

IHI JU Science & Innovation Panel (SIP)

13th Report to the IHI JU Governing Board

13th MEETING OF THE SIP

26 February 2026 (09:00 – 18:15 CET) and 27 February 2026 (08:45 – 13:00 CET)

This report summarizes the SIP opinions related to the following agenda items:

- IHI Progress Report
- IHI Cardiometabolic diseases portfolio
- Engaging in IHI, added value of industry contributions, and scientific advisory role in EU partnerships
- Exploring areas for future IHI activities
 - Preparing the 2026 two-stage Call
 - Looking forward to 2027
- Review of the latest ideas submitted by the wider health and research community

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1. IHI Progress Report

1.1. Portfolio, Project Highlights

The SIP welcomed the presentation by the IHI Executive Director and IHI Scientific Officers and in particular the overview of the numerous IHI projects on Big data / Artificial Intelligence / Digital Health. The SIP members found the portfolio very impressive and appreciated how the projects aim at harmonizing data and building a European innovation ecosystem around EHDS.

The SIP members stressed the importance of robust evaluation of AI-related projects, referring to existing evaluation criteria, and suggested building on the outcomes of the upcoming summer AI workshop to prepare for a dedicated SIP discussion in the autumn.

The SIP emphasized the need to cover the entire product lifecycle and to ensure the valorization of datasets generated within projects, allowing relevance and value beyond the project's duration. The SIP encouraged vertical integration between national and EU-level efforts, where SRG input on

future topics could yield significant public-health impact. On a strategic level and considering the Draghi report, deeper mapping of projects would allow identifying blind spots and better understand Europe's competitive position globally.

The SIP acknowledged IHI's data sharing tools and in particular the Data Sharing Playbook¹, which could be adapted and operationalized for AI-specific contexts, including practical mechanisms for sharing AI models. Moreover, seeing the variety of AI models, federated infrastructures (e.g., IDERHA), and datasets emerging from projects—often accessible only to contributors, the SIP recommended developing a comprehensive catalogue detailing generated datasets and access modalities, and clarifying the potential role of neutral third parties.

Finally, the SIP members noted that many IHI projects will run beyond the 2029 EHDS implementation date. Considering that compliance obligations fall primarily on entities rather than projects, the SIP highlighted the importance of timely interaction with national health data access bodies.

1.2. Ideas incubator

The SIP discussed the origin and quality of idea submissions and questioned whether to maintain the incubator as IHI approaches its end, highlighting the heavy workload of engaging the community relative to the limited number of resulting call topics, and raised concerns about a potentially large number of AI-generated submissions in future programmes.

1.3. Bibliometrics Report 2025

The SIP discussed the importance of proper citation and recognition of project outputs and agreed that bibliometric assessment should extend beyond traditional citations to systematically recognize datasets, digital tools, and AI/ML models as research outputs, and develop mechanisms to track their impact through usage metrics rather than citations, with further reflection needed on how best to integrate these measures into standard reporting processes.

2. IHI Cardiometabolic diseases portfolio

The SIP stressed the need to broaden the cardiometabolic portfolio by exploring links with biomaterials, new stent technologies, and cardiovascular research addressing gender differences, including the availability of gender-balanced datasets for AI development.

They highlighted opportunities to align with wider EU initiatives, such as the Safe Hearts Plan, where IHI could facilitate implementation and create synergies. Several SIP members underlined the importance of implementation in health systems, noting the sector's overstretched capacity and the need to involve missing actors such as payers and hospital managers. The discussion touched on

¹ <https://www.ih.europa.eu/news-events/newsroom/data-sharing-playbook-can-unlock-health-partnerships>

policy-relevant dimensions, including the role of CVD as a driver for MedTech, links with radioligands and theranostics, and upcoming regulatory developments, especially in AI and real-world evidence.

3. Engaging in IHI, industry contributions, and scientific advisory role in EU partnerships

3.1. Experience of the PREDICTOM project

The discussion highlighted both achievements and challenges in PREDICTOM². The SIP noted a strong progression of learnings across related projects but also pointed to the challenges of large cross-border consortia. Ethical approvals, data-sharing hurdles, and national restrictions were cited as key challenges. Questions were raised about how the project engaged with other EU initiatives, such as AI-MIND³, and how implementation pathways could be strengthened. Good communication with IHI officers was acknowledged as a success factor.

