



IHI

5th Call for proposals

Single-stage call



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Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

IHI JU aims to pioneer a new, more integrated approach to health research and builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU).

IHI JU aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI JU will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

As current health challenges and threats are global, IHI JU should be open to participation by international academic, industrial and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for Union citizens.

Topics overview

<p>HORIZON-JU-IHI-2023-05-01</p> <p>Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies</p>	<p>Applicant consortia will be competing for a maximum financial contribution from IHI up to EUR 30 000 000.</p> <p>IHI estimates that an IHI financial contribution of between EUR 12 000 000 and EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.</p> <p>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>
<p>HORIZON-JU-IHI-2023-05-02</p> <p>Development and proof of principle of new clinical applications of theranostics solutions</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000.</p> <p>IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 12 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.</p> <p>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>

<p>HORIZON-JU-IHI-2023-05-03</p> <p>Improved prediction, detection, and treatment approaches for comprehensive stroke management</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 40 000 000.</p> <p>IHI estimates that an IHI financial contribution of between EUR 10 000 000 and 13 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.</p> <p>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>
<p>HORIZON-JU-IHI-2023-05-04</p> <p>Maximising the potential of synthetic data generation in healthcare applications</p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 20 000 000.</p> <p>IHI estimates that an IHI financial contribution of around EUR 10 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.</p> <p>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>

Call conditions for single stage and two-stage calls

*For Call 5 please refer to the conditions relevant to the single-stage call

The submission deadline for full proposals (FPs) will be 16 January 2024.

Scientific evaluation of the single-stage call will take place in Q1 2024. GAP will be completed within 3 months from the notification to applicants of the evaluation results of the full proposal, and maximum eight months from the final date of submission of the FPs, in line with the applicable time to grant (TTG).

Conditions of the calls and call management rules

For call management, IHI JU will utilise the EC IT infrastructure available under Funding & Tender opportunities - Single Electronic Data Interchange Area (SEDIA).

The General Annexes of the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in this Work Programme.

To maximise the efficiency of the calls management, IHI JU will continuously explore and implement simplifications and improve its processes while maintaining the highest standards of the evaluation process, in line with the applicable Horizon Europe rules.

All proposals must conform to the conditions set out in Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination.

Any specificity for IHI JU is highlighted in the below sections.

General conditions relating to the IHI JU calls

ADMISSIBILITY CONDITIONS	THE CONDITIONS ARE DESCRIBED IN GENERAL ANNEX A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.

Standard admissibility conditions, pages limits and supporting documents

General Annex A ('Admissibility') to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

In addition, page limits will apply to proposals as follows:

- for a single-stage call, the limit for RIA full proposals is 50 pages;
- at stage 1 of a two-stage call, the limit for RIA short proposals is 20 pages;
- at stage 2 of a two-stage call, the limit for RIA full proposals is 50 pages.

Standard eligibility conditions

General Annex B to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme unless otherwise provided in this Work Programme.

Per the above and by way of derogation from General Annex B of the Horizon Europe Work Programme 2023-2024:

According to Article 119 of the Council Regulation (EU) 2021/2085, for indirect actions selected under calls for proposals covered by this Work Programme:

- applicant consortia must ensure that at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners;
- While the constituent or affiliated entities of the members other than the union of IHI JU can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA;
- further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided;
- the eligibility condition above and self-declaration requirement do not apply to the first stage of a two-stage application;
- at project level, the maximum amount of non-EU IKOP is set to:
 - one hundred percent (100%) for IHI JU Call 4
 - Thirty percent (30%) for IHI JU Call 5¹

This is justified as a means to ensure the achievement of project objectives based on Article 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openness to non-EU IKOP in these calls².

¹ Even if this threshold of 30% is not intended as an eligibility condition *per se*, proposals recommended for funding that will feature a non-EU IKOP amount higher than the 30% of IKOP, will be requested to remove the exceeding part. If this case, this non-EU IKOP reduction exercise will need to comply with eligibility criteria whereby at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners.

² It has to be noted that, pursuant Article 119(4) of Council Regulation (EU) 2021/2085, at the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners. furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

Entities eligible for funding

In relation to the single-stage calls for proposals covered by this Work Programme, the relevant provisions of the General Annex B to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis*.

