IHI JU Science & Innovation Panel (SIP)

1st Report to the IHI JU Governing Board

CONSTITUTIVE MEETING OF THE SIP

The first meeting of the SIP took place on March 31 and 1st of April 2022.

This short report summarizes the SIP opinions related to the following items addressed during the first meeting:

- The IHI JU Strategic Research and Innovation Agenda (SRIA)
- The Draft Scientific Priorities for 2022
- The collecting of Ideas/Topics for the first IHI calls

IHI JU Strategic Research and Innovation Agenda (SRIA)

While the SIP positively welcomed the SRIA general objectives, it stressed the importance of ***addressing end-user approaches and clear pathways for implementation***, specifically in relation to the IHI pre-competitive spirit aiming to engage all industries. It would be key to identify projects that could generate the necessary impact. As pointed out by one of the SIP members, implementation and delivery are very important and under researched steps of the innovation and translation cycle.

Draft Scientific Priorities for 2022

The SIP welcomed positively the draft Scientific Priorities for 2022. In addition, the SIP made a series of suggestions that were reflected in the draft amended Work Programme (WP). These suggestions were mainly aimed at adding clarity on the ***concept of unmet public health need*** (vs unmet medical need) and on articulating how the precompetitive objectives of IHI would address ***tangible impacts of IHI-generated innovations on patients and society***.

The SIP stressed the importance of considering the following elements when drafting topic texts:

- developing effective ***measures of translation of healthcare innovations*** (impact)
- ***sustainability*** measures and plans for the IHI funded projects (“plant the seeds to sustain outcomes”), based on learnings from IMI
- ***synergies with other EU funded initiatives*** and projects to avoid overlaps (EC and MSs)

- ***broaden the perspective of the 3As*** (affordability, accessibility and availability) to a 4th A (availability of healthcare staff [1]) when considering cost-effectiveness and sustainability of healthcare
- envisage ***other areas of high unmet public health need***: mental health, neurodevelopmental disorders, drug repurposing, prevention (coupled with performance and eventually payment) and include countries with the less resources

Collecting Ideas/Topics for the first IHI calls

The SIP made comments related to the need of clarification on the scope of topics' objectives [2] and regarding some wording and formulations in the proposed topics. These suggestions have been detailed for each topic in the formal consultation of the draft amended Work Programme 2022.

Consultation on the draft Amended work Programme 2022

The section below provides a summary of the SIP feedback on the topics proposed for the draft amended Work Programme 2022.

CALL 1 – single-stage

Topic 1: An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities

The proposed topic should explicitly ***include implementation into routine care and sustainability of the innovations***, even if the focus of a proposal is on the early stages of development. ***Context data would need to be included into the dataset informing decisions***, for example on the socioeconomic environment as well as professional and informal caregivers.

Topic 2: Next generation imaging and image-guided diagnosis and therapy for cancer

Validation and performance evaluation frameworks and benchmarks should be clearly considered as well as elements of ***trustworthy and explainable*** AI/ML-enabled image guided diagnosis and therapy, including ***combination with other sources of data*** such as EHRs.

Topic 3: Precision oncology: Innovative people centred, multi-modal therapies against cancer

The text topic should emphasize the fact that multimodal therapies can also benefit from ***bringing in new technologies and combinations of innovative diagnostic tools and drug screening tools***.

[1] The shortage of healthcare staff and its impact on healthcare systems increased since the COVID-19 pandemic
[2] For instance, for the topic "Next generation imaging and image-guided diagnosis and therapy for cancer", it seems very ambitious to combine diagnosis and treatment (focus issue?)

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

The inclusion and involvement of ***patient advocates*** is extremely important, in particular regarding ***questions on data ownership and sharing***, as well as the related legal implications.

CALL 2 – two-stage

Topic 1: Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring

The impact or outcomes of the topic could be enhanced by considering ***psychological and behavioral factors***, as well as emphasizing the ***role of wearables and proper validated AI/ML prediction models***.

The topic should be open to addressing the pathophysiology and consequences of ***COVID-19 or other emerging infectious diseases*** on the cardiovascular system.

Topic 2: Setting a harmonised methodology to promote uptake of Early Feasibility Studies for clinical and innovation excellence in the European Union

EFS should aim to inform a proper ***assessment of the (cost-) effectiveness*** of medical devices as well as subsequent ***stage 3 (comparative) studies***.

Clearly address the type and nature of the harmonised methodology that needs to be developed for EFS and clarify ***which regulatory (i.e. interplay between AI and MD regulations), ethical and technical aspects are to be developed***.

Besides other existing regulatory frameworks, and in order to avoid risk of duplication of funding of already applied methodologies on EFS, the ***proposed duration of projects on EFS may be too long*** in comparison to what is developed in other jurisdictions[3].

[3] e.g. FDA guidance on Early Feasibility Medical Device Clinical Studies, FDA Early Feasibility Studies (EFS) Program