IDIH

INTERNATIONAL COLLABORATION
DIGITAL TRANSFORMATION
HEALTHY AGEING

IDIH Report: Towards an international collaboration in digital health, v2.0

ATC

(VERSION 2.0, 30/06/2022)

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Abstract
This document is part of the project International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living (IDIH) funded under the European Union's Horizon 2020 Research and Innovation Programme. The current report elaborates **three Common Priority Topics for international collaboration** outlined by the experts of the four IDIH Expert Groups (preventive care, integrated care, independent and connected living, and inclusive living) as the result of a series of consultations. This document is a **roadmap toward international cooperation in digital health for active and healthy ageing** and it presents an **action plan for the implementation of the three Common Priority Topics** at national and international levels from policy formation to policy evaluation.

Keywords
Preventive, integrated, independent, and inclusive care; wearables; IoT, interoperability; data protection; health ethics; infrastructures; international collaboration; digital health; roadmap; active and healthy ageing

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Table of Contents

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

List of Figures

List of Tables

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

Abbreviations and Acronyms

Abbreviation	Description
AARP	American Association of Retired Persons
AD	Alzheimer's disease
AHA	Active and Healthy Ageing
AI	Artificial intelligence
APRE	Agenzia per la Promozione della Ricerca Europea (project partner)
AR	Augmented reality
ATC	Athens Technology Center S.A. (project partner)
CAD	Computer-aided diagnosis
Catalyst	Health 2.0 LLC (project partner)
CIHR	Canadian Institutes of Health Research (project partner)
CSA	Coordination and Support Action
DG CONNECT	Directorate General for Communications Networks, Content and Technology
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
EEN	Enterprise Europe Network
EG	Expert group
EHDS	European Health Data Space
EHRs	Electronic health records
ESCP-4i	European Strategic Cluster Partnerships Going International
EU	European Union
GAC	GAC Group
GDPR	General data protection regulation
GSBC	Global SMEs Business Council (project partner)
HIPAA	Health Insurance Portability and Accountability Act
IA	Innovation Action
ICT	Information and communication technologies
ILEG	Inclusive living expert group
IoT	Internet of Things
LQR	Longitudinal qualitative research
NIH	National Institutes of Health
OECD-DAC	Organisation for Economic Co-operation and Development – Development Assistance Committee
PD	Parkinson's Disease
QOL	Quality of life

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Abbreviation	Description
R&D	Research and development
R&I	Research and innovation
RDI	Research Development and Innovation
RIA	Research and Innovation Action
RTO	Research and Technology Organisation
S2i	Steinbeis 2i GmbH (project coordinator)
Sawarabi	Sawarabi Group (project partner)
SDGs	Sustainable development goals
SMEs	Small and medium-sized enterprises
SPS	School of Pharmaceutical Science Tsinghua University (project partner)
UKRI	UK Research and Innovation
VR	Virtual reality
WHO	World Health Organisation

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Executive summary

The vision of the IDIH project is to pioneer a transnational approach to global challenges in active and healthy ageing (AHA). The international Digital Health Transformation Forum gathers global top-notch experts, executives, and advocacy groups with the aim to:

- Pave a pathway that overcomes fragmentation in R&I investments in digital health for AHA;
- Tackle system biases in AHA; e.g., in terms of gender, regions, cultures etc.;
- Generate impact from the EU and international programmes;
- Target future trends and drivers of high impact and disruption in AHA.

Furthermore, the IDIH Digital Transformation Forum acts as a networking platform with the following aims to:

- Identify opportunities and shared priorities of mutual benefit;
- Promote and increase international collaboration;
- Advance digital health in the EU and key strategic partner countries;
- Support AHA through innovation.

This document combines the work performed by the IDIH Digital Transformation Forum and consolidates these efforts into the **roadmap toward International Cooperation in Digital Health for AHA**.

The **roadmap** answers the following questions:

- "**What to enhance?**" – An analysis of three common priorities in the areas of **data governance, digital inclusion,** and **interoperability by design,** their expected impacts, and barriers to be realized are presented as a reply to the question.

- "**How to enhance?**" – A concrete **action plan for the implementation of the three Common Priority Topics** at national/international levels; from policy formation to policy evaluation, an analytical plan for how to enhance is provided.

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1 Introduction

The current document consolidates the findings of the work performed by the Digital Transformation Forum actors and presents an analytical **roadmap for the International Collaboration in Digital Health for Active and Healthy Ageing (AHA)**.

During the lifespan of the IDIH project, a series of workshops and events were organised to collect and analyse the valuable opinion of:

- four IDIH Expert Groups (EGs): Preventive Care Group, Integrated Care Group, Independent and Connected Living Group, and Inclusive Living Group;
- Users Consultation Group (UCG);
- Policy Makers and Experts;
- International stakeholders in the AHA domain.

This document represents an analysis of the results of:

- Nine Workshops of the IDIH EGs;
- Two meetings of the UCG;
- Two Programme Level Cooperation (PLC) meetings with the participation of representatives of policy bodies and funding agencies;
- Two Open International Events (IDIH week 2021 and IDIH week 2022) with the participation of stakeholders in the AHA domain from the EU, Canada, China, Japan, South Korea, US, and other countries;
- Two thematic workshops (data sharing and data regulations; inclusive design).

The current document consists of the following chapters:

Chapter 2 presents the **methodology** and work performed by the IDIH consortium for gathering and analysing information collected by the Digital Health Transformation Forum.

Chapters 3 and 4 present the **roadmap toward International Cooperation in Digital Health for AHA**.

Chapter 3 is titled **"What to enhance"** and presents the IDIH recommendations for strengthening international cooperation in Digital Health for AHA between Europe and the IDIH strategic partner countries.

A strategy to address IDIH recommendations through an **action plan** for the implementation of the three priority topics at national/international levels; from policy formation to policy evaluation is presented in Chapter 4, which is titled **"How to enhance."**

The document concludes with recommendations to IDIH stakeholders in the conclusions section and an annex that presents an analysis of cluster organisations and partnerships in the international research, development, and innovation (RDI) collaboration landscape in the AHA domain.

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2 Roadmap methodology

2.1 Expert-driven approach and user-centered perspective

The elaboration of this **roadmap**, based on the **preliminary study phase of the IDIH project (WP1)**[1], is the result of the works of the **Digital Health Transformation Forum (WP3)** that, through an expert-driven approach, gathered top-notch experts, executives, and advocacy groups from six regions (**Europe, China, Canada, Japan, South Korea, a**nd **USA**) and identified **common priorities and opportunities of mutual benefit in digital health for AHA**, outlining the pathway toward enhancement of international cooperation in these domains.

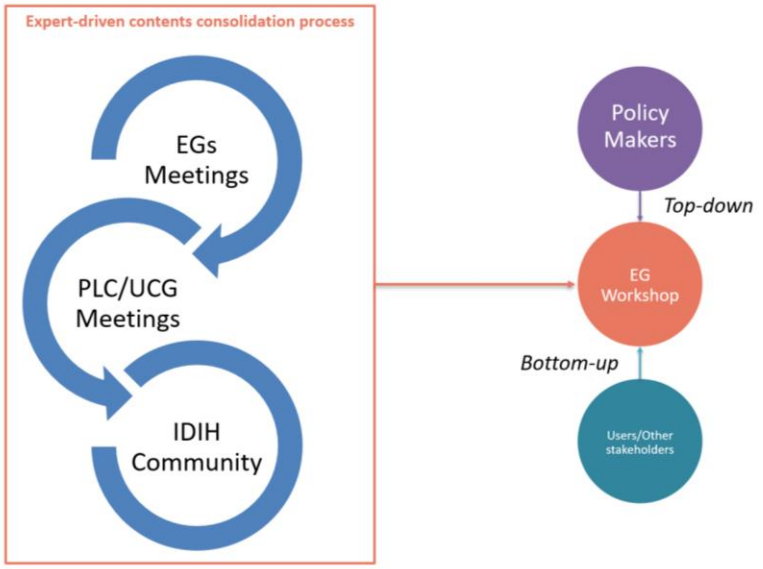

Figure 1: Overall methodological approach

During the EGs workshops of the Digital Health Transformation Forum (hereinafter also referred to as the "IDIH Experts Forum" or "Forum"), the experts gradually enriched and consolidated their outcomes. In particular, the priority setting exercise combined both a *bottom-up* and a *top-down* strategy and collected further input and feedback from both **users** (gathered in the UCG of IDIH) and **policy makers** [engaged in the PLC set by the project] as part of the activities for policy engagement (**WP2**). Moreover, as part of the awareness raising and impact maximization activities of the project (**WP4**), IDIH organised several other initiatives addressing a **wider audience of stakeholders** across countries, engaged – as part of the IDIH Community – to further improve the outcomes of the Digital Health Transformation Forum and address eventual bias in its results, inherent to the same functions of the EGs, as small groups of selected experts representing the six regions of concern by the project.

[1] See Reports: D1.1 IDIH Report on Trends Drivers and Enablers, D1.2 Panorama of the digital health landscape in the EU and in the Strategic Partner Countries, D1.3 Recommended areas to consider for international cooperation in digital health research and innovation.

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2.1.1 Four thematic Expert Groups to address four selected topics

While there is very little doubt about the need for international collaboration, the question becomes "where do we start?" We think it starts with **replacing people at the center of health services and promoting their engagement in co-producing their own health.**

IDIH presented a plan to achieve this goal with a specific focus on senior adults through an expert-driven approach. Then, four EGs were selected to specifically work on the following core aspects to reassess the priorities of the EU and the international strategic countries Canada, China, Japan, South Korea, and USA:

Figure 2: IDIH strategic topics

The four thematic areas preventive, integrated, independent, and inclusive care were selected based on preliminary search and consultations. The underlying premises were validated in line with the policy priorities identified through desk research and interviews with professionals and industry representatives in the EU and strategic international partner countries. To ensure a holistic view, experts were recruited to ensure all six regions/countries that were involved were represented as well as several stakeholder groups; i.e., research/academia, industry (digital health, healthcare investments, pharma), government agencies, and clinical practices. Interviewees were selected based on their experience with digital health, ageing populations, and knowledge of regional and/or global healthcare trends.

Although the four expert group meetings operated, at least at first, independently from each other, as part of the Digital Health Transformation Forum (Figure 2), they followed the **same format and had the same internal structure** including an EG Chair and an EG Facilitator (from the Consortium) who had responsibility for the moderation and presentation of the framework and EG results.

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Figure 3: The Digital Health Transformation Forum

EXPERT GROUPS | Chairs

- Preventive care: Giovanni Saggio, Università di Tor Vergata.
- Integrated care: Hicham Abghay, Francisco Javier Casado Hebrard, S2i.
- Independent care: George Demiris, University of Pennsylvania.
- Inclusive care: Matthew Lariviere, University of Sheffield.

EXPERT GROUPS | Facilitators

- Preventive care: Martina De Sole, Bruno Mourenza, APRE
- Integrated care: Hicham Abghay, Francisco Javier Casado Hebrard, S2i
- Independent care: Matthew Holt, Catalyst @Health 2.0
- Inclusive care: Vassilis Papanikolaou, George Zissis, ATC

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EXPERT GROUPS | *Modus operandi*

As a standardized approach to all EGs, experts were guided to provide a contribution following the same key steps in the operation of the Forum:

1. Discussion on the **panorama of trends and drivers** pertaining to the four strategic topics in Europe and the strategic partner countries.[2]
2. Discussion on the **policy priorities** that have driven research and innovation (R&I) in the field of Digital Health and AHA in the six regions/countries since 2014, with a look to future priority topics and **funding schemes** in these domains.[3]
3. In-depth discussions on specific areas of the respective working groups focusing on **new, innovative technologies for individuals, professionals, and organisations**.
4. Outline of **potential opportunities for collaboration** between the EU, Canada, China, Japan, South Korea and USA by demonstrating the most competitive strengths of each and respective good practices.
5. **Priority setting:** defining priority areas and specific topics that are suitable for international cooperation among the regions/countries involved.
6. **Outcome consolidation:** broadening the scope of the discussion based on the results obtained by single EGs and building a shared vision of how to enhance international cooperation in the field of Digital Health for AHA.
7. **Foresight exercise** based on reflection around enablers and barriers to envisage the impact expected from a scenario of enhanced cooperation around the final priority topics suggested by the Experts Forum.

This *7-step pathway* is summarized in the figure below in relation to the three Expert Group Workshops held during the project duration and the related results achieved:

- Preliminary recommendations
- 18 priorities
- **Three Common Priority Topics** and a **roadmap** to address them at an international level.

[2] Based on the preparatory work (WP1) carried out internally by the Consortium through desk research and interviews, information was published in the reports: D1.1 Report on Trends, Drivers and Enablers of Digital Health; D1.2 Panorama of the Digital Health Landscape in EU and in the Strategic Partner Countries; D1.3 Recommended areas to consider for international cooperation in Digital Health Research & Innovation.

[3] Based on report D2.1 Briefing note on (priority) topics for the Expert Groups elaborated internally by the Consortium, including an overview of relevant funding agencies and their policy agendas around Digital Health for AHA in each country/region, and a selection of projects in the four strategic topics (preventive care, integrated care, independent and connected living, inclusive living).

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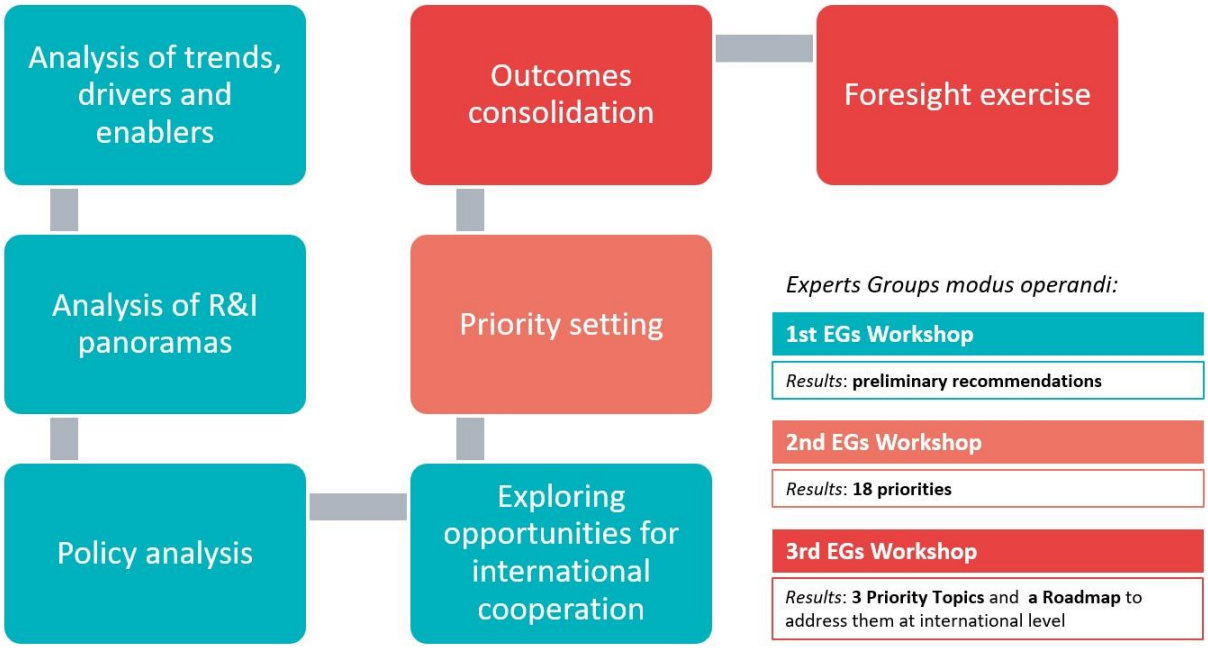

Figure 4: Expert Groups modus operandi

For the 1st and 2nd Expert Group Workshops, the EGs worked in parallel and shared their results, while during the third workshop they worked together directly in plenary.

Differently from the previous Expert Group workshops, the third workshop was conducted with the full participation of all the experts from the *preventive care, integrated care, independent and connected living* and *inclusive living* groups to broaden the scope of the discussion and combine the results obtained by the single Expert Group **toward a shared vision of how to enhance international cooperation in the field of digital health for AHA.** The results were elaborated around *three consolidated Priority Topics* and a *roadmap* to address them at an international level.

2.1.2 Consultation with the Users Consultation Group

The IDIH Experts Forum worked in close synergy with the **UCG** of IDIH. Composed of the most relevant representatives of "end users" of the digital transformation of health and healthcare in the EU and the five Strategic Partner Countries, the UCG guided the experts of the IDIH Forum to adopt **a user-centered perspective** by providing input and feedback to the work of the Forum.

Eight UCG members were engaged since the beginning of the project and they provided vision and feedback to the IDIH Experts through remote consultation and the organisation of two UCG meetings[4], whose results have been integrated in the elaboration of the final IDIH recommendations included in this **roadmap**.

[4] UCG meeting reports are freely available under https://idih-global.eu/outcomes/.

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Table 1: IDIH Users Consultation Group Members

Name	Organisation	Region
Anna Odone	European Public Health Association (EUPHA)	EU
Feng Cao	Chinese Geriatrics Society	China
Gloria Gutman	North American Chapter International Society for Gerontechnology	Canada
Ilenia Gheno	AGE Platform Europe	EU
Jie Wang	Smart Health Care and Home Care Branch of China Association of Gerontology and Geriatrics (S2HC-CAGG)	China
Peggy Maguire	European Institute of Women's Health (EIWH)	EU
Stephen Johnston	Ageing 2.0	USA/EU
Yasuko Akutsu	Ageing 2.0	Japan

2.1.3 Check and validation through the Programme Level Cooperation (PLC)

As mentioned previously, the role of **policy makers and funding agencies** was crucial, both as primary recipients of the IDIH roadmap and as fundamental participants in the priority setting exercise performed by the same experts. In this regard, a **PLC** was developed to engage the relevant funding agencies and facilitate the international policy dialog around digital health for AHA.

This **1st PLC meeting (March 27, 2021)** marked the start of this international policy dialog and represented an occasion for the IDIH EGs to present their preliminary results to the relevant funding agencies involved. In the 1st PLC meeting participated delegates from EU, Canada and US (see Table 2). This exploratory meeting of PLC delegates focused on the four topics considered as strategic for AHA, and around which the IDIH EGs had been organised; i.e., *preventive care*, *integrated care, independent and connected living*, and *inclusive living*. In particular, the priorities identified as suitable for international cooperation in each of these domains by the EGs (in total, **18 priorities**) were brought to the attention of the funding agencies, allowing them to receive feedback and further inputs in relation to the policy agendas and future national/ regional perspectives around digital health for AHA. Several **areas of major interest for the funding agencies** (summarized in Table 2) have been identified as domains at national/regional levels that have already been addressed/funded (in line with current policy agendas) and/or as topics with potential for R&I strategies at an international level, demonstrating the potential for future (possibly joint) funding initiatives. The results of this meeting were reported in the dedicated report[5] and constituted the basis for carrying out further activities within the Forum and the 2nd PLC meeting.

Table 2: Areas of major interest by funding agencies (1st PLC meeting)

Areas
Innovative digital solutions for AHA co-created among researchers, manufacturers, users, formal and informal carers
Dementia-friendly communities
Learning Health Systems
Unlock the potential of data coming e.g. from wearables or sensors through artificial intelligence, machine-learning algorithms
Sharing data on degenerative diseases

[5] IDIH Report on the first Programme Level Cooperation meeting https://idih-global.eu/wp-content/uploads/2021/12/D2.5_Report_1st_PLC_v2.0_APRE_Sept2021.pdf

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At the **2nd PLC meeting (European Commission/Canadian Institutes of Health Research/National Institute on Aging),** and the subsequent remote survey with the funding agencies from China, Japan and South Korea allowed, the PLC delegates to address the consolidated results of the IDIH Experts Forum, embracing a common vision of how to enhance international cooperation in the field of Digital Health for AHA, as proposed by the Forum as a whole, beyond the four EGs and the related Strategic Topics.

In particular, the funding agencies commented on the **three Common Priority Topics** identified as a common ground to enhance international cooperation in the field. Then, starting from a preliminary structure of this roadmap, they will also provide feedback on the IDIH recommendations for the key aspects to be addressed to better undertake and implement the path for the enhancement of the proposed international cooperation, addressing the three Common Priority Topics.

Eventual alignments of the IDIH recommendations and priorities with the current policy agendas at national/international levels will explored, as well as the interests of policy makers and funding agencies, about eventual future (possibly joint) funding initiatives based on the IDIH priority topics. Results of such exploratory phases during the 2nd PLC meeting and the following surveys will be presented in the dedicated report[6] and then integrated as part of the final version of the roadmap.

2.1.4 Share and co-create with the IDIH community

As part of the awareness raising and impact maximization activities of the project (**WP4**), IDIH has organised several other initiatives that address a **wider audience of stakeholders** in the participating countries to further improve the outcomes of the Digital Health Transformation Forum and address eventual bias in its results, which is inherent to the functions of the EGs as small groups of selected experts representing the six regions concerned with the project.
These initiatives, mainly based on the set up and functioning of an online long-term matchmaking community, which has more than 370 stakeholders, were discussed in open and public events[7], including:

- **IDIH Webinars:**
  - Inclusive design of digital solutions for AHA (November 5, 2021)
  - Data regulation and data sharing (March 10, 2022)
- **IDIH Stakeholders' Events:**
  - Digital Health for AHA. Addressing the needs of users (February 3, 2022)
- **IDIH Innovation Days (IDIH Week 2021 and 2022)**
  - IDIH Innovation Day (June 4, 2021)
  - IDIH Innovation Day (March 24, 2022/9.00 – 11.00 CET)
  - IDIH Innovation Day (March 24, 2022/15.00 – 17.00 CET)

The results of these consultations were fully integrated into the recommendations and priorities included in the roadmap. The implementation pathway toward the final iteration of this roadmap is summarized in the Figure 5.

[6] Report 2nd PLC meeting (to be published)
[7] See webpage dedicated to IDIH Events: https://idih-global.eu/news-events/#pagenews-newsletter

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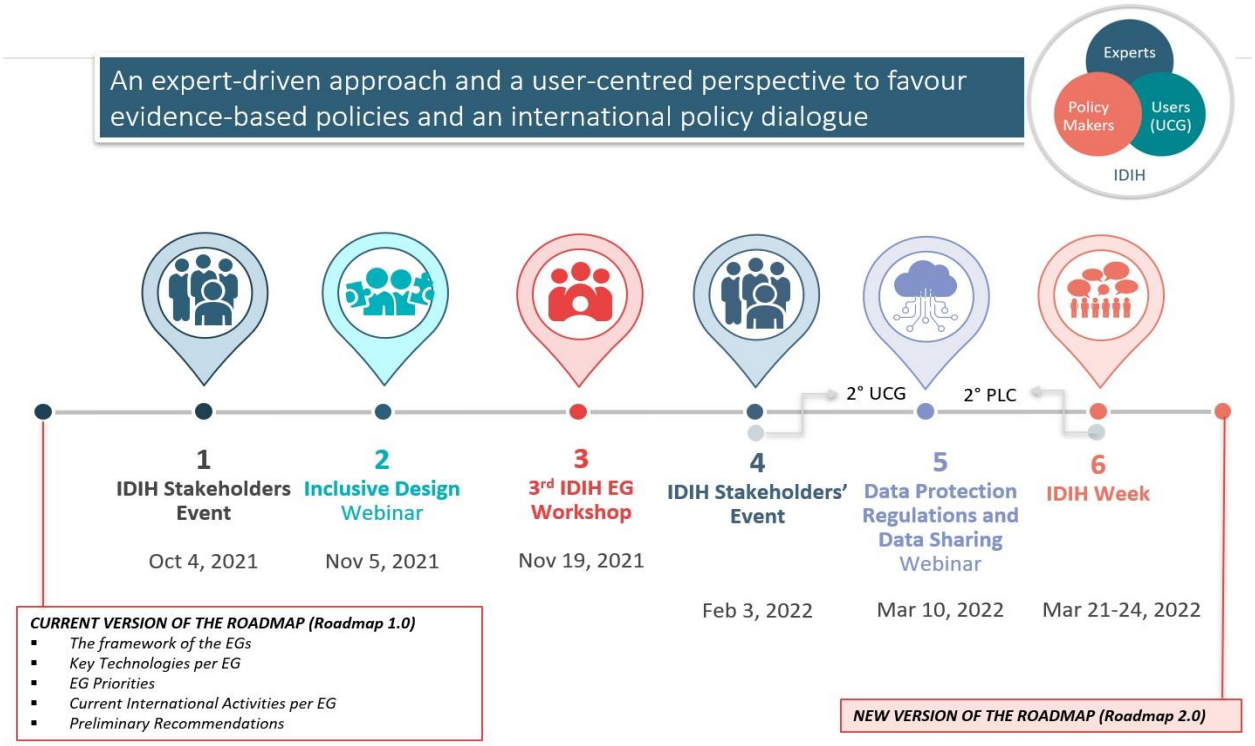

Figure 5: Key steps and consultation process for elaboration of the roadmap

For more information on the co-creation methodology and IDIH stakeholders' engagement, please consult [IDIH_StakeholdersEngagement_methodology_APRE.pdf]

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3 WHAT TO ENHANCE

This section of the roadmap intends to present the IDIH recommendations for strengthening international cooperation on Digital Health and Ageing between Europe and the IDIH Strategic partner countries. This section presents "what to enhance" internationally through PLC among the relevant policy makers and funding agencies:

- A **common understanding of healthy/active ageing** as a global challenge, considered a remarkable success story in human history.
- **Cooperation around three areas and, in particular, three priority topics:**

DATA GOVERANCE	DIGITAL INCLUSION	INTEROPERABILITY-BY-DESIGN
*To foster a **shared understanding of the determinants of healthy ageing** through new/existing multi-modal and **forward/backward longitudinal studies** and **Big Data analytics** based on the use of multiple data sources (such as patient reported data, patient validated data in EHRs, biometrics and biological data), validated with and by patients through **personalised-medicine approaches** and according with a **shared international validation framework** which also addresses cybersecurity aspects.*	*To favour **inclusive healthcare systems** through age-friendly technologies that address social isolation and loneliness, based on **empowerment models, inclusive co-design and enhanced digital literacy practices**, supported by international and multi/transdisciplinary research towards the adoption of the **5-As approach** (acceptability, applicability, accessibility, affordability, accuracy).*	*To ensure **accessibility, sharing and protection of data from different sources**, such as IoT wearables and sensors, through the development of **international standards**, and **procedures** and **incentives** for producers accessible for all countries based on an interoperability-by-design approach of digital solutions for preventive and integrated care, independent and inclusive living of the older persons.*

- **A shared vision toward a scenario of enhanced cooperation** at an international level around the expected impacts envisaged for these areas, after implementation of the IDIH Priority Topics

3.1 Common priority topics for international cooperation in Digital Health for AHA

During the first part of the project, through a thorough analysis of key enablers, expert consultations, and interviews, IDIH developed a clear picture of similar overarching **challenges related to digital health and ageing** faced by the EU and the strategic partners (China, Canada, Japan, South Korea, and USA). These countries experienced the same challenges in country-specific form with different degrees of urgency.

