All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 2: Safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Expected outcomes

The European Health Data Space (EHDS) is a key initiative under the European Strategy for Data and the European Health Union that enables the secondary use of health data for various purposes, including research and innovation. The outcomes of this topic will lead to the identification of paths for innovation through the EHDS while safeguarding intellectual property and trade secrets in health data.

This topic must contribute to all of the following outcomes:

- comprehensive frameworks, processes, policies and guidelines are available to support the procedural and operational aspects of the EHDS from an innovator's perspective;
- recommendations to inform EHDS governance are available to address the needs of a broad set of stakeholders, including citizens, hospitals, public institutions and the healthcare industry. The right balance must be struck between the need for an EHDS that enables efficient data sharing to promote research and innovation in healthcare, and the need for maintaining a strong Intellectual Property (IP) system and preserving confidential information within health research data;
- Recommendations are available for enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs) to address issues around innovation utilising the EHDS and the operationalisation of the EHDS; and
- Materials, guidance, recommendations, training and other support tools are available to educate interested parties about innovation and data sharing under the EHDS.

The target groups for all the outcomes are:

- those establishing the EHDS and the federated data network, through which data will flow and be used for secondary purposes;
- member state agencies involved with the establishment and functioning of HDABs;
- HDHs making sensitive and confidential data available through the EHDS for secondary use; and
- HDUs intending to access sensitive and confidential data for secondary use.

Scope

The background to this topic arises from the EU regulation for an EHDS. This topic focuses on the secondary use aspects of the regulation establishing the EHDS and recognises that to be successful there is a need to consider both the societal benefits of data-driven advancements in healthcare and the legitimate interests of public and private sector innovators for a strong IP system and an efficient means of supporting the secondary use aspect of the EHDS.

The specific challenges/problems addressed by the topic include:

- Balancing the societal benefits of data-driven innovation in healthcare against the legitimate interests of public and private sector innovators to safeguard relevant legal and regulatory rights related to their data (e.g., (*sui generis*) database rights, CCI (Confidential Commercial Information), trade secrets, RDP (Regulatory Data Protection)**,** patents, etc.);
- Empowering HDHs and users to engage with and use the EHDS for data-driven healthcare innovation by providing them with knowledge and tools to operationalise secondary data sharing and to safeguard intellectual property rights, trade secrets and regulatory data protections;
- Developing robust frameworks and guidelines to support the implementation of the EHDS to enable harmonised and efficient data sharing (including in the context of data anonymisation considerations) across all member states and safeguarding IP and trade secrets in support of innovation; and
- Exploring concerns regarding commercial and competition-sensitive data and risk of unauthorised disclosures.

The topic objectives are:

- Build trust and confidence in the EHDS: respecting and keeping proprietary information confidential, creating trust and confidence among stakeholders and promoting their active participation in the EHDS to enable responsible and timely data sharing;
- Propose implementation practices that will support the efficient inclusion of health data in the EHDS for secondary research purposes and support the procedural and operational aspects of the EHDS;
- Support innovators' competitiveness by safeguarding valuable IP and trade secrets data whilst fostering further research and innovation;
- Advancing data governance and confidentiality practices within the EHDS to ensure appropriate protection of IP and trade secrets;
- Ensuring data governance throughout the whole product life cycle, from development to post market monitoring and update;
- Minimising administrative burden for HDABs, HDHs and HDUs impacted by the EHDS;
- Ensuring that relevant legal and regulatory rights of innovators are respected and timely preserved to minimise uncertainty and maximise opportunities for innovation under the EHDS;
- Supporting an EHDS implementation that facilitates data sharing, innovation, and research to advance healthcare for EU citizens, and uses processes that take advantage of existing practices in industry and health authorities and are resource efficient.

