Eco-system for disease specific clinical workflow and data integration

DELIVERABLE D2.1

Reference architecture for open eco-system

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1 Introduction

This document serves as a comprehensive guide to the reference architecture of the SYMPHONY ecosystem, establishing a unified foundation for the development of components in the eco system and the interfaces between them. It offers a high-level perspective on the interconnected ecosystem components, their interfaces, and their alignment with the specific requirements outlined in Work Package 1 (WP1).

The reference architecture outlined herein is pivotal in shaping the overall structure and interoperability of the SYMPHONY project, providing a framework that ensures consistency and cohesion across the components. This document defines rules and interfaces crucial for integrating independently developed “components”, implemented via independent developed and released systems and services, into a user-friendly ecosystem solution.

2 Scope

This document delineates the reference architecture to be universally implemented across each of the SYMPHONY use cases.

The SYMPHONY project encompasses four distinct use cases, each addressing specific medical scenarios:

- UC1: Prostate Cancer
- UC2: Aortic Abdominal Aneurysm
- UC3: Atrial Fibrillation
- UC4: Multiple Sclerosis

The reference architecture serves as a unifying framework for all use cases, creating an open ecosystem that fosters seamless integration and interoperability. While the overarching architecture remains consistent, individual use cases may necessitate variations based on their unique requirements. As such, specific components of the architecture may be omitted if deemed unnecessary for a particular use case. This adaptive approach ensures that each use case within the SYMPHONY project can be conformant to the relevant parts of the reference architecture and omit parts which are not applicable.

3 Terminology & Abbreviations

Terminology & Abbreviations	Description/Definition
UC	Use Case
WP	Work Package
DICOM	Digital Imaging and Communications in Medicine
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
PC	Prostate Cancer
AA	Aortic Abdominal Aneurysm
AF	Atrial Fibrillation
MS	Multiple Sclerosis
EHR	Electronic Healthcare Records
PHI	Personal Health Information
PII	Personal Identifiable Information
Component	Independently developed and released system or service, which can integrate into a bigger solution. Each component can be developed and managed by a different vendor/provider.
Ecosystem	The integration of multiple components into a seamless integrated solution. The components are integrated via pre-scribed rules, guidelines, and interfaces. Additional compliant components can be added to the ecosystem, without having to modify the other components in the solution.
CDS	Clinical Decision Support
JSON	JavaScript Object Notation

4 Vision and Overview

4.1 Ambition and Benefits

The SYMPHONY project envisions a transformative leap in healthcare, aspiring to empower users with the ability to compose a dynamic and user-friendly ecosystem/solution. The ambition lies in creating a healthcare ecosystem that integrates seamlessly with diverse healthcare components, facilitating a comprehensive approach to diagnosis, treatment, and follow-up. The goal is to bring tangible benefits for customers, including practitioners and patients. Practitioners gain enhanced decision-making capabilities through an intuitive system, leading to improved treatment effectiveness and efficiency. Patients, in turn, experience better recovery and an overall improved quality of life.

4.2 Competitive Landscape

The competitive landscape is characterized by the need for innovative solutions that bridge the gap between diverse healthcare systems and enable interoperability. SYMPHONY aims to stand out by offering a vendor-agnostic integration approach, ensuring flexibility, and avoiding vendor lock-in. This competitive differentiator positions SYMPHONY as a pioneering solution in the evolving healthcare technology landscape.

4.3 Target Markets

SYMPHONY targets the European eHealth market, valued at USD 4.6 billion in 2023 and forecasted to grow to USD 9.5 billion by 2028. The project aims to capitalize on the market's growth potential, driven by a compound annual growth rate of 15.94%. [1] As a forward-looking initiative, SYMPHONY anticipates expanding its presence beyond Europe to address global healthcare challenges.

4.4 User Insights

Key user insights guide the development of SYMPHONY, emphasizing the importance of usability for both clinical users and patients. The system is designed to streamline clinical workflows, making it intuitive for practitioners to compose disease-centric workflows. Additionally, the architecture prioritizes usability for patients through features like automatic communication of data and events to the patient via smartphones, relieving caregivers from administrative tasks.