The identified main challenges were stratified in categories (please see the list below) to illustrate the **health, economic, and social framework conditions** at an international level. Further detailed information can be found in the IDIH report.

- **Regulatory framework**
- **Digital infrastructure**
- **Interoperability of data and standardization**
- **Data access**
- **Market situation**
- **Procurement system**
- **Digital literacy**

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Even though relevant key programmes and funding agencies support collaboration in digital health R&I on national and international levels (e.g., by the Multiannual Financial Framework and other financial frameworks), there are relatively few international R&I agreements between the EU and the strategic partner countries, especially with Asia. Thus, **further international demand for cross-border cooperation** seems to be evident, particularly **to address the challenges of AHA** with digital health solutions in a globally coordinated manner leveraging each partner's expertise. While the EU and the strategic partner countries are jointly facing a **common challenge**, namely that of an ageing population, they are also confronted with similar issues related to:

- **Insufficiency of essential regulatory frameworks** regarding ethical and security issues for eHealth data access;
- **Highly regulative and impeding procurement systems;**
- **Complex certification procedures** that hinder the industrialization of digital healthcare, the development of related start-up cultures, and hence the growth of the digital health market;
- **Lack of necessary funding for research and development,** which is either not available in sufficient quantity or scattered across different funds and objectives.

The IDIH project has identified the following **prioritized recommended areas for international cooperation** across the EU and its strategic partner countries **regarding digital health for AHA**:

- **Infrastructures: Data infrastructure improvement** and **enhanced data exchange** is one of the main priorities for the EU and most strategic partner countries regarding digital health. This includes topics such as citizen **empowerment** through access to their health data and the **standardization of health information** to facilitate relevant research.
- **Data management and ethics**: Scientific achievements require access to the infrastructure and also to data and knowledge. Without cross-border secure access to datasets, concepts with a potential impact on humanity can be neither tested nor verified and are doomed to failure. Therefore, an ethical framework should be put into place to allow the protection of data as well as responsible access to data. The possibility of new technologies and digital solutions to enter the market will depend on who controls the data.
- **Interoperability: Interoperability standards** based on fast healthcare interoperability resources (FIHR), application programming interfaces (APIs) or other adequate alternative technologies should be a high priority issue at a transnational level. Standardized data transfer and enhanced data exchange will not only allow better data collection but also process of data into meaningful knowledge. Resolving this important issue requires concerted action from all relevant stakeholders, such as large tech, health authorities, policy and regulatory agencies, and advocacy groups.
- **Healthcare system: Preventive care technologies and solutions supporting care at home** for elderly people living independently are key **to relief of the healthcare system, health** services in remote areas, reducing hospitalization rates or specialist doctors' appointments, and meeting the diverse needs both of providers and recipients of services.
- **Health topics**: The countries under study have recognized that a combination of R&I measures need to be taken into consideration to alleviate the healthcare burden from ageing and support AHA for all, including: 1) **understanding of the complex health challenges arising from multimorbidity** of the elderly, 2) **personalised medicine** for more effective, adult-

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centered solutions for the senior population, 3) **measures for health promotion, disease prevention and care at home,** and 4) **social challenges regarding healthcare and inclusion of elderly people**.

All these **challenges and recommended areas for international cooperation in digital health for AHA**, identified by IDIH during the first part of the project, **are totally in line with the three Common Priority Topics (data governance, digital inclusion, and interoperability by design)** defined according to a dedicated expert-driven approach, as explained in Chapter 1 of this roadmap. The **three Common Priority Topics** are presented and described below.

3.1.1 Common priority topic 1 – Area: Data governance

To foster a shared understanding of the determinants of healthy ageing through new/existing multi-modal and forward/backward longitudinal studies and Big Data analytics based on the use of multiple data sources (such as patient reported data, patient validated data in electronic health records (EHRs), biometrics and biological data), validated by patients through personalised-medicine approaches according to a shared international validation framework that also addresses cybersecurity aspects.

3.1.1.1 Description of common priority topic 1

The EU defines healthy ageing as "the process of optimizing opportunities for physical, social, and mental health to enable older people to take an active part in society without discrimination and to enjoy an independent, good quality of life"[8].

The World Health Organisation (WHO) defines healthy ageing as "the process of developing and maintaining the functional ability that enables wellbeing in older age." This includes a person's ability to:

- Meet their basic needs;
- Learn, grow, and make decisions;
- Be mobile;
- Build and maintain relationships; and
- Contribute to society.[9]

According to the EU definition, active ageing means helping people stay in charge of their own lives for as long as possible as they age and, where possible, to contribute to the economy and society[10]. The active ageing definition by WHO is "Active ageing is the process of optimizing opportunities for health, participation, and security in order to enhance quality of life as people age"[11].

[8] EuroHealthNet, healthy and active ageing, 2012, Bundeszentrale für gesundheitliche Aufklärung http://www.healthyageing.eu/sites/www.healthyageing.eu/files/featured/Healthy%20and%20Active%20Ageing.pdf

[9] World Health Organisation, Healthy ageing and functional ability, 26.10.2020: https://www.who.int/news-room/questions-and-answers/item/healthy-ageing-and-functional-ability

[10] European Commission, Active ageing: https://ec.europa.eu/social/main.jsp?langId=en&catId=1062

[11] World Health Organisation , Active Ageing – A Policy Framework, April 2002: https://apps.who.int/iris/bitstream/handle/10665/67215/WH0?sequence=1

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To comprehend AHA in-depth, it is important to define all the vital factors/determinants that affect the health and quality of life of the elderly. Understanding the evidence for these determinants will be helpful when designing policies and programmes that are successful.

The active ageing model of WHO includes six groups of determinants:

- Availability and use of health and social services
  Determinants: health promotion and prevention; continuous care
- Behavioural determinants
  Determinants: exercise and physical activity; drinking and smoking habits; feeding; medication
- Personal determinants
  Determinants: biology and genetics, and psychological characteristics
- Physical environment
  Determinants: safety houses, low pollution levels
- Social determinants
  Determinants: education, social care
- Economic determinants
  Determinants: wage, social security. This group is complemented by two crosscutting determinants; that is, gender and culture.

In the recent (February 8, 2022) publication "Determinants of healthy ageing: a systematic review of contemporary literature" a thorough study was conducted to identify current trends in the definition of the determinants for healthy ageing. This review identified determinants for healthy ageing including physical activity, diet, self-awareness, outlook/attitude, life-long learning, faith, social support, financial security, community engagement, and independence. In addition, there appears to be increasing acknowledgment of the instrumental role of social and mental/cognitive wellbeing as determinants of healthy ageing[12]. Another similar publication, "Determinants of Healthy Ageing in European countries" 2019, summarized the determinants found in EU policy related documents and studies at both the individual level and the environmental/societal level. The determinants at the individual level are health status, activity, resilience, social contacts, and involvement, and at the environmental/societal level, the determinants are provisions for accessibility, housing, age-friendly communities, and social security[13].

It is very important to continue research on clarifying and specifying the role of each determinant, as well as the interaction between determinants, in the healthy and active ageing process. We also need to better understand the pathways that explain how these broad determinants actually affect health and wellbeing. Moreover, it is helpful to consider the influence of various determinants over the life course so as to take advantage of transitions and "windows of opportunity" for enhancing health, participation, and security at different stages.

[12] T. Abud, G. Kounidas, K. R. Martin, M. Werth, K. Cooper, P. K. Myint, Determinants of healthy ageing: a systematic review of contemporary literature, Springer, 08.02.2022 https://link.springer.com/article/10.1007/s40520-021-02049-w#Sec13

[13] Wim v. d. Heuvel, M. Olaroiu, Determinants of Healthy Ageing in European Countries, 26.02.2019 https://juniperpublishers.com/oajggm/pdf/OAJGGM.MS.ID.555649.pdf

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Longitudinal qualitative research (LQR) is an emerging methodology in health behaviour and nursing research (Glanz et al., 2008; Polit & Beck, 2017)[14] [15]. Researchers are turning to LQR to understand experiences through time as well as identifying the facilitators and inhibitors of health/illness behaviours and transitions.

Data analytics in healthcare can be applied to every aspect of patient care and operations management, including improving the provision of clinical care, enhancing disease prevention, and measuring the effectiveness of various treatment options.

The ability of data analytics to convert raw healthcare data into actionable intelligence is expected to have the greatest impact on these areas of healthcare:

- Research and prediction of disease;
- Automation of hospital administrative processes;
- Early detection of disease;
- Prevention of unnecessary doctor visits;
- Discovery of new drugs;
- More accurate calculation of health insurance rates;
- More effective sharing of patient data;
- Personalisation of patient care.

From a business perspective, the interest is in how national healthcare administrations, other regulators, and business partners evaluate the worth of the product. From an ethical perspective, the interest is in how clinical data affect treatment decisions and how this affects patient health. The patient population in question is virtually everyone in society. For both of these reasons, the quality of clinical data and the integrity of the data are critical.

The integrity of data in a clinical trial is essential, however, the current data management process is too complex and highly labour-intensive. As a result, there is a risk for human-induced error and data falsification. New trends, such as blockchain technology have the potential to address some of these challenges.

The present governance framework in Europe that is applicable to the use of health data is largely defined by General Data Protection Regulation (GDPR). However, it is also impacted by national legislation covering general data protection issues as well as specific health sector issues. In some countries, these rules exist at both national and regional or state levels.

The legal cases on data usage, as well as a wide range of research situations, have shown that fragmentation of the health data legal landscape creates significant challenges to data use and re- use. In particular, there are new challenges on data use associated with different geographical areas, institutions, and medical practice and specialties. This fragmentation of healthcare systems and data

[14] Longitudinal Qualitative Methods in Health Behavior and Nursing Research: Assumptions, Design, Analysis and Lessons Learned, 26.10.2020, https://journals.sagepub.com/doi/full/10.1177/1609406920965799
[15] Developing longitudinal qualitative designs: lessons learned and recommendations for health services research, 06.02.2013, https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-13-14

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systems both geographically and technically was clearly expressed by the policy experts participating in the 2nd PLC meeting of the IDIH project.

While formal laws create a governance framework for the use of data, the organisations in which data are collected, processed, stored, and used as part of everyday healthcare activities impose a further layer of governance. This happens via the policies and practices that are in place to regulate the way in which staff and business partners can interact with the data for which they are legally responsible. This includes practices related to the data itself; that is, the data format, the way in which data are labelled, the languages in which data are captured (both human and machine), as well as policies for how the data may be used; that is, who has access rights, when data can be shared, and how data can be amended or deleted.

Such policies and practices impact not only how data may be used and shared, but in many cases, also undermine the practical potential to use data. Organisational-specific policies and practices vary and this presents challenges of interoperability; i.e., the ability of organisations to have clear and shared expectations regarding the format, labelling, language, and access rights for data. Technical, semantic, legal and operational interoperability must be ensured. If interoperability is not met, data remain effectively useless.

The European Health Data Space (EHDS) aims to overcome these obstacles. EHDS is a health-specific data sharing framework for the EU Member States establishing clear rules, common standards and practices, infrastructures, and a governance framework for the use of electronic health data by patients and research, innovation, policy making, patient safety, statistics or regulatory purposes.

Personalised medicine is the tailoring of medical treatment to individual characteristics of each patient. The approach relies on scientific breakthroughs in the understanding of how a person's unique molecular and genetic profile makes them susceptible to certain diseases. This same research is increasing our ability to predict which medical treatments will be safe and effective for each patient, and which will not.

Personalised medicine may be considered an extension of traditional approaches to understanding and treating disease. Equipped with tools that are more precise, physicians can select a therapy or treatment protocol based on a patient's molecular profile that may not only minimize harmful side effects and ensure a more successful outcome but can also help contain costs compared with a "trial-and-error" approach to disease treatment.

Personalised medicine has the potential to change the way we think about, identify, and manage health problems. There is already an exciting impact on both clinical research and patient care, and this impact will grow as our understanding and technologies improve.

The increasing incorporation of technology into the healthcare field is leading to greater precision in healthcare. However, advancements in cybersecurity measures are required. According to a 2016 report by IBM and the Ponemon Institute, the frequency of data breaches in the healthcare industry has been rising since 2010, and it is now among the sectors most targeted by cyberattacks globally. Cybersecurity of healthcare organisations is critical for patient safety, as well as for hospital

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operations. Cybersecurity measures aim to protect sensitive personal data by securing devices, electronic systems, networks, and data from attacks[16].

3.1.1.2 Common priority topic 1: Expected Impacts

Free and unobstructed access to healthcare data sources for researchers and technology providers will facilitate an increase in the effectiveness and quality of healthcare services for the elderly. Smoother and faster implementation of sophisticated digital solutions and services using state-of-the-art AI, machine learning, and Big Data analysis will help address the future demands of data handling and allow timely intervention for older people and/or their caregivers. The proposal for a Regulation for the European Health Data Space ("EHDS"), launched by the European Commission on May 3, 2022, includes a legal framework for the use of health data by the industry for innovation purposes, in particular through Artificial Intelligence ("AI") and Machine Learning ("ML") technology.[17]

Personalised medicine and engagement with older people will assist technology providers to develop personalised healthcare and wellbeing applications and services. These products and services will be designed and tailored to the specific requirements of the elderly and will improve their self-management and quality of life.

The implementation of technologies in healthcare systems will dramatically increase the quality and effectiveness of services provided to the elderly. The formal and informal caregivers' obligations and workload will be greatly reduced if the health of the elderly is improved and they are effectively supported in their daily activities.

Personalised healthcare services and "apps" for the elderly will increase the effectiveness of communication between caregivers and their patients. These services will allow caregivers to better understand patients' requirements and provide timely and appropriate interventions. Personalised healthcare services will be provided with respect to gender and ethnicity. Considering the diversity of the elderly population, healthcare solutions and services will be need-based instead of age-based.

Decision support systems for health policymakers, social service administrations, and healthcare organisations will allow them to effectively conduct qualitative and quantitative assessments. These assessments should be based on the analysis and interpretation of available optimized data for improved planning and evaluation of healthcare services. The incorporation of thoroughly assessed innovative services in the healthcare ecosystem should significantly reduce the burden on healthcare systems.

Societal awareness and citizen's engagement in the design and development process of innovative systems, primarily for the elderly and their caregivers, will facilitate seamless and uninterrupted integration with the current healthcare services. According to the WHO Strategic Objective 4, "Advocate people-centered health systems that are enabled by digital health," the wide acceptance of and familiarization with innovative services as well as recognition of their value will motivate citizens to willingly share their data, which, in turn, will increase the efficiency of healthcare services.

[16] Cybersecurity of Hospitals: discussing the challenges and working towards mitigating the risks, BMC, 03.07.2020, https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-020-01161-7
[17] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

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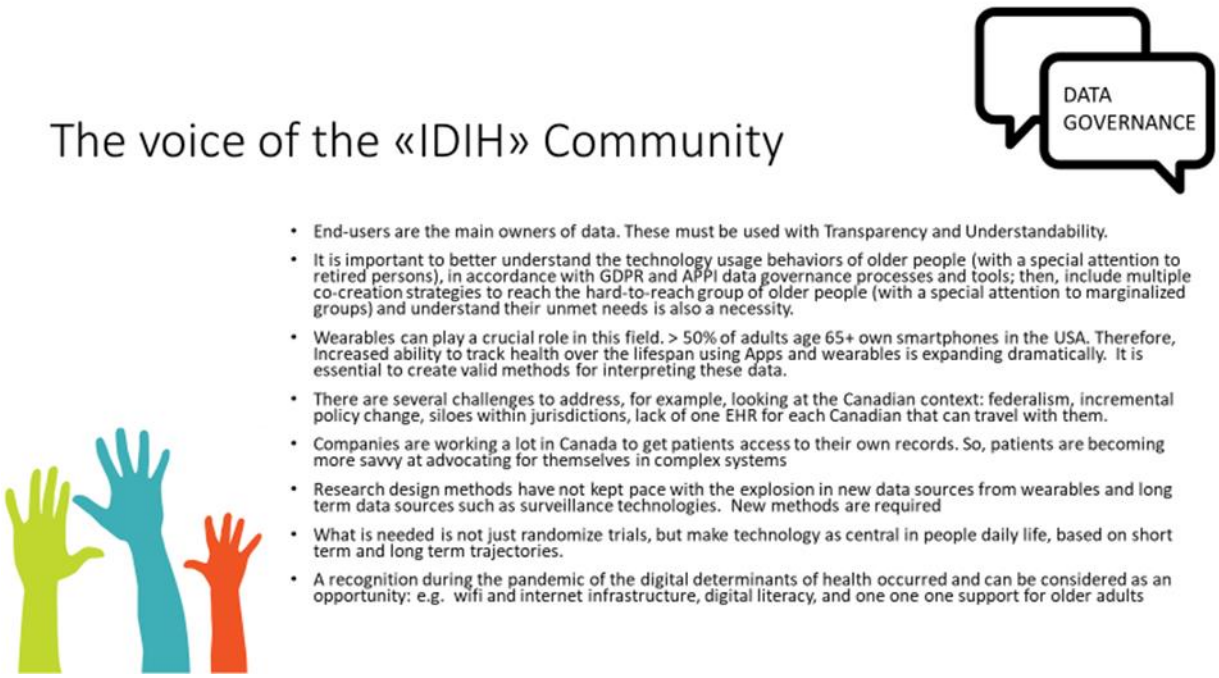
Access, elaboration, and analysis of rich, updated, and accurate datasets will improve research outcomes in medical, ICT, and social science domains and enable data-driven and interoperable solutions for different fields and applications.

Continuous elaboration and updates of health and active ageing determinants will drive research and technological development of healthcare and wellbeing services, thereby gaining academic and societal recognition.

Cybersecurity systems and mechanisms for technical and organisational frameworks need to be developed in accordance to national regulations to ensure privacy of the elderly and protect their personal data. These systems will allow free and secure access and exchange of datasets. The security mechanisms and frameworks will protect data integrity and minimize the risk of compromising the health of elderly patients.



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3.1.2 Common priority topic 2 – Area: Digital inclusion

To favour inclusive healthcare systems using age-friendly technologies that address social isolation and loneliness, based on empowerment models, inclusive co-design, and enhanced digital literacy practices, supported by international and multi/transdisciplinary research toward the adoption of the 5-As approach (acceptability, applicability, accessibility, affordability, and accuracy).

3.1.2.1 Description of common priority topic 2

Adaptable and age-friendly, smart solutions can help support and improve independent living throughout the course of life, independent of age, gender, impairments, cultural differences, and personal choices. A holistic approach that optimizes an individual's social and physical environments, supported by digital tools and services that deliver better health and care will improve not only independent living but also promote equity and active participation in society. According to the United Nations Sustainable Development Goals (in particular Goals 3 and 11), sustainable age-friendly environments represent the baseline for ensuring a better future for the entire population and addressing most issues for the growing ageing population[18].

Adapting systems and technology for an ageing population has benefits for older people, the consumer market industry, and the society. These benefits include market motivation, human-centered design, creation of enabling environments, and multistakeholder collaborations, which provide guidance when customizing strategy in the context of different regions and countries instead of employing a one-size-fits-all solution. These benefits will help mitigate the risk of exacerbating inequalities experienced by older people, such as those caused by ICT innovation, and will advocate for more affordable products in the silver market[19].

Ensuring digital inclusion for older adults implies overcoming five key barriers: access, installation, knowledge, design, and trust. Providing high-speed, low-cost internet services and devices, coupled with installation and support is the foundation for addressing connectedness. Consumers need digital literacy programmes and updated information on relevant technologies[20].

Functional ability can determine an individual's actual age (not chronological age but biological age). Assistive technologies can be provided that will benefit older adults and improve their quality of life by considering their functional ability.

Technology itself must be designed for everyone while considering the unique needs of older adults. Finally, individuals must have confidence that their privacy and personal data will be secure and used ethically. No one entity can solve these challenges alone; thus, collaboration and a public–private approach to reach digital equity become imperative.

[18] Kalderon Libal, A new EU platform will support Age-Friendly and Inclusive homes, communities, living and working environments, Futurium, EC, 17.03.2021, https://futurium.ec.europa.eu/en/active-and-healthy-living-digital-world/age-friendly-environments/news/new-eu-platform-will-support-age-friendly-and-inclusive-homes-communities-living-and-working?language=bg

[19] Digital inclusion of older people: harnessing digital technologies to promote healthy ageing in the Western Pacific Region, Intelligent Medicine, Volume 1, September 2021, https://www.sciencedirect.com/science/article/pii/S2667102621000401

[20] S. Akinola, How can we ensure digital inclusion for older adults?, 01.10.2021, https://www.weforum.org/agenda/2021/10/how-can-we-ensure-digital-inclusion-for-older-adults/

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In 2013, Schulz and Nakamoto identified four elements that need to be addressed to empower patients:

- Self-efficacy, including coping skills;
- Motivation to be self-determined;
- To be able to feel meaningfulness in activities; and
- Experience of impact on daily life[21].

The EMPATHiE project proposed a new definition of patient empowerment:

"An empowered patient was defined as having control over the management of their condition in daily life, with the capacity to participate in decisions related to their condition to the extent that they wish to do so; to become 'co-managers' of their condition in partnership with health professionals; and to develop the self-confidence, self-esteem, and coping skills to manage the impacts of their illness on everyday living."

The American Library Association (ALA) defines digital literacy as "the ability to use information and communication technologies to find, evaluate, create, and communicate information, requiring both cognitive and technical skills."

Digital technology has become a key component for full participation in society, and it can also be a powerful empowering tool for older adults, such as helping them to maintain their independence, access information easily, and stay connected with family and friends. In Japan, industry, academia, and the government collaborate toward building an "inclusive society"[22].

Elderly become familiarized with the use of technologies through guidance. The European Care Strategy aims to promote healthy living and prevent diseases while assisting older adults when they already have complex diseases and multimorbidities. Informal caregivers are also using digital solutions, such as social platforms, to help one another. This strategy targets the older population and their caregivers, promoting a "care economy" for the elderly.

The European Health Data Space will empower individuals across the EU to fully exercise their rights over their health data[23]. People will be able to easily access and share these data, while retaining greater control over them, fully in line with our overall EU approach to data protection[24]. Particularly, MyHealth@EU aims to empower citizens by giving secure access to their health data abroad and to strengthen cooperation and synergies between the Member States and the European Commission. Specifically, it enables the Member States to provide high-quality cross-border healthcare services to the EU citizens by allowing the seamless cross-border exchange of clinical documents (Patient Summary and ePrescription).

[21] A new understanding of health related empowerment in the context of an active and healthy ageing, BMC, 24.04.2019, https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4082-5
[22] IDIH Week 2022 – Japan Regional Workshop. March 2022, https://idih-global.eu/wp-content/uploads/2022/04/Japan-Regional-Workshop_materials.pdf
[23] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197
[24] Questions and answers - EU Health: European Health Data Space https://ec.europa.eu/commission/presscorner/detail/en/QANDA_22_2712

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As people age, training helps them adopt technology and increase their quality of life. Older adults can overcome the "digital divide," reconnect with family and friends, and gain skills to enhance their quality of life. Training programmes and support for the elderly can help them adopt new technologies and use digital applications to develop self-confidence and enhance social interactions. Training programmes and continuous support designed for older adults help them explore new technologies, which facilitate their learning process[25].

This has been described as the **5-As approach** for the design and development of inclusive services for the elderly.

Acceptability relates to cultural and social factors that affect an individual's ability to accept or seek healthcare services.

Affordability reflects on the economic capacity of individuals to spend money on resources and services that they need for their health. It is not only affected by the price of healthcare but also by reduced income due to ill health. Healthcare should be cost effective, implying that the price individuals pay for their care should produce effective and desired outcomes in health. Inability to pay for healthcare results in health inequalities.

Applicability denotes that individuals with health needs can identify forms of services that exist and can be reached. Service providers are responsible for making themselves known among various social and geographical population groups through transparency and providing information and conducting outreach activities. Complementary to this dimension is the notion of the ability of individuals to perceive their own need for care.

Accessibility refers to healthcare services being reachable and usable, both physically and in a timely manner.

Accuracy denotes the net clinical benefit to the patient; the expected health benefit (i.e., increased life expectancy, relief of pain, reduction in anxiety, etc.) needs to exceed the expected negative consequences (cost, time off work, mortality, morbidity, etc.)[26].

3.1.2.2 Common priority topic 2: Expected impacts

The adaptation of inclusive age-friendly design techniques for the development of digital services and apps will be able to reduce social isolation and loneliness of older citizens. These services will facilitate the communication of older people with their caregivers, family members, and friends. The need for such services and apps was evident during the isolation caused by the Covid-19 pandemic.

"Design for all" principles considering the particular needs and usability constraints of elderly users in the design and development of healthcare services will facilitate the provision of accessible technological products for them. It is also important to conduct thorough multi/transdisciplinary research to create a framework for the integration and provision of AHA services in respect to the 5-As approach. This will ensure equitable access for the elderly, regardless of their background.

[25] Qi Ma, Alan H. S. Chan and Pei-Lee Teh "Bridging the Digital Divide for Older Adults via Observational Training: Effects of Model Identity from a Generational Perspective", 3 June 2020
[26] N. Insan, Access to Healthcare, https://www.theaspiringmedics.co.uk/post/medical-school-interview-public-health-access-to-healthcare

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The design and delivery of training courses, taking into account age and cultural and gender related particularities, will help older people obtain basic digital skills. This will allow them to adopt digital healthcare services and apps that will improve the quality of their lives and allow them to become integrated members of the digital society.

