EHTEL
Collaborating for Digital Health and Care in Europe

Reading notes Brussels, 21/12/2022

To the attention of the
Health and Care Cluster of Large-Scale Pilots

Subject: Reference Architectures and Interoperability in Digital Platforms

This note provides **a selection and consolidation** of the relevant healthcare-related extracts included in an OPEN DEI[1] position paper entitled: "Reference Architectures and Interoperability in Digital Platforms". Attention is drawn in this reading note especially to healthcare, due to its interest to Health & Care Cluster members and EHTEL members as well. This note therefore also complements another reading note on "*Digital platforms and digital ecosystems in healthcare: towards a more open and integrative approach*" dated 20/12/2022.

In both reading notes, rather than using many direct quotes from the original documentation, areas of work from the position paper(s) are often adapted or interpreted.

Relevant extracts from

"Reference Architectures and Interoperability in Digital Platforms
[OPEN DEI] Position Paper | September 2022"

Digital platforms are online structures which permit **interactions and transactions** among users. **Economically and commercially**, as cited in the position paper:[2]

> "*From an economic viewpoint, Digital Platforms are restructuring the global economy, contributing to the digitalization of organizations, value chains and whole sectors by resetting entry barriers, changing the logic of value creation and value capture. From a commercial viewpoint, Digital Platforms ease the creation of ecosystems of stakeholders, supporting new forms of innovation and value creation, as well as related business and commercial models, focused on Digital Platforms' underlying vision and value proposition.*"

In this context, it is important to examine a **generalised set of solutions** for how digital platforms might be structured or distributed ("aligned"). Examining **reference architectures** and **interoperability frameworks** can prove useful in this regard.

[1] www.opendei.eu
[2] This quote from the position paper (p9) is, in turn, an extract from OPEN DEI's D2.1 "Reference Architecture for Cross-Domain Digital Transformation" (published October 2020): https://www.opendei.eu/case-studies/d2-1-reference-architecture-for-cross-domain-digital-transformation/

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1 OPEN DEI Reference Architectures Framework

Reference architecture models (RAM) represent a common structure and language that describes and specifies system architectures. They provide a framework for the standardisation of relevant technical systems.

The OPEN DEI **Reference Architecture Framework** (RAF) has been designed in order to build digital platforms that will support "**digital transformation journeys**" in the four business sectors targeted by the OPEN DEI project. These four sectors are manufacturing, agri-food, energy, and **healthcare**. (Note that healthcare is simply one among a total of four domains.) The overall framework is based on six principles: interoperability, openness, reusability, avoidance of vendor lock-in, security and privacy, and support to a data economy.

The OPEN DEI RAF provides an overview of what is needed in each of these four business sectors, and what is common to them. Each business sector includes **data spaces** that are based on activities such as data-sharing, data trading, and concepts of trust and security. Supporting these spaces are three sets of **services:** smart cloud services, smart edge services, and "smart world services[3]". (See Figure 1.)

