eHealth Standards and Profiles in Action for Europe and Beyond

Deliverable 4.2r2
Interoperability Guideline for eHealth Deployment Projects, Release 2

Executive Summary and Key Take-away Points

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Summary

The convergence towards a fully harmonised set of eHealth interoperability standards at international or European level is a long-term vision, but far from the reality today. Different approaches in terms of perspectives (business, information and technical), semantic and technical solutions, standards and profiles used, terminologies adopted, etc., are the natural consequence of the many factors influencing architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed.

The purpose of the eStandards Deliverable D4.2r2 is to provide practical guidance to eHealth deployment projects, in particular large-scale and cross-border projects, on the challenges, costs in terms of implementation requirements and possible approaches to achieving interoperability. A special focus of this document is the question how coexistence between competing or overlapping standards and standard options can be achieved in practical terms, which is a challenge that affects most eHealth projects.

The guidance provided in this document is based on the experience of a large number of research and eHealth deployment projects. Their experiences were documented in a collection of 19 case studies, and the recommendations and guidance were derived from there. This document presents the recommendations in an extended form with regard to practical implementation support.

The document furthermore discusses the role that the Refined eHealth European Interoperability Framework (ReEIF) and the associated collection of use cases and implementation scenarios developed by the Antilope and eStandards projects can play in supporting eHealth projects in the selection of standards, procurement of products and in achieving interoperability.

The document has been reviewed from a panel of eHealth experts associated with national competence centers, who had the opportunity to rate the key take away points. If you are not one of them you can do it now, using the last page of this document.
1 Executive Summary

The purpose of this document is to provide practical guidance to eHealth deployment projects, in particular large-scale and cross-border projects, on the challenges, costs in terms of implementation requirements and possible approaches to achieving interoperability. A special focus of this document is the question how coexistence between competing or overlapping standards and standard options can be achieved in practical terms, which is a challenge that affects most eHealth projects.

The guidance provided in this document is based on the experience of many research and eHealth deployment projects. Their experiences were documented in a collection of 19 case studies, and the recommendations and guidance were derived from there. This document presents the recommendations in an extended form regarding practical implementation support.

The Landscape of Interoperability Standards

In the common understanding, the idea of standards is often associated with communication protocols and the expectation of “plug and play” interoperability achieved when two or more systems are able to technically interact, to satisfy well-defined real-world business or clinical processes. This happens when human and/or machine users can share and use information for a specific purpose. In the general area of eHealth, there are no solutions that provide “plug and play” interoperability without even minimal adaptation. Therefore, the question of what are the acceptable costs for achieving “plug and play” interoperability in a specific eHealth context, is essential. To achieve interoperability, several dimensions need to be taken into account, not limited to technical or communication aspects, but also including information/semantics, business processes, and clinical guidelines. Therefore, for interoperability based on standards, standards covering all these areas are necessary. Standards developing organisations (SDOs) have developed several reference interoperability frameworks to help users or projects taking into account all of the different aspects. What these reference frameworks have in common is that they define different “layers” or “cells” for the different dimensions/aspects. Different kinds of standards can be selected to cover the different layers or cells.

Another important concept that needs to be looked at when discussing standards-based interoperability is profiling: All standards have the challenge to be on one hand generic enough to be universally applicable, and on the other hand to be concrete and unambiguous to enable interoperability in a specific context. This is usually resolved through profiling: the base standard captures common characteristics and defines rules for specializing it. Profiles specify how to use the base standard for a specific scope or in a specific setting by defining constraints and extensions. Profiling is usually a layered process: The universal profiles defined in the standard are refined into “jurisdictional profiles” taking into account national laws and regulations, and these may be further refined into local profiles for use in a specific eHealth project or deployment. It should be noted that the evaluation of the compliance and conformance of a system to a standard is usually based on a specific profile or set of profiles, rather than base standards alone. Profiles also provide a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. They offer developers a clear implementation path for communication standards supported by industry partners and carefully documented, reviewed and tested. Profiles give purchasers a tool that reduces the complexity, cost and anxiety of implementing interoperable systems.

