Eco-system for disease specific clinical workflow and data integration

DELIVERABLE D5.3

Final Report for Standards and Open API

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TABLE OF CONTENTS

1 Introduction

This report aims to provide a comprehensive overview of the usage of interoperability in the SYMPHONY Open Data Backbone, outlining its role in enabling seamless data exchange, integration, and collaboration across various systems, stakeholders, and work packages. The scope of this report encompasses an in-depth analysis of interoperability requirements, technical enablers, and potential challenges in achieving an open and standardized data ecosystem within the SYMPHONY framework. It also explores how interoperability enhances data accessibility, usability, and security while ensuring compliance with relevant regulations and best practices.

Furthermore, this report establishes the link between interoperability and the broader objectives of the SYMPHONY project, emphasizing its impact on facilitating data-driven insights, improving decision-making, and fostering innovation across multiple domains. It provides insights into the technological and organizational measures necessary to achieve effective interoperability and highlights its critical role in maximizing the utility of the SYMPHONY Open Data Backbone.

Achieving interoperability is a foundational objective of SYMPHONY because it directly supports the project's goal of integrating AI technologies into existing clinical workflows. By ensuring that data from medical devices, electronic health records, imaging systems, and research platforms can be exchanged in standardized formats (such as HL7 FHIR, openEHR, DICOM), SYMPHONY enables AI algorithms to be trained and executed within the same trusted clinical infrastructure. This interoperability allows automated pipelines to trigger AI inference on clinical data, store the results as structured DICOM or FHIR resources, and present them to clinicians through familiar systems—without disrupting established workflows or creating data silos.

By prioritizing interoperability, the SYMPHONY Open Data Backbone can serve as a robust, scalable, and adaptable data infrastructure capable of supporting diverse research, industrial, and policy-driven applications. This ensures that data can be seamlessly integrated across different work packages and domains, fostering a more interconnected and intelligent data ecosystem.

Interoperability within the SYMPHONY Open Data Backbone is deeply interconnected with various work packages, playing a crucial role in aligning technical development, data management strategies, and application-specific requirements. Given the project's multidisciplinary nature, interoperability acts as a unifying factor, enabling seamless interaction among different technical components, platforms, and stakeholders.

Several work packages directly depend on the interoperability framework to ensure effective data exchange and utilization. For instance, work packages related to data collection and processing require standardized interfaces and protocols to facilitate data ingestion from multiple sources. Similarly, work packages focusing on analytics, visualization, and decision support rely on harmonized data structures to ensure consistency and reliability in generating insights.

Moreover, interoperability is critical in ensuring compliance with legal, ethical, and regulatory frameworks outlined in governance-related work packages. Standardized data-sharing mechanisms allow the project to align with international data protection laws while ensuring fair and transparent access to information. Additionally, interoperability supports the integration of legacy systems, third-party applications, and external data sources, enhancing the scalability and adaptability of the SYMPHONY ecosystem.

By fostering interoperability across all work packages, the SYMPHONY Open Data Backbone not only enhances internal project efficiency but also creates long-term value

by enabling external collaborations and future expansions. This interconnected approach ensures that the project delivers a unified, high-impact, and sustainable data infrastructure capable of supporting innovation in various sectors.

2 Standards Used in SYMPHONY

The SYMPHONY project defines and adopts multiple interoperability and legal standards to enhance clinical workflows, ensure seamless data exchange, and maintain regulatory compliance in healthcare IT. The details of these standards and their adoption strategies are outlined in *Deliverable D7.3, D7.5 (Standardisation & Dissemination Plan) and Deliverable D2.2, D2.3 (Strategies for Adoption of Interoperability Standards & Security and Privacy Compliance)*. The focus of the SYMPHONY project is not on creating new standards but on integrating widely accepted clinical, legal, and technical standards to build an open and interoperable healthcare ecosystem.

