Health-RI International Advisory Board Report

June 2025

health RI
enabling data driven health & life sciences

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Abbreviations

IAB	International Advisory Board
EHDS	European Health Data Space
HDAB	Health Data Access Body
HDA	Health Data Authority
GDI	Genome Data Infrastructure
IAC	Industry Advisory Committee
PPAC	Patient and Public Affair Committee
HoNs	Head of Nodes
OVT	Obstacle Removal Trajectory
EOSC	European Open Science Cloud
ESFRI	European Strategy Forum of Research Infrastructure
ELIXIR	Research Infrastructure of Life Sciences
BBMRI	Research Infrastructure of Biobanking and Data Collection
EATRIS	Research Infrastructure for Translational Medicines
TRE	trusted research environments
PPP	public-private partnership

IAB composition

IAB members	Affiliation, country	Presence
Katrin Crameri (Chair)	Co-Lead «DigiSanté» - promotion of digital transformation in the Swiss healthcare sector; Co-Lead Digital Transformation Division, Federal Office of Public Health FOPH, Switzerland	In person
Neil Postlethwaite (Deputy-Chair)	Technical Director - Health Data Research UK, United Kingdom	In person
Vibeke van der Sprong	Deputy Director General - Danish Health Data Authority, Denmark	Absent
Serena Scollen	Head of Human Genomics and Translational Data - ELIXIR, Hinxton, UK	In person
Zisis Kozlakidis	Head Laboratory Support, Biobanking, and Services - IARC/WHO	In person
Daniel Rueckert	Professor of AI in Healthcare and Medicine - TU Munich, Germany	Absent
Jacques Demotes	Director General - ECRIN	Absent
Carlo Senore	Senior Expert - Epidemiology, AOU Città della Salute e della Scienza (CdS), Italy	Online
Zoltán Kaló	Professor of Health Economics at the Center for Health Technology Assessment, Semmelweis University, Hungary	In person
Danielle Welter	Principal Data Analyst - Luxembourg National Data Service LNDS	In person

Agenda

Timing	Agenda
8:30-9:00	*Walk in*
9:00-9:05	Welcome by the IAB chair and deputy chair
9:05-9:50	• Opening IAB meeting by the Health-RI board • Feedback from IAB recommendation July 2024 • Health-RI Board update on infrastructure design and implementation • National policy on EHDS implementation
9:50-10:50	**Strategic topic 1: EHDS Blueprint section discussion 1: National Health Data Catalogue, onboarding & DAAMs** **- State of play at Health-RI** **- How it is organized in your countries/organizations, success and lessons learnt** Topic leads: Louise Vosters, Edward Robinson, Marianne Knoop Pathuis-Baarda
10:50-11:00	*Coffee break*
11:00-12:00	**Strategic topic 2: EHDS Blueprint section discussion 2: Secure Processing Environments (SPEs) and AI** **- State of play at Health-RI** **- Steps towards AI4Health** **- Your opinions on SPEs, federated and centralized analysis approaches and AI** Topic leads: Niels Bolding, Anika Bongaarts, Anne van der Kant, Cristina Gonzalez
12:00-13:00	*Group Lunch & Photo*
13:00-14:00	**Strategic topic 3: Industry engagement in Health-RI** **- Our publication: "Data in bedrijf"/'Data in company'** **- Health-RI EHDS deep dive for industry** **- Your working models to engage industry** Topic leads: Gaston Remmers, Miriam Beusink, Joep Rijnierse

Timing	Agenda
14:00-15:00	**Strategic topic 4:National Disease domain node approach** **- Our approach on national and EU levels** **-Current working group activities** **1) patient-level data linkage 2) common data model for oncology** Topic leads: Lifang Liu, Anika Bongaarts, Patrick Kemmeren
15:00-15:30	*Coffee break*
15:30-16:30	Drafting the IAB report
16:30-17:00	IAB report presentation and discussion
17:00-17:10	Wrap up
17:30-	*Farewell drink*

General comments:

The advisory board members wish to thank the Health-RI team for the exceptional hospitality and warm welcome. The extra mile that the Health-RI team went to, to secure appropriate travel arrangements despite the country-wide rail strike on our arrival was very much appreciated.

