# IHI specific Key Performance Indicators

| KPI Name | Unit of measurement | Baseline[1] | Target[2] 2023 | Target 2025 | Target 2027 | Ambition >2027 | Status |
|---|---|---|---|---|---|---|---|
| **Resources, processes and activities (inputs)** | | | | | | | |
| **1.1.** Involvement of multiple health care stakeholders | Share of projects involving more than two types of health care stakeholders [research higher or secondary education organisations (private or public), small & medium enterprise (SME), large company (for-profit legal entity), non-governmental organisations (NGOs), healthcare professional organisation/healthcare provider, patient / citizen organisation, regulators or regulatory body, notified body, health technology assessment body (HTA), health care payer, charity and foundation, public authority] as project participants or advisors | 50% | 55% | 60% | 65% | 70% | |
| **1.2.** Cross-sectoriality of the partnership | Share of projects bringing together private members and/or contributing partners (or their affiliated or constituent entities) from two or more technology sectors[3] | 25% | 60% | 65% | 70% | 75% | |
| **1.3.** Engagement of regulators | Number of projects interacting with regulators[4] to contribute to new or improved guidelines or methodologies | 13 | 0 | 5 | 10 | 20 | |

[1] Baselines are derived (where possible) from the Innovative Medicines Initiative (IMI2) as predecessor to IHI.
[2] Reporting methodology: cumulatively reporting from the beginning of IHI until 31/12/2030.
[3] The IHI private members COCIR, EFPIA, EuropaBio and MedTech Europe have members from several technology sectors. Contributing partners might also cover further technology sectors.
[4] In this document, the term 'regulators' refers to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified Bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative.

| KPI Name | Unit of measurement | Baseline | Target 2023 | Target 2025 | Target 2027 | Ambition >2027 | Status |
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| **Outcomes** | | | | | | | |
| **2.1.** Cross-stakeholders' collaboration | Share of multi-stakeholders' publications identified through bibliometric data analysis [research / higher or secondary education organisations (private or public), small & medium enterprise (SME), large company (for-profit legal entity), non-governmental organisations (NGOs), healthcare professional organisation / healthcare provider, patient / citizen organisation, regulators or regulatory body, notified body, health technology assessment body (HTA), health care payer, charity and foundation, public authority] | 65% | 65% | 66% | 67% | 70% | |
| **2.2.** Public-private collaboration | Share of publications across public and private stakeholders identified through bibliometric data analysis (academic, pharmaceutical, biopharmaceutical, medical technologies, biotechnologies) | 65% | 65% | 66% | 67% | 70% | |
| **2.3.** Project outputs for use in clinical practice and health research development and innovation (R&D&I) | Number of:<br>• new tools for studying new potential drug targets such as new pharmacological tools, therapeutic modalities, and patient-derived assays available to the scientific community<br>• new tools to test diagnostically and/or therapeutically relevant hypotheses in pre-clinical models and/or clinically in uncharted areas of disease biology<br>• new tools for prediction, prevention, interception, surveillance, diagnosis, treatment, and management options to prepare for major epidemic outbreaks<br>• new biomarkers of disease (relevant for diagnosis, efficacy, safety, or prevention) identified and experimentally validated<br>• new taxonomies of disease or new stratifications to define patient sub-populations | 100 | 0 | 50 | 120 | 150 | |

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| **Outcomes** | | | | | | | |
| **2.4.** Integrated health care solutions considering end-users' needs | Number of project outputs that combine people-centred integrated solutions (pre-competitive tools, methods, solutions as well as products/services or combined products) | No baseline available | 0 | 3 | 7 | 10 | |
| **2.5.** Methodologies for value assessment of integrated solutions | Number of Methodologies for the assessment of the added value of combinations of products/services or combined products (including development of patient reported outcomes / experience measures and statistical methods/tools), submitted to health care authorities and organisations[5] | No baseline available | 0 | 2 | 3 | 5 | |
| **2.6.** New or improved clinical guidelines | Number of projects contributing to the development of new or improved clinical guidelines | 13 | 0 | 5 | 10 | 20 | |
| **2.7.** Management of health data | Number of common standards, protocols and frameworks developed by the projects to enable better access to data, sharing and analysis of health-related data | No baseline available | 0 | 3 | 7 | 10 | |
| **2.8.** Demonstration of data integration | Number of pilots developed by the projects demonstrating integration of data provided by the private and public sectors | No baseline available | 0 | 5 | 10 | 20 | |
| **2.9.** Demonstration of AI in health care | Number of pilots developed by the projects demonstrating feasibility of use of artificial intelligence in health care | No baseline available | 0 | 1 | 2 | 3 | |

[5] Health care authorities and organisations to which it is referred here are HTA bodies, and Regulatory Authorities, Payers and Public Authorities

- HTA agencies/bodies: http://www.adhophta.eu/toolkit/assets/tools/AdHopHTA_toolkit_tool24_document.pdf; https://www.eunethta.eu/about-eunethta/eunethtanetwork/)
- National and regional public procurement organisations
- National payer and reimbursement organisations (incl. health insurance companies)
- National healthcare authorities: examples are: Dutch NZA; http://www.euregha.net/ (membership list of regional and local health authorities); https://eurohealthnet.eu/list-of-members/ (first part of the membership, not the research members)

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| **Impacts** | | | | | | | |
| **3.1.** Creation of sustainable resources and infrastructures that facilitate translation of the knowledge to innovations | Number of established new research networks, new clinical networks, further public-private collaborations on health R&D&I, research infrastructures, biobanks, collaborative platforms etc. (that outlive the project and are accessible to broader scientific community) | 10 | 0 | 4 | 7 | 15 | |
| **3.2.** Development of preventive or therapeutic strategies in different therapeutic areas to address unmet public health needs | Share of projects that aim to develop new or improved existing methodologies also across disciplines addressing public health needs[6] included in the list of the WHO Europe Health 2020 priority areas[7] | No baseline available | 90% | 90% | 90% | 90% | |
| **3.3.** Cross-sector activities established by the partnership that will help contribute to a globally competitive EU health care industry | Number of activities in which cross-sector collaboration drives health innovation, such as:<br>• Spin-off companies, entities or activities created based on outputs of the project (e.g., new commercial or non-profit entities)<br>• Collaboration agreements between large companies[8] & SMEs[9] established for purposes that go beyond the scope of the project during and/or after project lifetime.<br>• Other activities where the joint contribution of different al partners has generated cross-sectoral health innovation. | No baseline available | 0 | 5 | 10 | 20 | |

[6] SBA definition (article 125.1) "For the purpose of this Regulation, an unmet public health need shall be defined as a need currently not addressed by the health care systems for availability or accessibility reasons, for example where there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people access to health care is limited because of cost, distance to health facilities or waiting times".

[7] https://www.euro.who.int/__data/assets/pdf_file/0011/199532/Health2020-Long.pdf; www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_WHO2020PriorityAreas.pdf

[8] For-profit legal entities with an annual turnover of EUR 500 million or more (Single Basic Act, Art. 123.5)

[9] Small and medium-sized enterprises (SMEs) are defined in the "EU recommendation 2003/361" (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361&from=EN) as of page 4 and in the European Commission "User guide to SME definition" (https://ec.europa.eu/docsroom/documents/42921) especially in page 13

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| | Examples of collaboration activities across health industry sectors that contributed to the transition to a green and digital economy (as outlined in the new Industrial Strategy for Europe[10]) | | | | | | |

[10] "European industrial strategy 2019-2024" (https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en) and "Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery" (https://ec.europa.eu/info/sites/default/files/communication-industrial-strategy-update-2020_en.pdf)