innovative health initiative

IHI JU Science & Innovation Panel (SIP)
12th Report to the IHI JU Governing Board

12th MEETING OF THE SIP
17.09.2025 (10:00 – 17:15 CET) – Hybrid meeting

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

- IHI Progress Report
- IHI Oncology portfolio
- Exploring areas for future IHI activities
    - Preliminary ideas for 2026
    - Horizontal theme 'Implementation science, from scaling to impact'
- Review of the latest ideas submitted by the wider health and research community
- Identifying ad hoc expertise for the SIP

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1. IHI Progress Report

The SIP welcomed the presentation by the IHI Executive Director on synergies with other EU programmes and initiatives and acknowledged the strong alignment between IHI and EU frameworks such as Horizon Europe. Regular interactions with entities including HaDEA, HERA, EIC, EIT, EDCTP3, and the European Partnerships in Health were noted as key contributors to this alignment. The SIP also recognised the growing engagement efforts undertaken by IHI, including participation in awareness-raising events and targeted activities aimed at involving regional stakeholders, SMEs, and biotech companies.

3. IHI Oncology portfolio

The SIP expressed its appreciation for the high-quality presentation, which provided a comprehensive overview of cancer epidemiology, demonstrated clear links with the EU Cancer Plan, outlined the IMI-IHI Cancer Portfolio, and concluded with a focused exploration of the potential of theranostics in specific areas of cancer research and treatment.

The SIP acknowledged the availability of existing resources such as health spotlights and factsheets on the IHI website but emphasized the need for broader dissemination of the information about the oncology portfolio such as the presented materials to academic and regional stakeholders. This was seen as essential for stimulating idea generation, fostering innovation, and enhancing academic collaboration. Furthermore, the SIP underlined the importance of transparency in the use of public funds, equitable geographical distribution of projects, and overall public accountability.

Regarding potential scientific gaps and opportunities, the SIP highlighted the need to advance understanding of high-mortality cancers, particularly pancreatic and brain cancers, and emphasized the importance of integrating prevention and early detection strategies alongside conventional treatments. The SIP also noted that hematologic malignancies have received limited attention. Additionally, the SIP identified a gap in addressing long-term quality of life and follow-up care for cancer survivors.

Considering existing initiatives and precompetitive research, the SIP discussed the IHI-funded EASYGEN project [1] developing a point-of-care manufacturing device, particularly the need for links to academic CAR-T cell manufacturing and noted ongoing collaborations and infrastructure development. Questions were raised regarding the potential for competition between academic centers. The SIP acknowledged IHI's role at the forefront of precompetitive research, with active efforts to address intellectual property challenges within such collaborations. Additionally, the SIP emphasized that future cancer treatments are likely to rely on locally produced cellular therapies, underscoring the importance of infrastructure development and support—an area where IHI could play a strategic role.

The SIP explored additional regulatory dimensions and the broader policy landscape, highlighting the ongoing evolution of pharmaceutical legislation and the critical need to demonstrate value to patients and taxpayers. It emphasized how IHI could further complement other EU efforts. Furthermore, the SIP addressed concerns around affordability and its implications for access to innovation, while also discussing the influence of IHI-funded projects on shaping clinical guidelines and regulatory frameworks across Europe.

In conclusion, the SIP praised the presentation for providing a solid strategic foundation and for illustrating promising opportunities for future collaboration. It also acknowledged the inclusion of cross-sectorial perspective, particularly in relation to improving access to innovation for patients across the European Union.

4. Exploring areas for future IHI activities

4.1. Preliminary ideas for 2026

[1] https://www.easygen-consortium.eu/

Three preliminary ideas were presented by the industry trade associations (1-3), and five ideas were presented by the European Commission (4-8). Unfortunately, pre-reads were made available to the SIP only on the day before the meeting. The opinion of the SIP is summarized as follows:

1) "European Accelerator"

The SIP welcomed the proposed idea aiming to reduce fragmentation in the European life sciences sector, which is currently shaped by diverse ecosystems, funding pathways, and limited coordination among stakeholders. The idea is to create a one-stop shop that connects physical and virtual incubator resources, start-ups, and the Innovative Health Initiative (IHI). This would help build a structured public-private incubation model to support the development of assets along the research and clinical development (RCD) value chain.

