Eco-system for disease specific clinical workflow and data integration

DELIVERABLES D7.3, D7.5

Standardisation & Dissemination Plan

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ITEA Roadmap challenge:
Smart Health

HISTORY

Document version #	Date	Remarks
V0.1		Starting version, template
V0.3		Second compilation of input by partners
V1.0		Final version

Deliverable review procedure:

- **2 weeks before due date**: deliverable owner sends deliverable –approved by WP leader– to Project Manager
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable
- **1 week before due date**: co-reviewer provides input to deliverable owner
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer

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1 Executive summary

This document describes the plan for standardisation and dissemination in the context of the SYMPHONY project.

A standard is an established norm, rule, or approach that can describe the characteristics of a technology, it's mode of operation, and its performance. Standardization is the process of developing, adopting, and controlling such standards based on the consensus of firms, users, interest groups, and governments.

The SYMPHONY project brings together a complete healthcare IT-ecosystem (end-users, technology & research partners and system integrators) from five European countries and from Canada. SYMPHONY will realize the ecosystem via Open APIs. Multiple platforms realizations that adhere to these Open APIs will be created, composed of multiple partner solutions. It will demonstrate these platforms in four clinical use cases, the focus of the project will not be on the creation of a new standard but on the creation of an ecosystem that will enable and end-to-end solution.

This document also describes the plan for using and disseminating the knowledge in the context of the SYMPHONY project, through various means including internal and external communication channels, the distribution of dissemination material and participation in dissemination activities. More specifically, the document includes

- SYMPHONY's dissemination strategy, describing the target audience active in verification and validation of evolving systems and the means for communicating with them
- Planned and performed dissemination activities will be recorded over the course of the project, including the participation in conferences and other relevant events and the publications in scientific journals.

2 Standardisation

2.1 Introduction

It is obvious that the interplay of technologies requires standards at many levels, from the data and the functional interfaces to the protocols.

The process of standardization has been studied by academics for many years. Standardization mostly occurs in international standard development organizations such as the International Organization for Standardization (ISO), regional standard development organizations such as the International Telecommunication Union (ITU) or national standardization organizations such as the Deutsches Institut für Normung (DIN) and scholars have, e.g., described these organizations in detail. However, sometimes, firms compete directly with other firms for a standard and engage in a market-based standardization process. The result could be a dominant standard or a dominant design. One crucial aspect that determines the success of platform ecosystems is the role of standardization in producing dominant designs. To reach dominant designs, generally accepted common standards should be developed and used by firms and society so that, e.g., the technological components of the systems can be connected, and quality and safety requirements can be guaranteed.

Despite the importance of standardization and the increasing popularity and significance of platform ecosystems and despite their evident links, both scholarly communities have not often studied the phenomena in combination. With this context and opportunity to offer new insights on the role of standardization in platform ecosystems, this special issue aims to advance knowledge in this field. In particular, the special issue focuses on how standards are an important element of platforms and their ecosystems. We aimed to bring together scholars studying standardization and platforms in a digital context. This included research on the impact of standardization, standardization strategies, standardization through consortia and/or strategic alliances, committee-based standardization, market-based standardization, standard selection, standards, and dominant designs, and standards battles and platform wars. Papers on other standardization topics about platform ecosystems were also considered. Following the journal’s standard submission and peer review process, we are delighted to share the five accepted papers for this special issue.

2.2 Overview of the clinical standards

Clinical standards and guidelines serve several important purposes:

- **Standardization:** They establish a common framework for diagnosis and treatment, ensuring that healthcare professionals follow evidence-based practices.
- **Quality Assurance:** They help maintain high standards of care, promoting the best possible outcomes for patients.
- **Education:** Guidelines are educational tools that help healthcare providers stay up to date with the latest research and best practices.
- **Resource Allocation:** They can inform healthcare policy decisions, helping governments allocate resources efficiently based on the needs of the population.

These guidelines are crucial for promoting consistent, evidence-based care and improving patient outcomes across Europe. It's important for healthcare professionals to regularly review and adhere to these guidelines to provide the best care possible.

In Europe, clinical standards and guidelines are often provided by organizations like the European Society of Cardiology (ESC) and the European Respiratory Society (ERS), among others. Here are European versions of the clinical standards for some common diseases, along with explanations of what these standards can do:

Heart Failure and AF:
ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure and AF (atrial fibrillation): These guidelines provide recommendations for the diagnosis and management of heart failure in European patients. They cover topics such as diagnostic criteria, pharmacological and non-pharmacological therapies, and patient follow-up. These standards help healthcare providers optimize care for heart failure patients and improve outcomes.