By way of derogation, in relation to the two-stage calls for proposals covered by this Work Programme, the following provisions shall apply:

- Legal entities identified in the topic text of the call for proposals shall not be eligible for funding from IHI JU. Nevertheless:
 - These entities will be entitled to provide contributions as IHI JU members other than Union or contributing partners.
- Legal entities participating in indirect actions selected under this type of calls for proposals shall not be eligible for funding where:
 - a. they are for-profit legal entities with an annual turnover of EUR 500 million or more;
 - b. they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);
 - c. they are directly or indirectly controlling a legal entity referred to in point (a).

In line with Article 5(2)(a) (additional conditions in duly justified cases) and Article 119(3) (private contributions to amount of at least 45 % of an indirect action's eligible costs and costs of its related additional activities) of the Council Regulation (EU) 2021/2085, under two-stage submission procedures, the following additional condition applies:

- The applicants which are IHI JU members other than the Union, or their constituent entities and affiliated entities, and contributing partners and that are pre-identified in the topics – under the section 'Industry consortium' – of a call for proposals shall not apply at the first stage of the call. The applicant consortium selected at the first stage shall, in preparation for the proposal submission at the second stage, merge with the pre-identified industry consortium.

In addition, in line with Articles 11 and 119(1) and (3) of the Council Regulation (EU) 2021/2085, legal entities providing in kind contributions as constituent entities or affiliated entities of IHI JU private members or as contributing partners that are:

- Not eligible for funding in two-stage calls for proposals; or
- Not established in a country generally eligible for funding in accordance with Part B of the General Annexes to the Horizon Europe Work Programme 2023 – 2024,

May exceptionally sign the grant agreement.

This is subject to the following conditions:

- Their participation is considered essential for implementing the action by the granting authority; and
- They participate without requesting any funding.

The essentiality of non-EU legal entities for implementing the action shall be ascertained by the granting authority.

List of countries and applicable rules for funding

With reference to Article 23 of the Council Regulation (EU) 2021/2085, the eligibility of participants in a proposal submitted to a call for proposals for any of the topics in this Work Programme will take into account any application of Art 22(5) of the Horizon Europe Regulation triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

Types of Action: specific provisions and funding rates

General Annex B ('Eligibility') to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

Technology Readiness Levels (Trl)³

TRL definitions included in General Annex B ('Eligibility') to Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

Evaluation rules

General Annex D ('Award Criteria') to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme with the following additions: The relevant calls for proposals launched under this Work Programme shall specify whether the call for proposals is a single-stage or two-stage call, and the predefined submission deadline.

Award criteria and scores:

Experts will evaluate the proposals on the basis of criteria of 'Excellence', 'Impact' and 'Quality and efficiency of the implementation' according to the type of action, as follows:

For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of proposals under both single-stage and two-stage submission procedures:

- the threshold for individual criteria will be 3;
- the overall threshold, applying to the sum of the three individual scores, will be 10;
- proposals that pass individual thresholds and the overall threshold will be considered for funding, within the limits of the available budget. Proposals that do not pass these thresholds will be rejected.

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. The highest ranked proposals, within the framework of the available budget, will be invited to prepare a Grant Agreement.

Under the two-stage evaluation procedure, and on the basis of the outcome of the first stage evaluation, the applicant consortium of the highest ranked short proposal (first stage) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (second stage).

³ The TRL is not utilised for IHI calls 4 and 5, however, it might be used in future IHI JU calls

If the first-ranked consortium and industry consortium decide that the preparation of a joint full proposal is not feasible, they must formally notify IHI JU within 30 days from the invitation to submit the stage 2 proposal. This notification must be accompanied by a joint report clearly stating the reasons why a stage 2 proposal is considered not feasible. In the absence of a joint notification within the deadline, it is deemed that the first ranked applicant consortium and the industry consortium are going to submit the joint stage 2 proposal. Accordingly, the second and third-ranked short proposals will be formally rejected.

If the preliminary discussions with the higher ranked proposal and the industry consortium fail, the applicant consortia of the second and third-ranked short proposals (stage 1) for each topic may be invited by IHI JU, in priority order, for preliminary discussions with the industry consortium. The decision to invite lower-ranked consortia to enter into discussions with the industry consortium will take into account the content of the report from the joint report from the first-ranked consortium and industry consortium.

Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first stage evaluation are communicated to the applicants.

As part of the panel deliberations, IHI JU may organise hearings with the applicants to:

1. clarify the proposals and help the panel establish their final assessment and scores, and/or
2. improve the experts' understanding of the information presented

In cases clearly identified in the relevant call for proposals where a given topic is composed of two or more sub-topics, one short proposal per sub-topic will be invited.

The IHI JU evaluation procedure is confidential.

The members of the applicant consortia shall avoid taking any actions that could jeopardise confidentiality.