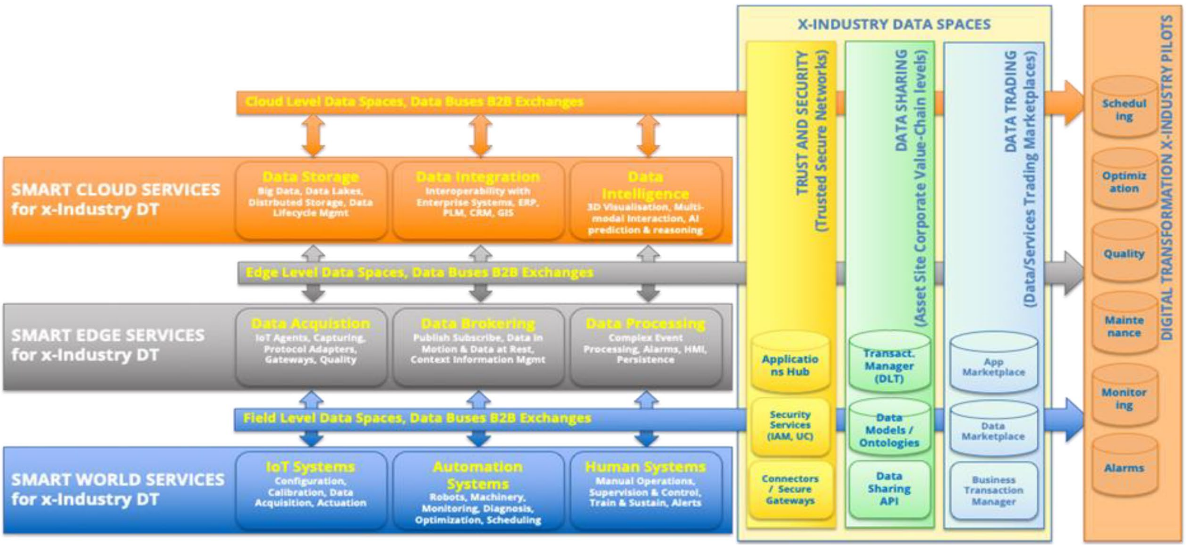

Figure 1: OPEN DEI reference architecture framework

2 A domain-independent interoperability frameworks for digital platforms

An **interoperability framework** is an agreed approach to interoperability for organisations that wish to work together towards the joint delivery of services. It can be defined as:

[3] Smart World Services for industry digital transformation refer to a range of services that can help industrial businesses to digitally transform their operations and processes. This can include items or processes like digitising workflows and processes, implementing Industry 4.0 technologies (such as the Internet of Things (IoT)), and using data analytics to improve efficiency and decision-making. Smart World Services can help companies to improve productivity, reduce costs, and increase competitiveness by leveraging digital technologies to optimise their operations and processes. (Source ChatGPT questioned on 06/01/2023.)

- a structure of processes and specifications designed to support the creation of interoperability;
- a particular set of beliefs or ideas referred to in order to enable interoperability.

An illustrative example of an interoperability framework is the **European Interoperability Framework**. The framework's **purpose** is for it to be used as a reference guide in calls for proposals and tenders in the Connecting Europe Facility (CEF) deployment, and possibly also for deployment at national and regional levels.

Initially designed for healthcare[4], the European Interoperability Framework has been adapted so that it can be applicable to all digital public services in Europe. It includes:

- **Four layers** of interoperability: legal, organisational, semantic, and technical;
- **A cross-cutting component** of the four layers, called 'integrated public service governance'; and
- **A background layer**, called 'interoperability governance'.

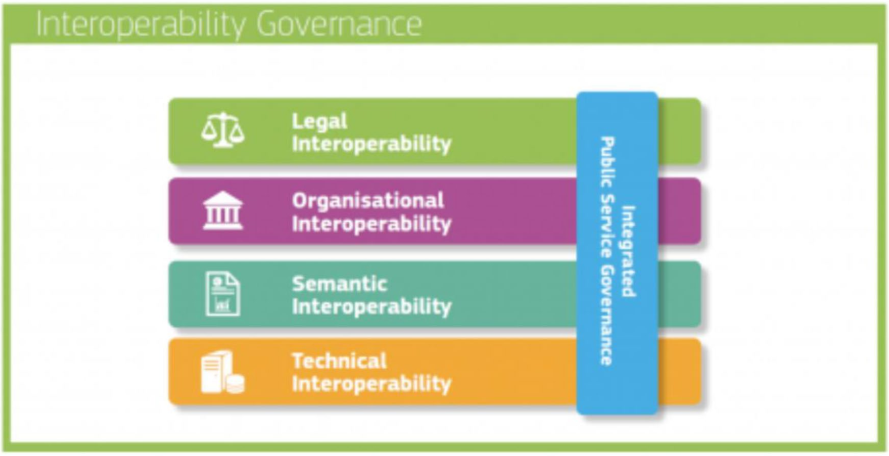

Figure 2: European Interoperability Framework

This European Interoperability Framework needs, however, to be extended in order to address the specific needs of digital platforms. Figure 3 describes such an **extended interoperability framework**.