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Finally, eHealth projects should be aware that the need of managing the coexistence of different standards and profiles is a fact, not a problem: the question should be if and how a set of standards can actually be used together. This only becomes a problem when competing or non-consistent standards are used. Standards are competing when distinct solutions are defined for the same scope (e.g. two terminologies used for representing the same domain for the same purpose), and they are non-consistent when they cannot be used together (e.g. a security standard requiring bidirectional communication and a transport protocol for store-and-forward communication). Competing standards usually belong to the same layer or cell of a reference framework. There is also the case of inconsistent implementations of the same standard or profile, which is typically due to lack of training. The costs for achieving interoperability are higher when projects need to address the lack of clarity in non-technical interoperability aspects (such as organisational or legal issues).

Managing the Coexistence of Competing or Overlapping Standards

The analysis of previous eHealth projects and scientific literature has shown that there are three general approaches for managing the concurrent use of competing or overlapping standards: Gateway based (addressing the Applications layer), Model driven and semantic mediation based (both addressing the Information layer). These approaches can be combined. The Gateway based and Model-driven approaches have proven successful in large-scale projects, while semantic mediation has so far mostly been used in research projects of limited scope.

Specific challenges that need to be addressed in heterogeneous eHealth networks are the mapping of identifiers and the mapping of terminologies (including bindings). Typical identifiers to be mapped are the Patient ID and the User ID (including associated authorisations). A few standards and profiles have been specifically developed for the management of a Master Patient Index and for distributed user authentication and authorisation systems. Concerning terminologies, this is a field with much overlap and competition between existing standards, so in the process of “translating” clinical content from the format used in one domain to the format used in another domain, terminology mapping is frequently needed. This is critical because a mapping without information loss is normally possible only for a subset of terms. If terminology mapping cannot be avoided, the management of terminologies and terminology mappings should be centralised by means of a terminology server.

Practical Approach to Achieving Interoperability

The practical approach to achieving interoperability that has been successfully applied by various eHealth projects in Europe and internationally can be summarised in the following seven steps:

1. **Identify use cases** from an end-user perspective, including glossary, scenario, actors, privacy requirements and variations.
2. **Select profiles and standards** that support the use case (e.g. by selecting a realisation scenario).
3. **Refine data content**, including document templates, metadata, master files, terminology.
4. **Write interoperability specifications (implementation guides)** that describe the standards/profiles selected, the refined data content, and other project specific local needs. This specification enables implementation of the use case across the various IT systems and devices.
5. **Organise testing** by preparing test cases and a test environment for implementers to demonstrate component interoperability and by organising cross-implementer connectivity testing.

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2 NOTE: in this document, the term “eHealth network” always refers to networks of health providers that want to share or exchange information, and not to the European eHealth Network (eHN), a policy group established by the European Commission and Member States.
6. **Educate end-users on interoperability**: Develop communications materials to familiarise end-users on the benefits and impact of Interoperability.

7. **Support or participate in communities of practice** to promote sustainable standards-based implementation and offer feedback to standards and profiling organisations.

**Feasibility and Costs of Achieving Interoperability**

Achieving interoperability is a cost factor in every eHealth project. However, scientific literature shows no evidence that the costs of implementation and operation of deploying eHealth interoperability is a major impediment. Furthermore, the costs of achieving interoperability need to be compared with the costs of non-interoperability and benefits of achieving interoperability. In practical terms, there are at least three ways to approach interoperability: profile based, customised standards approach and infrastructure vendor approach. Of these three approaches, profile-based interoperability has the lowest implementation costs and the lowest life cycle costs.

