

# Roadmap for Aligning Cardiovascular Digital Health in Austria with the European Health Data Space (EHDS) Ecosystem

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**Abstract.** Translating the proposed European Health Data Space (EHDS) regulations and requirements into reality is a challenging task. In this work, we provide a roadmap for aligning the EHDS requirement into the cardiovascular (CV) digital health domain in Austria. To achieve that, we first examined the current eHealth infrastructure and initiatives in Austria. Then, we created a CV-connected health model and addressed the challenges facing cardiac telerehabilitation in Austria. Finally, we mapped the European CV strategies to the Austrian context for EHDS implementation. Accordingly, we were able to provide an Enterprise Architecture (EA) framework for aligning CV digital health with the Austrian EHDS context. The created EA model can be also used as a guiding framework for aligning other medical domains in Austria with EHDS.

**Keywords.** Cardiovascular, Enterprise Architecture, Digital Health, Ecosystem, European Health Data Space

## 1. Introduction

The European Health Data Space (EHDS) is an ecosystem comprising rules, common standards and practices, infrastructures, and a governance framework for enabling the primary use of health data to improve care delivery (EHDS1), and for secondary use of data to support research, innovation, and policies (EHDS2). The EHDS aims to shape the future of healthcare in Europe by empowering individuals to control their health data and unleash the scientific and economic power of the secondary use of health data [1].

One main challenge of the EHDS is integrating Electronic Health Records (EHR), with Patient-Generated Health Data (PGHD) obtained by wearables and other devices, and also with health data stored in existing national registries. To address this challenge, we introduced the DH-Convener concept in 2021, as an integrative technical-clinical-

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user approach in alignment with EHDS, for integrating PGHD with the Austrian EHR (called ELGA) [2].

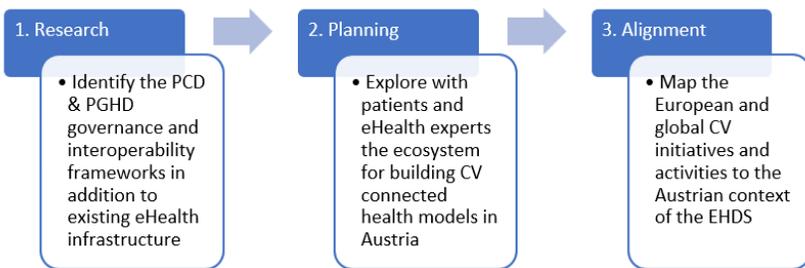
This paper aims to provide a roadmap for aligning the cardiovascular (CV) digital health in Austria with the EHDS ecosystem, based on 1) the current carried out activities in Austria for building the required EHDS infrastructure, 2) the DH-Convener approach for creating a connected-health model for cardiac rehabilitation, and 3) the recent responses of the European organizations in the CV domain to the EHDS initiative.

## 2. Methods

To create the roadmap, we followed the main three stages suggested in [3] for strategic and innovation roadmapping in the CV domain, as follows (see Fig. 1):

- In the first stage, we analyzed the existing standards and data governance framework for Patient Contributed Data (PCD) and PGHD. This work was performed through our participation in the Health Level 7 (HL7®)- PCD whitepaper workgroup [4]. Concurrently, we investigated the existing eHealth infrastructure in Austria and the ongoing national projects for EHDS implementation by 2025 (URL: [https://goeg.at/AT\\_eHDSI](https://goeg.at/AT_eHDSI)).
- In the second stage, we conducted workshops on health data democratization with patients [5] and eHealth experts [6], as the main enablers of building the EHDS ecosystem. Based on that, we created a connected health model for cardiac telerehabilitation in Austria [7], with highlighting the associated opportunities and barriers.
- In the third stage, we addressed the responses of the European organizations in the CV domain to the EHDS proposal. We also considered the global initiatives and roadmap for digital health in the CV domain.