Following each evaluation stage, applicants will receive an ESR evaluation summary report) regarding their proposal.

Indicative timetable for evaluation and grant agreement preparation

Information on the outcome of the evaluation (single-stage, or first stage of a two-stage):

- Single-stage: Maximum 5 months from the submission deadline at the single-stage.
- Two-stage: Maximum 5 months from the submission deadline at the first stage.

Information on the outcome of the evaluation (second stage of a two stage):

- Maximum 5 months from the submission deadline at the second stage.

Indicative date for the signing of grant agreement:

- Single-stage: Maximum 8 months from the submission deadline.
- Two-stage: Maximum 8 months from the submission deadline at the second stage.

General Annex G ('Legal and Financial setup of the Grant Agreements') to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

Budget flexibility

General Annex F to the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme.

Submission tool

Proposals in response to a topic of an IHI JU call for proposals must be submitted online, before the call deadline, by the coordinator via the Submission Service section of the relevant topic page available under Funding & Tender opportunities - Single Electronic Data Interchange Area (SEDIA). No other means of submission will be accepted.

Proposals including clinical studies⁴

Under the single-stage submission procedures and for stage 2 of the two-stage submission procedures: Applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system⁵.

Specific conditions on availability, accessibility and affordability (3a)

When the specific topic condition so requires, the following conditions shall apply:

- The participants must, during the lifetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly⁶ available and accessible, at fair and reasonable conditions.
- In particular, and always to the extent permitted by applicable competition law:
 - a. At the proposal stage⁷, and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.⁸
 - b. At the project interim review stage, if relevant⁹, the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be

⁴ Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

⁵ Template for providing essential information in proposals involving clinical studies - https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

⁶ This covers EU Member States and countries that are associated to Horizon Europe at the time of call opening.

⁷ As mentioned, for those 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage. Omission/inadequate treatment of 3A would be identified as a shortcoming. The content however, once considered adequate, will not be utilised for positive scoring and will not contribute towards any evaluation criteria.

⁸ Suggested components would be 1) Identification of planned clinical studies that might generate results for which the provisions are relevant; 2) Confirmation that the consortium members are aware of the provisions and will consider them accordingly. 3) Tentatively identifying markets/areas where the product/service could be made affordable, accessible, available. These points could be checked at the evaluation stage.

⁹ As discussed, this interim point allows a realistic appraisal of the 3A possibilities during the project lifetime, particularly as to the viability of specific expected 3A results.

conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.

- c. At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.¹⁰
- d. Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (totalling four years from project end), a confidential report¹¹ must be submitted to IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

JU right to object to transfer/exclusive licensing

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2023-2024 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

Country specific eligibility rules

Following the Horizon Europe Programme Guide, participation in IHI JU indirect actions will be open but eligibility for funding will be however limited to legal entities established in an EU Member State, Associated Country or Low and Middle Income Countries (please consult the list in the Horizon Europe Programme Guide¹²).

Given the invasion of Ukraine by Russia and the involvement of Belarus, legal entities established in Russia, Belarus or in any occupied territory of Ukraine are not eligible to participate in any capacity. Exceptions may be granted on a case-by-case basis for justified reasons, such as for humanitarian purposes, civil society support or people-to-people contacts.

¹⁰ Per the Model Grant Agreement ('MGA') Article 16, the beneficiaries must complete the Results Ownership List ('ROL') which identifies each result generated in the project and the owner thereof. The ROL should inform on the relevant results for which owners implement the 3A strategy in the PDECA for the four years following the project.

¹¹ Cognizant of IP sensitivities, confidential info, and commercial realities, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:
 - a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
 - b) Broad description of expected downstream actions (including product and service applications);
 - c) broad assessment of expected impact of the above downstream actions towards ensuring Affordability, Availability, and Accessibility.
2. **A Confidential Annex** in which:
 - a) The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:
 - i. The planned measures to be taken to effect the 3A obligations;
 - ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
 - iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

¹² https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

Topic 1: Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

Expected impacts to be achieved by this topic

The work supported under this topic seeks to pursue the aims of Directive 2010/63/EU¹³ on the protection of animals used for scientific purposes. It also contributes to the implementation of the 3Rs principles to “replace, reduce and refine the use of animals”, and ultimately helps progress towards no use of animals or animal-sourced materials in research, innovation and development, which is an expectation of society.

The following impacts are expected.

