Eco-system for disease specific clinical workflow and data integration

DELIVERABLE D7.7

Ecosystem governance

Project number:	ITEA 21026
Document version no.:	v1.0
Edited by:	Saurav Kumar Baidya
Date:	18/02/2026

ITEA Roadmap challenge:
Smart Health

HISTORY

Document version #	Date	Remarks
V0.1	26/01/2026	First draft for review
V1.0	18/02/2026	Final version (after updates based on the review)

TABLE OF CONTENTS

1 Introduction

The ITEA SYMPHONY project has pioneered disease-specific, open, and interoperable healthcare ecosystems to ensure that the right medical data is available at the right time for clinical decision-making. In SYMPHONY, Ecosystem Governance refers to the formal structures, rules, and coordination mechanisms that guide how data, stakeholders, technologies, and clinical processes interact within a shared healthcare ecosystem.

The scope of governance in SYMPHONY includes policies for data interoperability, privacy and compliance frameworks, stakeholder roles and responsibilities, and alignment with clinical workflows. It explicitly excludes operational management of individual hospital systems or product-specific implementation details.
Key governance drivers—such as interoperability, regulatory compliance, and clinical workflow alignment—ensure that data flows safely and consistently across domains while enabling innovation and trusted collaboration.

This document describes how ecosystem governance is defined, implemented, and leveraged within SYMPHONY to support scalable, secure, and clinically meaningful ecosystem development.

2 Principles of Ecosystem Governance

2.1 Openness, Interoperability and Reference Architecture

SYMPHONY's governance model is built on openness—enabling seamless integration of clinical workflows and data from heterogeneous sources. Interoperability is achieved through adherence to international standards (e.g., DICOM, FHIR, openEHR), structured data models, and APIs that allow systems to communicate and share information securely. The SYMPHONY reference architecture encompasses all the above giving the technical blueprint for the implementation of the all concerned disease specific ecosystems.

2.2 Privacy and Security

Robust privacy-preserving gateways and data processing pipelines ensure compliance with GDPR and other regulations. Patient data is managed with strict access controls, anonymization, and consent mechanisms, supported by certified platforms.

2.3 Multidisciplinary Collaboration

Because SYMPHONY does not include a clinical study, all technical implementations focus on enabling effective multidisciplinary collaboration. In several use cases, partners also sought informal input from clinical colleagues to validate practical relevance. Governance structures support coordination among clinicians, IT specialists, and researchers, while dashboards and decision-support tools integrate and visualize data from diverse sources to facilitate informed, consensus-driven teamwork.

2.4 Patient-Centricity

Although there are no direct patients involved in SYMPHONY, they are at the center of SYMPHONY approach. The deliverables eventually target to empower patients through personal health environments, mobile applications, and chatbots that provide access to their data, support lifestyle management, and enable direct communication with care teams.

3 Governance Mechanisms and Tools

3.1 Data Standards and Modelling

- **DICOM:** Universal standard for medical imaging, enabling exchange and quality assurance.
- **openEHR & FHIR:** Structured data models for EHRs, supporting semantic interoperability and secondary data use.
- **Templates and Archetypes:** Reusable documentation patterns for consistent data capture and sharing.

3.2 APIs and Gateways

- **API Gateways:** Secure, standardized interfaces (e.g. DICOM, FHIR) for data exchange between systems and external devices.
- **LLM Gateway:** Supports advanced analytics and reporting, including speech-to-text and chatbot integration. Since this is not a standardized API, the LLM gateway requires a specific governance focus on responsible use, auditability, and risk mitigation

3.3 Decision Support and Visualization

- **Dashboards:** Aggregate data from multiple sources for MDTs and clinical workflow optimization.
- **AI Results Viewer:** Visualizes AI assisted segmentation and measurement results for radiologists and clinicians.

3.4 Quality Assurance and KPIs

- **Key Performance Indicators (KPIs):** Track progress in automation, trust in AI, platform harmonization, accuracy, reduction of duplicate events, and technology readiness.
- **Continuous Feedback:** Real-time quality reporting and feedback loops for ongoing improvement.

3.5 Governance Roles and Workflows

To ensure consistent, accountable, and coordinated ecosystem governance, SYMPHONY defines clear responsibilities and workflows:

- **Governance Owner:** Sets governance policy; defines standards to be used (DICOM, FHIR, openEHR, IHE) and ensures alignment with project-wide objectives.

- **Reviewer:** Evaluates proposed models, APIs, workflows, and datasets for compliance with standards, privacy requirements, and interoperability guidelines.
- **Approver:** Grants formal approval for new artefacts (e.g., data models, APIs, clinical templates) before deployment across pilots.
- **Implementer:** Applies approved governance rules within technical and clinical environments, including configuration of gateways, deployment of templates, and integration of AI-enabled tools.
- **Workflow:**
    1. **Proposal submitted** (new dataset, API, model, workflow).
    2. **Review for compliance and interoperability** (Reviewer).
    3. **Approval** (Approver).
    4. **Implementation across pilots** (Implementer).
    5. **Monitoring + feedback loops** integrated into KPIs and QA processes.