See the corrected 2020 version that is also used for SYMPHONY: Corrigendum to: 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS) | European Heart Journal | Oxford Academic (https://academic.oup.com/eurheartj/article/42/5/507/5919233)

Prostate Cancer (PC):
EAU and AUA Guidelines are updated regularly and aim to assist medical professionals in the evidence-based management of PC.

Aortic aneurysm (AA):
ESC Clinical Practice Guidelines. Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. In addition to coronary and peripheral artery diseases, aortic diseases contribute to the wide spectrum of arterial diseases: aortic aneurysms, acute aortic syndromes (AAS) including aortic dissection (AD), intramural haematoma (IMH), penetrating atherosclerotic ulcer (PAU) and traumatic aortic injury (TAI), pseudoaneurysm, aortic rupture, atherosclerotic and inflammatory affections, as well as genetic diseases (e.g. Marfan syndrome) and congenital abnormalities including the coarctation of the aorta (CoA).

2.3 Overview of legal standards and frameworks

European legal frameworks related to healthcare and medical devices play a crucial role in ensuring the safety, quality, and efficacy of products and services, including privacy and data security of data systems. Even if SYMPHONY software might formally not be rated as a medical device, they are worthwhile as references and guidelines from overall perspective. Here are some of the most applicable ones, with a brief description of each. Being an important export market, the US HIPAA regulation is included below as a non-European example of regulation.

GDPR (General Data Protection Regulation)
Purpose: GDPR governs the processing of personal data of individuals in the European Union and European Economic Area (EEA). While not exclusive to healthcare, the GDPR has significant implications for the sector.
Scope: It emphasizes data protection, privacy rights, and the lawful basis for processing personal data. Given the sensitivity of health data, healthcare providers and organizations handling patient information need to be particularly attentive to GDPR compliance.

ISO 27001 (Information Security Management)
Purpose: This is an international standard for information security management systems (ISMS). While it is not exclusive to healthcare, it is crucial for healthcare providers, especially given the sensitive nature of patient data.
Scope: It provides a systematic approach to managing sensitive company information and ensuring data security. Entities that achieve ISO 27001 certification periodically undergo a rigorous assessment of their information security management practices.

ISO 27799 (Information Security Management in Health)

Purpose: This is an international standard for information security management systems (ISMS) applied to the Health Sector. Given the sensitive nature of patient data it is a field-specific extension to ISO 27001.
Scope: It provides a systematic approach to managing sensitive medical information and ensuring data security and privacy. Entities that achieve ISO 27001 certification periodically undergo a rigorous assessment of their information security management practices.
Note: In the Netherlands the dutch translation of ISO 27799 is known as the legally binding national NEN 7510 standard.

MDR (Medical Device Regulation - EU 2017/745)

Purpose: This regulation provides detailed requirements for the design, manufacturing, and commercialization of medical devices in the European Union. It ensures a high level of safety and health protection for EU citizens using these devices.
Scope: It covers a wide range of products, from simple bandages to the most sophisticated life-supporting machines. It mandates rigorous quality control standards, post-market surveillance, and increased emphasis on the entire lifecycle of the product.

ISO 13485 (Medical Devices - Quality Management Systems)

Purpose: This is an international standard that specifies requirements for a quality management system (QMS) for organizations involved in the design, production, installation, and servicing of medical devices, and the design, development, and provision of related services.
Scope: This standard can be used by internal and external parties to assess the organization's ability to meet both customer and regulatory requirements.

ISO 14971 (Medical Devices - Application of risk management to medical devices)

Purpose: It specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices.
Scope: The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. It applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.
Risk management can be an integral part of a quality management system. However, this document does not require the manufacturer to have a quality management system in place.

IEC 62304 (Medical device software life cycle processes)

Purpose: Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes.
Scope: The standard specifies life cycle requirements for the development of medical software and software within medical devices. It has been adopted as national standards and therefore can be used as a benchmark to comply with regulatory requirements.

HIPAA 1996 (US Health Insurance Portability and Accountability Act)

Purpose: Defines national standards for electronic health care transactions and code sets, unique health identifiers, and security.
Scope: The US Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

eHealth Network Guidelines

Purpose: The eHealth Network is a voluntary network, set up under the Cross-Border Healthcare Directive (2011/24/EU). It provides a platform for cooperation and exchange of information among EU Member States on digital health.
Scope: The guidelines address various aspects of eHealth, including patient summaries, ePrescriptions, health data exchange, and more.

