Ref. Ares(2022)6487426 - 20/09/2022

IHI JU Science & Innovation Panel (SIP)

2nd Report to the IHI JU Governing Board

2nd MEETING OF THE SIP
29/06/2022 (08:30 – 12:30 CEST)
Teams videoconference

This report summarizes the SIP opinions related to:

- Collecting ideas to support the preparation of potential IHI annual scientific priorities and potential topics for IHI calls for proposal
- Ideas for next IHI Calls – First review

Collecting ideas to support the preparation of potential IHI annual scientific priorities and potential topics for IHI calls for proposal

The SIP acknowledged the need to make publicly available the ideas submitted to IHI as well as the outcome and follow-up of their evaluation for transparency purposes, while complying with the EU General Data Protection Regulation by seeking prior approval of the submitter.

The SIP members highlighted the importance of managing expectations of submitters of ideas by ensuring adequate communication on items such as:

- One idea may not necessary lead to one topic
- Submitter to demonstrate relevance and feasibility of the idea
- Importance of building on previously funded projects at EU or national level
- Foresee in-kind contribution
- Timelines between the collection of ideas and the topics' preparation
- Criteria used for review of ideas

Regarding the review of the collected ideas, the SIP members are of the opinion to:

- facilitate the review process by using a bucketing system for the submitted ideas that corresponds to disease areas or themes such as digitalization[1], as mentioned in the SRIA
- distribute themes or buckets among SIP members with relevant expertise

[1] e.g. allowing grouping of themes similar to the current tagging system of projects listed on the IMI website

- appoint a rapporteur among SIP members per idea or cluster of ideas, under the coordination of the SIP Chairperson
- regarding the proposed approach to assess the submitted ideas (i.e. favorable/unfavorable), the SIP members are reflecting on how to best proceed to formulate the SIP outcome, in order to ensure consistency and transparency

In addition, some SIP members suggested eventually to extend the bucket list following the ideas submitted, e.g. by adding mental health, musculoskeletal, oral, respiratory, reproductive and child health, general health.

Ideas for next IHI Calls – First review

The SIP members plead to go beyond topics that follow-up on earlier proposals, since the IMI program was mainly focused on medicines and less on medical devices and medtech.

Preliminary feedback on the idea submitted by SIP member:

"Multi Cancer Early Detection (MCED) - Finding cancers in asymptomatic citizens"

One SIP member asked for preliminary feedback on an idea in the cancer domain. The other SIP members provided several comments illustrating that the idea was not sufficiently developed at this stage. Based on this preliminary feedback, and in order to ease further discussions and a fair review of ideas, the chairperson suggested that the SIP members use the IHI form as a common tool for structuring and presenting their own ideas.

Preliminary feedback on the ideas submitted by the EC

The following EC ideas were presented to the SIP:

1. Non-animal approaches for testing the quality of vaccine batches
2. Development of microphysiological systems (organ-on-a-chip technology) for drug discovery and safety and efficacy assessment
3. Development and rapid use of non-animal strategies in emerging infectious disease outbreaks
4. Development of allogeneic CAR-T cell therapies
5. Multimodal biomarkers for improved patient management of chronic diseases
6. Precision gene therapy for rare diseases
7. Innovative products and practices that generate less medical waste and enable cleaner, more circular healthcare systems
8. Strengthening the integrated response for the diagnosis and therapy of long COVID
9. Tackling mental health disorders in adolescents using remote technology: case study on eating disorders
10. AI-based biomarkers in longevity medicine research for better personalised diagnostics and therapies
11. Integrated genomics and computational modelling methods and tools for precision medicine
12. New manufacturing processes to address challenges and inefficiencies in production and value chains
13. Accelerating Clinical Trials and Clinical Investigations by improved recruitment and retention of participants

Overall, the SIP welcomed positively the amount of ideas submitted and provided the following comments and suggestions:

