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## Glossary of Terms

Terms with descriptions for use in DigitalHealthEurope  
deliverables

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# 1 Introduction

During the DigitalHealthEurope (DHE) kick-off meeting in Bonn from 24<sup>th</sup> and 25<sup>th</sup> January 2019, the Consortium found that there are two trends in terms used to describe digital health and integrated care.

Often the same, or very similar, words and phrases are used to describe different aspects and elements of digital health or, in contrast, a similar element is named differently on different sites or in documents.

This glossary has therefore been developed to provide a common language and understanding for the complex landscape of digital health in Europe. It is to provide the DHE Consortium with a consolidated source of descriptions for terms relevant to DHE's work. It is based on the experience of three EU funded projects and a larger 17 country-wide digital health survey.

The glossary is intended to be a living document that will evolve and develop throughout the project.

The glossary offers descriptions for digital health terms that cover the following topics:

- ▶ DHE most used terms
- ▶ Digital solutions for health and integrated care
- ▶ Health and care
- ▶ Twinning
- ▶ Data governance and donation
- ▶ Data protection
- ▶ Data analytics
- ▶ ICT security
- ▶ Others

## 2 Glossary of Terms

This section contains a list summarising all terms that are included in this Glossary (2.1). Sections 2.2-2.10 each list terms under different topics, starting with the most relevant terms; it continues with terms on digital solutions, health and care, twinings, data governance and donation, data protection, data analytics, ICT security and concludes with a list of other terms without a specific topic.

### 2.1 Summary of terms defined

The glossary terms are described under nine main categories. This list records abbreviations, terms and names which are then explained in the following sub-chapters. There are particularly detailed parts of the list that refer to data, data governance, and data protection.

- ▶ DHE most used terms
  - ▶ Collaboration platform
  - ▶ Digital health
  - ▶ Digital solution
  - ▶ Digital Transformation of Health and Care
  - ▶ EIP on AHA
  - ▶ MAFEIP
  - ▶ Persona
  - ▶ Twinning
- ▶ Digital solutions for health and integrated care
  - ▶ Big data
  - ▶ Clinical terminology guidelines
  - ▶ Connecting Europe Facility
  - ▶ Cross-border health care
  - ▶ Cross-border information exchange
  - ▶ Digital health literacy
  - ▶ eDispensing
  - ▶ e-Infrastructure
  - ▶ Electronic health record
  - ▶ Electronic patient identifier
  - ▶ ePrescription
  - ▶ Health information exchange network
  - ▶ Health technology
  - ▶ Mobile health
  - ▶ Patient empowerment
  - ▶ Patient portal
  - ▶ Patient Summary
  - ▶ People-centred health services
  - ▶ Personal health records
  - ▶ Personalised medicine
  - ▶ Telehealth
  - ▶ Telemedicine
- ▶ Health and care
  - ▶ Care co-ordinator
  - ▶ Care recipient
  - ▶ General practitioner
  - ▶ Health care professional
  - ▶ Health Care Provider Organisation

- ▶ Health care support worker
- ▶ Health
- ▶ Health care
- ▶ Health literacy
- ▶ Informal carer
- ▶ Integrated care
- ▶ Integrated care pathways
- ▶ Integrated Health & Social Care Provider Organisation
- ▶ Patient
- ▶ Social care professional
- ▶ Social Care Provider Organisation
- ▶ Social care support worker
- ▶ Third Sector Provider Organisation
- ▶ Twinnings
  - ▶ (the) Communication
  - ▶ Call for Twinning Tenders
  - ▶ Twinning Activities
  - ▶ Twinning Adopter
  - ▶ Twinning Contract
  - ▶ Twinning Contractor
  - ▶ Twinning Originator
  - ▶ Twinning Solutions
  - ▶ Twinning Types
- ▶ Data governance and data donation
  - ▶ Access Management
  - ▶ Assurance
  - ▶ Audit
  - ▶ Audit Trail
  - ▶ Change Control.
  - ▶ Compliance
  - ▶ Control
  - ▶ CRUD
  - ▶ Customer Data Integration
  - ▶ Data Architecture
  - ▶ Data Dictionary
  - ▶ Data Donation
  - ▶ Data Donator
  - ▶ Data Element
  - ▶ Data Governance
  - ▶ Data Governance Framework
  - ▶ Data Governance Methodology
  - ▶ Data Governance Office (DGO)
  - ▶ Data Mapping
  - ▶ Data Modelling
  - ▶ Data Privacy
  - ▶ Data Requestor
  - ▶ Data Stakeholders
  - ▶ Data Steward
  - ▶ Decision Rights
  - ▶ DGO
  - ▶ Enterprise Architecture
  - ▶ GRC
  - ▶ GRC-SQ
  - ▶ Health Data Cooperative

- ▶ Information Architecture
- ▶ Issue Framing
- ▶ Issue Resolution
- ▶ IT Governance
- ▶ IT Infrastructure Library (ITIL)
- ▶ IT Portfolio Management
- ▶ IT Service Management (ITSM)
- ▶ Master Data
- ▶ Master Data Management (MDM)
- ▶ Metadata
- ▶ Personal information
- ▶ Post-Compliance Paradigm Shift
- ▶ Risk Management
- ▶ Rogue Data Usage
- ▶ Sensitive Data
- ▶ Tone From the Top
- ▶ Workflow
- ▶ Data protection
  - ▶ Access Control
  - ▶ Aggregated Data
  - ▶ Anonymisation
  - ▶ Anonymised Data
  - ▶ Assumed Consent
  - ▶ Audit Trail
  - ▶ Auditability
  - ▶ Authentication
  - ▶ Authorisation
  - ▶ Clinical Trial
  - ▶ Confidentiality
  - ▶ Consent
  - ▶ Data Controller
  - ▶ (or Controller)
  - ▶ Data Destruction
  - ▶ Data Donation
  - ▶ Data Governance
  - ▶ Data Linkage
  - ▶ Data Processor
  - ▶ (or Processor)
  - ▶ Data Protection
  - ▶ Data Sharing
  - ▶ Data Sharing Agreement
  - ▶ Data Subject
  - ▶ De-identification
  - ▶ Disclose
  - ▶ Disclosure Control
  - ▶ Explicit Consent
  - ▶ Genetic Data
  - ▶ Health Data
  - ▶ Human Biological Sample
  - ▶ Identification
  - ▶ Implied Consent
  - ▶ Incidental Finding
  - ▶ Information Governance
  - ▶ Person Identification

- ▶ Personal Data
- ▶ Perturbation
- ▶ Policy
- ▶ Privacy
- ▶ Processing\*
- ▶ Prospective Data Collection
- ▶ Pseudonym
- ▶ Pseudonymisation
- ▶ Pseudonymised Data
- ▶ Re-Identification
- ▶ Research
- ▶ Secondary Use of Data (or Data Re-Use)
- ▶ Sensitivity
- ▶ Study Participant
- ▶ Supervisory Authority
- ▶ Third Party
- ▶ Trusted Third Party
- ▶ Data analytics
  - ▶ Artificial intelligence
  - ▶ Blockchain
  - ▶ Cloud computing
  - ▶ Dataset
  - ▶ Deep learning
  - ▶ Digital twin
  - ▶ High-performance computing
  - ▶ Internet of Things
  - ▶ Machine learning
  - ▶ Neural networks
- ▶ ICT security
  - ▶ Cryptography
  - ▶ Cybersecurity
  - ▶ Digital signature
  - ▶ Electronic signature
  - ▶ Encryption
  - ▶ End-to-end encryption
  - ▶ Secure Socket Layer
  - ▶ Transport Layer Security
- ▶ Others
  - ▶ Business model
  - ▶ Business model canvas
  - ▶ Business use case
  - ▶ Capability
  - ▶ Capacity (building)
  - ▶ Cost-effectiveness analysis
  - ▶ Disability Adjusted Life Years
  - ▶ European Committee for Electrotechnical Standardisation
  - ▶ European Committee for Standardisation
  - ▶ European Open Science Cloud
  - ▶ European Standards Organisations
  - ▶ European Telecommunications Standards Institute
  - ▶ FAIR data
  - ▶ Health Adjusted Life Years
  - ▶ Health-Related Quality of Life and Well-Being
  - ▶ High-level use case

