

IDHIS

EU's first Information Governance & Data privacy for Healthcare ICT systems Certification

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At the moment we are witnessing multiple efforts to establish (health) data platforms for research, such as Electronic Health Record systems or biobank infrastructures, and these infrastructures seek preferably wide access to and options for the reuse of data.

A lot of European initiatives, targets (digital) data collection and new information and communication technologies as tools to provide cost-efficient and high-quality medical care and treatment across Europe. Harmonizing the health sector is key at the moment. Simultaneously, private health-data platforms are emerging, such as private health management.

These initiatives have raised a critical debate in regard to issues, as data controllers and data processors, data providers and data users, in being compliant with the GDPR. To enhance the development of a European Reuse of Health Data Space, trust creation is a very important pillar. The information governance and the data flows within the re-use of health data ecosystem have to be secure, transparent, have integrity, be on a lawful basis - in other words to be GDPR compliant. Trust, especially on the protection of personal data, is important for individuals in their decision to share their data for further data use and for healthcare organisations such as hospitals to allow remote platforms to query their data.

In order to give confidence to all interested parties that a product, process or service is compliant to specified requirements such as GDPR, certification is essential. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party.

Therefore i~HD developed Europe's first information Governance & Data privacy for Healthcare ICT systems Certification scheme.

A set of 142 criteria focussing on accountability, transparency, Information Security Management and Implementation, audit readiness, data processing, Impact Assessments, Minimization, accuracy, retention, Enforcement and Corrective Capability were established in co-creation with EU Regulatory experts and standard developers.

The IDHIS scheme – intended shortly to be accredited by Belac (Belgian Notified Accreditation Body) describes in detail, following the most strict scheme standard requirements, the assessment and certification process.

The proof of concept of the IDHIS Scheme was established during the trial audit of a Belgian health ICT company executing patient support programmes for different pharmaceutical companies.

This presentation will zoom in on the development of the criteria – the evidence for auditing – the regulatory relevance – the lessons learned from the pilot audit.

IDHIS is a practical application to prove how Law can help to guarantee safe and reliable care for the patient.