Accordingly, we created an Enterprise Architecture (EA) framework for mapping the outputs of the 3 stages into the Austrian context of EHDS (see Fig. 2) and identified the corresponding actions to be taken.



**Figure 1.** Roadmap development stages (research, planning, and alignment)

## 3. Results and Discussion

Figure 2 depicts the results and the outputs of the three stages using the EA frameworks in healthcare [8]. Accordingly, the created EA framework provides the roadmap with the required “systems thinking” approach that incorporates the vision and strategy of the

EHDS, along with *business architecture, applications, data, and technology layers* [9] within the CV digital health domain.

The European Commission (EC) building blocks (legal and data quality frameworks, infrastructure, and capacity building) and services (MyHealth@EU for EHDS1 and HealthData@EU for EHDS2) [1] represent the *EA capabilities and technology layers*.

To realize EHDS1 (located in *the EA technology layer*), the Austrian government works on connecting Austria to the European eHealth Digital Service Infrastructure through the AT-eHDSI project (URL: [https://goeg.at/AT\\_eHDSI](https://goeg.at/AT_eHDSI)). The AT-eHDSI project will set up the National Contact Point for eHealth (NCPeH) to integrate the existing Austrian ELGA infrastructure [10] and to implement the first cross-border MyHealth@EU health service ePrescription/eDispensation, in cooperation with Austrian companies providing the national healthcare and insurance systems (SVC and ITSV).

To fulfill EHDS2 requirements (located in *the EA technology layer*), we need first to overcome all barriers described in [4-7, 11]. The main actions to be taken are: 1) build citizens' trust in data use, sharing, and altruism through setting national engagement and empowerment strategies (by adopting EHDS recommendations in this regard and success stories from other member states, e.g., Finland, Estonia, others), 2) improve the Austrian eHealth infrastructure with new privacy-preserving for dynamic consent, and 3) accelerate the current development process of the regulatory framework for digital health apps certification, reimbursement, and data sharing incentives.

Within *the EA data layer*, there are currently well-established national and European-wide activities that hold promise to unlock and demonopolize health data for EHDS2. For instance, the Medical University of Vienna is leading the Health Outcomes Observatory (H2O) project (EU-IMI funded project) (URL:<https://health-outcomes-observatory.eu/>) to create national observatories in Austria, Germany, Netherlands, and Spain that will be connected to a pan-European Observatory. Moreover, Statistics Austria launched the Austrian Micro Data Center (AMDC) (URL: <https://www.statistik.at/services/tools/services/amdc-mikrodaten-fuer-die-wissenschaft>) in 2022 to provide researchers access to anonymized data remotely.

Medical societies and healthcare professionals will play a major role in the EHDS implementation (*in the EA application layer*), by considering the importance of determining the EHDS requirements, supporting data harmonization, and providing experiences with existing registries. The current activity of the European Society of Cardiology (ESC) aligned to the goals of the EHDS [12], is the ESC Atlas [13] which collects cardiovascular data from across its 57 member countries. ESC also launched the EuroHeart project (URL: <https://www.escardio.org/Research/euroheart>) [14], which is the unified European registry for heart care. It also provides an optional technical infrastructure to enable collaborative research in patients with CV disease, such as running pragmatic randomized trials. On the other hand, the European Alliance for Cardiovascular Health (EACH) called for the creation of the "European Cardiovascular Health Data Knowledge Centre" [15] to address the current fragmentation and significant gaps in having comprehensive and reliable data required to 1) ensure CV data connectivity within EHDS and 2) drive Real-World Evidence (RWE) generation. At the global level, the World Heart Federation is launching the World Heart Observatory (URL: <https://worldheartobservatory.org>) for connecting and sharing data and knowledge with experience and action in the CV domain through an online hub and relevant searchable dashboards.