- ▶ High value dataset
- ▶ Information & Communication Technology
- ▶ International Electrotechnical Commission
- ▶ International Organisation for Standardisation
- ▶ International Telecommunication Union
- ▶ Interoperability
- ▶ Interoperability governance
- ▶ Legal Interoperability
- ▶ Medical data
- ▶ National Standards Bodies
- ▶ Organisational Interoperability
- ▶ Quality-adjusted life years
- ▶ Real world data
- ▶ Real world evidence
- ▶ Research data
- ▶ Research infrastructure
- ▶ Semantic interoperability
- ▶ Standards Developing Organisations
- ▶ Technical Committee
- ▶ Technical interoperability
- ▶ Technical specification
- ▶ Use case
- ▶ Utility
- ▶ Value chain



## 2.2 DHE most used terms

Terms	Abbreviation	Descriptions
Multi-stakeholder community		The concept behind the Collaboration platforms is adopted from the 3C collaboration model developed by Borghoff and Schlichter <sup>1</sup> that describes “Cooperation, Communication and Coordination as the main challenges for the members in a collaborative group”. Cooperation is the joint work production and completion of tasks, supported by tools such as joint document storage and repositories, wikis and notes keeping systems. Communication includes efficient exchange of information and negotiation of commitments via emails, instant messaging, discussion lists, and video- or phone conferences. Coordination enables people, activities and resources to be managed, leading to better communication and cooperation (e.g. staff and project management tools, scheduling tools, and the like). These tools will be adopted to ensure functional collaboration. The objectives of each collaboration platform are to identify relevant stakeholders and initiatives, engage with them to analyse key challenges and solutions related to each DTHC priority, elaborate common strategic agendas and commitments for action.
Digital health		Digital health and care refers to tools and services that use information and communication technology (ICT) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care has the potential to innovate and improve access to care, quality of care, and to increase the overall efficiency of the health sector <sup>2</sup> .
Digital solution		In the context of this project digital solutions are understood to be good and innovative practices including lessons learned.
Digital Transformation of Health and Care	DTHC	The Communication on Digital Transformation of Health and Care (DTHC) in the Digital Single Market identifies three priorities: <ol style="list-style-type: none"> <li>1. Citizens’ secure access to their health data, also across borders - enabling citizens to access their health data across the EU;</li> <li>2. Personalised medicine through shared European data infrastructure - allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities) across the EU;</li> <li>3. Citizen empowerment with digital tools for user feedback and person-centred care - using digital tools to empower people to look after their health, stimulate prevention and enable feedback and</li> </ol>

<sup>1</sup> Borghoff, U.M. & Schlichter, J.H. (2000): Computer-Supported Cooperative Work: Introduction to Distributed Applications. Springer-Verlag New York, Inc., Secaucus, NJ, USA.

<sup>2</sup> [https://ec.europa.eu/health/ehealth/overview\\_en](https://ec.europa.eu/health/ehealth/overview_en)

		interaction between users and health care providers.
European Innovation Partnership in Active and Healthy Ageing	EIP on AHA	The European Innovation Partnership in Active and Healthy Ageing (EIP on AHA) is an initiative launched by the European Commission to foster innovation and digital transformation in the field of active and healthy ageing. The concept of a European Innovation Partnership (an EIP) is of a partnership that can help strengthen European-wide research and innovation. A partnership brings together all the relevant actors at European, national and regional levels across different policy areas to handle a specific societal challenge that involves all the innovation chain levels. The EIP on AHA was the first EIP created in 2011. It focuses on the active and healthy ageing of the people of Europe.
Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing	MAFEIP	Web-based tool to support evidence-based decision-making processes for institutions and users in the health and care sector by estimating the health and economic outcomes of their innovations. It takes into account both increased efficiency and improved health and quality of life of the beneficiaries. <sup>3</sup>
Persona		Personas are designed end-users of technology solution with specific and distinct needs. They constitute eventual user segments. The concept is sometimes enhanced by an aspect of behavioural characteristics that takes into consideration psycho-social forces and health care choices and outcomes.
Twinning		Twinning schemes are a novel concept that aims to de-risk investment in digital innovative ICT solutions by financing the exchange of knowledge and good practices in digital health solution with high potential for reliability and scaling up. The first twinning scheme applied in the domain of digital health and care was launched in 2016 to contribute to the European scaling-up strategy of the EIP on AHA.

<sup>3</sup> <https://www.mafeip.eu/>

## 2.3 Digital solutions for health and integrated care

Terms	Abbreviation	Descriptions
Big data		Big data in health refers to large routinely or automatically collected datasets which are electronically captured and stored. The data is reusable in the sense that it is multipurpose data. It involves the fusion and connection of existing databases for the purpose of improving health and health system performance. It does not refer to data collected for a specific study (EU DG Santé definition).
Clinical terminology guidelines		A set of terminological resources that can be implemented in software applications. They represent clinically relevant information in a semantically structured form of code that can be used by automated applications. These codes represent explicit formal definitions of meaning and are based on a consensus of actual use by clinicians.
Connecting Europe Facility	CEF	The Connecting Europe Facility (CEF) is a key EU funding instrument to promote growth, jobs and competitiveness through targeted infrastructure investment at European level. It supports the development of high performing, sustainable and efficiently interconnected trans-European networks in the fields of transport, energy and digital services.
Cross-border health care		Cross-border health care means health care provided or prescribed in a Member State other than the Member State of affiliation (ie. Member State competent to give authorisation to receive treatment outside the Member State of residence. (Cross Broder Directive 2011 <sup>4</sup> )
Cross-border information exchange		Cross-border information exchange means the process of sending and receiving information across legislative boundaries using interoperable systems in order to read and further process this information in a meaningful way.
Digital health literacy		Digital health literacy refers to the ability to seek, find, understand and appraise health-related information from electronic resources and apply the knowledge gained to making appropriate health decisions in order to address or solve a health problem. (IC Health definition)
eDispensing		eDispensing is defined as the electronic retrieval of a prescription and the dispensing of the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine has been dispensed, the dispenser is to report the dispensation information using the ePrescription software (epSOS definition).
e-Infrastructure		Short term for electronic Infrastructure, comprising a set of ICT based resources (e. g. networks, grids, data centres, collaborative environments) and support operations (e. g. operation centres, service registries, credential delegation services, certificate authorities, training, help-desk services) intended to address the needs of researchers for digital services in terms of networking,

<sup>4</sup> EU: Article 3f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

		computing and data management and facilitating the collaboration among research communities by sharing resources, analysis tools and data. Examples of EU-funded e-infrastructures are GÉANT, EGI and EUDAT (Source: EC)
Electronic health record	EHR	EHR is a comprehensive medical and cross-institutional record or similar documentation of the past and present physical and mental state of health of an individual in electronic form. EHRs also provide for ready availability of these data for medical treatment and other closely related purposes. EHRs are real-time, patient-centred records that provide immediate and secure information to authorized users. EHRs typically contain a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results. A National EHR system is most-often implemented under the responsibility of a national health authority and will typically make a patient's medical history available to health professionals in health care institutions and provide linkages to related services such as pharmacies, laboratories, specialists, and emergency and medical imaging facilities (epSOS definition).
Electronic medical record	EMR	EMRs are digital versions of the paper charts in clinician offices, clinics, and hospitals. EMRs contain notes and information collected by and for the clinicians in that office, clinic, or hospital and are mostly used by health care providers for diagnosis and treatment.
Electronic patient identifier	eID	This commonly refers to a unique number or chip card used to electronically identify the patient (epSOS definition). Patient identification is necessary to correctly match a patient to an intended treatment and prevent harm due to potential mistreatment.
ePrescription		ePrescription consists of electronic prescribing and electronic dispensing: ePrescribing is defined as the electronic prescribing of medicine with the use of software and the electronic transmission of said prescription data to a pharmacy where the medicine can then be dispensed. eDispensing is defined as the electronic retrieval of a prescription and the dispensing of the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine has been dispensed, the dispenser is to report the dispensation information using the ePrescription software (epSOS definition).
Health information exchange network		Health Information Exchange (HIE) refers to the process of electronically transferring, or aggregating and enabling access to, patient health information and data across provider organisations. Exchange may take place between different types of entities – for example, e-transfer of patient data between ambulatory care providers or e-transfer of data at the regional level (OECD definition).
Health technology		Health technology means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease

		prevention, diagnosis or treatment used in healthcare. (Cross Border Directive 2011 <sup>5</sup> )
Mobile Health	mHealth	mHealth is the use of mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and wireless devices, for medical and public health practice. mHealth applications include examples such as treatment adherence, community mobilization, collecting community and clinical health data, wellness and self-care, chronic disease management, and remote patient monitoring (WHO).
Patient empowerment		Empowerment is “a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important.” Collective empowerment is “a process through which individuals and communities are able to express their needs, present their concerns, devise strategies for involvement in decision-making, and take political, social, and cultural action to meet those needs.” <sup>6</sup>
Patient portal		There are two major concepts of patient portals. The health care-centered patient portals are national health care-related online applications that allow access to all or part of an electronic medical record (EMR) and personal health information (health record, test results, prescriptions). They are typically owned and administered by national/regional health care institutions, authorities and bodies.  Health information portals provide general, non-personalized medical information on medications, treatments, illness, or chronic conditions, and inform patients about various health care or medical topics (DHE definition).
Patient Summary		A Patient Summary is an identifiable dataset of essential and understandable health information that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care; it can also be defined at a high level as: the minimum set of information needed to assure Health Care Coordination and the continuity of care. (eHealth Network <sup>7</sup> ).
People-centred health services		People-centred health services is an approach to care that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways. People-centred care requires that people have the education and support they need to make decisions and participate in their own care. It is organized around the health needs and expectations of people rather than diseases (WHO definition).
Personal health records	PHR	A PHR contains the same types of information as EHRs – diagnoses, medications, immunisations, family medical histories, and provider contact information – but is designed to be set up, accessed and managed by patients. Patients can use PHRs to maintain and manage their health information in a private, secure

<sup>5</sup> EU: Article 3f) of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare

<sup>6</sup> PaSQ, adapted from Luttrell et al. 2009 and the Duque project ([www.duque.eu](http://www.duque.eu))

<sup>7</sup> eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU

		and confidential environment. PHRs can include information from a variety of sources including clinicians, home monitoring devices and patients themselves (ONC definition). Some patient portals have functions that are equivalent to PHRs.
Personalised medicine		Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, health care systems need to better respond to patient needs. <sup>8</sup>
Telehealth		Telehealth is broader in definition than telemedicine as it includes computer-assisted telecommunications to support management, surveillance, literature and access to medical knowledge. (WHO definition)
Telemedicine		Telemedicine is the provision of health care services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves the secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients (EU Commission definition, COM(2008)689).

<sup>8</sup> Nimmesgern, E., Benediktsson & I., Norstedt, I. (2017): Personalized Medicine in Europe. In: *Clinical and Translational Science*. 10(2), 61-63. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5355974/>

## 2.4 Health and care

Terms	Abbreviation	Descriptions
Care co-ordinator	CC	An individual who is responsible for co-ordinating the care and support of a Care Recipient. It could be a role undertaken by a health care professional or the care recipient or family carer.
Care recipient	CR	An individual who receives or seeks any care services or support considered to be integrated care, from another person or organisation. In certain circumstances, a care recipient may be the term used for a person receiving a new project-based service.
General practitioner	GP	A physician providing primary care or working as non-specialist in a community centre setting.
Health care professional	HCP	A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist, or another professional exercising activities in the health care sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment (EU definition <sup>9</sup> ).
Health Care Provider Organisation	HCPO	An organisation that has been commissioned or contracted to deliver what the respective authority considers to be health care services and / or support (e.g. Hospitals, Health Authorities, General Practices).
Health care support worker	HCSW	An employed individual who is qualified to deliver care, services, treatment or support to a care recipient (e.g. Health care Assistant, Nursing Assistant).
Health		Health is a state of physical, mental and social well-being and not merely the absence of disease or infirmity. <sup>10</sup>
Health care		Health care means health services provided by health care professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices. (Cross Border Directive 2011 <sup>11</sup> )
Health literacy		The United States Patient Protection and Affordable Care Act of 2010 defines health literacy as the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions. Health literacy skills are those skills people use to realise their potential in health situations. They apply these skills either to make sense of health information and services or provide health information and services to others (CDCP <sup>12</sup> definition)

<sup>9</sup> EU: Article 3f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

<sup>10</sup> <https://www.who.int/about/who-we-are/constitution>

<sup>11</sup> EU: Article 3f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

<sup>12</sup> US Centers for Disease Control and Prevention.

Informal carer	IC	An individual who is registered in any organisation to deliver care, services, or support to a care recipient.
Integrated care		<p>Integrated care includes initiatives seeking to improve outcomes of care through linkage of e.g., social and health care or co-ordination of services of providers along the continuum of care. It thus overcomes the challenges of fragmentation between sectors and services.</p> <p>Integrated care can be defined, in the context of health, social care and support services to deliver person-centred coordinated care as follows:</p> <p>“I [the patient] can plan my care with people who work together to understand me and my carer(s), allow me control, and bring together services to achieve the outcomes important to me”.<sup>13</sup></p> <p>And from a systems perspective:</p> <p>“Integrated care’... is an organising principle for care delivery with the aim of achieving improved care through better coordination of services provided”.<sup>14</sup></p> <p>“Integration’ is the combined set of methods, processes and models that seek to bring about this improved coordination of care”.<sup>15</sup></p>
Integrated care pathways		An integrated care pathway streamlines the management of health problems across prevention, acute care, rehabilitation, chronic and palliative care so as to create a continuum of care.
Integrated Health & Social Care Provider Organisation	IH&SCPO	An organisation that has been commissioned or contracted to deliver what the region or country considers to be both health and social care services and/or support, and whose staff are employees (e.g. Health and Social Care Board Northern Ireland)
Patient		A patient means any natural person who seeks to receive or receives healthcare. (Cross Border Directive 2011 <sup>16</sup> )
Social care professional	SCP	An employed individual who is professionally educated to deliver social care services and support to a care recipient.
Social Care Provider Organisation	SCPO	An organisation that has been commissioned or contracted to deliver what the region or country considers to be social care services and / or support (e.g. Municipality Authority, Third Sector organisation).
Social care support worker	SCSW	An employed individual who is qualified to deliver care, services, treatment or support to a care recipient.
Third Sector Provider Organisation	TSPO	An organisation that provides care and support through registered volunteers without a formal contract with either an HCPO or SCPO (e.g. Red Cross, Alzheimer’s Association).

<sup>13</sup> Lewis R., Rosen R., Goodwin N. & Dixon J. (2010): Where next for integrated care organisations in the English NHS? London: The Nuffield Trust.

<sup>14</sup> Nuffield Trust (2011): An overview of integrated care in the NHS. What is integrated care?, p.7, London: Nuffield Trust.

<sup>15</sup> Ham, C & Walsh, N. (2013): Making Integrated Care Happen at Scale and Pace, p.1, London: King’s Fund.

<sup>16</sup> EU: Article 3f) of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare



## 2.5 Twinning

This sub-section of terms refers absolutely specifically to DHE. Other initiatives and projects taking place throughout Europe currently may use similar (or dissimilar) terms or definitions.

Terms	Definitions
(the) Communication	COM(2018) 233 final: Enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, Brussels, 25.04.2018
Call for Twinning Tenders	A DHE informational document on the purpose of twinning, twinning conditions, information on tendering and the evaluation and award criteria.
Twinning Activities	Twinning activities may include, for example, hosting meetings, technical groups, travelling, acquiring licenses, paying fees for professional services.
Twinning Adopter	The organisation representing a region/city/country or other collection of organisations that will adopt the twinning solution.
Twinning Contract	A fixed price contract concluded with successful tenderers.
Twinning Contractor	An organisation which submits a successful tender (tenderer) and may be Originator or an Adopter Region.
Twinning Originator	The organisation providing a twinning solution.
Twinning Solutions	Digital know-how which is transferred through the twinning activities to the Twinning Adopter. They may be products, services, processes, methodologies, strategies and/or business models. The solutions must be based on digital technologies. They must be innovative and not have been used in the adopting region(s) before the twinning takes place.
Twinning Types	<p>Twinning range from knowledge exchange to adaptation or adoption of the transferred solution and can be grouped into four types.</p> <ul style="list-style-type: none"> <li>• <b>Knowledge exchange and training:</b> targets local authorities which do not have much experience with EU networking but are eager to learn from other regions<sup>17</sup> in Europe. The twinning is seen as a first step to discuss a concrete solution (product, service, methodology) and how it can be transferred to the adopting region(s).</li> <li>• <b>Adaptation:</b> Well-established solutions are adapted to the local context (e.g. translation of the contents of an app, prevention programme, etc.). This type of twinning is suitable for multiple adopters, as the adaptation process across adopters is expected to be very similar.</li> <li>• <b>Partial adoption:</b> Twinning that perform partial adoption will have to provide concrete evidence on impact of the adoption, as well as the reasons why a full adoption is not possible (e.g. different healthcare systems, organisational, reimbursement issues, etc.).</li> <li>• <b>Full adoption / acquisition:</b> This type of twinning mainly targets local authorities with well established relations with other</li> </ul>

<sup>17</sup> This is the level to which DHE twinning refer. Other twinning initiatives may take place on different levels.

authorities in Europe (e.g. through memorandums of understanding, past EU project partnerships, etc.) and that have already planned collaboration on a specific topic/solution. The twinning aims to achieve a full adoption of the solution in the adopting region(s) using local infrastructure (including adaptation) or the Twinning Originator's infrastructure (via acquiring the solution or licensing it using appropriate business models).

