eHAction
Joint Action supporting the eHealth Network

D8.2.3 - Proposal on adopting a European eHealth Reference Architecture

WP8 - Integration in National Policies and Sustainability

Version 1

13-04-2021

For adoption

This document addresses the important topic of creating and adopting a European eHealth Reference Architecture aligned with the eGovERA framework.

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Acronyms and Abbreviations

Acronym	Description
ABB	Architectural Building Block
CBeHIS	Cross-Border eHealth Information Servicesystem
DBC	Digital Business Capability
DPS	Digital Public Service
EA	Enterprise Architecture
eHAction	eHealth Action
eHDSI	eHealth Digital Service Infrastructure
eHealth	Electronic Health
eHN	eHealth Network
eHRA	eHealth Reference Architecture
EIF	Enterprise Interoperability Framework
EIRA	European Interoperability Reference Architecture
EU	European Union
GDPR	General Data Protection Regulation
HHS	US Department of Human and Health Services
ICT	Information and Communication Technology
mHealth	Mobile Health
MWP	Multiannual Work Programme
NCP(s)	National Contact Point(s)

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Executive Summary

The diffusion of eHealth in Europe is speeding up. The Directive 2011/24/EU[1] on patients' rights in cross-border healthcare promotes policy co-ordination and Member State cooperation in eHealth through the eHealth Network (eHN), established by Article 14. In 2014 the eHN (Minutes – Topic 3: Connecting Europe Facility (CEF)[2]) adopted four priorities for eHealth:

- Cross-border ePrescription and eDispensation service,

- Cross-border patient summary service,

- eHealth services for European Reference Networks,

- Infrastructure services for interoperable Patient Registries,

Through the adoption of cross-border eHealth information services (CBeHIS) and overcoming implementation challenges. According to the common 'European strategy for data'[3], Member States have to upgrade and streamline national digital health systems in order to participate in and benefit from the future European Health Data Space (EHDS) for primary and secondary use too[4].

The eHN, through eHAction[5] and several subgroups operating under the eHN, is actively working on establishing a European eHealth vision, developing innovative and cross-border eHealth applications, which have been successfully implemented via ICT. Such ICT developments, carried out via eHealth programmes benefitting from large EU investments, aim to constitute a source of standardisation and interoperability of services and a valuable knowledge exchange platform.

However, strategic alignment and integration of the vast services that have been developed may not continue, anticipate problems or be future-ready if a holistic architecture for eHealth is not adopted.

Most of the solutions developed in the eHealth environment depend on each other to function properly, or only make total sense when they are interconnected. As such, through this document we aim to promote the importance of outlining a Reference Architecture for eHealth based on the Health eGovERA framework, resulting in eHealth interoperability.

This comprises of setting the reference architecture to assist eHealth programmes in reducing duplication, increasing the use of shared services, advancing common planning of eHealth synergies, closing performance gaps, and promoting the empowerment of the European eHealth strategy and goals.

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[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0024

[2] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20140513_mi_en.pdf

[3] https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

[4] https://ec.europa.eu/digital-single-market/en/news/member-states-meet-european-commission-discuss-protection-personal-data-health-sector

[5] http://ehaction.eu/mission-ambitions/

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1. Introduction

An architecture is a formal description of a complex whole, and of the principles that are applicable to the development of that whole and all its components. The term architecture is often used as a metaphor for structuring abstraction, to illustrate the importance of an enterprise architecture (EA) approach: It would not be considered appropriate to construct a building without a design or an architectural layout of the whole building. According to the EA approach, the same applies to building and changing organisations.

This analogy is extended to highlight the inappropriateness of developing digital health public services without a quality assurance tool, the eGovERA Health RA. Without an EA-based development of business resources or systems in an environment, the result could be resource duplication, lack of integration, inefficient information exchange or ineffective technology support, lack of valuable information to decision makers and a dispersion of information developed towards eHealth. These issues raise the need for a framework that provides a high-level knowledge about the previous and current projects supported by the European Commission.

A reference architecture is a technology independent content metamodel with a focus providing a baseline for the most salient architectural building blocks to analyse and design a digital solution. In our case, the focus is health digital public service. The adoption of a reference architecture accelerates the delivery through the re-use of building blocks and by the provision of a governance model to ensure consistency and applicability of the used technology. The benefits of this include:

- Improvement of interoperability by establishing standards and common mechanisms for information exchange;

- Reduction of development costs through the reuse of common assets;

- Improvement of national and cross-border communication, since stakeholders share the same architectural mindset.

This document was previously presented to the Commission and, as a result, one representative of the working group and of the Commission were selected to participate in the development of the Health eGovERA[6] framework. The eGovERA framework is a set of solutions for eGovernment portfolio management and digital transformation support decision-making for European public administrations based in the eGovERA Health RA and in the eGovERA Business Agnostic RA. After an eHN request, the topic of health was included in this framework in alignment with the eGovERA Health RA work to date and Commission needs. The use of this tool will be described in this document. Through the cooperation with the eGovERA team a document revision was performed to bring a high-level principle for the implementation of an eHRA in the Member States, aligned with the eGovERA framework.

The presented work contributes to the eGovERA Health RA with the provision of a governance model and recommendations to sustain the eGovERA framework. This framework can contribute to the normalisation of European digital health services and can provide the identification of different digital public services and architectural building blocks that are needed to realise any given digital business capability. The eGovERA also enables Member States to identify the funding mechanisms available to invest in each digital business capability. The first steps of the Health eGovERA project are to provide a tool to identify EU funds available for each digital public service and to support the management of the digital transformation, by taking into consideration existing EU and national building blocks.

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[6] https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/solution/egovera

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1.1.   Background

Digitalisation is driving consumers, companies and governments in search of greater efficiency and quality. Although Member States are at different development stages of maturity, they are engaged to develop strategies that promote digitalisation and innovation in the health sector. In order to accelerate Europe's digital transition within the health sector, all Member States should be aware of the benefits of sharing experiences and knowledge on eHealth. Therefore, it is fundamental to outline, propose and conceptualise a reference architecture for a coordinated European eHealth landscape and collect feedback about potential enhancements.

It is essential that the current EU governmental architectural frameworks are identified and compared with the current eGovERA Health RA proposal. One of these frameworks is EIRA[7] (European Interoperability Reference Architecture), which defines a reference model defining the most salient architectural building blocks needed to build an interoperable eGovernment system. The eGovERA Health RA intends to deliver a comprehensive set of viewpoints for decision makers in the eHealth landscape. eGovERA Health RA has a strong policy/strategy scope and is specific to eHealth scenarios.

The eGovERA framework is related with all digital public services across different areas (e.g. health, tax, education, etc.). The eGovERA vision consists of supporting the next generation (for 2030) of European digital public services enabling business continuity, transformation, and co-existence with the current state of affairs. It intends to help identifying the set of building blocks required by health digital business capabilities and the digital transformation roadmap in which they should be tackled, thus providing a strategic orientation for EU funds requests.

The eHRA (initial propose) was firstly developed to address the need of a reference model to navigate, manage and coordinate the development of the eHealth services within the EU. The main goal of this approach was to define the layout of the organisational components and the associated relationships among them, in order to understand the integration of objects for further improvement, based on an understanding of the totality. The rationale behind the initial development of the document was that 'European eHealth governance can benefit from a set of formalised enterprise architectural views'. The reference architecture supports complex changes in the meta-level governance environment, provides transparency and decision-making support, and allows onboarding of actors new to the system.

In July 2020, the eHN analysed the draft D8.2.3 eHRA document in order to ensure that the scope of the document enables the eHN vision relating to eHRA. On 23rd July 2020, the eHN requested eHAction to change the scope of the proposal and align the eHRA with eGovERA in order to include the health domain in the eGovERA framework. A health working group was created under the eGovERA domain, led by DG DIGIT, aiming to develop the elements of the eGovERA Health Reference Architecture, using some relevant principles from this draft document. The group was composed of DG DIGIT members and one Member State representative (Portugal), who worked together from September 2020 to January 2021 to elaborate the Health eGovERA in alignment with Member State needs and the eHN vision.

The result of this integrated work is the development of the eGovERA Health RA tool, that will help the Member States clearly identify problems and solutions, through the identification of all the needed health public services and the building blocks supporting the public health services. This will simplify the implementation of the needed building blocks and assist Member States in the applicable identification of costs.

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[7] https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/about

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The Health eGovERA Health RA tool is currently undergoing the early stages of piloting. In this phase, two Member States will be selected that have not previously worked on the development of the tool with an aim to using and reviewing it, elaborating a structured feedback to support the improvement of the Health eGovERA Health RA tool.

This development group of the eGovERA Health RA has identified five use cases which the tool could support. Below are the identified use cases on eGovERA Health RA that will be described further on in this document:

1. Applying for EU Funds Support in eGovernment and Digital Transformation
2. Digital Public Services Portfolio Management Decision Support
3. National Digital Agenda Support
4. eGovernment High-Level Architecture Design Support
5. ICT EU Legislation Impact Assessment Support

The original eHRA model can be found in Annex 1, in order to illustrate the elaboration process that was conducted by the working group. This model shared some principles with the eGovERA framework, and it supported the eGovERA Health RA development.

From this moment on, any reference to the 'eGovERA Health RA' will relate to the 'Reference Architecture Framework'. The reference to eHRA means the set of digital public capabilities, digital public services, architectural building blocks specific to healthcare sector, which are instantiated on eGovERA framework.