[4] i2-Health project (517476), Deliverable D2.1 2006, was further developed by the Antilope project (GA 325077) in 2013 and adopted by the eHealth Network as the Refined eHealth European Interoperability Framework (ReEIF) in 2015.

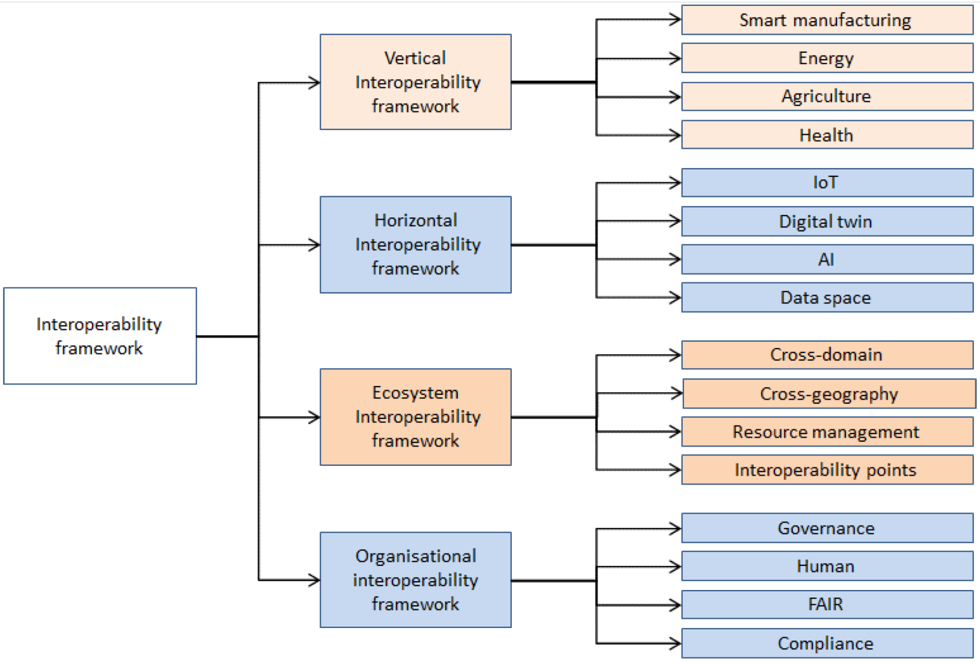

Figure 3: Extended interoperability framework

The extension of the overall interoperability framework involves four further sub-**frameworks**. These four frameworks relate to vertical interoperability, horizontal interoperability, ecosystem interoperability, and organisational interoperability. In turn, each sub-framework contains four, further, important categories of information.

Details of these additional 16 areas of work are included in the list below:

- A **vertical interoperability** framework, for domain specific needs. In OPEN DEI's case, these are: smart manufacturing, energy, agri-food and healthcare;
- A **horizontal interoperability** framework for technology specific needs: Internet of Things (IoT), digital twins, artificial intelligence (AI), and data spaces;
- An **ecosystem interoperability** framework for "systems of systems" specific needs e.g., cross-domain support, cross-geography support (i.e., geo-interoperability), resource management, interoperability points; and
- An **organisational interoperability** framework for governance, human aspects (e.g., human interoperability, empowerment), FAIR (Findable, Accessible, Interoperable, and Reusable) practice, and compliance.

3 Multidimensional interoperability

A further form of interoperability relates to what can be called "**multidimensional"** interoperability or multi-dimensional data interoperability. Multidimensional interoperability refers to the ability of systems, devices, or components to work together across different dimensions or contexts, such as spatial, temporal, and functional dimensions.

Particularly the **context** of space/the **spatial dimension** is well worth exploration. This is described specifically in terms of its meaning for a **cyber-physical infrastructure**.

The vision of a smarter cyber-physical infrastructure[5] requires a full **awareness of context**. AI systems for instance will require context-making to improve their performance and explainability: they need to be context-aware to be relevant and adaptive to changes in use cases and scenarios.