This structure ensures that governance is **not only technical**, but also **operational and accountable**, with clear ownership and consistency.

4 Collaborative Governance Structures

4.1 Consortium and Partner Networks

SYMPHONY's governance is enacted through a consortium of hospitals, research institutes, MedTeh and IT companies. Roles and responsibilities are clearly defined, with shared vision and contractual agreements ensuring alignment and accountability.

4.2 Standardization Network

Standardization groups focusing on openEHR, DICOM, FHIR, IHE etc. facilitate global collaboration among SYMPHONY partners and external organizations sharing models, templates and best practices for data governance.

4.3 Agile, Multi-Actor Model

Governance adapts to evolving needs through agile processes, regular reviews, and continuous stakeholder engagement. Decision-making is distributed, supported by multi-layer operating mechanisms such as work-package–level meetings and project-office–level governance sessions. These structures enable early issue detection, coordinated planning, and transparent escalation pathways.

To ensure effective collaboration, SYMPHONY applies formal conflict-resolution methodologies, including:

Structured escalation paths (from WP/Use case leads → project office → steering committee)

Consensus-building techniques, such as facilitated alignment workshops and evidence-based decision logs
Mediation and neutral arbitration when partners hold competing technical or clinical positions
Clear decision-rights matrices, defining who owns, reviews, approves, and implements each governance artefact

Through these mechanisms, SYMPHONY has effectively handled complex governance challenges—including substantial change requests, prioritization disagreements, and performance-related partner interventions—ensuring decisions are both efficient and collectively supported.

5 Governance Across SYMPHONY Use Cases

5.1 Aortic Aneurysm (AA)

- **Challenge:** Data silos, inconsistent measurements, incomplete dossiers during MDTs.
- **Governance Solution:** Standardized storage (DICOM), AI-driven segmentation, dashboards for data overview, and automated device measurements, IHE driven AI result and workflow standardization. Governance ensures data is consistently captured, validated, and accessible for clinical decision-making.

5.2 Atrial Fibrillation (AF)

- **Challenge:** Fragmented data, frequent hospital visits, manual data entry.
- **Governance Solution:** Integration of EHR platforms, FHIR based personal health environments, and guideline-based decision support. Governance enables harmonized data flows, protocol management, and secure patient data storage, with APIs for interoperability.

5.3 Multiple Sclerosis (MS)

- **Challenge:** Lack of coordination, complex workflows, slow data interpretation.
- **Governance Solution:** Coordinated interoperability across AI models and applications, explainable AI for lesion segmentation, mobile apps for monitoring, and digital twins for disease progression. DICOM, FHIR, IHE driven AI result and workflow standardization play an important role in interoperability. Overall governance ensures multidisciplinary collaboration and real-time data sharing.

5.4 Prostate Cancer (PC)

- **Challenge:** Heterogeneous, siloed data; lack of interoperability; rising demand and staff shortages.
- **Governance Solution:** Open, openEHR based interoperable IT ecosystem integrating legacy and new systems, structured reporting, patient-reported data, and decision dashboards. Governance supports data-driven care, quality reporting, and predictive analytics.

6 Challenges and Future Directions

6.1 Semantic Interoperability

Semantic healthcare interoperability continues to be constrained by fragmented data standards, inconsistent clinical terminologies, and limited cross-system context sharing, driving a future focus on harmonized ontologies, AI-assisted semantic mapping, and governance frameworks that enable truly fluid, meaning-preserving data exchange across the care continuum.

6.2 Scaling and Sustainability

Efforts to minimize double work, enable secondary data use, and ensure patient safety must be sustained as the ecosystems grow.

6.3 Innovation and Adaptation

Governance must support integration of new technologies evolving standards, and changing regulatory landscapes.

7 Conclusion

Ecosystem governance in SYMPHONY is the linchpin for delivering trusted, interoperable, and patient-centric medical data flows. By harmonizing standards, aiming to enable multidisciplinary collaboration, and empowering patients, SYMPHONY sets a blueprint for future-ready healthcare ecosystems.

8 Acronyms

AI	Artificial Intelligence
API	Application Programming Interface
DICOM	Digital Imaging and Communications in Medicine
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
IHE	Integrating the Healthcare Enterprise
IT	Information Technology
KPI	Key Performance Indicators
LLM	Large Language Models
openEHR	Open Electronic Health Records - a non-profit organisation that publishes technical standards for an EHR platform.
SSO	Surface Segmentation Object