- Break down silos between technological areas and disciplines, and bring together different stakeholders (e.g. health industry, academia, small and medium-sized enterprises (SMEs), patients, regulators, non-governmental organisations (NGOs) and policy makers) to foster the use of new approach methodologies¹⁴ (NAMs) and other non-animal approaches in the efficient development, testing and production of safe and effective innovative health technologies¹⁵ (e.g. medicinal products, medical devices, biopharmaceuticals, vaccines, *in vitro* diagnostics) and their combinations.
- Improve public health as patients will benefit faster from safe and effective health technologies developed using NAMs and other non-animal approaches that, where relevant, provide more human-relevant data and are more predictive than current approaches.
- Foster the development of health policies and standards on the use of NAMs and other non-animal approaches in health technologies which will positively affect public health.
- Enhance the competitiveness of the European health industry that will benefit from high quality innovative approaches and methodologies for the development and production of new health technologies, which can reduce the time and costs of processes while significantly reducing the use of animals or animal-sourced biomaterials.
- Help to make the EU more sustainable/autonomous by achieving regulatory validation and uptake of NAMs and other non-animal approaches for the development, testing and production of health technologies that are not dependent on shortages/issues with animal supply.

Expected outcomes

- Research and innovation (R&I) actions (projects) to be supported under this topic must contribute to all the following outcomes.
- Researchers will benefit from the implementation of NAMs and other innovative non-animal approaches which have been assessed and validated for their performance and found to be relevant, reproducible, predictive, and standardised, ultimately leading, as relevant, to their regulatory acceptance for use in infectious and/or non-communicable disease applications. The new approaches should lead to an improvement in the assessment of health technologies (and animal to human translation where relevant) and/or production processes, and to a significant reduction in the number

¹³ DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33) <https://eur-lex.europa.eu/eli/dir/2010/63/2019-06-26>.

¹⁴ New approach methodologies, as defined in <https://www.frontiersin.org/articles/10.3389/ftox.2022.964553/full>

¹⁵ Health technology, as defined in the [IHI Strategic Research and Innovation Agenda](#), means a medicinal product, a medical device, or medical and surgical procedures, as well as measures for disease prevention, diagnosis or treatment used in healthcare.

of animals used. In addition, these approaches may answer questions that current methods cannot, and improve the predictability and robustness of evidence generated for regulatory decision-making.

- European industry will benefit from the establishment and availability of NAMs and other innovative non-animal approaches for the testing, development and/or production of health technologies that are fit-for-purpose to support regulatory decision making.
- Researchers and developers of innovative healthcare solutions will have access to high-quality data, new recommendations and best practices to incentivise the use of NAMs and other non-animal approaches and their integration in industrial processes. This should be supported by an appropriate digital repository to ensure both the sustainability and scalability of the knowledge base.
- Regulators and policy makers will gain knowledge and have access to high-quality data on the characteristics and use of NAMs and other innovative non-animal approaches in the production and development of health technologies to foster the development of harmonised guidance and requirements, as well as uptake or translation into health policies.

Scope

Animals and animal-derived materials are widely used in biomedical research and in the production and development of health technologies. This raises serious ethical concerns, and there is growing societal pressure to move towards alternative approaches and methods. Besides major ethical concerns, there is also scientific evidence that supports moving away from animal-based approaches and finding more human-relevant methods and strategies for both the assessment of safety and efficacy of new health technologies and for manufacturing. Animal testing requires time-consuming protocols, high costs for animal supply, and the results are not always reproducible and applicable to humans. In addition, for the development and production of health technologies (e.g. *in vitro* diagnostics) as well as in biomedical research in general, materials of animal origin are required (e.g. biomolecules, sera). These animal-derived products require large amounts of animals for their production. Therefore, also in this context, there is a need to foster progress towards new alternatives (e.g. synthetic matrix, recombinant proteins, optimisation of production processes via artificial intelligence) to reduce the overall number of animals that are bred for these purposes.

NAMs and other innovative non-animal approaches have high potential to improve the development and/or production of health technologies, while contributing to the reduction and replacement of the use of animals. Recent improved biological knowledge, technological advances, computer simulations and innovative non-animal approaches and methods (e.g. organoids, complex 3D cell models, microphysiological systems¹⁶, *in silico* models, non-animal derived antibodies and other biomolecules¹⁷) provide the opportunity to move forward with safer and more effective tools for protecting human health and preventing/treating diseases that would in parallel entail an improvement of animal to human translation or better production processes, as well as helping progress towards the replacement of animals used in biomedical research in general.

