IHI JU Science & Innovation Panel (SIP)

3rd Report to the IHI JU Governing Board

3rd MEETING OF THE SIP

13/09/2022 (15:00 – 18:00 CEST) & 14/09/2022 (09:00 – 17:30 CEST)

IHI premises – 56, Av. de la Toison d'Or – 1060 Brussels

This report summarizes the SIP opinions related to:

- Feedback following the ideas collected & first lessons learnt (including update of the template for the SIP outcomes on ideas)
- Preparing IHI Calls 3 and 4, based on early draft ideas/ topic texts
- Preparing the Scientific priorities for 2023

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Feedback following the ideas collected & first lessons learnt (including update of the template for the SIP outcomes on ideas)

The SIP welcomed the presentation by the IHI office of the process for collecting ideas for identifying potential IHI topics, as well as the minor adjustments made to the template for the SIP outcomes on ideas.

The SIP endorsed the current version of the template to be used for submitting ideas and suggested to adapt it based on experience and future needs.

Among the submitted ideas, two passed the quality and completeness check of the IHI office and were transferred to the SIP prior to the meeting. The comments of the SIP are summarized below:

1. TI_001160: Defining the temporal responsiveness of the gut microbiome to major diet and lifestyle interventions (non-communicable diseases, health technology, cardiovascular diseases, metabolic diseases, neurodegenerative diseases, mental health, digital health, prevention)
   The SIP members find the presented idea very interesting. However, it is quite broad (i.e. which outcomes are targeted) and the challenges addressed are unclear (i.e. perspectives for interventions). An additional challenge of the topic is the alignment and interest of different stakeholders (i.e. securing in kind contribution of industry).

2. TI 001164: Improved care pathways in Parkinson's disease through digital technologies (neurodegenerative diseases, non-communicable diseases, prediction, diagnosis, disease management, digital health, health technology)
   The SIP members find the idea's focus on speech recognition too limited in scope and not clearly linked with expected patient outcomes (i.e., might benefit from including patient specificities, such as gender).
   The SIP questions the innovative dimension of the idea in relation with existing tools for automated speech recognition and recommends broadening the idea to other technological approaches, which might be applied to other neurodegenerative diseases, while focusing on outcomes and patient benefits.

Preparing IHI Calls 3 and 4, based on early draft ideas / topic texts

Twelve early draft ideas were presented to the SIP as grouped in seven thematic clusters (Clinical Studies, Digital interventions, HERA –Preparedness –Infectious diseases, Biomarkers and personalised medicine, Rare Diseases, Green, 3Rs). Nine ideas were aiming at single stage calls, whereas three ideas were for two stage calls. The SIP comments are summarized as follows:

1. Inclusive clinical research through increased recruitment and retention of diverse study populations (one stage idea/topic)
   The SIP's opinion on the idea is overall positive. However, a few challenges were identified that would need to be addressed: i.e. how different strategies for inclusiveness can serve different purposes and phases of studies; how to address recruitment and diversity in inclusion; how to manage cross-sectoral approach; sustainability and making trials more part of patient care; addressing challenges related to cultural and national legal frameworks; importance of network capacity building to improve recruitment and retention while keeping access to clinical trials and studies in EU.

2. Patient-centric blood sample collection to enable decentralised clinical trials (DCTs) and improve access to healthcare (two-stage idea/topic)
   The SIP's overall opinion of the idea is positive as it aims to address the needs of patients as well as various other stakeholders. However, it would be important to include patient populations with low literacy and elderly. Moreover, although enabling DCTs is important, validation should not only be done for clinical trials but also for routine health care. Finally, it would be valuable to include validation for countries with large distances or less developed logistic infrastructures.

3. Remote intervention technology (RIT) for prevention, monitoring and personalised treatment of mental disorders and their long-term health consequences (one-stage idea/topic)
   The SIP acknowledges the importance of the topic and the proposed idea to generate evidence in the field. However, some concerns were risen that might require further reflection. Indeed, the area of mental health is very broad and the potential impact on patient outcome would be a significant challenge. Many locally/nationally funded clinical trials in this field are currently ongoing. An IHI topic or proposals therein need to demonstrate a clear added value to these clinical trials of eHealth applications for mental disorders. Additional challenges are related to HTA of digital interventions, which may suffer from insufficient supporting evidence, as well as

the potential low interaction with healthcare professionals versus embedding RIT (i.e. the ethical and social innovation dimensions are also questioned in light of the vulnerability of patients suffering from mental disorders).