## 2.6 Data governance and data donation

Terms	Definitions
Access Management	A discipline that focuses on ensuring that only approved roles are able to create, read, update, or delete data – and only using appropriate and controlled methods. Data Governance programs often focus on supporting Access Management by aligning the requirements and constraints posed by Governance, Risk Management, Compliance, Security, and Privacy efforts.
Assurance	Activities designed to reach a measure of confidence. Assurance is different from audit, which is more concerned with compliance to formal standards or requirements.
Audit	An independent examination of an effort to determine its compliance with a set of requirements. An audit may be carried out by internal or external groups.
Audit Trail	A record that can be interpreted by auditors to establish that an activity has taken place. Often, a chronological record of system activities to enable the reconstruction and examination of the sequence of events and/or changes in an event. An audit trail of system resource usage may include user login, file access, and triggers that indicate whether any actual or attempted security violations occurred.
Change Control.	A formal process used to ensure that a process, product, service, or technology component is modified only in accordance with agreed-upon rules. Many organizations have formal Change Control Boards that review and approve proposed modifications to technology infrastructures, systems, and applications. Data Governance programs often strive to extend the scope of change control to include additions, modifications, or deletions to data models and values for reference/master data.
Compliance	A discipline, set of practices, and/or organizational group that deals with adhering to laws, regulations, standards, and contractual arrangements. Also, the adherence to requirements. Data Governance programs often support many types of compliance requirements: Regulatory compliance, contractual compliance, adherence to internal standards, policies, and architectures, and conformance to rules for data management, project management, and other disciplines.
Control	A means of managing a risk or ensuring that an objective is achieved. Controls can be preventative, detective, or corrective and can be fully automated, procedural, or technology-assisted human-initiated activities. They can include actions, devices, procedures, techniques, or other measures.
CRUD	Create, Read, Update, Delete. Used to describe access rights for data.
Customer Integration	Data An approach to managing multiple records containing information about an organization's customers. In this approach, instead of combining all information into a single repository, a combination of technologies, processes and services are used to align information in multiple

	repositories.
Data Architecture	A discipline, process, and program focusing on integrating sets of information. One of the four Enterprise Architectures (with Application Architecture, Business Architecture, and System Architecture). See also Data Modeling
Data Dictionary	A database about data and database structures. A catalog of all data elements, containing their names, structures, and information about their usage, for the benefit of programmers and others interested in the data elements and their usage.
Data Donation	Situation through which a person consents to the collection, transfer, processing, storage, disclosure, and use of your information for specific purposes stated in a policy statement.
Data Donator	A person donating personal data (may have the option to provide his/her email, signing the data with a private key, and restricting the allowed usage of the provided data)
Data Element	The smallest piece of information considered meaningful and usable. A single logical data fact, the basic building block of a Logical Data Model.
Data Governance	The exercise of decision-making and authority for data-related matters. The organizational bodies, rules, decision rights, and accountabilities of people and information systems as they perform information-related processes. Data Governance determines how an organization makes decisions – how we “decide how to decide.” See also Decision Rights.
Data Governance Framework	A logical structure for organizing how we think about and communicate Data Governance concepts.
Data Governance Methodology	A logical structure providing step-by-step instructions for performing Data Governance processes.
Data Governance Office (DGO)	A centralized organizational entity responsible for facilitating and coordinating Data Governance and/or Stewardship efforts for an organization. It supports a decision-making group, such as a Data Stewardship Council.
Data Mapping	The process of assigning a source data element to a target data element.
Data Modelling	The discipline, process, and organizational group that conducts analysis of data objects used in a business or other context, identifies the relationships among these data objects, and creates models that depict those relationships. See also Data Model.
Data Privacy	The assurance that a person’s or organization’s personal and private information is not inappropriately disclosed. Ensuring Data Privacy requires Access Management, eSecurity, and other data protection efforts.
Data Requestor	Person or institution that is looking for data and provides the necessary infrastructure, e.g. a publicly available Semantic Container initialized with a semantic description of the data request and intended purpose of the collected data

Data Stakeholders	Those who use, affect, or are affected by data. Data Stakeholders may be upstream producers, gatherers, or acquirers of information; downstream consumers of information, those who manage, transform, or store data, or those who set policies, standards, architectures, or other requirements or constraints.
Data Steward	A person with data-related responsibilities as set by a Data Governance or Data Stewardship program. Often, Data Stewards fall into multiple types. Data Quality Stewards, Data Definition Stewards, Data Usage Stewards, etc.
Decision Rights	The system of determining who makes a decision, and when, and how, and under what circumstances. Formalizing Decision Rights is a key function of Data Governance.
DGO	see Data Governance Office
Enterprise Architecture	Enterprise Architecture (EA) is a comprehensive framework used to manage and align an organization's business processes, information technology (IT) software and hardware, local and wide area networks, people, operations and projects with the organization's overall strategy. (DMReview definition) Enterprise Architecture is often subdivided into four architectural domains: Application Architecture, Business Architecture, Data Architecture, and Systems Architecture. Other types of architectures (security, compliance, controls, etc.) may be considered as part of EA, or they may be aligned with EA. In some organizations, EA is primarily focused on Business Architectures and Business Process Management.
GRC	An acronym for Governance, Risk, and Compliance used often by management in financial institutions to acknowledge the interdependencies of these three disciplines in setting policy. See also GRC-SQ and Risk Management.
GRC-SQ	An acronym for Governance, Risk Management, Compliance, Security, and Data Quality, used often by Data Governance and Data Quality programs to acknowledge the interdependencies of these five disciplines in managing data.
Health Data Cooperative	<p>An HDC is a health data bank. The account holders, also referred to as members, users, or citizens, can collect and store their health-related information, for example, from the EPR, fitness or sleeping apps, heart rate monitors, and glucose meters on their HDC account. They are the rightful data owners and make the decisions regarding information sharing.<sup>18</sup></p> <p>An HDC is concerned with the collection, storage, maintenance, management, and analysis of health data. To become part of an HDC, an individual has to pay a one-time unit price (membership fee), which entitles the person to be a member and owner at the same time.<sup>19</sup></p> <p>The data are citizen owned and managed; the account holder is the only person empowered to add, adjust, or remove information and to decide</p>

<sup>18</sup> Healthbank.coop (2016): Healthbank – My data, my choice, my health. (Internet), p.1, Available from: <https://www.healthbank.coop/faq/>

<sup>19</sup> Hafen E, Kossmann D & Brand A (2014): Health Data Cooperatives – Citizen Empowerment. In: *Methods of Information in Medicine*, 53, p.82–86.