4.5 Common Discriminator

A common discriminator for the SYMPHONY product range is the emphasis on an open ecosystem that encourages collaboration and integration. The ability to seamlessly integrate independently developed components is a distinguishing factor, promoting interoperability and standardized interaction patterns across the components. Proprietary interfaces and constraints are being avoided.

4.6 Architecture Key Drivers

4.6.1 Openness

The ecosystem must be open, such that multiple vendors can provide components to the eco system. This ensures evolution over time and avoids vendor lock in.

4.6.2 Life Cycle Decoupling

Independent developed systems necessitate life cycle decoupling as a key driver. This ensures adaptability and evolution over time without disrupting the overall system.

Each component in the eco system must be independently managed, without affecting the other components. Each component in the eco system has its own lifecycle and can be independently upgraded.

4.6.3 Usability for Clinical Users/Patients

The usability for clinical users and patients is a critical driver. The architecture is designed to enable user-friendly interfaces, intuitive workflows, and features that enhance the overall user experience.

4.6.4 Data availability and data limitation

The architecture must enable that all relevant data will be available to a component or user, as required by the clinical workflow. It must be traded off with data privacy and data access limitations. PHI data access must be minimized as much as possible.

4.7 Required Diversity Over Time

The SYMPHONY project anticipates diversity over time in various product aspects, including:

- (Imaging) AI Applications: Evolving and diverse AI applications catering to different diagnostic and therapeutic needs.
- Clinical Decision Support: Continuous enhancement and adaptation of decision support systems based on emerging medical knowledge.
- Data Stores/Hospital IT Systems: Flexible data store and IT system variations to accommodate the diversity of healthcare infrastructures.

The longer-term diversity for SYMPHONY includes a requirement of being ready for future product variations and diversifications, addressing evolving healthcare challenges. This can result in integration of new type of component and/or newly defined APIs, which is beyond the project timeline.

4.8 Range Description

The product range based on the SYMPHONY reference architecture addresses different market segments strategically. It involves a phased build-up, considering variations in AI applications, decision support, and data storage to meet specific healthcare needs. The plan acknowledges that country-specific aspects are situational dependent and may require tailored adaptations.

In summary, SYMPHONY's vision is anchored in creating a flexible, interoperable, and user-centric healthcare ecosystem that not only meets current market demands but also anticipates and adapts to future healthcare challenges. The project aims to surpass existing

challenges, ushering in a new era of enhanced data accessibility and collaboration within the healthcare ecosystem.

SYMPHONY covers the in-hospital scenarios, which include diagnosis, treatment and follow-up phases. SYMPHONY also covers the out of hospital clinical scenarios, including patient engagement.

5 Strategic objectives and requirements

5.1 Requirements

As detailed in previous sections, the SYMPHONY project is fundamentally designed to forge an ecosystem wherein components from different vendors collaborate harmoniously to address the varied requirements of extensive clinical workflows. This ambitious goal hinges on fostering effective communication among multiple components, each carrying unique responsibilities. These responsibilities are common to different clinical pathways within the same workflow and extend to various workflows for different diseases. This approach ensures a comprehensive and interconnected framework that spans the broader landscape of healthcare.

Building upon the established framework, we have categorized these components into four distinct categories, each endowed with unique responsibilities, as delineated below:

1. External Data Sources:

This group exclusively provides clinical data to the workflow, encompassing structured and standardized data with formats like DICOM or FHIR. It also accommodates unstructured data, ranging from free-text entries to sensor readings.

2. AI Powered Components:

Components falling under this category adeptly process specific inputs, employing one or more artificial intelligence algorithms to yield results in a structured and standardized format, such as DICOM or FHIR. These components play a pivotal role in enriching the data with clinically relevant results and guidance.

3. Data Store Components:

True to their nomenclature, these components are proficient in storing data in a standardized fashion. Moreover, they facilitate the seamless dissemination of stored data to other components through predefined standardized protocols, contributing to a cohesive and interconnected workflow.

4. Application Components:

In addition to presenting stored data to end-users, components in this category play a crucial role in showcasing and processing the outcomes of specific data enhancement processes. Their responsibility extends to initiating a human review and correction phase, ensuring that the results of AI-driven processes undergo meticulous scrutiny and approval before integration into the clinical workflow. This step is vital for validating and refining AI-generated insights with human expertise. Without these AI-powered components, human experts would perform the responsibilities they carry using these applications.