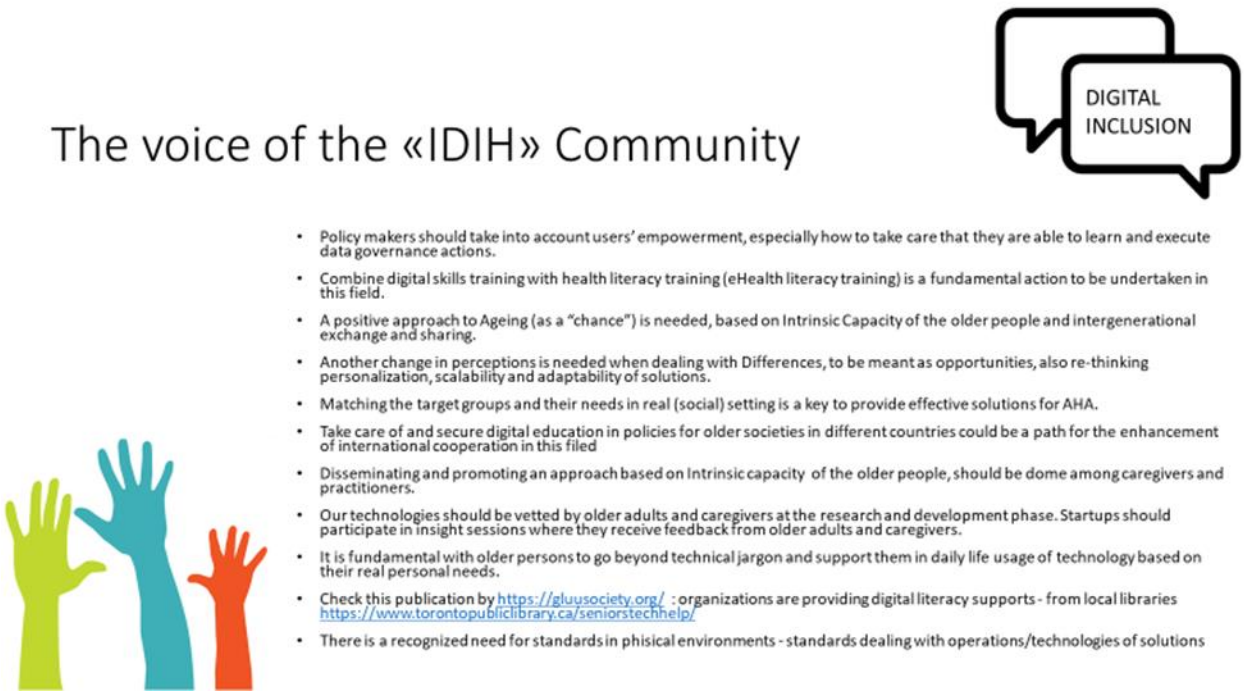
Multi/transdisciplinary research needs to focus on:

- Integration into the healthcare system of inclusive and age-friendly healthcare services adopted to the needs of older people; and
- Advanced methods that will lead to the empowerment of elderly citizens to eliminate the gap between them and the healthcare system.

Age-friendly products and services based on the personalised medicine approach should be delivered tailored to the specific needs and requirements of elderly people. This will facilitate the provision of improved personalised caregiving services designed to enhance the quality of life.

Synergies and networking activities among researchers and stakeholders in the EU and partner countries will facilitate expanded cooperation and knowledge sharing for the adaptation and replication of these successful models and tools.

During the Covid-19 pandemic it became evident that digital inclusion is a necessity for society to exercise basic human rights. Worldwide, the most vulnerable group to this phenomenon was the elderly who were facing loneliness and isolation during the pandemic. Therefore, at an international level, inclusive strategies need to be constructed and adopted to engage older people in programmes of digital literacy for AHA.



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3.1.3 Common priority topic 3 – Area: Interoperability by design

To ensure accessibility, sharing, and protection of data from different sources, such as Internet of Things (IoT) wearables and sensors, through the development of international standards, procedures, and incentives for producers so they are accessible in all countries based on an interoperability by design approach for digital solutions in preventive and integrated care and independent and inclusive living of the elderly.

3.1.3.1 Description of common priority topic 3

Despite policy recommendations made in 2019, there are many differences in data formats in hospitals, clinics and health regions in Europe. The goal is to make 100% of the EHR accessible to the whole population by 2030. This means that people with particular needs, such as older adults, will need to learn how to navigate the system and make use of the EHR. Even now where EHRs are available, citizens do not know how to access them.

"Lack of data availability, resulting from the fragmentation of standards and specifications for storing and sharing health data, strongly hinders innovation in digital health, i.e. the development of new products and services for public health (e.g. to accelerate the discovery, development and approval of new prevention approaches and treatments)"[27].

Data standards are created to ensure that all parties use the same language and the same approach when sharing, storing, and interpreting information. In healthcare, standards make up the backbone of interoperability, or the ability of health systems to exchange medical data regardless of the domain or software provider.

The list of the largest and most recognized standards development organisations include:

- HL7 – Health Level 7 International,
- NCDPD – National Council for Prescription Drug programmes,
- IHTSDO – International Health Terminology Standards Development Organisations,
- DirectTrust Standards,
- CDISC – Clinical Data Interchange Standards Consortium.

The main standards created by the standards development organisations and widely used across healthcare organisations fall into four large groups:

- Terminology standards;
- Content standards;
- Data exchange or transport standards; and
- Privacy and security standards.

Terminology standards. Created to communicate medical concepts with utmost precision, there are sets of codes, terms, and classifications that clinicians use on a daily basis. Health data may be exchanged without terminology standards, but there is no guarantee that all parties will be able to understand and use them.

[27] Bird & Bird LLP (2022). Unleashing the full potential of health data through facilitating secondary use? At https://www.lexology.com/library/detail.aspx?g=ac017c03-99ff-48a0-9380-5eac5dda0efe

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Content standards. Content or document standards dictate the structure of electronic documents and types of data they must contain. They ensure that medical data is properly organised and represented in a clear and easy to understand form.

Transport standards. Transport standards facilitate data exchange between different health systems. They define what formats, document architecture, data elements, methods, and APIs to use for achieving interoperability.

Privacy and security standards. Privacy and security standards establish administrative and technical rules to protect sensitive health data from misuse, unauthorized access, or disclosure. In the US, the privacy and security standards for medical information are outlined by the Health Insurance Portability and Accountability Act (HIPAA). In the European Union, health information falls within the scope of the GDPR[28].

Much time is spent by the Commission developing legislative proposals for European health data space[29]. There are many issues to address because this task is not only for privacy and cybersecurity concerns but also to consider differences in GDPR between member states. The goal is to use and reuse data for research.[30]

The EHDS sets essential requirements specifically for EHR systems in order to promote interoperability and data portability of such system, which would allow natural persons to control their electronic health data more effectively. In addition, where manufacturers of medical devices and high-risk AI systems declare interoperability with the EHR systems, they will need to comply with the essential requirements on interoperability under the EHDS Regulation.[31]

Covid-19 certificates are used in Europe and other countries all over the world. This shows when there is a need, a solution can be found. The COVID-19 certificate is very simple technologically, nevertheless it shows that it is possible to set a standard by which available data could be used globally to have better personalised research and medicine and also better exchange of health data.

Priority Topic 3 Expected impacts

Technology providers will create an ecosystem of validated, age-friendly AHA services and apps to facilitate access for interested organisations in the EU and other regions. Academic institutions and healthcare organisations will collaborate on data sharing and the creation of harmonized global datasets.

Best practices sharing and knowledge exchange at an international level will facilitate the creation of enhanced evidence-based common policies and guidelines. This collaboration will facilitate the standardization of key technological developments and findings and common approaches in the AHA

[28] I. Dunskiy, Data exchange standards in healthcare & the importance of FHIR, 23.07.2021, https://demigos.com/blog-post/data-exchange-standards-in-healthcare/
[29] Creation of a European Health Data Space, 24.03.2022, https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-health-data-space
[30] IDIH Week – Infoday March 2022, https://idih-global.eu/wp-content/uploads/2022/03/Info-Day_presentations.pdf
[31] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (2022) https://health.ec.europa.eu/system/files/2022-05/com_2022-197_en.pdf

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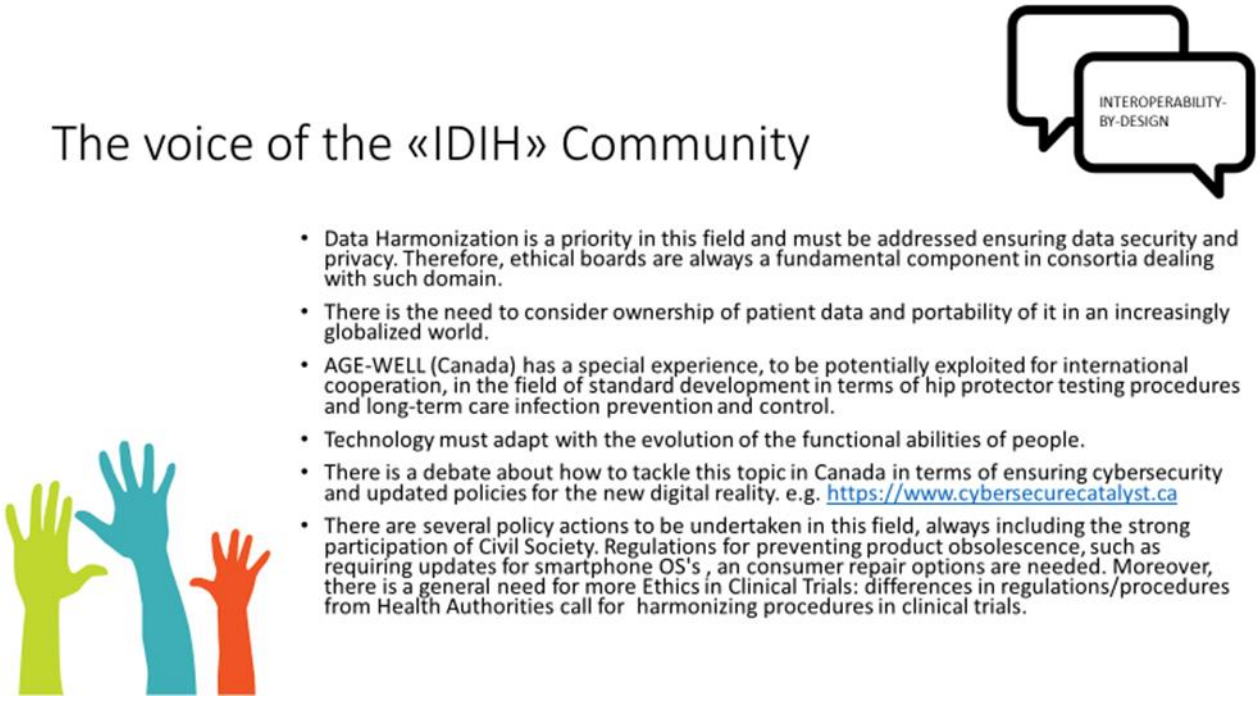
domain. The EU has already initiated a framework toward these recommendations for interoperability.[32]

International cooperation in the AHA domain will create synergies that allow an increase in participation by target groups. Consequently, the quality of the research outcomes will be significantly enhanced, creating a meaningful impact on societies.

The endorsement of worldwide accepted technological standards will allow the delivery of interoperable services and devices, which contribute to WHO Strategic Objective 3 "Strengthen governance for digital health at global, regional and national levels." The potential for integration and quality should exponentially increase the added value of these technologies, positively affecting integrated care at a national level. Interoperability will allow data sharing to provide better healthcare services.[33]



[32]Joinup, European Commission, Interoperable Europe https://joinup.ec.europa.eu/collection/interoperable-europe/interoperable-europe

[33] IDIH Week 2022 – US Regional Workshop recording, https://youtu.be/8_WlRXmlXXA

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4 HOW TO ENHANCE

This section presents a strategy to concretely address the IDIH recommendations through an **action plan** for the implementation of the three Common Priority Topics at national and international levels: from policy formation to policy evaluation.
This section highlights **barriers** to consider and possibly remove, as well as **enablers** upon which to leverage to possibly favour implementation of the IDIH Common Priority Topics.

4.1 Barriers for enhancing international cooperation around Digital Health for AHA

4.1.1 Barriers of common priority topic 1 – Area: Data governance

1. ***Lack of digital health literacy [level of likelihood: low]***
   According to the WHO, the definition for digital health literacy "is the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to preventing, addressing or solving a health problem".

   A very important factor for the evolution of healthcare systems for the elderly is digital health literacy.

   Digital health literate people can more actively manage personal health and healthcare. Preventive care can be positively affected with digital health literacy considering that digitally health literate older people can adopt healthy habits in their everyday activities and improve wellbeing.

   Digital health literacy and equity are closely linked. People who are lower along social gradients tend to have higher disease burdens and health needs, yet they are more vulnerable in regard to access and understanding of health information. They may be less aware of issues of privacy, health data use, and data protection and are also more likely to experience digital exclusion. Increasingly, health information is collected, disseminated, and transformed through online platforms, including websites and social media forums or blogs. This raises new challenges regarding the quality and reliability of the platforms and information, including the issue of a misleading marketing.

   Effective and equitable digital transformation in healthcare is vital for modern systems and empowering citizens and patients. However, current digital health tools often account for varying abilities insufficiently and wrongly assume that all users are homogenous. Digital health literacy is shaped by economic, environmental, cultural, and societal factors. Complex evaluation and regulation are slow to keep pace with innovation and societal changes. With few fixed guidelines for implementation and assessment, there are risks as well as benefits. Enabling an effective and equitable transition requires actions from health and other systems; digital innovation by states and societies as well as companies; development of public services and professionals; and broader education, social inclusion and social justice improvements. The WHO is increasingly paying attention to digital health literacy, with publications such as the important first WHO Guideline

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Recommendations on digital interventions for health system strengthening (2019) and Digital technologies: shaping the future of primary healthcare (2018)[34].

2. ***Conservative tendencies in the healthcare industry where verification and application processes are tight and strict, making political, economic and social change slower [level of likelihood: low]***
Digital health solutions continue to grow in both number and capacity. Despite these advances, the confidence of the various stakeholders; that is, patients and clinicians to payers, industry and regulators, in medicine remains quite low. As a result, there is a need for objective, transparent, and standards-based evaluation of digital health products that can bring greater clarity to the digital health marketplace.

   Healthcare requires a robust and transparent validation process for digital health products. All healthcare stakeholders would benefit from a more standardized, objective, rigorous, and transparent process for validation. Primarily, the three main validation domains include technical validation (e.g., how accurately does the solution measure what it claims?), clinical validation (e.g., does the solution have any support for improving condition-specific outcomes?), and system validation (e.g., does the solution integrate into patients' lives, provider workflows, and healthcare systems?).[35]

3. ***Lack of organisational resources for healthcare systems to meaningfully engage/empower patients in the process and address management challenges. [level of likelihood: medium]***
Patient empowerment: To promote the development and implementation of policies, strategies, and healthcare services that empower patients to be involved in the decision-making and management of their condition according to their preferences, while raising awareness about their rights and responsibilities[36].

   Patient engagement has become a cornerstone of quality of care and is a frequently stated goal for healthcare organisations. Patient engagement can inform patient and provider education and policies, as well as enhance service delivery and governance.[37]

   Some of the reasons why patient participation is still absent in some key health areas, and not strong enough in others, include lack of awareness and recognition of patient empowerment; a slow pace in sharing and adopting good practices; lack of resources in the healthcare system but also of patient organisations; poor knowhow on how to meaningfully involve patients and patient organisations; and a patient community with very different levels of capacity and different priorities across the EU.

[34] EuroHealthNet, Digital health literacy: how new skills can help improve health, equity and sustainability, September 2019, https://www.moh.gov.gr/articles/ehealth/6447-synopsh-politikhs-gia-ton-pshfiako-grammatismo-sthn-ygeia?fdl=15371
[35] Digital health: a path to validation, 13.05.2019, https://www.nature.com/articles/s41746-019-0111-3
[36] European Patients Forum, https://www.eu-patient.eu/globalassets/library/publications/patient-empowerment---toolkit.pdf
[37] Engaging patients to improve quality of care: a systematic review, BMC, 26.07.2018, https://implementationscience.biomedcentral.com/articles/10.1186/s13012-018-0784-z

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4. ***Lack of a harmonized regulatory framework for data integration and interoperability that would facilitate data transfer and exchange, mainly due to scattered decision-making throughout the management levels of public affairs [level of likelihood: high]***

   Health data exchange is a major challenge due to sensitive information and privacy issues. Considering the European context in which health data must be exchanged between different EU member states, with each having a different national regulatory framework as well as different national healthcare structures, the challenge appears even greater.

   The development of a unified European framework for the exchange of health-related data is a critical problem that needs to be solved in order to match the regulatory frameworks at the European level and within the EU member states and because of the sensitive information that is exchanged. Thus, a “privacy by design” and "ethics by design" approach must also be undertaken to generate trust in the end-users and unlock eHealth potentialities and facilitate the framework’s adoption across Europe.[38]

   The adoption and use of health data standards form the basis for enabling interoperability across organisations and between electronic health record systems. Throughout the healthcare system, several different standards development organisations (SDOs) create, define, update, and maintain health data standards through collaborative processes that involve healthcare IT users, but there is no single standard. This lack of a common standard for capturing, transmitting, receiving, storing, and managing patient data causes delays and inaccuracies, which is a major hurdle to interoperability efforts[39].

5. ***Non-availability of health data and electronic health records [level of likelihood: high]***

   Acquiring data is an important task because today much research in healthcare data science is “put on hold” due to data inaccessibility. Key infrastructures for secondary use of EHR data are still underdeveloped, and this represents an important research gap.

   Access to clinical data, such as electronic patient records, is very restricted due to the high sensitivity of data accumulated in EHR systems. Ethical permission is needed and also good contact with the healthcare provider. Reuse of such data for research and quality improvement work is regulated at multiple levels [GDPR (2016), HIPAA (2003), and national and institutional guidelines] aiming to ensure the privacy of individuals and healthcare institutions. At the same time, there are forces that push for use of valuable information available within the healthcare system to be used not only for research but also for improving healthcare. A proper balance between privacy and utility of personal health data has been studied previously, however, no consensus has yet been reached. It still remains a limiting factor in adopting novel data science methodologies for clinical settings[40].

[38] The European cross-border health data exchange roadmap: Case study in the Italian setting, Journal of Biomedical Informatics, June 2019, https://www.sciencedirect.com/science/article/pii/S1532046419301017
[39] How Health Data Standards Support Healthcare Interoperability, 08.03.2022, https://ehrintelligence.com/features/how-health-data-standards-support-healthcare-interoperability
[40] Challenges and opportunities beyond structured data in analysis of electronic health records, 14.04.2022, https://wires.onlinelibrary.wiley.com/doi/10.1002/wics.1549

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4.1.2 Barriers of common priority topic 2 – Area: Digital inclusion

1. ***Digital technology is still too expensive for some older citizens to purchase. The high cost of implementing digital solutions may be the cause and should be addressed. [level of likelihood: high]***

   At the Consumer Electronics Shows (CES) in the past few years, there were a handful of tools introduced that were particularly aimed at older people, from a gamified rehab tool to a robot caretaker, from a fall detector to an AI-based smart remote caregiver solution. However, these devices are more in the high-end category, and middle-class seniors struggle to pay for these devices.

   Smartphones, smartwatches, wearables, assistive technology solutions, and other health tools available in the market often come with a very high price tag. The high price rules out a large segment of the society, seniors included. As is known, choosing a device or a platform is also a value-based decision for elderly people.

   Although technologies are highly valued based on the activities afforded and services available to support them, the cost of technologies is a major factor that could keep older adults from using them. Our study showed that older adults were concerned about the ongoing expenses that they must pay to use the technology on top of its initial cost. For example, Muse, an EEG-powered sleep tracking and meditation device, costs between $300 and $500, depending on various features and tracking abilities. The real tracking power comes from the ongoing use of an app to track one's wellbeing, which costs around $130 per year. Older adults who do not see the immediate need for and benefit of the product will not adopt the technology[41].

2. ***Not all citizens have equitable access to digitally enabled infrastructure (e.g., secure broadband, mobile data). [level of likelihood: medium]***

   Recent reports by the International Telecommunications Union (ITU) indicated that women and older persons experience digital inequity to a greater extent than other groups in the society; they either lack access to technologies or often do not benefit completely from the opportunities provided by technological progress[42].

   The growing divide between those who have reliable access to broadband services and an acceptable device for connecting to the Internet and those who do not is one of the fundamental obstacles to digital equity. A study in the US determined that low income and elderly population, people of colour, and those who live in rural and tribal areas disproportionately lack broadband access: 43% of adults with income below $30,000 a year report not having home broadband services in comparison to 7% of adults with household earnings of over $100,000 a year. Access to broadband services is essential for modern life, access to public services and, importantly, equal educational, economic, and social opportunities.

[41] Experiential Value of Technologies: A Qualitative Study with Older Adults, International Journal of Environmental Research and Public Health, 16.02.2022, https://mdpi-res.com/d_attachment/ijerph/ijerph-19-02235/article_deploy/ijerph-19-02235.pdf

[42] https://www.un.org/development/desa/ageing/2021-unidop-digital-equity-for-all-ages.html

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Ensuring digital equity, therefore, means taking an equitable approach to broadband access and other digital infrastructures. In short, this means ensuring high-quality broadband services are available to every household in every community, that they are affordable, and that everyone has access to a secure device, regardless of income[43].

As of January 2021, there were 4.66 billion active internet users worldwide, which is 59.5% of the global population. Of this total, 92.6% (4.32 billion) accessed the internet via mobile devices.

Although very common among the young, internet use is not as habitual among the older generation: 98% of those aged 16–24 used the internet in the last three months vs. 61% of those aged 65–74. While internet use remains high among the young across the EU, it varies greatly among the older age groups.

In 2020, Denmark recorded the highest share (94%) of people aged 65–74 who used the internet in the last three months, followed by Luxembourg and Sweden (both 91%), the Netherlands (90%) as well as Finland (88%). In contrast, only 25% of people aged 65–74 in Bulgaria used the internet in the last three months, followed by those people in Croatia (28%) and Greece (33%)[44].

3. ***Some older citizens may be concerned that digital inclusion may disrupt 'non-digital' forms of inclusion and social relationships. [level of likelihood: medium]***
Social isolation is another concern. Some older people reject online shopping as they welcome the social benefits of daily face to face contact when shopping in person.

Professor Vicki Hanson said: "The efficiency gained by conducting online interactions is not a powerful motivator for technology adoption by older adults who may be experiencing loneliness and isolation. In many cases, making digital technologies appealing to older adults means ensuring that digital engagements do not replace social interactions and, if possible, facilitate new social and community-building opportunities where they can meet people[45].

Finally, we suggest that new and emerging technologies hold great promise for the future by overcoming traditional barriers to maintaining social contact and supporting exchanges and information acquisition. Nevertheless, we caution that these new technologies can have the dehumanizing effect of distance, thus creating the potential for insensitivity and increased negativity. In sum, we are cautiously optimistic about the promise of technology to expand, but not replace, traditional forms of social contact[46].

[43] Buchholz, Carrasco, Warren, The equity imperative - digital transformation for all citizens, 19.10.2021, https://www.centreforpublicimpact.org/insights/the-equity-imperative-digital-transformation-for-all-citizens
[44] Eurostat, How popular is internet use among older people?, 17.05.2021, https://ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20210517-1
[45] Why some older people are rejecting digital technologies, 12.03.2018, Lancaster University https://www.sciencedaily.com/releases/2018/03/180312091715.htm
[46] Social Relations and Technology: Continuity, Context, and Change, National Library of Medicine, 25.12.2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5954608/

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4. ***Differences in healthcare systems and models across countries may represent a level of complexity to be addressed by international and multi/transdisciplinary research. It is necessary to consider national, as well as individual, differences for the verification and standardization of research results[47]. [level of likelihood: high]***

   According to the WHO, a health system "consists of all organisations, people and actions whose primary intent is to promote, restore or maintain health." Healthcare systems differ widely across countries worldwide. Countries adopt different systems to provide healthcare to their citizens, with different levels of government and private sector involvement. The crucial result is that the services exist and that individuals can access and afford them. With different economic, geographic, and political domestic situations, it is unrealistic to expect one approach to healthcare to work for all countries. A universal objective, rather than a single system, is more important to deliver high-quality healthcare to numerous individuals at an affordable cost. [48].

4.1.3 Barriers of common priority topic 3 – Area: Interoperability by design

1. ***Differences in data security policies and regulations remain an issue for international R&I. It is important to include a preliminary study phase on this field and consider favouring a policy dialog at an international level, supporting and accompanying the R&I actions proposed. [level of likelihood: high]***

   Organisations must navigate both a growing number and increasingly complex system of regulations and rules, such as the GDPR, the California Consumer Privacy Act, the Cybersecurity Law of the People's Republic of China, and many others worldwide.

   Privacy and data protection regulations are necessary, but can also create fragmented, and sometimes conflicting, priorities and costs for companies that can weaken defense mechanisms. Within an organisation's budgetary boundaries, companies have to defend and protect against attacks while they also seek to comply with complex regulations.

   Therefore, policymakers are required to weigh their decisions with this impact in mind. Individual regulations may have similar intent; however, multiple policies add complexity for businesses that need to comply with all regulations, and this complexity introduces new challenges to cybersecurity and data protection, rather than improving them. Policies must be creative in increasing protection while decreasing regulatory complexity. Cooperation among different policymakers is critical[49].

[47] For example, in Korea, most medical services are available to all citizens due to the implementation of the national health insurance system. However, if it is not covered by national insurance, public accessibility is low, so other solutions are needed.

[48] How Health Care Works Around the World, https://world101.cfr.org/global-era-issues/global-health/how-health-care-works-around-world

[49] These are the top cybersecurity challenges of 2021, https://www.weforum.org/agenda/2021/01/top-cybersecurity-challenges-of-2021/

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2. ***If data interoperability and some international standards already exist, huge implementation challenges still affect research outcomes; this is often due to the lack of interoperable health data made available by the healthcare services according to specific government policies [50].[level of likelihood: medium]***

   One of the most frequently cited barriers to data sharing and reuse is the lack of common standards or proliferation of incompatible standards. For example, inconsistent data formats are impediments to the creation of longitudinal datasets, as changes in measurement and collection practices complicate the process of comparing and aggregating data. Standards are a condition for interoperability. When commonly used machine-readable formats are preferred for accessibility, interoperability is occasionally not guaranteed. These common formats may enable "syntactic" interoperability; i.e., the transfer of "data from a source system to a target system using data formats that can be decoded on the target system." However, they do not guarantee "semantic" interoperability, which is "defined as transferring data to a target so that the meaning of the data model is understood." Both, syntactic and semantic interoperability are required. Data must be searchable in addition to being accessible and interoperable.

   This may necessitate the cataloguing and/or searchability of data[51].

[50] *US government has spent huge amount of money in these efforts. It remains to be seen whether other countries have the willing to do the same.*

[51] Risks and challenges of data access and sharing: https://www.oecd-ilibrary.org/sites/15c62f9c-en/index.html?itemId=/content/component/15c62f9c-en

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4.2 Enablers for enhancing international cooperation around Digital Health for AHA

Among the possible enablers of international cooperation in digital health for AHA, the IDIH consortium recommends considering the IDIH project findings on:

- the panorama of the digital health landscape in the EU and in the strategic partner countries
- the trends, drivers, and enablers of digital health supporting AHA.

Moreover, as part of the analysis of the **funding schemes supporting international cooperation in digital health for AHA,** IDIH encourages the policymakers and funding agencies interested in a follow up of the IDIH Common Priority Topics to take into account the policies and schemes already put in place in the EU and the IDIH Strategic Partner Countries to address digital health for AHA through international cooperation, as enabling factors for further strengthening international collaborative research. The IDIH Guidebook for RDI Stakeholders, therefore, could also be considered as a reference document in this regard.

Additionally, a comprehensive collection of key policy drivers is included in the Action plan of this roadmap, already available as a legacy of the IDIH project for the purposes of the first agenda setting phase.

