REPUBLIC OF ESTONIA
MINISTRY OF SOCIAL AFFAIRS

Aurelie Gommenginger
European Health and Digital Executive Agency
(HaDEA)
Aurelie.GOMMENGINGER@ec.europa.eu Our ref 22.07.2026 No 2-11/1854

Request for a six-month extension of the duration of project EST2EHDS (GAP-101129188)

Dear Aurelie Gommenginger

The Ministry of Social Affairs of the Republic of Estonia respectfully requests a six-month extension of the EST2EHDS project, moving the project end date from 30 November 2026 to 31 May 2027.

We fully recognise the importance of completing the project within the agreed timeframe and ensuring that the Union's financial contribution delivers the intended results. We remain firmly committed to the objectives of EST2EHDS and to completing the agreed scope of work. This request has therefore been considered carefully and is based on a detailed review of the status of the project and the remaining activities.

Following this review, we have identified a significant risk that several substantive activities and deliverables cannot be completed to the required standard by the current project end date. This risk is primarily linked to an earlier underestimation of the workload, sequencing requirements and legal, organisational and technical complexity of the activities required to deliver the planned results.

The requested amendment does not involve an increase in the project budget or an expansion of the agreed scope. Its purpose is to provide sufficient time to complete, validate and consolidate the agreed work at an appropriate level of quality.

The Ministry of Social Affairs has continuously reviewed the implementation approach considering the evolving European Health Data Space (EHDS) framework and the interdependencies between national and European-level developments. The remaining activities are well defined, procurement procedures have been initiated, and the necessary implementation work is under way. The requested extension is intended to ensure that these activities can be completed based on sufficiently mature regulatory, organisational and technical requirements.

Estonia is not establishing a new health data ecosystem from the ground up. Instead, EHDS implementation must be integrated into an already functioning national system used daily by healthcare providers, public authorities and researchers.

This increases the importance of careful design choices and thorough validation, as changes introduced under the EHDS will have long-term implications for existing national services and infrastructures.

During the project, it has become clear that this integration requires more extensive analysis, coordination and sequencing than originally anticipated. Requirements concerning health data access, application management, secure processing environments, dataset descriptions, data quality and cross-border data exchange are closely interconnected, and decisions in one area directly affect the design and feasibility of the others. Coordinating these interdependencies and developing a coherent national approach across the relevant legal, organisational and technical components has therefore proven more time- and resource-intensive than initially estimated.

The project must also clarify the legal and operational relationship between the EHDS framework for the secondary use of health data and Estonia's existing national mechanisms. This includes the role and responsibilities of the future health data access body, the relationship between EHDS procedures and existing national authorisation and ethics processes, the adaptation of existing national systems, and the legal and operational arrangements for secure processing environments. These questions have required broader interinstitutional coordination and more detailed legal and organisational analysis than originally foreseen. They must be sufficiently clarified for the project outputs to provide a coherent and actionable national implementation pathway.

The detailed EU-level EHDS framework has continued to evolve throughout the project period through the preparation of implementing acts, technical specifications and common governance arrangements. While Estonia has continuously advanced its preparatory work, several key implementation choices depend on the further clarification of EU-level requirements.

Part of the detailed national design work has therefore necessarily been undertaken in parallel with the continued development of the European framework. It has been important to ensure that national investments and implementation decisions remain aligned with emerging EHDS requirements. Premature decisions could lead to inefficient use of resources, duplication of effort or the need for substantial redesign. Additional time is therefore required to ensure that the proposed national solutions are sustainable, interoperable and consistent with the applicable EHDS implementation framework.

The need for additional time concerns primarily the substantive work under WP5, WP6, WP7, WP8 and WP9.

Under WP5, the core capabilities for the national data catalogue have been established. The remaining work concerns the preparation and publication of detailed dataset descriptions. This requires appropriate domain expertise, technical implementation and careful consideration of how to provide prospective data users with sufficiently detailed information while managing the cybersecurity implications of publishing information concerning sensitive clinical data environments.

Under WP6, the proposal and action plan for the national data access application management system depend on clarification of the future national governance and procedural model for the secondary use of health data. The analysis must establish how the required EHDS functions relate to existing national application, authorisation and ethics processes, which existing systems can be adapted, and which additional capabilities are required. Without sufficient clarity on these matters, the deliverable would remain too general to provide a practical basis for implementation.

Under WP7, the work on secure processing environments has been organised in consecutive stages. The final proposal and action plan must build on the findings of the analysis already under way and take account of the developing national legal framework and the wider decisions concerning the organisation of secondary use. Additional time is required to incorporate the results of the preceding analysis into a coherent and usable national proposal.

Under WP8, the cross-border gateway analysis must assess Estonia's preparedness for HealthData@EU and align the proposed arrangements with national systems for data access, secure processing and institutional governance. Following the relevant procurement procedure, sufficient time is required to complete the substantive analysis, consult the relevant stakeholders, validate the conclusions and coordinate the results with the related work packages.

Under WP9, additional time is required for both the data quality framework and the associated data validation solution. Extending the completion of the data quality framework until the end of January 2027 would allow it to be reviewed and refined based on the initial experience gained from its implementation. The final framework would consequently reflect both the original design requirements and practical lessons concerning its application within the national health information system.

The data validation solution requires further development, integration and end-to-end testing. A large and heterogeneous range of software systems used by healthcare providers exchange data with the national health information system and will be affected by the introduction of the validation solution. The number and diversity of these systems add considerable technical and organisational complexity, as interfaces, data flows, validation rules, feedback mechanisms and error-handling processes must function consistently across multiple software environments. Additional time is required to test these interactions and ensure that the solution can be introduced reliably without disrupting existing national data exchange processes.

The additional six months would be used to complete and consolidate activities already included in the agreed project scope. This would allow the ongoing analyses and technical work to be completed, procurement results to be incorporated, conclusions to be validated with the responsible authorities and implementation partners, and consistency between the interdependent work packages to be ensured. The final evaluation, sustainability and reporting activities could consequently be completed based on the actual substantive project results.

Without an extension, there is a significant risk that some deliverables would have to be finalised before the relevant legal, institutional and technical dependencies have been sufficiently addressed and before the conclusions have been properly validated. This could result in outputs that are formally complete but not sufficiently mature, coherent or actionable to support national implementation decisions. It could also require parts of the work to be substantially revised after the end of the project.

The requested extension reflects a revised and more realistic assessment of the time required to complete the agreed work responsibly and to ensure that the project delivers meaningful and practically usable results.

We therefore respectfully request that the duration of the EST2EHDS project be extended by six months, until 31 May 2027.

We would be grateful for the favourable consideration of this request.

Sarah-Harriet Sonnenberg +372
sarah-harriet.sonnenberg@sm.ee