	<p>when and with whom he or she wants to share personal health information.<sup>20</sup></p> <p>An HDC is the equal property of all its members. This cooperative approach ensures that decisions are made collectively. Each member has one vote, which, for example, can be used during elections on a new executive management. As a result of this approach, the HDC model is citizen centred, which entails that the cooperative acts in the interest of its users.<sup>21</sup></p>
Information Architecture	<p>In its broadest definition, a discipline, process, and/or program focusing on the design and organization of data, unstructured information, and documents. In the context of Enterprise Architecture, it is a synonym for Data Architecture, which is one of the four Enterprise Architectures (with Application Architecture, Business Architecture, and System Architecture). In the context of designing documents and web pages, it is the structuring of large sets of information, as opposed to the development of the content of any content unit within the larger set.</p>
Issue Framing	<p>A process for scoping and defining a problem prior to solving it. How a decision is framed limits the possible choices that are seriously considered.</p>
Issue Resolution	<p>A structured process for reaching a solution to a problem while considering the needs of all stakeholders. Most Data Governance programs acknowledge that successful resolution of data-related issues requires politically-neutral facilitation of the decision-making process, with participation by Data Stakeholders.</p>
IT Governance	<p>ITGI (The IT Governance Institute) defines Information Technology governance as “the leadership, organizational structures, and processes that ensure that the enterprise’s IT sustains and extends the enterprise’s strategies and objectives.”</p>
IT Infrastructure Library (ITIL)	<p>A series of publications providing Best Practice guidance for IT Service Management.</p>
IT Portfolio Management	<p>A key function of IT Governance, IT portfolio management is the formal process for managing IT assets such as software, hardware, middleware, an IT project, internal staff, an application or external consulting.</p>
IT Service Management (ITSM)	<p>The implementation and management of Quality IT Services that meet the needs of the Business. IT Service Management is performed by IT Service Providers through an appropriate mix of people, Process and Information Technology. (Baseline IT definition)</p>
Master Data	<p>Master Data are the “nouns” upon which business transactions take action. Master Data describes core entities of an enterprise that are used by multiple business process and IT systems. Examples are parties (e.g., customers, employees, vendors, suppliers), places (e.g., locations, sales territories, offices), and things (e.g., accounts, products, assets, document sets). See also Reference Data.</p>

<sup>20</sup> MIDATA.coop (2016): My Data – Our Health. (Internet), Available from: <https://midata.coop>.

<sup>21</sup> Hafen E, Kossmann D & Brand A (2014): Health Data Cooperatives – Citizen Empowerment. In: *Methods of Information in Medicine*, 53, p.82–86.

Master Management (MDM)	Data	A structured approach to defining and managing an organization’s Master Data.
Metadata		Data about data. The definition and scope of metadata depends upon context. In the context of Information Management, metadata is generally thought of as providing information (what database stores it? what data type is it? how long is the field? etc.) about a data element. Within the context of Data Governance, the term also includes “business” metadata such as the names and roles of Data Stewards. Metadata repositories are employed to store and report on metadata.
Personal information		It is information that identifies or could be used to identify a person, such as the name, contact details (such as address, phone number, email address, password, identification number on government-issued ID), financial information (such as bank account number), device details (such as IP address, web browser user-agent information), demographic details (such as gender or age) and information about interests and affiliations.
Post-Compliance Paradigm Shift		Change in expectations that says that it’s no longer acceptable to simply “do” work. Instead, for work that exists in an environment with compliance requirements, the work is not complete until you 1. Do it, 2. Control it, 3. Document it, and 4. Prove compliance.
Risk Management		In a broad sense, to assess, minimize, and prevent negative consequences posed by a potential threat. The term “Risk Management” has significantly different meanings that can affect Data Governance programs. At an enterprise level, “risk” refers to many types of risk (operational, financial, compliance, etc.); managing risk is a key responsibility of Corporate Boards and Executive Teams. Within financial institutions (or in the context of a GRC program), Risk Management may be a boundary-spanning department that focuses on risk to investments, loans, or mortgages. At a project level, “Risk Management” is an effort that should be undertaken as part of Project Management, focusing on risks to the successful completion of the project. From a Compliance/Auditing/Controls perspective, “Risk Assessments” and “Risk Management” are high-effort activities included in the COSO, and COBIT frameworks and required by Sarbanes-Oxley and other compliance efforts. Data Governance programs may be asked to support any of these Risk Management efforts, and may need input from these efforts to resolve data-related issues.
Rogue Data Usage		Accessing or using information in a manner that is not authorized or proper.
Sensitive Data		Data that is private, personal, or proprietary and must be protected from unauthorized access.
Tone From the Top		Explicit or implicit messages sent by an organization’s leadership. To be successful, compliance and governance programs generally require a strong tone from the top about expectations for participation.
Workflow		The movement of data, documents, or tasks through a work process; generally used in the context of technologies that automate workflows. Data Governance programs often strive to address workflows by embedding governance controls (e.g., approvals, decision steps) or by providing loop-outs to governance processes (e.g., issue resolution, change control)

## 2.7 Data protection

Source: The European Medical Informatics Framework (EMIF: <http://www.emif.eu>)

Terms	Abbreviation	Descriptions
Access Control		ISO 7498-2:1989: prevention of unauthorized use of a resource, including the prevention of use of a resource in an unauthorized manner.
Aggregated Data		IMI Code of Practice: Data of several individuals that have been combined to show general trends or values.
Anonymisation		IMI Code of Practice: Process of removing all elements allowing the identification of an individual person (i.e., of rendering data anonymous). ISO/TS 25237:2008: process that removes the association between the identifying data set and the data subject. UK Information Commissioner's Office: process of rendering data into a form which does not identify individuals and where identification is not likely to take place.
Anonymised Data		IMI Code of Practice: Data which was identifiable when collected but which are not identifiable anymore (have been rendered anonymous). Anonymous data are no longer personal data. UK Information Commissioner's Office: data in a form that does not identify individuals and where identification through its combination with other data is not likely to take place.
Assumed Consent		ISO: informational consent done in the absence of any formal recorded or verbal indication of agreement or any overt action (or inaction) on the part of the data subject.
Audit Trail		ISO/EN 13606-1:2008: chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed.
Auditability		ENV 13608-1:2000: property that ensures that any action of any security subject on any security object may be examined in order to establish the real operational responsibilities.
Authentication		ISO 7498-2:1988: process of reliably identifying security subjects by securely associating an identifier and authenticator.
Authorisation		ISO: permission to perform certain operations or use certain methods or services.
Clinical Trial		IMI Code of Practice: Any investigation in human subjects intended to discover or verify the effect of one or more investigational health interventions (e.g., drugs, diagnostics, devices, therapy protocols) that generate safety and efficacy data before making the health intervention available in health care <sup>22</sup> .

<sup>22</sup> Adapted from its definition in Directive 2001/20/EC of 4 April 2001 ("on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use"). This includes clinical trials carried out in either one or multiple sites, whether in one or several countries.



Confidentiality		ISO 13606-4:2009: ensuring that information is accessible only to those authorised to have access.
Consent		ISO/TS 14265:2011: any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed.
Data Controller (or Controller)		IMI Code of Practice: The natural or legal person, or any other body, which alone or jointly with others determines the purposes and means of the processing of personal data <sup>23</sup> .
Data Destruction		ISO/TS 14265:2011: operation that results in the permanent, unrecoverable removal of information about an object from memory or storage (e.g., by multiple overwrites with a series of random bits).
Data Donation		Data donation research is research in which people voluntarily contribute their own personal data that was generated for a different purpose to a collective dataset. <sup>24</sup>
Data Governance		Data Governance is a system of decision rights and accountabilities for information-related processes, executed according to agreed-upon models which describe who can take what actions with what information, and when, under what circumstances, using what methods. <sup>25</sup>
Data Linkage		UK Information Commissioner's Office: technique that involves bringing together and analysing data from a variety of sources, typically data that relates to the same individual.
Data Processor (or Processor)		IMI Code of Practice: The natural or legal person, or any other body, which processes personal data on behalf of the controller.
Data Protection		ISO TS 25237: 2008: technical and social regimen for negotiating, managing, and ensuring informational privacy, confidentiality, and security.
Data Sharing		UK Information Commissioner's Office: the disclosure of data from one or more organisations to a third party organisation or organisations, or the sharing of data between different parts of an organisation.
Data Sharing Agreement		UK Information Commissioner's Office: common set of rules to be adopted by the various organisations involved in a data sharing operation.
Data Subject		IMI Code of Practice: The person whose personal data are collected, held or processed <sup>26</sup> . ISO/TS 14265:2011: identified or identifiable natural person, who is the subject of personal data.
De-identification		IMI Code of Practice: Process of rendering data pseudonymised or anonymised.