2.1 Clinical Standards

Clinical standards ensure that healthcare professionals follow best practices for diagnosis, treatment, and patient care. SYMPHONY adheres to well-established European clinical guidelines:

- **Heart Failure & Atrial Fibrillation (AF):** ESC Guidelines for diagnosis and treatment.
- **Prostate Cancer (PC):** EAU & AUA guidelines for evidence-based treatment.
- **Aortic Aneurysm (AA):** ESC Clinical Practice Guidelines covering conditions such as aortic dissection and Marfan syndrome.
- **Multiple Sclerosis (MS):** NICE & ECTRIMS guidelines and McDonald Criteria for diagnosis and monitoring.

These standards promote evidence-based care, quality assurance, and interoperability across healthcare systems.

2.2 Legal Standards and Frameworks

Several regulatory frameworks influence the development of SYMPHONY, particularly concerning data protection, medical devices, and information security:

- **GDPR (General Data Protection Regulation):** Regulates data privacy and processing of patient information in the EU.
- **ISO 27001 & ISO 27799:** Establish standards for information security management, with ISO 27799 specifically tailored for healthcare.
- NEN 7510: The Dutch information security standard for healthcare.
- MedMij: defines Dutch interoperability and trust framework rules for exchanging health data between healthcare providers and personal health environments (PHEs).
- **MDR (Medical Device Regulation - EU 2017/745):** Defines safety and performance requirements for medical devices.
- **ISO 13485 & ISO 14971:** Set guidelines for medical device quality management and risk management.
- **IEC 62304:** Establishes life cycle requirements for medical device software.
- **eHealth Network Guidelines:** EU-wide recommendations for cross-border healthcare data exchange.

2.3 HL7 FHIR

Fast Healthcare Interoperability Resources (FHIR) is a modern standard developed by Health Level Seven International (HL7) that facilitates the exchange of healthcare information in a structured, flexible, and scalable manner. In SYMPHONY, HL7 FHIR is a critical component that ensures interoperability between different healthcare applications, enabling real-time data sharing, integration, and accessibility.

The key advantages of implementing HL7 FHIR in SYMPHONY include:

- Modular and Scalable Architecture: FHIR is based on modular "resources" that represent fundamental healthcare data elements such as patients, medications, and observations, allowing for flexible data modeling.
- RESTful APIs for Real-Time Data Exchange: The standard supports RESTful web services, enabling efficient and standardized communication between different systems and applications.
- Support for Structured and Unstructured Data: FHIR can handle various data formats, including JSON and XML, ensuring compatibility with diverse data sources.
- Improved Interoperability with Legacy Systems: FHIR is designed to work alongside previous HL7 standards, making it easier to integrate with existing healthcare IT systems.

In SYMPHONY, HL7 FHIR is leveraged to ensure secure and structured data sharing across different work packages, particularly in applications related to patient data management, clinical decision support, and AI-driven analytics.

2.4 OpenEHR

OpenEHR is an open standard for electronic health records (EHRs) that focuses on structured, semantically rich, and vendor-independent healthcare data. It is designed to support lifelong, interoperable, and computable health records by providing a standardized way to model and store clinical data.

The key reasons for adopting OpenEHR in SYMPHONY include:

- Archetype-Based Data Modeling: OpenEHR utilizes a two-level modeling approach that separates domain knowledge from technical implementation, enabling high flexibility and reusability.
- Long-Term Data Consistency: Since OpenEHR is vendor-neutral, healthcare records remain interoperable and accessible regardless of changes in software or IT infrastructure.
- Enhanced Clinical Decision Support: The structured nature of OpenEHR data facilitates AI-driven analytics, automated workflows, and real-time clinical decision support tools.
- Compliance with International Standards: OpenEHR aligns with regulatory requirements, ensuring the integrity and reliability of medical records.

In SYMPHONY, OpenEHR is employed to enable structured and interoperable data storage in Clinical Data Repositories (CDR:s), ensuring that clinical data remains standardized, reusable, and accessible across multiple work packages.

2.5 DICOM

Digital Imaging and Communications in Medicine (DICOM) is the globally accepted standard for managing, storing, transmitting, and retrieving medical imaging data. It is widely used in radiology, cardiology, pathology, and other medical imaging disciplines. In SYMPHONY, DICOM plays a crucial role in ensuring the interoperability of imaging data across various systems and stakeholders.