Context can be defined in the following three ways:

- Context is **multi-dimensional**. It encompasses four dimensions:
  1) Semantic (meaning and logic)
  2) Spatial (physical space and situational space)
  3) Societal (values and value)
  4) Systems (networks and ecosystems).

- Context is represented by **meta-data models** that describe the activities of people, places, and things, over time. Context needs to be shared between networks of heterogeneous devices and applications, thereby empowering them proactively to offer enriched, situation-aware, and usable content, instructions and experiences.

- Context is made up of the **elements of relationships between entities, objects, locations, and actions** – commonly known as the Who, What, When, Where, How and Why of any scenario, situation or circumstance. The answers to these six questions are currently often stored in different data silos and different data spaces. The answers need to be made interoperable, shareable, and addressable by multiple, competing AI algorithms that can maintain their coherence at scale.

Context awareness is a propriety topic of the Spatial Web Foundation[6], a not-for-profit standards organisation. The foundation is working on a **contextual model** and **communication protocol** that capture the notion of multi-dimensional data interoperability. Spatial domains enable the **secure management of digitally mediated rights and permissions** for:

- Who/what is authorised to access the domain;
- What content or data is available to view;
- Who can publish and modify content;
- Who can transact or interact with it.

4 Other topics of specific interest for Federated Digital Platforms

Under the term of “Federated digital platforms”, OPEN DEI refers to **online platforms that are designed to support decentralised and distributed networks** of users and organisations. These platforms allow users to connect and collaborate with each other and with other organisations in a way that is not controlled by a central authority.

[5] Cyber-physical systems (CPS) are physical systems that are integrated with computational and communication capabilities. They rely on the interaction between the physical components of the system and the computational and communication elements in order to perform their functions. Cyber-physical infrastructure refers to the physical infrastructure (such as buildings, roads, and bridges) that is connected to and interacts with computational and communication systems to enable and support the operation of CPS. These systems can be used in a variety of applications, such as transportation, energy, manufacturing, healthcare, and agriculture. (Source: ChatGPT questioned on 06/01/2023.)
[6] https://spatialwebfoundation.org/

OPEN DEI focused on **three topics** considered to be of interest to federated digital platforms. These were the trustworthiness of the platform, its universal resource management, and executable policies for digital governance.

Trustworthiness

The concept of **trustworthiness** can be applied to products or services, as well as technology or data, and different types of organisations or governments.

The attribute of trustworthiness is defined in the work of the International Standards Organisation (ISO). For contexts relating to AI and smart cities, ISO/IEC TR 24028[7] and ISO/IEC 30145-2:2020[8], trustworthiness is described as the ability to meet stakeholders' expectations in a verifiable way. It may include characteristics such as reliability, security, privacy, safety, and resilience, among others.

Universal resource management

Internet of Things (IoT) devices are incorporated more and more often as a data source in digital health solutions in general and digital health platforms in particular.

IoT platforms are an essential mechanism in providing interoperability because they connect various devices (e.g., sensors, access points, and data networks) and provide services to the user. Indeed, interoperability, such as requesting services and sharing resources among diverse IoT platforms, is more than simply important for an IoT environment, in practice it is essential.

The digital identities of objects are of particular importance in the context of IoT platform interoperability.

Today, **digital identities** are often managed by de facto central authorities, namely identity providers (e.g., banks, citizen's national registers). (The result is that users do not have full control over their digital identities: in theory, identity data *could* be shared between service and identity providers without any user involvement.)

Recently, new identity management models that focus on **decentralised identities** have emerged and gained traction. One of the notable examples is the model of "self-sovereign identity"[9] (SSI). The key concept in such decentralised systems is that control over identity data is put back into the user's hands. This gives a user greater control over two elements: how its identity is represented to parties that are reliant on the identity information; and, in particular, the personal information that it reveals to other parties.

This paradigm shift, from centralisation to decentralisation, poses new challenges for the **practical deployment of privacy-preserving display of attributes** (which allow the user to select attributes that should – or should not – be revealed to the service provider).