<sup>23</sup> In a clinical trial, the organisation(s) responsible for the trial is usually considered being the controller (for collaborative projects, see EDPS "Opinion related to the clinical study in the frame of the research project PROTECT WP4", issued on 29 November 2012)

<sup>24</sup> <https://theoryandpractice.citizenscienceassociation.org/articles/10.5334/cstp.178/>

<sup>25</sup> <http://www.datagovernance.com/defining-data-governance/>

<sup>26</sup> See European Data Protection Supervisor, retrieved 06/08/2014

		ISO/TS 25237:2008: general term for any process of removing the association between a set of identifying data and the data subject.
Disclose		ISO/TS 14265:2011: reveal data to those not routinely authorized to have it.
Disclosure Control		UK Information Commissioner's Office: technique used to control the risk of individuals being identified from statistical data – typical methods include removing or disguising data relating to individuals with unusual sets of attributes.
Explicit Consent		ISO 18308:2010: permission that is freely and directly given, expressed either viva voce or in writing.
Genetic Data		IMI Code of Practice: All personal data relating to the genetic characteristics of an individual which have been inherited or acquired as they result from an analysis of a biological sample from the individual in question, in particular by chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis or analysis of any other element enabling equivalent information to be obtained <sup>27</sup> . This Code considers only genetic data rich enough to identify a data subject.
Health Data		Under the GDPR, health data is defined as “ <i>personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status</i> ”.
Human Biological Sample		IMI Code of Practice: Any biological material collected from human (including blood, sputum, extracted DNA/ RNA, etc.).
Identification		ISO/TS 25237:2008: process of using claimed or observed attributes of an entity to single out the entity among other entities in a set of identities.
Implied Consent		ISO: informational consent that is freely and directly given, indicated by an action or an inaction rather than a formal verbal or written indication of agreement on the part of the data subject.
Incidental Finding		IMI Code of Practice: Previously undiagnosed medical conditions that are discovered unintentionally and are unrelated to the current medical condition which is being treated or tests being performed <sup>28</sup> .
Information Governance	IG	ISO 27799:2007: processes by which an organization obtains assurance that the risks to its information, and thereby the operational capabilities and integrity of the organization, are effectively identified and managed.
Person Identification		ISO/TS 25237:2008: process for establishing an association between an information object and a physical person.
Personal Data		IMI Code of Practice: Any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

<sup>27</sup> As defined in Article 4 para (10) of “General Data Protection Regulation”

<sup>28</sup> See Incidental findings, retrieved 06/08/2014

		Also commonly referred to as Personally Identifiable Information or PII <sup>29</sup> .
Perturbation		UK Information Commissioner's Office: alteration of values within a data set to guard against data-linkage.
Policy		ISO/TS 22600-1:2006: set of legal, political, organizational, functional and technical obligations for communication and cooperation.
Privacy		ISO/IEC 2382-8: freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual.
Processing*		IMI Code of Practice: Any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaption or alteration, retrieval, consultation, use disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.
Prospective Data Collection		IMI Code of Practice: Data needed for the specific research project which have not yet been collected or are not yet part of another research project. In contrast, retrospective data has already been collected for another research project or for health care (i.e., requiring secondary use of data).
Pseudonym		ISO/TS 25237:2008: personal identifier that is different from normally used personal identifiers. Note 1: This may be either derived from the normally used personal identifier in a reversible or irreversible way, or alternatively be totally unrelated. Note 2: Pseudonym is usually restricted to mean an identifier that does not allow the derivation of the normal personal identifier. Such pseudonymous information is thus functionally anonymous.
Pseudonymisation		IMI Code of Practice: Process of removing all elements allowing the identification of an individual person, except the key(s) allowing linking the data to the person. Such key shall be randomly generated and subject to technical and organisational measures to prevent its unauthorised use. ISO/TS 25237:2008: particular type of anonymization that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms.
Pseudonymised Data		IMI Code of Practice: Personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution. The only difference between pseudonymised and anonymised data is that in the latter case there exists no key to link data to the data subject.
Re-Identification		IMI Code of Practice: The process of linking de-identified

<sup>29</sup> Many guidelines use the term Personally Identifiable Information or PII

		<p>data to the study participant.</p> <p>UK Information Commissioner's Office: process of analysing data or combining it with other data with the result that individuals become identifiable.</p>
Research		<p>IMI Code of Practice: Any scientific research project including clinical trials and fundamental research, aiming at gaining scientific knowledge in the health sector.</p>
Secondary Use of Data (or Data Re-Use)		<p>"Open Data Directive" (EU) 2019/1024): The use by persons or legal entities of documents held by: (a) public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the documents were produced, except for the exchange of documents between public sector bodies purely in pursuit of their public tasks; or (b) public undertakings, for commercial or non-commercial purposes other than for the initial purpose of providing services in the general interest for which the documents were produced, except for the exchange of documents between public undertakings and public sector bodies purely in pursuit of the public tasks of public sector bodies.</p> <p>IMI Code of Practice: Processing of already existing medical data for a purpose different from the purpose for which they have been initially collected<sup>30</sup>.</p> <p>ISO: any legitimate use of a health care record other than for the purpose of supporting the direct delivery of health care services to the subject of care.</p>
Sensitivity		<p>ISO: measure of importance assigned to information to denote its need for protection.</p>
Study Participant		<p>IMI Code of Practice: Any person participating in a research study, whether or not a clinical trial. It can refer to patients or healthy volunteers (it does not include health care professionals).</p>
Supervisory Authority		<p>IMI Code of Practice: The public authority (or authorities) in each member state responsible for monitoring the application of the administrative measures and regulations adopted within their member state pursuant to the Data Protection Directive. In this code, additionally other supervisory authorities may be considered e.g., the European Medicines Agency.</p>
Third Party*		<p>IMI Code of Practice: Any natural or legal person other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor, are authorised to process the data.</p> <p>ISO: any natural or legal person, public authority, agency or any other body other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor, are authorised to process the data.</p>
Trusted Third Party	TTP	<p>IMI Code of Practice: The person or body that, in the case of</p>

<sup>30</sup> E.g., medical data collected to conduct a clinical trial on breast cancer used to run a study aiming to identify new biomarkers, but which was not planned in the consent form

		<p>pseudonymised data, is in charge of holding the key so as to safeguard the privacy of the patient or study participant<sup>31</sup>. The trusted third party has to act in an independent manner. It ensures that the re-identification key is not disclosed to anyone not authorised to access.</p>
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<sup>31</sup> The Trusted Third party is responsible for keeping the “pseudonymising key” and shall not disclose it to anyone, unless otherwise authorised.

## 2.8 Data analytics

Terms	Abbreviations	Descriptions
Artificial intelligence	AI	Artificial intelligence refers to systems designed by humans that, given a complex goal, act in the physical or digital world by perceiving their environment, interpreting the collected structured or unstructured data, reasoning on the knowledge derived from this data and deciding the best action(s) to take (according to pre-defined parameters) to achieve the given goal. (Source: EC)
Blockchain		The best known distributed ledger technology providing trust, traceability and security in systems that exchange data or assets, enabling a final and definitive record of transactions to be held in a network across a series of nodes and avoiding one centralised location and the need for intermediaries' services. (Source: EC)
Cloud computing		The storing, processing and use of data on remotely located computers accessed over the internet. (Source: EC)
Dataset		A collection of data, published or curated by a single agent, and available for access or download in one or more formats. (Source: The Data Catalogue Vocabulary (DCAT) of W3C <sup>32</sup> )
Deep learning	DL	A particularly accurate machine learning approach with less need of human guidance, referring to the fact that the neural network has several layers between the input and the output, learning the overall input-output relation in successive steps. (Source: EC)
Digital twin		A digital replica (computer model) of a real-world device, process or person that can be used in virtual testing to predict problems before they occur, find optimal solutions, and reduce risks.
High-performance computing	HPC	HPC refers to computing systems having extremely high computational capabilities, today able to perform more than 10 <sup>15</sup> operations per second (petascale) and expected in a few years to reach 10 <sup>18</sup> operations per second (exascale). (Source: EC)
Internet of Things	IoT	A dynamic global network infrastructure with self-configuring capabilities based on standard and interoperable communication protocols where physical and virtual "things" have identities, physical attributes and virtual personalities, use intelligent interfaces, and are seamlessly integrated into the information network. (Source: IERC/ITU)
Machine learning	ML	One of AI's sub-disciplines, denoting the ability of a piece of software to learn from its environment or from a very large set of representative data, enabling systems to adapt their behaviour to changing circumstances or to perform tasks for which they have not been explicitly programmed. (Source: EC)
Machine-readable		A file format structured so that software applications can easily identify, recognise and extract specific data, including individual