SIP members emphasized links with other Horizon Europe Cluster 1 activities and partnerships⁴, such as the Brain Health co-funded partnership⁵, to map gaps and future research needs. The SIP also highlighted the importance of data findability, referencing HMA-EMA RWD catalogues⁶ and the need for earlier-stage diagnostic and predictive datasets.

3.2. Experience of the AUTOPIX project

The discussion focused on data-sharing challenges and long-term sustainability within AUTOPIX⁷, including how curated datasets are classified over the project's lifecycle and how to integrate data generated prior to the project from an industry perspective.

The SIP members noted that the EHDS could create growth opportunities for SMEs, raising questions about data commercialization models, an area where the EU needs to improve its position. The group discussed the need for projects that strengthen data-sharing strategies and support the development of robust data-sharing plans. Federated data approaches (as in IDERHA⁸) and potential models for hospitals supplying data were also considered, with a call to accelerate incentives for industry participation.

² <https://www.predictom.eu/>

³ <https://www.ai-mind.eu/>

⁴ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/cluster-1-health_en

⁵ <https://www.brainhealth-partnership.eu/>

⁶ <https://catalogues.ema.europa.eu/>

⁷ <https://www.autopix-project.eu/>

⁸ <https://www.iderha.org/>

Finally, suggestions were made to explore hybrid models through pilots, drawing on IDERHA, GREG⁹ and H2O¹⁰, and to develop a “data leveraging playbook” to guide future efforts.

3.3. The added value of Industry in-kind contributions in IHI activities

The SIP noted that the “US most favored nation” strategy is making companies more cautious in providing in-kind contributions. Several members emphasized that strong alignment across partners is essential to maintain EU competitiveness.

Questions were raised about how collaborations function over long project durations and how to assess whether mutual expectations are being met; public–private partnerships were seen as helping to shift culture, and there was interest in developing a tool for measuring and tracking collaboration quality. The importance of the individuals involved was also highlighted. It was noted that companies often bring valuable assets that cannot be formally captured under current IHI rules, suggesting a need to inform future policy design.

Additional reflections included the role of skills-transfer programmes from industry to academia, the ability of bibliometrics to track cross-sector collaboration through author affiliations, and the relevance of monitoring spin-outs. IKAAs were also noted to be linked to sustainability, given they are reported to funding bodies and thus create traceability for long-term impact.

3.4. The role of the scientific advisory body in European partnerships – Lessons learned from SIP members

Members reflected on the evolution from the IMI Scientific Committee to the IHI SIP and discussed how such a scientific advisory body should continue in future Joint Undertakings. They praised IHI’s office support and SIP current functioning but noted challenges in following up discussions and called for more frequent, topic-focused meetings. Several members felt that too much time was spent on community ideas relative to the number of topics generated, and that clearer feedback loops on topic text evolution would be valuable. Broader engagement with SRG members and a more explicit outreach role for SIP members were suggested.

Participants highlighted the importance of early, safe-space discussions on draft topics and suggested that SIP outputs (e.g., AWP comments) should be presented as consolidated positions. They emphasized the need for patient representation and deeper interactions with industry partners. The onboarding of new SIP members was viewed as crucial, given the complexity of IHI, and several noted that the SIP role extends beyond pure scientific advice.

Members also discussed the SIP’s visibility, suggesting that SIP representatives could act as ambassadors as some stakeholders are unaware of the group. They stressed the value of the safe

⁹ <https://ihi-greg.eu/>

¹⁰ <https://health-outcomes-observatory.eu/>

environment for open discussion but acknowledged the heavy workload. Concerns were raised about ensuring that scientists can meaningfully comment on innovation and industry dimensions, and that discussions remain sufficiently deep. Finally, members reiterated the importance of maintaining a diverse composition, including industry and the Commission, to navigate IHI's complexity, and noted that third-party ideas, while demanding, demonstrate that IHI remains open and not a closed ecosystem.

