



Interoperability Quality Label and Certification processes

Executive Summary

The eHealth European Interoperability Framework, interoperability with the first study published in 2012 by the European Commission, is now considered as a priority for the deployment of the eHealth technologies in Europe. There is today no doubt that interoperability will be the key challenge to be addressed in the forthcoming years.

To develop a unified market in Europe, the stakeholders need to be confident that ICT solutions that are procured meet specific standards and profiles in a way that ensures interoperability, even if the solutions are proposed by companies coming from other countries than the country of the healthcare provider. Promoting a quality label or certificate at the European level, will leverage the integration of solutions and offer a good opportunity to the industry to sell their products in Europe within one recognized testing process, avoiding redundancy among different testing processes that are not compliant.

Even if projects are using standards and profiles described in the eEIF (eHealth European Interoperability Framework), their deployment at the national/regional or local level have to take into account the local regulations, the organizational schemes (for example innovative activities or new use cases that are not described at the European level), semantic specificities (for example local coding systems) or technical requirements for their success. These extensions have to be developed harmoniously with what were already defined at the European level and therefore the European testing processes shall be extended.

All these issues have to be analysed from the point of view of interoperability testing. During the preceding three years, European projects such as HITCH and EHR-QTN provided recommendations for the success of the future quality label or certification processes at the European level. Among them, the flexibility of the testing processes, the development of an ecosystem by promoting one interoperability framework and the definition of a European Conformance Assessment in line with ISO standards were the major key points upon which the results of this work package were built.

This deliverable provides description of quality label or certification processes, gives models, concrete examples and guidance that can be implemented in Europe and recommendations and guidelines for the deployment of such processes.



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Starting by the functional model of the Conformance Assessment governance, it describes all the bodies that need to be involved in the quality label or certification processes. The past studies presented an overview of how this model was used in the European countries or by profiles consortia such as IHE and Continua Alliance. The deliverable continues by describing two implementations selected in Europe are presented as two concrete examples: the national project called DMP (national EHR) in France and the epSOS project (exchange of medical data for a patient travelling in Europe).

The flexibility between European and national/regional levels is also considered. Directions and recommendations are presented, based on the reusability of the testing plan, test cases and test tools. Extensions are allowed and will be challenging at a European level for their integration in newer versions of the eHealth European Interoperability Framework.. In addition, test methods developed for these extensions shall be available on open licenses for better dissemination in Europe. Guideline to establish a Quality label or certification processes completes the approach.

To maintain and sustain such processes in Europe, governance rules have to be established. A reasonable approach based on the existence of stakeholders ecosystems composed by eHealth application users, vendor associations, local, regional and national authorities, centres of competences and independent experts ready to cooperate, consists to create a coordination that will operate under the supervision of the group. EXPAND project already proposes a governance based on maintenance shops that will sustain epSOS assets before their endorsements by the CEF.

In conclusion, the results of the deliverable build upon and expand all the previous recommendations that were raised in the past. The processes are now ready to be implemented. The three key messages that were developed in this study are:

- *Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program;*
- *Harmonise the quality label and certification processes in Europe and among countries and regions;*
- *National or regional interoperability testing processes maintain their flexibility while being harmonised with a modular European Conformance assessment scheme*
- *European quality label or certification processes still allow flexibility in national or regional approaches.*