IHI JU Science & Innovation Panel (SIP)

5th Report to the IHI JU Governing Board

5th MEETING OF THE SIP
26/01/2023 (09:00 – 16:00 CEST) – Hybrid meeting

This report summarizes the SIP opinions related to:

- IHI Progress Report
- Collected ideas submitted to the SIP
- Preparing Calls 5 and 6
- Synergies with other programmes and initiatives

* * * * *

IHI Progress Report

The SIP welcomed the presentation of the progress report on the scientific and innovation activities of IHI, including the IHI communication policy and the numerous project highlights[1]. The SIP wishes to congratulate the IHI Programme Office on this impressive amount of work and outputs.

The SIP received additional information related to applications of potential associated members and contributing partners, and an overview on the planning of additional activities of members other than the Union.

In order to provide further advice on the scientific achievements of the Innovative Health Initiative Joint Undertaking, the SIP suggests inviting one or more participants to hear about their experience, merits of the program as well as encountered challenges.

Collected ideas submitted to the SIP

The ideas suggested by the wider health and research community, as of December 2022, were reviewed and discussed by the SIP.

[1] E.g. eTRANSAFE, EHDEN, EUbOPEN, Gravitate-Health, RADAR-CNS, PREFER, AIMS-2-TRIALS)

1. Multi Cancer Early Detection –finding cancer in asymptomatic citizens (TI_001172)

The SIP's opinion is that the idea is addressing a very important area, which raises complex questions, representing significant challenges, such as:

- With the aim to detect or predict malignant disease in asymptomatic citizens, how will health systems deal with a much higher demand for clarification of positively screened cases?
- How can appropriate follow up be assured, including the care and needed research?
- What will be considered appropriate treatment for cases diagnosed early, which also turns healthy citizens into sick patients early, and exposes them to aggressive and possibly harmful further diagnostic and therapeutic interventions?

Considering these challenges/complex questions, further thinking would be needed on best translating the idea into a topic to ensure its feasibility.

2. Novel nuclear theranostics for personalized cancer diagnosis and care (TI_001173)

The idea is very interesting and has the potential to deliver results in the future care of advanced cancer. The SIP believes that it is important to develop theranostic tools to improve the therapeutic index of targeted treatments and to control the financial cost to public health. The SIP is of the opinion that the idea is ambitious, timely and scientifically sound and that it should be duly considered by the Governing Board as a priority.

3. A supportive framework for the introduction of medical technology for prevention, diagnosis, treatment and management of rare diseases (TI_001181)

The SIP finds the idea interesting, scientifically sound and is of the opinion that it could be considered, while taking into account the following important aspects to ensure its feasibility:

- the need to define which devices/device-groups might be "orphan devices" for prevention, diagnosis, treatment and management of rare diseases, and
- the importance of having need-based assessment for device classes of interest that could be carried out by of the European Reference Network for rare diseases.

Preparing Calls 5 and 6

The European Commission[2] and the industry[3] founding members presented a series of proposed ideas and early draft topic texts. The feedback of the SIP opinion is as follows:

[2] Ideas presented by the European Commission are identified by the acronym EC in the numbering (#EC1 to #EC7)
[3] Ideas presented by the Industry are identified by the acronym IND in the numbering (#IND1 to #IND14)

#EC1 – Localised Production of personalized medicines tailored to patient needs

The idea is very interesting including the involvement of community pharmacists. However, based on the details provided at this stage, some important questions would need to be taken into consideration in relation with feasibility, such as modalities of 3D printing in pharmacy, regulatory acceptability regarding GMP requirements on site, and in particular when combining different APIs for "polypill". The SIP asked to specify which type of call (single-stage or two-stage) would fit best in this setting.

#EC2 – Strengthen innovation in vaccine development by advancing new technologies for needle-free vaccine delivery

In line with the HERA conference on future of vaccines, which identified needle-free vaccines as important, the SIP finds this idea very interesting and would recommend including children and vulnerable people.