[7] https://www.iso.org/standard/77608.html
[8] https://www.iso.org/standard/76372.html
[9] Self-sovereign identity systems rely on decentralised technologies, such as blockchain and distributed ledgers, to enable secure and transparent communication and collaboration.

Executable policies for digital governance

One challenge to IoT interoperability is its support by **policy and regulation**. There is a need to maintain and enforce policies that can be interpreted and shared by both machines and humans. Existing regulations have been drafted as text with little regard for their interpretability and executability by machines.

Translating existing regulations into machine-interpretable and machine-executable code can permit the governance of the **behaviour of machines in a policy-compliant way** and dynamic adaptation of that behaviour as policies change and evolve over time.

The ultimate challenge is to determine **where and when technology can replace humans** when it comes to the interpretation of policies, and where and why not.

5 Interoperability frameworks and reference architectures applied to digital platforms in healthcare

When referring to Interoperability in the healthcare domain, people usually just consider the communication challenge. Therefore, they do not use reference architectures, but – rather – address the four basic eHealth interoperability layers: legal, organisational, semantic and technical. However, when moving to more complex, interdisciplinary systems, an architectural approach is inevitable[10], [11]
62,63.

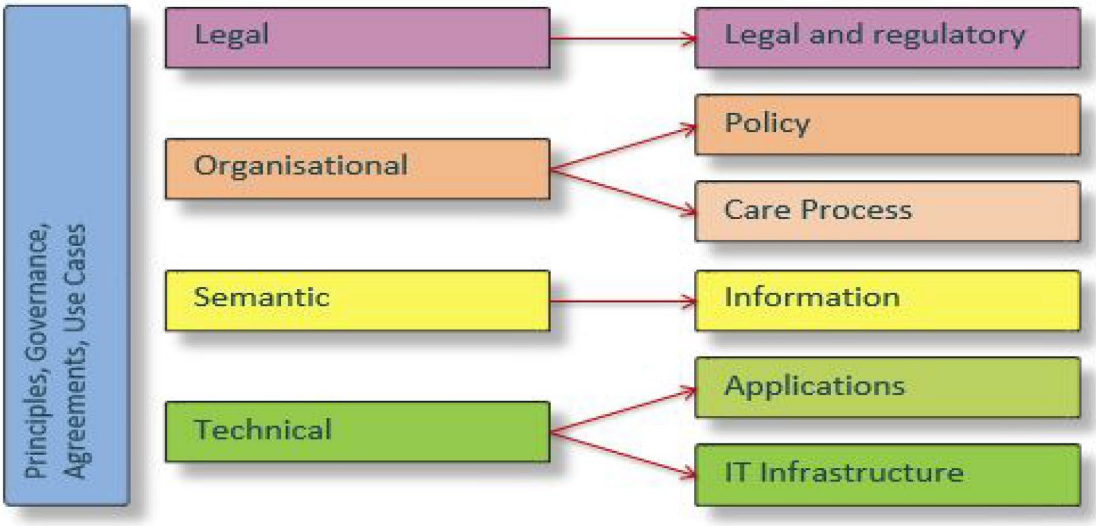

Figure 4: eHealth interoperability layers [12]

[10] Blobel, B., Ruotsalainen, P., Oemig, F. (2020) Why Interoperability at Data Level Is Not Sufficient for Enabling pHealth? Stud Health Technol Inform. 2020; 273: 3-19

[11] Blobel, B., Oemig, F., Ruotsalainen, P. Lopez, D.M. (2022) Transformation of Health and Social Care Systems—An Interdisciplinary Approach Toward a Foundational Architecture. Front. Med. 2022;9:802487. doi: 10.3389/fmed.2022.802487

[12] Source: Refined eHealth European Interoperability Framework, adopted by consensus by the eHealth Network, Brussels, 23 November 2015 https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5b56dffdc&appId=PPGMS

Those four interoperability layers can also be mapped onto all the **different stakeholders** who intervene in the digital health value chain at three levels: strategic, tactical, and operational.