2.4 Overview of technical standards

Many SYMPHONY industrial partners are actively involved in IEC and ISO committees, they will ensure that results from the project are aligned with the (evolving) definitions of the applicable standards. Such as: DICOM (interoperability for image data), HL7 (interoperability for general medical data) and IEC; and that the standards are adapted to the new advancements of the project in order to guarantee a solid market position for the symphony outcome.

A list of specific standards that are related to the SYMPHONY activity is provided below.

Table 1: Overview of applicable standards related Healthcare platform technology.

International Standard	Organization	Scope	Year of Issue / Maintenance
DICOM	NEMA	Communication and storage of any type of patient imaging as well as results of processing of those data using software systems such as AI algorithms	2023
FHIR	HL7	Communication of any patient information that would be used together with imaging data, from and to electronic health record keepers, including personal medical devices.	2023
IHE Profiles and Technical Framework Documents	IHE International	Initial design of patient data workflows for the use cases	N/A
openEHR	openEHR Foundation	Reference standard specification for storage, retrieval and exchange of health data in electronic health records (EHRs)	2023

FHIR (Fast Healthcare Interoperability Resources)

Purpose: To facilitate the exchange of healthcare information electronically.
Description: FHIR is a standard developed by Health Level Seven International (HL7). It provides a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of

electronic health information. One of FHIR's distinguishing features is its modular approach, using "resources" — a set of standardized specifications for health data that can be used by themselves or combined to define more complex structures. These resources can represent patient data, clinical concepts, or any other information in healthcare. By building data structures from a set of standardized building blocks, FHIR ensures interoperability between healthcare applications, both on mobile platforms and in the cloud. It's designed to be easy to implement, and its flexibility has made it increasingly popular in the healthcare IT community. Another notable feature of FHIR is its support for RESTful architectures, making it suitable for use with modern web technologies.

DICOM (Digital Imaging and Communications in Medicine)

Purpose: Handling, storing, printing, and transmitting medical imaging information.
Description: DICOM is the international standard for transmitting, storing, and exchanging medical images. It ensures the interoperability of systems that produce, display, and store digital medical images. DICOM allows integration of imaging devices like scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS).

IHE (Integrating the Healthcare Enterprise)

Purpose: Improve the way computer systems in healthcare share information.
Description: IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate better, are easier to implement, and enable care providers to use information more effectively.

openEHR

Purpose: To serve as an open-source foundation for the development and management of an information model for electronic health records.
Description: openEHR operates as an innovative open-source architecture that utilizes a two-level modelling approach. At the core of this design are "archetypes" and "templates." Archetypes define the high-level clinical concepts and structures, while templates focus on specific use-cases or contexts, detailing how archetypes are to be used in particular scenarios. This flexible modelling system allows for the integration of a wide range of clinical vocabularies, such as LOINC and SNOMED CT, ensuring that electronic health records are both comprehensive and universally interpretable. This approach ensures not only adaptability and scalability but also interoperability across different healthcare systems and platforms.

3 Dissemination strategy

3.1 Means of communication

In order for dissemination to be effective, multiple communication channels are used in order to be able to effectively reach the desired target audiences. One focus of dissemination will be on scientific publications and to address the academic research community. Publications within the area of interest of the project include both technology-oriented journals and conferences. Results to be published will naturally tend to fall into one of the two categories, with some overlap between the two in case conference proceedings are published as journal paper.

Several important target audiences for dissemination activities have been identified; these include academic researchers, clinicians, healthcare IT professionals, as well as the general public. Different dissemination products are expected to appeal differently to each of these categories, and therefore it is necessary to be aware of what the focus of dissemination is expected to be during the different stages of the project, and how the results to be disseminated are to be best tailored to their target audience.

3.2 Timing

Concerning the timing of our dissemination strategy, three distinct phases of implementation can be identified.

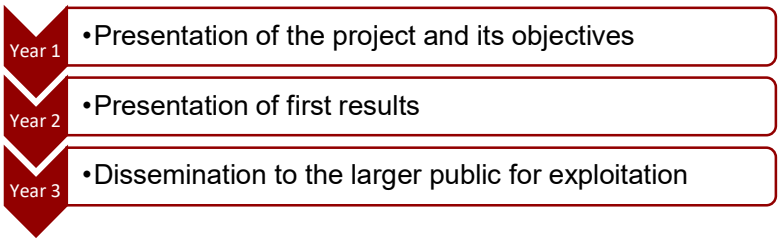

Figure 1: Focus of dissemination activities shifts over time.