1.2.   Scope

The reference architecture for a coordinated European eHealth landscape offers a framework that creates a set of views, combining the vision and strategy, business architecture, information systems, and technology domains. The eGovERA Health RA should provide the eHealth Network and the associated Member States with a reference model and a governance framework to be used as a high-level planning tool that provides an overview of eHealth services within the Member States and support them in the identification of all the health services needed to realise the needed digital capability and, therefore, it supports them in the specifying the expected benefits and use of the requested resources.

This document contributes to the development process of the eGovERA framework and eHN for eHealth at EU and national levels. From the perspective of Member States, it proposes an umbrella architecture that aims for a common view of national and European initiatives and the value provided by those initiatives. This reference architecture should not interfere with EU Member State policies but can be used as a tool to support the Member States in the identification of the health public services components needed for their functioning and improvement.

1.3.   Motivation and Goals

The proposal on a European eGovERA Health RA aims to propose to the eHN and the Member States the adoption of a reference architecture and a governance framework for this architecture to be used as a high-level planning tool that provides an overview of eHealth services within the EU. The reference architecture is reflected in the eGovERA framework, which provides a structure that aims to constitute a model to navigate, manage and coordinate the development of the health services in the Member State in a sustained manner. At the same time, it should aim to deliver a set of

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comprehensive viewpoints for decision makers on the current eHealth landscape within the Member States.

The overall purpose of the document 'Proposal on adopting a European eHealth Reference Architecture' is categorised in two main parts:

STREAM I – Reference architecture framework: this involves the definition of conceptual reference architectural artefacts that are needed in order to build a reference architecture for eHealth services in EU.

Reference architecture cartography: this involves mapping existing solutions towards the conceptual reference architectural artefacts. To pursue this cartography, a macro working plan proposal is needed for the development and implementation of a reference architecture for eHealth services within the EU.

A reference architecture framework captures the fundamental patterns and concepts that should be applicable for all domains and more specific architectures. It identifies at high level the different components or architectural artefacts needed for more specific implementations. It can also serve as a guide towards designing more specific reference architectures. In order to accomplish the creation of this conceptual reference architecture, there is a need to:

- Identify all the architectural artefacts that are required to deliver a coordinated national eHealth landscape;

- Identify how these architectural artefacts relate to each other;

- Propose a governance framework that represents the structure and the architectural artefacts that support the initiatives promoted by the EU.

STREAM II – A governance framework to provide appropriate mechanisms to support the oversight of the eGovERA Health RA. This governance framework may assist the board and management in fulfilling their governance roles and responsibilities.

Governance identifies the planning, decision-making, and oversight processes and groups that will determine how the EA is developed, verified, versioned, used, and sustained over time with respect to measures of completeness, consistency, coherence, and accuracy from the perspectives of all stakeholders. This pillar addresses several accountabilities on executives and stakeholders, namely in leadership aspects, organisational structure, and procedures that ensure that European eHealth supports and achieves its goals and follows the defined strategies.

To fulfil such responsibilities, as well as attain its strategies and goals, the network must understand the status of the eHealth programmes and decide what governance initiatives and controls must be provided to obtain the necessary conditions for the network to move towards achieving these strategies and goals.

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2. The Importance of Adopting an eHealth Reference Architecture

2.1. Understanding the Main Concept of Health eGovERA Framework

This chapter intends to present a generic view about the enterprise architecture and the eGovERA framework use cases related with the health domain.

Enterprise architecture (EA) is a strategic activity and planning tool, which facilitates decision-making by enabling a conceptual and holistic view on the subject, which can be an organisation, consortium or, as in the eHealth case, an ecosystem.

In the EA Community[8], enterprise architecture is a framework or 'blueprint' for how the enterprise (one organisation or a group) achieves current and future objectives. It examines the key business, information, application, and technology strategies and their impact on business functions. Each of these strategies is a separate architectural discipline and EA is the glue that integrates each of these disciplines into a cohesive framework. Aligned with eGovERA framework, Figure 1 identifies the main architectural layers needed to set guidelines for developing public services.
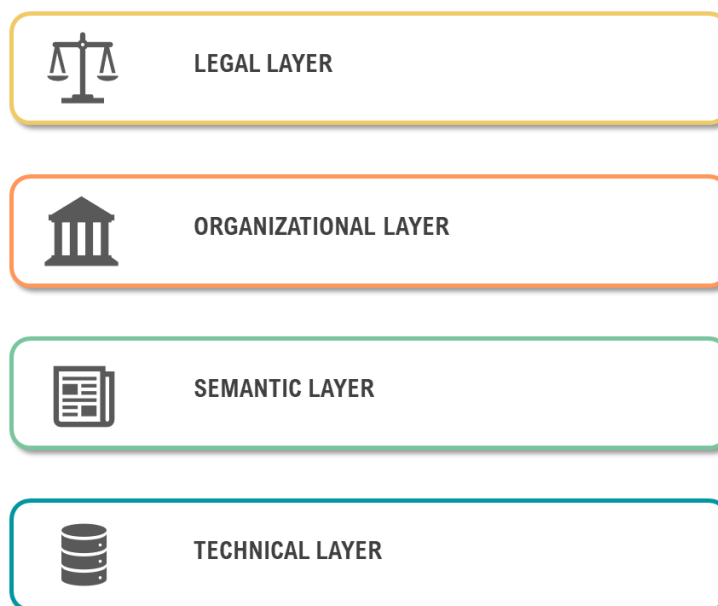

LEGAL LAYER

ORGANIZATIONAL LAYER

SEMANTIC LAYER

TECHNICAL LAYER

Figure 1 – Architecture Layers aligned with the eGovERA framework.

The legal layer aims to ensure that Member States operating under different policies and legal frameworks can work together and legislation does not hinder the development of European public services[9]. This layer includes the architectural building blocks (ABBs) related to the different legal acts, frameworks, policies and strategies influencing or governing the digital public services.

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[8] http://www.eacommunity.com/resources/download/bolton_what.pdf

[9] https://joinup.ec.europa.eu/collection/nifo-national-interoperability-framework-observatory/european-interoperability-framework-detail

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The organisational layer aims to document and align business processes and relevant information exchanged[10]. This layer includes the ABBs related to public administration business processes, responsibilities and expectations to achieve commonly agreed and mutually beneficial goals.

The semantic layer ensures that the precise format and meaning of exchanged data and information is preserved and understood between parties[10]. It describes the data's physical and logical aspects, as well as the management of the data resources. In the context of eHealth, data governance must be considered, enabling primary and secondary use, in compliance with privacy and security principles. This layer includes the ABBs related to format and meaning of exchanged data and information.

The technical layer covers the applications and infrastructures linking systems and services. It provides the foundation that supports the applications, data and business processes identified in the other three architectural layers. This layer covers the ABBs related to the applications and infrastructure systems and services.

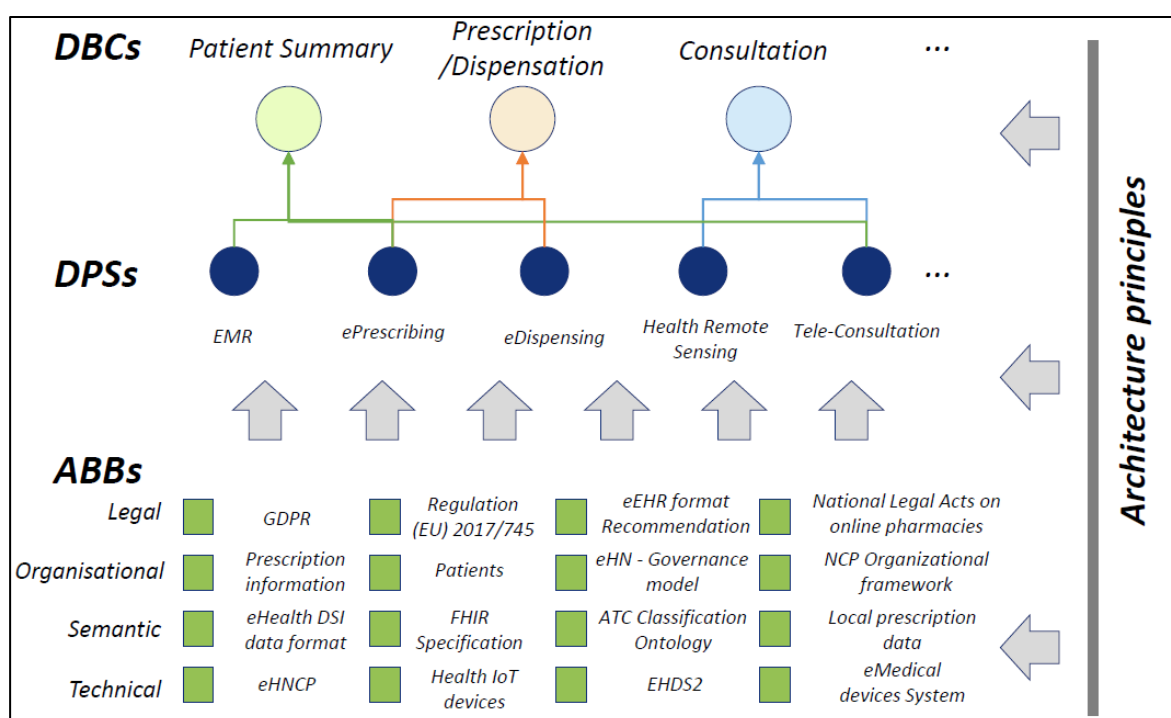Figure 2 identifies the relationships among the main elements of the eGovERA Health Reference Architecture:

Figure 2 – eGovERA© Reference Architecture Components

Below is described the principles presented on the figure 2:

- **Domain** - Policy domain to which the digital public services belong. In particular: 'Health' or 'Business Agnostic' (BA).