**Non-Technical Factors**

An eHealth project is always more than a technical exercise, and the project management needs to “think holistic” and consider non-technical factors related to the stakeholders of the project. A good project management and successful stakeholder involvement are key factors for the success of an eHealth project. The careful selection of an experienced project manager with an understanding of the eHealth domain and standards to be implemented, an interdisciplinary project team covering all required skill-sets, a high-quality project description agreed by all stakeholders, a realistic time plan, careful risk management, and continuous change management are important aspects.

Furthermore, there are several policy elements that affect the successful completion and long-term sustainability of an eHealth deployment project: education, privacy & security, clinical research, incentives, innovative business models, cross-vendor integration, and future standardisation trends.

eHealth projects should design methods of ensuring acceptance by the end-users of the system (e.g. patients and health professionals). This includes making the system as user-friendly as possible, designing user-interfaces tailored to each end-user group and facilitating further personalisation. Offering training material and a system of incentives for end-users, especially for those whose workload increases because of the implementation of the new system would smooth transition. Projects also need to take into account that misunderstandings and communication problems between stakeholder groups are very likely due to their interdisciplinary nature. The project management should be aware of this and apply best practices for interdisciplinary project management and intercultural communication. Furthermore, the project team needs should also be interdisciplinary in nature and cover all required skill sets and stakeholder perspectives. Finally, eHealth standards are complex and their correct implementation requires years of experience. eHealth projects should focus on involving experienced team leaders, continuous developer training and the utilisation of well-tested software libraries implementing standards whenever possible. Supporting or participating in communities of practice linked to standards and profiling organisations would help make standards organisation much more responsive closing the gap to implementation.

**System Architecture**

Experience shows that it is better to start with a small system and grow over time, than to aim for the perfect solution immediately. However, an enterprise architecture strategy is needed to promote consistency across the growing systems. eHealth projects should define their architecture based on a
decomposition into layers representing different domains with increasing level of detail. Also, interoperability should be addressed in such a layered approach. Components of the system architecture should be decoupled based on function or service, using well-defined interfaces between the components. This reduces complexity and simplifies implementing or procuring the individual components. The degree to which a centralised approach, a decentralised or a hybrid approach is selected for the overall system architecture needs to be carefully analysed, since both centralised and decentralised solutions have their own risks that should be known and managed. In any case, projects should ensure that more than one end user application can be built as edge system for the eHealth network (e.g. for accessing and visualizing information from the eHealth network), catering for different user needs and user preferences. One approach for enabling different end user applications is Pre-commercial Procurement (PCP).

Two main sources of complexity in the system architecture are IT security and the mapping between different standards, or different versions of a standard. IT Security will be among the most complex parts of the system architecture, and needs to be addressed from the start. A balance between security objectives and usability of the systems needs to be achieved. Projects should always use well-known and well-tested algorithms and software modules and design multiple layers of security. Concerning the mapping between standards or standard versions, the development of reusable information building blocks is one approach to simplifying this challenge.

When a multi-layer eHealth “network of communities” is considered, connecting for example several regional networks into a larger national network, or connecting national networks across borders, the IHE cross-community integration profiles should be taken into account, being the first standard for an eHealth “network of communities” that has seen large-scale implementation in several countries. There are however, some challenges in deploying these profiles. Nictiz (the Dutch Healthcare ICT competence centre) has published a “Guide to Interoperability between XDS Affinity Domains”³ that helps addressing these challenges.

Finally, when designing a local, regional or national eHealth solution, the European requirements arising from EC regulations such as the General Data Protection Regulation, the eIDAS regulation on the management of electronic identity, and the Directive on Public Procurement must be taken into account.

**Clinical Information Modelling and Templates for Clinical Documentation**

Firstly, eHealth projects should be pragmatic when it comes to the selection of content formats: while fully encoded information is clearly preferable, human-readable, semi-structured or free-text documents are a good starting point.

Secondly, the design of clinical documents or clinical content in general should be performed in two steps: (1) define a clinical information model that is independent from a concrete syntax and encoding, and (2) map this into the clinical document or message format used. This offers a separation of concerns and helps translate content to different formats.

