



EU Common Semantic Strategy in eHealth
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Acronyms

Acronym	Description
AC	Action Coordinator
AP	Associated Partner
CA	Consortium Agreement
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
CPD	Continuing Professional Development
CSS	Common Semantic Strategy
EC	European Commission
eD	eDispensation
eHealth	Electronic Health
eHAction	eHealth Action
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Expert Group
eHN	eHealth Network
EIF	European Interoperability Framework
eP	ePrescription
EU	European Union
EHRxF	Electronic Health Record Exchange Format
ERN	European Reference Networks
GA	Grant Agreement
ICT	Information and communications technology
IPR	Intellectual Property Rights
JA	Joint Action
LC	Leadership Council
LHF	Low Hanging Fruit
LEAR	Legal Entity Appointed Representative
mHealth	Mobile Health
MS/C	Member State/Country
MWP	Multiannual Work Programme
PS	Patient Summary
QA	Quality Assurance
QM	Quality Management
RM	Risk Management
SC	Steering Council
Tcon	Teleconference
WP	Work Package
WPL	Work Package Leader
H2020	Horizon 2020
WG	Working Group

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1 Executive summary

For more than a decade, semantics in eHealth has been a major interoperability challenge in Europe. This has been mentioned in the EC recommendation on electronic health record systems in 2008, and the focus of the early work of CALLIOPE and SemanticHealthNet. Both Member States and EC recognise that progress has been slow, or limited to two use cases (Patient Summary and ePrescription/eDispensation). A European Common Semantic Strategy (CSS) in eHealth will need to address past experience and project us towards attainable concrete work. In particular it is important to obtain a mandate from the eHealth Network and real support from MS/C for such an endeavour.

The eHealth Interoperability work should focus on patients' rights and technologies to improve patient access to data and the work of health professionals in line with the spirit of the Multi-Annual Workplan 2018-2021, and the EC Communication on eHealth 25th April 2018. To reach eHealth interoperability in the EU, with real services as a hallmark, a stepwise approach is needed. This is being addressed through the building and implementation of the eHealth DSI. Considering that health systems differ in the EU, the initiative of organising and standardising these systems should be done with extended investment to achieve the interoperability of eHealth systems, not just at technical level, but more critically at semantical level as well.

The main purpose of this document is to provide information on work conducted to advise the eHealth Network on future steps on semantics; namely, to reiterate and structure the proposal for the creation of a sub-group on semantics and the drafting of an EU Common Semantic Strategy in eHealth to be adopted in 2019.

Following on from past attempts, the 13th eHN meeting held on 15th May 2018 agenda point 2 topic considered a "Discussion note on eHealth interoperability and policy actions to improve semantic interoperability in the EU"¹. This was intended to initiate a constructive discussion in the eHealth Network with the objective to further improve semantic interoperability in the EU. It was suggested that the eHealth Network set up a sub-group consisting of semantic experts responsible for defining an EU-level strategy on semantic interoperability. However, the recommendation for the creation of a permanent cooperation between national interoperability and semantic experts as a subgroup of the eHealth Network was not adopted by the eHN. A possible reason for this was that the information and proposal details were scarce and had not been fully prepared in advance by the MS.

Instead, it was decided that the eHealth Member States Expert Group (eHMSEG) and eHAction would take, at different levels, steps to further advance the efforts of launching or deepening semantic EU-wide cooperation in the area of eHealth.

The aim of such a subgroup would be to strive for better and standardized semantic interoperability in the EU through the alignment of eHealth standards, focussing on mechanisms to increase the alignment and convergence in the ways Member States document clinical processes. The timeframe could set a ten-year trajectory, with implementation activities proposed for the first five years.

¹ Cover Note by eHealth Network Secretariat
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

The document accompanying this agenda item follows preparatory work and input from the workshop held on 1st and 2nd October 2018, to which all MS were invited to send their respective semantic experts. It served to help those experts think strategically, although clearly it is not a strategy document, but a working document.

An important first part of the platform would be to address the need to exchange information on common semantic challenges. Interaction with semantic work under the eHMSEG Semantic task force is needed and will be ensured by the participation of 2 members of this task force in the preparation of the Strategy, and its later governance and implementation. Semantics is a very important cornerstone of interoperability and a good semantic strategy should contain standard terminologies and standard data sets; a terminology centre could be created with contributions from all MS/C. The adoption of international standards, clear definitions and use cases can help avoid issues.

In conclusion, based on the work so far, as well as the discussion on the eHAction Leadership and Steering Councils, preparation of a mature set of proposals to the eHealth Network will require an additional six months of work under the umbrella of the eHAction, reporting to the eHN in May 2019. At this meeting a subgroup on Semantics should be formally established with as many member states, to refine the EU Common Semantic Strategy proposal, looking towards its adoption in November 2019.