Continuing from the descriptions, the successful integration of these four major component types demands the creation of diverse system designs tailored to the specific clinical workflows they support. Each component within this ecosystem assumes a pivotal role, providing essential support to practitioners in clinical decision-making processes and in the investigation of the progression of patient cases over time. Particularly, these components contribute to evaluating the efficacy of applied treatments during different phases of patient care. The interconnected nature of these components forms a cohesive framework, guided by the unique requirements of the clinical workflows they serve.

5.2 Compliance Requirements

5.2.1 Privacy

5.2.1.1 Privacy of Individual Components:

Data Encryption: Ensure all sensitive data, including patient records, is encrypted both in transit and at rest within each component of the system.

Access Controls: Implement strict access controls to limit who can view and modify data within each component. Role-based access can help manage this effectively.

Audit Trails: Maintain detailed logs and audit trails within each component to track access and changes made to sensitive data.

Data Minimization: Only collect and store the minimum necessary data within each component to limit exposure and potential privacy risks. Only share PHI data with a component when it is required for the functioning of the component.

Anonymization Techniques: Use techniques like pseudonymization or tokenization to replace identifying information with artificial identifiers within individual components when the identification is not critical for the functioning of the component.

Security and privacy and compliance with General Data Protection Regulation (GDPR): To ensure Data privacy and security, all developments will be compliant with the GDPR regulations.

5.2.1.2 Privacy of Integrated System:

Secure Communication Protocols: Ensure that data exchange between different components of the eco system occurs through secure channels, using protocols like HTTPS and TLS.

Interoperability Standards: Adhere to established interoperability standards to ensure seamless data sharing while maintaining privacy and security standards across integrated systems.

Consistent Access Controls: Enforce uniform access control policies across all integrated components to prevent unauthorized access to sensitive information.

Data Segmentation: Employ techniques to segment and compartmentalize data, allowing only authorized entities access to specific datasets based on their need and permissions.

Regulatory Compliance. All data storage and access must be according to the applicable regulation in each country. Each component in the eco system must be validated for the regulatory compliance for each country.

5.2.1.3 "Need to Know" Basis De-Identification:

Data Masking/De-Identification: Employ robust de-identification techniques to remove or mask personally identifiable information (PII) from datasets, limiting access to only essential information required for specific tasks.

Tokenization: Use tokenization to replace sensitive data elements with tokens, allowing authorized users access to data without exposing the actual sensitive information.

Dynamic Access Controls: Implement dynamic access controls that grant access to specific data elements based on the user's role and necessity, ensuring a "need to know" approach.

5.2.2 Security

5.2.2.1 Security of Components:

Strong Authentication: Implement multi-factor authentication for access to sensitive data and systems within each component to enhance security.

Intrusion Detection/Prevention: Deploy robust intrusion detection and prevention systems to monitor and protect individual components against unauthorized access or cyber-attacks.

Secure Configuration: Configure servers, databases, and other components with security best practices, such as disabling unnecessary services, changing default passwords, and limiting network access. Each component must perform a security risk assessment and mitigate the identified risks.

5.2.2.2 Security of Integrated System:

Data Encryption in Transit and At Rest: Enforce encryption for data transmission between integrated components and when storing data to prevent unauthorized access.

Secure APIs and Interfaces: Ensure that APIs and interfaces used for data exchange between different components are secured against potential threats like injection attacks and unauthorized access.

5.2.3 A distributed, and extendible data infrastructure

The open data backbone needs to be scalable and support very large amounts of data for running analytics to help decision making in treatment or diagnostics. A distributed, and extendible data infrastructure is considered, based on cloud platforms and/or on-premises infrastructures in hospitals. Within the scope of the SYMPHONY project, this responsibility would be hauled by the data store components and the project itself will cover the integration and data access aspects by defining relevant interfaces among its components.