Thirdly, several projects have shown that it is very useful to implement a clinical information model as a mock-up application with a graphical user interface, both as a means of validation of the model, and as a tool for communication between clinicians and technical experts. However, projects rarely can or need to start from scratch. It is highly advisable to start from best practices and already tested

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interoperability assets. The team should communicate adaptations or localisation to standards and profile organisations. In this way, possible misunderstandings will be avoided, while standards and profiles will be continually improved. Supporting or participating in communities of practice would certainly simplify this task and foster eHealth interoperability in the long term.

Projects need to be aware that non-interoperability can be a problem even if all parties in an eHealth system use the same clinical document or message format, but different templates/archetypes to represent clinical content. To ensure interoperability, eHealth projects also need to control the templates/archetypes and terminology bindings used. As an additional recommendation, when clinical content is represented through coded terminologies, and it is possible to represent one clinical concept through codes from multiple terminologies, all equivalent codes should be stored in the document. This greatly increases the chance of success of a terminology mapping at a later point in time. This approach is called “multi-coding”. Finally, the availability of appropriate tools and user interfaces to facilitate coding is one of the key factors for the acceptance of terminologies by health professionals. Coding should be transparent to the health professionals and be based on an interface terminology they are used to in the everyday practice. These interface terminologies need to be maintained continuously to ensure usability.

**Tooling: Starting from the State of the Art**

Projects should make sure to avoid the “Not-Invented-Here syndrome” by carefully analysing existing standards, architectures and tools before deciding to develop their own ones. Good software tools are a critical success factor for eHealth projects. Projects should check the lists of available libraries, reference implementations and test tools provided in the annex to this report for suitable tools. Furthermore, sharing test data, best practices and common pitfalls can help stimulate collaboration and build excellence. Developing and publishing software under an open source license can contribute to the scalability and sustainability of a project. However, it should be clarified if the advantages of an open source model apply when open interfaces are supported. Finally, projects should be aware that there may be very useful standards and software components developed outside the “eHealth community” for topics that are not eHealth specific, such as IT security.

**The Refined eHealth European Interoperability Framework**

The Refined eHealth European Interoperability Framework (ReEIF)⁴ and the associated collection of use cases and implementation scenarios⁵ are important resources that can support eHealth deployment projects in the selection of standards and profiles for the implementation of specific use cases. First, the ReEIF can be used to compare standards by first selecting a use case, and then comparing different realisation scenarios that implement the use case based on different standards. Only in a real-world situation can standards be evaluated correctly. Secondly, the ReEIF can be used in the procurement of eHealth products and system components implementing actors and transactions of one realisation scenario. The EC Public Procurement Directive requires that technical specifications for public procurement be based on standards recognised in the EU. Although 27 IHE profiles used in many eHealth projects can be referenced in public procurement, additional specifications are needed to enrich and refine the clinical contents specifications in realisation scenarios associated to the ReEIF use cases. eHealth projects can help in that respect, by publishing their own realisation scenarios. Such

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⁵ ReEIF Use Case Repository. Online: [http://usecase-repository.ihe-europe.net](http://usecase-repository.ihe-europe.net)
initiatives would significantly reduce the cost of interoperability and facilitate improvement of standards and profiles.

Finally, the interoperability between systems that use different standards can be achieved by using the same data model, agreements on which data elements should be translated and how, and by using transformation tools. A decision tree can help to select the most appropriate approach for translation.

**Summary and Conclusion**

The specification, implementation, roll-out, operation and maintenance of a large-scale eHealth project is a formidable challenge. Newly starting projects have the advantage that they can learn from the successes and failures, challenges and solutions, experienced and developed by earlier projects. This document tries to offer on one hand an overview of the issue of competing and overlapping standards, which most projects will run into sooner or later, and on the other hand pragmatic advice on some key success factors for eHealth projects, proven solutions, tools and experiences made by earlier projects. We hope that this guideline will contribute to a culture of sharing and giving back to advance standard-based interoperability, continuously improve standards, and lower the costs of sustainable and resilient interoperability solutions. We also hope that this guideline will help eHealth projects to make the right design decisions and avoid known problems and pitfalls, and thus better serve their end users, health professionals and patients, to provide or receive better care. This is, and must remain, the ultimate goal on which the success of eHealth projects will be measured.