Despite these positive responses of the European organization in the CV domain on the EHDS proposal [12-15], creating synergy and harmonization of the current activities

is still needed to 1) avoid duplication of efforts, 2) and facilitate connectivity with global initiatives as well. It is also important to follow the ESC recommendations for the national cardiac societies across Europe to participate in 1) data harmonization, and 2) capacity building for implementing interoperability and security for proper EHDS implementation

The DH-Convener aims to integrate PGHD (created *within the EA business layer*) with ELGA (located *in the EA data layer*) to enable the application of big real-time data analytics, i.e., Artificial Intelligence (AI) and Machine Learning (ML) tools along with CV apps and telemonitoring platforms (*in the EA application layer*). Thus, all data users (*in the EA business layer*) can access, control, and share these data in the clinical routine workflow (EHDS1) or for research, innovation, regulation, and policy-making (EHDS2).

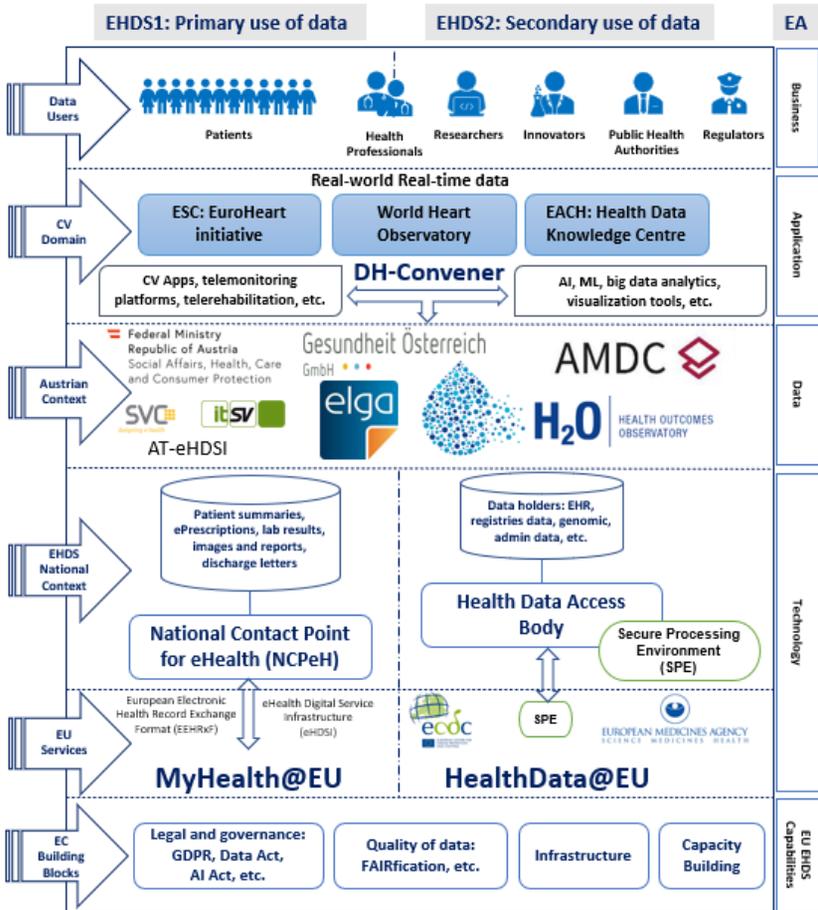


Figure 2. EA framework for aligning CV digital health with the Austrian EHDS context

#### 4. Conclusions

The EHDS initiative is welcome by several European organizations in the CV domain as well as the academic and research institutions in Austria. The Austrian government

started in building the required infrastructure based on the provided EC building blocks and services. The EA framework we present here reflects a clear roadmap for aligning CV digital health in Austria with EHDS requirements for both primary and secondary use of health data. Furthermore, it harmonizes the Austrian EHDS national context with current initiatives and action plans of the European organizations and global initiatives in CV. Ultimately, it also provides a blueprint for mapping other healthcare domains in Austria to the EHDS requirements.

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