¹⁶ [Microphysiological Systems: Stakeholder Challenges to Adoption in Drug Development - PMC \(nih.gov\)](#)

¹⁷ [EURL ECVAM Recommendation on Non-Animal-Derived Antibodies](#)

While the potential for using non-animal approaches for the production, development and testing of new health technologies is enormous, more evidence and high-quality data for their performance evaluation in comparison with established animal-based approaches for a specific application (such as a production process, primary pharmacology, or next-generation-risk-assessment – NGRA) and for their validation are required by the industry and regulators to implement these alternative approaches in R&D and decision-making processes. In addition, policy makers require a large body of up-to-date, high-quality knowledge to inform relevant health policies and ensure the long-term goal of full transition to non-animal approaches.

The current topic seeks to address these challenges by exploiting the latest relevant scientific advancements to develop NAMs and other non-animal approaches, which could be more readily available and more efficient than those involving animals, and which should improve either the development, including efficacy and safety assessment, of new health technologies for infectious/non-communicable diseases or the production processes of such technologies.

The projects funded under this topic should aim to do the following.

- Develop new NAM/s or other non-animal approach/es (or a combination of those) or use existing ones in an innovative way to improve (early-stage) assessment of new health technologies (and animal to human translation where relevant), or to improve the production processes of health technologies (such as bio/pharmaceuticals, vaccines, medical devices including *in vitro* diagnostics, and radio-chemicals).
- Specify the context of use (e.g. primary pharmacology, toxicology, safety, quality control, production processes) of the novel approach/es, how it/they can be integrated efficiently in the relevant workflows and propose and implement a plan to carry out their performance evaluation and validation, as well as demonstrate their added value in comparison to relevant established animal-based approaches.
- Make a comparative evaluation of the different approaches to replace, reduce and refine animal use, including the identification and assessment of parameters that influence their usefulness such as their reliability, reproducibility, robustness and fitness for purpose.
- Generate evidence on the robustness, reliability, and applicability of these novel approaches in an industrial research and development (R&D) context and to support regulatory decision making in testing, development or production of health technologies, as relevant. Accordingly, applicants should develop a strategy/plan for generating appropriate evidence to support regulatory acceptance and engage with regulators in a timely manner (e.g. through the European Medicines Agency [EMA] Innovation Task Force or qualification advice).
- Gather and produce high quality datasets to generate a solid knowledge base for supporting the use of NAMs and other non-animal approaches in the field of health technology and drive 3Rs implementation. To ensure the sustainability of the results and foster future development and validation of innovative non-animal approaches, applicants should develop a fit-for-purpose scalable digital data repository. Applicants should consider and leverage as much as possible existing infrastructures.
- Establish a collaboration platform between all relevant stakeholders from public and private sides, including regulatory agencies and policy makers, to exchange information, prepare white papers and guidelines to foster uptake or translation into health policies, supporting an adequately reflected transition to full implementation of non-animal approaches in health technology development and manufacturing. Patients and/or patient organisations may be included and actively contribute to such activities by providing, for example, their insight on the use of human-derived samples, as relevant.

- Accelerate the broad implementation of the NAMs and other non-animal approaches in research through a strong communication and dissemination plan, fostering also exchanges and cross fertilisation with other projects funded in this area.

Projects funded under this topic are expected to contribute to relevant EU health policy initiatives such as the new Industrial Strategy for Europe, the European Health Emergency and Response Authority (HERA) and the EC proposal on the European Health Data Space (EHDS).

Furthermore, applicants are expected to explore and/or implement synergies¹⁸ and complementarities with relevant initiatives/projects, at national, European and international level. They should also consider, as relevant, the activities of the 3Rs Working Party of EMA¹⁹.

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

Animals and animal-derived materials are widely used by several industry sectors (pharmaceutical, medical devices, *in vitro* diagnostics, vaccines), academia, as well as SMEs for their R&D or manufacturing activities. There is a need to move towards alternatives and accelerate the development and use of NAMs and other non-animal approaches in health technologies.

The exchange of data, expertise and knowledge is currently limited, for example, between the chemical and the pharmaceutical sectors concerning toxicological testing or between different areas of basic and applied research. Therefore, there is a need to generate, compile and share data and knowledge, as well as expertise, across biomedical and health technology sectors.

This topic requires cross-sectorial multidisciplinary private-public partnerships to help address the scientific challenges and accelerate the development and use of effective NAMs and other non-animal approaches in the testing, development, and production of health technologies.

The involvement of patients, regulators and policy makers is also needed to guide and advise on regulatory acceptance criteria, foster acceptance, and to facilitate their uptake or translation into health policies.

Indicative budget

Applicant consortia will be competing for a maximum financial contribution from IHI up to EUR 30 000 000.