The full deliverable together with the complete reviews by the panel of experts will soon be made available in the eStandards web site, [http://www.estandards-project.eu/index.cfm/deliverables/](http://www.estandards-project.eu/index.cfm/deliverables/)
2 Overview of Key Takeaway Points

Chapter 3. The Landscape of Interoperability Standards

3.1 Standardisation is not just a technical thing
The common sense of “plug and play” standards (i.e. just implement/buy and use it) should be applied with caution in the field of eHealth, because interoperability is not restricted to technical or communication aspects, but should take into account several dimensions, such as information/semantics, laws or business/clinical process.

3.2 Standardisation requires context adaption using realisation scenarios
In general, no solutions achieve interoperability without requiring adaptations of the used standards/profiles; the “plug & play” is therefore a relative attribute to be determined in terms of acceptable adaptation costs in a specific context. (Base) standards have in fact to be generic enough to be universally applicable, providing, however, means to be concretely used. The complexity of the path for implementation has been the pitfall of many standards, in the past leading to low adoption.

3.3 Standards need to be profiled
The mechanism used for adapting standards to the needs of a specific context or setting is called “profiling” and it has been used extensively by IHE and Continua (in this case at the national and international level):
- It is usually a layered process: standards can be profiled in universal profiles, then refined into “jurisdictional profiles” taking into account national laws and regulations, and furtherly specialised into local profiles for being use in a specific eHealth project or deployment. Substantially all profiles published by international standard organisations must be further specialised to be used in concrete deployments.
- How a standard can be profiled (i.e. how to use it for a specific scope or setting by defining constraints and extensions) is usually part of the standard itself. Standards and profiles should always define how to profile them and how to evaluate conformance (when applicable).
- The evaluation of the conformance of a system to a standard is usually based on a profile, and not on a base standard.

3.4 Use frameworks to address all aspects of interoperability
Several reference interoperability frameworks have been developed to help taking into account all of the different aspects impacting interoperability. (Examples include the Refined Health European Interoperability Framework (ReEIF) and the HL7 Service Aware Interoperability Framework (SAIF). Those different aspects / perspectives are in general represented in those framework through different “layers” or “cells”.

3.5 Balance out efforts and results of a framework analysis
The cost of formalizing all the possible viewpoints and layers should be balanced with the need of timely delivery of concrete solutions. This balance can be obtained applying an iterative step-by-step process identifying the essential elements that should be made explicit / formal in the chosen framework to allow the delivery of the solution, progressively integrating missing parts and relationships based on the identified gaps.
3.6 Non-competing standards can be used together and complementary
The need of managing the coexistence of different standards and profiles should be considered a fact. Sometimes, the same standards or profiles are used differently. The question usually depends on whether the standards used or selected are competing (i.e. distinct solutions defined for the same scope, usually belonging to the same layer or cell of a reference framework) or consistent (e.g. adoption of standard X doesn’t prevent the use of standard Y even if not competing). Assessment of these characteristics can be facilitated by adopting an interoperability framework.

3.7 Costs for achieving interoperability are usually higher on the organisational level
The costs for achieving interoperability are directly related to the layers of the reference frameworks: gaps belonging to the highest layer (e.g. legal/organisation in ReELIF, enterprise conceptual in SAIF) lead usually to highest adaptation costs, while technical gaps can be bridged in some cases using custom adaptors (e.g. in the easiest case tools applying syntactical mappings and transformations).