2 Context

The European Commission has acknowledged the need for eHealth interoperability for more than a decade. The EC Communication “e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area”² was presented on 30 April 2004 and outlines the potential of eHealth systems and major challenges for its wide deployment. This action plan called for joint EC and Member States action on interoperability of electronic health record systems.

Later in 2007 there was a Declaration of the High-Level eHealth Conference acknowledging the importance of starting joint initiatives among Member States by strengthening a range of activities related to interoperability of electronic health record systems. This triggered initiatives such as epSOS³ and CALLIOPE⁴, as well as the first Joint Action: the eHealth Governance Initiative (eHGI)⁵.

Already in 2008, the European Commission expressed the need for enhanced cross-border interoperability of electronic health record systems through the publication of its Recommendations on 2 July 2008 (2008/594/EC)⁶. Back at the time, this communication showed the steps to be followed to achieve interoperability among MS/C. The Semantic topic was one of the main points to be improved and structured for this proposal. Ten years after this first initiative, the implementation of an EHRxF and interoperability is still a strong necessity to be achieved in the EU.

² <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52004DC0356>

³ <https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved>

⁴ CALLIOPE project:

<http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5bCALLIOPE%20-%20published%20by%20DG%20INFSO%5d.pdf>

⁵ <http://www.ehgi.eu>

⁶ Recommendation C(2008) 3282 (2008/594/EC): <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=EN>

In a collaborative project two years later, CALLIOPE⁷, various eHealth experts proposed an interoperability roadmap, the context of which still remains for the most part amazingly valid especially with regards to semantic interoperability. Amongst the many useful recommendations in this 2010 document⁸, there were also concrete “possible steps”, suggested as recommendations outlined from that project.

The eHealth interoperability topic gained even more importance through the Directive on the application of patients’ rights in cross-border healthcare (2011/24/EU) published on 9 March 2011. There, the legal foundation was created to set up the eHealth Network (art. 14) whose main objective is to “work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications...”⁹. Furthermore, the Commission came with a detailed roadmap to empower patients and healthcare workers, to link up devices and technologies, and to invest in research towards personalised medicine for the future through the eHealth Action Plan 2012-2020¹⁰. Now, with the Digital Single Market strategy¹¹, the Commission has made eHealth interoperability part of its priority in order to strengthen EU competitiveness.

Concrete steps to enhance eHealth interoperability in the EU have been made with the building and implementation of the eHealth DSI. However, in order to achieve our health policy ambitions at national and EU-level, more should be done to accomplish greater interoperability in the EU. Especially, in the area of eHealth standards there is a lot to win. Adoption of eHealth standards is imperative to realise technical interoperability. It technically enables us to exchange and share data across organisations and regional/national borders. If accomplished, it allows us, on the one hand, to reap the benefits of having access to an immense source of data to be used for the greater good of European society and, on the other hand, allows patients to travel with their data within the EU health system and have safer access to health services in all countries through data transfer possibilities.

3 Background of current proposal

Following on from past attempts, during the 13th eHN meeting held on 15th May 2018, agenda point 2 topic was “Discussion note on eHealth interoperability and policy actions to improve semantic interoperability in the EU – draft”¹²; this was intended to initiate a constructive discussion with the objective to further improve semantic interoperability in the EU.

⁷<http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5bCALLIOPE%20-%20published%20by%20DG%20INFSO%5d.pdf>

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=EN>

⁹ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare, article 14 (a)

¹⁰ https://ec.europa.eu/health/sites/health/files/ehealth/docs/com_2012_736_en.pdf

¹¹ https://ec.europa.eu/commission/priorities/digital-single-market_en

¹² https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co021_en.pdf

Furthermore, JAseHN¹³ adopted report (D5.4.3.2) including recommendations for the Rolling Plan on ICT standardisation. These recommendations should be seen in the light of the discussion on semantic interoperability.

The cover note for the item at the 13th eHealth Network meeting on 15th May 2018, Brussels said: *“... it was suggested that the eHealth Network set up a sub-group consisting of semantic experts who will be responsible for defining an EU-level strategy on semantic interoperability. The recommendation for the creation of a permanent cooperation between national interoperability and semantic experts as a subgroup of the eHealth Network that will have the responsibility to bring the recommendation forward and to come up with concrete actions for the next eHealth Network meeting was, however, not adopted by eHN, a possible reason was that the information and proposal details were scarce and had not been fully prepared a priori”*.¹⁴

It was then decided that eHMSEG and eHAction would take, at different levels, steps to further advance the efforts of launching or deepening semantic EU-wide cooperation in the area of eHealth.