IHI estimates that an IHI financial contribution of between EUR 12 000 000 and EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45 % of the action's eligible costs and costs for action-related additional activities are provided by contributions [In-kind contributions to operational activities (IKOP), financial contribution (FC), in-kind contributions to additional activities (IKAA)] from private members and / or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA. Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities. See call conditions for further information.

¹⁸ Examples of synergies at European level (not exhaustive list): [RISK-HUNT3R RISK](#), [Precision Tox](#), [ONTOX](#), projects that will be generated from [HORIZON-HLTH-2024-TOOL-05-06-two-stage topic](#), [HORIZON-HLTH-2024-IND-06-09](#)

¹⁹ [3Rs Working Party \(3RsWP\) plenary meeting - Public session on the 2023 work plan](#)

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

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

Topic 2: Development and proof of principle of new clinical applications of theranostics solutions

Expected impacts to be achieved by this topic

- Improved availability of effective treatments for patients based on multi-modal theranostic²⁰ solutions.
- Stronger resilience and improved strategic autonomy of Europe's health systems, for example, by implementing new manufacturing capabilities for medical radioisotopes and radiopharmaceuticals (in accordance with the EU SAMIRA²¹ action plan).
- Depending on the disease area of the application, contributing to the objectives of Europe's Beating Cancer Plan and the Horizon Europe Mission on Cancer.

Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must contribute to at least three of the following outcomes:

- Patients will benefit from increased treatment efficacy, reduction of time-to-treat, fewer side effects, and reduced duration of hospitalisation.
- Healthcare professionals benefit from education, training on theranostic treatment approaches, recommendations, and clinical guidelines on the most appropriate use of theranostic solutions.
- European healthcare systems benefit from a broader spectrum of theranostic treatments and improved cost-effectiveness and affordability of theranostic solutions due to scale effects and more robust European supply chains.
- Technology developers, healthcare professionals and patients benefit from increased information on the sensitivity, quantification, stratification and staging of diseases.

Scope

Multi-modal theranostic solutions, currently dominated by radionuclide-based therapy and companion diagnostics, are emerging as safe, personalised, and effective approaches for the treatment of several diseases. However, the use of such therapies is limited to a few specialised centres with the need to increase clinical treatment capacities, and to widen the arsenal of theranostics, possibly including novel non-nuclear approaches, e.g. enabled by nanotechnologies.

To address this challenge, project(s) funded under this topic should aim at developing new, or innovative combinations of existing multi-modal theranostic solutions including radiopharmaceuticals and/or non-radioactive theranostic solutions. Applicants should clearly identify a disease(s) of unmet public health need, (e.g., oncology, neurology and/or advanced multi-disease conditions) and explain their choice with relevant evidence where possible.

²⁰ Theranostics refers to the pairing of diagnostic biomarkers with therapeutic agents that share a specific target in diseased cells or tissues.

²¹ The [SAMIRA action plan](#) is the EU's first comprehensive plan for action to support a safe, high quality and reliable use of radiological and nuclear technology in healthcare.

In particular, for the selected disease(s), the project(s) funded under this topic are expected to address all the following objectives:

- develop innovative theranostic solutions and consider conducting early phase clinical trial(s) as proof of concept(s) to demonstrate the added value of the proposed theranostic solutions for patients;
- develop tools for the quantification of the chosen disease(s) through the development of novel modalities to ensure proper planning and monitoring of patient care, which may include imaging, artificial intelligence and pathology models;
- facilitate the development of tools to increase European theranostic manufacturing capabilities and treatment capacities, including guidance on quality assurance and improving logistics of supply at the EU level;
- develop education and training materials on the deployment of multi-modal theranostic solutions and their integration in clinical settings including recommendations for the organisation and composition of disease-specific medical expert boards.

In addition, applicants are expected to consider the potential regulatory impact of the results and if relevant develop a strategy/plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification/scientific advice).

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

Theranostic solutions require a highly multidisciplinary team of specialists for their clinical application and integration in a patient treatment workflow. Furthermore, the production of theranostic pharmaceuticals, based on radionuclides or nanomedicine products, involves and requires specialised knowledge and expertise. Therefore, a cross-sectorial collaboration is necessary for clinical deployment of theranostic solutions between academia, healthcare professionals as well as the health industry sectors which for instance contribute with the production of diagnostic and therapeutic agents and the development of imaging technologies. It is recommended to include regulators in all steps during development and related planning.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 12 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by in-kind contributions to operational activities (IKOP), financial contributions (FC), or in-kind contributions to additional activities (IKAA) from private members and/or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA. See call conditions for further information.