3.8 Link standards to interoperability frameworks
To enable the different scales (European, National, Regional) to better estimate the feasibility and the costs (in terms of what needs to be changed) to achieve practical interoperability for identified use cases, it is important to know where the standards to be used are placed in the mentioned reference frameworks. This characterisation could then also be used in the design of a reasonable migration strategy, as a set of step-by-step transition architectures, from “competing” to hopefully “converged/harmonised” standards.

Chapter 4. Managing the Coexistence of Competing or Overlapping Standards

4.1 Competing standards are a fact of life
Managing the coexistence of competing or overlapping standards is a very common challenge that most eHealth projects have to address — today and in the near future.

4.2 Standards compete only if they operate on the same level of interoperability
Overlap or competition between standards usually happens between standards addressing the same “layer of interoperability” as described in the “Refined eHealth European Interoperability Framework”.

4.3 Three ways of managing concurrent standards
There are three general approaches for managing the concurrent use of competing or overlapping standards: Gateway based (addressing the Applications layer), Model Driven and Semantic Mediation based (both addressing the Information layer). The approaches can be combined. The Gateway based and Model-driven approaches have proven successful in large-scale projects, while semantic mediation has so far mostly been used in research projects of limited scope.

4.4 There are standards for authentication
A challenge that needs to be addressed in heterogeneous networks is the mapping of identifiers such as the Patient ID and the User ID (and associated authorisations). A few standards and profiles have been specifically developed for the management of a Master Patient Index, and distributed user authentication and authorisation systems.

4.5 Use terminology mapping when necessary
Controlled terminology is a field with much overlap and competition between existing standards, so in the process of “translating” clinical content from the format used in one domain to the format used in another domain, terminology mapping is frequently needed. This is critical because a mapping without information loss is normally possible only for a subset of terms. If terminology mapping cannot be avoided, the management of terminologies and terminology mappings should be centralised with a terminology server.

Chapter 5. Practical Recommendations

5.1. Practical Approach to Achieving Interoperability

5.1.1 Seven steps to achieve interoperability
This section discusses the practical approach to interoperability successfully applied by various eHealth projects in Europe and internationally. The approach can be summarised in seven steps:

1. **Identify use cases** from an end-user perspective, including glossary, scenario, actors, privacy requirements and variations.
2. **Select profiles and standards** that support the use case and promote interoperability, while addressing local needs.
3. **Refine data content**, including document templates, metadata, master files, and terminology. HL7 C-CDA and the openEHR foundation have developed template repositories to support clinical content profiles, frequently associated with terminology value sets.
4. **Write interoperability specifications (implementation guides)** that describe the standards / profiles selected, the refined data content, and other project specific local needs. This specification enables implementation of the use case across the various IT systems and devices.
5. **Organise testing** by preparing test cases and adopting a test environment for implementers to demonstrate component interoperability and by organising cross-implementer connectivity testing.
6. **Educate end-users on interoperability**: Develop communications materials to familiarise end-users on the benefits and impact of Interoperability. This step may already begin earlier on, once the use case has been identified.
7. **Support or participate in communities of practice** to promote sustainable standards-based implementation and offer feedback to standards and profiling organisations.

Furthermore, on a more horizontal level, eHealth projects should plan for evaluation of the cost-effectiveness of interoperability and set up governance mechanisms for change management and maintenance of interoperability specifications.

5.2 Feasibility and Costs of Achieving Interoperability

5.2.1 Costs of interoperability are not prohibitive
Scientific literature shows no evidence that the costs of implementation and operation of deploying eHealth interoperability is a major impediment.

5.2.2 Costs of interoperability must be weighed against the benefits
The costs of achieving interoperability need to be related to the costs of non-interoperability and benefits of achieving interoperability. A (non-exhaustive) list of cost factors and potential benefits is provided in this chapter based on a literature review.

5.2.3 Profile based approach is most cost-effective
There are at least 3 ways to approach interoperability: profile based, customised standards approach and infrastructure vendor approach. Of these three approaches, Profile based interoperability has the lowest implementation costs and the lowest life cycle costs.