Relevant work has been done in different EU funded projects and this document does not claim to have collected and synthesised all relevant background work. JAseHN efforts are considered key as a former joint effort and will be listed (see ANNEX 3). A specific project looking at semantics but more importantly at SNOMED CT, namely ACCESS CT¹⁵, was considered particularly relevant, and eStandards¹⁶ and VALUeHEALTH¹⁷ may contain likewise some relevant ideas. Ongoing work that is worthy of notice is obviously the work under the Semantic Task Force of the eHMSEG created in June 2016.

4 Scope of the Strategy

The main purpose of this document is thus to provide information on work conducted to advise the eHN on future steps on semantics; namely, the proposal for the creation of a sub group on semantics and the drafting of an EU Common Semantic Strategy in eHealth to be adopted in 2019.

The aim of such an initiative would be to strive for better semantic interoperability in the EU through the alignment of eHealth standards, focussing on mechanisms to increase the alignment and

¹³ http://jasehn.eu/wordpress/wp-content/uploads/2018/07/D5.4.3.2_RECOMMENDATION_PAPER_Rolling_Plan_ICT_Standardisation.pdf

¹⁴ Cover Note by eHealth Network Secretariat: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

¹⁵ Assess CT project: <http://www.assess-ct.eu/start0.html>

¹⁶ eStandards - Deliverable 4.1 and 4.2r1:

http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards_D4_1_Solutions_for_a_Coexistence_of_eHealth_Standards.pdf

http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards_D4_2r1_Interoperability_Guideline_for_eHealth_Deployment_Projects_r1.pdf

¹⁷ VALUeHEALTH – D2.1, D4.1 and D4.2:

http://www.valuehealth.eu/ValueHealth/assets/File/VALUeHEALTH_D2_1_Value_Propositions_with_regard_to_Interoperability_Final.pdf

http://www.valuehealth.eu/ValueHealth/assets/File/VALUeHEALTH_D4_1_%20eHealth%20interoperability%20service%20architecture.pdf

http://www.valuehealth.eu/ValueHealth/assets/File/VALUeHEALTH_D4_2_Asset_development_methodology_corresponding_to_prioritised_interoperability_services_Final.pdf

convergence in the ways that Member States document clinical processes, support research and regulation (e.g. of medicines).

This document was reviewed and updated after the workshop held on 1st and 2nd October 2018, to which all MS were invited to send their respective semantic experts. The workshop was intended to align the approach of the semantic experts towards the CSS document. The minutes of the Workshop are available.

4.1 Planning

Following a first phase based on some desk research and compilation of eHN policy documents, to help inform the work at the workshop for semantic, an ongoing “working document” has been maintained, which will form the basis of the elaboration of the EU CSS for eHealth document.

Following the workshop, different documents are needed/were already elaborated:

1. A Cover Note for the eHealth Network meeting of 13th November 2018, for the topic “Common Semantic Strategy” – to seek eHN support on the next steps;
2. A Very Draft version of the “EU Common Semantic Strategy in eHealth” itself – to be appreciated during the May 2019 eHN meeting and approved in November 2019;
3. Within the scope of point 2, but also implementing an eHN decision: a concrete proposal for minimal semantic governance taking into account the needs of CEF eHDSI services, and general support for eHealth Network, as well as needs resulting from activities spurring from EHRxF (May 2019) and other EU activities related to semantic standardisation in eHealth (ERNS¹⁸, RD-Action¹⁹ and others).

The time frame for a serious Semantic Strategy should be around 5 years until full implementation. So, the specification of general objectives, methods for interoperability, general processes and description have to be established and that process will require much further work than that which was possible from 1st October 2018 till now. The management tools should be specified; the EC support on CSS is needed via DG CNECT/DG SANTE funding streams, but MS/C will need to ensure some contribution as well.

4.2 Work so far

The October 2018 workshop was performed with the presence of 13 MS/C representatives, while four additional MS sent information about national semantic efforts. Discussions about CSS have been held during the previous Joint Action although a common view about the work on semantics at EU level was not obvious for all MS/C yet.

This Workshop included ideas regarding EC communication, such as: “How can the EHRxF and semantic strategy be achieved?” “Should there be just one group working on both EHRxF and CSS?” “What do stakeholders / Standard Development Organisations / MS/C want?” Through the slide

¹⁸ https://ec.europa.eu/health/em_en

¹⁹ <http://www.rd-action.eu/>

presentations, the main ideas concerning this topic were collected and led to best solutions to be inserted in a cover note about the semantic strategy.