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

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' apply.

Topic 3: Improved prediction, detection, and treatment approaches for comprehensive stroke management

Expected impacts to be achieved by this topic

- Patients will be offered accelerated access to the healthcare system through improved and holistic management of stroke including prevention, diagnosis, treatment, and rehabilitation that will lead to better outcomes for their health.
- Development of advanced visualisation approaches, connected artificial intelligence (AI)-based devices and modelling-based systems supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.
- Medical technology, pharmaceutical and biotechnology companies develop and offer integrated, advanced solutions for prevention, diagnosis, and treatment of stroke. This will facilitate coordinated decision-making by the different healthcare professionals involved in the stroke care pathway.
- Better implementation and scale up of existing treatments that have proven to be effective, ensuring wide coverage of the right treatment options for patients at the right time; also avoiding disparities in countries and regions.
- Contribute to the EC proposal for an 'European Health Data Space' (EHDS) by promoting better exchange of, and access to, different types of health data and data generated by health technologies.

Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic must aim to deliver results that contribute to all the following expected outcomes.

- Patients will benefit from superior healthcare compared to the current standard of care through the availability of a clear pathway for prevention, diagnosis, and treatment of their stroke. This should be achieved by early and rapid diagnosis of stroke, more integrated and precise interventions, and treatment strategies with the patient in the centre.
- Healthcare professionals will have access to integrated patients' health data, improved visualisation, predictive computational models and clinical support decision systems for stroke, and benefit from efficient coordination among and within stages of care and clinical specialities.
- Healthcare systems will benefit from more effective organisation of stroke management and personalisation of care delivery. This will increase treatment and care effectiveness and efficiency.
- Researchers will benefit from access to integrated data, innovative modelling-based tools, and a more patient-centred definition of clinical outcomes after stroke (including patient reported outcome measurement and patient reported experience measurement), which will facilitate the continued improvement and development of future intervention strategies.
- Health care systems, researchers, and industry will benefit from new innovative modelling tools enabling integration and analysis of a wider, actionable range of patient-specific data, including federated analysis of data.

Scope

Globally, stroke is the second leading cause of death and the third leading cause of disability. One in four people are in danger of stroke in their lifetime²².

In Europe in 2017, nearly 1.5 million people suffered a stroke, nine million Europeans lived with a stroke, and more than 430,000 people died due to a stroke. The total cost of stroke in that year was €60 billion. The number of new strokes and the number of people living with stroke is set to rise due to the ageing population of Europe, as age is the greatest, non-modifiable risk factor for stroke²³.

Stroke is a heterogeneous, multifactorial disease regulated by non-modifiable (e.g., age, sex, family history) and modifiable risk factors (e.g., high density lipid-cholesterol, low density lipid-cholesterol, cigarette smoking) and underlying pathologies (such as diabetes, hypertension, atrial fibrillation) and as such, it requires a multi-factorial approach²⁴. However, stroke is a preventable, treatable, and manageable disease and thus the potential to reduce its burden and its long-term consequences exists²⁵.

The challenge in stroke management is the lack of efficient and comprehensive pathways along the whole continuum of the disease – including the variation of structural settings depending on the location of the patient (rural vs. central) and between countries. While several effective treatment approaches are available, there are still silos existing between the different stages of care (e.g., primary, acute care, intensive care, chronic hospitalisation, rehabilitation). The implementation of connected healthcare pathways will lead to an improvement in the outcome for the patients and thereby drive efficiency and effectiveness from a clinical and health resource perspective.

Better communication, sharing and integration of data along the whole stroke care pathway has the potential to be a game changer for stroke patients and for the healthcare professionals as well as payers.

Integrating data is key to allow for modelling, artificial intelligence (AI) and machine learning (ML)-based evaluation to identify groups and individual persons at risk and assure early recognition of stroke, thereby providing faster diagnosis and optimal, patient-specific treatment, resulting in better outcomes for patients. Effective, personalised and rapid care is critical and can make a substantial difference between full recovery and possible permanent impairment or death.

Moreover, comprehensive stroke management continues in the post-acute treatment setting and includes long-term follow-up for secondary prevention and rehabilitation. This is important, as a high percentage of patients are readmitted to the hospital or suffer a second stroke. More than a quarter of patients do not adhere to medication and/or have their blood pressure controlled. Patients frequently report that post-stroke follow up is impaired by siloed data between their generalist and specialist care.

