

## Topic 4: Access and integration of heterogeneous health data for improved health care in disease areas of high unmet public health need

**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.**

### Expected impacts to be achieved by this topic

This topic aims to achieve the following:

- Better and faster integration of future products, services and tools along the health care pathway responding to patients' specific needs and leading to improved health outcomes and patient well-being.
- Wider availability of interoperable, quality data, respecting FAIR principles, facilitating research and the development of integrated products and services.
- Advanced analytics/artificial intelligence supporting health Research & Innovation, resulting in a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment, b) wider availability of personalised health interventions to end-users, c) better evidence of the added value from new digital health and artificial intelligence (AI) tools, including reduced risk of bias due to improved methodologies.

### Expected outcomes

Proposals under this topic should aim for delivering results that contribute to the following expected outcomes for specified disease areas of high unmet public health need:

- Researchers, including industry stakeholders have long term access to diverse data enabled by the linkage and integration of novel and cross-sectoral sources, including industry sources.
- Researchers, including industry stakeholders have long term access to new tools that enable the integration and analysis of these data.
- Citizens, including patients, are given interoperable tools to access their own health data from different sources to support disease self-management and empower joint health care professional - patient decision making.
- Health care professionals and health care providers<sup>1</sup> have access to integrated data from diverse sources and clinical (and other) decision support systems to deliver better health care services to patients and populations in the most suitable and efficient manner.

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<sup>1</sup> Health care providers refer to organisations that deliver health care goods and services. Typical health care providers are hospitals, long-term care facilities, providers of ambulatory health care, laboratories, nursing care facilities, pharmacies and so on.

## Scope

Over the past few years, there has been an explosion in the generation of data that could be harnessed for use in healthcare delivery and research. These data include data generated by digital technologies, patient reported outcome and experience measures, as well as data from clinical trials and routine clinical care. However, accessing, integrating & analysing these data to maximise the value for patient care and research is extremely challenging.

This topic aims to provide a scalable platform for the seamless integration or linkage of these diverse data and develop tools to allow the data to be used in clinical care, patient self-management and research in disease areas of high unmet public health.

In their proposals, applicants should **clearly identify a disease area** of high unmet public health need<sup>2</sup> for their proposed activities and **explain their choice** with empirical evidence where possible.

For the selected disease area, the project(s) funded under this topic are expected to:

- **Develop/ further develop a scalable, open platform** for the seamless integration or linkage of data from diverse public and private data sources relevant to the disease area selected. These data sources should, as a minimum, include all of the following: clinical trials; registries, routine clinical care; patient reported outcome and experience measures; data generated by digital technologies such as sensors, wearables and mHealth apps. Preferably, projects should also integrate data that has not usually been used before for the purpose of medical decision-making.
- Develop or further develop **tools focussed on the needs of patients**, leveraging these diverse data sources to support patient self-management and empower joint health care professional - patient decision making.
- Develop / further develop **clinical (and other) decision support systems** leveraging these diverse data sources to allow clinicians to deliver better health care services to patients in the disease area selected.
- Demonstrate the **added value of the platform** and tools compared to current approaches through a use case (study) applied to the disease area selected.
- Demonstrate the **widespread applicability and scalability of the platform & tools** using data sources from outside of the project
- Publish sufficient information, including access protocols, on the data that has been used in the project to **facilitate long-term access and re-use**, while ensuring compliance with the General Data Protection Regulation.

Applicants should also aim to deliver the following:

- Public release of a set of minimum technical requirements for the developed platform/tools that includes interoperability, connectivity, data protection, cybersecurity and

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<sup>2</sup> Unmet public health needs are needs currently not addressed by the healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life, ...) and/or the number of people affected by it. For example, Alzheimer's disease.

authentication/identification requirements that need to be met to allow the efficient integration of additional data from new devices/sensors/sources into the decision-support system after the project ends.

- Sustainable, ideally open-source tools that help ensure the quality and FAIRness<sup>3</sup> of data at source (e.g., automated tools to help data entry, semantic coding, and data management in particular in registries and databases maintained by health care professionals/providers and research institutions) as well as methodologies, quality standards and metrics to assess the data quality.
- Sustainable tools to increase cross-border and cross-sector interoperability of health data from the diverse sources mentioned above. Ideally, these tools use open exchange formats.
- Sustainability plan/business model to ensure the long-term impact of the projects' results.

Other considerations:

- Applicants should build on clearly identified existing tools & platforms where possible, and ensure the platform and tools developed can be applied to other disease areas or be relevant for other scientific and clinical communities (i.e. ensuring interoperability with other solutions).
- Applicants must demonstrate they have access to sufficient diverse data, including from industry sources, to meet the objectives of this topic. The data sources (name & country), types, and size must be described in the proposal alongside convincing evidence that the consortium will have access to these data for the project implementation.
- Applicants are expected to explore the integration of the outputs with the European Health Data Space (EHDS)<sup>4</sup> when it becomes operational and explore synergies with other relevant health data initiatives.

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

The data to be integrated in the funded projects are expected to come from diverse public and private sources. To access, understand and integrate these data and to develop platforms and tools for clinical decision making and patient self-management requires significant cross-sectoral expertise including from patients, health care professionals, healthcare data specialists, academic researchers, SMEs, pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together to achieve the objectives of this topic.

### Indicative budget

Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants, the rest being covered by financial contribution received from IHI JU (see call conditions for further information).

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<sup>3</sup> FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability.

<sup>4</sup> [https://ec.europa.eu/health/ehealth/dataspace\\_en](https://ec.europa.eu/health/ehealth/dataspace_en)

### **Indicative duration of the actions**

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

### **Dissemination and exploitation obligations**

To be determined

INDICATIVE TEXT