<sup>32</sup> <http://www.w3.org/TR/2014/REC-vocab-dcat-20140116/#class-dataset>

format		statements of fact, and their internal structure.
Neural networks		A machine learning approach inspired by the human brain in that it has a network of small processing units (analogously to human neurons) with lots of weighted connections among them, adjusted during the training phase to minimise the error between the expected output and the output computed by the network. (Source: EC)

## 2.9 ICT security

Terms	Abbreviations	Descriptions
Cryptography		The mathematical science that deals with transforming data to render its meaning unintelligible (i.e., to hide its semantic content), prevent its undetected alteration, or prevent its unauthorized use. If the transformation is reversible, cryptography also deals with restoring encrypted data to intelligible form. (Source: heise.de)
Cybersecurity		Cybersecurity are the processes employed to safeguard and secure assets used to carry information of an organisation from being stolen or attacked. It requires extensive knowledge of the possible threats. Identity management, risk management and incident management form the crux of cyber security strategies of an organization. (Source: cybrary.it)
Digital signature		A value computed with a cryptographic algorithm and associated with a data object in such a way that any recipient of the data can use the signature to verify the data's origin and integrity. A digital signature ensures signer authenticity, provides accountability, secures sensitive data, and guards against tampering. (Source: cybrary.it; heise.de)
Electronic signature		Most frequently referred to as the legally binding, electronic equivalent of an individual's handwritten signature, which can be as basic as a typed name, a credential such as a password, or a digitized image of the handwritten signature. A deprecated term with currently no consensus on its meaning, often used as a synonym for "digital signature". (Source: heise.de; Am J Transl Res. 2016; 8(3): 1560–1580)
Encryption		Encryption is a process of maintaining data integrity and confidentiality by converting plain data into a secret code with the help of an algorithm. The corresponding reverse process is "decryption", a transformation that restores encrypted data to its original form. Only authorized users with a key can decrypt encrypted data. Encryption is regarded as an effective way to defend against the abuse of IT technologies, such as hacking, identity and personal data theft, fraud and the improper disclosure of confidential information. It ensures the protection of cybersecurity, data protection and privacy. (Source: cybrary.it; heise.de)

End-to-end encryption		Continuous protection of data that flows between two points in a network, effected by encrypting data when it leaves its source, keeping it encrypted while it passes through any intermediate computers (such as routers), and decrypting it only when it arrives at the intended final destination. Examples are SSL and TLS. (Source: heise.de)
Malware		Malware is a short term for malicious software. Malware is defined as any software that is used to interrupt or disrupt computer operations, gather sensitive information, or gain access to certain files or programs. (Source: cybrary.it)
Phishing		'Phishing', a word play on 'fishing', uses communication methods, like email and instant messages, to trick individuals into divulging sensitive information directly or directing them to a malicious web site where malware will be downloaded to their device, resulting in further compromise of other devices, applications, or systems to which the now infected device connects. (Source: EC)
Secure Socket Layer	SSL	A Secure Sockets Layer (SSL) is the standard security technology for establishing an encrypted link between a web server and a browser. SSL was developed by Netscape for transmitting private documents via the Internet. (Source: cybrary.it)
Transport Layer Security	TLS	Transport Layer Security is a protocol that ensures privacy between communicating applications and the users on the Internet. When a server and client communicate, TLS ensures that no third party may overhear or tamper with any message. TLS is the successor to the Secure Sockets Layer (SSL). (Source: cybrary.it)



## 2.10 Other

Terms	Abbreviations	Descriptions
Business model		A business model describes the rationale of how an organization creates, delivers, and captures value, in economic, social, cultural or other contexts. The process of business model construction and modification is also called business model innovation and forms a part of business strategy.
Business model canvas	BMC	<p>A business model is a representation of how an organisation makes (or intends to make) money. Based on an extensive literature research and real-world experience we define a business model as consisting of nine building blocks that constitute the business model canvas:</p> <ol style="list-style-type: none"> <li>1. The value proposition of what is offered to the market;</li> <li>2. The segment(s) of clients that are addressed by the value proposition;</li> <li>3. The communication and distribution channels to reach clients and offer them the value proposition;</li> <li>4. The relationships established with clients;</li> <li>5. The key resources needed to make the business model possible;</li> <li>6. The key activities necessary to implement the business model;</li> <li>7. The key partners and their motivations to participate in the business model;</li> <li>8. The revenue streams generated by the business model (constituting the revenue model);</li> <li>9. The cost structure resulting from the business model.</li> </ol>
Business use case		A business use case is to describe, in technology free terminology, how a business process is used by people or systems external to the business to achieve their goals (composed from several definitions in the literature).
Capability		“The organisational ability to intentionally and systematically use improvement approaches, methods and practices, to change processes and products/services to generate improved performance.” <sup>33</sup> The key word here is ‘use’. While capacity provides the potential for improvement, it is the active application and use of improvement approaches and practices that determine whether improved results will be realised. <sup>34</sup>
Capacity (building)		Capacity can be defined as the ability of individuals and organisations or organisational units to perform functions effectively, efficiently and sustainably. Capacity building is an evidence-driven process of strengthening the abilities of individuals, organisations, and systems to perform core functions sustainably, and to enable continuous improvement and development over time.

<sup>33</sup> Furnival J., Boaden R. & Walshe K. (2017): Conceptualizing and assessing improvement capability: a review. *International Journal for Quality in Health Care*, p.1-8, Available from: <https://doi.org/10.1093/intqhc/mzx088>

<sup>34</sup> NHS Improvement, Building capacity and capability for improvement: embedding quality improvement skills in NHS providers, 2017, Available from: [https://improvement.nhs.uk/documents/1660/01-NHS107-Dosing\\_Document-010917\\_K\\_1.pdf](https://improvement.nhs.uk/documents/1660/01-NHS107-Dosing_Document-010917_K_1.pdf)

Cost-effectiveness analysis	CEA	Analysis that calculates and compares the costs and effects of two or more interventions, allowing to establish priorities among them. <sup>35</sup>
Disability Adjusted Life Years	DALYs	One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability <sup>36</sup> .
European Committee for Electrotechnical Standardisation	CENELEC	One of the three European Standardisation Organisations responsible for standardisation in the electrotechnical engineering field (Source: CENELEC).
European Committee for Standardisation	CEN	One of the three European Standardisation Organisations (Source: CEN).
European Open Science Cloud	EOSC	A cloud for research data in Europe, promoted by the European Commission to provide all researchers, innovators, companies and citizens with seamless access to an open-by-default, efficient and cross-disciplinary environment for storing, accessing, reusing data, tools, publications and any EOSC Resource for research, innovation and educational purposes. The EOSC is implemented by the EOSC System and governed by the EOSC Governance. (Source: EC)
European Standards Organisations	ESO	Organisations recognised by the European Union and by the European Free Trade Association as being responsible for developing and defining voluntary standards at European level (Source: CEN).
European Telecommunications Standards Institute	ETSI	One of the three European Standardisation Organisations responsible for standardisation in the field of Information and Communications Technologies (Source: ETSI).
FAIR data		Data that are Findable, Accessible, Interoperable and Reusable (FAIR) to the greatest extent possible, enhancing their usefulness and propensity for reuse, by humans and at scale by machines. FAIR data are not necessarily Open data; data can be FAIR and shared under restrictions, for instance data that contain personal information, have not been consented for release, contain confidential commercial information, or are restricted for reasons of public interest. (Source: EC)
Federated database		Wikipedia: meta-database management system which transparently maps multiple autonomous database systems into a single federated database. The constituent databases are interconnected via a computer network and may be geographically decentralized. The constituent database systems remain autonomous; and the federated database, or virtual database, is a composite of all constituent databases in a federated database system.