The SIP noted that the concept appears heavily industry-driven and questioned its connection to academic ecosystems. It suggested that infrastructure linking innovation to hospitals and healthcare providers should be considered. A two-stage approach was proposed, which could initially limit engagement with public partners to allow for gradual integration.

Concerns were raised about the 3A criteria (Affordability, Availability, and Accessibility)[2] highlighting that these may be difficult for start-ups to meet due to integration challenges. The SIP referenced the EU Start-up and Scale-up Strategy and recommended aligning the initiative with broader EU innovation goals to better support emerging companies.

While acknowledging the importance of supporting start-ups, the SIP questioned whether IHI is the right framework for this purpose. It asked for clarification on the types of activities that would be funded and the role of precompetitive research and development. The SIP concluded that IHI could be suitable for a pilot initiative, with funding primarily directed to start-ups, supported by committed private partners and potentially involving foundations.

The SIP also pointed out the lack of regulatory engagement, noting that regulatory processes are often burdensome for start-ups. It recommended involving regulators early in the process, possibly through an advisory board, and learning from best practices. To measure success, the SIP suggested tracking the number of start-ups progressing through investment stages.

Finally, the SIP discussed the common model of university spin-offs in the EU and the challenge of moving innovation beyond Technology Transfer Offices (TTOs). It emphasized the need for better access to private investors and government programs and highlighted the value of matchmaking between stakeholders. Regulatory support was identified as especially important for drug development and attracting funding.

[2] Affordability, Availability, Accessibility: key requirement under Article 125(3) of the Single Basic Act (Council Regulation (EU) 2021/2085) for projects funded under institutionalised European partnerships, such as IHI.

2) *NEXUS – New EXperimental combinations Using Simulation*

The SIP noted that the idea aims to identify optimal drug combinations using artificial intelligence, automated literature screening, clinical cohorts, aggregated trial data, and knowledge graphs that reflect patient diversity and biomedical insights. The tools developed would estimate how population changes affect trial outcomes, support patient stratification, and guide the design of clinical trials for combination therapies and specific indications.

The SIP questioned the accuracy of the proposed tool and suggested involving industry partners to test and refine it. Success criteria still need to be clearly defined. The multiplicity of the envisaged data sources raised concerns stressing the need to select datasets carefully to avoid bias in model training. The SIP emphasized the importance of wet lab validation alongside AI development to ensure reliability of the algorithms.

The SIP noted the tool's potential to inform Phase III clinical trial design and asked whether it could also support earlier phases in drug development, post-authorisation treatment optimization strategies and regulatory pathway development.

Ultimately, the SIP referenced existing AI-based treatment optimization projects and suggested considering specific treatment contexts. In particular, the SIP questioned whether a one-size-fits-all approach is feasible given the diversity of algorithms and proposed focusing the tool's development initially on oncology.

3) *REAL-CT – Real-world Embedded AI-Linked Clinical Trials*

The proposed idea aims to establish standardized protocols and best practices for clinical trial design, supported by AI-driven tools for patient identification and recruitment strategies that would integrate into routine clinical care through the use of electronic health records (EHR) and real-world data (RWD).

The SIP mentioned that tools for pragmatic trials are already available and questioned the added value of the proposed idea compared to existing solutions and how it could improve the integration of clinical trials into routine care. The necessity of AI can be challenged, given that inclusion/exclusion criteria are predefined. On the other hand, AI could help identify eligible patients by screening large EHR datasets to match criteria, e.g., using lab value thresholds for trial planning.

Leveraging AI could for instance contribute to reduce clinical trials costs by leveraging existing clinical exams but also to reduce redundancies that could be burdensome for patients. Therefore, the role of patients would be important to consider in the overall process, in particular when considering GDPR concerns about identifying patients before consent, stressing the need for systematic improvements in CTs. The development of a governance and ethical framework by addressing GDPR, consent for AI-driven pre-screening, and cross-border data sharing should be considered early in the design phase. The SIP suggested looking into other approaches aiming at reducing trial size and accelerating time-to-market/time-to-patient access.

The SIP raised the question of alignment with EHDS because clinical trial data is explicitly included in the EHDS scope for secondary use. Moreover, the 2019 European Commission Recommendation (EU) 2019/243 sets out a framework for a European EHR exchange format and, under EHDS, sponsors and health data holders must make electronic health data from clinical trials available through Health Data Access Bodies (HDABs). This highlights the need to anticipate a stronger cross-sectoral approach in order to avoid potential issues related to vendor-locked EHRs and lack of APIs (Application Programming Interfaces). This could be done by piloting AI-linked recruitment in real-world settings through feasibility testing within hospital EHR systems using FHIR[3]-based APIs to ensure interoperability.