Furthermore, the IDIH action plan addresses several **key initiatives, stakeholders, and networks to be engaged in knowledge mobilisation** workshops as part of the policy/programme formation phase of the proposed plan, who are also considered as enablers facilitating the process of enhancement of international cooperation around the IDIH Common Priority Topics.

Among these initiatives, we highlight the **Cluster Organisations**, defined as member organisations with ecosystems players from the triple helix: academia (research organisations), industry among which are notably small and medium-sized enterprises (SMEs)], and government (R&I support organisations such as accelerators or incubators, but also policy support organisations).[1] This means they are ideal facilitators in the R&I landscape and one of their main goals is to support their members' collaboration efforts. In line with the EU's strategy in this field, strongly supported by the European Commission Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), cluster organisations have a strong interest in international collaboration and are thus, to a large majority, constantly seek international collaboration opportunities with relevant organisations from other countries (inside and outside of the EU). These collaboration schemes are developed for the purpose of supporting their members and above all the academic/research organisations and SME of the clusters' ecosystems.

Therefore, cluster organisations can be seen as important enablers for international collaboration in RDI, supporting also international policy dialog.

International cluster collaboration is specifically driven through the so called European Strategic Cluster Partnerships Going International (ESCP-4i). These are groups of cluster organisations working on a given thematic field/sector and aligning their international strategic approach for the benefit of their members. Cluster partnerships help develop common actions (such as business missions, cooperation agreements, gateway services, export consortia, and so on), as well as strengthen

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European SMEs' access to specific strategic partner countries markets. They also help create a long-term collaboration agenda with strategic partners in third world countries.[52]

DG GROW has been supporting the ESCP-4is for several years and several of them are/were active in the field of health.[53] These ESCP-4is are therefore considered an important target group for IDIH support activities; they identify target markets and develop a strategy that supports their SME members entering that market. They are constantly looking for collaboration partners in theses international markets to set up a collaboration scheme. The ESCP-4i scheme corresponds to both a funding opportunity (for EU organisations) and a path for future interactions with stakeholders.

What makes these collaboration schemes particularly interesting is the fact that EU cluster organisations in average count some 100 members each out of which a large majority SMEs. This is why it can be considered that connecting cluster organisations and similar member networks from the EU with counterparts from the targeted countries can have a very strong multiplier effect and such collaboration schemes can be real catalysts for R&I collaboration among members.

Cluster partnerships going international help the clusters of partnerships to improve their network, sign MoUs, and increase their exports, which ultimately leads to an increase in the revenues of the clusters, the ecosystem players, and the region.

The European Strategic Cluster Partnerships programme has four generations to date including different topics and focus sectors for the internationalization of the partnerships:

- First generation (2016–2017)
- Second generation (2018–2019)
- Third generation (2020–2022)
- Fourth generation (2021–2024)

This study focuses on cluster partnerships that span all four generations and are related to the health sector, although there are no cluster partnerships concentrating on this sector in the fourth generation. It can be expected that relevant additional initiatives will be implemented in the future under the same scheme.

With regard to the target countries of relevance for the IDIH project, the following can be summarized. China is home to an important cluster community. EU-China cooperation has been established with the aim of managing global challenges such as health, climate change, food security, and clean energy supply.

Canada has developed a large promising cluster and supercluster community, supported by ambitious governmental policies in favour of R&I. The Canadian government has decided to concentrate its actions by supporting a limited number of superclusters thanks to $950 million CAD investments for five years as of 2018.

In Japan, somewhat similar to the European Cluster Collaboration Platform (ECCP), the Japan External Trade Organisation (JETRO) has developed a mapping tool that provides information about the

[52] European Cluster Partnerships: https://clustercollaboration.eu/eu-cluster-partnerships
[53] Definitions of a cluster and a cluster organisation can be found on the European Cluster Collaboration Platform, a DG GROW initiative: https://clustercollaboration.eu/cluster-definitions

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industrial clusters in various regions of Japan and various sectors. The EU-Japan cluster cooperation has been well established since 2008.

South Korea has a well-developed cluster policy, mainly related to its so called "industrial complexes." EU-Korea collaboration is focusing on strategic technology areas (e.g., 5G) but collaboration on the level of clusters is established in other sectors as well.

Collaboration with the USA in the field of clusters is based on a Cluster Cooperation Arrangement that was signed in April 2015 as a first of its kind. It has been implemented ever since and is now, after a less active period, getting more attention since the general cooperation in STI with the USA is renewed. Numerous good practice examples of collaboration between cluster organisations exist, often supported through the ESCP-4is, which is very active in this target market in different sectors.

In the Annex *Cluster Partnerships as Enablers for International Collaboration*, the partnerships gathering clusters targeting the same target markets as IDIH are studied and there are six partnerships targeting the markets of the United States; four of the partnerships target the markets of Japan and/or China, while two of the partnerships target the markets of Canada and/or South Korea. Some of them are finished and some are still ongoing at the time of writing this roadmap. It can be expected that more are to come in the next generation of ESCP-4is, which is a clear opportunity for RDI actors. As previously stated, we can expect a strong multiplier effect from such collaboration, and they can be real catalysts for R&I collaboration among members and with peers in international countries.

Regarding IDIH, a number of results from the project can be considered as relevant to the community of cluster organisations and cluster partnerships. As an example, the following activities carried out in IDIH could be exploited in a larger perspective thanks to these initiatives:

- Reports (report on trend drivers and enablers, panorama of the digital health R&I landscape report, and recommended areas for international cooperation);
- Guidebook for RDI stakeholders: on funding and cooperation schemes;
- Podcast series;
- IDIH Week and other events/webinars;
- Exchange with the Digital Health Transformation Forum of Experts

Thus, European strategic cluster partnerships going international have been identified as target groups to ensure an efficient uptake of the IDIH results and targeted dissemination toward the ongoing ESCP-4is has been made with the abovementioned material.

At the same time, we encourage future cluster partnerships to consider IDIH achievements as a background in order to benefit from the lessons learned and engage in international collaboration with RDI and policy actors from the third world countries.

More information about the analysis of cluster organisations as enablers to enhance international cooperation in digital health for AHA are included in the **ANNEX 1 of this roadmap.**

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4.3 Action plan

To **support follow up of the three Common Priority Topics** identified by the **IDIH Digital Health Transformation Forum** as common ground for enhancing international cooperation in digital health for AHA, IDIH intends to provide policy makers and funding agencies from the EU and the five IDIH strategic countries with **a concrete proposal for how to implement the IDIH recommendations**. Therefore, an **action plan** is included here as part of the section "How to enhance."

In line with the United Nations' Decade of Healthy Ageing - A 10-year plan for a decade of healthy ageing 2020–2030 – this action plan has been conceived to cover a period of eight years starting from 2022, culminating in 2030. The timing proposed for the single phases of this action plan appeared reasonable to the policy representatives consulted at the PLC set by the project. In particular, if five years for the policy/programme implementation has been considered as an average timeframe for the implementation of R&I programmes between the EU and the Strategic Partner countries, the duration of the other phases have been defined considering stakeholder engagement activities (e.g. knowledge mobilisation workshops) carried out in parallel in the different regions involved. Finally, the evaluation period is lasting three years, where monitoring and evaluation could start right after the first two years of implementation of the actions foreseen, thus overlapping the implementation phase for one year.

The success of the proposed action scheme may be affected by external factors considering political agendas and priorities that may change, for example, with change in government or other national/international contingencies and emergencies, causing delays in implementing cooperation agreements. At the beginning of the IDIH project, the European Union and some of the Strategic Partner Countries had a long-lasting history of cooperation with the formal establishment of Science and Technology Agreements, but within the three years of the project, the political ecosystem relevant for IDIH has changed significantly (e.g. EU-US RDI cooperation under Trump administration, revitalised now under Biden; and EU-China relations now based on the new global approach of the EU towards international cooperation, based on strategic autonomy (see 4.4 Agenda setting).

This **action plan** was developed considering the steps of the **policy making process**, suggesting specific durations for each key step, developing an **overall timeframe for implementation in eight years**, and looking at the goals of the **UN Decade for Healthy Ageing** in 2030.

1. **Agenda setting:** highlighting to policy makers the relevant framework policy priorities at regional/international levels to be considered, justifying the need for action in the field proposed by the IDIH Forum [*at **time 0***].
2. **Policy/programme formation:** supporting the policy makers and relevant funding agencies to map a state-of-art programme in the field of digital health and ageing, consult the key stakeholders at national/international levels (through PLC), and identify the trends and enablers to be potentially exploited [*suggested duration: **2 years***].
3. **Decision-making and policy/programme implementation:** supporting the policy makers and relevant funding agencies to single out and manage a particular course of action; e.g., joint funding scheme/partnerships and other initiatives at national/international levels, considering the available resources and opportunities at stake [*suggested duration: **5 years***].

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4. **Policy/programme evaluation:** suggesting the policy makers and relevant funding agencies develop a methodology for a follow up to determine whether the policy/programme brought about the desired results and impact; pointing out, in particular, knowledge mobilisation through workshops with users and policy makers (now experienced as best practice from CIHR/Canada) as an option to be put in place in this phase and possibly replicated in different countries internationally [*suggested duration: **2 years***].

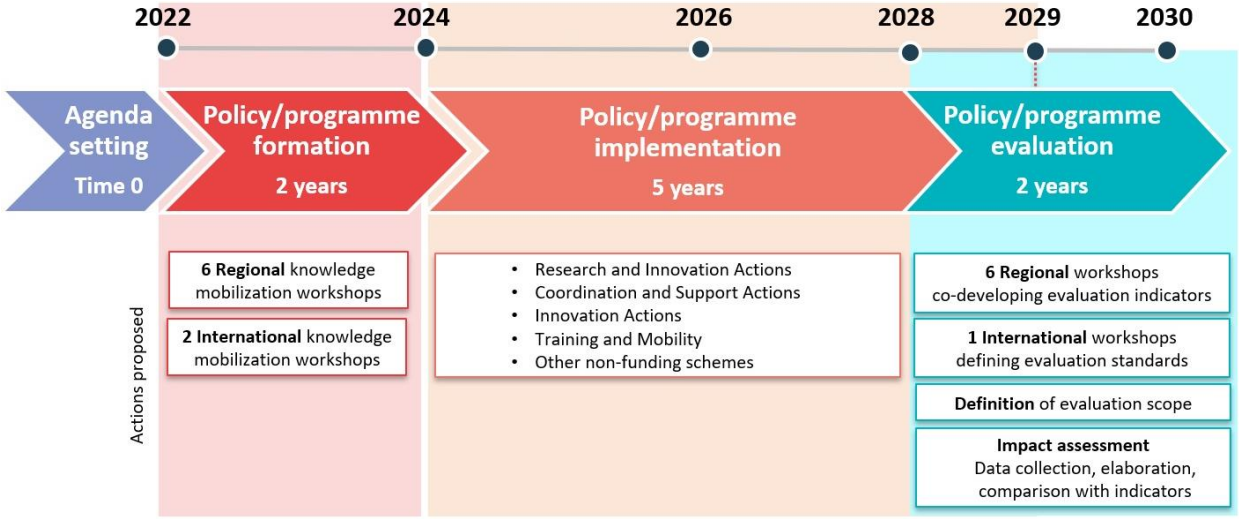
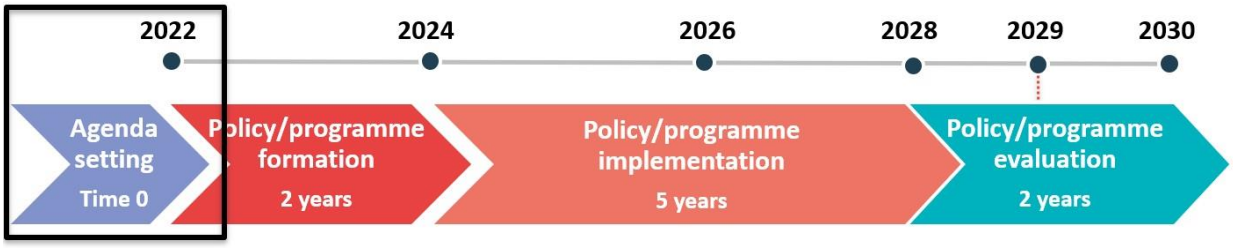


Figure 6: Action plan for the IDIH roadmap

4.4 Agenda setting



Agenda setting [time 0 to 2022]

As a result of the IDIH analysis[54] of the policy framework that, at national and international levels, may support implementation of the IDIH recommendations, **several key policy drivers and highlights** are to be considered as a basis – at time 0 (2022) of this action plan, justifying further action in the three areas suggested by IDIH for international cooperation in the field of digital health for AHA: *data governance, digital inclusion, and interoperability by design.*

Key policy drivers for agenda setting at the EU and international levels:

- *Europe's strategy for international cooperation in a changing world*
- *The Communication of the European Commission "Shaping Europe's digital future"*

[54] See reports Briefing note on (priority) topics for the Expert Groups, Guidebook for RDI stakeholders.

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- *WHO Decade of Healthy Ageing*
- *Green Paper On Ageing*

Policy highlights for agenda setting in strategic countries:

- *Canada*
- *China*
- *Japan*
- *South Korea*
- *United States*

Europe's strategy for international cooperation in a changing world

The Commission leads many global research partnerships. These partnerships are important for the EU to meet its international commitments in line with the SDGs. However, international cooperation in R&I is taking place in a transformed global landscape, where geopolitical tensions are rising, and human rights and fundamental values are being challenged. The Commission Communication on the Global Approach to Research and Innovation has developed "Europe's strategy for international cooperation in a changing world," which aims to preserve a leading role for the EU in R&I to deliver innovative solutions to make European societies inclusive, "green," digital, and healthy. This strategy is based in the promotion of multilateralism, openness, and reciprocity in EU cooperation with the rest of the world. The EU will facilitate global responses to global challenges, such as climate change or pandemics, respecting international rules and fundamental EU values, and strengthening its open strategic autonomy by, in parallel, modulating its bilateral cooperation with non-EU countries in certain areas.

Under this strategy, with the vision of pooling global efforts to tackle global challenges together, the EU has identified the **digital transition** as a common ground to enhance international cooperation.

The 2030 Digital Compass will guide the EU's efforts in fostering a global approach to the main **technological and regulatory developments**, including the area of **international connectivity and standards.** The EU should foster an international approach to trusted data flows while promoting its model of a safe open and resilient global internet and pursuing ambitious goals in terms of market access.

- *Collaboration in R&I is one tool for fostering digital partnerships with regions around the world.*
- *International digital partnerships on the following topics will be promoted:*
  - ***Human centric policy and regulations**;*
  - *Adapted and improved solutions for **digital connectivity;***
  - *Enhanced innovation partnerships with the digital R&I ecosystems;*
  - *Enhanced focus and research partnerships on key technologies such as **artificial intelligence (AI), blockchain, IoT, Big Data, space data,** applications of digital technologies to "green" transition, **health,** and **education.***

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Moreover, while much of the cooperation with specific countries will take place within multilateral global partnerships, this outlined European strategy is also a path for strengthening bilateral cooperation to enhance knowledge and pool resources, especially in areas of EU interests. Therefore, several EU orientations toward some of the IDIH strategic countries are discussed below:

The EU is also an important source of new technologies and a key partner for **Canada** in science, technology, and innovation. With the Canada-EU Agreement for Scientific and Technological Cooperation, Canada and the EU established priority areas for STI cooperation, which include **information communication technologies, health, researcher mobility, and research infrastructure.** Moreover, exploratory talks for the association of Canada to Horizon Europe are ongoing.

China: The EU and China have been discussing on a joint roadmap to establish agreed framework conditions and guiding principles for collaboration to reach a level playing field and reciprocity while upholding fundamental values and maintaining high ethical and scientific integrity standards. Based on this objective, they aim to identify the **research fields in which cooperation could be mutually beneficial**, such as climate science and biodiversity protection, circular economy, **health**, food, agriculture, aquaculture, and ocean observation.

In particular, a Letter of Intent was signed between the EU and **Japan** in May 2020 to strengthen cooperation in science, technology, and innovation, and to enhance the synergies between the next EU R&I programme Horizon Europe, and **Moonshot**, Japan's research and development programme. This will enable researchers and innovators to cooperate more easily on global challenges such as: **health,** climate change, **digital transition and ageing societies,** fighting the coronavirus pandemic, including through **open access to research data and results.**

Also, cooperation with **South Korea** is a priority for the EU and there is strong potential to work for mutual benefit in a wide range of areas, such as **5G, Internet of Things (IoT), cloud and Artificial Intelligence (AI),** nanoelectronics and nanosafety, infectious diseases, and antimicrobial resistance. Moreover, recently, during the 7th Republic of Korea-EU Joint S&T Cooperation Committee Meeting held on February 2022, five priority areas for cooperation were particularly addressed: **ICT, Health/BIO**, Climate Change and **Emerging Future Technology**, **Research Hub**, and **human capital development** were addressed.

United States: The Joint Communication A New EU–US Agenda for Global Change lays out a number of proposals for cooperation with the US, including a call for the formation of a green technology alliance and the establishment of a new EU–US trade and technology council (TTC), as a forum for the EU and the US to coordinate approaches to key global trade, discuss economic and technology issues, and deepen transatlantic trade and economic relations based on shared democratic values. The working groups include the following topics: **technology standards**; climate and clean tech; secure supply chains, information and communication technology and services (ICTS), and security and competitiveness; **data governance and technology platforms;** misuse of technology; threat to security and human rights; export controls; investment screening; promotion of SME; **access to and use of digital tools**; and global trade

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

challenges. Building on this text, the Commission also proposes to **increase reciprocity in bilateral cooperation** and raise the levels of coordination and coherence between EU and US R&I investments, beginning with climate, **digital**, energy, environmental, and **health** challenges.

The EU also intends to enhance its cooperation with major science powers such as **Canada**, **Japan**, and **South Korea** to explore new possibilities for closer cooperation, such as associations under Horizon Europe.

Shaping Europe's digital future

The Communication of the European Commission "Shaping Europe's digital future" outlines the EU approach to digital transformation, toward *a European society powered by **digital solutions that are strongly rooted in our common value, and that enrich the lives of all of us:** people must have the opportunity to develop personally, to choose freely and safely, and to engage in society **regardless of their age, gender, or professional background.** Businesses need a framework that allows them to start up, scale up, pool, and use data, to innovate and compete or cooperate on fair terms. Europe needs to have a choice and pursue the digital transformation in its own way.*

This vision and the approach to the European technological sovereignty in the path for digital transformation should be considered considering the EU Global Approach to R&I by highlighting how such sovereignty *is not defined against anyone else but is defined by focusing on the needs of Europeans and of the European social model. **The EU will remain open to anyone willing to play by European rules and meet European standards, regardless of where they are based**.*

In this sense, any further initiative of international cooperation accompanying the digital transformation should be implemented according to this strategy and approach.

Moreover, the EU has been working for several years on a Data Strategy and Data Governance Act. The Commission has proposed regulation on European data governance as part of its data strategy. This new regulation will play a vital role in ensuring the EU's leadership in the global data economy. On February 23, 2022, the Commission proposed regulation of harmonized rules on fair access to and use of data (Data Act). The Data Act is a key pillar of the European strategy for data sharing. Its main objective is to make Europe a leader in the data economy by harnessing the potential of the ever-increasing amount of industrial data to benefit the European economy and society.
"Every second, doctors, nurses, pharmacists, researchers and health regulators all over the EU generate and use large numbers of essential healthcare data that are critical to their lifesaving work. Health data are the blood running through the veins of our healthcare systems. The COVID-19 pandemic has shown that up-to-date health data are key to taking well-informed public health measures and to responding to crises. The pandemic has also triggered a huge acceleration in the uptake of digital tools. Unfortunately, there are still complex obstacles that make it difficult to reach the full potential of digital health and health data. There are still some challenges in harnessing the power of health data"[55]:

[55] European Commission (2022). Questions and answers on EU Health: European Health Data Space (2022) at EU Health: European Health Data Space (europa.eu)

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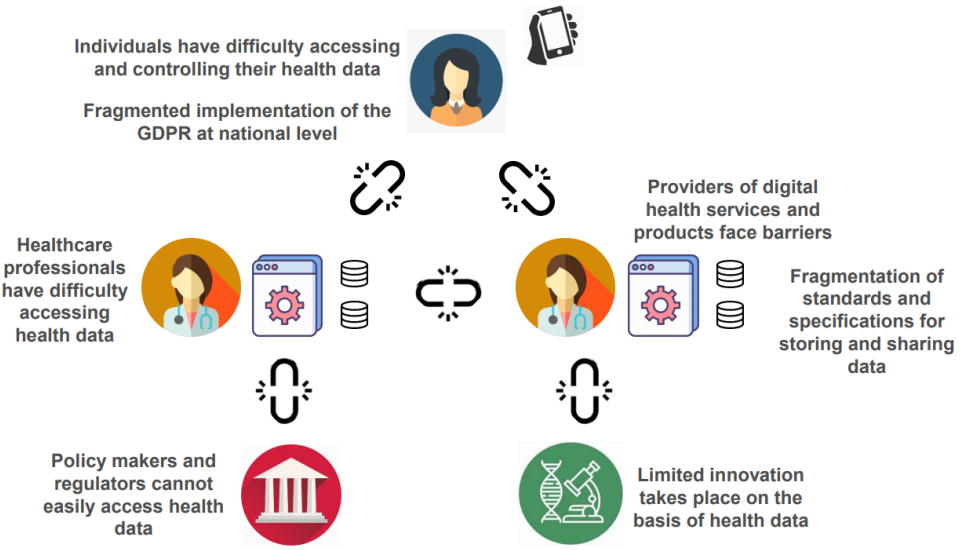

Source: Health Data, new challenges and solutions, European Commission[56]

"The **European Health Data Space**[57] will overcome these obstacles. It is a health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data by patients and research, innovation, policymaking, patient safety, statistics or regulatory purposes.

The European Health Data Space will empower **individuals** across the EU to fully exercise their rights over their health data. People will be able to easily access and share these data, while retaining greater control over them, fully in line with our overall EU approach to data protection.

At the same time, the work of **health professionals** will be made easier and more effective. With improved interoperability, health professionals will be able to access a patient's medical history across borders, thus increasing the evidence base for decisions on treatment and diagnosis, including when the patient's data is in another EU country.

By strengthening interoperability to support data exchange between healthcare providers within countries and across borders, **healthcare providers** will avoid duplications of tests, with positive effects for patients and healthcare costs."

"Researchers will also benefit from a more direct way of obtaining access to data within a trusted and secure framework. Researchers will have access to larger amounts of high-quality data. They will be able to access the data more efficiently and less expensively, through a data access body that guarantees the privacy of the patients.

Regulators and policymakers will also have easier access to health data for policy making and a better functioning of healthcare systems. This will lead to better access to healthcare, reduced costs, increased efficiency, more resilient health systems, new research and innovation and enable more evidence-based policymaking.

[56] European Commission (2022). Health Data, new challenges and solutions at https://www.promisalute.it/upload/mattone/documentiallegati/Martinello_EHDSpresentation-ProMISWinterSchool_13660_9702.pdf

[57] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (2022) https://health.ec.europa.eu/system/files/2022-05/com_2022-197_en.pdf

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

The industry will benefit from an EU-wide market for electronic health record systems, with the same standards and specifications. Greater availability of electronic health data will improve people's health, and facilitate the production of innovative medicinal products and devices that offer better and more personalised care. The industry will be also able to develop new devices that use artificial intelligence technology."[58]

Potential impact of EHDS implementation on IDIH priority topics:

Data governance

"When providing a framework for the secondary use of electronic health data, the EHDS builds upon the proposed Data Governance Act and the proposed Data Act. As a horizontal framework, the Data Governance Act only lays down generic conditions for secondary use of public sector data without creating a genuine right to secondary use of such data. The proposed Data Act enhances portability of certain user-generated data, which can include health data but does not provide rules for all health data. Therefore, the EHDS complements these proposed legislative acts and provides more specific rules for the health sector. These specific rules cover the exchange of electronic health data and may impact the provider of data sharing services, formats that ensure the portability of health data, cooperation rules for data altruism in health and complementarity on access to private data for secondary use.

On secondary use of electronic health data, researchers, innovators, policy makers and regulators would be able to have access to quality data for their work in a secure way, with trusted governance and at lower costs than relying on consent. The common framework for secondary use would reduce the fragmentation and barriers to cross-border access. The preferred option requires the Member States to set up one or more health data access bodies (with a coordination body), that can provide access to electronic health data to third parties, either as a new organisation or part of an existing organisation, building on the Data Governance Act. Parts of the costs will be offset through fees charged by health data access bodies. The setting up of health data access bodies is expected to lower costs to regulators and policy makers for accessing electronic health data, thanks to greater transparency of the effectiveness of medicinal products, resulting in a reduction of costs in the regulatory processes and public procurement in health. Digitalisation can also reduce unnecessary tests and ensure transparency in spending, allowing savings to the health budget. EU funds will provide support for digitalisation. The goal is to ensure transparency of information concerning datasets to data users, for which a stepwise approach was also adopted. This would mean that the dataset description would be mandatory for all datasets, excluding those held by microenterprises, while the self-declared data quality label, would only be mandatory for data holders with publicly funded datasets and voluntary for others. These nuances introduced after the impact assessment do not substantially alter the calculation of the costs for data holders stemming from the impact assessment"[59]

Digital Inclusion

"Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. Natural persons should be able to

[58] European Commission (2022). Questions and answers on EU Health: European Health Data Space (2022) at EU Health: European Health Data Space (europa.eu)

[59] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (2022) https://health.ec.europa.eu/system/files/2022-05/com_2022-197_en.pdf

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provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or control access to their electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services should be established by the Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic.
To support health data access bodies and data users, it should be provided a template for the joint controller arrangements health data access bodies and data users will have to enter. To achieve an inclusive and sustainable framework for multi-country secondary use of electronic health data, a cross-border infrastructure should be established. HealthData@EU should accelerate the secondary use of electronic health data while increasing legal certainty, respecting the privacy of natural persons and being interoperable"[60].

Interoperability by design
"The COVID-19 pandemic has revealed the urgent need and the high potential for interoperability and harmonisation, building upon existing technical expertise at the national level. At the same time, digital health products and services, including telemedicine, have become an intrinsic part of the delivery of healthcare.
The EHDS sets essential requirements specifically for EHR systems to promote interoperability and data portability of such system, which would allow natural persons to control their electronic health data more effectively. In addition, where manufacturers of medical devices and high-risk AI systems declare interoperability with the EHR systems, they will need to comply with the essential requirements on interoperability under the EHDS Regulation.
Currently, the cross-border exchange of electronic health data is still very limited, which is partly explained by the significant diversity in standards applied to electronic health data in different Member States. In many Member States, there are substantial national, regional and local challenges to interoperability and data portability, hampering continuity of care and efficient healthcare systems. Even if health data are available in electronic format, it does not usually follow the natural person when they use the services of a different healthcare provider. The EHDS proposal will address these challenges at the EU level, providing mechanisms for improving interoperability solutions used at national, regional and local levels and reinforcing the rights of natural persons. Therefore, EU-wide action in the content and form indicated is required to promote the cross-border flow of electronic health data and to foster a genuine internal market for electronic health data, digital health products and services.
Most Member States are expected to implement the MyHealth@EU platform by 2025. Only when more Member States will have implemented the MyHealth@EU platform and developed the necessary tools, will their use, development and maintenance become more efficient across the EU"[61].