The key benefits of integrating DICOM into SYMPHONY include:

- Standardized Image Storage and Transmission: DICOM enables seamless storage and retrieval of medical images from different modalities such as CT, MRI, and ultrasound.
- Structured Metadata for Image Interpretation: The standard includes detailed metadata, allowing for improved image analysis, classification, and automated processing.
- Cross-Vendor Compatibility: DICOM ensures that imaging data can be exchanged between different healthcare institutions and software platforms without loss of fidelity.
- Secure Data Handling: With built-in encryption and authentication mechanisms, DICOM helps protect patient privacy and ensures compliance with medical data security regulations.

SYMPHONY incorporates DICOM to facilitate interoperability within the imaging-related work packages, ensuring that medical images and their associated metadata are seamlessly shared and processed within the Open Data Backbone.

2.6 IHE Profiles

Integrating Healthcare Enterprise (IHE) Profiles are a set of interoperability frameworks designed to improve the sharing of healthcare data across systems. These profiles define specific implementation guidelines for existing standards (such as HL7 and DICOM) to ensure consistent and efficient data exchange.

The benefits of using IHE Profiles in SYMPHONY include:

- Workflow Optimization: IHE Profiles standardize workflows for clinical document exchange, imaging, and laboratory data, enhancing operational efficiency.
- Interoperability Across Heterogeneous Systems: IHE ensures that different healthcare IT solutions can seamlessly communicate with each other.
- Support for Regulatory Compliance: Many IHE Profiles align with legal and regulatory frameworks, simplifying compliance with data protection laws.
- Improved Data Security and Authentication: IHE includes profiles for secure access control, encryption, and authentication, ensuring data privacy and integrity.

SYMPHONY implements IHE Profiles to enhance data interoperability across multiple healthcare domains, ensuring that clinical workflows, imaging systems, and decision-support applications operate in a unified and efficient manner.

SYMPHONY project benefits from three specific profiles, namely IHE AIW-I, IHE AIR and IHE IID to utilize their capability.

2.6.1 IHE AIW-I

The AI Workflow for Imaging (AIW-I) profile, particularly the Triggered Pull Workflow is an ideal fit for the MS use case because it provides a standardized and interoperable framework for orchestrating AI-based inference workflows across diverse environments and stakeholders.

In our use case, multiple actors interact within a distributed medical imaging ecosystem, including initiators, managers, performers, and watchers. The AIW-I profile defines these roles precisely through its standardized actor model:

- Task Requester - initiates the inference process by submitting a structured task request.
- Workflow Manager - coordinates and orchestrates the workflow execution, ensuring proper communication and data flow between systems.
- Task Performer - executes the AI inference and generates the corresponding results, such as DICOM Surface Segmentation Objects (SSO) or Structured Reports (SR).
- Watcher - monitors the workflow lifecycle and can access task and result information at any time for validation or review.

This well-defined structure enables seamless interoperability between heterogeneous systems (e.g., hospital PACS, AI engines, and privacy-preserving gateways) while maintaining traceability, transparency, and reproducibility of AI results - key requirements for the Symphony environment and its clinical workflows

2.6.2 IHE AIR

The AI Results (AIR) profile is highly relevant for the Symphony project as it provides a standardized, interoperable framework for the storage, retrieval, and display of AI-generated imaging analysis results within clinical workflows. In Symphony, AIR is leveraged to ensure that results produced by AI algorithms—such as quantitative measurements, qualitative findings, segmentations, and saliency maps—are seamlessly integrated into the radiologist’s reading environment and broader clinical data backbone.