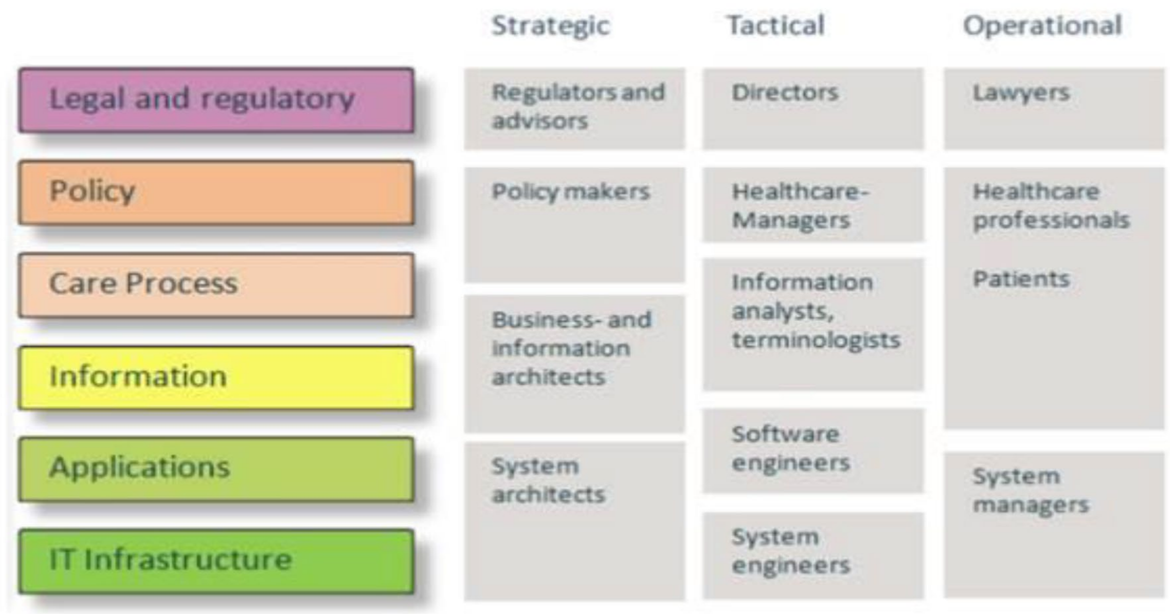

Figure 5: eHealth Strategic, Tactical and Operational viewpoint

Experts from the **large-scale pilots' projects of the OPEN DEI healthcare cluster** have come to a number of conclusions when comparing the reference architectures of their various projects[13].

A **reference architecture** for digital platforms selection/development should be technology agnostic, and should identify at least the four following aspects:

- **System stakeholders** (including users, operators, owners, developers, maintainers);
- **Fundamental concerns** (including the purpose of the system, suitability of the architecture to fulfil the set objective, feasibility, risks, maintainability, evolution);
- **Architecture** views (representing a related set of concerns as seen from the perspective that a view is taken, i.e., it is a "viewpoint"); and
- The **rationale** for each important **architecture decision**.

The **CREATE-IoT**[14] **3D RAM** was considered as sufficiently broad to describe each of the large-scale pilot project's architecture comprehensively. For this reason, the experts have proposed the CREATE-IoT 3D RAM model as a standard Reference Architecture Model (RAM) to be used in future digital healthcare and any Ambient Assisted Living (AAL) projects.

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[13] See the article "Reference Architectures, Platforms, and Pilots for European Smart and Healthy Living—Analysis and Comparison" published by MDPI and available at https://www.mdpi.com/2079-9292/10/14/1616

[14] https://european-iot-pilots.eu/project/create-iot/

Figure 6: The general structure of CREATE-IoT 3D RAM

7 Conclusion and Recommendations

As a result of formulating this overview of the challenges faced by digital platforms that cut cross a variety of domains, the OPEN DEI project came up with **two specific recommendations.** The first one relates to the need for a **cross-domain convergence framework**; the second refers to the **building blocks** associated with the design of data spaces.