In the context of **Horizon Europe**, the EU research & innovation framework programme for 2021-2027, under the first Work Programme of Cluster 1 Health which covers 2021-2022 period, some calls for

[60] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (2022) https://health.ec.europa.eu/system/files/2022-05/com_2022-197_en.pdf
[61] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (2022) https://health.ec.europa.eu/system/files/2022-05/com_2022-197_en.pdf

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proposals have already been published which should be relevant for a follow-up of IDIH's priority topics.

Here below the list, special attention should be paid to the projects funded under each call to understand how their project results could be exploited at the international level.

HORIZON-HLTH-2021-STAYHLTH-01-03: Healthy Citizens 2.0 - Supporting digital empowerment and health literacy of citizens

Key aspects: Digital technologies are a driving force for empowering citizens in taking on an active role in the management of their own health and well-being as well as for supporting innovations for coordinated person-centred care models.

Relevance in respect to IDIH priority topics:

- *Data Governance:* Health care and social services are better integrated, affordable, open to diversity and inclusion: they comply with precautionary protections concerning sensitive health data, consider the needs of end users (citizens, formal and informal carers) and innovation carriers (SMEs, hospitals) and favour tools of social innovation.
- *Digital Inclusion: it* is vital to ensure that online-based patient-centred programmes do not leave behind the very people they are primarily designed to empower. Moreover, citizen's digital health literacy is essential for the successful transformation of health care systems. Develop a comprehensive and inclusive European strategy in improving (digital) health literacy for the benefit of all citizens focusing on health promotion, disease prevention, treatment and (self-)care as well as on monitoring its impact on the quality of life, wellbeing, productivity and the economy, taking into account geographic, social and economic determinants of inequities in digital health literacy.
- *Interoperability by design:* Member States actively contribute to health literacy efforts, monitor and evaluate them. Create a network of champions in digital health literacy across the EU (and beyond) to foster exchange and uptake of best practices. Set concrete targets as well as areas for improvement on health literacy levels across Europe. Develop monitoring mechanisms and indicators to assess health literacy levels and their evolution across Member States.

International cooperation component: Map health literacy research in the EU (and beyond).

List of funded projects:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-stayhlth-01-03

HORIZON-HLTH-2022-CARE-10-01: European partnership on transforming health and care systems

Key aspects: There is a need to accelerate the transition towards more efficient, sustainable, resilient, innovative and accessible health and care systems in Europe. To this end, the creation of a research and innovation (R&I) partnership with a focus on health and care systems' transformation represents a unique strategic opportunity to bring together stakeholders, create synergies, coordinate R&I actions, facilitate the digitization of health and care services and support the transformation of health and care systems with innovative solutions driven by knowledge and evidence.

Relevance in respect to IDIH priority topics:

- *Data Governance:* The Partnership should align with EU-wide initiatives on open access and FAIR data.
- *Digital Inclusion:* Citizens and health and care professionals should increase digital and health literacy.
- *Interoperability by design:* To increase the likelihood of successful system transformation, the partnership will facilitate exchange of information and good practices among countries,

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

provide robust guidance and tools, network institutional stakeholders and involve regional ecosystems.

International cooperation component: Although this Partnership will focus on the transformation of European health and care systems, cooperation with international organisations, and non-European institutions and experts may be considered. Researchers across European countries and regions are engaged in enhanced collaborative research on transforming health and care systems.

List of funded projects:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-care-10-01

HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re -use of health data (in particular of electronic health records and/or patient registries)

Key aspects: Health data exists in many forms and multiple fragmented repositories; there is still significant room for improvement in the way both structured and unstructured health data is stored, analysed and interpreted. Build on and contribute to existing European and international data standards, specifications and schemas for health data,

Relevance in respect to IDIH priority topics:

- *Data Governance: Contribute to the work on the creation of the* European Health Data Space. In compliance with FAIR data management principles as well as national and EU legal and ethical requirements (in particular with regard to personal data protection).
- *Digital Inclusion:* Developing and piloting AI-powered virtual assistants that will utilise the tools and solutions developed (as mentioned above) in order to demonstrate improved usability of health data for end-users.
- *Interoperability by design: Novel solutions improve quality, ensure interoperability and enable re-use of health data,* data analytics and metadata from different repositories across countries. developing data interoperability standards, trust and harmonization of GDPR's interpretation across the EU for the sharing and processing of personal health data will support establishing a sound health data culture in view of the European Health Data Space.

International cooperation component: topic more focussed on EU.

List of funded projects:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-tool-06-03

HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

Key aspects: address the data needs of health regulatory bodies and HTA bodies across the EU, as outline d in the recently published "HMA-EMA Joint Big Data Taskforce Phase II report: 'Evolving Data-Driven Regulation' and its associated DARWIN (Data Analysis and Real World Interrogation Network) project.

Relevance in respect to IDIH priority topics:

- *Data Governance:* To harness the potential of RWD and synthetic data from digital twins and advanced analytical models, and make them actionable for health regulatory decision-making and for health technology assessment, targeted research is needed on the evidentiary value of these data for a number of relevant use cases. methods need to be developed to increase the usability of such data by different stakeholder groups. Doing so will contribute to the European Health Data Space and maximize the positive impact of DARWIN in driving up the quality of evidence and decisions on the development and use of medicines and digital health innovations.

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- *Digital Inclusion:* Proposals should involve national competent authorities (national health care product regulatory bodies and/or medical device notified bodies) and could involve citizens and patients' representatives where relevant.
- *Interoperability by design:* Develop a set of evidentiary standards to be pre-specified and used in the analysis of real-word evidence and/or synthetic data applied to different types of regulatory advice and/or health technology assessment and decisions on the safety and efficacy/effectiveness of medicines and digital health innovations.

International cooperation component: topic more focussed on EU.
List of funded projects:
https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-tool-11-02

HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation
Key aspects: speed up and facilitate innovations in the field of data-driven tools and services for wellbeing, prevention, diagnosis, treatment and follow-up of care, among others. Integration of national/regional health data hubs/repositories/research infrastructures is appropriate to achieve the scope of the topic.
Relevance in respect to IDIH priority topics:

- *Data Governance:* Widen the basis for GDPR-compliant research and innovation on health data. consider the use of synthetic, i.e. artificially generated, data as they allow researchers and developers to test, verify and fine-tune algorithms in large-scale data experimentations without re-identifiable personal data. In addition, the proposed anonymization techniques will have to be sophisticated and robust enough to tackle the challenge of anonymized data sets that still make it possible to trace back to individuals. The aim is to allow secure GDPR-compliant data processing for research, and clinical purposes.
- *Digital Inclusion:* limited access by developers to health data and secure testing environments hinder the development of innovative data-driven digital health products and services.
- *Interoperability by design:* foster the development of secure, interoperable, transparent - and therefore trustable - cross-border health data hubs that can facilitate the provision of the required testing environments for innovators. This will support the uptake of new data tools, technologies and digital solutions for health care.

International cooperation component: topic more focussed on EU.
List of funded projects:
https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-ind-13-02

HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub
Key aspects: The EU has supported innovation of digital tools for better and more personalised treatments and self-monitoring of citizens and patients throughout Europe. However, adoption and deployment of digital health solutions in practice, both in the public health system and by private players remains low.
Relevance in respect to IDIH priority topics:

- *Data Governance:* In compliance with FAIR data management principles and GDPR.
- *Digital Inclusion:* Empowered patients and citizens of all ages, gender, social and economic background adopt and use digital tools to monitor their health status independently.
- *Interoperability by design: link various existing repositories of digital health solutions, which are* already deployable as part of different EU projects and initiatives. It is necessary to integrate them into a European Digital Health Smart Innovation Hub, which will serve as a European reference platform for scalable digital health solutions, both for public organizations

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and private actors, connecting supply and demand side. Integrating existing repositories into a sustainable European repository, serving as a reference of ready to market solutions (supply side) and public and private organisations adopting them (demand side), as well as best practices.

International cooperation component: topic more focussed on EU.

List of funded projects:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-ind-13-04

WHO Decade of Healthy Ageing

The United Nations Decade of Healthy Ageing (2021–2030) is a global collaboration, aligned with the last ten years of the SDGs, that brings together governments, civil society, international agencies, professionals, academia, the media, and the private sector to improve the lives of older people, their families, and the communities in which they live.

The United Nations Decade of Healthy Ageing 2020–2030 addresses ***four areas*** for action at multiple levels and in multiple sectors in order **to promote health, prevent disease, maintain intrinsic capacity, and enable functional ability** with the support of four related ***enablers.***

In particular, **combating ageism** is a leading principle for any action supporting AHA at national and international levels, as recently reaffirmed also by the WHO Global Report on Ageism explaining how even small shifts in how we think, feel, and act toward age and ageing will reap benefits for individuals and societies.

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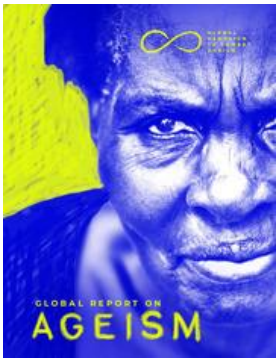

Older people have often been seen as uniformly frail and vulnerable, while younger people have been portrayed as invincible, reckless, and irresponsible. Stereotyping (how we think), prejudice (how we feel), and discrimination (how we act) based on age, are not new; COVID-19 has amplified these harmful attitudes. Moreover, ageism has severe and far-reaching consequences for people's health, wellbeing, and human rights and it costs society billions of dollars. Ageism is associated with poorer physical and mental health, increased social isolation and loneliness, greater financial insecurity, decreased quality of life, and premature death among older people. Once the issue has been scientifically framed, the report suggests achieving long-lasting, vastly better development prospects at the heart of the SDGs. ***We must change the narrative around age and ageing.*** *We must raise the visibility of and pay closer attention to ageism attitudes and behaviours, adopt strategies to counter them, and create comprehensive policy responses that support every stage of life.*

A 10-year plan for a Decade of Healthy Ageing 2020–2030 has already been defined to coordinate concerted, catalytic, and sustained ecosystem collaboration, which is required to tackle multiple healthy ageing factors, thereby resulting in transformative changes in a multidisciplinary and multistakeholder environment.
Here are some highlights from the UN plan:

- Combining geographical data and existing studies that include older adults is a viable technique to investigate the interaction and impact of several factors on functional ability. Several countries already use national and subnational data to improve policies and programmes for older people. However, **the lack of data on healthy ageing or older age groups increases their invisibility.** Governments need to invest in data to monitor healthy ageing over the course of an individual's life.
- Despite an increased worldwide commitment, the level of reporting and pace of progress need to be accelerated and **new indicators** need to be identified. Regular tracking will reveal whether we are proceeding through an improvement scenario. The baseline assessment includes two types of indicators:
    - Indicators of progress at a **national level**
    - Indicators of outcome and impact on **people's lives.**
- The focus of research on healthy ageing should not be solely on health issues. New knowledge is required to link the **social, biological, economic, and environmental determinants of healthy ageing**. For this purpose, new studies and the **interconnection** of several stakeholders are necessary.

The emerging trend to **transform disease-based approaches *into* person-centered programmes** optimizing functional ability personal goals should be encouraged and addressed.

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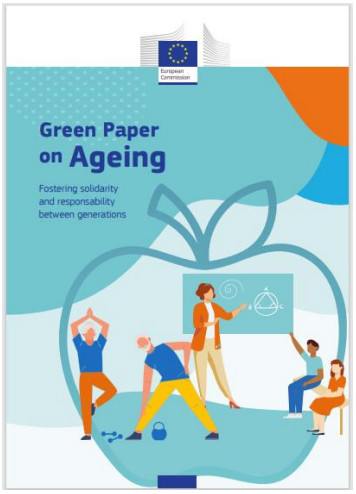
Green Paper on Ageing



Demography represents a hot topic on the EU policy agenda as well. The Commission's June 2020 report on the impact of demographic change showed that, in the last 50 years, life expectancy at birth has increased by about 10 years for both men and women.

In this framework, the "*Green Paper on Ageing. Fostering solidarity and responsibility between generations*" was adopted on January 27, 2021 to launch a **broad policy debate** on the challenges and opportunities of Europe's ageing society. It sets out the impact of this pronounced demographic trend across the economy and society and will be followed by a long-term vision for rural areas that will also investigate the question of depopulation, in compliance with the UN 2030 Agenda for Sustainable Development and UN Decade for Healthy Ageing.

Several key action areas have been identified by the Green Paper on Ageing toward 2030:

- **Laying the foundations:**

Laying the right foundations at early stages of our lives can help prevent, limit, and postpone some of the challenges linked to ageing. This includes ***promoting healthy lifestyles*** *and investing in* ***people's education*** *throughout their lives.*

- **Making the most of our working lives:**

To compensate for the shrinking working-age population, the EU should promote policies to bring more people into the labour market (women, migrants, people with disabilities, and senior entrepreneurs), ***enable longer working lives,*** *and improve productivity and opportunities.*

- **New opportunities and challenges in retirement:**

Most retirees are fit and provide an important contribution to society and the economy through ***intergenerational learning and cohesion*** *(volunteering) owing to their healthier lifestyles and medical progress. This also necessitates providing them with adequate,* ***fair, and sustainable pension schemes*** *to safeguard them from poverty during old age.*

- **Addressing the growing needs of an ageing population:**

Health promotion and disease prevention*, in the form of healthy lifestyles, can help limit or postpone illness or disability. A comprehensive policy response may involve investing in* ***quality services, infrastructure, and community-based service****.*

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Relevant policy priorities and topics in Canada

For the 2020–2030 period, the Canadian Institutes of Health Research (CIHR) is developing a new strategic plan to guide their operations and investments from 2020 to 2030. With this plan, they also seek to lay the foundation for a shared vision on how Canada's health research ecosystem could look in the next 30 years.

The new strategic plan will build on lessons learned since the last strategic planning exercise in 2014. Principally, this means better alignment with others in the health research ecosystem. For this purpose, they started with a robust environmental scan of provincial and territorial health priorities. Presently, they are actively engaging with numerous stakeholders as they develop the plan, including citizens, patients, charities, provincial funders, indigenous communities, government departments, researchers, health professionals, trainees, and research administrators. As part of the CIHR, the Institute of Ageing (IA) identifies and addresses knowledge gaps and opportunities related to Canada's ageing population through research and other actions. The institute focuses on health and wellness across the entire trajectory of life while specifically addressing the health challenges of the elderly.

Relevant policy priorities and topics in China

Among the current Chinese policies around digital health for AHA, **inclusive living** is supported and developed.

China has implemented an old-age security system, and a relatively sound medical and social security system can provide better inclusive living support. However, while the Healthy China Action Promotion Committee with the Healthy China Action (2019–2030) envisages support for healthy ageing in preventive care, **preventive care still needs to be improved and further international cooperation is necessary.**

According to the promotion of active ageing in China from the Oxford Institute of Population Ageing, the Active Ageing Index (AAI) is more suited to the needs, priorities, and datasets of EU countries since it was first developed for EU countries. Thus, **the improvement of the AAI application to the Chinese scenario is mandatory, with indispensable cooperation with EU stakeholders.**

Relevant policy priorities and topics in Japan

The Prime Minister's Office published the policy paper: **Healthcare Strategy for 2020–2024 on March 27, 2020.** According to this paper, the goal to be accomplished by 2024 is to extend the life expectancy of both male and female Japanese people by three years (and these three years must be active and healthy ones). The paper states that, in order to accomplish this goal, the world's most advanced medical care must be provided to all Japanese people.

However, the reality is that the medical **gap between urban and rural areas** is rapidly widening as the elderly population increases and the young population declines especially in rural areas very quickly.

Technologies and innovations are needed to fill this gap and protect the universal coverage that has greatly contributed to extending the lifespan of Japanese people.

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In addition to the R&I topics aiming at commercialization in the short term[62], more ambitious long-term research topics are set as **"Moonshot" projects**. The most focused are aimed to:

- Develop the technologies that can guarantee/protect universal coverage to all Japanese people;
- Develop the technologies that can ***control our body to improve our quality of life***.

The **Healthcare Strategy for 2020–2024** mentioned above pointed out the following problems as major barriers for R&I in digitalization of healthcare, which may represent further trends for development in this field.

- In order to utilize various novel **healthcare services from the private sector** effectively, these services **need to be incorporated into public insurance**. However, the foundation for this is not well prepared.
- In the global trend toward open innovation, life related venture companies, such as drug discovery companies, are becoming the main players in R&I. In Japan, the ecosystem is not able to support them from funding to finish. Additionally, if new seeds for development are found/created, there still is not enough **manufacturing-infrastructure** for commercialization.
- New players with **digital technologies,** including AI and bigdata-analysis, are entering the healthcare market. However, without **collaboration with the "old" players**, new players could not expand on their knowledge and experiences.

Relevant policy priorities and topics in South Korea

The state of R&I in South Korea has recently been propelled by the announcement of the **Korean New Deal in mid-July 2020**. Its primary agenda as a national development strategy is to support the nation's recovery from the current pandemic crisis, further combat the challenges of growth, which has been slowing down since the 1990s, and widening the levels of polarization.

- Under the Digital New Deal, **Smart Healthcare** is one of the 10 key projects where Korea's digital capacity, based on its competitive information and communication technology (ICT), is aimed to be strengthened through building large-scale ICT infrastructures including a 'Data Dam' or a large collection of data to support Big Data development.

Such technological enhancement will foster the post-pandemic medical industry, increasing the accessibility to digital healthcare for rural residents and vulnerable patients. The Korean government is dedicating 0.6 trillion Korean Won (KWN), roughly equivalent to 500 million USD, to building smart medical and healthcare infrastructures from the year 2020 to 2025, resulting in newly created 5,000 jobs. The establishment of **digitized or an "untact" infrastructure** will protect the country from unexpected shocks, including infectious diseases, such as the novel coronavirus, by ensuring a stable provision of medical services and a safe working environment for medical staff. By 2022, 100 billion KWN will be invested from the treasury to build nine **smart hospital models**, 1,000 specialized respiratory clinics, and an environment for AI medical diagnosis for eight diseases. These numbers will

[62] These are: drug discovery, medical devise and healthcare, regeneration/cell medicine, and gene therapy, genome data, infrastructure, disease basic research, seeds-development, and research infrastructure.

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increase by 2025 to 18 smart hospital models and the capability to diagnosis 20 diseases using AI as additionally 100 billion KWN will be invested.

Furthermore, to provide convenience to the public, the Ministry of Health and Welfare (MOHW) will work to institutionalize 'untact' or digitized medical treatments based on full discussions with stakeholders, including the medical sector. Measures will be developed to address concerns over patient safety, accountability for medical mishaps, and the overconcentration of patients at tertiary hospitals. The government will continue to expand pilot projects extending health insurance coverage on remote medical treatment by utilizing ICT[63].

- The Korean government established a National Strategy for AI on December 17, 2019[64]. With the vision of "**Toward AI World Leader beyond IT,"** Korea aims to achieve digital competitiveness, create a huge economic effect of AI, and improve the quality of life for people by 2030.

The strategy consists of 100 government-wide action tasks under nine strategies in three main areas of AI (*AI ecosystem, AI utilization, and people-centered*). In particular, its ambition to create an innovative AI ecosystem includes the promotion of convergence of AI and the region's flagship industries, such as automobiles, energy, and *healthcare* ("Gwangju AI Cluster," 2020–2024, total project cost of 393.9 billion KRW).

Relevant policy priorities and topics in the United States

Two main policy frameworks are currently driving R&D, as well as healthcare and assistance, in the United States in the field of digital health for AHA:

- **21st Century Cures Act[65]**
  - ***Priority/Key Areas*:** i) Accelerate research on preventing and curing serious illnesses; ii) Accelerate drug and medical device development; iii) Address the opioid abuse crisis; and iv) improve mental health service delivery[66]
  - ***Relevance***: The 21st Century Cures Act is widely known for helping to fund efforts in precision medicine, but it also aims to improve healthcare IT by addressing interoperability and information blocking. Under the act, providers and insurers may be penalized if they implement healthcare IT in nonstandard ways or healthcare IT that restricts the access, exchange, or use of authorized electronic health information. In addition, the act also barred the FDA from regulating mobile health apps designed to maintain and encourage a healthy lifestyle if it is not related to the diagnosis, prevention, or treatment of diseases. Therefore, innovative, but low-risk technologies may be more readily available.

[63] Government Releases an English Booklet on the Korean New Deal, 28.07.2020, http://english.moef.go.kr/pc/selectTbPressCenterDtl.do?boardCd=N0001&seq=4948
[64] See: "Toward AI World Leader, beyond IT". National Strategy for Artificial Intelligence, Ministry of Science and ICT Artificial Intelligence Policy Division, December 2019.
[65] Ref. H.R.34; Public Law No: 114-255
[66] Public Law 114–255—DEC. 13, 2016, https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf

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- **Creating high-quality results and outcomes necessary to improve the Chronic Care Act (CHRONIC; signed as part of the Bipartisan Budget Act of 2018)**[67]
    - ***Priority/key areas*:** i) Promote high-quality care in the home; ii) Advance team-based care; iii) Expand innovation and technology; iv) Identify the chronically ill population prospectively; and v) Empower individuals and caregivers in care delivery.
    - ***Relevance***: Nearly 20 million American seniors are covered by Medicare Advantage insurance plans, which previously had very limited coverage on telehealth services and "non-medical" benefits. The CHRONIC Care Act gave Medicare Advantage plans more flexibility on what they can cover under "non-medical" benefits for the chronically ill and increased the availability of telehealth services especially for those who had stroke symptoms. The act also expanded the Independence at Home (IAH) demonstration, which allows seniors with multiple chronic conditions to receive care from primary care teams in their homes to reduce hospital readmissions.

Moreover, the *Ageing Well in the 21st Century: Strategic Directions for Research on Ageing*, most recently updated in 2016, is the NIA's "roadmap" for progress in ageing research and it outlines our goals and vision. It provides a point of reference for setting priorities and a framework for systematically analysing the Institute's scientific portfolio and assessing progress. In particular, the goals set by this strategy are:

- **Understanding the dynamics of the ageing process**
    - **Goal A:** Better understand the biology of ageing and its impact on the prevention, progression, and prognosis of disease and disability.
    - **Goal B**: Better understand the effects of personal, interpersonal, and societal factors on ageing, including the mechanisms through which these factors exert their effects.
- **Improving the health, wellbeing, and independence of adults as they age**
    - **Goal C:** Develop effective interventions to maintain health, wellbeing, and function, and prevent or reduce the burden of age-related diseases, disorders, and disabilities.
    - **Goal D:** Improve the understanding of the ageing brain, Alzheimer's disease, and other neurodegenerative diseases. Develop interventions to address Alzheimer's disease and other age-related neurological conditions.
    - **Goal E:** Improve our understanding of the consequences of an ageing society to inform intervention development and policy decisions.
    - **Goal F:** Understand health differences and develop strategies to improve the health status of older adults in diverse populations.
- **Supporting the research enterprise**
    - **Goal G:** Support the infrastructure and resources needed to promote high-quality research.
    - **Goal H**: Disseminate information to the public, medical and scientific communities, and policy makers about research and interventions.

[67] Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017, https://www.congress.gov/bill/115th-congress/senate-bill/870

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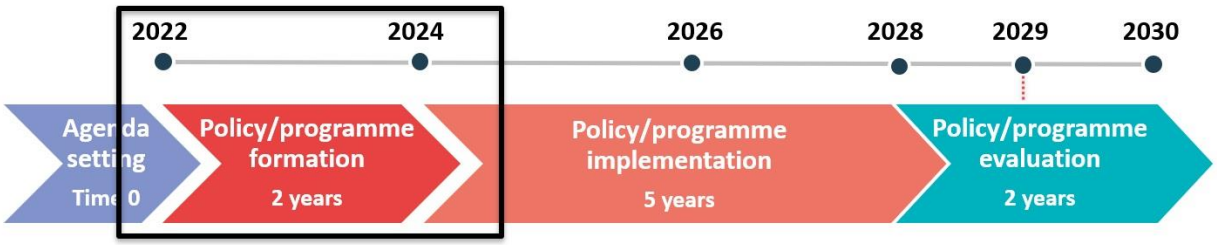
4.5 Policy/Programme formation



Policy/Programme Formation [2022–2024]

In order to support the policy makers and relevant funding agencies to map the state-of-the-art situation in the field of digital health and ageing, IDIH reviewed the panorama of the digital health landscape in the EU and in the strategic partner countries and has explored the trends, drivers, and enablers of digital health supporting AHA.

An analysis of the funding schemes supporting international cooperation in digital health and ageing has also been carried out and the results have been gathered in the dedicated Guidebook for RDI Stakeholders.

Starting from this first published information concerning the R&I landscape around digital health and ageing in the EU and in the strategic partner countries (Canada, China, Japan, South Korea, and the United States), IDIH intends to encourage policy makers and funding agencies to complement this first mapping of the state-of-the-art by **further exploring the trends and the enablers so that they can be potentially exploited for the purposes of policy/programme formation** around the three Common Priority Topics proposed by the IDIH Digital Health Transformation Forum.

As described below, IDIH recommends initiating **a round of consultations** with key stakeholders at national and international levels, as part of a **knowledge mobilisation effort** through which relevant policy makers and funding agencies could further gain evidence-based and updated information on trends, drivers, and enablers of digital health potentially supporting AHA through international cooperation.

Considered as a consolidated best practice in Canada[68], the knowledge mobilisation approach could be successfully replicated in the EU and the strategic partner countries for the purposes of this policy/programme formation phase by organising **at least one regional workshop (one in each region)** and **two international policy dialog workshops** (eventually held in synergy with the ENRICH GLOBAL Health Innovation Thematic Group), especially leveraging on key initiatives stakeholders dealing with digital health and AHA, such as those suggested as target groups in the steps below.

[68] Guidelines for Effective Knowledge Mobilisation, Government of Canada, https://www.sshrc-crsh.gc.ca/funding-financement/policies-politiques/knowledge_mobilisation-mobilisation_des_connaissances-eng.aspx

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	Aims of the Knowledge Mobilisation Workshops	Target Groups
Regional Workshops:	Update the state-of-the-art of regional R&I landscapes around digital health and ageing and discuss the policy/programme options with relevant regional stakeholders for implementation of the IDIH Common Priority Topics through co-creation sessions and foresight exercises based on desired scenarios of strengthened international cooperation.	R&I communities and networks; care providers, tech providers, users' associations, policy makers/funding agencies
International Workshops (ENRICH GLOBAL):	Compare regional R&I landscapes around digital health and ageing and identify common paths for decision-making at an international level.	policy makers/funding agencies

This phase, which is supported by the Programme Level Cooperation already set internationally by the IDIH project among six relevant funding agencies, will better orient decision-making for the eventual implementation of international cooperation initiatives around the three *Common Priority Topics* proposed by the IDIH Digital Health Transformation Forum.