There are different views on whether the semantic joint work needed should be separated from the MS work to support and adopt an EHRxF, due to the high level of structuring of both tasks. Separating these efforts can lead to more detailed differences between them. Therefore, there is a need to talk about common ground. On the other hand, at eHAction level it may be perhaps useful to join forces from the Semantic Strategy and EHRxF efforts due to lack of resources and the will to keep coherence.

The role of eHMSEG and the CSS working group is to elaborate a general strategy; it can refer to cross border use, as well as going deep into the tactical/business level. The eHMSEG planning under its Semantic Task Force is to narrow down topics to concrete use cases, taking them from the national context to the different context of cross border use between each MS/C.

5 Conclusions and next steps

As conclusions we can say:

1. Significant **background material exists**, as well as, **lessons learnt** from one decade of eHealth in the EU **WITHOUT a Common Semantic Strategy** but having pointed out its need and its principles 10 years ago.
2. Reasons for the slow progress in joint semantic resources may have been: the lack of clear strategy and structured governance, absence of an annual workplan, and insufficient eHN empowerment.
3. Still to this date, **national semantic initiatives are heterogeneous, unstable and not strategic** in most MS/C with significant **staffing, knowledge and expertise shortage**.
4. **Knowledge about the interdependencies** of semantics within national infrastructures and the cross-border efforts has accumulated to the point that we know that a European Electronic Health Record exchange format (**EHRxF**) **is not possible without joint semantic efforts under a Common Semantic Strategy (CSS), although they are not the same thing**.

As next steps, the eHAction Coordination, having worked with the MS in the 1st workshop on the proposal of a CSS, and having heard more extensively comments from the eHAction Leadership Council, as well as the eHAction Steering Council, found it possible to provide the eHN with this brief note, while further ongoing work is needed and should have as many participating MS/C as possible. In line with this, the following plan is suggested:

1. Bring some of this work to the attention of the eHealth Network in November 2018 and seek its support for the elaboration of an EU Common Semantic Strategy as well as recommendations on Governance and Working Bodies to secure its execution;
2. Continue to mature an EU CSS proposal and its execution plan until May 2019, at which point a draft strategy can be endorsed, for a final refinement phase until its adoption in November 2019;
3. Between May 2019 and November 2019, there needs to be synchronisation between initiatives coming from the EHRxF recommendation, the necessities of cross-border eHDSI, and closure of the strategy proposal in iteration with stakeholders, professionals, etc.;

4. By November 2019, an execution plan and the governance/execution processes can be clarified under the umbrella of the new eHN Implementing Decision.

6 Additional References

Ref no.	Document
1	Cross-Border Healthcare Directive 2011/24/EU https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024
2	Discussion note on eHealth Interoperability and policy actions to improve semantic interoperability in the EU through eHealth standards from the European Commission (DG SANTE) https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf
3	JAsEHN D5.4.2 Policy paper proposing actions to promote the use of common standards and technical specifications in eHealth within the EU https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co07_en.pdf
4	JAsEHN D5.4.1.2 Final report about a platform consisting of the standards developing and profiling organizations relevant to eHealth in Europe and National Competence Centres https://www.ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5bb38d3bf&appId=PPGMS
5	JAsEHN D5.5 Report on European semantic interoperability in eHealth https://www.ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5b938fe2a&appId=PPGMS
6	JAsEHN eHealth Network Refined eHealth European Interoperability Framework (https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf)
7	Trillium Bridge Recommendations for Policy Convergence https://www.pathlms.com/hl7/courses/1461
8	ASSESS CT D2.4 – Use of terminologies for representing structured and unstructured clinical content http://assess-ct.eu/fileadmin/assess_ct/deliverables/final_submissions/assess_ct_ga_643818_d2.4.pdf
9	ASSESS CT Recommendations December 2016 http://assess-ct.eu/fileadmin/assess_ct/final_brochure/assessct_final_brochure.pdf
10	ASSESS CT D1.4 Current and future use of SNOMED CT http://assess-ct.eu/fileadmin/assess_ct/deliverables/final_submissions/assess_ct_ga_643818_d1.4.pdf
11	ASSESS CT D2.3 Multilingual and multidisciplinary study of terminology coverage and quality http://assess-ct.eu/fileadmin/assess_ct/deliverables/final_submissions/assess_ct_ga_643818_d2.3.pdf
12	ASSESS CT D3.3 Cost-benefit analysis and impact assessment http://assess-ct.eu/fileadmin/assess_ct/deliverables/final_submissions/assess_ct_ga_643818_d3.3.pdf
13	ASSESS CT D4.4 Policy and strategy recommendations http://assess-ct.eu/fileadmin/assess_ct/deliverables/final_submissions/assess_ct_ga_643818_d4.4.pdf
14	eHDSI Community - Assets https://ec.europa.eu/cefdigital/wiki/display/EHSEMANTIC/ASSETS