European Commission

EN

Horizon Europe

Work Programme 2023-2024

4. Health

(European Commission Decision C(2022)7550 of 6 December 2022)

- Development of an implementation plan including supporting tools and training modules (by researchers, alone or in collaboration with HTA bodies, to be delivered to HTA bodies/agencies)

- Recommendations for broader dissemination.

HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 3.00 and 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 8.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "*Maintaining an innovative, sustainable and globally competitive health industry*". More specifically, this topic aims at supporting activities that are contributing to the following impact area: "*High quality digital services for all.*" To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes, and provide appropriate qualitative and quantitative indicators to measure their progress and specific impact:

- European Health Record (EHR) stakeholders (e.g. developers, suppliers, integrators, and operators) have at their disposal and use fit-for-purpose standards, guidelines, and toolsets for prioritised health information domains to address interoperability of EHRs in

line with the principles set in the EEHRxF Recommendation[268], contributing also to security and privacy.

- Stakeholders have at their disposal better quality and better integrated health datasets within the European Health Data Space,[269] to foster innovations in the health sector and leverage the potential of new analytics solutions such as AI and big data, get new insights and detect trends from aggregated data, including for cross-border health threats.

- Citizens are provided with an expanded access to their health data, also across borders, and innovative digital services for high-quality health and care across the EU.

Scope: EHR interoperability has yet to become a reality in a number of use cases and health information domains. It is a complex, multi-dimensional challenge. EHRs across the Member States are diverse; so are languages, cultures, and practices in the health sector. Different technical specifications, technologies and clinical terminologies are used, involving a range of stakeholders, within and across care settings.

Proposals should address all of the following:

- Research, develop and validate harmonised interoperability formats for sharing data in specific priority health information domains that should be selected with reference to the EU policies and priorities. The output formats should enable EHR interoperability across the Member States and address cross-border health data exchange by design and in line with the principles set in the EEHRxF Recommendation.

- Leverage and scale up the potential of EHR through enhanced interoperability to improve the quality, safety, and efficiency of patient care, enforce patients' right to data portability, enhance care coordination, guide crisis planning, reduce medical errors, and lower costs. For example, based on the lessons learnt from COVID-19, enable incorporating EHR data into the early stages of clinical crisis planning and leveraging it to identify potential cross-border health threats based on analysis of patients' data trends.

- Address semantic interoperability for prioritised information domains so that the transmitted health record contains standardised coded data.

- Maximise synergies with relevant initiatives, activities and programmes, building upon previous and linking to on-going actions[270].

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268 Commission Recommendation on a European Electronic Health Record exchange Format (EEHRxF) (C(219)800)

269 https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

270 Such as "Support for European eHealth Interoperability roadmap for deployment" https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-hcc-07-2020; "Prototyping a European interoperable Electronic Health Record (EHR) exchange" https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-08-2018; "Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem" https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-ind-13-05

- Closely coordinate and collaborate with various stakeholders, from patients and healthcare professionals to EHR providers, healthcare industry (including SMEs), policymakers and legislators to progress towards a more comprehensive EHR interoperability.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 4.00 and 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 25.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Developers and regulators have access to robust modelling and simulation tools to accelerate the effective development of orphan and/or paediatric medicinal products.
- Clinical researchers, developers and regulators use accurate computational models to improve the statistical robustness in clinical trials intended for small populations and guide cost-effective clinical trial designs.