1. Strengthening programme level cooperation initiated by IDIH

As a first step in the policy/programme formation phase, IDIH recommends leveraging on the international policy dialog initiated in the framework of the project itself, as part of the Programme Level Cooperation (PLC) set among the six relevant funding agencies from the EU and the five strategic partner countries.

In this regard, policy makers and funding agencies interested in a follow up of the IDIH Common Priority Topics are encouraged to strengthen the relationships among their peers at:

- **[EU] Directorate-General for Communications Networks, Content and Technology (DG CONNECT), European Commission –** https://ec.europa.eu/info/departments/communications-networks-content-and-technology_en
- **[USA] National Institute on Ageing (NIH – NIA), United States of America –** https://www.nia.nih.gov/
- **[CANADA] Canadian Institutes of Health Research (CIHR) – Institute of Ageing, Canada –** https://cihr-irsc.gc.ca/e/8643.html
- **[CANADA] Canadian Institutes of Health Research (CIHR) – Institute of Health Services and Policy Research (IHSPR) –** https://cihr-irsc.gc.ca/e/13733.html
- **[SOUTH KOREA] KIHDI – Korea Health Industry Development Institute –**
- **[CHINA] NNSFC – National Natural Science Foundation of China –** https://www.nsfc.gov.cn/english/site_1/index.html
- **[JAPAN] METI - Ministry of Economy, Trade and Industry –** https://www.meti.go.jp/english/
- **[JAPAN] MIC – Ministry of Internal Affairs and Communication –** https://www.soumu.go.jp/english/

Contact persons for the abovementioned funding agencies have been identified and are reported in the IDIH reports of the PLC meetings:

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- Report of the 1st PLC meeting
- Report of the 2nd PLC meeting (available on the project website after approval of the EC)

Moreover, APRE, as a partner responsible for PLC in IDIH and beyond, coordinating the initiative of the recently established ENRICH GLOBAL Health Innovation Thematic Group and supporting IDIH project sustainability, could serve as **a contact point** to facilitate the liaisons among the policy makers and funding agencies interested in a follow up of the IDIH Common Priority Topics, during the policy/programme formation phase and for the time necessary to implement this action plan.

APRE – Agenzia per la Promozione della Ricerca Europea

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Website: www.apre.it

Besides the **spontaneous initiative of the policy makers and funding agencies to deepen bilateral/multilateral relations**, the activities here envisaged to strengthen the programme level cooperation and support this policy/programme formation phase, are those currently foreseen by the ENRICH GLOBAL Health Innovation Thematic Group under the umbrella of the ENRICH GLOBAL international network.

Initially concentrating its efforts on digital health for AHA, building on the IDIH legacy, the ENRICH Global Health Innovation Group will work as an expert-driven and long-lasting umbrella mechanism to enhance international cooperation and policy dialog on global health issues at large. In particular, the group will address policy makers and R&I stakeholders in the field (researchers, care providers, users/patient associations, health-tech providers, etc.) by engaging them in workshops and initiatives at an international level inspired by open innovation and evidence-based policymaking.

Therefore, as part of this policy/programme formation phase, IDIH encourages the policy makers and the funding agencies interested in the implementation of the IDIH recommendations to take part in:

- **Two international policy dialog (Thematic) workshops** (to be held online by 2024), which will be organised by the ENRICH GLOBAL Health Innovation Thematic Group to discuss global challenges and compare policies in a mutual learning and exchange environment that will also encourage eventual joint funding initiatives and will be further nurtured with evidence-based information by a panel of international experts and key stakeholders from the *International Experts Forum for Health Innovation,* also managed by the ENRICH GLOBAL Health Innovation Thematic Group.
    - **Proposal for focus of themes:**
        - **Data governance and interoperability by design in digital solutions for AHA:** accessibility, sharing, and protection of data toward international standards.
        - **Inclusive design and access of digital solutions for AHA:** best practices of empowerment and digital literacy

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2. Engaging R&I communities and networks at national and international levels

In order to promptly identify the trends and enablers for the implementation of IDIH Common Priority Topics in the EU and in the strategic partner countries, IDIH encourages the relevant policy makers and funding agencies to activate synergies with R&I communities and networks at national and international levels through **knowledge mobilisation regional workshops.** The following are some key initiatives, in terms of players to be involved and knowledge legacies to be exploited, to be considered in the organisation of the regional workshops.

Europe and beyond

- Global Coalition On Ageing: As the world's leading business voice on ageing-related policy and strategy, it advances policy and market solutions that ensure ageing as a path for economic growth, winning business strategies, and social wellbeing. The main activities are: educating and driving change among policymakers, thought leaders, and the general public; partnering with global organisations and institutions to lead the private sector; aligning business strategies and workforce policies with ageing market opportunities; and creating platforms to demonstrate thought leadership on a global scale.
- The AAL Community: The AAL programme has developed several valuable assets over the last 10 years, all of which will be of benefit for any future European support for AHA. The AAL Community is a thriving community of innovators, all working together in the field of AHA alongside care organisations, local authorities and, of course, families and older people themselves. They are all engaged in the projects funded by the AAL programme, with roughly one in 10 AAL projects reaching market maturity.
- European Innovation Partnership on Active and Healthy Ageing (EIP AHA): The European Innovation Partnerships (EIP) is an EU initiative introduced by the "Innovation Union," which is one of the seven flagship initiatives in the framework of the EU 2020 Strategy, to address major societal challenges. The overarching goal of the EIP AHA by 2020 was to enable citizens to live longer independently in good health by increasing the average number of healthy life years by two. The EIP on AHA had as its foundations two main pillars: action groups and reference sites. The Blueprint, Innovation to Market (I2M) and the "Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing" (MAFEIP) are three, further, crosscutting horizontal initiatives that feed the EIP on AHA.[69]
- EC eHealth Stakeholder Group/Task Force: The European Commission created two EGs working on eHealth: the eHealth Stakeholder Group and a temporary eHealth Task Force. Members of the eHealth Stakeholder Group are all umbrella organisations and associations with a European outreach. They represent the following sectors and groups: the health-tech industry, patients, healthcare professionals, and the research community. It consists of healthcare professionals, representatives of patients, delegates of the medical,

[69] Since the beginning of 2021, the EIP on AHA has been aligning its objectives closely with the life-course approach, illustrated in the Green Paper on Ageing. It focuses more concretely on scaling-up and deploying of digital tools for life-long health promotion and prevention, life-long learning, empowerment with digital tools, promotion of smart, healthy and age-friendly environments, and enhancing the European Silver economy and digital healthcare ecosystem. It has also adopted a more collaborative approach through the set-up of the *Futurium* community platform "Active and Healthy Living in the Digital World".

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pharmaceutical and ICT industries, legal experts, and policy makers. The Task Force produced a report with recommendations on how to develop the full benefits of eHealth in 2020.

- Futurium: Built on the legacy of EIP on AHA, this platform aims to disseminate related knowledge and experience, as well as promoting the exchange of best practices and cooperation by addressing the challenges related to active and healthy living and ageing with digital technologies on an international level. Related stakeholders from around the world are invited to join and contribute to this dialog.
- European Public Health Alliance (EPHA): A member-led organisation made up of public health NGOs, patient groups, healthcare professionals, and disease groups, the EPHA works to improve health and strengthen the voice of public health in Europe. Its mission is to bring together the public health community to provide thoughtful leadership and facilitate change; to build the public health capacity to deliver equitable solutions to European public health challenges, and to improve health and reduce health inequalities. Digital health is one of the work areas of the EPHA. The EPHA works to ensure that digital tools are inclusive and integrated into current healthcare systems, rather than being used to replace them. The EPHA advocates for a continuity of care in cross-border Europe and for the strengthening of digital health literacy skills in order to ensure better access to healthcare for all.
- Enterprise Europe Network (EEN): This is the world's largest support network for SMEs with international ambitions and it is a key instrument in the EU's strategy to boost growth and jobs, bringing together around 600 support organisations from more than 60 countries. It helps businesses to innovate and grow on an international scale. The network is linked with powerful databases, and it shares knowledge and sources technologies and business partners across the globe, with nodes in Canada, China, Japan, and South Korea.
- Healthy Ageing Incubator (Eurasenior Incubator): First European incubator dedicated to support innovative project in healthy ageing was founded in 2020 by Eurasanté, a development agency dedicated to tech transfer and business development in the life sciences sector. Its ambition is to offer a unique support programme to accelerate the development of innovative projects for the elderly. All the programmes of the incubator are open to international entrepreneurs and start-ups willing to establish a meaningful presence in northern France.
- AGE Platform Europe: This is a European network of non-profit organisations of and for people aged 50+. It aims to voice and promote the interests of the 200 million citizens aged 50+ in the EU (Eurostat, 2018) and to raise awareness on the issues that concern them most. Their work focuses on a wide range of policy areas that impact older and retired people. It is a key player in European projects dealing with digital health and ageing, such as SHAPES Innovation Action (IA), GATEKEEPER, PHArA-ON, and e-ViTA.
- JADECARE: The Joint Action on the Implementation of Digitally Enabled Integrated Person-centered Care (JADECARE) is part of a series of initiatives the EU has launched to face the challenges of the transformation of health and healthcare in the EU. JADECARE intends to reinforce the capacity of healthcare authorities to successfully address important aspects of the healthcare system transformation, in particular the transition to digitally enabled, integrated, person-centered care in the EU.

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Canada

- AGE-WELL Networks of Centers of Excellence (NCE) (Ageing Gracefully Across Environments Using Technology to Support Wellness, Engagement and Long Life): NCE Inc. is Canada's technology and ageing network. Launched in 2015 through the federally-funded NCE programme, AGE-WELL addresses a wide range of complex issues in technology and ageing through receptor-driven transdisciplinary research, training programmes, partnerships, knowledge mobilisation, and the commercial development of technologies. AGE-WELL drives R&I across eight Challenge Areas (CAs), designed to "move the dial" when it comes to supporting older adults and caregivers in Canada and achieving a social and economic impact. AGE-WELL research projects are supported by six crosscutting themes. The network has 46 member universities and research centers across Canada. More than 400 industry, government, and non-profit partners have joined AGE-WELL and the number continues to grow. Over 4,900 older adults and caregivers are involved to ensure that products are practical and useful.
- North American Chapter International Society for Gerontechnology (ISG): ISG is the largest international organisation specializing in gerontechnology and it has seven international chapters among which is the North American chapter. The society is open to membership by individuals participating in any kind of engineering, design, gerontological, scientific, industrial, or administrative activities related to gerontechnology; national or international societies related to gerontechnology, industries or organisations, producing, providing or commercialising products and services aimed at the wellbeing, health, and autonomy of elderly citizens, and by non-scientific non-profit-making organisations concerned with the challenges of an ageing society.

China

- Smart Health Care and Home Care Branch of China Association of Gerontology and Geriatrics (S2HC-CAGG)**:** This is a newly established organisation that is part of the China Association of Gerontology and Geriatrics. It is a branch of the association called "Smart Health Care and Home Care" that was established in 2018, whose members are mainly research institutions, but also professionals and industry providers in the frontline of senior care. S2HC-CAGG actually holds a meeting at an academic level once a year addressing "smart health care and smart senior care." The China Association of Gerontology and Geriatrics, of which S2HC-CAGG is a member, is the oldest association in China in the field of ageing. It was established in 1986 and almost all the other organisations in this field are under its umbrella. However, in China the government is the major primary force behind ageing and healthcare, so S2HC-CAGG normally works very closely with the central and local governments.
- CBTC – China-Belgium Science and Technology Center: As a national level overseas economic and trade cooperation zone, the establishment of CBTC reflects two global economic engines of China and Europe. In the context of the "One Belt One Road" grand strategy, it focuses on the advancement of technological frontiers and joint efforts to explore new industrial spaces and patterns of pragmatic cooperation. CBTC is committed to building a two-way green channel for China–Europe high-tech industries with multiple elements of technology, capital, and markets for technology transfer, strategic investment, industry cooperation, and market access for both parties, thereby providing a cooperation platform and support. For instance,

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BioWin is an initiative of CBTC that as a "China–Europe Collaborative Innovation Network" has covered the interconnection and cooperation of key industries, such as local biopharmaceuticals, medical devices, therapeutic vaccines, and digital health. It can provide comprehensive support and services for companies' R&D innovation, skill development, and business expansion.

Japan

- National Center for Geriatrics and Gerontology (NCGG): This organisation is composed of the National Hospital for Geriatric Medicine and the Research Institute. It is one of the six national centers for advanced and specialized medicine in Japan. Its mission is to promote the physical and mental health of the elderly so that they can achieve life-long independence and improvement of the health and welfare of the people and society. With close cooperation and interactions between the hospital and the research institute, NCGG as a whole continually makes efforts toward the realization of a healthy society with good longevity. As part of the NCGG:
    - **The Center for Development of Advanced Medicine for Dementia (CAMD)** was established in 2010 to accelerate basic and applied studies on dementia, especially focusing on Alzheimer's disease.
    - **The Center for Gerontology and Social Science (CGSS)** was founded in 2012 to promote empirical research in the field of gerontology and social sciences, focusing on the independence of older people's mind and body, and contributing to the development of a vigorous society with good longevity. The research key words in CGSS are social participation, independence support, social support, social welfare, home care, and regional comprehensive care.
- Smart Ageing Research Center of Tohoku University: This organisation is taking the lead in R&I for ageing-related research in Japan for H2020 and it took an active part in "My-AHA (my active healthy ageing)" project under H2020 as one of 10 international consortium partners. Researchers from Tohoku University and the JINS corporation actively joined the project aiming to reduce frailty by improving physical activity, cognitive function, the psychological state, nutrition, and sleep. From 2020, another project "e-ViTA (EU-Japan Virtual Coach For Smart Ageing)" started with the players of H2020 (University Siegen is the representative partner of EU). The Smart Ageing Research Center of Tohoku University will take the lead in Japan again and AIST (the National Institute of Industrial Science and Technology) and other groups will join. This project aims to provide a smart living environment to extend the independent life of the elderly.
- Agile Co-creation of Robots for Ageing (ACCRA): ACCRA is a joint European-Japanese initiative including a multidisciplinary team of six European partners and three Japanese partners. The project has a three-year duration. It is structured to allow for balanced contributions and efficient synergistic collaboration between Europe and Japan. The ACCRA project is a response to the call "Japan cooperation on Novel ICT Robotics based solutions for AHA at home or in care facilities" of the EU's Funding Programme Horizon 2020.
- CARESSES: This organisation aims to design the first healthcare robots that adapt the way they behave and speak to the culture of the person they assist. It involves a multidisciplinary team of EU and Japanese researchers with a background in transcultural nursing, AI, robotics,

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testing, and evaluation of health care technology. It is a worldwide leading company in robotics and networks of nursing care homes.

South Korea

- Korea Research Institute of Biosciences and Biotechnology (KRIBB): This organisation established the **Ageing Research Center** as a strategic research group aimed at: i) *the identification of new ageing genes and understanding their mechanisms*; and ii) *the development of original technology related to ageing diagnoses and control*.[70]
- Electronics and Telecommunications Research Institute (ETRI): This group was funded in 1976 and it is committed to contributing to the nation's economic and social development through research, development, and distribution of industrial core technologies in the field of information, communications, electronics, broadcasting, and convergence technologies.
- Korea Institute for Advanced Technology (KIAT): This organisation collaborates with 14 countries to operate technology cooperative institutions and bases for overseas technology transfer and commercialization. It supports cooperative activities for technology commercialization by utilizing the EEN and Global Commercialization Center (GCC).
- Korea Innovation Center Europe: KIC Europe is aimed to build a global innovation ecosystem across Korea and the EU. By leading the global cooperation in innovation through industry, the public, and alliances, we aim to facilitate and provide a bridge for Korean SMEs and start-ups with European partners and institutes."[71]
- Global Digital Health Partnership: South Korea joined the Global Digital Health Partnership with 30 other countries, including the EU members Austria, Italy, Sweden, and the Netherlands, when the organisation was established in 2018. Its aim is to **facilitate global digital health collaboration and cooperation**. Being one of the world's largest government-to-government global health Information technology (IT) partnerships, the GDHP strives to identify the best international practices for the use of digital health data in order to advance digitized healthcare, provide opportunities for networking and knowledge transfer, and facilitate horizon scanning to more accurately predict emerging trends or threats, such as COVID-19. The current GDHP work plan focuses on five work streams: *cyber security, interoperability, evidence and evaluation, policy environments, and clinical and consumer engagement*. Overall, South Korea's advanced eSkills and prevention policies based on digital solutions can be a positive contribution to cooperation in the partnership.
- Seoul Clinical Laboratories (SCL): CyberDX focuses on testing a large data-based medical AI engine to analyse medical examination data for detecting patients' risks as an appropriate means for prevention. It focuses on disease prevention by providing tailored analytics by comparing a patient's examination data with thousands of samples. It showed an impressive outcome in analysing the risk of developing Alzheimer's disease

[70] Aging Research Center, KRIBB – Korea Research Institute of Bioscience & Biotechnology, https://www.kribb.re.kr/eng/sub02/sub02_01_03.jsp

[71] European Commission, 10.01.2020, https://ec.europa.eu/info/news/5th-eu-korea-research-and-innovation-day-2020-jan-10_en

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United States

- American Association of Retired Persons (AARP) Foundation: Among the major players that advocate for older Americans, the AARP is a not-for-profit organisation that serves vulnerable people 50 and older by creating and advancing effective solutions that help them secure the essentials. AARP prides itself as one of the leading organisations that recognizes the potential of the "longevity economy," which is the economic opportunity that elderly Americans present. Throughout its history, the organisation has consistently researched the 50+ consumer market and explored opportunities to engage with various sectors in an effort to improve the quality of life for older adults. AARP Innovation Labs created the "**Hatchery**," to bring together top-tier entrepreneurs to share ideas for keeping people 50 and older healthy and designing new products and services for this purpose. The Hatchery uses design challenges, pitch competitions, and other start-up accelerators to co-create products and services. In 2019, the AARP Foundation launched new tools designed to equip low-income older adults with skills and resources to increase financial stability and connection to their communities. Among these is Connect2Affect Connected Communities. This pilot programme investigates the viability of using hands-free, voice-activated technology to maintain sustained social connectedness for low-income older adults aged 50+ who are living in independent housing or federally subsidized rental properties.
- The importance of private insurers for older adults: Private insurers that offer medical assistance (MA) plans such as **Aetna, Cigna, Kaiser Permanente, Blue Cross Blue Shield, Humana, UnitedHealthcare**, and many others, provide more comprehensive health plans that facilitate ageing. As MA plans are paid a capitated amount per beneficiary and these insurers are incentivized to keep their patients as healthy as possible through various healthcare delivery models and tools. To maximize cost savings and promote health outcomes, these insurers have increasingly leveraged digital health. **UnitedHealthcare** invests $3.2 billion annually in data, technology, and innovation and it is one of the leading organisations moving toward a digital health-powered healthcare system. Other health insurers also started venture funds to fuel digital health entrepreneurships. **Cigna** launched Cigna Ventures with $250 million in capital to invest in early and growth-stage start-ups while Kaiser Permanente Ventures invested $170 million in capital for companies in all stages. These insurers are critical in the health innovation space and are some of the largest proponents for digital health in chronic care management, health promotion, and AHA.
- Academic medical centers (AMCs): These organisations play a crucial role in the digital health ecosystem. AMCs power research efforts that help validate and commercialize technologies. Although AMCs have traditionally focused on biomedical research, many universities have now developed centers for digital health and/or health innovation. Another noteworthy research institution is the University of California Center for IT Research in the Interests of Society (CITRIS), which leads several global research efforts including telehealth, as well studying whether AI can detect and prevent falls. CITRIS partnered with global researchers from Denmark as well as several members of the EU to create the "Transatlantic Telehealth Research Network" and has published literature outlining the global research agenda for telehealth.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

3. Consulting Users Associations

In order to **ensure that a user-centered perspective is at the foundation of any further action for the implementation of the IDIH Common Priority Topics** at an international level, IDIH recommends engaging in knowledge mobilisation workshops with those associations at regional and international levels that represent older persons, patients and their families, as well as care providers/caregivers (formal and informal) and professionals.

These organisations are mainly umbrella organisations (II level associations) with demonstrated advocacy power and they have already been addressed by IDIH as part of the setup of the UCG, whose members are listed below.

Moreover, a list of NGOs accredited to the UN OEWG on Ageing (open-ended Working Group on Ageing for the purpose of strengthening the protection of human rights of older persons) can be also considered for further engagement in the knowledge mobilisation workshops.

UCG members		
Name **Position**	**Organisation**	**Region**
Jie Wang **Vice President**	Smart Health Care and Home Care Branch of China Association of Gerontology and Geriatrics (S2HC-CAGG)	China
Anna Odone **Digital Health Section President**	European Public Health Association (EUPHA) https://eupha.org/	EU
Ilenia Gheno **Research Project Manager**	AGE Platform Europe https://www.age-platform.eu/	EU
Peggy Maguire **Director General**	European Institute of Women's Health (EIWH) https://eurohealth.ie/	EU
Stephen Johnston **Co-Founder**	Ageing 2.0 https://www.ageing2.com/	USA
Gloria Gutman **President**	North American Chapter International Society for Gerontechnology https://www.gerontechnology.org/	USA/Canada
Gloria Gutman **Vice President**	International Longevity Center-Canada https://www.ilccanada.org/	Canada
Yasuko Akutsu **CEO/Ambassador**	MT Health Care Design Research Inc. http://hcdr.co.jp Ageing 2.0 Tokyo chapter ambassador	Japan

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Moreover, besides UCG members, IDIH has identified other relevant organisations, listed in the table below:

Region	Organisation
Canada	International Longevity Center
Canada	Canadian Association for Retired Persons (CARP)
China	Chinese Geriatrics Society
China	Smart Health Care and Home Care Branch of China Association of Gerontology and Geriatrics (S2HC-CAGG)
China	Chinese Ageing Well Association
Europe	European Patients' Forum (EPF)
Europe	International Alliance of Patients' Organisations (IAPO)
Europe	European Senior Organisation of the PES
Europe	Alzheimer Europe (AE)
Europe	European Federation of Neurological Associations (EFNA)
Europe	European Parkinson's Disease Association (EPDA)
Japan	Japan Geriatrics Society (JGS)
Japan	Japan Federation of Senior Citizens Club
South Korea	Care Rights
South Korea	Réseau FADOQ
United States	National Council on Ageing (Center for Healthy Ageing)
United States	National Alliance on Caregiving
United States	Alzheimer's Association

4. Mobilise R&I ecosystems through a quadruple helix approach

R&I ecosystems that are relevant at regional and international levels in the field of digital health and ageing can be further explored by engaging **cluster organisations** in knowledge mobilisation workshops together with user associations in order to adopt a *quadruple helix* approach and ensure the inclusion of a wide range of stakeholders and views.

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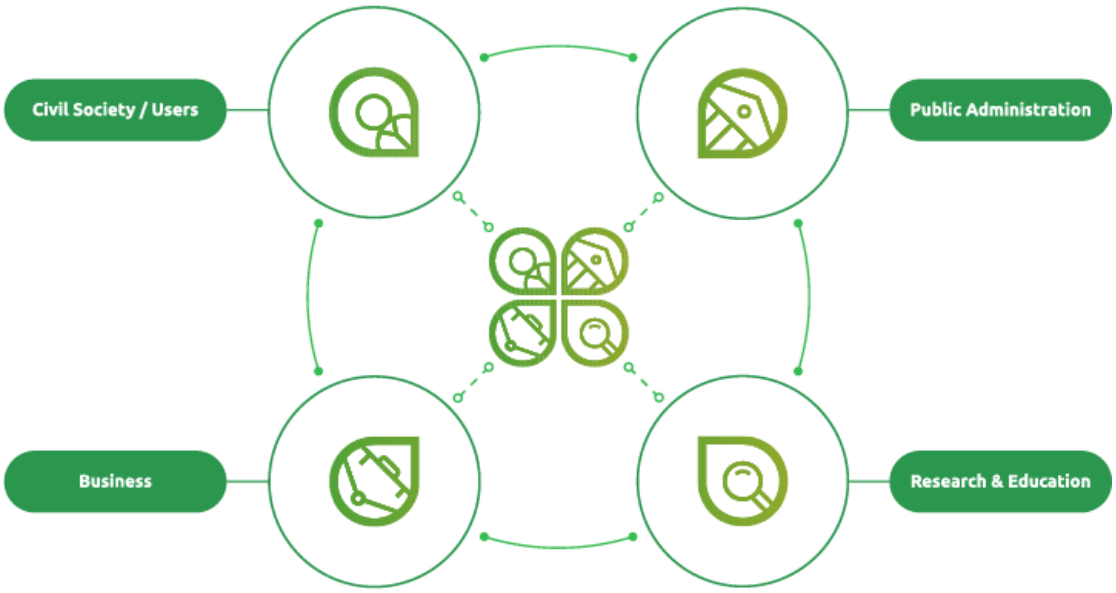

Figure 7: Quadruple helix approach (infographics by the BIOVOICES project GA.774331)

Member organisations gather actors from the *quadruple helix*: academic/research organisations, industry players, among which notably are SMEs, R&I support organisations, such as accelerators or incubators, and also policy support organisations[72]. Cluster organisations are **ideal facilitators in the R&I landscape**. Moreover, in line with EU's strategy in this field, which is strongly supported by the European Commission DG GROW, cluster organisations have a strong interest in international collaboration and thus, for a large majority, they are constantly seeking international collaboration opportunities with relevant organisations from other countries (inside and outside of the EU).

This is why cluster organisations can be seen as important enablers for international collaboration in RDI, supporting also international policy dialog.

International cluster collaboration is specifically driven through the so called European Strategic Cluster Partnerships Going International (ESCP-4is). These are groups of cluster organisations that are working on a given thematic field/sector and aiming to align their international strategic approach for the benefit of their members. Cluster partnerships help develop common actions (such as business missions, cooperation agreements, gateway services, export consortia, and so on) as well as strengthen European SMEs' access to specific third-country markets. They also help create a long-term collaboration agenda with strategic partners in third world countries.

What makes these collaboration schemes particularly interesting is the fact that EU cluster organisations have on average 100 members each out of which a large majority are SMEs. This is why connecting cluster organisations and similar member networks from the EU with counterparts from the targeted countries can have a very strong multiplier effect and such collaboration schemes can be real catalysts for R&I collaboration among members.

More information is included in Annex 1 of this document.