<sup>35</sup> <https://www.who.int/heli/economics/costeffanalysis/en/>

<sup>36</sup> [https://www.who.int/healthinfo/global\\_burden\\_disease/metrics\\_daly/en/](https://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/)

Federated infrastructure		An infrastructure where a range of distributed facilities, resources and services are coordinated by an overarching level.
Health Adjusted Life Years	HALYs	<p>Health-Adjusted Life Years measure the health of a population, to estimate burden of disease. HALYs are used to measure the combined effects of mortality and morbidity in populations; comparisons between illnesses or interventions.</p> <p>They are commonly used to compare the cost-effectiveness of different health interventions. HALYs are based on epidemiological data, hence their accuracy depends from the completeness and accuracy of the data<sup>37</sup>.</p>
Health-Related Quality of Life and Well-Being	HRQoL	Indicator to measure the “impact that health status has on quality of life. A utility of 0 indicates no quality of life or dead, whereas a utility of 1 indicates quality-of-life in perfect health”. <sup>38</sup>
High-level use case		<p>A situation in which a specific eHealth application or service could potentially be used. A high level use case may call one or more use cases.</p> <p>A functional description of a process, as seen from the end-user’s point of view. It describes interactions between the actors in the process, in a non-technical way. (Antilope project<sup>39</sup>)</p>
High-value dataset		<p>“Open Data Directive” (EU) 2019/1024): Documents the re-use of which is associated with important benefits for society, the environment and the economy, in particular because of their suitability for the creation of value-added services, applications and new, high-quality and decent jobs, and of the number of potential beneficiaries of the value-added services and applications based on those datasets”. (Source:</p> <p>Report on high-value datasets from EU institutions<sup>40</sup>: The definition of high-value dataset takes into account two different points of view: the one of the publishers and the one of the re-users. These two perspectives may in certain circumstance be interlinked and overlap. From the <i>publisher’s perspective</i>, a dataset may be considered of high-value when one or more of the following criteria are met: it contributes to transparency; its publication is subject to a legal obligation; it directly or indirectly relates to their public task; it realises a cost reduction; or it brings value to a specific target audience. From a <i>re-user’s perspective</i>, the value of a dataset depends primarily on its use and re-use potential, which can effectively lead to the generation of (new) business models. The use and re-use potential of a dataset is defined by the size and the dynamics of the target audience of the dataset, as well as by the number of new and existing systems and services that are using (or could use) the particular dataset.</p>

<sup>37</sup> [https://www.who.int/gho/mortality\\_burden\\_disease/life\\_tables/hale/en/](https://www.who.int/gho/mortality_burden_disease/life_tables/hale/en/)

<sup>38</sup> [https://tool.mafeip.eu/assets/files/MAFEIP\\_User\\_Guide\\_v2\\_Website.pdf](https://tool.mafeip.eu/assets/files/MAFEIP_User_Guide_v2_Website.pdf)

<sup>39</sup> <https://www.antilope-project.eu/front/index.html>

<sup>40</sup> [https://ec.europa.eu/isa2/sites/isa/files/publications/report-on-high-value-datasets-from-eu-institutions\\_en.pdf](https://ec.europa.eu/isa2/sites/isa/files/publications/report-on-high-value-datasets-from-eu-institutions_en.pdf)

Information & Communication Technology	ICT	In North America often referred to as 'Information Technology' (IT).
International Electrotechnical Commission	IEC	International organisation for the preparation and publication of international standards for all electrical, electronic and related technologies (Source: IEC).
International Organisation for Standardisation	ISO	International organisation gathering 162 national standards bodies to develop International Standards (Source: ISO).
International Telecommunication Union	ITU	International organisation for the development of international standards in the field of Information and Communications Technologies (Source: ITU).
Interoperability		The ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems. (New EU EIF).
Interoperability governance		"Interoperability governance covers the ownership, definition, development, maintenance, monitoring, promoting and implementing of interoperability frameworks in the context of multiple organisations working together to provide services. It is a high-level function providing leadership, organisational structures and processes to ensure that the interoperability frameworks sustain and extend the organisations' strategies and objectives." (Re eHEIF).
Legal Interoperability		Legal interoperability means to "[a]llign legislation so that exchanged data is accorded proper legal weight" (Re eHEIF).
Medical data		IMI Code of Practice: Any data concerning patients or study participants health, collected within the context of health care or clinical trials (e.g., name, address, living conditions, health data, life style habits, social security number, image data...) <sup>41</sup>
National Standards Bodies	NSB	National organisations composed of technical committees to develop standards that are considered necessary by market actors and/or to support the implementation of European legislation (Source: CEN-CENELEC).
Organisational Interoperability		Organisational interoperability means "[to] [c]oordinate processes in which different organisations achieve a previously agreed and mutual beneficial goal" (Re eHEIF).
Quality-adjusted life years	QALYs	Measure of the life expectancy of an individual adjusted by its quality of life. A QALY is one year spent in perfect health. <sup>42</sup>
Real world data		Real world data is big data, referring specifically to any type of data not collected in a randomised clinical trial. This data can complement randomised clinical trial data to fill the knowledge gap between clinical trials and clinical practice, provide new

<sup>41</sup> Unless otherwise specified, medical data refers to individual subject data and not aggregated subject data.

<sup>42</sup> <https://www.nice.org.uk/glossary?letter=q>

		insights into disease patterns and help improve the safety and effectiveness of health interventions (EU definition).
Real world evidence		Real world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective). <sup>43</sup>
Research infrastructure	RI	Research infrastructures (RIs) are facilities, resources and services used by the scientific community to conduct research and foster innovation. They include: major scientific equipment, resources such as collections, archives or scientific data, e-infrastructures such as data and computing systems, and communication networks. RIs can be single-sited (a single resource at a single location), distributed (a network of distributed resources), or virtual (where the service is provided electronically).
Research data		Documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results. (Source: “Open Data Directive” (EU) 2019/1024)
Semantic interoperability		Semantic interoperability refers to the ability of computer systems to transmit data with unambiguous shared meaning. Semantic interoperability is a requirement to enable machine computable logic inferencing knowledge discovery and data federation between information systems. It is therefore concerned not just with the packaging of data but the simultaneous transmission of the meaning with the data. This is accomplished by adding data about the data linking each data element to a controlled shared vocabulary.  Semantic interoperability means the “[p]recise meaning of exchanged information which is preserved and understood by all parties” (Re eHEIF).
Standards Developing Organisations	SDO	The term standards developing organization (SDO) generally refers to the industry- or sector-based standards organizations that develop and publish industry specific standards (Source: Wikipedia).
Technical Committee	TC	A substructure of standards development organisations in charge of developing standards as prioritised in the work programme of the ESO or NSB (Source: CEN).
Technical interoperability		Technical Interoperability is usually associated with hardware/software components, systems and platforms that enable machine-to-machine communication to take place. This kind of interoperability is often centred on (communication) protocols and the infrastructure needed for those protocols to operate (ETSI definition).  Technical interoperability means to “[d]iscuss technical issues

<sup>43</sup> <https://www.fda.gov/ScienceResearch/SpecialTopics/RealWorldEvidence/default.htm>

		involved in linking computer systems and services” (Re eHEIF).
Technical specification		“A technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system” (Regulation of European Standardisation).
Use case		A textual and graphical depiction of the actors and operations that address information exchange in the context of a set of specific tasks for a workflow performed by different systems or devices. (ISO TR 28380-1 IHE Global Standards Adoption)
Utility		Value usually ranging from 0 (death) to 1 (perfect health) that expresses the preference that individuals or society in general have for a specific health state. <sup>44</sup>
Value chain		Michael Porter (1995) introduced the notion of a value chain in his book "Competitive Advantage: Creating and Sustaining Superior Performance". The concept of value added, in the form of the value chain, can be used to develop an organisation's sustainable competitive advantage in the business field of the 21st Century. All organisations consist of activities that link together to develop the value of the business, and together these activities form the organisation's value chain. Such activities may include purchasing activities, manufacturing the products, distribution and marketing of the company's products and activities.

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<sup>44</sup> <https://www.nice.org.uk/Glossary?letter=U>

### 3 Sources used to compile the Glossary of Terms

This DigitalHealthEurope Glossary of Terms was compiled using sources of information from the following projects to inform its development:

- ▶ CareWell project ([www.carewell-project.eu](http://www.carewell-project.eu))
- ▶ International Digital Health Benchmarking study #SmartHealthSystems (<https://www.bertelsmann-stiftung.de/index.php?id=11340>)
- ▶ BeyondSilos project ([www.beyondsilos.eu](http://www.beyondsilos.eu))
- ▶ VALUeHEALTH: Establishing the value and business model for sustainable eHealth services in Europe, <http://www.valuehealth.eu/>
- ▶ European Medical Informatics Framework (EMIF: <http://www.emif.eu>)