Key reasons for adopting IHE AIR in Symphony:

- Interoperable AI Results: AIR defines a set of “result primitives” (e.g., measurements, qualitative findings, regions, parametric maps) and encoding rules based on DICOM SR, Segmentation, and Parametric Map objects. This ensures that AI results are not siloed in proprietary formats but are accessible and usable across different PACS, viewers, and downstream systems.
- Result Trees for Navigation: AIR introduces the concept of Result Trees, which organize large sets of AI results hierarchically. This is crucial in Symphony, where multiple algorithms may generate numerous findings per study. Result Trees enable radiologists to efficiently navigate from summary findings (e.g., “Pneumonia present”) to supporting evidence (e.g., segmentation, measurements), reducing cognitive overload and supporting clinical decision-making.
- Convergent Encoding: By harmonizing AI and human-generated results in the same DICOM-based structures, AIR allows Symphony to pool, share, and analyze results across sites and vendors, supporting both clinical and research use cases.

- Display and Workflow Integration: AIR mandates baseline display capabilities for all result primitives, ensuring that any AIR-compliant viewer in Symphony can present AI results in a clinically meaningful way, including overlays, measurements, and interactive navigation.
- Security and Auditability: AIR recommends grouping with IHE ATNA for secure storage, access control, and audit trails, aligning with Symphony's requirements for data protection and regulatory compliance.

In practice within Symphony:
AIR is used to encode and distribute AI inference results (e.g., lesion detection, segmentation, risk scores) as DICOM SR and Segmentation objects, which are then referenced in Result Trees for structured navigation. This enables radiologists and clinicians to review, validate, and incorporate AI findings into reports and patient records, while also supporting secondary uses such as research and quality assurance.

2.6.3 IHE IID

The Invoke Image Display (IID) profile is implemented in Symphony to enable seamless, standards-based launching of image viewers from non-image-aware systems, such as EHRs or orchestration platforms, directly into the context of a specific patient or study.

Why IHE IID is relevant for Symphony:

- Workflow Orchestration: In Symphony, AI inference workflows (e.g., via IHE AIR or AIW-I) often result in new imaging results that need to be reviewed by clinicians. IID allows the orchestration system or EHR to generate a standards-based URL that, when activated, launches a compliant image viewer (PACS or web viewer) directly to the relevant study or series, including the newly generated AI results.
- Interoperability: IID decouples the image display function from the invoking system, ensuring that any IID-compliant viewer can be launched from any IID-compliant invoker. This is essential in Symphony's heterogeneous ecosystem, where multiple vendors' viewers and workflow engines may be in use.
- User Experience: By supporting both patient-based and study-based invocation, IID enables clinicians to access diagnostic-quality images and AI results with a single click from their workflow tool, without manual context switching or re-identification of studies.
- Security and Audit: IID supports secure HTTPS invocation and can be integrated with authentication and audit mechanisms, ensuring that only authorized users can access patient images and that all accesses are logged, in line with Symphony's compliance requirements.
- Integration with AIR and AIW-I: IID is used in Symphony to trigger the display of AI results (encoded via AIR) immediately after inference completion. For example, once an AI workflow (AIW-I) completes and stores results, the orchestration layer can use IID to launch the viewer for the relevant study, allowing the clinician to review both the original images and the AI-generated findings in context.

In practice within Symphony:
Viewers are configured to listen for IID URLs, allowing the orchestration system to invoke result viewing as soon as AI inference is complete. This ensures a smooth, integrated user experience and supports rapid clinical validation and action on AI findings.

3 SYMPHONY Standards and Regulations Implementation

Use-case	Standard / Regulation*	Implementation Status (Planned / In Progress / Completed)	Implementation Details (How is the standard/regulation being applied?)
MS, AA	DICOM	Completed	Input and output for medical image information and AI inference results, including but not limited to DICOM SSO and DICOM SR objects.
MS, AA	IHE AIR	Completed	DICOM UPS and DICOM SR is used to exchange AI results as well as the communication of life cycle messages of the inference process.
MS, AA	IHE IID	Completed	Viewers are listening to URLs where IID is expected to allow orchestrators in IHE AIR to invoke results viewing once the AI inference results are ready for the user.
MS	IHE AIW-I	Completed	The triggered pull workflow of the AIW-I profile is fully implemented using a DICOM UPS-RS server deployed on the Gateway. The setup includes a Task Requester, which initiates the inference by creating a valid workitem; a Task Performer, deployed in the cloud, which listens to the UPS-RS server and processes the inference requests; and a Watcher, which monitors all incoming requests and generated results. The UPS-RS server and all client components communicate via WebSockets. The server filters messages based on each client's subscription type and status, then broadcasts event reports accordingly. All DICOM UPS-RS endpoints are implemented in full compliance with the DICOM standard. DICOMweb is used for the exchange of input data (DICOM MRI) and output data, which may include DICOM SC, SR, and SSO instances.
Prostate Cancer	OpenEHR	Completed	The OpenEHR standard is used as the semantic model in the CDR:s. The framework is continuously developing with more archetypes.