Early on, focus will lie on building general awareness among industry and the general public, including potential customers, generating interest by communicating application scenarios that appeal to a broad audience. As the project progresses, focus will also encompass the smart services and tools that are being developed.

3.3 Internal dissemination strategy

Continuous and effective internal communication is key to the success of international projects such as SYMPHONY. For this reason, internal dissemination is considered as an essential part of the dissemination strategy as a whole, in particular because partners joined to learn from each-other. Internal communication allows to:

- Keep track of project-related decisions and action points;
- Clearly communicate the role and responsibility of each project participant;
- Communicate on WP and demonstrator progress;
- Disseminate the right level of information to project participants;

- Identify problems and provide solutions.

3.4 External dissemination strategy

Much of the effort is aimed at ‘external communication’ to promote the project, and disseminate results. The major external dissemination objectives are to:

- Effectively use these communication channels to present the SYMPHONY project’s results;
- Establish links and encourage synergies with similar projects and initiatives;
- Provide the foundation of a comprehensive exploitation strategy.

Details of each dissemination activity/tool are provided in the section 5 (“Dissemination Tools”)

4 Dissemination rules

4.1 Presentation and publication guidelines

All Partners will actively contribute to the publication policy, both at own initiative and upon request of other partners, work package leaders and the project managers.

When another partner is mentioned in a publication, written permission shall be requested from this specific partner. If a partner wishes to publish information generated in the SYMPHONY project the approval of all partners has to be requested:

- This request shall be made preferably per e-mail;
- Reactions should be sent within 7 days;
- Without reaction permission is automatically granted after 7 days;
- In case of non-unanimous reactions the PM will take the final decision;
- A copy has to be sent of the final publication to the project office for central archiving.
- The document will be published on the website until written indication is given that this is not allowed (e.g. due copyright rules from journals). In this case only the reference will be added.

4.2 Graphic identity

This section describes the features that contribute to giving a common graphic identity to all dissemination activities allowing for a better visibility and recognition of the project.

4.2.1 Layout and templates

Common/similar **layouts** *are used for the SYMPHONY dissemination materials.* **Templates** *for project meeting minutes, deliverables and PowerPoint presentations were made available in the beginning of the project by the project coordinator, Philips.*

4.2.2 Logos

In addition to the SYMPHONY project logo the ITEA4 logo should be used when possible (both are shown on the frontpage of this document).

4.3 Compulsory acknowledgements

Any partner in the SYMPHONY project will in their dissemination activities clearly acknowledge the ITEA4 Program with reference to the project “SYMPHONY” and the project number 21026.

Preferred reference:

"This work was labelled by ITEA and funded by local authorities under grant agreement "ITEA-2021-21026-SYMPHONY"
+include link to the project website and where appropriate to the online experimentation platform

5 Dissemination tools

5.1 Internal dissemination tools

The project coordinator, Philips (NLD), together with the respective work package leaders, has put in place a variety of mechanisms to optimize the communication workflow.

5.1.1 Project meetings

There are several types of project meetings in action :

- General Assembly meetings taking place twice a year;
- Monthly project management team meetings;
- Fortnightly/Monthly work package meetings;
- Additional calls when needed for day-to-day coordination of the project.

At the moment of writing of this document so far, apart from the kick-off meeting, one general assembly meeting has been organized and one is due soon. An impression of these meetings is given in Figure 2. The General assembly meetings serve to update each other on project results, and to align the activities for the next period.

Figure 2: Impression from SYMPHONY Kic- off Meeting in Best, the Netherlands

5.1.2 Information sharing

SYMPHONY consortium members use a file sharing and storage system to safely share project information, presentations and even photos. Access is shielded by a user code and password. The user-friendly file transfer environment is structured around Documents (frozen) and Workspace (works in progress). The Documents section contains a.o. the current project plan and approved deliverables. Within the Workspace section different work packages (WPs) each have their own space.

5.1.3 Workshops

In addition to the general assembly's smaller workshops have been and will be held on either National level, use cases or specific topics.

5.1.4 Other Tools

Other internal communication tools include mailing lists (participant, WP and at the consortium levels), internal staff meeting and meeting minutes, web conferencing etc.