To conclude, the SIP chair who is also a former member of the IMI Scientific Committee has agreed to compile a note based on her experience from IMI and IHI, and which could inform a forward looking proposal for what an advisory body should look like for a future EU Joint Undertaking (JU) succeeding IHI, drawing directly on lessons from both governance models.

4. Exploring areas for future IHI activities: Preparing the 2026 two-stage Call

4.1. Update on themes in the pipeline

European Healthcare Incubator Network

There is broad agreement that Europe needs more robust mechanisms to support biotech and pharmaceutical start-ups, especially in the earliest stages where mentoring, access to expertise, and low-TRL development are critical. The proposed incubator initiative seeks to address these gaps by establishing a network of incubators capable of providing targeted advisory services and enabling more effective matchmaking between emerging companies and established industry actors. Despite the strategic intent acknowledged by the SIP, the SIP raised questions and asked for further clarification about its design and governance.

Real-world Embedded AI-Linked Clinical Trials (REAL-CT)

The SIP discussion centered on refining the scope, terminology, and strategic positioning of a proposed initiative aimed at improving clinical trial (CT) design and execution through enhanced use of real-world data (RWD), digital tools, and future capabilities under the European Health Data Space (EHDS).

4.2. New themes for preliminary discussion

Decode the immunoscience of age-related exacerbations (DEAGE)

The SIP acknowledged the relevance of the proposed theme, but a request was raised to clarify which range of diseases is intended to be covered within the envisaged initiative.

AI-driven approach to eliminate the need for longer-term second species toxicology testing (WAIVER)

Overall, there is strong support for the initiative, confirming that both the scope and the objectives are highly relevant. The SIP highlighted ongoing and upcoming UK efforts—particularly the initiative reviewing the use of two species in regulatory toxicology studies—and recommended that the topic text should reflect how this work could influence the project and where synergies might be built.

Establish a platform of skin New Approach Methodologies (NAMs) for non-clinical assessments of biologics

The SIP discussion highlighted the need to strengthen the idea's focus on advancing NAMs beyond current OECD and EMA requirements, with clearer emphasis on their regulatory qualification to support the EU's ambition to phase out animal testing. The SIP members recommended improving the clarity of the challenge, impacts, and secondary benefits, taking inspiration from recent presentation materials. Further clarification is also needed on whether the models will apply to single or multiple drug types, with the intention of developing several models over time. Cross-sector collaboration should be expanded—particularly the involvement of MedTech in organ-on-chip systems and the integration of companion diagnostics.

4.3. Looking forward to 2027

IHI 2026 – 2027 Science Plan

Considering the IHI 2026-27 Science Plan, the SIP noted the importance of aligning with the evolving policy landscape, including the EU Life Sciences Strategy, the AI Act, the EHDS, the forthcoming Biotech Act, the 3Rs agenda, as well as updates to environmental and chemical regulations and the revision of the MDR/IVDR.

The SIP welcomed and provided preliminary suggestions on the following early ideas presented by EFPIA:

- Value of surrogate endpoints
- AI-Based predictive tools

The SIP members provided their perspectives on future proposals involving AI-based predictive tools, particularly regarding their clinical relevance, robustness of underlying data, transparency of algorithms, ethical considerations, and potential to enhance decision-making across the healthcare ecosystem.

Horizon Europe portfolio

The SIP discussion focused on how the proposed programme could practically connect with IHI while avoiding overlaps with existing initiatives. It was noted that New Approach Methodologies (NAMs) provide a good example of constructive complementarity, and ongoing efforts—such as the

BRIDGE11 project's engagement with the European Commission—aim to ensure alignment with future programmes and policy developments. Some emphasized the importance of actively building synergies within topic texts and clustering related programmes and projects to bring researchers together, with CSAs cited as effective tools for this, including in the NAMs domain.

Opportunities to strengthen uptake through European Research Area (ERA) actions¹² were also highlighted. Researchers from existing NAMs projects have already approached EMA regarding validation strategies, prompting suggestions for an NAMs-focused workshop to help frame the scope. Early engagement with regulators—both EMA and relevant EC policy actors such as the JRC—was strongly recommended, particularly for discussions on validation pathways.