5.2.4 Interoperability Standards

Within the SYMPHONY project, interoperability standards will be selected that:

- have a mature release status
- are accepted and adopted by international industry
- are mandated or promoted by governments or regulatory bodies
- and are providing structures for both data models and communication protocols

5.2.4.1 Open data backbones

This consists in the delivery of an approach to gather and share information and data across care sectors and levels of care including clinical and social care, supported by an open data backbone to ensure access to the information in a secure, standard based, open and efficient manner. With the backbone, the health data will be unlocked from proprietary systems and will be made available to applications and algorithms by standardized and technology agnostic data access interfaces. There will be no single data backbone for SYMPHONY. There will be 4 harmonized data backbones conforming to same set of Open APIs.

Data ingestion components will be developed that include adapters and converters to connect, read, clean, and convert heterogeneous data coming from different sources in various formats to standard formats. To increase interoperability, ingested data will be compliant to widely adopted data models and ontologies.

Data processors will be developed to enable automatic operations such as extracting semantic information from input data (e.g., Natural Language Processing (NLP) based semantic information extraction) and mapping to structured data and enriching structured data. The role of semantics is vital for achieving interoperability in sharing of health records.

Data interoperability is covered via different angles such as, message exchange protocols, data models, ontologies and context sharing.

5.2.4.2 Standards for the data exchange and storage:

Within SYMPHONY available international standards will be used as much as possible as preferred data exchange method. Only as fallback, a proprietary mechanism must be defined. Availability of a standard for workflow definitions will be checked in SYMPHONY work package 3 and if found, its details will be fed back into this document. Currently no such standard could be found that is widely used in the field.

5.2.4.2.1 FHIR [2]

FHIR has rapidly grown as answer to overcome the deficiencies of HL7 V2 and V3, adopting modern web-ready standards like REST and OAuth2, and strong focus on semantic meaning and machine readability. It enables EHR vendors to create a more open system and provides ways to exchange structured clinical data.

5.2.4.2.2 DICOM [3]

DICOM is the standard for the exchange of medical imaging data. In the area of AI processing, IHE is recognizing the need for standardization for AI Results based on Imaging Data [4]. It leverages DICOM Structured Reports to capture AI Results in a semantic meaningful way. It also defines standards for storing derived data like Segmentations. Also, the AI Workflow for Imaging has been standardized as an IHE profile.

5.2.4.2.3 CDS Hooks [5]

CDS Hooks is a specification published by HL7 International to define a set of RESTful APIs and message models in JSON to be exchanged among different actors of a clinical decision-making system.

5.2.5 Local Regulations and Rules

Medical applications operating in specific countries must comply with local regulations mentioned here. Countries that are part of European Union must comply with both European and national regulations.

Also, use of AI in medical domain has many legal aspects which are not in scope of this document. Every component of the project should adhere to the rules that applies to it, considering the intended use of that component.

5.2.5.1 Türkiye:

Law on Protection of Personal Data (KVKK): The law is the main document that all registered companies in Türkiye must follow requirements in terms of personal data acquisition, management, transfer, and processing within the country.

Compliance with the following items of law is required for Turkish partners:

- Direct consent from patients to get personal health data and its processing and transferring,

- Anonymization of personal health data in case the reasons requiring processing are eliminated.
- In case of personal health data transfer abroad, obtaining the explicit consent from the patients and other requirements specified in the articles related with which countries to be transferred.

Regulation on Personal Health Data: The regulation specifies procedures of personal health data for scientific use, storage, processing in compliance with KVKK. It's also legal bounding document for Turkish partners' works in the project scope that will be done.

Regulation on Clinical Research of Traditional and Complementary Medical Practices: It regulates the procedures and principles regarding conducting scientific research on humans and protecting the rights of volunteers in the fields of traditional and complementary medical practices. According to this regulation, ethical committee of the hospital where data will be collected must approve the clinical research within the project and its methods. Without the approval of ethical committee, any personal health data cannot be collected, managed, transferred, and processed.

5.2.5.2 Europe

5.2.5.2.1 Medical Device Regulation (MDR)

Remains the primary framework for ensuring the safety and effectiveness of medical applications and devices.

Apps classified as medical devices must undergo conformity assessments, clinical evaluations, and adhere to post-market surveillance requirements.

Each classified medical device component in the eco system must comply with MDR compliance.

5.2.5.2.2 General Data Protection Regulation (GDPR)

Continues to govern the privacy and data protection aspects of medical apps, focusing on user consent, data minimization, and security.

