IHI JU Science & Innovation Panel (SIP)

8th Report to the IHI JU Governing Board

8th MEETING OF THE SIP

14 September 2023 (09:00 – 17:00 CEST) – Online meeting

This report summarizes the SIP opinions related to:

- IHI Progress Report
- Preparing the next IHI Calls (single stage and two-stage)
- Exploring potential EHDS related ideas of relevance within IHI
- Proposed ideas from the wider health and research community

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1. IHI Progress Report

The SIP welcomed the presentation of the progress report on the scientific and innovation activities of IHI and in particular, the main updates since last meeting regarding the IKAA planning and synergies.

2. Preparing the next single-stage call

The IHI founding members presented three early draft topic texts as potential single-stage calls. The SIP opinion is as follows:

1. Improving clinical management of structural heart disease, coronary artery disease and heart failure care

The SIP welcomes the proposed topic with the slightly revised title and scope based on its previous opinion. The shifting away from the monitoring approach to focus on the diagnostic and therapeutic approaches will avoid overlap with previous call 2 topic in cardiovascular diseases. The SIP is of the opinion that this should be an opportunity to optimize diagnostic tools for particular groups of patients such as children and the elderly. Another element to consider in this setting is the connection with primary care. The need to consider more outpatient care would aim for better patient outcomes since

they could be treated in the familiarity of their homes and would potentially generate a reduction of healthcare associated costs for society.

2. Fostering a resilient healthcare workforce through user-centric development and implementation of emerging technologies in hospital settings

The SIP acknowledges the importance of the topic. Within the topic, it would be relevant to have appropriate representation of all healthcare related disciplines and address not only healthcare workforce, but also management, decision-makers, payers, etc. In addition, it would be relevant to consider the need for blended skills, including the upscaling of staff along with the AI-driven transformation of healthcare. [1]

3. Advanced digital modelling tools for personalised drug-based treatments for cancer/cardiovascular diseases

The SIP understands the EU context of developing digital virtual twin models and computational models in general, in which the topic text has been drafted. However, the SIP is of the opinion that it should it be more clear in which way this topic is complementing what is already foreseen in the ongoing EU programs and initiatives. Regarding the diseases that are considered in the current draft topic text, attention should be paid to not overlap with previous call 1 topic 3 on personalized oncology. Moreover, it would be relevant to broaden the scope, on one hand, to include treatments based on medtech or drug-device combinations and, on the other hand, to go beyond analyzing existing data by including the generation of data. Finally, the SIP would also welcome the inclusion of patient quality of life measures and the consideration of cross-border elements in relation with GDPR compliance and interoperability, and in particular, appropriate patient information and consent procedures.

3. Preparing the next two-stage call

The IHI founding members presented one early draft topic text as potential two-stage call. The SIP's opinion is as follows:

Support healthcare system resilience through focus on persistency in chronic disease care

The SIP sees the potential benefit in helping patients confronted with a fragmented healthcare system. The SIP is of the opinion that there is a need to be clear on the terminology related to patient adherence to treatment and persistency and therefore, to consider the inclusion of standardization

[1] Relevant references to consider are:
- Article published in The New England Journal of Medicines 'Artificial Intelligence in Medicine' of 30 March 2023 https://www.nejm.org/doi/full/10.1056/NEJMe2206291
- Final report of the EIT Health Think Tank 'Transforming Healthcare with AI' Hub' of March 2021 https://thinktank.eithealth.eu/

methods, including the digital-tools dimension, in order to facilitate future comparative effectiveness research, meta-analytic studies and HTA, while taking into account the specificities of different healthcare systems.

Additional elements that the SIP finds relevant to consider are related to:

- the need for including strategies aiming at increasing caregivers' ability, knowledge and motivation to engage with patients on persistency,
- patient-centric communication taking into account patients' conditions and addressing reasons for dropping out of treatment, and
- addressing the overall relevance of "treatment burden" for the healthcare system.

4. Exploring potential EHDS related ideas of relevance within IHI

4.1. Presentation by the European Commission aiming at setting the scene of EHDS, including the legislative proposal and its state of play.