- **Digital Business Capability (DBC)** – DBCs are the key skills and capabilities a company or a government requires to transform itself into a sustainable and successful business by considering digital technology as the enabling component.

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- ***Digital Public Service (DPS)*** – An interoperable DPS is a service provisioned by or on behalf of a public administration in fulfilment of a public policy goals servicing to users either citizens, businesses or other public administrations. A European public service comprises any public service exposed to a cross-border dimension and supplied by public administrations, either to one another or to businesses and citizens in the Union. One or more DPS can realise one DBC.

- ***Architectural Building Blocks (ABB)*** – An abstract component that captures architectural requirements and directs and guides the development of DPSs. An ABB represents a re-usable component of the four presented layers: legal, organisational, semantic and technical.

2.2.   The eGovERA Use Cases

The eGovERA framework is currently being developed around five use cases defined by the Commission, with an aim to support the Member Sates in the health landscape. Below is a brief description of these use cases and their relationship with the initial eHRA (Annex 1).

2.2.1. Applying for EU Funds Support in eGovernment and Digital Transformation

This use case is intended to help identifying the set of building blocks required by health-related digital business capabilities and the digital transformation roadmap in which they should be tackled, thus providing a strategic orientation for EU funds requests.

Through populating the eGovERA platform with data on national building blocks related to health, and based on the resulting assessment, it is possible to identify a quadrant illustrating the prioritised digital business capabilities and the Member State's ability to deliver them; it will result in the identification of the applicable public services that can be improved or developed. The eGovERA Portal will illustrate all the building blocks required to be implemented or improved for the functioning of the service. Based on this information, the Member State can decide whether to request the support of the European Commission to develop one or more digital business capability in order to start its digital transformation process. In the last phase of this process, the Member State leverages the results of the eGovERA Portal to justify the request for funds to the European Commission.

In a similar way that was initially proposed by the eHRA, it is possible to identify all the Member State health building blocks related to public services and analyse which ones should be prioritised to be developed or improved in order to meet national needs.

2.2.2. Digital Public Services Portfolio Management Decision Support

This use case intends to identify a series of elements in order to support the management of decisions related to the health-related digital public services. Some key elements can be seen below:

- Describe the state of the art on the digital business capabilities;
- Establish benchmarks;
- State priorities;
- Define a roadmap to deliver those digital business capabilities.

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The Health eGovERA tool, related to business capabilities assessment and the eGovERA transformation roadmap, can be used to identify and prioritise the digital business capabilities that need to be developed or improved, considering the specifics of the state of affairs in the Member State.

2.2.3. National Digital Agenda Support

In some cases, it has been difficult for Member States to identify the objectives and priorities for their national digital agenda, considering that the Health eGovERA tool can support the Member States in addressing this task.

The Health eGovERA portfolio management decision support and the eGovERA digital transformation roadmap will provide guidance to identify the objectives and the priorities on the digital transformation journey. Based on it, the Member State can define a logical roadmap considering the areas that needs development, avoiding duplication of work and reusing the already existents ABBs.

2.2.4. eGovernment High Level Architecture Design Support

The design of the health digital public services can be a hard activity due to the need to identify all fundamental elements that should be implement in my digital public services.

The Health eGovERA reference architectures can be used as a model to guide the development of digital public services (one or multiple in a specific policy area), starting from the needed organisational elements to be put in place, to base registries and systems to be developed or modernised.

2.2.5. ICT EU Legislation Impact Assessment Support

The legal requirements relating to implementation of digital public services must always be considered prior to the design and implementation of any public service. The identification of the related legislation must be taken into account, in order to avoid legal issues on the development of the project.

The Health eGovERA will provide a set of reference architectures, per different policy area, where relevant legislation at EU level is taken into account. Health eGovERA can help public administration officials understand the impact of such legislation when developing digital public services.

2.3.   How the Adoption of the European eHealth Reference Architecture can Support Policy Decision Making

The adoption of an eGovERA Health RA intends to help in identifying the set of building blocks that are required by the healthcare sector, such as health-related digital business capabilities and the digital transformation roadmap in which they should be tackled, considering the identified areas that still need more investment in the national health landscape thus providing a strategic orientation for specific EU funds requests.

This approach can bring some benefits to the Member States such as:

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- **A clear definition of elements to be financed**

  o Identifying all the needed digital health public services at the national level and evaluating the need of investment considering the current maturity level through a score classification;

  o Identifying the building blocks supporting the digital health public services to be implemented based on the previous evaluation, which will optimise the health investments by prioritising the less developed or non-existent building blocks;

  o Defining a clear step-by-step guide to the implementation of the required building blocks. By identifying the co-dependencies with other building blocks and reusing the already existent structure, duplication of work will be avoided, and in doing so defining a solid efficient implementation plan will be assisted.

- **Enables group decision-making**

  o Supporting Member States in the identification of the associated costs, enabling a faster definition of the cost break-down structure.

  o Supporting Member States in the identification of clear benefits and designation of the use of the needed resources.

  o Providing valuable information for the policy makers, based on the eGovERA tool, with robust scores and a clear benefit list to support the policy decisions based on concrete data. Enhancing the maturity development of the health sector.

- **Holistic approach aligned with LOST (legal, operational, semantic, technical) layers**

  o Achieving a holistic approach, including an architectural view that is in alignment with all the LOST layers.

- **Clear sequence of activity steps to be included in the national digital agenda**

  o Indication of the Member State journey to develop the proposed use cases.

  o Quick assessment of strategic focus to prioritise the Member State's key objectives.

- **Alignment with a European reference model**

  o A European reference model, detailed per policy area and including the infrastructural elements.

The eGovERA model includes the relevant EU legislation and national legislation.

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3. POLICY AND GOVERNANCE FRAMEWORK DESCRIPTION

3.1.   Need for an eHealth Reference Architecture Governance Framework

Governance identifies the planning, decision-making and oversight processes and groups that will determine how the EA is developed, verified, versioned, used, maintained and sustained over time with respect to measures of usability, completeness, consistency, coherence, and accuracy from the perspectives of all stakeholders. Governance places several accountabilities upon executives and stakeholders, namely in leadership aspects, organisational structure, and procedures that ensure that the European eHealth supports and achieves its goals and follows the adopted strategies.

To fulfil such responsibilities, the governance framework must account for the status of the eHealth programmes and decide which governance initiatives and controls must be provided to obtain the necessary conditions for the network to move towards these strategies and goals.

A proposed set of actions to accomplish this goal should involve the following stages:

1. Define the stakeholders, roles and responsibilities involved in the identification and definition of digital public services, digital business capabilities and architectural building blocks, responsible for the overseeing of the eGovERA Health RA;

2. Identify recommendations for future work regarding the needs for digital transformation.

3.2.   Guiding principles

Considering that EA is most effectively practised when applied in a common way at all levels of scope (national to regional), it is crucial to adopt common principles or general rules that can constrain how the network should fulfil its mission, guiding its stakeholders on the actual design and analysis work that goes into the common programmes and projects.

EA can be the key business to define the best practices that may enable eHealth envisioned efforts to evolve their effective initiatives of today in a roadmap towards the future. It can help to define a clear picture of a broadly accepted vision to guide the mission.

When perceiving the necessity to propose a European eGovERA Health RA, some principles were identified, namely:

Security and Privacy

It must be assured that patients and healthcare providers interact with eHealth systems in an environment of trust and in full compliance with the legislation at national and European levels, e.g. Network and Information Security Directive and General Data Protection Regulation; furthermore, eIDAS conformity for personal identification; this means that eHealth services must guarantee that the privacy of patients and the security and confidentiality of information provided by businesses are respected.

Appropriate security monitoring and planning, including an analysis of risks and contingencies and the implementation of appropriate contingency plans, must be completed to prevent unauthorised access to relevant information. It must ensure that whoever has authorised access will make proper use of data. With a security event log, all activity could be controllable. This principle is enforced

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more specifically to identity management and security specifications with regards to the usage of technological standards and protocols, notably with specifications of the audit trail. Additionally, EA helps the community apply the principles of the GDPR and incorporate them into the architecture design.

Transparency

Within the necessary security constraints, patients and healthcare stakeholders must have the right to verify the information that national and/or European systems have collected from them at both levels and have a meaningful pronouncement on whether this information may be used for purposes other than those for which it was originally agreed. Patients and National Contact Points for eHealth should be able to understand administrative and business processes. They should have the right means to track their procedures and have insight into the principles behind decisions that could involve them.

Preservation of Information

Preservation of all electronic information exchanged at the European level must be stored at the national level in accordance with GDPR and national legislation. The goal is to ensure that relevant data is kept along with its legibility, reliability and integrity over time and can be accessed by the relevant parties, considering a common compliance regulation, via security and privacy principles.

Openness & Reusability

Interoperability involves sharing and exchanging information and knowledge between relevant stakeholders and organisations; hence, such an environment implies a certain degree of openness and standardisation. Reusability can be the key to an efficient development of European eHealth services. Reusability means that organisations confronted with a specific problem seek to benefit from the work of others by looking at similar problems solved by others, assessing its usefulness or relevancy to their own and decide to benefit from the solutions that have proven their value elsewhere.