Each component in the eco system must comply with GDPR compliance.

5.2.5.2.3 Artificial Intelligence Act (AI Act) [6]

- **Risk-Based Approach**: The AI Act introduces a risk-based classification system for AI applications. High-risk AI systems, which could include certain medical apps, will be subject to stricter requirements.
- **Transparency Obligations**: AI systems must be transparent and provide users with information about their capabilities and limitations.
- **Data Governance**: The AI Act emphasizes the quality and integrity of data used by AI systems, ensuring that the data is error-free and representative.
- **Human Oversight**: It requires mechanisms for human oversight to minimize risks associated with automated decision-making.
- **Record-Keeping and Reporting**: There will be requirements for detailed documentation and reporting, like those under MDR.

- **Conformity Assessment**: High-risk AI applications will need to undergo a specific conformity assessment, which may be in addition to any required under MDR.
- **Market Surveillance**: Enhanced market surveillance measures for AI products will be enforced.

Each AI component in the eco system must comply with the AI act.

5.2.5.2.4 Integration of Regulations

Medical apps using AI will need to navigate a complex regulatory landscape, ensuring compliance with MDR, GDPR, and the AI Act.

The AI Act's requirements will add another layer of compliance, particularly for apps that use AI in a way that is classified as high-risk.

Developers and manufacturers need to stay updated on the AI Act's progress and prepare for its eventual implementation.

5.2.5.3 The Netherlands

5.2.5.3.1 MedMij Regulations

- **Focus on Health Data Exchange**: MedMij is specifically focused on the secure and standardized exchange of health data between different systems, including medical applications that are controlled by the patient such as personal health monitoring systems.
- **Standardization**: MedMij sets out standards for how health data should be exchanged in a way that is secure, reliable, and user-friendly. The main standard for this is FHIR.
- **Interoperability**: A key aspect of MedMij is to ensure interoperability between different health data systems, making it easier for patients to access and share their data across various platforms.
- **Patient Consent and Control**: MedMij emphasizes patient control over their health data, aligning with the principles of GDPR in terms of user consent and data rights.
- Integration in the Netherlands: Under MedMij, apps that exchange health data must meet specific Dutch standards for data exchange and interoperability (FHIR), in addition to the broader requirements of the MDR, GDPR, and potentially the AI Act.

The regulatory landscape ensures that medical apps are safe, effective, protect user data, and facilitate efficient health data exchange.

5.2.5.3.2 Practical Implications

Developers and manufacturers of medical apps in the Netherlands need to be mindful of these multiple layers of regulation.

Compliance with MedMij is particularly important for apps that are part of or interact with the Dutch healthcare system, especially those that handle electronic health records or facilitate data exchange between patients and healthcare providers.

Staying updated with the evolving regulatory landscape, including potential changes brought by the AI Act, is crucial for legal and operational conformity.

5.2.5.4 Sweden

PDL (Patient Data Law) Regulations:

- **Storage of data**: Data cannot be stored or managed by entities that are under obligation to provide data to third party countries. For example, storage or staff belonging to American legal entities, even if the physical storage is within EU.
- **Traceability**: PDL requires full traceability of all access to patient data, so every read, write or change of data needs to be logged.
- **Access restrictions:** Access to patient information must be restricted to only show what is necessary.
- **Deletion of data:** Unlike in GDPR deletion of patient data is only allowed after approval by the caregiver responsible for the data.

5.2.5.5 Spain

Health system services in Spain are administered at the regional level, not nationally. In Murcia, a dedicated Digital Transformation initiative is scheduled to commence in January 2023 to address privacy and security considerations relevant to software developments. While specific requirements are not yet defined, overarching rules, such as preventing identity usurpation, guide the process. Security audits are systematically conducted at three levels: software code, application, and APIs. This strategic approach ensures that the efforts on SYMPHONY align seamlessly with the outcomes of this Digital Transformation initiative.