The SIP recognizes the importance of the initiative and the challenges related to current technological disparities across EU Member States in an overall highly regulated environment. Therefore, building on previous successful initiatives from other areas, such as the Single EU payment architecture, while putting forward the patient perspective, will be key when addressing cross-border exchanges, including modalities of patient access to data (e.g. consider patient to have access to results originating from the data and not limited to raw data). Finally, considering the secondary use for research purposes and validation strategies will contribute to anticipate subsequent queries emanating from medicines' regulatory bodies (e.g. EMA).

4.2. Presentation by the IHI office of the IMI/IHI project highlights

The SIP congratulates the IHI office for compiling the numerous project highlights in a structured manner highlighting the trajectories of datasets within EHDS for secondary use ("HealthData@EU") and primary use ("MyHealth@EU") of health data. The SIP highlights the importance of data collection through common standards and of incentives to run network studies.

4.3. Presentation of four preliminary ideas by the IHI founding members

The following topic ideas were presented for potential inclusion in the next calls or future IHI calls, with topics 1 and 2 as potential two-stage calls, and topics 3 and 4 as potential single-stage calls.

1. Data passport consent to opt in/out for research purposes – Centralized, pan-European portal where EU citizens can view, manage and own their individual health data usage consent

   The SIP recognizes the strategic importance of this topic and the need to consider patient consent and compatibility with patients' rights within GDPR and EHDS legal context. However,

it would be necessary to specify the extent of the research dimension within this topic in order for the SIP to provide a more detailed opinion on the alignment with the IHI SRIA.

2. Guidance of RWD for regulatory /HTA decision making/Enabling Regulatory, HTA & payer RWE acceptance to promote evidence-based adoption

   The SIP finds the topic of high interest. However, since there are many initiatives ongoing in this area, it would be important to ensure synergies and avoid overlapping. Therefore, the integration of clinical performance studies of medical devices could be considered. Moreover, this could build upon existing experience in conducting RWD/RWE studies for regulatory purposes including HTA bodies and payers (e.g. EMA report on RWE framework to support regulatory decision-making)[2].

3. Safeguarding intellectual property and trade secrets in secondary use of health data in the European Health Data Space (EHDS)

   The SIP finds the topic interesting. However, the definition of the envisaged framework should be better described and specified. Currently, it is not sufficiently clear how it will address data sharing governance (e.g. availability of data versus actual use of data) and measures of protection depending on the stakeholder (e.g. industry versus other stakeholders?).

4. Guidelines and tools for datasets definition in the European Health Data Space contributing to datasets quality and utility

   The SIP acknowledges the EHDS regulation basis for the proposed topic (e.g. article 55 on dataset description, article 56 on data quality and utility label) and is of the opinion that the role of the regulator is key in the proposed setting. The SIP referred to other standards for datasets to be considered, and of importance to regulators, such as the CDISC Consortium, including the need to consider addressing the data-generating processes (DGP) involved.

5. Proposed ideas from the wider health and research community

Preliminary discussions took place on the recently submitted idea titled “Neuro-electronic medicine and the European health strategy”.

The SIP highlighted the following elements:

[2] https://www.ema.europa.eu/en/documents/report/real-world-evidence-framework-support-eu-regulatory-decision-making-report-experience-gained_en.pdf

- The idea is described in a rather general manner, and does not include sufficient details about the background, state of the art, current knowledge gaps, and limitations of current approaches, objectives, specific impacts, and advancements beyond the state of the art.
- The idea presents a technology that could potentially revolutionize and significantly outperform current solutions, such as deep brain stimulation and cochlear implants, thus enabling even more targeted therapy with a better impact on patients' quality of life. However, the SIP is of the opinion that the idea is not sufficiently describing the level of maturity of the technology (e.g., supported by scientific publications) and the feasibility of integrating it into clinical practice (e.g. technological and regulatory standpoints).
- The idea will be further discussed and the final SIP outcome will be delivered in due time.