Applicants should envisage the following activities as part of their proposal:

<u>With regards to the outcome supporting the procedural and operational aspects of the EHDS</u>

- Conduct research into data strategy, management and governance;
- Conduct comparative reviews of existing data exchanges and the needs for transparency, interoperability and standardisation of data;
- Through elaborate use cases, explore the procedural and operational aspects of the EHDS from various perspectives, including:

    - Assessing data sharing platforms and technologies, such as data security measures like encryption technologies, access control mechanisms, black boxes, federated learning, and their implications on the data sharing and IP system;
    - Investigate the sharing of different types of data covered by the EHDS, including trade secret and sensitive data, for secondary use. This will help to address different scenarios regarding purpose, time of sharing, and territorial scope, potentially leveraging test environments to evaluate operational and practical aspects of data sharing and data usability under the EHDS.

- Identify best practices, guidelines, standards, and tools for intellectual property, trade secret, and opt-in/out management that can be used and advanced within the EHDS frameworks;
- Develop proposals for comprehensive frameworks, processes, policies and guidelines balancing the needs of HDHs to safeguard the IP system and minimising administrative burden while facilitating data sharing and collaboration;
- Develop mechanisms and technologies for IPR-aware data anonymisation/ pseudonymisation and synthetic data generation, with the goal of facilitating the reuse of electronic health data that is subject to IP protection;
- Prepare recommendations for technical standards for access controls, data minimisation, secure data storage, and anonymisation techniques, handling of evolving data sets, etc., which might benefit innovation related to trade secrets and IP protected data covered by the EHDS.

<u>With regards to the outcome striking the appropriate balance</u>

- Evaluation and comparative study of laws, including trade secret laws and other laws of the EU Strategy for Data and of the EU member states, to identify common and differentiating features and legal bases in order to propose recommendations for member state implementation of HDABs and to develop guidance for IP and data protection covering areas such as dataset descriptions, data sharing policies and agreements, access controls, and governance practices and data use;
- Comprehensive research into the interplay between IP, transparency, data protection, state aid, competition laws, international treaties, the need for openness, and the potential risk for misuse of data under the EHDS;
- Conduct research exploring compatibility and gaps of the EHDS versus existing laws around data and data sharing, IP, including protection of confidential information and trade secrets, and related laws, such as privacy, the EU data governance act, the EU data act, the EU AI act and regulatory data protection;
- Propose guidelines and frameworks regarding data sharing and data use to support the balance of the societal benefits of data-driven healthcare research and innovation under the EHDS against the legitimate interests of public and private sector innovators for a strong IP system, including, for example, a classification of data into categories depending on IP sensitivity;
- Develop guidance on responsible use and mechanisms to hold irresponsible / misusing users accountable and prevent misuse;
- Develop clear rules for data ownership and IP ownership determination for all kinds of newly generated data using EHDS;
- Propose a harmonisation framework including standard agreements for IP ownership to enable secondary use of data provided via the EHDS for research purposes;

- Analyse and provide recommendations on exploitation and publication of results by HDU and impact on HDHs with IP and trade secret protected data.

With regards to the outcome establishing frameworks for dialogues

- Engagement of public and private innovators in the European Health Data Space 2 (EHDS2) Stakeholder Engagement initiative to shape the definition of responsible secondary use of data for research and innovative purposes under the EHDS, including territorial considerations;
- Preparing recommendations to develop a framework for dialogues between innovators and health data access bodies (HDABs) to address issues around innovation and operationalisation under the EHDS, balancing all the relevant stakeholders' legitimate interests.

With regards to the outcome educational aspects

- Development of training packages, including educational materials, guidance, recommendations, and other support tools to educate stakeholders about innovation, data sharing and the IP system under the EHDS;
- Educating stakeholders about using the EHDS for innovative purposes.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with relevant regulators in a timely manner.

Expected impacts

The action contributes to all the general objectives of IHI JU and particularly to specific objective 4 "exploit the full potential of digitalisation and data exchange in health care".

The action under this topic is expected to achieve all of the following impacts:

- Fostering data-driven research and innovation advancing healthcare in the EU;
- A world-leading approach to IP protection of data;
- Improved balance between data utilisation and access control rights;
- Best practices for data sharing, data security and prevention of unauthorised disclosure;
- Recommendations for legal and ethical standards; and
- Increased industry confidence in the EHDS.