6 Reference Architecture

6.1 Architectural Overview

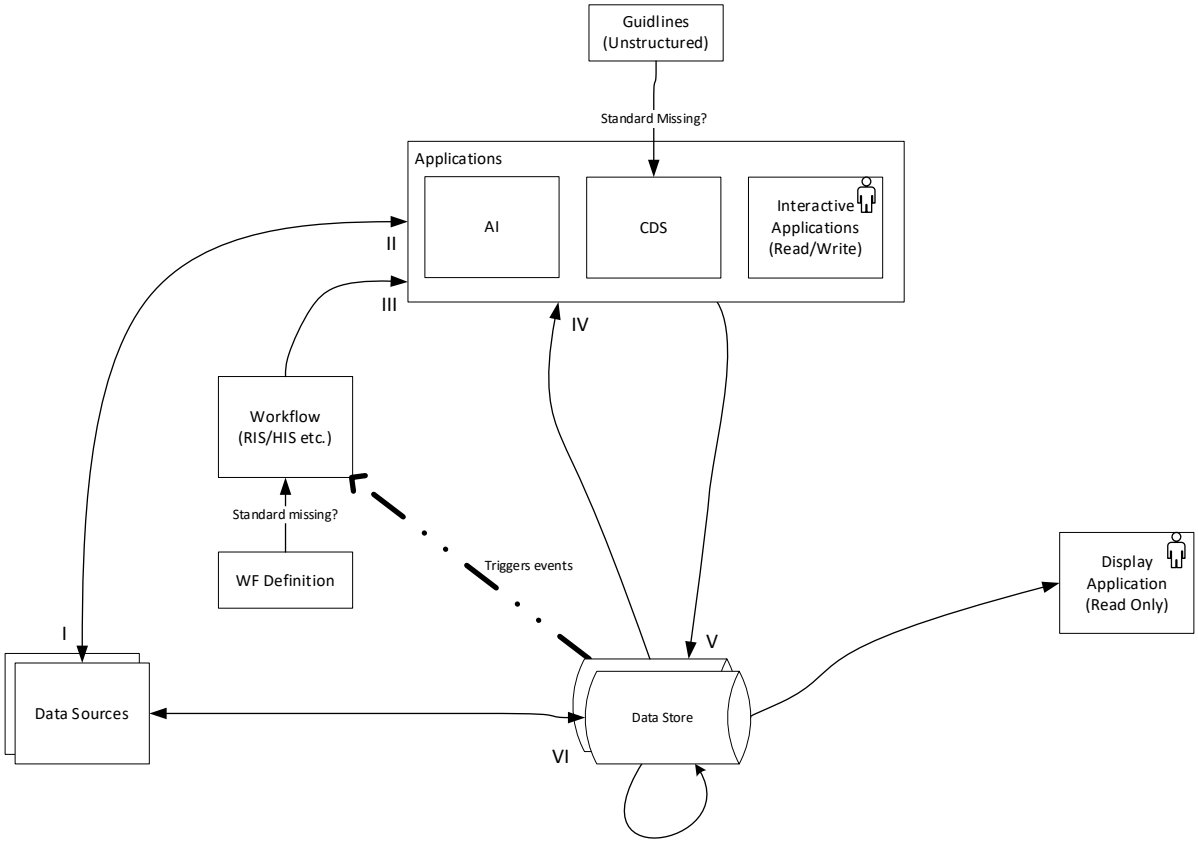

Figure 1 Reference Architecture

The diagram above illustrates a reference architecture intended for application in each of the project's use cases. It comprises multiple components, which may function as individual applications. The internal details of these units are beyond the scope of this level of design.

Upon the initial investigation, it became apparent that these components, supplied by one or more partners, carry a predefined set of responsibilities, classifiable under a specific category, as explained below. Additionally, note that certain connection points are marked with numbers. Given their critical role in integration, these connection points must adhere to specific rules to facilitate pluggability, and detailed explanations for these rules will also be provided. Components that are expected to be used by a user and to have a user interface are marked with an icon.

6.2 Component Categories

This section delineates the rules that categorize a component into a specific category.

6.2.1 Data Sources

These components serve as the primary generators of data, residing either within clinical service providers such as hospitals or general practitioners, or they may exist in cloud environments, such as those provided by personal healthcare monitoring services.

Devices for acquisition, including magnetic resonance imaging (MRI), computerized tomography (CT), ultrasound imaging (US), and X-Ray imaging, fall within this category. Additionally, healthcare information management systems such as picture archiving and communication systems (PACS) and electronic medical record (EMR) systems are also included.