Finally, the SIP reflected on the differing roles of IHI and Horizon Europe: IHI operates in a precompetitive space, whereas Horizon Cluster 1 can be highly competitive. Ensuring the relevance of regulatory considerations was seen as crucial, with parallels drawn to ongoing work on clinical trials in biotechnology.

SIP discussion on ongoing horizontal themes

1) Mental Health

The SIP discussion underscored the growing relevance of mental health (MH) within EU research agendas, noting that Horizon Europe already has well-developed work on mental health and digital addiction. Participants highlighted several system gaps, such as rising ADHD diagnoses, limited access to psychologists, and broader healthcare workforce shortages. It was suggested to analyze the mental-health journey across the lifespan to identify gaps suitable for IHI projects.

SIP members also noted ongoing work on MH biomarkers and recommended connecting to existing industry groups active in this space. Issues of under-resourcing and suboptimal access to MH care were emphasized, with counselling often prioritized over therapy and primary prevention remaining underfunded. Current reliance on questionnaires was viewed as outdated, prompting calls for new approaches to prevention, diagnosis, and referral pathways.

Strategic considerations included identifying research gaps, ensuring clear EU added value, securing cross-sector collaboration, and assessing industry relevance, including opportunities to involve philanthropic partners. Industry was encouraged to present potential project ideas to the strategic ideation group.

Several operational next steps were proposed: mapping MH elements in ongoing IHI projects; sharing insights with SIP to identify gaps for the 2027 portfolio; gathering inputs from the IHI office, industry. Further actions include identifying topics of interest for industry, exploring MedTech contributions, and organizing an online session to review learnings from ongoing IHI work in mental health.

¹¹ Breakthrough Regulatory Innovation and Development through sandbox Environments (<https://bridge-ihl.eu/>)

¹² <https://european-research-area.ec.europa.eu/era-policy-agenda-2025-2027>

2) Healthcare delivery optimization (HCDO)

The discussion focused on clarifying industry relevance, strengthening cross-sector engagement, and identifying concrete research and innovation opportunities related to healthcare workforce efficiency, productivity, and system resilience.

The SIP questioned the specific interest and role of industry, noting that several topics appear predominantly research-oriented. It was suggested to establish a dedicated subgroup with industry partners to refine priorities and ensure alignment with ongoing initiatives. The need to understand how current IHI projects have already addressed workforce-related challenges was also raised.

Some members highlighted strategic alignment for MedTech, particularly links with mental health through the cognitive load on healthcare workers and pointed to existing calls and capacity-analysis work that touch on this agenda. The broader attractiveness of the sector was discussed, with emphasis on education, upskilling, national workforce self-sufficiency, and the indirect benefits generated by ongoing IHI projects.

Prevention emerged as a recurrent theme, especially in reducing the burden on healthcare systems caused by high patient volumes and socio-economic factors. The SIP stressed the need for new technologies to increase productivity, improve care pathways, support digital adoption, and enhance efficiency throughout the patient journey. Proposals included workforce skills development, cross-training, staff exchange schemes, crisis-management preparedness, and potential synergies with the BE READY programme¹³. Decentralized care and remote-monitoring solutions were identified as areas where multiple IHI projects already provide useful foundations.

Key questions remain regarding the precise research focus, national components, and definition of value within an EU-level partnership. Looking ahead, participants highlighted relevant work in Hospital@Home¹⁴ models, ongoing IHI calls on care pathways, and related ICU and digital health projects. A portfolio overview—similar to presentations on cardiovascular or digital topics—was recommended to map current assets and identify remaining gaps. Ensuring participation of the right partners, including insurers and non-profit healthcare actors, was seen as essential for impact and deployment.

5. Review of the latest ideas submitted by the wider health and research community

The SIP reviewed the latest three ideas submitted by the broader health and research community and discussed how to finalize the outcomes with respective recommendations to be published on the IHI website.

¹³ <https://beready4pandemics.eu/>

¹⁴ <https://www.ihi.europa.eu/projects-results/project-factsheets/hospitalathome>