Interoperability Standards

To reach interoperability, it is imperative to adopt common functional needs and meet them with 'open' technology, avoiding 'tight' technologies or products not interrelated to each other.

In the roadmap towards European eHealth, Member States should be able to easily adapt and mature their technological environment without compromising their activities. Member States should continue to give access to their eHealth services sovereignly from any explicit technology, product or provider, but universal standards and protocols must be defined so interoperability is easily achieved.

By coupling in standards, Member States will allow maximum interoperability between each other without compromising evolution, being ready to cope with change.

3.2.1. Involvement with Stakeholders

The communication and reporting of an EA function is an important driver in maintaining an understanding of current capabilities and future options for the eHealth mission; a repository of architecture artefacts, plans, solutions, and other information may not be enough. What the EA recommends is a regular reporting procedure on capabilities and options through the lens of the architecture, delivered in a standardised way and from common dashboards for overall analysis on progress of the eHealth developments.

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In order to ensure the fulfilment of the presented Reference Architecture for Health, the definition of a robust and stable governance model is required. This subchapter aims to provide further insights into the responsibilities that should fall upon the eHN Subgroup on Semantics and the eHN Technical Subgroup.

Considering that the eGovERA framework is structured in four layers, previously presented, the eHN Subgroup on Semantics and the eHN Technical Subgroup should be responsible for overseeing the management of the ABBs, regarding their respective layer of expertise. These Subgroups should exert the functions under the influence of the eHN and have strict communication between them in order to achieve mutual support.

In particular, the eHN Subgroup on Semantics should have the ability to set up rules to identify new semantic building blocks, formulate recommendations on the use of common semantic standards at EU level, manage the common EU health semantic services, act as a repository for semantic assets and convey strategic decisions regarding semantics to the eHN.

The eHN Technical Subgroup should contribute to a robust and stable structure regarding technical interoperability issues, as well as providing recommendations for new ABBs, aligned with the needs of the organisational and semantic layers. This subgroup should support the eGovERA tool in reaching substantiated decisions, strategies and measures on technical interoperability issues, to facilitate growth and innovation of the EU eHealth landscape.

For the legal and organisational layers, no specific eHN subgroup exists at this moment. The eHN should define how to address the needs of those layers in the future.

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3.2.2. Recommendations

The clear identification of all health structures, capabilities and building blocks, aligned with their respective level of maturity, could be a hard task for the policy makers in different Member States. The need is focused on understanding the relationships and dependencies between business strategy, organisational structure, business processes and supporting information systems in the overall context of enterprise architecture at national level, in order to identify EU funds that meet national needs. It encompasses multi-disciplinary topics, ranging from modelling business processes, through developing enterprise ontology and architectures, and representing information system services, to identifying best practices and patterns.

Recommendation 1: Secure and take advantage of achievements of other EU projects

The relationship between digital public services/architectural building blocks and outcomes of past/ongoing/future workgroups would allow the Member States to get to know and get access to what has already been accomplished in previous EU projects. To make full use of available outcomes from past and ongoing EU workgroups, the outcomes should be presented in a concise and simple manner to Member States. The eGovERA tool addresses the opportunity for Member States to align their national policies and strategies with EU initiatives. At the same time, it would enable the Member States to follow recommendations included in project deliverables, identify interoperability standards and common regulations for cross-border information exchange and provide some direction for implementation. As a result, reusable components bringing more stability, rationalisation and increased quality of services. More specifically, this would avoid duplication of effort, extra costs and further interoperability problems.

Recommendation 2: Identify the Architectural Building Blocks regarding the National Landscape

The Commission should identify the key ABBs that are needed, at a national level, to implement the different health services. This activity will also support the Member States to adapt the implementation of the eGovERA health tool according to their specific needs. The eGovERA tool, as a reference architecture, should be able to recommend the best practices to the Member States.

Recommendation 3: Ensure the existence of feedback mechanisms to the Member States and the Commission, regarding the eGovERA framework

eGovERA aims to be a sustainable framework. It should integrate a survey to collect the user experience in Member States. A process should be leveraged by the framework owner to review, periodically, whether the tool meets Member State expectations and needs. Considering the comments provided by Member States, a report should be prepared and made available for consultation with Member States and the Commission. The evaluation of the framework functionalities would enable a continuous improvement, by adjusting them to needs of the Member States.

Recommendation 4: Ensure a process of continuous update of ABBs in the eGovERA framework

Digital public services are composed of architectural building blocks, which are divided in to four layers: legal, organisational, semantic and technical. Considering the natural and constant evolution characteristic of the healthcare sector, new building blocks could arise. The eGovERA framework should be able to incorporate these new building blocks as soon as they are identified.

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Recommendation 5: Addition or Revision of ABBs should be leveraged by the existing eHN subgroups

The relevant eHN subgroups (Subgroup on Semantics, Technical Subgroup) should be responsible to propose a continuous mechanism of identification, evaluation and inclusion of ABBs that are related to the healthcare sector and that fall within their expertise.

3.1.   Expected Outcomes of Implementing European eHealth Reference Architecture

The implementation of an EA should be considered to potentially address the ever-increasing costs that the EU and Member States have on healthcare, and any ability to constrain growing healthcare costs will directly and positively impact the future sustainability of Member State healthcare systems via eHealth.

A coordinated European approach to eHealth through an EA strategy would contribute to this situation by improving the capacity of the EU and its involved Member States to do more with the existing resources, and by enabling these resources to be deployed to meet real needs. This would result from improving system quality and safety (and therefore reducing avoidable supply and demand for eHealth services), improving system accessibility and interoperability, and improving system processing and cost efficiency.

From a macro perspective, the implementation of a European eHealth Reference Architecture would provide stakeholders and health organisations with necessary key business tools, such as:

- Mapping the big picture: A Reference Architecture gives a 'systems thinking' view that combines vision and strategy, legal architecture, business architecture, information systems, and technology domains;

- The possibility to align IT investments with business goals: creating a platform for business/ICT stakeholder collaboration is essential. Effective EA supports strategy, analysis, and planning by providing stakeholders with a blueprint of the current state of the business and IT landscapes, and of the desired future state (vision).

- Provide IT developers with common requirements for software applications towards a common maturity: a reference architecture can provide IT developers and/or IT policy makers with the necessary knowledge on the relevant protocols, standards or software requirements of an application towards universal interoperability in the European eHealth community.

Thus, it is worth attempting to understand complex eHealth services, in order to provide eHealth stakeholders with improved and suitable tools for devising healthcare systems, which could enhance eHealth success within Member States.

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4. Annexes

4.1. Annex 1 - European eHealth Reference Architecture (eHRA)

4.1.1. Reference Model

The correct structure of a reference model is key to assure the coherence between the strategy, tactic and operation levels across the EU. A reference model is an abstract framework or a conceptual model that aims to interlink a set of clearly defined concepts. Therefore, a framework which has strong steering elements addressing both strategy and technical issues is needed. Figure 3 represents the designed framework to get a visual description of the structure inherent to EU health services and how each artefact relates to each other.
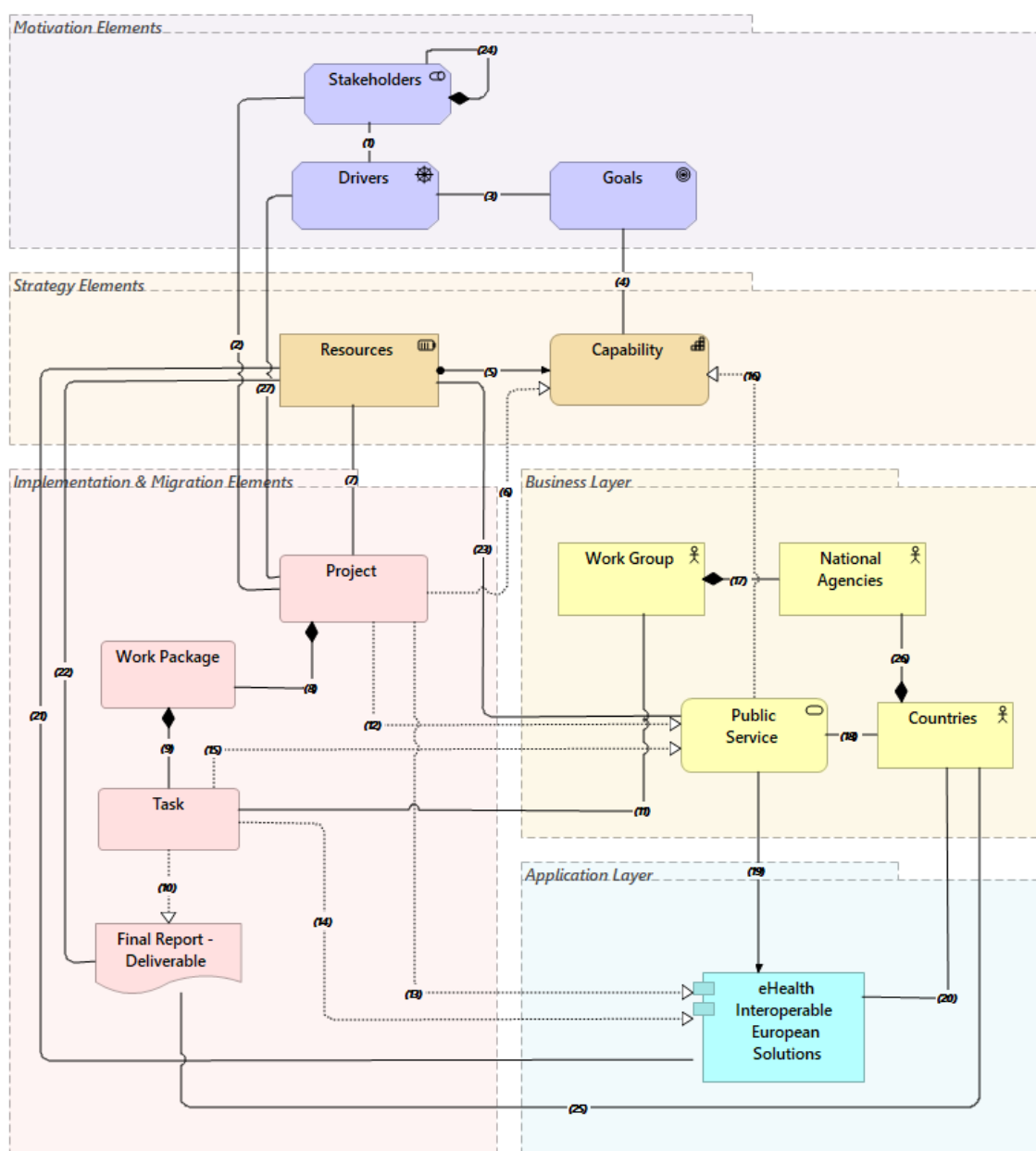

