



EMIF Deliverable 10.2: First report on federation procedures, ethical and legal issues

Executive summary

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In this first report the pre-conditions relevant for the development of the EMIF ICT data framework are described. The ultimate goal is to build a framework enabling health care providers as well as researchers to re-use patient data in such a way it is acceptable to all partners. Some of the pre-conditions are defined by EU laws and other regulations. These EU laws and regulations are non-negotiable conditions for the development of the EMIF ICT data network.

In addition local organisations (e.g. institutions owning specific data sources) within a country are ruling their individual guidelines according to both the institution's interpretation of the local law and its internal ethics position. These local governance conditions are relevant for the sustainability of the data collection.

Both sets of pre-conditions have consequences and impact on the development of the three functionalities of the EMIF ICT infrastructure:

1. a consolidated approach to share information that describe the nature, content and quality of EHR1 data ('fingerprinting').
2. extraction, coding, aggregating and sharing of these data of individual, anonymized/pseudonymized patients from the different EU-databases into a remote research environment
3. statistical analyses to be developed to analyse the aggregated2 data within the remote research environment ('statistical analyses').

The direct consequences of the first exploration are that:

- The purpose of use, the primary goal of collating data from different EU-database into a central, federative and trustworthy ICT infrastructure should be explicitly defined. This primary goal should be compatible with local governance rules and national interpretation of privacy laws for secondary use of the data of individual EU-databases.
- The EMIF consortium has to develop a provision that keep record of all data requests from the individual members to administrate for which purpose the data are collected, how these data are used and processed within the federation in such a way that conflicts with local governance rules are avoided.

In 2013-2014 a framework will be developed to challenge the different functionalities with local governance rules and potential emerging commercial and academic conflicts of the different EMIF contributing EHR databases. Such framework will involve all database holders/organisations as participants of the EMIF horizontal layer and has the sole aim to identify governance issues of conflicts of interest that require adaptation of technical functionalities.



Contacts

EMIF-Platform: Johan van der Lei – Nigel Hughes
j.vanderlei@erasmusmc.nl - nhughes@its.jnj.com