Innovative solutions for faster acquisition, integration, and better retention of multiple types of data and better organisation among the various actors across the entire stroke pathway are crucial to achieve optimal prevention and treatment focused on the needs of patients. Use of novel technologies for federated data analytics and interpretation could help in this direction and assist in providing the right treatment to patients in a timely manner, improving their outcomes.

Applicants to this topic should address all the aims below in their proposals.

²² Feigin VL et al. World Stroke Organisation (WSO): Global Stroke Fact Sheet 2022. *International Journal of Stroke*, 2022;17(1):18–29.

²³ The Economic Impact of Stroke – SAFE (Stroke Alliance Sor Europe) https://www.safestroke.eu/wp-content/uploads/2020/10/03.-At_What_Cost_EIOS_Full_Report.pdf

²⁴ Goldstein LB et al. Primary Prevention of Ischemic Stroke. *Stroke*, 2006;37:1583-1633.

²⁵ Norrving B et al. Action Plan for Stroke in Europe 2018-2030. *European Stroke Journal*, 2018;3(4):309-336.

- Develop approaches to integrate patient-relevant health data, from primary care / outpatient clinic, hospital, and rehabilitation settings, as relevant, improving data retention along the care pathway. Applicants could consider starting with a focus on patients at higher risk with the possibility to expand to other patients.
- Develop a next generation of systems that promote interoperability of data from different settings (including intensive and acute care units) and support better clinical decision making. Strategic approaches for integration with the EHDS and community-based, collaborative integrated care should be considered.
- Create solutions to foster better access to data for all involved healthcare professionals (primary care, hospital care and after hospital release e.g., rehabilitation) and support exchange of knowledge and information between the different actors – including at the level of algorithms and datasets that can be exchanged under ethically and legally sound conditions.
- Develop innovative tools and approaches, for example ‘virtual human twin’ model approaches and AI/ML for enhanced computational modelling, optimised for transparency to users and non-users, federated data analytics, and visualisation for enhanced output/results view and interpretation. These tools aim at appropriate risk stratification, timely prediction of stroke and stroke recurrence, faster diagnosis, and treatment.
- Propose innovative approaches to improve and expedite diagnostic and treatment decisions for streamlining operations and guiding patients in the continuum of stroke care in a patient-centric way. This should include consideration of the complexity of the organisational dimension.
- Propose approaches to improve implementation and scale-up of treatment in Europe relying on multimodal clinical data capture and their better interpretation and use in patient management and clinical decision-making. This should include consideration of the regional differences in stroke management and access to treatment options across Europe.
- Propose approaches to enhance precision of care delivery as well as improving patient experience and quality of life using new technologies, tools, and educational means (e.g., education on identification of risk factors, signs of stroke, treatment adherence).

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

This topic requires cross-sectorial collaboration, including contributions from all the different healthcare professionals, health data specialists, patients and their care network, academia, as well as the different industry sectors, including medical technology (e.g., focusing on connected care and medical devices) and pharma sector (providing pharmaceutical interventions for stroke). Such a cross-sectional public-private partnership is needed to break the silos in care, bring the necessary diverse expertise together and combine different types of resources to address the challenge of delivering an efficient and comprehensive stroke management focused on patients’ needs.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and 13 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by contributions [In-kind contributions to operational activities (IKOP), financial contributions (FC), in-kind contributions to additional activities (IKAA)] from private members and/or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA (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.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply.

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 generation methodologies and/or datasets facilitating research and development of integrated products and services that will 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; and 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 of the following expected outcomes:

- academic and industrial researchers should have access to relevant, robust, and generalisable synthetic data generation methodologies, including open source when relevant, to create and share pools of synthetic patient data in specific use cases;
- academic and industrial researchers should have access to relevant, high quality synthetic datasets;
- thanks to better availability of robust synthetic datasets for training data models, healthcare providers and industry should have a wider range of performant AI-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. Furthermore, it is still unclear whether highly detailed synthetic data, which are often needed for research, can be categorised as anonymous.

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, complement work that is already ongoing, 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: a) fully synthetic datasets that do not contain any real data; b) hybrid datasets composed of a combination of data derived from both real and synthetic data; and c) 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. This should include assessing the risk of re-identification;
- 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 EC proposal for an European Health Data Space (EHDS)²⁶ 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.

IHI estimates that an IHI financial contribution of around EUR 10 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by in-kind contributions to operational activities (IKOP), financial contributions (FC), or in-kind contributions to additional activities (IKAA) from private members and/or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA. See call conditions for further information.

²⁶ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

Indicative duration of the actions

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

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.