Use-case	Standard / Regulation*	Implementation Status (Planned / In Progress / Completed)	Implementation Details (How is the standard/regulation being applied?)
Prostate Cancer, MS	HL7 FHIR	Completed	HL7 FHIR is used in Cuviva RPM platform for data retrieval, including questionnaire and sensor data, and data storage. Cambio supports the HL7 FHIR protocol connecting other systems and vendors to the platform and its CDR. In the MS use case, all clinical, demographic, and genetic patient data are stored and exchanged using HL7 FHIR, together with non-imaging analyses and results such as severity prediction scores, sarcopenia detection scores, vision test results, and questionnaire responses.
Prostate Cancer	MDR	Completed	Cuviva RPM platform is MDR Class IIa certified. Cambio Clinical Data Repository (CDR) Platform is not in itself under the MDR governance. However, in combination with other applications it might be. In the Symphony project, we have chosen the application to be MDR compliant. Cambio Clinical Decision Support (CDS) is a MDR tool that complies with MDR class IIa.
Prostate Cancer	ISO13485 and ISO14971	Completed	ISO13485 and ISO14971 standards compliance are part of MDR certification. Cuviva and Cambio are compliant to these ISO standards and ISO certified.

4 Open API Implementation in SYMPHONY

4.1 Open API Architecture

SYMPHONY's Open API architecture follows a modular and microservices-based approach, ensuring scalability and flexibility in handling healthcare data. The architecture consists of the following core components:

API Gateway & Request Routing

- Centralized API Gateway manages authentication, load balancing, and rate limiting.
- Performs anonymization and re-identification (de-anonymization) of patient data directly on the Gateway, ensuring privacy-preserving data exchange across AI modules and clinical systems (see Section 4.3 for detailed workflow).
- Supports RESTful API for structured data exchange (HL7 FHIR & OpenEHR) and DICOMweb for medical imaging retrieval.
- Implements GraphQL for dynamic queries, enabling AI-driven applications to extract relevant healthcare insights efficiently.

Data Processing & Interoperability Layer

- FHIR Server (e.g., HAPI FHIR, Microsoft Azure FHIR Server, onFHIR) processes structured health data for real-time clinical use.
- OpenEHR CDR (Clinical Data Repository) maintains longitudinal patient records and ensures semantic interoperability.
- DICOM PACS (Picture Archiving and Communication System) integrates with DICOMweb APIs for medical imaging access.
- DICOM UPS Server (Unified Procedure Step) enables interoperable data processing workflows by managing and coordinating AI and imaging tasks across systems using standardized DICOM service interfaces.

4.2 Open API Endpoints & Functionalities

SYMPHONY's Open API exposes endpoints categorized into four major functionalities:

- **Patient Data Management (HL7 FHIR & OpenEHR)**
- **Medical Imaging & DICOMweb Integration**
- **DICOM UPS Integration**
- **AI & Analytics Integration – IHE AIR, and IHE AIW-I Profile**
- **Security & Access Control – OAuth 2.0**

4.3 Security, Privacy and Access Control

SYMPHONY's Open API is secured through multiple layers, ensuring data privacy, regulatory compliance, and secure authentication mechanisms. It adopts industry-leading encryption standards, robust authentication frameworks, and comprehensive access control policies to protect sensitive healthcare data.