5.3 Non-Technical Factors

5.3.1 Policy elements that influence success
There are several policy elements that affect the successful completion and long term sustainability of an eHealth deployment project: Education, Privacy & Security, Clinical Research, Incentives, Innovative Business Models, Cross-vendor integration, and Future standardisation.

5.3.2 The importance of attention to usability
eHealth projects should specifically design methods of ensuring acceptance by the end-users of the system (e.g. patients and health professionals). This includes making the system as user-friendly as possible, designing user-interfaces tailored to each end-user group, offering training material, and designing a system of incentives for end-users, especially for those whose workload increases as a consequence of the implementation of the new system.

5.3.3 Projects need an interdisciplinary project approach
A good project management and successful stakeholder involvement are key factors for the success of an eHealth project. The careful selection of an experienced project manager with an understanding of the eHealth domain and standards to be implemented and the ability to motivate the team, an interdisciplinary project team covering all required skill-sets, a high-quality project description agreed by all stakeholders, a realistic time plan, careful risk management, and continuous change managements are important aspects.

5.3.4 Be aware of possible communication problems in your project
eHealth projects are interdisciplinary in nature. Misunderstandings and communication problems between stakeholder groups are, therefore, likely. The project management should be aware of this and apply best practices for interdisciplinary project management and intercultural communication.

5.3.5 Need for good preparation and tooling
eHealth standards are complex and their correct implementation requires experience. eHealth projects should focus on involving experienced team leaders, continuous developer training and the utilisation of well-tested software libraries implementing standards whenever possible.

5.4 System Architecture

5.4.1 Start small, but with the end-goal in mind
It is better to start with a small system and grow over time, than to aim for the perfect solution immediately. An enterprise architecture strategy is needed, however, to promote consistency
across the growing systems.

5.4.2 Layered approach of projects
EHealth projects should define their architecture based on a decomposition into layers representing different domains with increasing level of detail. Also, interoperability should be addressed in such a layered approach.

5.4.3 Modular approach reduces complexity
Decouple components of the system architecture based on function or service, using well-defined interfaces between the components. This reduces complexity and simplified implementing or procuring the individual components.

5.4.4 Choose between centralised or federated model
Carefully analyse whether to follow a centralised, decentralised, or hybrid approach. Both centralised and decentralised solutions have their own risks that should be known and managed.

5.4.5 Profiles need still further specification for deployment
The IHE cross-community integration profiles are the first standard for an eHealth “network of communities” that has seen large-scale implementation in several countries. There are however, some challenges in deploying these profiles. Nictiz has published a “Guide to Interoperability between XDS Affinity Domains” that helps addressing these challenges.

5.4.6 Balance between security versus availability
IT Security will be one of the most complex parts of the system architecture, and needs to be addressed from the start. A balance between security objectives and usability of the systems needs to be achieved. Projects should always use well-known and well-tested algorithms and software modules and design multiple layers of security.

5.4.7 Define requirements that can be met by different vendors
Make sure that more than one end user application can be built for your eHealth project (e.g. for accessing and visualizing information from the eHealth ICT systems), catering for different user needs and user preferences. This also prevents vendor lock-in. One approach for enabling different end user applications is Pre-commercial Procurement (PCP).

5.4.8 Use manageable, small information objects
One source of complexity most projects have to address is the mapping between different standards, or different versions of a standard. The development of reusable information building blocks is one approach to simplifying this challenge.

5.4.9 Take European requirements into account when you plan a project
When designing a local, regional or national eHealth solution, take into account the European requirements arising from EC regulations such as the General Data Protection Regulation, the eIDAS regulation on the management of electronic identity, and the Directive on Public Procurement.

5.5 Clinical Information Modelling and Templates for Clinical Documentation

5.5.1 Start with coding the basics and weigh costs and benefits of coded information
eHealth projects should be pragmatic when it comes to the selection of content formats: While fully encoded information is clearly preferable, unstructured free text information is better than nothing.