5.2 External dissemination tools

External dissemination designates actions aiming at ensuring the visibility and awareness of the results outside the Consortium borders, i.e., in the scientific community, in academic institutions, in other research organizations, or among the lay public. These tools include:

5.2.1 Project Public Information Sharing

Project public information will be shared through SYMPHONY website and LinkedIn page mentioned below:

https://symphony-iteaproject.eu/

https://www.linkedin.com/company/symphony-itea-project-number-21026/about/

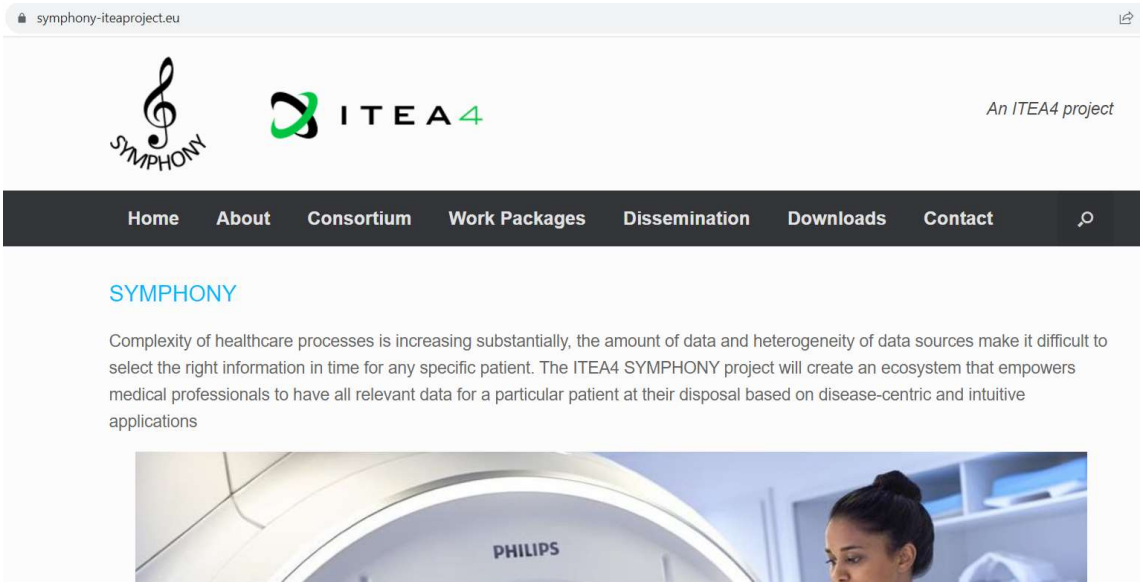

Figure 3: SYMPHONY Website

5.2.2 Publications and presentations

SYMPHONY project results will be submitted for publication in scientific journals, conferences, and workshops. The submission of papers jointly written by project participants is encouraged.

Given the diversity of use cases and tools being addressed in SYMPHONY, a wide variety of national and international journals, conferences and workshops can be targeted to disseminate SYMPHONY results. The selection of certain dissemination platforms will, apart from the topic, also depend on the timing. Not all conferences are held every year, and also the timing within the year may vary.

Journals targeted by SYMPHONY include:

- European Urology (and sub-journals)
- EP Europace
- Diagnostics – journal for medical diagnosis
- Heliyon - research across life, physical, social, and medical sciences
- Journal of Clinical Epidemiology
- European Radiology Journal Frontiers in Cardiovascular MedicineComputers in Biology and Medicine
- International Journal of Cardiology
- Netherlands Heart Journal
- International Journal of Computer Assisted Radiology and Surgery
- European Journal of Vascular Surgery
- Journal of Vascular Surgery

Conferences:

- European Heart Rhythm Association (EHRA)
- European Society of Cardiology (ESC)
- MICCAI (Medical Image Computing and Computer Assisted Intervention)
- European Association of Urology (EAU)
- SPIE medical Imaging
- European congress radiology
- CIRSE
- IHE Forums (Webinars, Connectathons etc.)

5.2.3 Press releases and social media

Press releases may be organized on an ad hoc basis to disseminate special milestones and/or project results. Very often media coverage cannot be orchestrated but “happens” as a result related dissemination activities.

5.2.4 Education and Innovation

Educating young scientists and involving them in innovation is an important aspect of the SYMPHONY project. SYMPHONY is actively involved in graduation assignments for M.Sc. and Ph.D. students which (partially) take place at industrial partner premises. In addition some industrial researchers have also an university position.

Several partners also employ company internal means to educate colleagues in the activities and results of the SYMPHONY project.