- Need to highlight the cross- sectorial nature of the ideas, i.e. idea 1: non- animal-based methods to be applied to more areas beyond vaccines (e.g. devices).
- Some ideas include methodological challenges (e.g. ideas 5, 6, 7, 11), which would need to be reviewed to ensure agreement of stakeholders (e.g. idea 7, although very interesting, it may be difficult to measure appropriately the impact of climate in healthcare)
- Overall, ideas include the regulatory dimension. However, this should be reviewed in relation to the relevant methodologies and technologies used (e.g. testing methods, target diseases and patient groups)
- Need to address the attractiveness and competitiveness of the EU landscape when projects generated from ideas would be launched (e.g. idea 12, appropriate public incentives to go green).
- The SIP and recognized the importance of Preparedness topics such as idea 8. However, they also highlighted the existing large IMI and H2020/HE portfolio and national funding, notably covering long Covid, and as such questioned the innovative or added- value components.
- For some of the ideas presented, the SIP members recommended additional landscaping in order to avoid potential redundancies with existing initiatives (e.g. idea 10 versus EU project on AI- based personal diagnostics would also benefit from focusing on specific disorders and to seek for synergies (e.g. EIT Health).
- Idea 13 is interesting and relevant. However, GDPR, national health systems' legal constraints, etc., represent significant challenges in designing and launching an EU-wide topic.

<u>Preliminary feedback on the ideas submitted IHI Industry founding members</u>

The following ideas were presented to the SIP, grouped by themes (hence the order of the numbering of the ideas)

- Platforms for screening, prediction, and prevention of NCDs and infectious diseases (#1)
- Standardisation and defragmentation of data to unlock personalised care pathways in non-communicable diseases (#2)
- Validated markers for disease state, progression, response to guide therapy choices (#3)
- Patient generated evidence and real-world data to support decision making, improve patient outcomes & accelerate innovation (#4)
- Novel technology platforms ecosystem for rare and pediatric diseases (underserved diseases) (#8)
- Increase participation of under-represented and underserved communities in clinical research (#11)
- Combination of long acting injectables against the threat of infectious diseases (#5)
- Towards broad clinical introduction of radiopharmaceutical therapy (#16)
- Decentralised/remote monitoring, interventions and personalized decision making in chronic therapies (#7)

- Patient-centric blood sample collection will enable decentralized clinical trials and improve access to healthcare (#7A)
- Preclinical research / 3Rs (#9)
- In silico studies (#13)
- New X-ray sources to enable novel imaging and therapies (#14)
- Use of ionizing radiations in non-oncology diseases, such as heart diseases (#15)
- Sustainable use of chemicals in healthcare products (#10)
- Noninvasive technologies to allow faster recovery (#12)

Overall, the SIP members welcomed these ideas and noted the magnitude and the crosscutting character of the topics covered. The SIP recommended to better frame some ideas in order to generate implementable projects with potential results in specific situations.

The following additional comments were made:

- The SIP members highlighted potential overlaps of several ideas with existing initiatives (e.g. idea #1 with the HE call "Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression"[2]; idea #3 possible overlap with H2020 projects). Moreover, the SIP members questioned the difference between ideas #1 and #3.
- The SIP members suggested connecting Ideas #3 and #4 to the European Health Data Space framework.
- Regarding interaction with regulators, e.g. idea #7A, the SIP members proposed to consider specifically including the qualification of novel endpoints. This would also facilitate (or even be a requirement for) using it in non-experimental (real-world) data collection.
- The SIP members pointed out similarities of idea #10 with the idea on green production (presented by the EC), and as such, they could be combined.
- Regarding idea #11, the SIP notes that underrepresented populations should be part of clinical trials but not as a formal requirement. Some challenges were identified, related to the need to develop a specific policy in this sense, as well as the question on "representativeness", which does not invalidate the results of clinical trials (e.g. importance of the research questions).
- The SIP members considered relevant to study the role of clinical trials (CTs) in the development and evaluation of new technologies/medicines and whether it should be used in addition (upfront) or instead of other clinical studies / randomized CTs (e.g. idea #13).

Finally, some additional general items were discussed related to the need of a pipeline of ideas for calls addressing all relevant stakeholders' interests, as well as the need for appropriate output-related KPIs and tracking of IHI deliverables.

[2] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-stayhlth-01-04-two-stage