[72] Definitions of a cluster and a cluster organisation can be found on the European Cluster Collaboration Platform, a DG GROW initiative: https://clustercollaboration.eu/cluster-definitions

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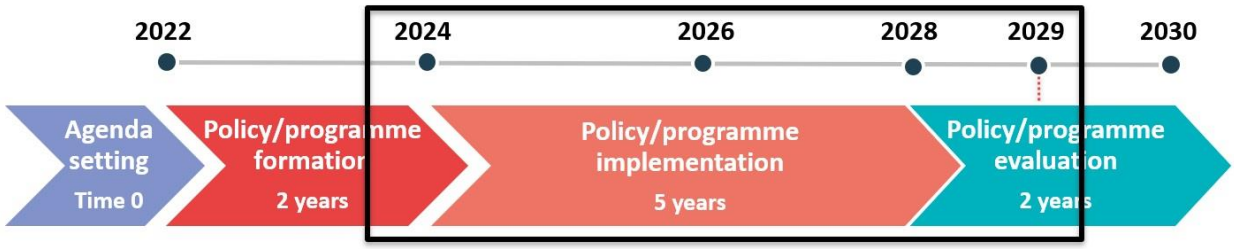
4.6 Decision-making and policy / programme implementation



Decision-making and policy/programme implementation [2024–2029]

After having carried on an extensive consultation with relevant stakeholders at regional and international levels through mobilisation workshops to explore the possible paths for implementation of the IDIH Common Priority Topics, policy makers and funding agencies should **further assess and single out a particular course of action at regional and international levels**; e.g., joint funding scheme/partnerships and other initiatives at national/international levels.

Policy makers and funding agencies will identify the best implementation options to pursue considering the contingent national contexts and contingent factors, as well as the resources available and the opportunities at stake. However, IDIH provides them with several recommendations, here presented, to address the implementation of the Common Priority Topics, taking as an example the *Types of Actions* under the European Framework Programme for Research and Innovation (Horizon Europe), but also conceiving partnership schemes not supported with funding.

Types of Actions recommended by IDIH	
Research and innovation actions (RIA)	Activities that aim to create new knowledge and/or explore the feasibility of a new or improved technology, products, processes, services or solutions. They therefore include basic and applied research, development, integration of technology, testing, and demonstration and validation of a small-scale prototype in a laboratory or simulated environment
Innovation actions (IAs)	Activities aimed at planning and designing new, altered or improved products, processes or services, possibly including prototyping, testing, demonstration, piloting, large-scale product validation, and market replication.
Coordination and support actions (CSA)	Activities that contribute to the objectives of the programme and that are not R&I activities in the strict sense.
Training and Mobility Actions	Providing researchers with the right combination of scientific and transversal skills through international, interdisciplinary, and intersectoral mobility.

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Priority Topic 1 – Area: DATA GOVERNANCE

Recommended: RIA

- The research and development of **multi-modal and forward/backward longitudinal studies** and the implementation of advanced Big Data analytic techniques could be reached through multinational stakeholder collaboration schemes capable of undertaking projects that fit the characteristics of RIA.
- Multinational consortia of stakeholders with supplementary profiles and expertise could collaborate for research and development of state-of-the-art **personalised-medicine approaches** and supportive technologies through the participation in RIA.
- The implementation and adoption of new technological and methodological approaches for healthcare services requires the **research and development of a reliable international validation framework** capable of being embraced by the research/academic community and society. To this end multidisciplinary international consortia need to undertake RIA. In support of these actions, **international policy dialog** among the involved stakeholders should be undertaken toward the development, adoption, and sharing of an international validation framework.
- Sharing of health-related data and the development and implementation of new technologies and methodological approaches for healthcare services require a validation framework capable of **addressing cybersecurity aspects that will ensure both the privacy and security of the patients/end-users.** Cybersecurity experts and researchers in collaboration with healthcare providers, including services integrators and manufacturers, could collaborate in RIA. In addition to these projects, the implementation and validation of innovative technologies can be applied through ***IAs.***

Recommended: CSA

- Health data owners (healthcare institutions, national healthcare, and social services providers etc.) in collaboration with policy related organisations, end-user associations, and academic and research institutions could orchestrate and organise international initiatives toward the **adaptation of frameworks for the provision and sharing of data sources at an international level.** Such activities would ideally fit with the characteristics of coordination and support actions (CSA). Another relevant issue to point out is the **educational aspect** to be included in such actions, as well as the awareness about data security, making individuals feel comfort and security when their data has been accessed and used, and empowering stakeholders to advance healthcare by fostering **responsible and high-quality digital health innovation.**

Recommended: IA

- Multinational consortia could facilitate the implementation and adaptation of innovative approaches for personalised healthcare services through participation in ***IAs***.

Recommended: Training and Mobility

- The facilitation of researcher exchanges and the collaboration of academic teams all over the world for scientific research on the above-mentioned topics can be achieved through the organisation of **training and mobility actions.**

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Priority Topic 2 – Area: DIGITAL INCLUSION

Recommended: RIA

- The development of **inclusive healthcare systems and services addressing the needs and functional abilities** of the elderly can be achieved through international multidisciplinary RIA with active involvement of the end-users in all stages of the design (inclusive co-design) and integration processes. The involvement in the RIA projects of social and communication scientists in the international multidisciplinary consortia will lead to the development of elderly empowerment models and tools and services capable of defeating social isolation and loneliness. In particular, these RIA need to undertake the formulation of a holistic framework capable to lead the research and development teams to the provision of age-friendly technologies adopted to the specific needs of the elderly population. This initiative should not target only patients and citizens but also informal carers (family, relatives, neighbours, etc.) who play a key role complementing the primary care.

Recommended: CSA

- Public information, education, digital literacy, and the presence of support systems are needed to get people familiar with the use of and access to digital solutions and therefore benefit from technology. It is necessary that digital solutions should be oriented on a ***need-based*** instead of *age-based* approach. The **digital divide gap of the elderly** needs to be addressed by sharing and replicating best practices, especially in the field of **education and digital literacy** (against any form of *ageism*), that will be thoroughly studied and validated by multidisciplinary consortia through international CSAs. In addition to that, the research and study of practices **toward the adoption of the 5-As approach** need to be addressed by multi/transdisciplinary consortia in CSA projects.

Recommended: Training and mobility

- Training and mobility actions will supplement the abovementioned initiatives and allow researchers and scientists of all the involved disciplines to thoroughly study and explore the relevant topics.

Priority Topic 3 – Area: INTEROPERABILITY BY DESIGN

Recommended: RIA/IA

- **The integration of heterogeneous technologies for the provision of preventive and integrated care and independent and inclusive living** for the elderly needs to be addressed both by RIA and IAs by international multidisciplinary consortia with the active involvement of end-users.
- **Interoperability issues need to be thoroughly researched and new standards and methodologies need to be designed and developed by the project teams.** These new pilot studies and studies should be based on information or data that already exists. Data gathered from a variety of sources need to be securely collected and shareable with international platforms and data hubs that are able to be re-used and exploited by the scientific community,

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technology providers, and stakeholders. Therefore, RIA of multidisciplinary consortia need to get involved in projects and initiatives that will address the abovementioned issues.

Recommended: CSA

- **Address health systems fragmentation at both international and national levels** as a shared challenge in the regions concerned and, therefore, to be considered as a basis for further international cooperation, as well as the activation of **a bottom-up interregional cooperation approach**, leveraging, thus, on the potential (in terms of impact) of local authorities.
- **Standardization bodies, research and academic organisations, healthcare industry representatives, and policy organisations will need to enable the dialog for the adoption of an international standardisation framework** for the facilitation of interoperability and communication of the healthcare technological systems and services at an international level. CSAs are ideally fit for this purpose.

Recommended: Training and mobility

- Data scientists, engineers, and research and academic teams will be able to exchange knowledge and collaborate on the development of interoperable healthcare systems and technologies through the participation in training and mobility actions.

4.7 Policy/Programme evaluation

Policy/Programme Evaluation [2028–2030]

"Evaluation is a key learning tool for the European Union to understand not only what works and what does not, but critically why, and under what circumstances."

"Evaluation matters. The evaluation policy for European Union development cooperation"
European Commission (2015)

In order to support policy makers and the relevant funding agencies with a methodology for follow up to assess to which extent the policy/programme actions implemented around the IDIH Common Priority Topics have brought the desired results and impacts, IDIH is recommending here to further adopt a **knowledge mobilisation approach** to support the evaluation of actions undertaken, starting after the first two years of their implementation.

The EU's new approach to evaluation policy has been underpinned by institutional reforms in this region and a vision for more citizen-based governance. *"This shift involves a move from citizens as simply voters, volunteers, and consumers to citizens as problem solvers and creators of public goods."*

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In this new strand of development, *"government's role [is] to arrange and facilitate interactions processes within networks in a such a way that problems of under or nonrepresentation are properly addressed and interests are articulated and dealt in an open, transparent, and balanced manner"*[73].

In particular, by engaging the same stakeholders mentioned in the Policy/Programme Formation phase, policymakers and funding agencies will develop **quantitative and quality indicators** (Step 1) to **measure the impact** of actions implemented (Steps 1–4), based on the needs and priorities resulted from that first stage of extensive consultation at regional and international levels.

1. **Preparation of an evaluation methodology, including quantitative and quality indicators co-developed with relevant stakeholders.**

In a very preliminary stage of this phase, policy makers and funding agencies should develop a **methodology for evaluation,** including quantitative and quality indicators of the impacts and the actions undertaken for the implementation of the IDIH Common Priority Topics, starting from the results achieved with the policy/programme formation phase (through stakeholders' consultation), and based on an intervention logic, as defined by the OECD-DAC[74]:

*Evaluation is the 'systematic and objective assessment of an ongoing or completed project, programme or policy, its design, implementation and results.' Evaluation provides an **objective and timely assessment** of the performance of a strategy, policy, programme, project, or any intervention. It identifies and explains not only **what** changes have occurred, but critically **why** these changes have occurred. Evaluations follow rigorous methodologies based on intervention logic. Evaluation embraces both intended changes and unintended changes. It provides a judgment on whether a change can be attributed to a particular cause or to what extent particular factors have contributed to a given change.*

The EU undertakes a range of different evaluations that could be consider at a regional level and also in the other strategic countries of concern. The most common are project/programme evaluations and strategic (long-term geographic, thematic, and corporate) evaluations, as summarized in the figure below from a paper of the European Commission[75]:

[73] "Evaluation matters. The evaluation policy for European union development co-operation". European Commission (2015).
[74] Development Assistance Committee of the Organisation for Economic Co-operation and Development.
[75] "Evaluation matters. The evaluation policy for European union development co-operation". European Commission (2015).

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Evaluation	Scope / Focus	*Example of specific focus*	User/ Learning Purpose
Strategic evaluations	Corporate issue of strategic importance	*Joint programming*	Senior managers / to inform strategic decisions on corporate issues
	Geographic Thematic / Sector	*EU cooperation with a specific Country / Region* *EU Support to a Sector / Theme*	Senior managers & managers / to inform strategic choices on programming, and in defining policy
Sector, Project and Programme evaluations	Set of interventions in a specific sector at country level Individual project / Programme		Operational services Sector/ Project/Programme manager / to improve on-going/ future sector, project and programme management / design

Figure 8: Types of Evaluation at EU level (European Commission, 2015)

Evaluations should be in line with the evaluation policies and regulations set at the EU and international level:

- Evaluation standards of the OECD Development Assistance Committee;
- Evaluation methodological guidance for external assistance;
- EU institutional framework for effective management of evaluation activities.

The United Nations evaluation activities are managed by the UN evaluation group. Development banks, such as the World Bank, also possess strong evaluation functions and EU works closely with them.

Evaluations should be based also on the OECD-DAC evaluation criteria, namely:

Relevance *is the extent to which the objectives of a policy or an intervention are consistent with the beneficiaries' needs and EU policies and priorities. Is the strategy currently, and likely to continue to be, appropriate for the beneficiaries?*

Effectiveness *is the extent to which the development intervention's objectives were achieved, or are expected to be achieved: Have the objectives been delivered and with what level of quality?*

Efficiency *is the measure of how economically resources/inputs (funds, expertise, time, etc.) are converted to results: Is there appropriate and optimal provision and use of resources to deliver the objectives sought?*

Sustainability *is the continuation, or probable continuation, of benefits from a development intervention after major development assistance has been completed: Are the positive results of the interventions likely to last once the intervention comes to an end?*

Impact*: Positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended: To what extent and why does the cooperation have an impact, or not?*

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As part of this preliminary step, IDIH recommends organising **at least one regional "validation" workshop (one in each region)** and **one international "validation" workshop** (eventually held in synergy with the ENRICH GLOBAL Health Innovation Thematic Group), key initiative stakeholders dealing with digital health and ageing, such as those suggested as *target groups* in the steps below.

	Aims of the "Validation" Workshops	Target Groups
Regional Workshops:	Co-develop a set of quantitative/qualitative indicators for the evaluation of the actions undertaken to implement IDIH Priority Topics.	R&I communities and networks; care providers, tech providers, user associations, policy makers/funding agencies
International Workshops:	Compare regional evaluation methodologies and develop standards at an international level.	Policy makers/funding agencies

2. Define the use and scope of the evaluation using intervention logic

What should be evaluated and why? These elements should be clearly stated in the Terms of Reference of the evaluation. During the inception phase of an evaluation, the **intervention logic** of the intervention is reconstructed, revealing the expected chain of results (from input to impact) and assumptions made during decision-making. A limited number of evaluation questions derived from that intervention logic should be formulated.

3. Collect data and compare with indicators

During the implementation phase, the necessary information is collected with **data collection** tools, such as documentary analysis, surveys, field research, and interviews. Evaluators cross-validate the information sources ("triangulate") and critically assess the validity and reliability of the data. Limitations in the data collection must be explained.

4. Data elaboration and final assessment

The **final report** offers clear responses to the evaluation questions and reveals a logical chain from the findings to conclusions and recommendations. Good recommendations are realistic, evidence-based, targeted, clear, and prioritized. All these elements, as well as a description of the evaluation methodology used, are reflected in the final report, which is published and distributed on a large scale.

Notes: another assessment methodology to be considered for evaluation of **actions engaging cluster organisations**, is:

A smart guide to cluster policy monitoring and evaluation: This smart guide is addressed to policy makers and cluster managers engaged in cluster policy making who are interested in monitoring and evaluating the impact of their policies. The objective is to provide them with easy access to material of high practical value and sound methodological underpinnings, available in a concise and easy to read manner. It thus complements the Smart Guide Cluster Policy published by the European Commission (2016) that already advocated monitoring and evaluation as a strategic tool for the implementation of cluster policies and programmes.

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5 Conclusions

The proposed priority topics are fully in accordance with the current technological and societal trends and national policies in the strategic regions and are expected to provide benefits to the healthcare systems and to end users - especially older citizens of the related countries - for active and healthy living/ageing. To this end, the expected benefits for the elderly population per priority topic are presented as follows.

5.1 Benefits for the older people from priority topic 1

Access to healthcare data sources for health professionals, researchers, and technology providers will increase the effectiveness and quality of healthcare services for the elderly. The implementation of sophisticated services using state-of-the-art AI, machine learning, and Big Data analytics will increase the evidence base for decisions on treatment and diagnosis from the health professionals. Personalised medicine services are designed and tailored to the specific requirements of the elderly and will improve their self-management and quality of life. In addition to that formal and informal caregivers' workload will be greatly reduced. The effectiveness of communication between caregivers and their patients will be increased through the implementation of personalised healthcare services and "apps" for the elderly.

5.2 Benefits for the older people from priority topic 2

Inclusive age-friendly design techniques for the development of digital services and apps will allow reducing the social isolation of older citizens. Age-friendly products and services tailored to the specific needs and requirements of elderly people will facilitate the provision of improved personalized caregiving services designed to enhance the quality of life. Design and delivery of training courses, considering age and cultural and gender-related particularities, will help older people obtain basic digital skills. This will allow them to adopt digital healthcare services, to improve the quality of their lives, and to become integrated members of the digital society. The empowerment of elderly citizens will eliminate the gap between them and the healthcare system. A framework for the integration and provision of AHA services concerning the 5-As approach will ensure equitable access for the elderly, regardless of their societal or economical background and status.

5.3 Benefits for the older people from priority topic 3

Strengthening interoperability to support data exchange between healthcare providers within countries and across borders, healthcare providers will avoid duplications of tests, with positive effects for patients and healthcare costs. The work of health professionals will be made easier and more effective. With improved interoperability, health professionals will be able to access a patient's medical history across borders, thus increasing the evidence base for decisions on treatment and

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diagnosis, including when the patient's data is in another country.[76] Particularly this priority is fully in accordance with the targets and objectives of the European Data Health Space proposal.

The definition of the priority topics, their expected impacts, and the barriers to their implementation are the results of three years of collaborative work of the IDIH partners with the members of the Digital Health Transformation Forum and other external experts and policymakers from the strategic regions (EU, Canada, China, Japan, South Korea, and the USA). These results together with a thoroughly elaborated Action Plan for their realisation comprise the current roadmap for international collaboration of stakeholders from the strategic regions in the AHA domain.

The communication and collaboration with a copious amount of people and organisations from all the strategic regions was a painful and stressful process for the IDIH partners considering the Covid-19 pandemic period that prevented the organization and conduction of face-to-face meetings and events. To this end it is important to share this experience, present the "lessons learned" from this process, and how the IDIH consortium managed to sustain the Digital Health Transformation Forum activities and deliver the current document.

5.4 Lessons learned

In a scenario where the wide geographical origin of stakeholder groups involved in the elaboration of a joint strategic roadmap does not allow for continuous in-person consultations or in a scenario where exceptional circumstances such as a pandemic crisis forbid international travel, it is particularly critical to select and set up a sound suite of tools and means capable to support the remote, constructive dialogue of the participants. This comprises, for example, co-creation sessions, online and offline questionnaires, opinion gathering, and matchmaking tools.

Extreme time zone differences may additionally require performing the same workshop in duplicate sessions between Europe and North America, and between Europe and Asia, respectively, to facilitate the participation of stakeholders from their locations and to secure homogenous input provision across different countries.

Organisers further need to be aware of potential technical difficulties that may arise during the events and hamper the online exchange such as infrastructural shortages, bandwidth limitations, and limited knowledge of participants in using such tools. A comprehensive briefing of the participants about the online tools to be used is therefore highly recommended.

Another essential basis for effective consultations is to improve the mutual understanding of the terminology and concepts the different regions refer to, both at the bureaucratic and the technical level. This can, for example, be achieved using briefing notes before the consultations and summaries of the findings after each meeting for consecutive, remote validation, which is of additional help to avoid misinterpretations when involving non-native English speakers.

[76] European Commission (2022) Questions and answers - EU Health: European Health Data Space at https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2712

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It is expected that the roadmap toward international cooperation in digital health for AHA will be primarily used and exploited by policymakers and funding agencies in the EU and the strategic partner countries, who are the primary target group of this deliverable.

The roadmap is addressed to policy makers and funding agencies from the EU and the strategic partner countries, but also to other relevant target groups, such as the user/patient associations, healthcare organisations and services, academia and industry, R&I experts, clusters/ European strategic cluster partnerships going international/networks, and other enablers to enhance international collaboration in digital health for AHA.

It is foreseen that the dialog of the IDIH Digital Health Transformation Forum and the implementation of the suggested policy recommendations in the areas of data governance, digital inclusion, and interoperability by design will follow up via the ENRICH GLOBAL Health Innovation Group[77].

[77] About the Health Innovation group, ENRICH GLOBAL, https://www.enrich-global.eu/thematic-groups/health-innovation/

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6 Annex: Mapping of cluster partnerships as enablers for international collaboration

6.1 Introduction

Cluster organisations are defined as member organisations that gathering actors from the triple helix: academic/research organisations, industry players among which are notably SMEs, R&I support organisations, such as accelerators or incubators, and also policy support organisations.[78] This means they are ideal facilitators in the R&I landscape and one of their main goals is to support their members' collaboration efforts. In line with the EU's strategy in this field, strongly supported by the European Commission DG GROW, cluster organisations have a strong interest in international collaboration and are thus, for a large majority, constantly seeking international collaboration opportunities with relevant organisations from other countries (inside and outside of the EU). These collaboration schemes are developed for the purpose of supporting their members and above all the academic/research organisations and SME of the clusters' ecosystems.

This is why cluster organisations can be seen as important enablers for international collaboration in RDI, supporting also the international policy dialog.

International cluster collaboration is specifically driven through the so called European Strategic Cluster Partnerships Going International (ESCP-4is).[79] These are groups of cluster organisations that work on a given thematic field/sector and aim to align their international strategic approach for the benefit of their members. Cluster partnerships help develop common actions (such as business missions, cooperation agreements, gateway services, export consortia, and so on), as well as strengthen European SMEs' access to specific third-world markets. They also help create a long-term collaboration agenda with strategic partners in third world countries.

DG GROW has been supporting the ESCP-4is for many years and several of them are/were active in the field of health. These ESCP-4is were therefore considered an important target group for the IDIH support activities. They identify target markets and develop a strategy that supports their SME members when entering that market; they are constantly looking for partners to collaborate with in theses international markets to set up a collaboration scheme; and the ESCP-4i scheme corresponds to both a funding opportunity (for EU organisations) and a path for future interaction with stakeholders.

What makes these collaboration schemes particularly interesting is the fact that EU cluster organisations on average have 100 members each out of which a large majority are SMEs. Therefore, it can be considered that connecting cluster organisations and similar member networks from the EU with counterparts from the targeted countries can have a very strong multiplier effect and such collaboration schemes can be real catalysts for R&I collaboration among members.

[78] Definitions of a cluster and a cluster organisation can be found on the European Cluster Collaboration Platform, a DG GROW initiative: https://clustercollaboration.eu/cluster-definitions
[79] European Cluster Partnerships: https://clustercollaboration.eu/eu-cluster-partnerships

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The internationalization of cluster partnerships helps the clusters of the partnerships to improve their network, sign memorandum of understandings (MoU), and increase their exports, which ultimately leads to increases in the revenues of the clusters, of the ecosystem players, and of the region.

The European Strategic Cluster Partnerships programme has four generations to date with different topics and focus sectors for the internationalization of the partnerships:

- First Generation (2016–2017)
- Second Generation (2018–2019)
- Third Generation (2020–2022)
- Fourth Generation (2021–2024)

This study focuses on cluster partnerships that span all four generations and are related to the health sector, although there are no cluster partnerships concentrating on this sector in the fourth generation. It can be expected that relevant additional initiatives will be implemented in the future under the same scheme.

With regards to the target countries of relevance for the IDIH project, the following can be summarized:

China is home to an important cluster community. EU-China cooperation has been established with the aim of managing global challenges such as health, climate change, food security, and clean energy supply.

Canada has developed a large and promising cluster and supercluster community, supported by ambitious governmental policies in favour of R&I. The Canadian government has decided to concentrate its actions by supporting a limited number of superclusters thanks to $950 million CAD investments for five years as of 2018.

In Japan, somewhat similar to the European Cluster Collaboration Platform (ECCP), the Japan External Trade Organisation (JETRO) has developed a mapping tool that provides information about the industrial clusters in various regions of Japan and various sectors. The EU-Japan cluster cooperation has been well established since 2008.

South Korea has a well-developed cluster policy, mainly related to its so called “industrial complexes.” EU-Korea collaboration is focusing on strategic technology areas (e.g., 5G) but collaboration on the level of clusters is established in other sectors as well.

The collaboration with the USA in the field of clusters is based on a Cluster Cooperation Arrangement that was signed in April 2015 as a first of its kind. It has been implemented ever since and is now, after a less active period, getting more attention since the general cooperation in STI with the USA is renewed. Numerous good practice examples of collaboration between cluster organisations exist, often supported through the ESCP-4is, which is very active in this target market in different sectors.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

6.2 Approach and Methodology

This report was elaborated based on in-depth "desk" research. The cluster partnerships under the health sectoral topic were searched through the database available on the ECCP, which is the reference platform for European clusters[80]. The clusters operating in the health sector were further selected upon their targeting of IDIH strategic partner countries, which are in common with the strategic partner countries involved in IDIH (Canada, China, Japan, South Korea, and the United States). For the cluster partnership to be selected, it has or had to target one or more of the abovementioned countries. The clusters were further analysed with regard to their objectives and their results when available.

6.3 European Strategic Cluster Partnerships Going International

The cluster partnerships, their composition, their objectives, and achieved and/or expected results are presented, further classifying them by generation of the ESCP-4i programme that they were operating under.

6.3.1 First Generation

6.3.1.1 BioXclusters plus (ESCP on personalised healthcare)

Name	Country of origin	Targeted countries	SMEs involved	Duration
BioXclusters plus	France Spain Italy Germany	Australia Brazil Canada China Japan Republic of Korea United States	880	24 months

From the first generation of the cluster partnership programme, **bioXclusters plus** targeted Australia, Brazil, Canada, China, Japan, Republic of Korea (South Korea), and the United States. It is a continuation of bioXclusters plus, a pilot initiative funded by the European Commission from 2012 to 2014. The Partnership consisted of four cluster organisations:

- Bioregion of Catalonia (Biocat) in Spain
- LyonBioPole in France
- bioPmed/Bioindustry Park in Italy
- Bio Biotech Cluster development GmbH in Germany

The project lasted for **24 months,** from **2016** to **2018,** and around **880 SMEs** were involved.

Objectives

The objective of the alliance was to create the most competitive European meta-cluster in the field of personalised healthcare as a responsive tool for the global health challenges in the years to come.
It was intended to solve the next decade's European healthcare and SMEs growth problems by promoting a shared vision of personalised healthcare as the paradigm for future global healthcare

[80] European Cluster Collaboration Platform: https://clustercollaboration.eu/

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solutions. To meet this new paradigm, the bioXclusters plus alliance aims to be the most competitive European meta-cluster effort in personalised healthcare, delivering cutting-edge solutions on a worldwide scale through its innovation ecosystem and serving as a gateway to Europe for global companies. In this sense, the consortium's internationalization strategy sought to concentrate its efforts on both previously studied and untapped areas.

Results and achievements

The main achievements of the partnership were:

- The bioXclusters plus alliance, as the first meta-cluster of personalised healthcare aimed at global markets and operating as a strategic gateway to European health-tech SMEs, has increased its exposure due to sophisticated marketing and communication tools.
- The alliance was able to set up and implement tools to access the markets of target countries, conduct market studies, the offer regulatory and R&D help and any other assistance that the SMEs may require.
- To establish gateways for the cluster's organisations, the alliance had **eight C2C meetings**, **three fact-finding missions (in Japan, China, and the United States)**, and **three inbound missions**, all of which resulted in the signing of **eight cooperation agreements covering all of the target nations.**
- The EU SMEs also had the opportunity to access business-to-business sessions, which included partnering meetings and pitch presentations.
- Considering Japan, the alliance was one of its first actions and the business mission included **26 EU companies being offered the opportunity to travel to Japan, do research, and learn of the Japanese health market.**
- The alliance continued working together in the next phase of the "LASER-GO GLOBAL," which is presented further in this report.
- A group **of 21 SMEs** had the opportunity of benefiting from **tailored support services**. The SMEs were selected after a selection process.
- European SMEs also benefited from **four international business-to-business sessions**, including partnering, meetings, and pitch presentations.
- The alliance was also shortlisted in 2016 for the best ESCP-4i during the European Cluster Conference in Brussels; its achievements and operating models were presented to a large audience of cluster managers during an event organised by the European Cluster Collaboration Platform on behalf of DG GROW in Brussels in February 2017.

