

# European Health Data Space

## 2<sup>nd</sup> meeting HDABs-CoP General Assembly

### Meeting Summary

#### Data/time

**2024-06-25** (14:00 – 17:00), online

#### Participants

**Countries:** AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, NO, PL, PT, SE, SI, SK

**European Commission Units & Agencies:** DG SANTE C1, R4, DG CNECT, HaDEA

**Invited:** Administrative Contractor (Infeurope), Capacity Building Contractor (NTT DATA)

#### Agenda

1. Opening of the Meeting - Introduction
2. Reporting of the work carried out by the Subgroups
3. Updates from main stakeholders
4. Updates from EC
5. Steering Board chair & rapporteur end of term
6. Any Other Business
7. Wrap up & closure

#### Meeting Summary:

The **Competent Authorities Community of Practice (CoP) General Assembly (TF)** held its **second meeting on the 25<sup>th</sup> June 2024**, and counted on the participation of 24 MS, DG SANTE, DG CNECT, HaDEA, and the Capacity Building team (EC contractor). The aim of this meeting was to provide progress and status updates on the works of the Subgroups (SG) and Steering Board (SB). Information from relevant projects such as the EHDS2 Pilot Project, TEHDAS2, the development of the Central Services, the Capacity Building project on secondary use, and the EHDS Legislative process was provided. The Deputy Head of Unit of DG SANTE C1 welcomed all participants to the first full functioning General Assembly of the CoP after the kick-off held in January and thanked them for their contributions to date. Following a brief review of the agenda, it was adopted without objection.

On the progress and status updates on the SG's, each SG Chair or Rapporteur provided an overview of the SG achievements, plans for 2024, and identified any challenges and next steps.

The Chair for **SG1 Data Access Application Management System (DAAMS)** presented a summary of the state-of-play of DAAMS across all MS. An initial list of core functions of the DAAMS was identified by the SG and it was explained that several polls were conducted to survey participants' interests and needs for future topics. The chair reported that the SG challenges include lack of guidance or direction for collecting group needs, undefined process for cross-SG communication, and differing interpretation on the roadmaps in several SG's.

The Rapporteur for **SG2 Health Datasets Metadata Catalogue and Data Quality and Utility** reported that the overall aim of the SG is to bring all members to a common knowledge denominator through a series of knowledge sharing sessions and share the state-of-play regarding the national dataset catalogues. For the state-of-play on national dataset catalogues, 20 out of 28 MS provided input with a wide range of maturity levels in the national implementation ranging from non-existing catalogues to fully developed national datasets catalogues. To date, several sessions have been held in this SG on metadata catalogues, Health DCAT-AP, EHDS2 Pilot project, and future workshops are planned. SG2 identified as challenges the timelines and parallel projects. The SG will next align with the schedule of the EHDS legislation & HealthDCAT-AP specifications availability and group MS by maturity level for tailoring subsequent workshops.

The Chair of **SG3 Secure Processing Environments (SPE)** reported that the overall aim is to focus on building a common understanding of what an SPE is and identifying the key functionalities and requirements. Based on the SPE state-of-play, it was determined that several countries do not currently have a SPE, and that there is an overall low participation in the SPE National Implementation Mapping Model. To date, FI and NO have presented their national SPEs, and future sessions are planned to expand on TRE/TEE solutions. The challenges identified were the low participation and stakeholder engagement within SG3, perhaps due to the complexity of the subject, and a lack of common understanding on TEE/TRE/SPE concepts.

The Chair of **SG4 Cross-Border Gateways** reported that the overall aim is to focus on designing and developing the cross-border gateway to assist MS in designing and developing their cross-border IT infrastructure, as they begin to design, implement, pilot and/or go live in production. The high-level architecture was provided by the HealthData@EU Pilot Project. Unlike other SG's, SG 4 cannot refer to an existing cross-border IT infrastructure which is already used by a MS, as it is currently being developed within the Pilot project. Several presentations from the Pilot, Central Services were provided to the SG, and future workshops are being planned. The SG4 identified several challenges, including the lack of MS implementation, only France, Finland and Denmark have so far deployed a Cross-border IT infrastructure, the assessment of the needs from the participants is still missing. The interdependency between other projects and the legislative process were also mentioned as a challenge.

The Chair of **SG5 Deployment and Operations** reported that the overall aim is to support the implementation of the 5 digital business capabilities in the HDABs of every member state. SG5 provides an overall picture of the implementation status of each MS. This SG is important to facilitate collaboration among MS, support MS in sharing their plans including sustainability and business continuity plans and progress status and monitor the maturity level of each member state. To date, two state-of-play exercises were performed on the overall national

implementation plan from the HDAB Direct Grant, and a maturity model. Nearly two thirds of MS reported the implementation plan. The maturity plan intends to assess the MS maturity level based on different elements such as legislation, policy, compliance, and the leadership – governance. Very few MS have completed both maturity models. The SG5 identified several challenges, including the ability to assess MS needs for operations, lack of participation of MS for a harmonised implementation, and a common EHDS interpretation. It was reported that there is a need for a SG5 Rapporteur.