Authentication & Authorization

- Implements OAuth 2.0 with JWT tokens for secure user authentication and session management.
- Supports Fine-Grained Access Control (FGAC) through Role-Based Access Control (RBAC) and Attribute-Based Access Control (ABAC) to ensure appropriate data access permissions based on user roles and attributes.

Data Privacy & Compliance

- All FHIR, OpenEHR, and DICOM data are encrypted using AES-256 & TLS 1.3, ensuring secure data transmission and storage.
- Implements GDPR-compliant Data Subject Rights (DSR), allowing patients and authorized users to manage and control access to their personal healthcare data.
- Ensures de-identification and anonymization of sensitive health information when necessary to maintain compliance with privacy regulations like HIPAA and GDPR.

Secure Data Storage & Logging

- Patient data is stored in FHIR Clinical Data Repositories (CDR) and OpenEHR databases, implementing immutable versioning to maintain a traceable record of modifications while preventing unauthorized alterations.
- Audit logs are securely stored and protected against tampering, ensuring that every access request, modification, or deletion of healthcare data is properly recorded.
- Data masking and tokenization techniques are applied to protect personally identifiable information (PII) and prevent unauthorized access to sensitive patient data.

By integrating these security, privacy, and access control measures, SYMPHONY ensures regulatory compliance, confidentiality, and integrity across all healthcare data transactions, providing a trustworthy and scalable interoperability framework.

5 Implementing Standards: Challenges and How We Resolved Them

Standard(s)	Challenge(s)	How to Overcome
IHE AIR	Current trial version of the profile does not describe any standard procedure steps to allow user interaction during the inference workflow. If the inference requires any input from the user, then the AI application is not suitable to use within this profile.	There is no clear way of overcoming this issue but since the profile is still in the trial phase, we are planning to communicate this need to IHE.
DICOM	Algorithm providing companies are rarely knowledgeable enough to construct standardized output themselves. They usually have knowledge enough to digest objects that are already provided in a standardized and structured format but when it comes to provide outputs in a standardized format, they usually lack the knowledge to construct proper objects. Their focus is usually in developing a better algorithm that is more successful in the main objective of the algorithm, instead of the implementation of that algorithm into the real clinical workflow.	We see projects like Symphony especially valuable because they provide the perfect opportunity to have knowledge sharing between different parts of the ecosystem. While developing our respective systems, we had quite a few knowledge sharing sessions, to spread out the missing knowledge, as well as a few sample source code structures where knowledge persisted. Using this support, many partners were able to add the missing knowledge into their company's know-how.
FHIR	FHIR is a standard superior for transfer of data. However, when, like in Sweden, using OpenEHR for storing clinical data, you need to map between FHIR and OpenEHR. On the other hand, in the MS use case, vision tests are performed to produce clinical results. Some of these test types, such as Contrast Sensitivity and Critical Flicker Fusion, are not yet standardized in FHIR, which necessitates using custom data structures for representation and integration.	Develop the mapping between FHIR and OpenEHR. We created custom data models aligned with FHIR principles and extended the existing standards to enable the storage and exchange of results from these vision tests. Upon project completion, we plan to propose the standardization of these extended models to contribute to future FHIR developments.