#EC3 – Developing novel therapeutic interventions for mental disorders

The SIP finds the topic very interesting. Indeed, there is a huge gap in the market of medical therapeutics and in particular, for children and adolescents, which could be included. In addition, seeing the importance of including more imaging techniques in the management of mental diseases, the SIP is of the opinion that it could be interesting to engage with medical devices or biomarkers industry. Building on learnings from IMI project NEWMEDS, which included functional MRI, and RADAR-CNS, digital health should be included, such as monitoring with wearables, acceptability of treatment, and combination with other therapies. Potential synergies with ongoing initiatives could be envisaged (e.g. www.parea.eu).

#EC4 – Nutri (gen)omics: towards improving disease prevention and treatment through omics-informed personalized nutrition

The SIP acknowledges the importance of the topic in supporting healthy nutrition to prevent disease and in particular for patients in accompanying treatment in order to improve outcomes. It could be interesting to combine this approach with microbiome-oriented research. However, this idea, as it stands, represents a challenge in identifying appropriate partners and in particular from the industry.

#EC5 – Advanced pharmacology modelling tools for personalized treatment selection and precision dosing

The SIP finds the topic very interesting and stresses the importance of ensuring open data on the model to be available, and on ensuring publicly accessible datasets.

#EC6 – Maximising the potential of synthetic data generation in healthcare applications

The proposed idea is very appealing, and would potentially be of interest to medtech companies. In addition to data generation, it could be interesting to include data augmentation techniques. The SIP recommends assessing how it differentiates (e.g. research enabling or application based) with previous call topic on synthetic data or if it could be merged with the topic. If any overlap would be identified with Horizon EU, the implementation aspect in an IHI project could be a valuable complementary approach.

#EC7 – Use of data from acute care and ICUs to advance modelling and visualisation, diagnostic tools and algorithms, and enhanced treatment schemes

The SIP is questioning the limitation to the ICU and whether it would be relevant to include other hospital based devices (e.g. operating room, acute care?). The SIP expressed doubts about the feasibility and clinical application of the idea as it is presented currently and is of the opinion that it could be merged with the industry idea #IND9.

#IND1 – Implementation of non-animal approaches for the development and testing of health technologies

The SIP finds the focus on implementation very good, including the regulatory approach, which is key in this setting. Indeed, engaging with all stakeholders including regulators is essential to anticipate impact on future implementation. Some initiatives were mentioned and that would be interesting to keep in mind, when advancing with the idea, such as the two-stage call HORIZON-HLTH-2024-TOOL-05-06, or the Norway legislation to ban animal research. Knowing what is already being done or underway in the field is important since an IHI topic focusing on implementation would be a valuable complementary approach. The potential to reduce use of animals in the development of medical devices would also attract the interest of medtech companies (e.g. implantable devices…).

#IND2 – Inclusive clinical research through increased recruitment and retention of diverse study populations

The SIP acknowledges the fact that its previous recommendations regarding this idea have been taken into account and that the topic is now presented as a two-stage proposal. The SIP finds it important to engage with established researcher communities to ensure success of the proposed platform. It is advised to highlight a little a bit more the scope, e.g. by specifying if it include registries or retrospective studies. Highlighting the expected improvement of technologies and their impact on patients from diverse populations and including a sustainability plan so that this initiative will be continued in the future, are additional recommendations from the SIP. Moreover, it would be important to engage with regulators, in particular regarding the definition of diverse populations (in EU it is less straightforward compared to the US FDA ethnicity dimensions) and when considering the conduct of the clinical trials (e.g. endpoints, subgroup analyses and impact on necessary trial sizes and relevant recruitment targets).

#IND3 – Clinical trials in very small populations (rare diseases)

The SIP considers that, as it is presented, the text is very mature and represents a potentially very important call. It takes into account other initiatives. However, in the envisaged consortium, the SIP finds it relevant to consider other healthcare professionals beyond hospital specialists, to seek alignment with ERANET and to verify differentiating elements or potential synergies with previous idea (#IND2).

