

eHDSI Reference Documents



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Offer an **overview of the eHDSI Reference Documents**.



New eHDSI Reference Documents

These are the latest source documents added to the **eHDSI list of Reference Documents**. Once new documents are added, the table will be updated as follows: the **"NEW"** label will be added to the latest documents and removed from the current ones.

- [Regulation \(EU\) 2018_1725.pdf](#)
- [Commission Implementing Decision 2011_890_EU.pdf](#)

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eHDSI Reference Documents

The below table lists the reference documents (used as sources for the eHDSI Requirements Catalogue), identified until this moment and which could impact the eHDSI services.

Generic Documents	Document responsible authority
How the EU works – Your guide to the EU institutions	European Commission, Directorate-General for Communication
Legal acts (Directives, Regulations, Implementing acts)	
<u>Health sector specific</u>	
Directive 2011/24/UE , on the application of patients' rights in cross-border healthcare	European Parliament, Council
NEW: Commission Implementing Decision 2011/890/EU on providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth	European Commission
Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another MS	European Commission
REGULATION (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	European Parliament, Council
Agreement between National Authorities responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services (draft v2 20/10/2016)	eHealth Network, JAseHN Task 6.2
The legal framework and guidance on data protection under the Cross-border eHealth Information Services (CBeHIS) T6.2 JAseHN (draft v2 20/10/2016)	eHealth Network, JAseHN Task 6.2
Commission recommendation 2008/594/EC on cross-border interoperability of electronic health record systems	European Commission
Medical devices regulatory framework: <ul style="list-style-type: none">• The new Regulations on medical devices• Medical Device Regulations in Europe	

The EU legal framework on e-health_E94886_ch13.pdf	
<u>Cross-sector</u>	eHealth Network
CEF Telecom guidelines Regulation (EU) N° 283/2014 of 11 March 2014 on guidelines for trans-European telecommunications networks and repealing Decision N° 1336/97/EC	European Parliament, Council
REGULATION (EU) No 1316/2013 establishing the Connecting Europe Facility (CEF)	European Parliament, Council
REGULATION 2016/679, 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (Data protection) - General Data Protection Regulation (GDPR)	European Parliament, Council
NEW: Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data	European Parliament, Council
Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (eIDAS)	European Parliament, Council
EIDAS implementing acts <ul style="list-style-type: none"> • Implementing regulation (EU) 2015/1501: technical and operational requirements of the interoperability framework • Implementing regulation (EU) 2015/1502 minimum technical specifications and procedures for assurance levels for eID means • Implementing decision (EU) 2015/1506 specifications relating to formats of advanced electronic signatures and advanced seals to be recognised by public sector bodies 	European Parliament, Council
CEF work programme 2015	European Commission
CEF work programme 2016	European Commission
CEF work programme 2017	European Commission
Directive 2005/36/EC on the recognition of professional qualifications	European Parliament, Council
Guidelines, frameworks, standards and CEF Building Blocks	
<u>Health sector specific</u>	
eHN - Governance model for the eHealth Digital Service Infrastructure during the CEF funding	eHealth Network
Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU, release 2, adopted by the eHN meeting on 21/11/2016: <ul style="list-style-type: none"> • General guidelines • PS guidelines R2 (R1) • eP guidelines R2 (R1) 	eHealth Network
Guidelines of an Organisational Framework for eHealth NCP	eHealth Network
European Interoperability Framework	European Commission
Refined European Interoperability Framework , by eHealth Network	European Commission
eHealth interoperability framework study (11/2013)	European Commission
Article 29 Data Protection Working Party WP 189 - Working Document 01/2012 on epSOS	
Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services	Draft
<u>Cross sector</u>	
CEF Governance model	European Commission
Other references	
...used as source for the Requirements and recommendations	
CEF call eHealth	
Non-paper Workplan and budget	

D3.1.2 Final definition of functional service - ePrescription	epSOS
D3.2.2 Final definition of functional service - Patient Summary	epSOS
Business requirements of the Central Terminology server	
eHealth Member States Experts Group Semantic Task Force Semantic Requirements (draft v0.5)	eHDSI
D3.5.2: Semantic Service Specifications, Appendix F: Terminology Access Services	epSOS
D3.A – PS eP eD CM CDA - Implementation Guide_v1.1 (2015) (supersedes Appendix B1/B2)	EXPAND (D3.A), epSOS (Appendix B1/B2)
D3.9.1 – Appendix B.3 10 ePSOS Central Reference Terminology Server	epSOS
D3.10.1 Appendix A5 – Clinical and semantic issues	epSOS
Framework Agreement on National Contact Points in the context of the Smart Open Services for European Patients Project (epSOS) (version 2)	epSOS
D.3.7.2 epSOS Final security services specification definition - epSOS Security Policies	epSOS
Security controls (Req/Rec) - epSOS baseline security catalog: Requirements and Recommendations	epSOS
D3.6.2 Identity management specification definition	epSOS
D3.4.1 - Common Components Specification	epSOS
Test framework	
Audit framework– organisational, semantic, technical	
Support framework	
The use of CEF eID in the CEF eHealth DSI (draft report v2)	Study conducted by DIGIT for SANTE A4
SML/SMP/eDelivery PKI Impact Assessment for the CEF eHealth DSI	Study conducted by DIGIT for SANTE A4
...NOT used as source for the Requirements and recommendations [1]	
IHE profiles: XCPD, XCA, XDR, XCF	IHE
HL7 Clinical Document Architecture release 2	HL7 International
CTS2	
ISO27001	
ePrescription workflow	IHE
ATNA	
D3.8.2 Final National Pilot Set Up and Deployment Guide	epSOS
D3.9.2 Testing methodology, test plan and tools	epSOS
D2.2.7 Recommendations	epSOS

[1] Not to be considered as source for the business needs (implementation guidelines, technical documents...).