Throughout the data acquisition process, certain systems within this category may employ AI and/or interactive applications to guarantee acquisition quality. This occurs prior to finalizing the acquisition and transmitting the data to storage.

Furthermore, the data generated or acquired by these systems is intended to be stored in one or multiple data stores, contingent upon usage requirements and storage duration. While some data sources may have internal storage systems for short-term access, these are not within the scope of this design level.

6.2.2 Data Stores

These systems primarily bear the responsibility of storing data, as implied by their name. While some of these systems only store data temporarily for staging purposes, allowing other components to use it, others store it for long-term persistent storage. Data stores also have the capability to communicate with each other, facilitating the movement or copying of data from one to another or extending a query. Within the scope of the SYMPHONY project, these components are expected to store DICOM, FHIR/OpenEHR, sensor, and unstructured data such as text notes.

Data being sent to these stores might trigger actions in workflow engine components.

6.2.3 Applications

Components within these categories are typically integral to a clinical workflow orchestrated by a workflow system. Consequently, their processes are initiated through standardized interfaces, including CDS Hooks or FHIRCast, as outlined in the IHE AI Workflow for Imaging Profile.

6.2.3.1 AI Applications

These applications improve, refine the or enrich provided data using machine learning methodologies, resulting in diverse and extensive outputs. In the project's scope, each of these applications is expected to manage both unstructured and structured data in formats like DICOM and FHIR/OpenEHR, producing results in standardized formats. This ensures the attainment of pluggability and interoperability with other systems by adopting standard output formats in place of proprietary ones.

6.2.3.2 Clinical Decision Support Systems

The primary aim of these systems is to assist clinicians in decision-making processes by employing predefined clinical guidelines and data. These systems can navigate decision paths and interpret complex information trees to aid decision-making. Currently, there is no standard available for configuring these systems with guidelines. As clinicians are the main consumers of clinical guidelines, they are typically presented in an unstructured text format, often using language, or wording familiar to the specific medical field.

6.2.3.3 Interactive Applications

Users view or edit data generated by other components through these applications. As their usage requires writing as well as reading, these systems typically require communication with

multiple data sources. Systems used to monitor and edit the work of other systems also fall within this category.

6.2.4 Workflow Systems

Unstructured workflow definitions are input into these systems to coordinate the flow of information between components and/or treatment steps. Examples in this category include Radiological Information Systems (RIS) or Hospital Information Systems (HIS). Currently, there is no widely accepted and employed standard for defining workflows in these systems.

6.2.5 Display Applications

Data acquired, generated, and enhanced needs to be displayed for the consumption of clinicians to support clinical decision making in many steps. These components are designed to bring data together from multiple sources and display that coherently.

6.3 Interfaces

6.3.1 I. Applications to Data Sources

This interface is meant to share the enhanced results of applications back to the data source.

In the structured data domain, FHIR will be used as default standard to store results.

In the imaging domain the DICOM standards will be leveraged. IHE AI results provides guidance, by using DICOM SR and SSO objects to transfer objects in this interface.

6.3.2 II. Data Sources to Applications

Raw data that has been acquired by the data source would be sent to applications for further enhancement and processing using this interface. Unstructured data such as text or sensor readings as well as structured data in DICOM and FHIR/OpenEHR formats, is expected to be received on this endpoint.

6.3.3 III. Workflow Management to Applications

On certain events defined with standards, this endpoint will receive triggering messages that would carry information designed with widely accepted standards namely, CDS Hooks, FHIR Cast. Usage of these standards are also defined in AI Workflow for Imaging Profile of IHE [4].

6.3.4 IV. Data Stores to Applications

This is the main source for the applications to read data from data stores. Structured data will be transferred in compliance with DICOM and FHIR/OpenEHR standards for the applicable data types. Unstructured data such as text notes is expected to be served to relevant applications with this interface.

6.3.5 V. Applications to Data Stores

Structured outputs of the applications would be sent to data stores using this interface. DICOM SR and SSO objects as well as objects defined in FHIR/OpenEHR standards are expected to be used as data transfer objects.