#IND4 – 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

The SIP notes that its previous comments were taken into consideration and the currently presented idea is more focused and structured. Some questions still remain regarding the role and place of diagnostics, as well as regarding the fit of the development of non-human primate models with the intention to reduce their use.

#IND6 – Clinical validation of biomarkers for disease state, progression, and treatment response

The SIP finds the idea very broad and wishes to further discuss it, for instance during a dedicated session about neurodegeneration and provide detailed comments at a later stage.

#IND7 – Early detection and diagnosis of Alzheimer's Disease to support the effective stratification of patients for better outcomes

The SIP would like to review this idea in more depth (together with idea #IND6), in order to clarify the scope on early diagnosis versus other potential endpoints. In addition, the SIP recommends exploring potential for synergies (e.g. JPND, upcoming Call 1 project on clinical support decision system).

#IND8 – Heart failure and structural heart disease care along the entire patient journey

a) **Monitoring and clinical management for improved heart failure and structural heart disease care along the entire patient journey**
b) **Evaluating and integrating emerging technologies and novel sensors for managing cardiovascular and metabolic disease (#IND12)**

The idea is interesting but needs further development, in particular how part a) and b), will be articilated. The SIP notes that it is important to show how the approach envisaged for heart failure will be developed in the area of CVDs where many wearables already exist. Moreover, it is important to see how the implementation part will be structured in the necessary longer-term follow up of heart failure.

#IND9 (+ #EC7) – Improved prediction and interventional approaches for comprehensive stroke management

The SIP notes the intention to merge this idea with idea #EC7, which would be interesting, in particular because it is important to address the collection of data generated by all available devices and to use them in real time, including in the operating room. However, the fact that stroke patients have a different trajectory in the hospital needs to be taken into account when developing further this idea.

#IND10 (+ TI 001173) – Feasibility and clinical application of multi-modal theranostic solutions

The SIP welcomes the intention to merge this idea with the idea submitted by an SME on "Novel nuclear theranostics for personalized cancer diagnosis and care" as it holds the potential to generate a very promising complementary approach.

#IND11 – Decentralised/remote monitoring, interventions and personalized decision making in chronic therapies

The SIP has some questions regarding the extent of the proposed monitoring and how its results and consequences would be integrated in the clinical care, and how potential safety issues would be addressed, knowing that current healthcare systems are still poorly equipped for that.

#IND13 – Safe & Sustainable by Design (SSbD) packaging solutions for healthcare products and equipment

The SIP finds the idea relatively broad, because it addresses packages and equipment, which are potentially two different topics. The idea has the potential to foster industry collaboration with academia and such project could generate important evidence and innovation susceptible to proactively influencing the medical devices regulations.

#IND14 – Sustainable development and manufacturing of pharmaceutical and medical products and their quantitative environmental impact assessment

The SIP finds the idea very interesting and recommends including the digitalization of the procedures. In addition, the environmental impact dimensions would need to be added (e.g. use of land, water, waste management, …), as well as the materials-related perspective.

Synergies with other programmes and initiatives

Main interactions with other EU programmes and initiatives, as of January 2023, were presented to the SIP, including an overview of EU, national and regional programmes and initiatives in the health area, presented by the SRG representatives.

The SIP noted the impressive number of programmes and initiatives and acknowledged that the information provided will help its members in providing their advice in due time.

Additional overview of relevant initiatives will be shared within the SIP as needed.

AOB & concluding remarks

At the end of the meeting, in preparation of future SIP meetings, the SIP discussed the prioritization of the horizontal items identified during previous discussions. Among these items, the SIP discussed the importance of identifying how IHI can help in building an ecosystem and contribute to the competitiveness of Europe when providing advice on the scientific priorities to be addressed in the work programmes. The SIP also proposed to further investigate on how to bridge academics and industry, and how to ensure more research is conducted to identify unmet public health needs.