Figure 3 - *Proposed EU eHealth Digital Services framework for enterprise architecture*

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The proposed framework is a planning tool which aims to facilitate strategic activity to support decision making by enabling a conceptual view of the whole. The framework is composed of five domains of enterprise architecture:

1. Motivation Elements;

2. Strategy Elements;

3. Business Layer;

4. Application Layer;

5. Implementation and Migration Elements.

The creation of a common understanding is necessary to achieve coordination between all Member States. Therefore, for each architectural artefact a common terminology was defined, based on the ArchiMate[10] language.

4.1.1.1. Motivation Elements[11]

The motivation level of enterprise architecture is utilised for modelling the motivations or reasons which significantly guide the design of an architecture. Components on this level primarily comprise of stakeholders, associated drivers and pursued values, goals as well as outcomes that impact these motivations.

Motivation elements are used to model the motivations, or reasons, that guide the design or change of an enterprise architecture.

- *Stakeholder* - Represents the role of an individual, team or organisation. A stakeholder has one or more interests in, or concerns about, the organisation. In order to direct efforts to these interests and concerns, stakeholders change, set and emphasise goals. Examples of stakeholders are DG CONNECT, DG DIGIT, DG SANTE, eHealth Network and eHMSEG. *Relationship (1)* indicates the needs or concerns identified by each *stakeholder,* since not all the stakeholders pursue all drivers. *Relationship (2)* exhibits how each *stakeholder* or groups of stakeholders are related with each *project*.

- *Driver –* Also called 'concerns', they represent an external or internal condition that motivates an organisation to define its goals and implement the necessary changes, in order to achieve them. The drivers are forces that shape an organisation's strategy. *Relationship (3)* indicates the definition of *goals*, based on the defined *drivers*. For each *driver* one or more goals can be addressed. Examples of *drivers* can be security, interoperability, data protection, etc.

- *Goal -* Represents a high-level statement of intent, a direction, or desired end state for an organisation and its stakeholders. *Relationship (4)* indicates the *capability*/competency that may be achieved with the accomplishment of the proposed *goals.*

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[10] https://www.archimatetool.com/

[11] https://pubs.opengroup.org/architecture/archimate3-doc/chap06.html#_Toc10045334

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4.1.1.2. Strategy Elements[12]

The strategy elements are typically used to model the strategic direction and choices. They can be used to express how the organisation wants to create value for its stakeholders, the capabilities it needs for that, the resources needed to support these capabilities, and how it plans to configure and use these capabilities and resources to achieve its aims.

- *Capability -* Represents the ability that an organisation, person, or system possesses. The ability to achieve a desired effect under specified standards and conditions through combinations of means and ways to perform a set of tasks[13]. *Relationship (4)* indicates the set of skills and competencies (*capabilities),* provided by a set of *resources* or abilities, that, being developed and applied, allow the organisation to achieve a result in a certain field.

- *Resource -* Represents an asset owned or controlled by an individual or organisation. Financial assets are examples of resources. In our reference model the resources can be associated with the available funds for an existing project or new calls for projects, but they can be also deliverables produced by other work groups, such as standards (e.g. SNOMED CT, LOINC, DICOM, HL7), legislation, (cyber)security policies, data models, technical or semantic specifications, business processes, application components, application services, etc. These types of *resources*, used or available to each *project* and *task*, are made explicit by *Relationships (5), (7) and (8). Relationships (21) to (23)* aim to identify the deliverables produced by other work groups that can be used or continued in the subsequent *projects* and *tasks.*

4.1.1.3. Business Layer[14]

Business layer elements are used to model an organisation in a technology-independent manner, whereas strategy elements are used to model the strategic direction and choices of the enterprise.

- *Business Actor -* Represents a business entity that can perform a behaviour. A business actor can represent such business entities at different levels of detail and may correspond to both a person and an organisation. In our reference model, we identified three types of business actors:

    Work Groups – such as Electronic Health Record exchange format (EHRxF), Common Semantic Strategy (CSS), Digital_ID4Health. Work groups are set up to pursue one or more tasks (Relationship (12)).

    National Agencies – each work group is composed of national agencies, through which each country is represented by both Relationship (18) and Relationship (26).

    Countries – Relationships (20) and (22) indicate which countries are using each public services, applications and technologies produced in the context of the projects funded by the European Commission.

- *Business Service / Public Service -* Associated with a value, a public service is an activity that public authorities identify as being of importance to citizens, businesses and public administrations and that would not be supplied (or would be supplied under different

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[12] https://pubs.opengroup.org/architecture/archimate3-doc/chap07.html

[13] https://essay.utwente.nl/65421/1/Papazoglou_MA_MB.pdf

[14] https://pubs.opengroup.org/architecture/archimate3-doc/chap08.html

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conditions) if there were no public intervention[15]. The EU countries consume public Services **(Relationship (20))**.

4.1.1.4. Application Layer[16]

The Application Architecture provides a framework focused on developing and/or implementing applications to fulfil the business requirements and to achieve the quality necessary to meet the needs of the business.

The application and technology layer are related with an operational level, guided by the documents produced by the working groups from the business layer.

- **eHealth Interoperable European Solutions/Application component** – represents an encapsulation of application functionality aligned with implementation structure, which is modular and replaceable. These application components facilitate the delivery of electronic public services and cross-border exchange of information between public administrations (or citizens) according to the implementation and advancement of EU, national or local public policies[17]. Examples of *Application Components* are the NCPeH and the eIDAS Node. These implemented *Application Components* can be used by *EU Countries (**Relationship (22))**.*

4.1.1.5. Implementation and Migration Elements[18]

The implementation and migration level specify how to deliver the architecture that best meets the stakeholder requirements by modelling work packages, deliverables, gaps and implementation events which are required in order to achieve a change in state related to the architecture implementation or migration. With respect to the motivation and strategy level of enterprise architectures, deliverables represent concrete realisations of the strategically defined goals.

The implementation and migration include modelling implementation programs and projects to support program, portfolio, and project management.

- **Project** – a temporary effort that has a defined beginning and end in time, and therefore defined scope and limited resources in order to create the unique and measurable outcome[19]. Projects can create public services **(Relationship (13))**. Projects can also be related to the implementation of an application component **(Relationship (14))**. A project may be divided in to work packages and tasks. Examples:

    *Projects – e.g. eHAction, JAseHN. **Relationship (8)** indicates the parts that each project comprises;*

    *Work Packages – e.g. WP8. Each work package is responsible for delivery of part of the project or management and aggregates different tasks (**Relationship (9)**);*

    *Tasks – e.g. Task 8.2. Each task will develop a defined activity to be integrated in the WP. **Relationship (11)** defines the groups of specialists created in order to pursue the proposed*

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[15] https://joinup.ec.europa.eu/sites/default/files/distribution/access_url/2017-10/eira_v2_0_0_overview.pdf

[16] https://pubs.opengroup.org/architecture/archimate3-doc/chap09.html#_Toc10045389

[17] https://joinup.ec.europa.eu/sites/default/files/distribution/access_url/2017-10/eira_v2_0_0_overview.pdf

[18] https://pubs.opengroup.org/architecture/archimate3-doc/chap13.html

[19] https://www.pmi.org/about/learn-about-pmi/what-is-project-management

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tasks. These groups are created according to project needs; it could be present or not in a project.

- **Deliverable –** is a plan addressing the proposed strategic goals and represents the result of a task, also named as the final report (indicated by **Relationship (10)**). Deliverables can include: data models, data policies, dataset catalogues, data standard catalogues, data-level mapping, representations, specifications (legal, organisational, semantic or technical), etc. Since a semantic catalogue is a type of deliverable, **Relationship (25)** allows the identification of what each country is using as a semantic catalogue/value set.

4.1.2. Cartography Process – a Practical Example

4.1.2.1. eHRA High-Level Viewpoints

Throughout this section, architectures within a subject area where each represents a different viewpoint will be summarised. A viewpoint specifies the elements expected to be represented in the view that may be formally or informally defined.