The action will also contribute to several European policies/ initiatives, which include:

- The European Health Data Space;
- The European Commission's Pharmaceutical Strategy for Europe, specifically the pillar on competitiveness, innovation, and sustainability;
- Related measures under the ongoing revision of the pharmaceutical legislation;
- The Trade Secret Directive;
- The European Strategy for Data, incl. GDPR, Data Act, Data Governance Act, AI Act;
- The Digital Strategy; and
- The Digital Single Market Strategy.

Overall, these expected impacts aim to create a secure, collaborative, and innovative ecosystem within the EHDS, which will increase trust and confidence among stakeholders, optimise data utilisation,

enhance protection of intellectual property, and facilitate advancements in healthcare research and innovation.

Why the expected outcomes can only be achieved by an IHI JU action

The Intellectual Property ("IP") system exists to support innovation and is a key driver for all healthcare industries operating in EU. Thus, understanding how the EHDS interacts with, and might impact, the IP system will be key to its success and that of the European innovation landscape.

Public and private partners will be Health Data Holders (HDHs) and Health Data Users (HDUs) who may simultaneously be innovators. Thus, combining the strengths and expertise of private and public partners is essential to develop holistic solutions balancing the protection of IP (including trade secrets) with an EHDS that facilitates data sharing and utilisation for research and innovation.

Industry partners bring expertise in secondary use of health data, IP and trade secret management, which can be leveraged to develop effective strategies for protecting innovation whilst also facilitating health data sharing. They also understand the concerns of industry in protecting innovation with IP.

Public partners bring their knowledge of and insights into the healthcare sector, and expertise in health data management as well as technology transfer. Public partners will provide insights into the needs of the healthcare system and societal considerations for sharing health data for secondary use.

The proposed public-private collaboration is essential to develop robust frameworks, policies, and processes addressing the complex challenges posed by the EHDS. A close collaboration is necessary for the implementation of an EHDS that facilitates secondary use of data whilst also respecting the needs of innovators for a strong IP system. The collaboration will enable the EHDS to exploit the full potential of digitalisation and data exchange in health care.

The relevant stakeholders for this topic are those involved with the establishment of the EHDS for secondary use purposes and those who will provide and access data utilising the EHDS, which includes:

- HDHs and HDUs, including healthcare providers, pharmaceutical companies, and medical technology companies;
- Patient organisations and other Non-Governmental Organisations in the health research space;
- Universities and institutions or other organisations with an interest in health data;
- EU and Member State authorities responsible under the EHDS to handle and protect data of HDHs; and
- EU and Member State authorities who will establish federated data networks, HDABs and secure processing environments under the regulation for the EHDS.

Pre-identified industry consortium and contributing partners

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries, it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to a constituent or affiliated entity of a private member.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 5 200 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

- The indicative in-kind contribution from industry beneficiaries is EUR 4 929 500. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

- The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 36 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The pre-identified industry consortium and contributing partner(s) expect to contribute to the IHI JU project by providing the following expertise and assets:

- Legal, paralegal experts and advisors/consultants specialised in IP & trade secrets protection in the digital and medical environments;
- Governmental Affairs and Policy experts;
- ISRM (Information Security & Risk Management) experts;
- Data strategy and governance experts;
- Communication expertise for webinars & workshops;
- Data privacy experts;
- Public affairs experts.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partner(s).

This may require mobilising the following expertise and/or resources:

- Academic and/or research organisations involved in innovation and competition with particular expertise in legal and IP;
- ISRM (Information Security & Risk Management) experts;
- Hospital networks/health data holders/ health data users (clinical research units);
- Implementers of large digital healthcare infrastructures for primary and secondary data use (i.e., which make use of the EU policies mentioned in the expected impact section) from across the EU;

- Project management expertise related to qualitative market research and public relations;
- Project management organisations with project management expertise of large multi-stakeholder European public-private partnerships;
- Legal expertise and, in particular, privacy and data protection expertise;
- Experts from, or with connections to country ministries, involved with implementing and operating Health Data Access Bodies;
- Publicly accessible datasets.

At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' do not apply.