

IHI JU Science & Innovation Panel (SIP) 4th Report to the IHI JU Governing Board

4th MEETING OF THE SIP
18/10/2022 (09:00 – 13:15 CEST) – Hybrid meeting

This report summarizes the SIP opinions related to:

- Preparing the Second amended Work Programme 2022, including the proposed topics for the IHI JU Call 3 (single stage)
- Preparing the Work Programme 2023, including the proposed Scientific Priorities for 2023 and topics for the IHI JU Call 4 (two-stage)
- Collecting ideas submitted to the SIP

* * * * *

Preparing the Second amended Work Programme 2022, including the proposed topics for the IHI JU Call 3 (single stage)

Overall, the SIP noted that comments made on the draft calls were well taken into consideration by the IHI office and that topic texts have been revised to reflect the comments made at the previous meeting. The latest revised versions of the five topics of Call 3 were shared with the SIP members and were further discussed and commented as follows:

1.1. Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

The SIP members highlighted again the importance of using very precise wording regarding biomarkers (e.g., single, combined, digital). The IHI office welcomed the remark and invited the SIP members to make any additional suggestions if still necessary.

1.2. Patient generated evidence to improve outcomes, support decision making, and accelerate innovation

The SIP welcomed the topic as it is and in particular the fact that it has a focus on clinical expertise and patients.

1.3. Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiencies

The SIP commented on the need to include innovative interventions and that outcomes are sought to document improved efficiency of such innovations. It was noted that the draft topic refers to high-end technologies (AI etc.). However, even when interventions are supported by favorable research results and cost effectiveness, their sustained implementation in hospital settings encounters a range of hurdles. The draft topic may thus more concretely seek to address the hurdles and necessary steps to realize the potential efficiencies and hospital resource benefits. In addition to staffing, efficiencies and implantation, sustainability should also be addressed as an outcome.

1.4. Strengthening the European ecosystem for Advanced Therapy Medicinal Products (ATMPs) and other innovative therapeutic modalities for rare diseases

Beyond the regulatory pathways that are already mentioned in the draft topic text, the SIP members discussed including in the scope pricing and reimbursement, in particular in light with the upcoming HTA regulation. In addition, to the issue of access and availability (i.e. national disparities across EU), the topic should clearly address additional dimensions such as ways to ensure appropriate governance and post-marketing surveillance.

1.5. Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

No comments were made by the SIP regarding this topic.

Preparing the Work Programme 2023, including the proposed Scientific Priorities for 2023 and topics for the IHI JU Call 4 (two-stage)

2.1. Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical drug safety assessment

The SRG members mentioned that The Netherlands might legislate to move away from, or even ban animal testing altogether, which could constitute a limitation for EU research and competitiveness vs US. The topic should more clearly reflect the overall 3R context and aims, in particular by rewording its title, which is currently too narrow as such.

2.2. Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare

The SIP welcomed the topic text and didn't make any further comments.

Collecting ideas submitted to the SIP

3.1. Defining the temporal responsiveness of the gut microbiome to major diet and lifestyle interventions

The idea is interesting but the topic is complex in terms of science with many confounders and parameters, so that a large-scale approach is needed (3000 persons would not even be enough due to variability). “Moreover, the idea is not focused, does not include clear elements of innovation and how it differentiates from previous projects.”. The chair will circulate the template to document formally the SIP opinion. At this stage, and in the current form of the submitted idea, the opinion would not be favorable.

3.2. Improved care pathways in Parkinson’s disease through digital technologies

It is unclear if the idea includes involving the wider research community. If not, such involvement should be considered. The idea is addressing a specific subgroup of patients with Parkinson disease, which is considered too narrow. Other subgroups of Parkinson disease patients as well as other neurodegenerative diseases should be included. The clinical evaluation and the demonstration of effectiveness should also be part of any potential future topic arising from the idea. Any overlap with IHI’s call 1 should be checked. The chair will circulate the template to document formally the SIP opinion. At this stage, and in the current stage of development of the submitted idea, the opinion would not yet be favorable.

3.3. Reconciling the technical and legal requirements of the European Health Data Space

The SRG members reported a similar topic coming up in the 2023 work programme (CSA in Digital Europe and a EU4Health topic). Legislation concerning the EHDS is not yet adopted and therefore the idea is considered premature. However, data-related issues are already encountered in daily life, including national legal disparities, where perspectives of citizens and patients may be conflicting. In addition, an idea in this area and any future calls should include R&I, as a pre-competitive starting point and not just implementation. Moreover, the creation of cryptographic methods has already been funded under H2020. The chair will circulate the template to document formally the SIP opinion. At this stage, the currently formulated idea is not yet mature for obtaining a favorable opinion from the SIP.

Based on the discussion about these three ideas, it appears that the template used for conveying the Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics, would need to be revised. In fact, the SIP members are not comfortable with the idea to formulate an unfavorable opinion. It would be worthwhile amending the template in order to reflect the fact that an idea as formulated is not yet mature for obtaining a favorable opinion from the SIP.