The first recommendation is to **agree on and standardise a cross-domain convergence framework**. It involves two construction processes, one related to architecture and the other to interoperability:

- An **architecture construction process**, whereby the resulting construction platform solution architectures can have integrated in them two aspects of architecture i.e., both the OPEN DEI reference architecture framework and the architecture orientation of the BSDA initiative[15].

- An **interoperability construction process** which enables the identification of interoperability points, cases, and profiles. Interoperability **points** are where interoperability takes place in an architecture. Interoperability **cases** outline why

[15] BDSA stands for Business-Driven Software Architecture. The BDSA initiative an industry group or organisation focused on promoting best practices and standards for business-driven software architecture in the digital platform space.

interoperability is needed. Interoperability **profiles** are specifications that leverage transport, syntactic, semantic, behavioural, and policy, interoperability.

The second recommendation is to **agree on and standardise associated building blocks in the design of data spaces**. The OPEN DEI design principles for data spaces position paper[16] identifies four categories of building blocks on infrastructure, trust, data value, and governance:

- The infrastructure category which includes
  1) the data models and formats,
  2) the data exchange APIs[17], and
  3) the provenance and traceability building blocks;

- The trust category which includes
  1) the identity management,
  2) the access & usage control / policies, and
  3) the trusted exchange building blocks;

- The data value category which includes
  1) the metadata & discovery protocol,
  2) the data usage accounting, and
  3) the publication & marketplace services building block; and

- The governance category which includes
  1) the overarching cooperation agreement,
  2) the operational building blocks, and
  3) the continuity model building blocks.

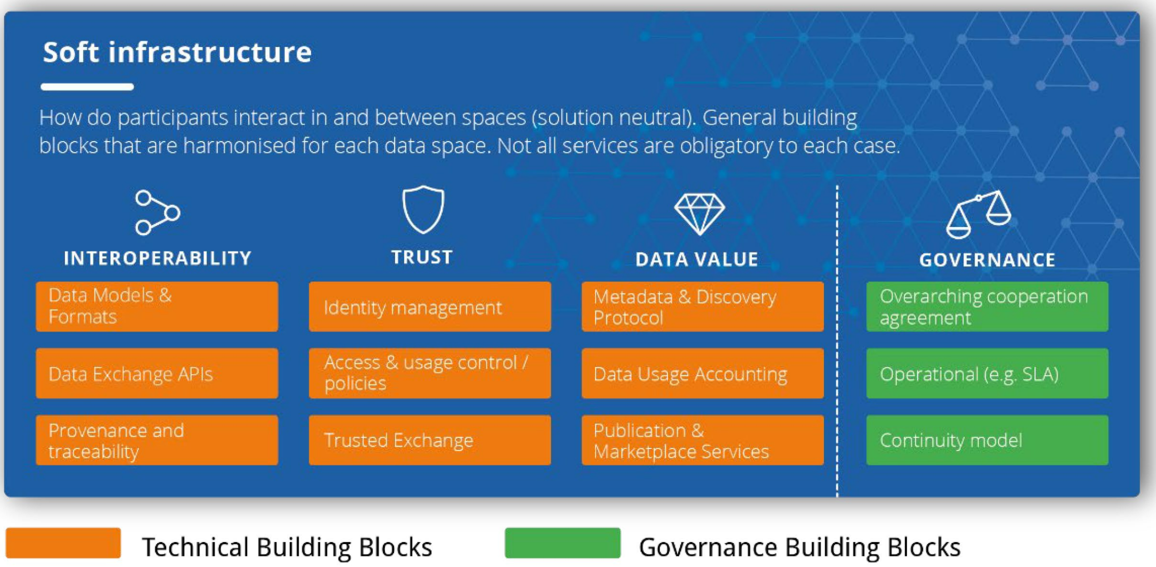

Figure 7: Data spaces building blocks

[16] See on OPEN DEI website, in the Resource section: https://www.opendei.eu/case-studies/workshop-on-the-common-european-mobility-data-space-02-december-2021/
[17] Application programming interface.