period.

Criterion 4.b

Description: (b) availability: specifications are publicly available for implementation and use on reasonable terms (including for a reasonable fee or free of charge);

Satisfied: YES, see notes

Notes: The concept of “reasonable” is very subjective and difficult to quantify: very different opinions can be collected about this point, as pointed out also by the questionnaire results.

The evaluation if the SNOMED CT fee is “reasonable" may also strongly depend on the purpose, context and extension of use. Country versus organization-wide licence, operation versus research; and so on.

In this first assessment we consider this criterion satisfied, considering also the result of criterion 1 about market acceptance, assuming that if there is a Market Acceptance it (partially) implies also the fee is considered reasonable.

Additional information about the actual value chain on using SNOMED CT that can be derived from the WP3 activity may help to better quantify this criterion.

Criterion 4.c

Description: (c) intellectual property rights essential to the implementation of specifications are licensed to applicants on a (fair) reasonable and non-discriminatory basis ((F)RAND), which includes, at the discretion of the intellectual property right-holder, licensing essential intellectual property without compensation;

Satisfied: YES, see notes

Notes: see note about the "reasonable fee" above.

Criterion 4.d

Description: (d) relevance: (i) the specifications are effective and relevant; (ii) specifications need to respond to market needs and regulatory requirements.

Satisfied: YES

Notes: There is a worldwide recognition about the relevance of SNOMED CT.

Criterion 4.e

Description: (e) neutrality and stability: (i) specifications whenever possible are performance oriented rather than based on design or descriptive characteristics; (ii) specifications do not distort the market or limit the possibilities for implementers to develop
competition and innovation based upon them; (iii) specifications are based on advanced scientific and technological developments.

**Satisfied: YES, see notes**

**Notes:** There is not at this stage of assessment a definitive position on how the sub-criterion 4.e.i applies to SNEMED CT, for the time being the performance orientation has been interpreted in term of domain coverage, maintainability, extendibility, responsiveness, etc. All those proprieties are taken in account in the standards development and decision-making processes of SNOMED CT.

**Criterion 4.a**

**Description:** (f) quality: (i) the quality and level of detail are sufficient to permit the development of a variety of competing implementations of interoperable products and services; (ii) standardised interfaces are not hidden or controlled by anyone other than the organisations that adopted the technical specifications.

**Satisfied:** YES

**Notes:** Criterion 4.f.ii is not applicable.