The SIP mentioned the interest to much better identify, screen and recruit trial participants from electronic systems used in healthcare (including point of care).

The SIP recommended to map practical synergies with EHDS and consider EMA's network for RWD analysis to support regulatory decisions and pharmacovigilance (DARWIN EU) to align proposed activities with EU frameworks to ensure compliance and leverage existing infrastructures. Engaging with Horizon Europe consortia and exploring partnerships with initiatives such as Real4Reg[4] and More-EUROPA[5] could be relevant to avoid duplication and share methodologies. Finally, it would be pertinent to consider an industry engagement strategy by defining value proposition for MedTech to secure investment and participation in such consortia.

4) DRUP-Cancer – Industry-supported Drug Rediscovery Protocol (DRUP) trials

The idea was presented as a drug rediscovery platform aiming to streamline investigator-driven pragmatic trials expanding nation-wide access to affordable, equitable multi-modal interventions for advanced cancer patients based on the model of the PRIME-ROSE initiative[6] and expanding it beyond rare cancers, before considering expansion to other diseases (e.g., cardiovascular).

The SIP noted the expected outcomes of selecting candidate drugs for repurposing and developing regulatory guidance for DRUP trials as well as guidance for reimbursement. It was also noted that new therapeutic indications should be requested to be approved before reimbursement.

A useful resource to consider is the HMA-EMA EU Repurposing pilot (*Report by the EU regulatory network on the learnings and recommendations from testing a proposal for a framework to support not-for-profit organisations and academia in drug repurposing*)[7].

The SIP emphasized the need to bring together industry and clinician scientists, especially when considering rare cancers, where data pooling from heterogeneous trials is challenging. To further

[3] Fast Healthcare Interoperability Resources
[4] https://www.real4reg.eu/
[5] https://www.eurordis.org/projects/more-europa/
[6] https://www.matrix-fkb.no/en/prime-rose/home
[7] https://www.ema.europa.eu/en/documents/report/eu-repurposing-pilot_en.pdf

develop the idea, it would be relevant to seek synergies with or build on experience from ongoing EU funded initiatives such as REMEDi4ALL[8] and REPO4EU[9].

Furthermore, it would be pertinent to consider the global repurposing research landscape, including academic and philanthropic initiatives such as Cures Within Reach[10].

The SIP also referred to the new EU pharmaceutical legislation, questioning the future of the PUMA pathway[11] for pediatric drug repurposing. The question is whether PUMA will remain viable or be replaced by alternative incentives or public-private models. Similarly, the FDA's Project Renewal is a public health initiative led by the FDA's Oncology Center of Excellence (OCE), where regulators and academia collaborate on new indications (e.g., capecitabine[12], temozolomide[13]) highlights the need for a collaborative model between industry and regulators, including HTA bodies.

The SIP recognized that repurposing lacks commercial viability due to high costs. Therefore, public funding is essential because it bridges the investment gap where private incentives are insufficient. It enables non-commercial clinical trials led by academic institutions or public-private partnerships, supports pan-European collaboration to pool patient populations and data, and reduces financial risk for industry, encouraging participation in collaborative models.

The SIP recommended considering prioritizing certain disease areas for drug repurposing, by focusing on conditions that share common biological or genetic pathways, even if they belong to different therapeutic fields. This approach allows cross-pollination of knowledge and treatments, i.e. between cardiology and oncology, where certain cancer drugs target pathways (e.g., angiogenesis, inflammation) that are also relevant in cardiovascular diseases; between dermatology and immunology, where autoimmune mechanisms in skin disorders overlap with those in systemic inflammatory diseases; between neurology and oncology, where compounds affecting cell growth or signaling in cancer may have applications in neurodegenerative diseases; between metabolic disorders and rare diseases, where shared enzyme or receptor targets can open opportunities for repurposing. This strategy should be supported by genomic and molecular profiling, which can reveal common targets across seemingly unrelated diseases.