4. Accelerator for the discovery and early development of long acting injectables [monoclonal antibodies and small therapeutic molecules] against Infectious Diseases with AMR and/or pandemic potential (two-stage idea/topic)
   The SIP recommends to rationalize – based on differentiation vs other initiatives - the positioning of this idea within IHI vs. other funding schemes. In addition, in order to demonstrate more clearly the pertinence of the approach, the idea should also be aiming for a more cross-sectorial approach.

5. Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need (one-stage idea/topic)
   The SIP welcomes very positively this idea and supports the extension to non-communicable diseases. Some comments were made in relation with the need to include digital biomarkers, to address interoperability issues and on how to leverage synergies (i.e., digital twin projects). Prevention and considering matching companion drugs to increase impact on care as well as regulatory involvement and sustainability were also commented.
   Concerning several clusters and in particular biomarker ideas, the SIP made reference to the IMI SC recommendation for involvement with regulators and regulatory science, and to include in 'expected outcomes: regulatory interactions e.g., scientific advice and, in particular for biomarkers, qualification advice and whenever possible qualification opinion as novel methodology.

6. Clinical validation of biomarkers for disease state, progression, and treatment response (one-stage idea/topic)
   The SIP sees this idea as very broad and would advise focusing on specific diseases or disease areas, as well as specifying if single biomarkers or combination of multiple markers will be considered. Some definitions might be necessary as well, in particular when considering regulatory interactions (i.e. consider PROBAST and TRIPOD).

7. Patient input and patient generated evidence to improve patient outcomes, support decision making, and accelerate innovation (one-stage idea/topic)
   The SIP considers the topic and the multi-stakeholder approach of the idea as very important. However, the SIP recommends providing a clearer articulation of complementarity and differentiation with other initiatives as well as better defining which gaps would be addressed (i.e. disease specific versus general) and how to build on existing projects.

8. Improve quality of medical interventions for patients and increase associated hospital efficiencies by combining innovative interventional approaches and clinical decision support systems (one-stage idea/topic)

The SIP finds the idea important and supports considering shortage of staff, assessing the impact on hospital efficiency, aiming at efficiency gains of innovative procedures, and evaluating innovative ways of delivering care.

9. Strengthening the European ecosystem of technological centres of excellence for Advanced Therapy Medicinal Products (ATMPs) and innovative therapeutic modalities for rare diseases (one-stage idea/topic)
   The SIP reflected on the centers of excellence (focus on addressing new technologies) as being complementary to ERNs (focus on clinical aspects). Moreover, the SIP noted that there is a need to ensure a clear distinction between the described expected outcomes and impact and to consider the influence of national specificities and of hospital exemption for ATMPs in the challenges.

10. Novel manufacturing methods and materials for greener more circular healthcare systems (one-stage idea/topic)
    The SIP welcomes and supports the idea and notes the links to existing projects. A reference was made to the recommendations for sustainable medical devices of the Health Council of the Netherlands[1]

11. Accelerating the implementation of novel non-animal approaches for the development and testing of health technologies (one-stage idea/topic)
12. The SIP noted the potential regulatory challenges of the idea (i.e., need for comparative evaluation and method comparisons) and the initiatives in place at the FDA[2] and EMA[3].

13. Enhancing the Use of Pigs in Biomedical Research & Development (two-stage idea/topic)
    The idea is supported by the SIP. A minor comment was made regarding the terminology used (digital pens vs digital cages).

Preparing the Scientific priorities for 2023

The SIP would like to see more call topics on prevention, “green” topics and climate impact, as well as topics on healthcare staffing issues and hospital efficiency (in synergy with e.g. European Partnership on Transforming Health and Care Systems).

Topics on infectious diseases, AMR and pandemic preparedness & system resilience were also mentioned as a priority, while making sure synergies and/or gaps are appropriately addressed versus existing and newly developed EU structures (i.e., HERA).

Finally, topics in the area of digital R&D would be very important in their potential for transformative breakthroughs.

[1] Towards sustainable devices in healthcare | Advisory report | The Health Council of the Netherlands
[2] https://www.fda.gov/science-research/about-science-research-fda/advancing-alternative-methods-fda
[3] https://www.ema.europa.eu/en/news/ema-implements-new-measures-minimise-animal-testing-during-medicines-development