These viewpoints are starting points for modelling efforts. They can accelerate architectural efforts, support organisational standards, facilitate peer review and aid new modellers. However, these basic viewpoints should not constrain modelling activities. Organisations and individual modellers should address stakeholder concerns by selecting from the basic viewpoints, modifying them, or defining new ones.

For each viewpoint, the grey colour highlights the view we want to catch. If we need to see the detail of a specific stakeholder, the *Stakeholders Viewpoint* focuses on the reference model artefacts subset related to that stakeholder. Each viewpoint represents a part of the architecture and comprises elements from different layers.

The Organisational view is one of the most important viewpoints that shall be considered to support organisations, in an effort to present a view and to allow the widest reach possible within EU projects and planning.
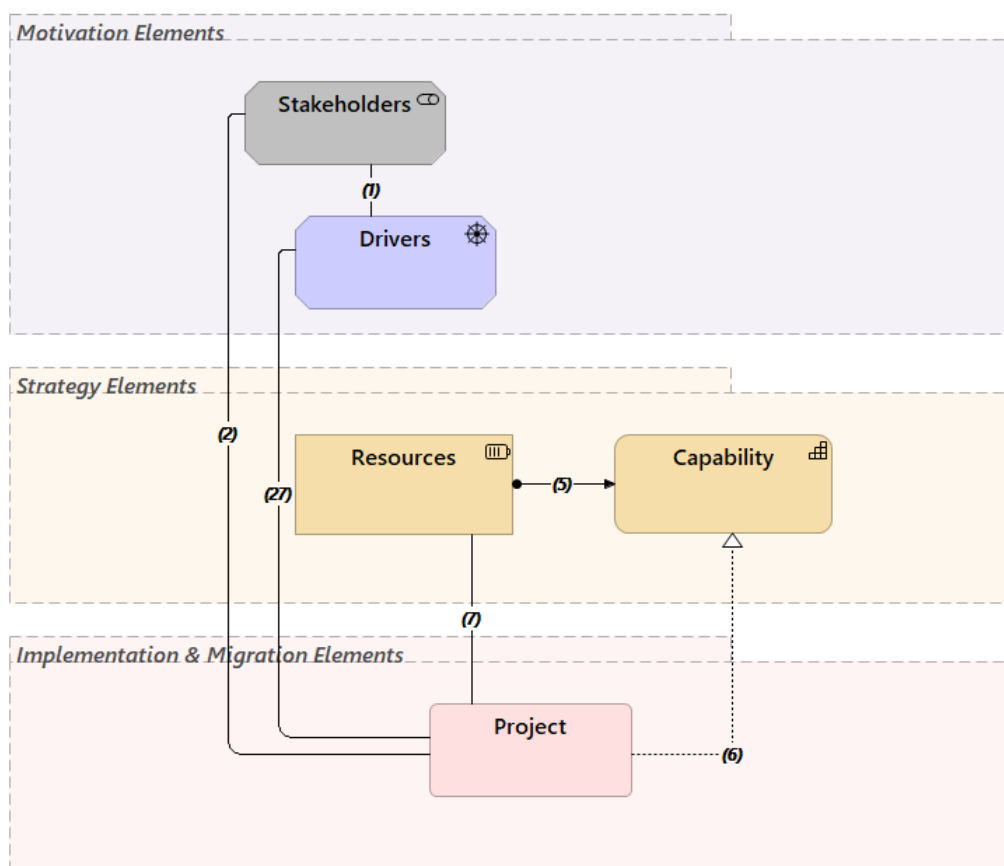
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Figure 4 – Stakeholders Viewpoint

Narrative [Figure 4]: The *Stakeholders Viewpoint* enables the vision about all projects related to each stakeholder. Considering each project, this viewpoint identifies the drivers that conduct the configuration of each project and which capabilities are added or created by each project outputs. Furthermore, for each project, the financial resources can be identified.

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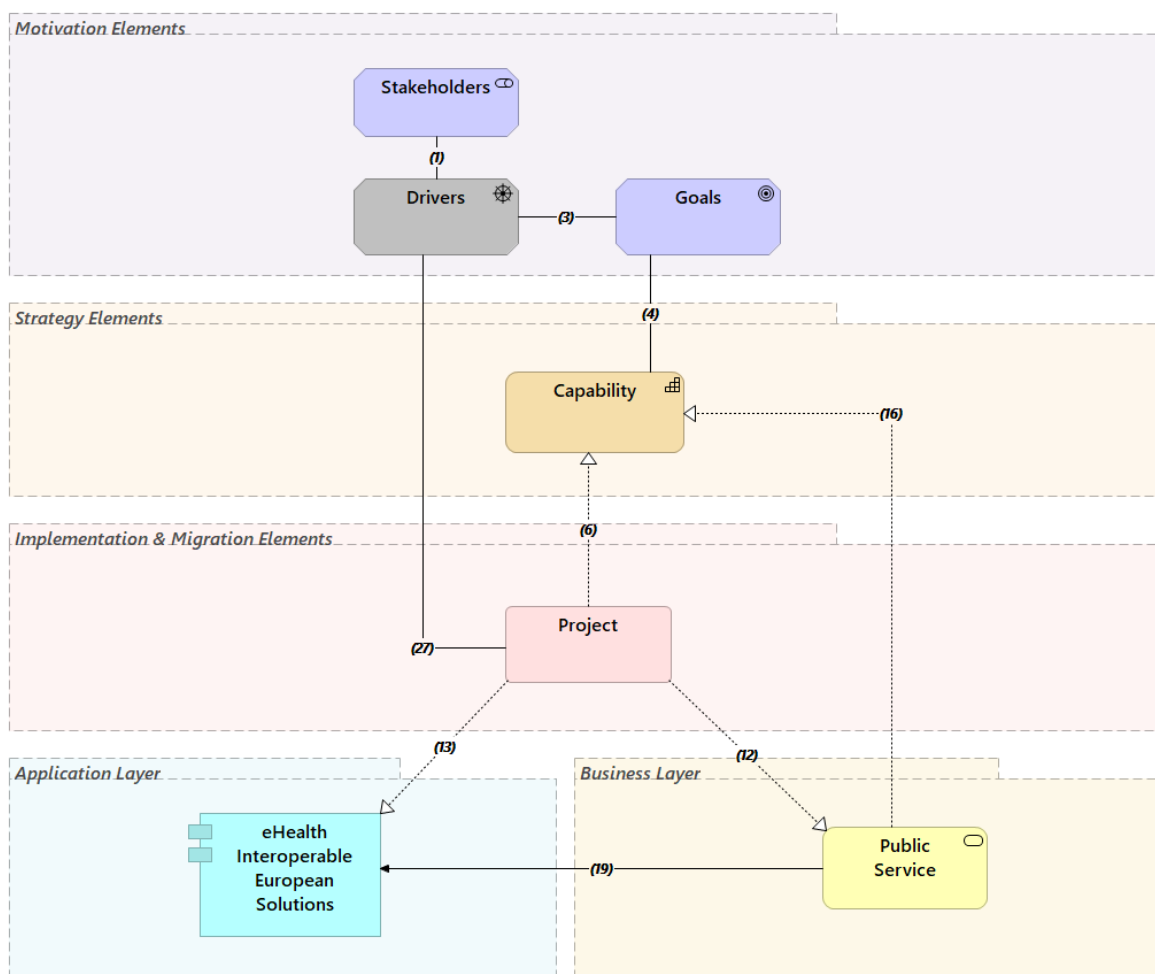
Figure 5 – Drivers Viewpoint

Narrative [Figure 5]: The *Drivers Viewpoint* identifies the project goals and stakeholders related to the chosen driver. The outputs of each project, such as technical components or public services, are also identified in this viewpoint. Additionally, the capabilities that are added or created by each project output are also presented in this viewpoint.

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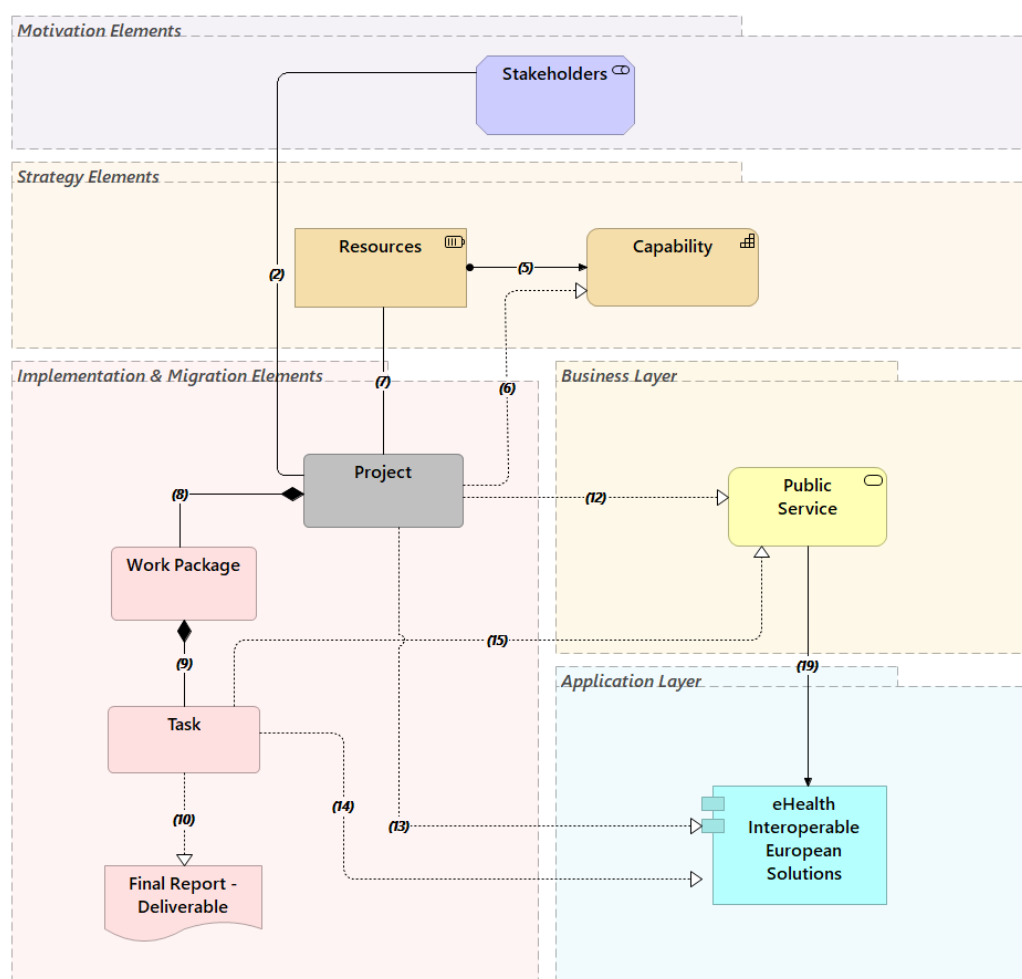
Figure 6 – Project Viewpoint