The agenda for the day was interesting and appropriate, following on smoothly from previous meetings.

The board thanked the Health-RI team for the seriousness with which they had upheld and followed through on each of the board's previous suggestions and recommendations, noting the significant progress as shared in the session and the pre-read documentation circulated. The issues around completing the AI-related action with the team in Munich was understood given the political changes which had adversely impacted AI related investments in the Netherlands.

The discussion around patient and public engagement followed nicely on from the Data Improves Lives campaign discussed at the last meeting and it was good to see a high level outline of next steps.

1] EHDS Blueprint section discussion 1: National Health Data Catalogue, onboarding & DAAMs

Key Points:

- **R1:** The mapping exercise Health-RI have undertaken against the EHDS Blueprint is excellent. The board concurs with Health-RI's approach and suggests that the focus should now be on highlighting to key stakeholders across the Dutch ecosystem, where Health-RI already have or soon will have services in production that can provide the requisite services to the Blueprint and pushing forward with those in a leadership position. Critical as part of this advocacy is to highlight these services to the 'quartermaster' within government once that appointment is made.

- It's very heartening to see the Health-RI Catalogue live and demonstrable with metadata for 200 datasets on board and many more in the pipeline. The Data access request functionality is also nice to see up and running.

- Neil Postlethwaite offered to link Edward Robinson of Health-RI with Health Data Research UK's equivalent product manager looking after data access requests, to exchange learnings, especially around efficiency of integrations with other access request systems

- The board suggests a close watching brief over potential clashes with the upcoming TEHDAS2 guidelines and mandated requirements around dataset descriptions within the catalogue and ensure good alignment with the Health-RI FAIR data point approach.

- The term "harvesting" metadata might usefully be reconsidered as it may be taken wrongly; also the term "enrichment" when applied to metadata doesn't quite work due to its very specific meaning in the EHDS context.

- **R2:** The board suggests Health-RI consider requesting and leading a short, sharp (maybe 3-month) ELIXIR focus group to examine potential gaps between the services Health-RI already has to support the EHDS Blueprint and other data infrastructure available in ELIXIR ecosystem, noting it's key to avoid duplications with the activities of the existing EHDS Community of practice

- The board suggests Health-RI continue to consider and innovate around both non-financial and financial incentives and solutions for those data holders that are i) not intrinsically motivated to share metadata to the catalogue and those that ii) do not publish and thus their datasets typically aren't referenced

- In addition, it would be helpful for assessing the general impact to know how many of the datasets listed in the metadata catalogue have already been reused by third parties.

- The board reiterates its strong support as noted in the last meeting for Health-RI's strategy of pursuing a single Health Data Access Body (HDAB) and single consent registry for the Netherlands

2] EHDS Blueprint section discussion 2: Secure Processing Environments (SPEs) and AI

Key Points:

- **R3:** Health-RI should consider hosting a national SPE and provide related services. This would be a good strategic move for Health-RI and position Health-RI to make an even greater contribution to the Dutch health data landscape and secure further leveraged funds in this area

- The board notes that when looking at the federated deployment model – it is key to consider overall cost and work in providing the option is taken into account. It appears attractive however federated nodes still require management, compute power, information security, governance support and have associated long term costs. The board suggests use of the federated deployment option needs to be considered alongside the synergies provided by a level of data centralization where possible.

- In light of recent political and regulatory developments in the United States concerning digital sovereignty, data access, and cloud infrastructure governance, the board encourages Health-RI to consider carefully the implications of deploying infrastructure and services that work on sensitive data on U.S. based hyperscaler clouds. While these platforms offer scalability and speed and in many cases the ability to deploy within geographical regions, their extraterritorial jurisdiction—particularly under laws such as the U.S. CLOUD Act—raises concerns about data control, privacy, and compliance with EU standards. In addition, availability of these services might be affected not through technical issues but political decisions. These issues apply across the EU, however Health-RI would be wise to explore sovereign or EU-based alternatives, hybrid-cloud architectures, and data localization approaches that align with the principles of trust, transparency that might improve this situation in the longer-term.