6.3.6 VI. Data Sources to Data Stores

Main purpose of this interface is to store data from sources. Structured data that is defined by DICOM and/or FHIR/OpenEHR as well as unstructured data such as free form text is expected here. Also, proprietary formats for sensor readings are also consumable here.

7 Strategic interfaces

SYMPHONY as an ecosystem of API interfaces would represent a sophisticated network of interconnected APIs that support and enhance the functionality and services of SYMPHONY's digital platform. Here's how SYMPHONY could be described in this context:

7.1 Core Characteristics of SYMPHONY's API Ecosystem

7.1.1 Interoperability

SYMPHONY's APIs are designed for seamless interaction, enabling diverse systems and applications to communicate and exchange data efficiently within the SYMPHONY environment.

7.1.2 Standardization

The APIs adhere to standard protocols and formats, such as REST, ensuring consistent and compatible interactions across the SYMPHONY platform. For the exchange of medical data in The Netherlands we agreed upon FHIR, for other countries this could for instance be OpenEHR.

7.1.3 Scalability

Each component of the ecosystem is engineered to handle varying loads, maintaining consistent performance as the volume of API interactions fluctuates.

7.1.4 Security

Strong security measures, including authentication protocols, encryption, and rate limiting, are integral to protect data and control access within the SYMPHONY ecosystem.

7.2 Components of SYMPHONY's API Ecosystem

7.2.1 Public APIs

Open to external developers, these APIs allow for the extension of SYMPHONY's services to third-party applications, extending the SYMPHONY based solutions with new components and capabilities.

7.2.2 Private/Internal APIs

Preferably all cross-component interactions are via public APIs. Only in absence of these, SYMPHONY will fall back to private or internal APIs.

APIs that initially start as private APIs, will be considered to transition to public APIs when they are sufficiently mature and generic.

7.3 Integration and Data Flow

7.3.1 Data Exchange

APIs within SYMPHONY enable a fluid flow of information between components in the SYMPHONY eco system. Within a component these can be exchanged between databases, cloud services, and client interfaces, enhancing data accessibility and utility.

7.3.2 Microservices Architecture

SYMPHONY utilized an API first approach, where each component exposes its functionality through dedicated APIs, contributing to the overall agility of the platform. A component might utilize a microservices structure, which supports the API first approach.

7.4 Management and Governance

7.4.1 API Management and Governance

SYMPHONY project will act as the governing body of the approved reference architecture APIs, which are critical in the integration of components into the eco-system.

SYMPHONY will adhere to international approval cycles related to the standardized APIs.

7.4.2 Lifecycle Management

Continuous monitoring and iterative updates are essential to maintain the effectiveness and security of each API throughout its lifespan. Each component should have its own life cycle, addressing independent updates for security and functionality concerns over time. It is crucial for the APIs to be backward compatible throughout their life cycles. An agreed-upon deprecation process, including phase-out planning, is necessary to prevent failures that could disrupt pluggability and use case solutions.

Monitoring of availability should be conducted at each component level. While centralized monitoring is beyond the scope of this project, it could be considered as a valuable next step for future initiatives.

7.4.3 Documentation and Developer Support

Comprehensive and accessible documentation is provided for developers, alongside support channels, fostering an engaged and collaborative developer community around SYMPHONY. Minimally each partner should provide documentation for development and serviceability of each of the components. A single location and format for sharing those at eco-system level is out of scope of this project.

8 References

[1] Market Data Forecast, March 2023. [Online]. Available: https://www.marketdataforecast.com/market-reports/eu-e-Health-market. [Accessed 04 January 2024].

[2] HL7 International, "FHIR 5.0.0," 26 03 2023. [Online]. Available: https://www.hl7.org/fhir/.

[3] National Electrical Manufacturers Association, "DICOM Standard," 2023.

[4] IHE Radiology Technical Committee, "Technical Frameworks," 6 August 2020. [Online]. Available: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_Suppl_AIW-I.pdf.

[5] HL7 International, "CDS Hooks," 2022.

[6] European Commission, "Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS," Brussels, 2021.

9 Document Revision History

Revision	Release Date	Author	Description of changes	CR / Reason
1	2023-01-05	Yusuf Sayıta	Initial version	N/A