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 4: Maximising the potential of synthetic data generation in healthcare applications

#### Expected impacts to be achieved by this topic

To exploit the full potential of digitalisation and data exchange in health care, this topic is expected to contribute to the following expected impacts:

- Wider availability of interoperable, synthetic data facilitating research and the development of integrated products and services to benefit patients.
- Improved insight into real-life behaviour and challenges of patients with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies.
- Advanced analytics/artificial intelligence tools supporting health research and innovation resulting in a)
  better clinical decision support for increased accuracy of diagnosis and efficacy of treatment, b) faster
  prototyping and shorter times to market of personalised health interventions, c) better evidence of the
  added value from new digital health and AI tools, including reduced risk of bias due to improved
  methodologies.

#### **Expected outcomes**

The proposals should contribute to all the following expected outcomes:

- Academic and industrial researchers have a better understanding of the applicability and suitability of different synthetic data generation methods in specific use cases.
- Academic and industrial researchers have better tools, including open access when relevant, to create
  and share pools of synthetic patient data for research.
- Academic and industrial researchers have access to relevant, high quality synthetic datasets.
- Thanks to better availability of robust synthetic data sets for training data models, healthcare providers and industry have a wider range of performant Al-based and other data-driven tools to support diagnostics, personalised treatment decision-making and prediction of health outcomes.

## Scope

Healthcare research using individual patient data is often constrained due to restrictions in data access because of privacy, security, intellectual property (IP) and other concerns. Synthetic health data, i.e., data that is artificially created to mimic individual patient data, can reduce these concerns, leading to more rapid development of reliable data-driven methods including diagnostic, precision medicine, decision support and patient monitoring tools. However, while many synthetic data generation (SDG) methods are currently available, it is not always clear which method is best for which use case, and SDG methods for some types of data are still immature.

To address these challenges and maximise the opportunity offered by synthetic data, projects funded under this topic should address the following objectives:

- Assemble a cross-sectoral public-private consortium including synthetic data experts, public and private data owners, and healthcare solution developers.
- Using high-quality public and private datasets, develop/ further develop and validate reliable SDG
  methods for relevant healthcare use cases. The use cases to be explored must be described and
  justified in the proposal and should:
  - Ensure the broad applicability of the SDG methods developed and include data types that are not currently adequately addressed, such as device data, image data, genomic data, etc.
  - Include methods to generate fully synthetic datasets not containing any real data; hybrid datasets, i.e., combination of data derived from both real and synthetic data; and synthetically-augmented datasets.
  - Pay particular attention to bias, both in source data and in the SDG methods.
- Validate the synthetic data generation methods applied in the project using source data.
- Demonstrate the quality and applicability of the synthetic data generated in the project through the development of relevant models.
- Encourage the uptake of the results of the project through a strong communication and outreach plan.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects, including the European Health Data Space (EHDS)<sup>1</sup> when it becomes operational.

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

Development and validation of synthetic data generation methods and tools for data-driven applications requires multidisciplinary collaboration across private and public entities, including public and private data owners, healthcare solution developers, and synthetic data experts.

#### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 20 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 

IHI estimates that an IHI financial contribution of around EUR 10 000 000 would allow a proposal to address these outcomes appropriately. *NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.* Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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 (see call conditions for further information).

#### Indicative duration of the actions

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

<sup>&</sup>lt;sup>1</sup> https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\_en

# Dissemination and exploitation obligations

[To be determined: The specific obligations described in the Conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" [apply][do not apply]