Narrative [Figure 6]: The *Project Viewpoint* illustrates each project structure. A work package is a group of related tasks within a project. Since work packages look like projects themselves, they can be perceived as sub-projects within a larger project. The output of each task, final report, public service, or technical component, is also depicted in this viewpoint. The capabilities added or created by each project output are also presented in this viewpoint. In addition, the stakeholder related to the project is also presented, as well as the financial resources available for the project or other resources required to carry out project tasks (deliverables produced by other work groups, standards, legislation, cybersecurity policies, data models, technical or semantic specifications, etc.).
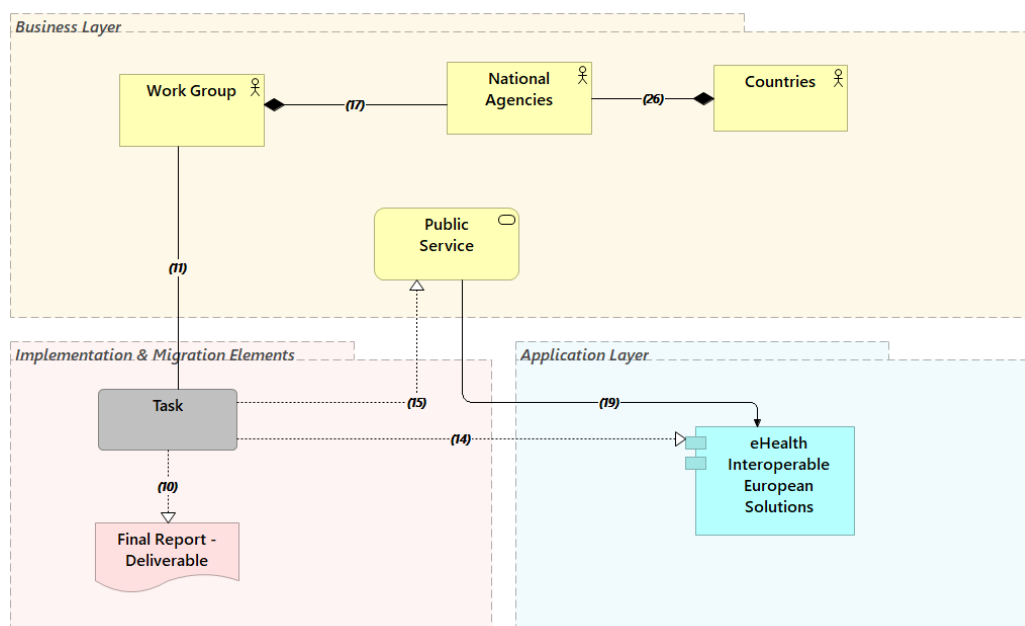
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Figure 7 – Task Viewpoint

Narrative [Figure 7]: The *Task Viewpoint* identifies the outputs of a given task, deliverables, public services, and technical components, along with the participants who are responsible for performing the task or part of it. If needed, a work group could be created and it could be composed of participants from different countries (international project consortia), which are represented by their national agencies or affiliates.
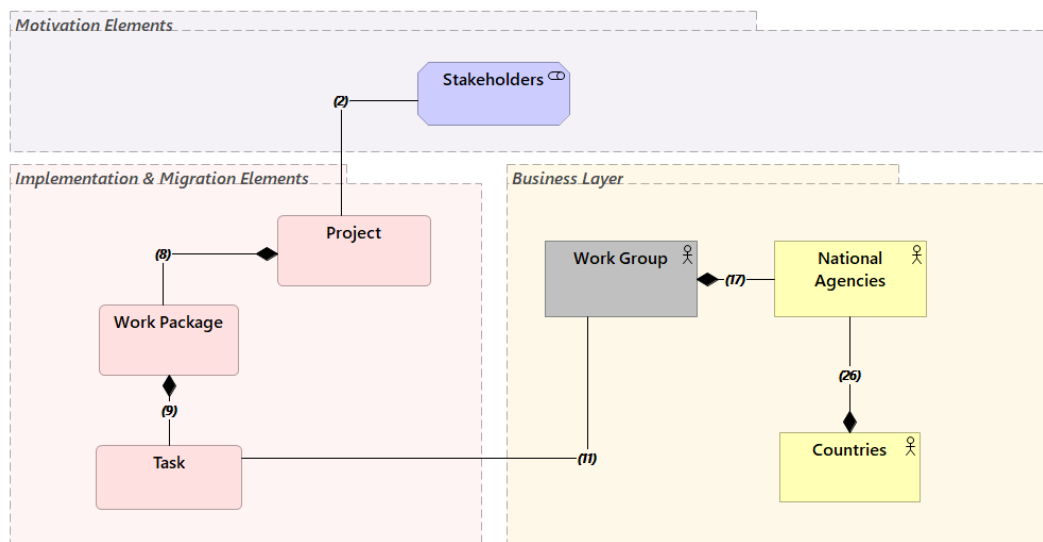

Figure 8 – Work Group Viewpoint

Narrative [Figure 8]: The *Work Group Viewpoint* identifies the work group composition, all of the national agencies involved, by country. For each work group, the tasks which were within their responsibility are present, as well as the related projects. The stakeholders, who are interested in the project's outcome, are also represented.
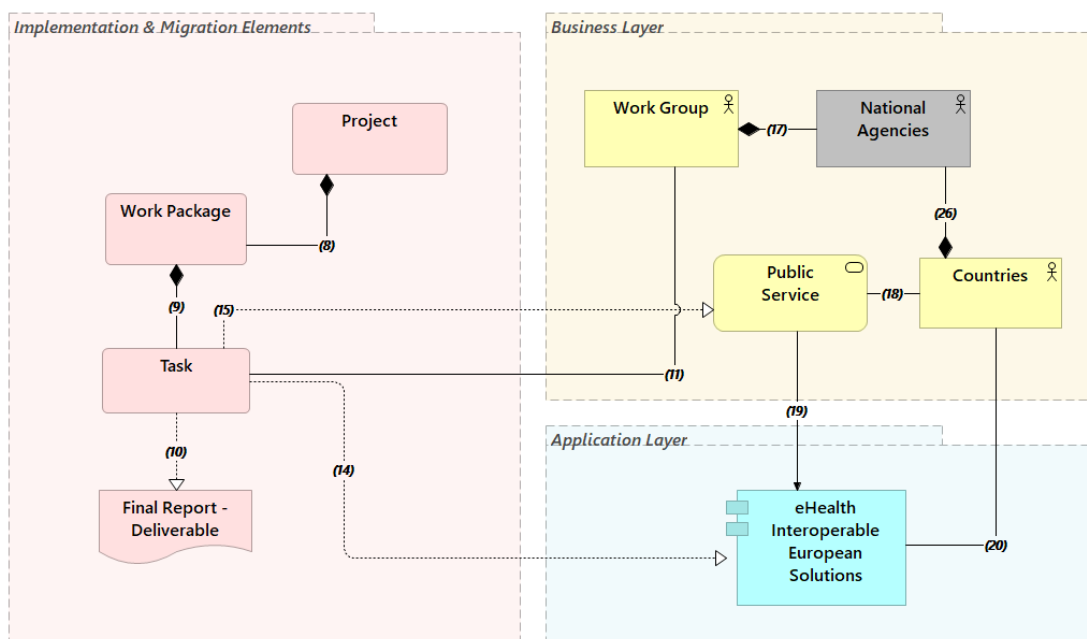
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Figure 9 – National Agencies Viewpoint