The Chair of the **SG6 Stakeholders’ Fora** reported that the aim is to create the most valuable exchange of deliverables, insights, updates and knowledge sharing between relevant stakeholders, projects and initiatives and the EHDS2 CAs CoP. To complete this, the SG is set to gather perspectives from stakeholders, collect insights from ongoing projects, and identify capacity building needs. Two tasks were identified, in which the SG mapped a list of stakeholders, and created a prioritisation list based on the parallel topics of the CoP. In total, 19 stakeholders were mapped, and await the finalisation on an engagement approach. The challenges identified include potential duplication and overlapping with other SGs on engaging a stakeholder, and lack of regular communications with other SGs. The SG will work next on co-creating a prioritisation of 4 to 6 stakeholders and discuss a methodology in the SB.

Across all SGs, several common themes arose. It was reiterated that **improved coordination between the SGs across the CoP and cross-fertilisation is required**. Support was shown for a face to face cross-SG Connectathon to improve communication. Additionally, it was noted that several MS are not participating within the SGs. Lastly, additional guidance for the collection of SG needs will be required.

On the **SB progress report**, the responsibilities, structure, and outputs were reviewed. It was reiterated that the main responsibilities are to coordinate the SGs work, monitor implementation of the common baseline plan for progression at the national level, and prepare a risk assessment plan. The 2024 Workplan was reviewed, in which most deliverables are completed or are ongoing, however outstanding items include the HDAB implementation needs, and the preparation of the 2025 Workplan. Several milestones were reviewed, including the contributions to the progress monitoring and risk assessment of the SGs. The next steps for the SB will include continued contribution and monitoring of the risk assessment and the SG needs assessment and the preparation of the 2025 Workplan.

On the **updates from main stakeholders, the EHDS2 Pilot and the TEHDAS2 teams** provided overviews on the timeline, completed works, and future works.

The **EHDS2 Pilot project** is approaching the final stages of the project, lasting over 2 years in duration, to be completed in Autumn/winter 2024. The aim of the project is to create and test a beta version of the HealthData@EU infrastructure with 17 partners across 9 countries and to test concrete cross-border user cases. A final stakeholder forum on “Exploring the European Health Data Space: a journey guided by the HealthData@EU Pilot Project” will take place on 12<sup>th</sup> November 2024 in Lisbon. A supplement will be published in the European Journal of Public Health to discuss the landscape, addressing setup and implementation aspects of the EHDS, including opportunities, challenges, and barriers in March 2025.

**TEHDAS2** is a Joint Action project in which the MS nominated the FI Innovation Fund, Sitra, as the coordinator. Work began retrospectively on 1<sup>st</sup> May 2024 and will last 32 months. The expected result of TEHDAS2 is to produce guidelines and technical specifications for common

aspects of the implementation of the proposed EHDS. TEHDAS2 will work on its deliverables in three waves, including public consultations starting in January 2025.

With regards to the **EHDS Regulation**, regulatory and legislative updates were provided by EC DG SANTE C1. The progress since March 2024 was summarised. The remaining steps include the lawyer-linguist revision during the summer 2024 which aims to “clean up” the text and provide a translated text. The formal adoption by the EP and Council is planned for the end of 2024 and its publication in the Official Journal (OJ), shortly after. It was noted that 20 days after the publication in the OJ, the EHDS Regulation will enter into force triggering the start of the transition periods. An overall timeline for the EHDS application was reviewed through 2036, and it was reiterated that there is much work to accomplish over a relatively short amount of time, particularly regarding the adoption of crucial Implementing Acts by the end of 2026. Several **key points of the legislation were reviewed**, including **opt-out**, and the governance **structure for the EHDS, which will include 4 main bodies: the EHDS board, EHDS1 steering board, EHDS2 steering board and a stakeholder forum**.

EC DG SANTE R4 provided an update on the **Central Platform** completed works and the next development steps. A brief demonstration was provided of the Release 1 work to date which shows the EU Dataset Catalogue, the data access application process, etc.

The **Capacity Building Team** was introduced, and it was reported that there will be a close collaboration between the CoP and the Capacity Building Team, who will create and distribute trainings on the 5 digital business capabilities ensuring that the needs of the CoP are fulfilled. The team will design, pilot and deliver capacity-building trainings and toolkits to support the national implementation of the DBCs. The team will join SG meetings to learn more about MS needs and to ensure follow-up on work carried out. Regarding the approach and the scope, both fundamental (90 minutes) and extended (120 minutes) courses will be offered in addition to toolkits. All toolkits and trainings will be piloted to test if all needs within the SGs are met. The toolkit will aim to be implemented in mid-2025, and currently the team is assessing the SG needs and gathering information.

Regarding the SB Chair and Rapporteur (EE) it was announced that they have reached the end of their term in this position, in alignment with the Working Arrangements, the Chair was thanked for their contributions. **The current rapporteur (HR) will take over the chairmanship of the SB, and a new rapporteur (IT) was elected by consensus after a call for expression of interest.**

In AOB, it was indicated that the **next General Assembly meeting is being planned, and MT volunteered to host in January 2025**. It was reiterated that there will not be reimbursement by the EC, however MS can utilise funds from the direct grants for the travel/accommodation expenses for a CoP F2F event.

The Head of Unit Digital Health in DG SANTE thanked all participants for their contributions and indicated optimism and reassurance about the progress and growth by the CoP. The accomplishments were summarised, and it was indicated that the established roadmaps are encouraging for future collaboration between the MS and parallel projects.

The meeting was thereafter adjourned.