- Neil Postlethwaite offered to connect Health-RI personnel with federated analysis leads within the UK health data ecosystem

- The board suggests it is key to ensure Health-RI's partner TREs providers/vendors are brought along on the EHDS SPE journey

- A presentational comment was noted in that it can appear that the 3 options (SPE, federated analysis, trusted staging) are mutually exclusive, when we didn't believe that was the intention

3] Industry engagement in Health-RI

Key Points:

- The board notes how well Health-RI are doing in the area of industry engagement compared to the countries the board members represent. The breadth of industry sectors represented in the IAC and the work done to date to capture the industry engagement stories is excellent and leading.

- The board suggests the Health-RI team consider expanding the IAC board memberships to include an industry partner covering wearable/sensor data as this is becoming key in both healthcare and private individual use

- **R4:** The board suggests the work done to create the industry engagement and motivation stories could be further leveraged to generate FAQs/short videos/social media content targeted at public, patients and groups of individuals to help them understand the motivations of industry health data usage with the objective of increasing levels of trust by enhancing understanding

- Data saves lives only if evidence generated from real-world data is considered a global public good and made available to different stakeholders. A potential method of improving levels of trust around industry data usage could be to include (by design) an automated possibility to remind industry data users of their duties related to Art. 61 (publication of results when using RWD) https://eur-lex.europa.eu/eli/reg/2025/327/oj#art_61 (paragraph 4)

- The board also suggested a method of learning here could be some small pilots working with industry which have clear public benefit. Health Data Research UK has just begun a project with GSK around the Shingrix vaccine and potential associated reduction in dementia risk which has been well received by patients and public. (https://www.hdruk.ac.uk/news/first-of-its-kind-study-evaluates-link-between-shingles-vaccine-and-reduced-risk-of-dementia/)

4] National Disease domain node approach

Key Points:

- The board notes Health-RI's leverage of existing investments to secure further funding with the CANDLE project and commends the Health-RI team for their leadership and convening power across many member states and collaborative working with partners such as ELIXIR and other pan-EU research infrastructures, which has resulted in this funding being granted. The national cancer data nodes through the CANDLE project stand as forerunners to EHDS national implementation based on the EHDS business digital capabilities and business requirements specified.

- **R5:** The board is fully supportive of Health-RI's drive to change legislation to allow use of the national ID (BSN) for data linkage and secondary data use. The current situation of using other identifiers to achieve linkage such as data of birth, name, etc should be a tactical stopgap whilst this legislative change is pursued. Ideally, the BSN

should also be permitted for the primary use of data, for example when data flows via the Health Data Space are also used for B2B processes.

- With regard to the proposed oncology common data model, the board suggests starting with an existing data model (preferably OMOP) and extending that model based on identified gaps, rather than the current approach which appeared to be merging multiple models to generate yet another new model that will not be fully interoperable with any of the source models. Health-RI may wish to contribute to efforts of the OHDSI Oncology working group (https://github.com/OHDSI/OncologyWG) if not already involved.

Strategic perspectives

- As noted in last year's IAB meeting, Health-RI's work within the European Health Data Space and associated initiatives is strategic and an area that should continue to receive focus. The Health-RI infrastructure services mapping work to the EHDS blueprint is critical and the board strongly advises and is willing to support (**R1**) Health-RI to really highlight these capabilities in order to avoid potential duplicate investments and waste of public money.

- The IAB recognizes that everything associated with the EHDS is in a state of evolution and key to successful working in this environment will be to quickly stand up services that support required functionality, re-using existing services whenever possible and iterating rapidly from that base.

- The board reiterates its strong support as noted in the last meeting for Health-RI's strategy of pursuing a single Health Data Access Body (HDAB) and single consent registry for the Netherlands and suggests that additionally, Health-RI taking up provision of a national SPE **(R3)** and providing a trusted center for data linkage would be strategic.