6.3.1.2 LASER-GO (European cluster partnership in photonics for health)

Name	Country of origin	Targeted countries	SMEs involved	Duration
LASER-GO	Austria, Lithuania, France	Canada, Malaysia, Singapore, South Africa, United States	218	18 months

Also, from the first generation of the programme and within the preparation phase of Strand1, the partnerships targeted the countries of Canada, Malaysia, Singapore, South Africa, and the United States. Within the report, the focus for this cluster was on the countries of Canada and the United States. The partnership consisted of three partners which were:

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- Laser & Engineering Technologies Cluster (LITEK) in Lithuania
- Human Technology Styria GmbH (HTS) in Austria
- OPTICSVALLEY in France

The project lasted for **18 months** from **2015** to **2016** and around **218 SMEs** were involved.

Objectives

The Photonics for Health Strategic Partnership is being created based on the following concepts.

- Using photonics-enabled technology in health-related applications as a focal point.
- Establishing connections with other clusters engaged in areas that can broaden the cross-sectoral reach of current collaborations and provide access to new value chains, such as mobility, smart cities, and active and assisted living, with a preference for clusters with complementary activities.
- Using political support in target markets when arranging visits and activities abroad and aligning with regional and EU export policies and economic diplomacy assistance efforts.

Results and Achievements

The main achievements of the partnership were:

- During the project, all the planned actions were successfully **achieved, and contacts were established with 32 business networks and/or cluster organisations** in the target market of North America and Southeast Asia.
- **Six overseas missions** were organised, including in the US and Canada.
- Additional key performance indicators (KPIs) were used, which included the following:
    1. **90 SMEs that have profited directly or indirectly** from the measures that were supported.
    2. As determined by a survey at the end of the activity, the supported initiatives resulted in an **increase in turnover (approximately 5%) from foreign operations of SMEs**, both directly and indirectly.
    3. The quantity and value of the resultant collaboration projects between the cluster members amounted to no less **than 5 million euros.**
- As for the SME cooperation achievements:
    1. Targeted nations have submitted requests for orders to component suppliers.
    2. Requests for technical expertise in the development of new product components have been made, and NDAs have been signed-in response, including firms from third world nations.
    3. Product catalogues and information regarding the firms' services were made available to intermediaries in the target nations, resulting in better understanding of the EU photonics sector's potential.
    4. Business missions have been formulated worldwide to introduce firms to prospective multipliers in the affected areas.
    5. A roadmap and action plan, coupled with a new business model has been designed to assure the continuation of the initiated operations after project completion to pursue the discovery of foreign markets in the targeted nations. All six cluster organisations decided to form an alliance with **access to more than 1,600 enterprises and approximately 120** research and technology organisations (**RTOs**) from three bioregions and three photonics areas.

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6.3.2 Second Generation

6.3.2.1 MAGIA: MedTech Alliance for Global for Internationalization

Name	Country of origin	Targeted countries	SMEs involved	Duration
MAGIA	Belgium, France, Germany, Italy	China, United States	500	24 months

From the second generation, MAGIA partnerships targeted the third countries of China and the United States from the targeted countries of this report.

The partnerships consisted of four partners:

- BioMed/ Bioindustry Park in Italy;
- LyonBioPole in France;
- BioWin in Belgium;
- Life Science Nord in Germany.

The partnership lasted for **24 months,** from **2018** to **2020**, and **500 SMEs** were involved.

Objectives

The MAGIA project's goal was to improve the competitiveness of medical SMEs in two worldwide target markets and raise awareness of the European MedTech industry's innovativeness through international collaboration and resource sharing.

The alliance was dedicated to supporting the internationalization of SMEs and aimed to achieve a solid and reciprocal understanding of the activities of the four clusters to strengthen their collaboration. In this context, each cluster was visited by partners in the first few months of the collaboration and working groups involving SMEs were organised to assess their needs and identify the two target markets to be addressed as a priority. China and United States were selected in this manner.

The collaboration deployed initiatives with the goal of building a European strategic cluster partnership on MedTech based on a similar vision for a long-term relationship by sharing their individual expertise and experiences.

The main objectives were as follows:

- Establish strategic partnership foundation by thoroughly analysing each partner organisation; identifying opportunities through the identification and sharing of cluster's skills and competences as well as strengths and needs (particularly in terms of internationalization) from the respective MedTech ecosystem; based on these needs, the partners would highlight the markets to target from a shortlist of countries that the consortium had previously identified as relevant.
- Dedicated training sessions, presence of specialists, and fact-finding expeditions focused on MedTech business international development will provide chances for cluster partners and their SMEs to obtain information regarding the target markets.

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- Developing a unified marketing and branding strategy to establish the ESCP as a meta-cluster with a visual and marketing identity that may serve as the strategic "center" of future pan-European projects.
- Developing a cooperative internationalization plan for the ESCP, including a partnership agreement (PA), which expresses the partner's readiness to collaborate on a long-term basis, and the ESCP's strategy execution roadmap.

Results and achievements

The achievements of the alliance were:

- The MAGIA partners benefited from a fruitful sharing of best practices in the field of cluster services for internationalization, as well as a better understanding of the consortium's SMEs' internationalization needs, thanks to study visits carried out in the four partner regions and the mapping of the MedTech companies of the meta-cluster.
- The MAGIA project focused on the development of a set of tools to assist SMEs in their internationalization, such as market intelligence resources to keep up with current market trends and insights from trusted market experts in the form of video materials and interactive webinars to get a first orientation in the new and complex market environments in the United States and China.
- The project published **two market studies**:
    1. MAGIA Market Study on the Chinese MedTech Industry 2019
    2. MAGIA Market Study on the US MedTech Industry 2019
- The alliance worked to identify various key structures in the target markets and then selected **eight PAs (MoU – Memorandum of Understandings) that were signed via the alliance (one with the US and seven with China)**. The organisations with whom the partnerships were signed are as follows:
    1. Medical Alley Association (United States);
    2. Beijing B&R International Co-Incubation (China);
    3. Beijing Jishuitan Hospital (China);
    4. China Association for Medical Devices Industry (China);
    5. Professional Committee of Regenerative Medicine Technology Industry of China (China);
    6. Shanghai Medical Instrument Trade Association (China);
    7. Shulan Health Group (China);
    8. Tsinghua University Institute of Internet Industry (China).
- "To expand their presence outside of Europe and better assist their SMEs, the four clusters created a combined internationalization plan (Joint Internationalization Strategy – JIS) in the latter stages of the project. This was based on the findings of a thorough examination of each partner's resources and assets, two MedTech market research studies conducted in the United States and China, and two MAGIA fact-finding missions conducted in both countries. The MAGIA JIS established MAGIA's joint European strategic vision, with an objective of defining a common internationalization strategy based on complementary expertise, skills, and networks to support the international development and competitiveness of the European MedTech sector; creating a European platform to foster cooperation between cross-sectoral

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clusters in Europe; representing and promoting the European MedTech industry in the world, and establishing a cooperative research and development programme."[81]

- The plan was followed by a PA, which formalized the partners' commitment to work in collaboration in the long term, beyond the project's lifetime; this plan was backed by letters of intent signed **by 57 European MedTech SMEs**.
- The MAGIA partnership was continued and further developed under MAGIA2MARKET as part of the 3rd generation ESCP-4is.

6.3.2.2 LASER-GO GLOBAL: European cluster partnership in photonics for health

Name	Country of origin	Targeted countries	SMEs involved	Duration
LASER-GO GLOBAL	Austria, France, Germany, Lithuania	Australia, China, Israel, Japan, New Zealand, South Korea, Singapore, United States	240	18 months

From the second generation was the next phase of the LASER-GO alliance. LASER-GO Global targeted the countries of Australia, China, Israel, Japan, New Zealand, the Republic of Korea (South Korea), Singapore, and the United States.

The partnership consists of a total of seven partners including the three partners from the LASER-GO alliance. The partners are:

- Biocat (Bioregion of Catalonia) in Spain;
- Laser & Engineering Technologies Cluster (LITEK) in Lithuania;
- Human.Technology Styria GmbH (HTS) in Austria;
- OpticsValley in France;
- Medecin Paris in France;
- Systematic Paris in France;
- Optence e.V./Photonics hub in Germany.

The partnership lasted for **18 months** from **2018** to **2019** and included **240 SMEs**.

Objectives

The partnership's goal was to foster European cluster collaboration in the area of cross-sectoral health-photonics technologies. In the sectors of health, biotechnology, and photonics, the partnership brings together six clusters from five advanced and fast-growing European Union nations, representing about 1,600 businesses and 100 scientific and research institutes in the area.

"During Strand 1 of the COSME-funded Clusters Go International initiative, three clusters (LITEK, OpticsValley, and HTS) formed the alliance. During the implementation of this project, three more

[81] MAGIA: Publishable Summary from the ESCP-4i Platform: Achievement of the second generation https://clustercollaboration.eu/sites/default/files/2021-02/strand-1-magia.pdf

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cluster organisations (Optence, which during the project merged with Bayern Photonics to create Photonics Hub, Biocat, and the Medicine Paris Region) joined the consortium. As a result, by the end of the project, the consortium had brought together six clusters from five EU member states (France, Germany, Austria, Spain, and Lithuania), totalling over 1,600 enterprises and 100 scientific and research institutions in the sectors of health, biotechnology, and photonics."[82]

The specific objectives were:

- To develop metrics and techniques for establishing a global value network, including partners from target markets in existing or future partnerships with cluster SMEs in new product development or adoption in target markets.
- To create realistic business chances for partnering by forming a network of technology scouts and network representatives (network affiliates) from the local photonics and health-tech ecosystems.
- To organise global value network initiatives based on a systematic assessment of the value chain of the SMEs engaged in partaking clusters and matching their propositions with those of the organisations from the corporate network in the target markets to generate business instances for new product collaboration, and to that end to develop the value chain mapping methods to measure the product and technology options of a particular company in a particular market.
- To establish specific actionable strategies for international expanded alliance engagement: the global value chain and LASER-GO pathway for 2020–2025, and the plan for cooperation with European strategic cluster partnerships[83].

Results and achievements

The achievements of the alliance are:

- During the project period, the alliance explored the targeted export markets in the target countries, gathered information on these markets from European companies, developed new business relationships, shared emerging market experiences, established business representations, and delivered European companies' products and sole offers.
- The partnership met its goal of 240 firms participating in the initiative.
- Furthermore, export of new items to target markets increased by 20%, and cluster firms received approximately 20 million euros in research and development funding.
- The alliance shortlisted 30 innovative champions among 240 enterprises that the cluster collaboration had targeted. The catalogue served the cluster missions by exhibiting some of the high-tech products that they are promoting as well as assisting in the commencement of dialogs that led to new business prospects in the target markets.
- The alliance conducted several overseas missions in Iran, Singapore, South Africa, Australia, New Zealand, the USA (Boston and San Francisco), Canada, Israel, Malaysia, South Korea, and Japan.[84]

[82] LASER-GO GLOBAL: Publishable Summary from the ESCP-4i Platform: Achievement of the second generation https://clustercollaboration.eu/sites/default/files/2021-02/strand-2-laser-go-global.pdf
[83] LASER-GO GLOBAL: Publishable Summary from the ESCP-4i Platform: Achievement of the second generation https://clustercollaboration.eu/sites/default/files/2021-02/strand-2-laser-go-global.pdf
[84] LASER-GO GLOBAL Completed Projects: https://litek.lt/portfolio-item/laser-go-global/?lang=en

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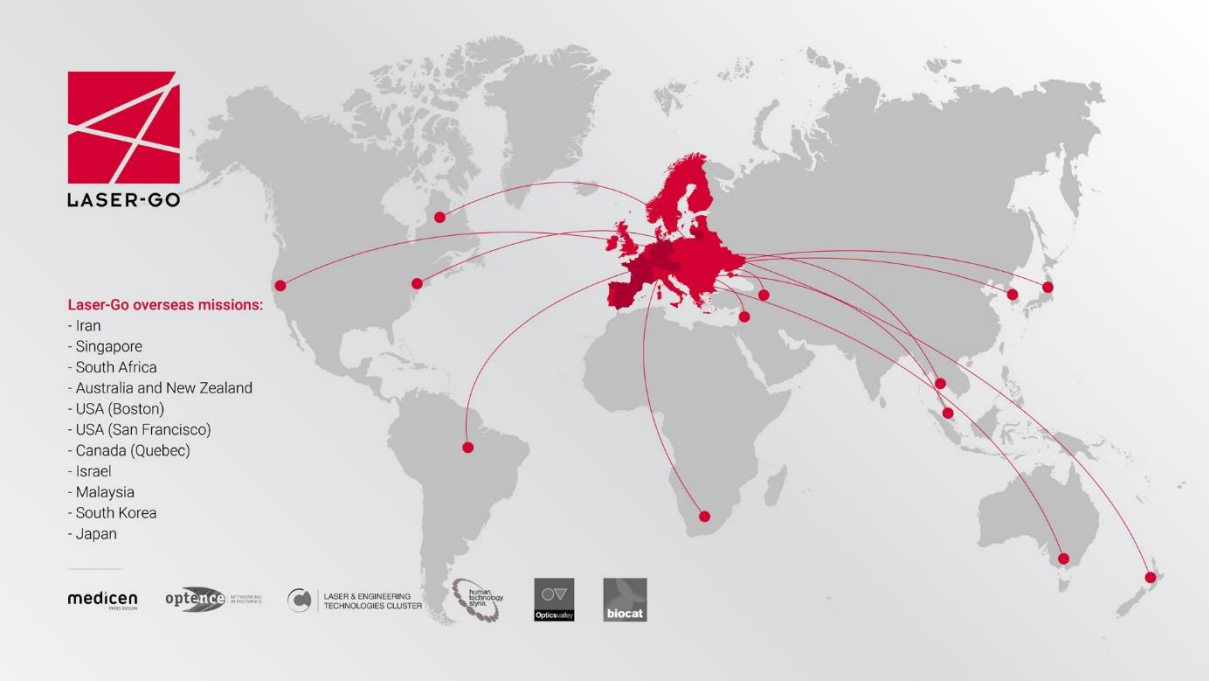

Figure 9: LASER-GO GLOBAL Completed Projects

- The mission to Canada resulted in the signing of the MoUs between the LASER-GO GLOBAL partners (Opticsvalley and Medecin) and MEDITEQ and OPTONIQUE in Canada.
- The mission to the USA resulted in the signing of MoU between the LASER-GO GLOBAL and Optics Valley Arizona.

The quantifiable outcomes were the following:

- The cluster's eight missions have been completed.
- Twenty-two cooperation agreements have been inked, with another six in the final stages of development.
- Sixty businesses have been identified as potential business partners.
- Sixty-two businesses were chosen as possible distributors.
- Five collaboration efforts were proposed, two cooperation instances were started, and two partnership requests were received.
- There are nine business cases that have been discovered.
- For 40 SMEs, B2B leads were created.
- Six follow-up visits have been completed.
- 631 contacts have been formed.
- 220 meetings were held, of which 40 were C2B events.
- 661 clusters and SMEs met, of which 264 were from third world countries.[85]

[85] LASER-GO GLOBAL: Publishable Summary from the ESCP-4i Platform: Achievement of the second generation https://clustercollaboration.eu/sites/default/files/2021-02/strand-2-laser-go-global.pdf

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6.3.3 Third Generation

6.3.3.1 NE4HEALTH: New European electronics for global health and wellbeing

Name	Country of origin	Targeted countries	SMEs involved	Duration
NE4HEALTH	Germany, Latvia, Poland, Romania, Spain	Israel, Japan, United States	85 (to date)	18 months

The NE4HEALTH project from the third generation targeted the countries of Israel, Japan, and the United States.

The partnership consisted of five partners:

- LATERA Cluster in Latvia;
- Functional Print Cluster in Spain;
- Organic Electronics Saxony in Germany;
- The Health Cluster in Romania (RoHealth) in Romania;
- Interzion Foundation in Poland.

The alliance lasted for **18 months,** from **2020** to **2022** (an ongoing project when the report was created), and involved **85 SMEs** to date.

Objectives

The NE4HEALTH project's principal goal is to bring together a group of world-class clusters dedicated to the internationalization of electronic (printed, embedded) technologies utilized in the health and wellness sectors.

The specific objectives are:

- Fostering mutual knowledge among clusters and SMEs, high level transregional collaboration, and partnership formation in important European areas, as well as matchmaking efforts that might lead to open innovation spaces.
- To assist SMEs in identifying business and internationalization opportunities in the electronics for health sector by highlighting some of the key technological challenges in terms of cost, performance, standardization, reliability, survivability, install ability, environmental impact, health and safety, predictability, and operability.

The project is expected to deliver the following:

Internationalization strategy:

- To detect global trends and pick target nations that are more receptive to the establishment of an early market and, as a result, internationalization based on characteristics such as high energy costs, abundant resources, market size, and support framework.
- To conduct a thorough analysis of these target markets, including a thorough grasp of their competitive dynamics and the identification of important players with whom to make contact during the project.

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- To establish and implement an internationalization roadmap with specific measures for each target market, as well as a monitoring scoreboard with verifiable metrics, all of which will be developed and implemented by the consortium.

Value chain approach:

- Consolidate actual transregional value chains, which include firms and other agents currently within the partners' local value chains.
- To integrate SMEs into trans-European consortiums in order to compete and gain a worldwide leadership position in the electronics and health sectors.

Results and achievements (Planned)

The expected deliverables, milestones and reports are as follows:

- Deliverable Reports
  - D1.1 NE4HEALTH Value Chain Analysis
  - D2.1 Common SWOT analysis
  - D2.2 Good Practice Handbook
  - D2.3 Market Studies on TTCs
  - D2.4 Report on Networking Events and Missions
  - D3.1 Internationalization Strategy Plan
  - D3.2 Implementation Roadmap
  - D3.3 Partnership Agreement
  - D4.1 Strategic, Dissemination, Communication and Exploitation Plan (SDCEP)
  - D4.2 Mid-term Report on dissemination and communication (incl. impacts)
  - D4.3 Final Report on dissemination and communication (incl. impacts)
  - D5.1 Project Management and Quality Handbook
  - D5.2 Networking Report
  - D5.3 Mid-term Report (Technical – Performance Indicators)
  - D5.4 Final Report (Technical – Performance Indicators)
- Milestones
  - M1.1 Effective involvement of SME members
  - M2.1 Market studies on TTCs finished
  - M2.2 Networking Events and Missions accomplished
  - M3.1 Joint Internationalization Strategy
  - M3.2 PA signed
  - M4.1 Strategic Dissemination, Communication and Exploitation Plan (SDCEP) endorsed
  - M4.2 Visual identity and brand framework of the project developed.
  - M5.1 Kick-off Meeting
  - M5.2 Interim Evaluation
- Final Report: Detailed analysis of outputs and achievements, results (M5.3)[86]

[86] New European Electronics for Global Health and Wellbeing: https://clustercollaboration.eu/content/new-european-electronics-global-health-and-wellbeing

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6.3.3.2 MAGIA2MARKET

Name	Country of origin	Targeted countries	SMEs involved	Duration
MAGIA2MARKET	Belgium, France, Germany, Italy	China, Japan, United States	560 (to date)	24 months

The MAGIA2MARKET is the next phase of the MAGIA project from the second generation. The project targets the countries of China, Japan, and the United States.

The partnership consists of four partners:

- BioPmed in Italy;
- LyonBioPole in France;
- BioWin in Belgium;
- Life Science Nord in Germany,

The alliance lasted for **24 months,** from **2020** to **2022** (ongoing project when the report was created) and included **560 SMEs**.

Objectives

The objective of the project was to build and reinforce knowledge networks between Europe, the USA, China, and Japan, and provide soft landing services and international opportunities to MedTech SMEs. The MAGIA2MARKET follows the first phase of the MAGIA project and brings together four European leading MedTech clusters, joining forces to continue the successful European strategic cluster partnership on MedTech.

The services provided by this alliance are:

- Customized assistance for businesses planning travels to the United States, China, and/or Japan.
- Attendance at webinars aimed at defining MedTech synergies and cross-sectoral prospects.
- Virtual talks on the problems and solutions for commercialization in the target nations to provide advice and direction.
- The chance to attend high-quality events and ensure that participants are well prepared for pitch sessions and meetings with possible partners.
- Companies will be introduced to the alliance's important colleagues in the target nations.

The project will be developed by the partners in six work packages.

The first pillar of the project intends to reinforce the MAGIA Alliance's communications plan and marketing strategy, which were created during the project's first phase. Throughout the project's lifespan, the plan will function in tandem with the other work packages. The WP's overarching purpose is to raise the Alliance's exposure both inside and outside of Europe.

The following activities will be heavily influenced by lessons learned and accomplishments of the MAGIA Alliance during the project's first phase. A major goal is to strengthen the MAGIA Alliance's partnerships in the United States and China to provide outstanding market entry conditions for

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European SMEs and generate actual commercial prospects. The main operations will be fact-finding missions (C2C) and SMEs matching missions (B2B) in China and the United States.

Another pillar is focused on forming strategic alliances with Japan, as a new target market, and specifically with the Japanese MedTech innovation ecosystem, to help European SMEs gain entry into this market. The main tasks will be to organise a fact-finding (C2C) expedition to Japan and develop strategic relationships.

A part of the activities will take advantage of the missions' network of connections and the work completed as part of the previous project accomplishments to provide firms with a set of services to help them cope with the target nations' markets and MedTech ecosystems. The WP will be devoted to the development of the Go2Market assistance programme. Companies will be notified about MAGIA consortium's training resources and will be able to assist in the search for business or development partners, specialized suppliers, or consultants to handle any internationalization-related issues.

The activities will pave the way for the MAGIA Alliance's continued success, long-term viability, and goals, and further provide the groundwork for internationalization support activities throughout the four MAGIA clusters. All clusters will benefit from the considerations made in this part of the project, as there will be a well-founded estimate of the effort required when the project is completed.

Results and achievements (planned)

The MAGIA partners seek to build on the success of their European Strategic Cluster Partnership on MedTech, which is founded on a shared vision and long-term relationships. Magia2Market will be based on the consortium's specialized expertise and experiences garnered via the MAGIA project, as well as its own worldwide experiences. The specific objectives will be:

- Implementing a collaborative internationalization plan that was established at the end of MAGIA Strand-1 to completely integrate US, Chinese, and Japanese activities.
- To ensure effective gateways for European SMEs, MAGIA is strengthening and sustaining long-term relationships with MAGIA partner networks overseas.
- Maintain and expand the knowledge base for the three markets of the United States, China, and Japan to provide SMEs with the necessary tools for strategic market planning.
- Create tangible market prospects for SMEs in the United States, China, and Japan, primarily through customized matching efforts.
- Develop a unified branding approach to effectively convey MAGIA's operations and boost European SMEs' visibility in target markets.
- Maintain flexibility to future changes in the core markets of the United States, China, and Japan while adhering to the EU trade policy's strategic aims.

Analysis

Among the six cluster partnerships that are presented within this report, not double counting the clusters, the greatest number of clusters within this partnership are from France and Germany with each country having four clusters participating in multiple partnerships, followed by Spain with two clusters while Italy, Lithuania, Austria, Belgium, Latvia, Romania, and Poland each have one cluster coming together to form an alliance in the six cluster partnerships stated above. BioPmed from Italy and LyonBioPole from France are the two clusters participating thrice in three of the six partnerships

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stated above. Clusters Biocat from Spain, OpticsValley from France, Life Sciences Nord from Germany, HTS from Austria, and Biowin from Belgium, each come together in two partnerships.

All six of the partnerships target the markets of the United States. Four of the partnerships target the markets of Japan and/or China while two of the partnerships target the markets of Canada and/or South Korea.

If counted directly, a total of 2,483 SMEs were involved and benefited from the services and assistance provided by the partnerships (the number of individual SMEs could lower due to repetitive counting).

For the completed projects from the first generation and second generation of the ESCP-4i, at least 12 missions were carried out in the target countries. Generation three and generation four of the programme are still ongoing so are not being counted. BioXclusters plus alliance carried out a special mission to Japan where 26 European companies had the opportunity to visit Japan and establish contacts. The US market saw the highest numbers of missions from the partnership.

Table 3: Missions to target countries

	Canada	China	Japan	South Korea	USA
BioXclusters +		1	1		1
LASER-GO	1				1
MAGIA		1			1
LASER-GO GLOBAL	1		1	1	2

BioXclusters plus held eight C2C meetings, signed collaboration agreements with all of its target countries, and provided specialized assistance to SMEs. The SMEs increased their overseas operation's turnover and signed NDA agreements because of LASER-GO GLOBAL, and the value of the partnership projects among the cluster members amounted to approximately 5 million euros. MAGIA conducted market research for all its target markets and signed eight memorandums of understanding. LASER-GO GLOBAL also inked memorandums of understanding and released a catalogue of 30 inventive champions who assisted the cluster's missions by displaying some of their high-tech items. Exports for LASER-GO GLOBAL increased by 20% owing to cluster manufacturers receiving approximately 20 million euros in R&D financing.

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6.4 Conclusion and recommendations

To sum up this short overview of the initiatives gathering clusters targeting the same target markets as IDIH, we can count six partnerships that targeted the markets of the United States; four of the partnerships targeted the markets of Japan and/or China, while two of the partnerships targeted the markets of Canada and/or South Korea. Some of them are finished and some are still ongoing. It can be expected that more are to come in the next generation and we clearly see the perspectives offered to IDIH with regards to the exploitation of results.

It can be expected that more are to come in the next generation of ESCP-4i, which is a clear opportunity for RDI actors. As previously stated, we can expect a strong multiplier effect from such collaboration, and they can be real catalysts for R&I collaboration among members and with peers in international countries.

Regarding IDIH, a number of results from the project can be considered as relevant to the community of cluster organisations and cluster partnerships. As an example, the following activities carried out in IDIH could be exploited in a larger perspective thanks to these initiatives:

- Reports (report on trends drivers and enablers, panorama of the digital health R&I landscape report, and recommended areas for international cooperation);
- Guidebook for RDI stakeholders on funding and cooperation schemes;
- Podcast series;
- IDIH Week and other events/webinars;
- Exchange with the Digital Health Transformation Forum of experts,

Thus, European strategic cluster partnerships going international have been identified as target groups to ensure an efficient uptake of the IDIH results and targeted dissemination toward the ongoing ESCP-4i is made with the abovementioned material.

At the same time, we encourage future cluster partnerships to take IDIH achievements as a background in order to benefit from the lessons learned and engage in international collaboration with RDI and policy actors from the third countries.

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