5) Genome of Africa

[8] REMEDi4ALL – European Platform for Medicines Repurposing (https://remedi4all.org/)
[9] REPO4EU – Precision Drug Repurposing for Europe and the World (https://repo4.eu/)
[10] https://www.cureswithinreach.org/programs/current-research-map/
[11] Under Paediatric Regulation (Regulation (EC) No 1901/2006), a framework for off-patent medicines, the Paediatric Use Marketing Authorisation (PUMA) was introduced to encourage repurposing for pediatric indications, with incentives including 10 years of data exclusivity.
[12] https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-updated-drug-labeling-including-new-indications-and-dosing-regimens-capecitabine
[13] https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-new-and-updated-indications-temozolomide-under-project-renewal

The proposal focuses on conducting large multinational GWAS supported by robust health data, strengthening sequencing capacity in Africa, and establishing an African data analysis center. It also includes developing a biobanking network and a Pan-African ethical framework for data sharing.

The SIP questioned whether this is primarily a policy rather than a research-driven initiative and debated the relevance of pharmacogenomics, while acknowledging the importance of ethnicity given that migration increases the likelihood of patients receiving medicines not developed for diverse populations. Similar work is already underway in the US but faces regulatory and ethical challenges.

The SIP emphasized the need for diversity, more equally represented ethnic differences and concluded that issues such as inclusivity in clinical trials are already being addressed. The current proposal as it is presented does not align well with the IHI framework.

6) Validating emerging NAMs

The proposed concept is to accelerate the development, qualification, and regulatory acceptance of New Approach Methodologies (NAMs), support their prioritization in line with EFPIA's Basket 2[14], and create a secure environment for data sharing.

The SIP mentioned that a multi-million project is ongoing in the U.S. NIH, with EMA also involved. A 3Rs Working Party has been established at EMA in 2010. There is still a lack of validated human NAMs (for testing medicines to be used in humans). It would be worthwhile considering two EMA reflection papers on NAMs as relevant references, namely the *Draft Reflection Paper on the Current Regulatory Testing Requirements for Medicinal Products for Human Use and Opportunities for Implementation of the 3Rs* [15] which includes detailed identified opportunities for 3Rs implementation and the *EU Horizon Scanning Report on New Approach Methodologies (NAMs)*[16].

To advance the development and adoption of NAMs, the initiative should broaden its scope to include the MedTech sector, ensure relevant integration of digital solutions such as digital twins, and prioritize the validation of alternative testing methods.

To accelerate the adoption of NAMs, efforts should focus on validating these methods and creating a centralized database of validated alternatives to animal testing to guide researchers and developers.

[14] EFPIA has piloted a 3-Basket Approach to categorise current animal tests used in the development of pharmaceuticals. Basket 2 refers to animal testing purposes for which there are concrete ideas and hypotheses for the development of alternative methods (Source: EFPIA Recommendations on Phasing Out Animal Testing for Chemical Safety Assessments JUNE 2025 - https://www.efpia.eu/media/meef32ki/efpia-recommendations-on-phasing-out-animal-testing-for-chemical-safety-assessments.pdf)

[15] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-current-regulatory-testing-requirements-medicinal-products-human-use-opportunities-implementation-3rs-revision-1_en.pdf

[16] https://www.ema.europa.eu/system/files/documents/report/new-approach-methodologies-eu-horizon-scanning-report-en.pdf

Strong collaboration between regulators and industry is essential to ensure acceptance and implementation, while clearly defining the precompetitive space will foster cooperation in this competitive field. Additionally, regulatory differences between the EU and the US, particularly regarding in silico trials, should be addressed to promote alignment and global competitiveness.

7) A technology-based approach to improving transplantation in Europe

The idea proposes innovations based on new cold storage and transport solutions, 3D printing, tissue engineering, regenerative medicine and ATMPs, advanced genomics techniques (including CRISPR, genotyping, and gene editing for tolerance), AI-driven organ matching, and improved post-transplant monitoring to transform the future of transplantation and personalized medicine.

The discussion focused on the development and scale-up of Advanced Therapy Medicinal Products (ATMPs), particularly in relation to academic leadership, regulatory complexity, and cross-sector coordination. ATMPs, such as CAR-T cell therapies, are highly innovative but face significant barriers to broader implementation across the EU. Lessons from CAR-T therapies and emerging technologies such as AI, digital twins, and 3D bioprinting highlight the need for coordinated EU-level action to accelerate innovation and ensure equitable access.