Health-RI International Advisory Board
June 2025

To:
The Honourable Ministers of:

- The Netherlands Ministry of Health, Welfare and Sport
- The Netherlands Ministry of Education, Culture and Science
- The Netherlands Ministry of Economic Affairs

Subject: Letter of Recommendation – Support for Health-RI

Dear Ministers Jansen, Bruins and Karremans,

As the International Advisory Board of Health-RI, we are writing to express our strong and continued endorsement of the Health-RI initiative and to urge your Ministries to recognize and support its central strategic importance in shaping the future of health data infrastructure in the Netherlands and its alignment with European ambitions.

Over the past two years, Health-RI has made remarkable progress. What began as a vision is now a functioning infrastructure with demonstrable impact: a live national health data catalogue, a working data access mechanism, governance frameworks for consent and linkage, and increasing alignment with the European Health Data Space (EHDS) blueprint. These are not abstract plans, but real, usable services that reflect diligent implementation and responsible leadership. As a Board, we were especially impressed at our latest meeting in Utrecht on 11 June 2025, by how thoroughly the Health-RI team has responded to our past recommendations, translating guidance into clear, actionable outcomes.

At a time when Europe is moving rapidly toward a federated and interoperable health data ecosystem, the Netherlands—through Health-RI—is in a position not only to comply but to lead. The mapping of Health-RI's existing services against EHDS requirements is exemplary and already highlights how the Netherlands can avoid duplicative investments by consolidating national efforts around a single, coherent infrastructure. Health-RI is also actively building connections with key European actors, participating in major international collaborations, and serving as a trusted bridge between public health, research, and innovation.

The Board is fully supportive of Health-RI's drive to change legislation to allow use of the national ID (BSN) for data linkage and secondary data use. The current situation of relying on indirect identifiers such as date of birth or name to achieve linkage should be seen only as a temporary workaround while legislative change is pursued. Ideally, the BSN should also be permitted for the primary use of data—especially in cases where data flows via the European Health Data Space are also used for

business-to-business (B2B) processes. Such a change would greatly improve data quality, efficiency, and trust across the ecosystem.

Equally important is the way Health-RI is engaging with both patients and industry. From meaningful conversations around public trust and consent, to carefully designed strategies for responsible industry participation, Health-RI is modeling what a balanced, inclusive data ecosystem can look like. In a landscape where trust, transparency, and governance are as crucial as technology, this kind of leadership is indispensable.

At this critical juncture, we believe it is essential that your Ministries recognizes Health-RI not simply as a funded programme, but as national infrastructure—core to delivering the promise of data-driven health and science for public benefit. This means ensuring the initiative has the long-term policy alignment, investment, and institutional mandate to scale, evolve, and integrate into the full spectrum of care, research, and public health services.

In closing, Health-RI has reached a level of maturity and strategic relevance that positions it not only as a national asset, but as a European exemplar. We respectfully urge your Ministers to continue and deepen your support for the initiative, and to rely on Health-RI as a trusted and capable partner in the design of a secure, effective, and citizen-centered health data future.

Yours sincerely,

Dr. Katrin Crameri, MPH (Department Head Digital Transformation, Federal Office of Public Health, Switzerland)
Chair of the International Advisory Board of Health-RI
on behalf of the IAB members:

Neil Postlethwaite (Technical Director - Health Data Research UK, UK)
Serena Scollen (Head of Human Genomics and Translational Data - ELIXIR, Hinxton, UK)
Zisis Kozlakidis (Head Laboratory Support, Biobanking, and Services - IARC/WHO)
Carlo Senore (Senior Expert - Epidemiology, AOU Città della Salute e della Scienza (CdS), Italy)
Zoltán Kaló (Professor of Health Economics at the Center for Health Technology Assessment, Semmelweis University)
Danielle Welter (Principal Data Analyst - Luxembourg National Data Service (LNDS)

Cc: Board of Health-RI

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