



**25<sup>TH</sup> EHEALTH NETWORK MEETING 28 NOVEMBER 2023,  
BRUSSELS  
COVER NOTE**

**13.1 HealthData@EU Pilot (*for information*)**

1) Introduction

The HealthData@EU Pilot project aims to build a pilot version infrastructure of HealthData@EU, the common European infrastructure that connects health data access bodies and other entities for the reuse of health data, including research, innovation, policy making and regulatory purposes. It will investigate and demonstrate the value of such infrastructure and will also assess its ability to scale towards a Union-wide infrastructure, as a core component of the European Health Data Space.

The project will connect data platforms in a network infrastructure and develop services supporting the user journey for research projects using health data from various EU Member States. It will also provide guidelines for data standards, data quality, data security and data transfer to support this cross-border infrastructure. Priority services include a metadata discovery service and a common health data access request.

The HealthData@EU Pilot project brings together key actors of secondary use of data in Europe, such as existing health data access bodies, i.e. national authorities empowered by national mandate and legal basis to enable access to health data to third parties, and other international or EU-level organisations, e.g., health data research infrastructures or European health related agencies.

The project was launched in October 2022 and will last two years. Led by the Health Data Hub, the HealthData@EU Pilot project brings together 17 European partners including health data access bodies, health data sharing infrastructures and European agencies EMA and ECDC. The consortium will collaborate closely with the European Commission and their team working on developing the central services for secondary use of health data.

2) Issue at stake

The HealthData@EU Pilot is a first iteration to prepare for the implementation of the European Health Data Space (EHDS) infrastructures in the area of secondary uses of health data. It builds on the work of TEHDaS and it aims to lay the ground for the connection of health data access bodies, which will be supported through direct grants under EU4Health, and other potential future authorised participants.

3) Summary

The pilot project's general Assembly was held in Paris on 19 and 20 October 2023, marking



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the end of the project's first year. The meeting provided an opportunity to review the progress but also the challenges facing the various work packages in the year ahead.

Progress in the technical work packages has enabled the project to complete a first proof-of-concept phase for the architecture (WP5) and to launch the technical workgroup responsible for developing the healthDCAT AP extension to describe the metadata (WP6). A first version of the common data access application form was also discussed and should be available before the end of 2023 (WP7). These advances will enable the project to move on to a deployment phase on a small number of nodes in 2024 and to test the deliverables within the use cases.

A progress report on the use cases highlighted the difficulties of accessing data (complexity and heterogeneity of processes in the various participating MS) despite the involvement of the players. This underlines again the importance of harmonising these procedures to improve access to health data for research, policy making and innovation, as envisaged in the proposed regulation for a European Health Data Space.

Finally, the European Commission stressed the importance of the project in preparing for the practical implementation of the secondary use of health data within the framework provided by the European Health Data Space, before the scale-up phase that will start in 2024.

#### 4) Format of procedure in the meeting

This agenda point is for information. If you have specific questions, please flag them so they can be addressed under AOB.