The SIP discussed the challenges related to the idea and highlighted that ATMP development is largely driven by academic centers, raising concerns about how to support technology transfer and scale-up to industrial levels, as seen with CAR-T therapies. It also pointed out challenges linked to regional and national ownership of organs and questioned how healthcare economics could make these processes more efficient. Moreover, the challenges related to the regulatory specificities between SoHO (Substances of Human Origin) cells and organs and the involvement of multiple agencies across the EU complicate governance and coordination.

Therefore, the SIP is of the opinion that a topic in this area should address following areas:

- ATMP scale-Up: with the development of EU-level guidance for technology transfer and industrial manufacturing, leveraging lessons from CAR-T therapies.
- Governance: by establishing a central coordination mechanism for SoHO and organ governance, aiming to harmonize regulatory frameworks across Member States.
- Digital solutions: through the creation of an EU-wide digital platform for organ allocation and AI-based matching, integrating real-world data for predictive analytics.
- Innovation in transplantation: by investing in advanced cold storage and transport technologies, and supporting research in 3D bioprinting, tissue engineering, and regenerative medicine.
- Post-transplant monitoring: with the development of standardized protocols and interoperable systems for long-term patient monitoring and data sharing.

8) Cybersecure medical devices and IVD

The proposal is to develop and pilot best practices for cybersecure medical devices and IVDs, focusing on vulnerability management, supply chain due diligence and practical implementation through pilot projects.

Although the SIP recognizes that the increasing connectivity of medical devices and IVDs brings significant benefits for patient care but also introduces cybersecurity risks that can compromise patient safety, data integrity, and healthcare system resilience, it found that the presented idea didn't provide sufficient details with regards to meaningful expected outcomes and fell short in illustrating the alignment with IHI SRIA.

The SIP suggested considering the geopolitical context and potential overlaps with the defense industry, such as the use of drones. Moreover, it proposed reviewing previous projects on digital certification for connected devices and projects in alignment with EU cybersecurity regulations (e.g., NIS2, MDR/IVDR) and international standards.

4.2. Horizontal theme 'Implementation science, from scaling to impact'

The IHI office presented implementation science as "*the scientific study of methods to promote systematic uptake of research findings and other evidence-based practices into routine practice and hence to improve the quality and effectiveness of health services and care*" and was illustrated with examples of IMI/IHI projects addressing the barriers that slow or halt the uptake of proven health interventions and evidence-based practices.

The SIP noted the impressive outcomes of MOBILISE-D achieved within tight timelines and suggested to maximize learning from successes by engaging with the consortia to understand how this was accomplished.

For projects that remain at early stages and need additional support to move from research to real-world application, there is a need to balance solving research questions with leveraging existing platforms and fostering a startup mindset to ensure innovation translates into implementation.

Currently, there is a lack of mapping for resources linked to the 3As (Availability, Accessibility, Affordability) and therefore it would be relevant to promote deliverables and assets from projects like EHDEN [17]. More generally, it is essential to clearly define and measure the expected impact on implementation-related deliverables as a core component of projects review and evaluation methodology.

Building on learnings from the C4C project [18], namely through the recently published paper [19] that explores the development and implementation of the developed services, using the Technology

[17] European Health Data & Evidence Network (https://www.ehden.eu/)
[18] https://conect4children.eu/
[19] https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2025.1531276/full

Readiness Levels (TRLs) and Service Readiness Levels (SRLs) frameworks to measure service progression and operational maturity, the SIP emphasized the importance of anticipating further barriers to uptake. It also highlighted the strategic use of project resources for field intelligence, including engagement with regulators, to support future implementation.

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

The SIP reviewed the five most recent ideas submitted by the broader health and research community. One of these had already received a favorable opinion and the SIP was informed that it is currently under assessment in preparation for a potential call in late 2026. Two ideas were considered unsuitable for further consideration. The SIP agreed to retain one idea due to its relevance, although its scope will need to be adjusted to better align with IHI's priority areas. Lastly, the most recently submitted idea was discussed in greater detail, and the SIP reached consensus on how to formulate its outcome.

5. Identifying ad hoc expertise for the SIP

During a close session, the SIP members representing the European Commission, the industry and the States Representatives Group (SRG) exchanged with the IHI Office and the SIP chairperson and vice-chairperson on the procedure to engage with ad hoc panelists in supporting the SIP with additional scientific or technical expertise in accordance with Article 124.2 (e) of the Single Basic Act. The SIP members agreed to identify gaps and areas to be covered taking into consideration the themes currently explored for future IHI activities.