IHI JU Science & Innovation Panel (SIP)

7th Report to the IHI JU Governing Board

7th MEETING OF THE SIP
3rd July 2023 (15:00 – 18:00 CEST) & 4th July 2023 (09:00 – 16:00 CEST) – Hybrid meeting

This report summarizes the SIP opinions related to:

- IHI Progress report
- Project highlights
- Exploring areas for future IHI Calls
    - Support optimisation of healthcare delivery (and improving outcomes)
    - Contribute to address mental health challenges
    - Contribute to creating a safe space for innovators: regulatory sandboxes
    - Support building trust in RWE / RWD for different uses

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1. IHI Progress Report

The SIP welcomed the progress, in particular the completion of five grant agreements for consortia funded under IHI Calls 1 through 3, and the way forward for opening Calls 4 and 5.

From the report about the Governing board activities, the SIP acknowledged the appointment of a new Executive director for the IHI JU and the high-level plans for the 2024 workplan and budget. The SIP welcomed that strategic discussions had been started about optimising IHI relevance for, and impact on healthcare. The SIP is interested in, and offers to be involved in the discussions (related are preliminary SIP reflections under point 3.1 below).

2. Project highlights

The SIP appreciated the presentation of outcomes, sustainability achievements and learnings from projects presented by the IHI office.

3. Exploring areas for future IHI Calls

The opinions reported below reflect the discussion that followed introductory views from IHI funding members representing the Union (EC) and members other than the Union (industry).

3.1 Support optimisation of healthcare delivery (and improving outcomes)

The SIP is of the opinion that this area is a priority and requires comprehensive consideration, including of the circumstances needed for innovating in healthcare, such as addressing cultures, processes and principles that prevail in healthcare.

The SIP reflected on how they could generate recommendations for IHI on this theme; amongst others, scoping workshops may be useful, including with existing European Partnerships (e.g., THCS), selected project coordinators and experts.

SIP members have broad experience with change management in healthcare and improving outcomes, and they preliminarily flagged a range of system factors that need to be addressed such as:

- overcoming the disconnect between sequenced interventions and loss of information in the system; filling gaps between new solutions; stepping up to disrupt existing processes which in healthcare may have notable inertia; modelling pathways for integrating screening, prevention, diagnosis, treatment, rehabilitation and follow-up; achieving to substitute existing instead of adding-on new solutions;
- overcoming lack of health professionals for hospital, out-patient and home care; considering the demographic evolution and pressures to deliver more and better healthcare with fewer resources, overcoming traditional working arrangements for health professionals; patient-health professional relationship; persisting need for increasing health literacy and competences;
- up-scaling of new solutions and preparing for implementing at scale, and with due consideration of feasibility in a given context as well as acceptability to providers and patients; bridging EU, national and regional responsibilities; managing different levels of maturity and readiness of regional healthcare systems; reducing waste in the broad sense (e.g. as in lean management); considering what is realistic and where there is willingness; considering healthcare is a closely-regulated system (at several levels, different frameworks);
- selecting outcome measures and developing clear objectives for ‘optimisation’ (both SMART and strategic, e.g. for fewer interventions, value-based interventions, less system expenditures, and better overall health); developing policy principles for introducing change such as for personalised medicine; considering not only high-tech solutions for eclectic settings but useful solutions for everyday settings.

3.2 Contribute to addressing mental health challenges

The SIP was of the opinion that IHI should contribute to address mental health challenges; it will be important to find one or more focus areas for IHI to work on, given the field is very broad as SIP members exemplified (e.g., not-very-well-defined diseases, poorly targeted treatment, insufficient psychometric properties of current diagnostic approaches, living an independent life, addiction, workforce mental health, dysfunctional social environments).

SIP members flagged the need for better data collection (on mental health and where possible on neurodegenerative diseases; on diagnosis, treatment, management, services), new services for underserved persons, telemedicine / remote monitoring, work on psychotropic drugs and non-pharmacological interventions, addressing any deceleration of pharmaceutical research.

The SIP members confirmed the importance of the pillars of the EC's Comprehensive approach to mental health (prevention, access to care, reintegration and follow-up/tertiary prevention) and see an example in young people including the paediatric population, and other underrepresented groups with limited access, who remain to be better served in healthcare and with public-private partnerships in this thematic field.

The SIP is interested in exchanges with regional health authorities and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and also welcomed the idea for a Health summit, before moving forward in this thematic area.

3.3 Contribute to creating a safe space for innovators: regulatory sandboxes[1]

The SIP is of the opinion that the IHI could play an important role in preparing for and accompanying regulatory sandboxes. For example, this could be in the context of solutions by non-commercial developers and on pre-competitive aspects to inform building regulatory sandboxes and their components. This could encompass eliciting solutions from a broad set of developers and researchers, approaches for collating evidence, and approaches for effective multi-stakeholder engagement to underpin controlled experimentation in regulatory sandboxes.

The SIP supported regulatory sandboxes as topic for the IHI Regulatory science summit planned for 2024.

The SIP members noted the important role of EU Member States, the perspective to attract investments, the need for identifying skills, the acceleration of disruptive changes, the opportunity to broaden support and translation pathways to include medical technology industry solutions, and the global attractiveness concerning regulatory sandboxes.

The SIP discussed to revert in subsequent meetings to regulatory sandboxes and the IHI role, at least among SIP members who are specially interested; this can include to identify other stakeholder groups who are needed to advance the topic.

3.4 Support building trust in RWE / RWD[2] for different uses

The SIP is of the opinion that a focus and directions for future RWE projects remain to be found.

A specific focus could be to explore data that are passively (autonomously) generated by personal devices, which may have advantages such as non-intrusiveness (enabling analysis of the more natural and authentic behaviour of end-users), reduced bias, rich context, continuous monitoring,

[1] Regulatory sandboxes are schemes that enable testing innovations in a controlled real world environment, that may include temporary loosening of applicable rules while safeguarding regulatory objectives such as safety and consumer protection. Regulatory sandboxes are part of the Commission's proposal for a Reform of the EU pharmaceutical legislation (https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en).

[2] Real-world evidence / real-world data; examples of IMI projects: https://www.imi.europa.eu/projects-results/project-factsheets?tools=TR11

and reduced user effort (potentially lowering the dropout rate). Another specific focus could be solutions for rare or paediatric populations, in particular also for devices. The SIP members noted several important global standardisation initiatives (e.g. EHDEN, ICH, GetReal, CIOMS) even though some definitions vary. At the practical and regional level across the EU, work remains to be done to efficiently provide useful data sources e.g. for federated analyses.

SIP members flagged that different decision-makers have now determined to accept RWE for different use cases; it was not discussed in how far this has to do with trust, but reliability, regulatory use and objective data (including pharmacogenomics) were mentioned.

The SIP generally supported RWE as topic for the IHI Regulatory science summit planned for 2024.

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