IHE AIW-I	1. DICOM UPS-RS is a central component of the AIW-I profile, yet most open-source PACS systems, including Orthanc, do not support it over DICOMweb. This limited tool availability complicated standard-compliant integration. 2. Implementing UPS-RS required managing intricate DICOM-specific constructs, including the creation of JSON-based workitems with all required attributes and the enforcement of strict state transitions. The specification's reliance on JSON for WebSocket messaging further increased complexity. 3. WebSocket connections used for UPS-RS event notifications were vulnerable to disruptions caused by network instability or server restarts. This introduced the risk of missed task updates for subscribed clients. 4. Aligning with the AIW-I profile was difficult due to its rigorous workflow structure and data field requirements. Critical UPS fields such as the Scheduled Workitem Code, Input Information Sequence, and Performed Procedure Information had to be accurately populated, but no standard code existed for MS lesion detection. 5. The AI algorithm operated on non-DICOM formats, such as NIfTI, which introduced challenges in converting data between DICOM and model-compatible formats. Preserving spatial fidelity during this process was essential, as minor misalignments could result in incorrectly positioned segmentation outputs. 6. While DICOM UPS allows referencing multiple studies, including both current and prior exams, output objects such as DICOM SR and SSO are typically linked to a single	1. This limitation was addressed by developing a custom UPS-RS server that supported task creation, status transitions, and subscription management in full compliance with the AIW-I profile. 2. The entire workflow was standardized on JSON to ensure consistency across UPS workitems and event messages. This approach facilitated seamless RESTful communication and maintained adherence to the UPS-RS specification. 3. Heartbeat monitoring and exponential backoff reconnection logic were implemented to detect disconnections and automatically restore WebSocket subscriptions, ensuring uninterrupted delivery of task notifications. 4. The IHE Technical Framework was followed closely, and private or generic codes with descriptive labels were used to define AI procedures. Additional logic was implemented to manage image sequencing and explainability settings specific to the AI model. 5. DICOM images were converted to NIfTI format for model processing, and inference outputs were precisely mapped back into the original DICOM coordinate system. Orientation and scaling metadata were carefully preserved, and the pipeline was validated to ensure accurate alignment of segmentation results. 6. All output objects were associated with the most recent study, while comparison findings such as increases or decreases in lesion count were embedded descriptively within the Structured Report.

Standard(s)	Challenge(s)	How to Overcome
	study. This created challenges in representing longitudinal changes, such as differences in lesion burden over time.	This maintained clinical relevance while respecting DICOM's single-study constraint for result objects.
OpenEHR	OpenEHR is a standard for storing data based on clinical topic knowledge. It is developed in clinical consensus about what the data means, which makes developing it time consuming but clinically robust.	Leveraging the clinical knowledge in the hospitals and in the international and national care programs (as described in Deliverables in WP3). Active participation in international and national openEHR working groups.

6 Conclusion

This deliverable presents the final outcomes of SYMPHONY's efforts to implement, evaluate, and harmonize interoperability standards and open API frameworks across its Open Data Backbone. The activities conducted within this scope have demonstrated the project's strong alignment with internationally recognized clinical, technical, and legal standards, and established the foundational infrastructure for cross-platform, secure, and scalable data exchange.

As detailed in Section 3, the integration and validation of standards such as HL7 FHIR, OpenEHR, DICOM, and IHE profiles (AIR, AIW-I, IID) have been successfully completed across various clinical use cases. These standards enable consistent data representation, facilitate interoperability among heterogeneous systems, and ensure seamless integration of AI-generated insights within existing clinical workflows. For instance, HL7 FHIR and OpenEHR have been utilized for structured data exchange in patient monitoring and decision support systems, while DICOM and IHE profiles have been fully adopted to manage AI-driven imaging workflows in MS and Aortic Aneurysm use cases.

Section 5 outlines the key challenges encountered during the implementation phase—ranging from technical limitations in system interoperability to compliance with regulatory frameworks such as GDPR and MDR—and highlights the concrete measures taken to overcome them. These include the deployment of fully compliant DICOM UPS-RS servers, real-time communication through WebSockets, structured representation of AI inference results using DICOM SR and SSO objects, and the secure invocation of imaging data via IHE IID mechanisms. Collectively, these efforts have significantly advanced SYMPHONY’s capacity to deliver an interoperable, explainable, and regulation-compliant data infrastructure.

The implementation status tables further confirm that all planned standards have been successfully realized in the relevant clinical contexts, enabling real-time, traceable, and privacy-preserving data flows. This ensures that both human and AI-generated insights can be accessed, interpreted, and acted upon within harmonized clinical environments.

In conclusion, the outcomes of Deliverable D5.3 provide a robust demonstration of SYMPHONY’s capability to establish a standards-based, vendor-neutral, and future-proof healthcare IT ecosystem. By ensuring interoperability at both semantic and technical levels, the project not only supports the integration of AI technologies into clinical workflows but also lays the groundwork for sustainable collaboration, scalability, and regulatory readiness across the digital health landscape.