Narrative [Figure 9]: The *National Agencies Viewpoint* allows an understanding of which projects the national agencies of each country are involved in, as well as which task and project they are contributing to. Furthermore, this viewpoint identifies the results of the work the national agency is involved in, the deliverables produced, the public services created or improved, and even the technical components implemented.
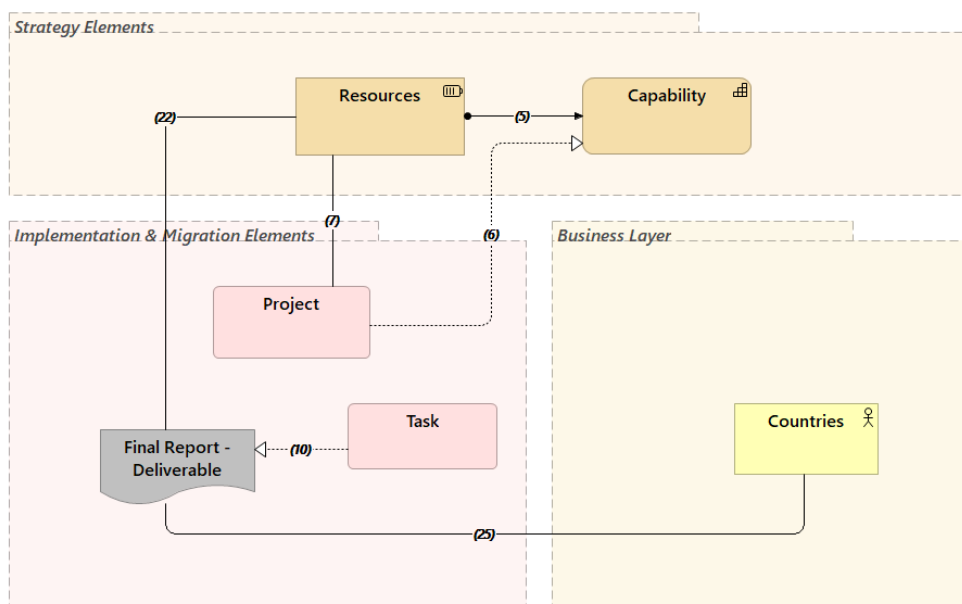

Figure 10 – Final Report Viewpoint

Narrative [Figure 10]: The Final Report *(or Deliverable) Viewpoint* identifies whether a given deliverable was a resource for another project and which capability the project achieved. This viewpoint also enables one to understand which countries are using or adopting the deliverable.
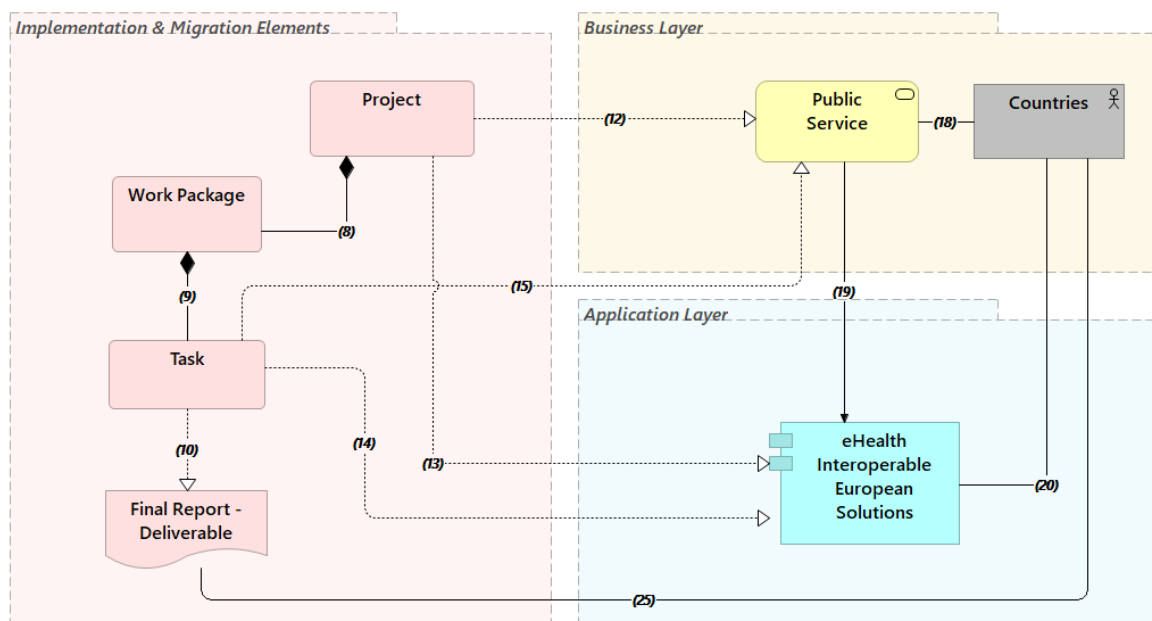
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Figure 11 – Countries Viewpoint

Narrative [Figure 11]: The *Countries Viewpoint* gives the perspective of what public services, technical components and deliverables (such as sematic catalogues, technical specifications, etc.) are being produced in order to be adopted by a given country.
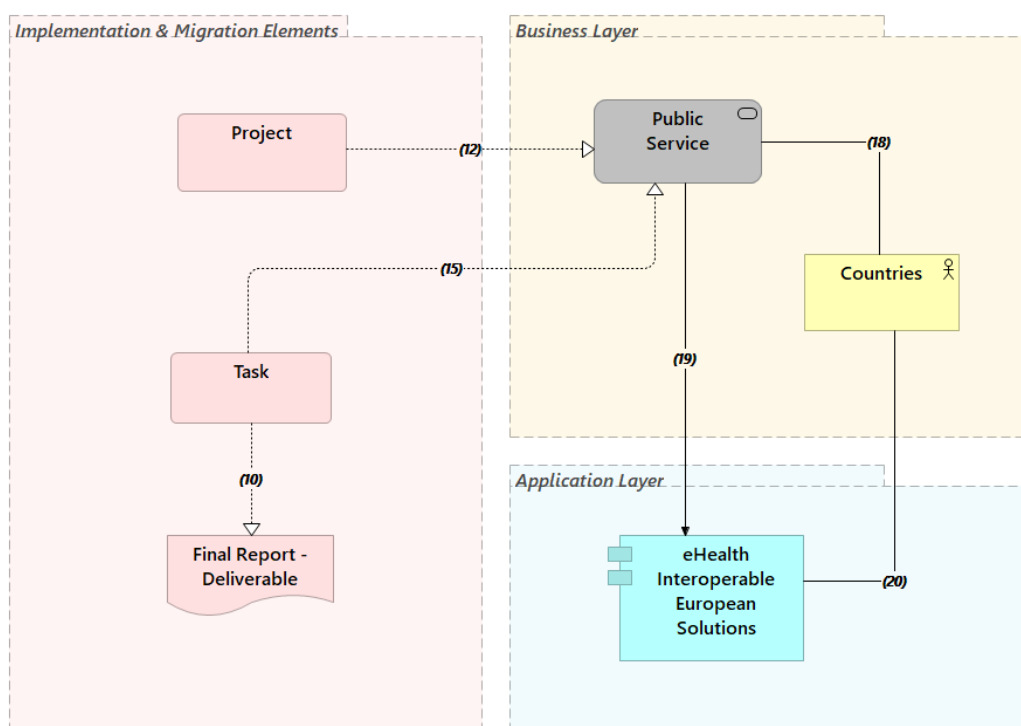

Figure 12 – Public Service Viewpoint

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Narrative [Figure 12]: The *Public Service Viewpoint* exhibits the projects, work packages tasks and deliverables related to a given public service, and what countries are adopting and/or improving that public service. Furthermore, this view presents the eHealth solution that supports each public service.
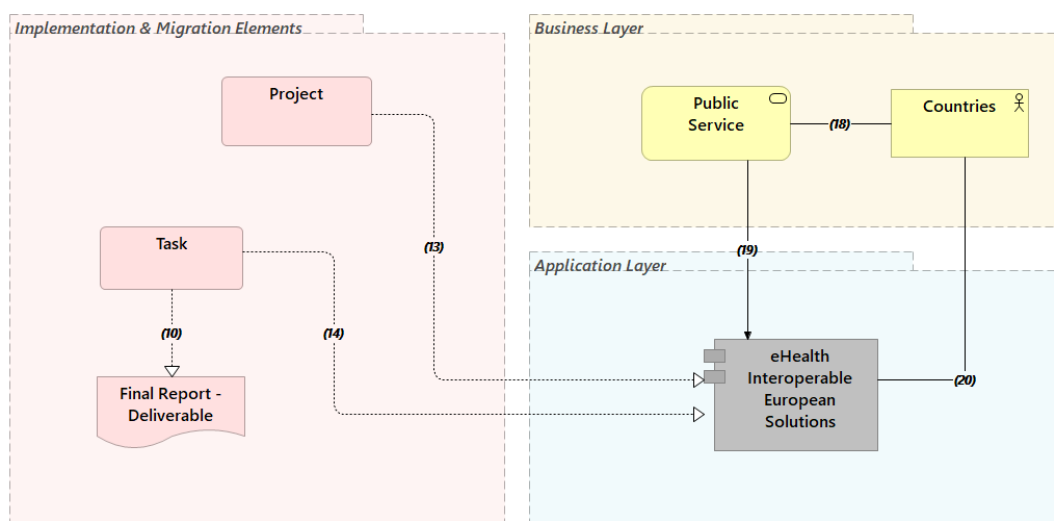

Figure 13 – *eHealth Interoperable European Solution Viewpoint*

Narrative [Figure 13]: The *eHealth Interoperable European Solution Viewpoint* is similar to the *Public Service Viewpoint.* This viewpoint displays the projects tasks, the deliverables related to a given technical component, and what countries are adopting that component. Furthermore, this view presents the all the public services supported by a given eHealth solution.