5.5.2 Design a logical information design and map this to technical formats
The design of clinical document formats or other clinical content should be performed in two steps: first define a clinical information model that is independent from a concrete syntax and encoding, and then map this into the clinical document or message format used. This offers a separation of concerns and helps in translating content to other formats.

5.5.3 Use mock-up applications to evaluate the information model components
It very useful to implement a clinical information model as a mock-up application with a graphical user interface, both as a means of validation of the model, and as a tool for communication between clinicians and technical experts.

5.5.4 Agree on using the same technical formats
Non-interoperability can be a problem even if all parties in an eHealth system use the same clinical document or message format, but develop different templates/archetypes to represent clinical content. To ensure interoperability, eHealth projects need to also control the templates/archetypes and terminology bindings used.

5.5.5 Allow for multi-coding of concepts and value sets
When clinical content is represented through coded terminologies, and it is possible to represent one clinical concept through codes from multiple terminologies, all equivalent codes should be stored in the document. This greatly increases the chance of success of a terminology mapping at a later point in time. This approach is called “multi-coding”.

5.5.6 Clinicians must be presented with user-oriented, non-technical data entry. Coding should be done by the application, in the background
The availability of appropriate tools and user interfaces to facilitate coding is one of the key factors for the acceptance of terminologies by health professionals. Coding should be transparent to the health professional and be based on an interface terminology, which needs to be maintained continuously.

5.6 Tooling: Starting from the State of the Art

5.6.1 Use what’s out there, but substantiate your choices
Avoid the “Not Invented Here” syndrome, i.e. try to avoid “reinventing the wheel”. Carefully analyse existing standards, architectures and tools before deciding to develop your own.

5.6.2 Look at reference implementations and testing tools
Good software tools are a critical success factor for eHealth projects. Check the lists of available libraries, reference implementations and test tools provided in this section for tools suitable for your project.

5.6.3 Aim for open source solutions for better cooperation
Developing and publishing software under an open source license can contribute to the scalability and sustainability of a project. Clarify if this applies to your project.

5.6.4 Look over the fence
Chapter 6. The Refined eHealth European Interoperability Framework

**Key Takeaway Points:**

6.1 *Choose standards that fit your project*

The ReEIF can be used to compare standards by first selecting a use case, and then comparing different realisation scenarios that implement the use case based on different standards. Only in a real world situation can standards be valued correctly.

6.2 *Look at the EC Public Procurement Directive for your project*

The ReEIF can be used in the procurement of eHealth products and system components implementing actors and transactions of one realisation scenario. However, the EC Public Procurement Directive requires that technical specifications for public procurement are based on EU standards. IHE profiles used in many ReEIF implementation scenarios have been approved for public procurement use, but additional EU specifications are needed to enrich the clinical contents related to the ReEIF use cases.

6.3 *Interoperability can only be achieved with agreements on all levels of interoperability*

Interoperability between systems that use different standards can be achieved by using the same data model, agreements on which data elements should be translated and how, and by using transformation tools. A decision tree can help to select the most appropriate approach for translation. Other factors for interoperability are: protocols on interface and network technology, syntax and semantics in interfaces, an interoperability model in application architecture, and a functional reference model.
3  Tell us what you think

Dear sir, madam,

As described in the request letter that we sent you, we ask you to state whether you agree with the Key Takeaway Points that we have placed at the start of each chapter of the eStandards D4.2 r2 document.

Please state in the second column whether you agree with the contents, and place any comments in the third column regarding any obstacles you have.

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<tr>
<th>Key Takeaway Points</th>
<th>Agree with these points? Score: 1 (not) to 5 (completely agree). Plus your comments.</th>
<th>Consistent with your experience? Score: 1 (not) to 5 (completely agree). Plus your comments.</th>
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Another question we would like to ask you, is whether you have any important recommendations on the subject of this document that we have missed. If so, please enter that in the textbox below:

Other suggestions relevant to the document that your organization has missed: