



# Business plan Health-RI

Final version

December 8, 2017

# Preface

Dear colleague,

We are pleased to present to you the Health-RI business plan – an ambitious yet realistic plan to assemble all stakeholders and create a sustainable infrastructure that will facilitate world-class personalized medicine & health research in the Netherlands.

The Health-RI business plan has been developed over the past months based on input and discussions with a comprehensive series of stakeholders. The Health-RI conferences held in November 2015 and December 2016, as well as the Health-RI stakeholder meetings in May 2016, June 2017 and October 2017 proved highly productive in providing feedback, direction and commitment that have been crucial for developing this plan for building Health-RI.

To continue in that vein of transparency and inclusivity, this plan is made public and consists of a 15-page summary and the full business plan. We hope that as an important shareholder in the Dutch Life Sciences & Health community you will recognize the valuable benefits of the plan to your own organization, as well as to the wider life-science research community and Dutch society as a whole.

After the Health-RI conference on December 8, we will enter into a process to evolve from the current temporary governance to a permanent governance as described in the plan, including the financial structures. We look forward to meet with you soon to formalize the role of your organization within Health-RI and hope to receive your full commitment like we have had in the earlier stakeholder meetings: only together we can realize and operationalize this important initiative.

On behalf of the Health-RI steering committee,

Gerrit Meijer & Ronald Stolk

Co-chairs Health-RI

Health-RI steering committee:

Jaap Heringa, Alain van Gool, André Dekker, Peter Luijten, Ruben Kok, Ronald Stolk, Gerrit Meijer

# Health-RI – laying the foundations for personalized health in the Netherlands

Good health is one of the most precious things in life. Without it, we are unable to reach our full potential and enjoy life to the full. So staying healthy as much of the time as possible, and if we do fall ill, returning quickly to good health, is important to us all. The prevalence of chronic disease means we are not there yet, but within the next twenty years we will be.

By the year 2040, medicine will be truly predictive, preventive, personalized and participatory – P4 Medicine. The health sector will primarily focus on keeping people healthy rather than treating the sick. Disease will be identified in its early stages, before radical intervention is required, and treatment will be based on our own unique characteristics – right down to our individual DNA. Care will move out of expensive hospital settings into lower cost community and home-based settings. Healthcare will be democratized and personalized, with individuals engaged and empowered to take an active role in looking after their health. Prescriptive healthcare systems will be replaced by learning healthcare systems that learn and improve the delivery of care with every patient treated. As a result, everyone will benefit – individual citizens from healthier lifestyles and disease prevention, healthcare systems and payers from reduced costs, and society from greater productivity and more efficient use of resources.

Will it happen in the Netherlands, and equally importantly, be driven by the Netherlands – a country that is already a world leader in life-science research? Not unless concerted action is taken now to realise a national infrastructure that brings together all stakeholders in the end-to-end process of bringing personalised medicine & health and a learning healthcare system to reality. The disturbing truth is that even in today's world of seamless digital connectivity, research resources remain fragmented, vital data remains locked away in silos, and even when it is accessible, a lack of standardization limits its interoperability and re-use. It is therefore no surprise that the innovation gap between research results and healthcare practice remains alarmingly wide.

Health-RI will take the concerted action that is needed to bridge the innovation gap towards personalised medicine & health in the Netherlands. Health-RI will create a shared national infrastructure and a shared service center that unlocks the data and resources needed for world-class evidence-based health research along the full citizens journey from conception to the end of life. Equipped with the data and tools to develop a better understanding of the transitions between health and disease, algorithms to predict and detect these transitions in individuals, and personalized treatments to reverse them with little or no side effects, the Dutch health research community will be able to realize the personal and societal benefits of P4 Medicine for the good of the nation. The unlocking of data will also create the optimum environment for a learning healthcare system that continuously adapts to people's needs, while the active participation of individual citizens in both the process and the agenda will make sure those needs are fully understood.

Creating a shared infrastructure fit for developing the predictive, preventive, personalized and participatory medicine of the future will require some creative thinking. Ethical, legal and societal issues, for example, will preclude the setting up of centralised and monopolised data repositories. Health-RI therefore embraces approaches that do not rely on centralised data, like the Dutch Techcentre for Life Sciences (DTL) 'Personal Health Train' initiative, which allows researchers to query distributed databases via a secure, authenticated network, only requiring data owners to make their data FAIR (Findable, Accessible, Interoperable and Reusable). Ownership and control of such data could ultimately be extended to individual citizens, so imagine a world in which you control your data and are free to donate it securely to whichever research groups you choose. It's something that cancer patient Dirk Jan van der Pol is already exploring, see 'It's my data' below.

Building on the current strength of public-private partnership research in the Netherlands, Health-RI will bring together the best of the country's expertise and resources for open-science health research, make them accessible to researchers by means of connecting activities and shared services, and act as a collective voice for the sector both nationally and internationally. In doing so, it will lay a strong foundation for creating a democratized, value-based, learning healthcare system for the Netherlands that will empower its citizens to stay healthy and achieve their true health potential.

## It's my data

*When Dirk Jan van der Pol\* was diagnosed with thyroid cancer in 2003, the overwhelming emotion he experienced was one of powerlessness – a feeling that critical decisions in his life were being taken over by the healthcare system. After recovering from his thyroid removal operation, he decided not to let that happen again. He immediately started to collect as much of his personal medical data as he could find. Today he holds around 52 terabytes of that data, including his full genome sequence. Much of it he had to fight for.*

*Within a couple of years of the operation to remove his thyroid, Dirk Jan developed chronic obstructive pulmonary disease (COPD). His doctors put it down to coincidence, but somehow, he felt that it was linked to his cancer. Via patient forums and social media, he has since discovered around 200,000 other people around the world who have had a similar experience – thyroid problems followed within a few years by COPD. His background in healthcare and data science also enabled him to identify at least two genes in his genome that could possibly link the two problems. All circumstantial evidence, of course, but it has been sufficient to attract the attention of the research community to something that could be a real problem. If enough of the other 200,000 patients who Dirk identified were able to grant access to the type of personal data that he held via initiatives like the DTL's Personal Health Train, answering the relevant research questions would be much simpler. It's just one example of how the research infrastructure that Health-RI is committed to creating in the Netherlands could close the loop between patients, the research community, and new innovations in patient care.*

*\* Among his other interests, Dirk Jan van der Pol is an ambassador for the Human Genome Foundation*



# Executive summary business plan



# Health-RI is the solution to today's challenges in the health research environment

## Challenges and issues in the health research environment



**Fragmentation of infrastructures** due to limited willingness to share data/facilities, competition for funding and limited coordination of funding in the past



Infrastructures, contributors and researchers operate in separate worlds. **Integration and professionalization is needed**



The promise of personalized medicine & health is **not delivered** (the **innovation gap**)



There is a **lack of reproducibility of research outcomes** (50% not usable)



Researchers are **rewarded for generating publications**, not for translating science to society



**Return-on-investment** of health research is **insufficient**



With major investments, other countries\* are already setting up similar infrastructures, giving their **researchers better access to research facilities and to relevant data**

## Opportunities and solutions to these challenges



Develop a **top-of-the-bill infrastructure** for health research in the Netherlands supported by a **shared service center**



**Strong collaboration** between infrastructures, contributors, and all relevant stakeholders, including scientists, health professionals and citizens



Acceleration of the development of a **learning healthcare system**



Implement data stewardship based on **FAIR principles** (**F**indable, **A**ccessible, **I**nteroperable, **R**e-usable) and stimulate secure re-use of resources



Change incentives to **reward researchers for sharing**



**Efficient use** of available **funds** via coordination of an investment agenda

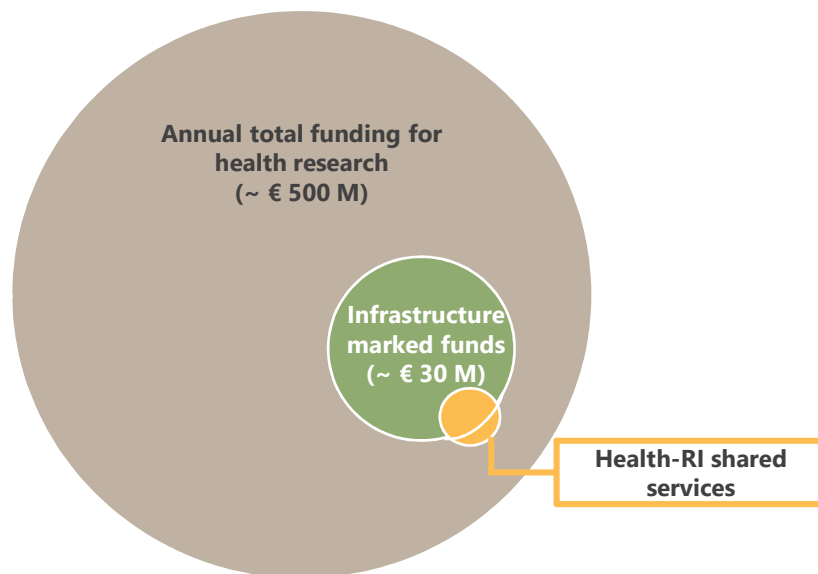


Shared infrastructure to facilitate **access to data** under **inclusive governance**

\*Swiss SPHN (Switzerland), US Precision Medicine Initiative (USA), Genomics England (United Kingdom), Stratified Medicine Scotland (Scotland), Medizininformatik (Germany)

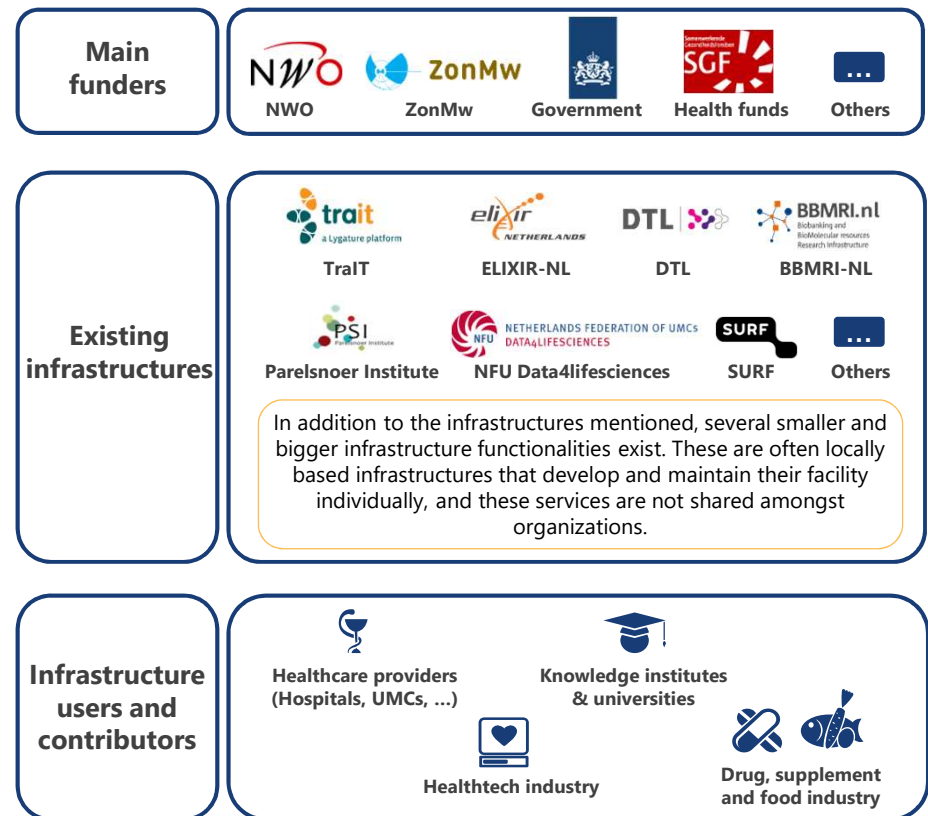
# Health-RI will improve efficiency by connecting infrastructures in the Dutch health research field

## Size of the Dutch Health research environment in Euros



- **Annual total funding** for health research is ~€ 500 million<sup>\*S1,S2,S3</sup>
- Around **€ 30 million** is marked directly for infrastructure
- With a **small part of the total budget**, Health-RI will improve efficiency by organizing *the* national infrastructure
- In addition to the health research budget yearly around **€ 100 million** is spent on registries of health(care) data<sup>S4</sup>

## Selection of players in the Health-RI field (non-exhaustive)



\*The € 500 million is an estimation based on the budgets of funders in the health research environment<sup>S1,S2,S3</sup>



# Health-RI has defined its mission, ambition and strategy, demonstrating how Health-RI will create value for society



## Mission

### Why are we in business?

**Creating value** for society by **facilitating** all steps in **the process of health research**.

As a result, Health-RI will **achieve major societal transformation**, for:

- **Researchers:** enabling them **to perform excellent cross-disciplinary and data-intensive research**
- **Funders:** enabling them to obtain **optimal return-on-investment**
- **Citizens:** who will be more **involved** in high quality research, leading to **faster implementation of personalized health**
- **Others** (e.g. government, care providers, industry, health insurers, etc.): who will be part of **a well organized network for health research and prevention**



## Ambition

### Where do we want to be in 2023?

We will have realized **a state-of-the-art infrastructure** for data, samples and images that will be key to facilitating **excellent health research** and **sustainably bridging the health innovation gap**.



## Strategy

### How do we get there?

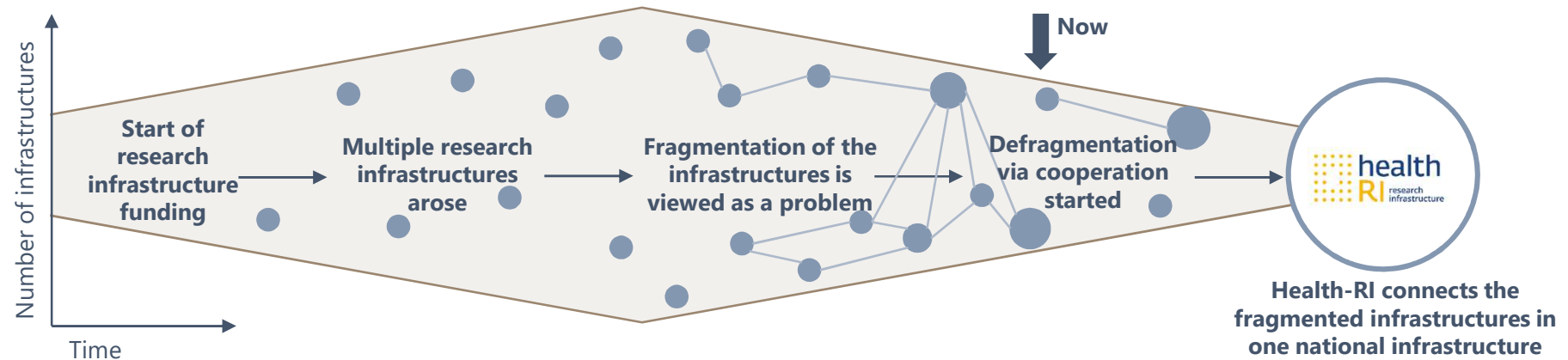
- By **all stakeholders** in the ecosystem **working together at strategic, tactical and operational levels**
- By functioning as a shared service center that provides a single **platform** for delivering an **integrated suite** of functionalities, assets and support **to researchers**, leading to compliance-by-design
- By delivering a **balanced financial model** with **transparent and logical prioritization of resources** that are made **collectively available**
- To this end, Health-RI will work with **jointly determined standards, conditions and 'rules of engagement'**

### How are we going to achieve this?

- Establish an **effective and efficient** organization
- **Defragment** infrastructures
- **Cooperate** with all stakeholders
- Adopt an **integral funding system**
- Make a **long-term commitment**



# Connecting existing and new infrastructures is an essential step towards a national infrastructure



## Selection of current infrastructures (non-exhaustive)



TraIT enables integration and querying of information across the four major domains of translational research: clinical, imaging, biobanking and experimental (any-omics)<sup>S5</sup>



BBMRI-NL makes biomaterials, images and data from (longitudinal) research retrievable, accessible and exchangeable for research on the prevention and treatment of diseases<sup>S8</sup>



ELIXIR-NL provides the FAIR-based interoperability platform for tools, data resources and cloud services. It develops and implements virtual research environments for data stewardship and distributed analytics<sup>S6</sup>



The Parelsnoer Institute offers researchers an infrastructure and standard procedures for the establishment, expansion and optimization of clinical biobanks for scientific research<sup>S9</sup>



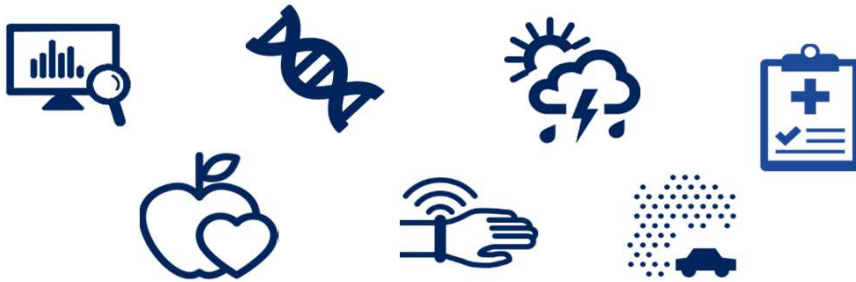
DTL has established a network of expert groups that offer their high-end technologies and the associated expertise and infrastructure to researchers who do not have access to such facilities at their home institute<sup>S7</sup>



Data4lifescience (D4LS) is connecting the data infrastructure for biomedical research of the eight University Medical Centers<sup>S10</sup>

# Health-RI facilitates health innovation along the citizens' journey

## Collected personal data



**Health is one of the most important quality aspects along the entire timespan of our lives.** Health-RI facilitates research that leads to innovations that allow us to stay healthy as much of the time as possible, and if we do fall ill, to regain health as much and as quickly as possible. With this live long scope, Health-RI interacts with the whole range of health related topics, like *environment & health, healthy ageing, primary healthcare, prevention, food & health, mental health, healthy youth, personalized medicine, and others.*

Increasingly, personal data are being collected that are relevant for the understanding of our personal health. **Citizens collect more and more of their own data and a vast array of data is gathered in the health system.** Having personal data on these health aspects available for research is crucial to reach this goal of better health outcomes. As a consequence, Health-RI interacts with health related initiatives and concepts like *a learning healthcare system, value based healthcare, closing the innovation gap, big data, e-health, quantified self, and self management.*

In a health sector that broadens at spectacular speed to allow inclusion of **a wide variety of aspects that influence our personal health**, from biology to socio-economic aspects, to how our food and lifestyle interact, there is a **huge potential to better learn how we can self-manage our personal vitality, functioning and health.** Health-RI will offer the platform that allows citizens and all other stakeholders in the health research domain to securely combine and interpret such variable data.

Health-RI thus supports a broad variety of disciplines and sources of information to **allow for a democratic and accessible science and innovation environment** in which citizens can participate extensively. The infrastructure offers stakeholders specialized in certain aspects or phase of our lifespan, from early conception to ageing, to **build on each other's expertise and information.**

Health-RI thus strongly supports the health sector to **offer high quality innovative services along the 'citizen's journey'**, with great attention to prevention and early detection of health-threats, and with increased handles to treat disease at the personal level: **personalized medicine and health.**

# Health-RI will build on existing infrastructures and attract new partners to establish *the* Dutch health research infrastructure

Health-RI consolidates the activities of multiple Dutch ESFRI and e-infrastructure nodes by their landing into the Health-RI platform

Health-RI is highlighted as *the* future Dutch research infrastructure for health research by other parties

## Health-RI ecosystem

Non-exhaustive (endorsed by >70 stakeholders)



## Network Health-RI

Non-exhaustive and to be extended ("inclusive network")



## Health-RI organization

These initiatives will launch and converge into the Health-RI organization



Highlighted Health-RI as a **key player** in various agenda programs<sup>S11</sup>



Mentioned Health-RI as a **necessary data infrastructure to achieve personalized medicine**<sup>S12</sup>



Listed Health-RI as a one of the **"must have large-scale research facilities"**<sup>S13</sup>



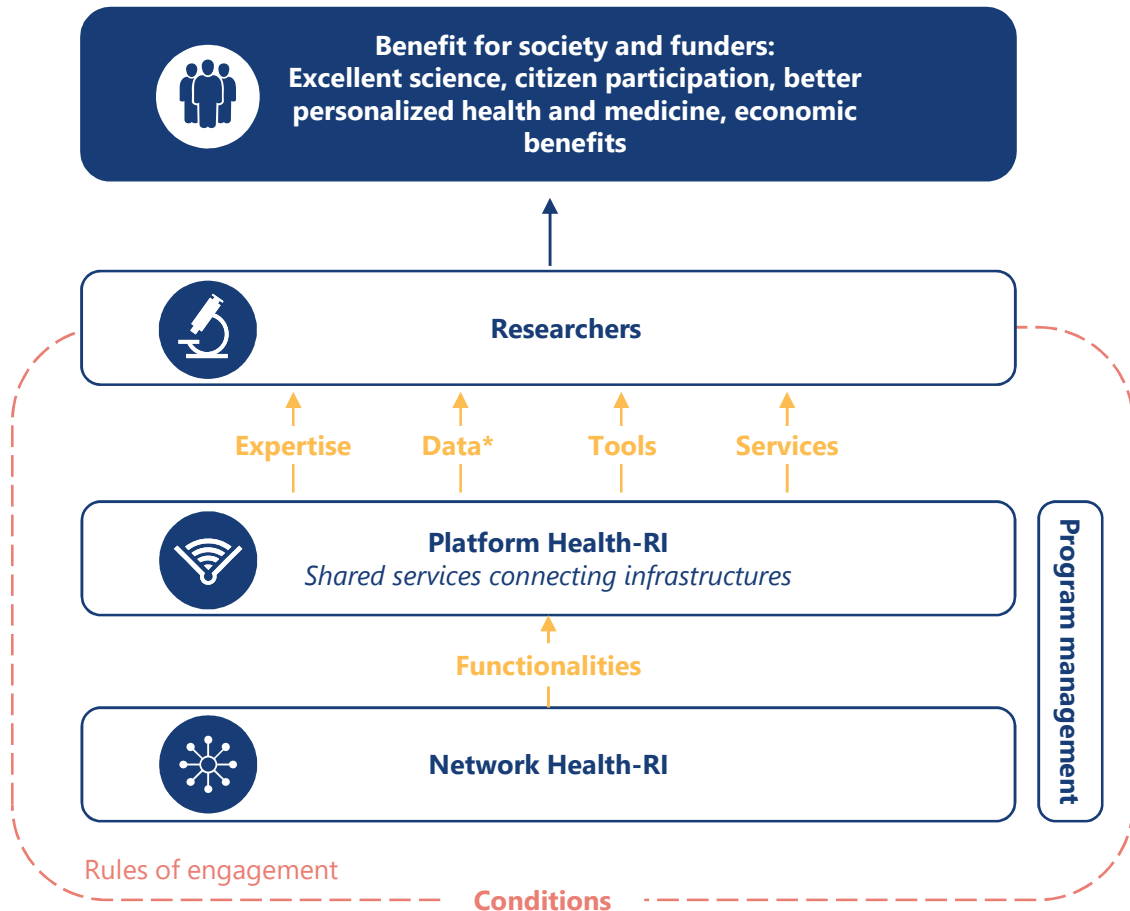
Named Health-RI "an **essential (data) infrastructure for health research and personalized medicine**"<sup>S14</sup>



Listed Health-RI next to personalized medicine initiatives abroad<sup>S15</sup>

\*Swiss SPHN (Switzerland), Precision Medicine Initiative (USA), Genomics England (United Kingdom), Medizininformatik (Germany)

# The Health-RI platform will function as the interface between the Health-RI network and researchers



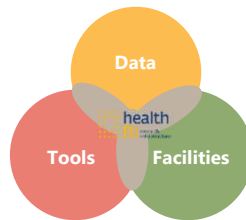
**Health-RI will offer functionalities to researchers by means of connecting activities and shared services. The Platform Health-RI will be the interface between the network and its users, the researchers.**

- On an **operational level**, contributors are enabled to provide local functionalities via the platform, conveniently accessible to researchers through a one-stop-shop. Health-RI will operationalize this platform and provide support in the use of its functionalities. Furthermore, Health-RI will provide **shared services** to researchers and contributors directly at a level not offered by individual stakeholders (further explanation on next page).
- We distinguish two types of contributor: '**data contributors**' offering data, samples, images etc. and '**infrastructure contributors**' offering tools, facilities and services.
- In addition to the operational activities of Health-RI, Health-RI will act as a collective voice and perform activities on **tactical** and **strategic level** to achieve its ambition to transform the system and eliminate commonly experienced bottlenecks in the research process (further explanation on next page).

\* Data refers to data, samples and images

# Health-RI will provide shared services and acts as the collective voice

## Provide shared services via the platform



- Health-RI will provide shared services that contributors cannot provide individually, but that are nevertheless essential to connecting different resources (data, tools, services) to users, reusing data, and efficiently performing excellent cross-disciplinary and data-intensive research.
- Some examples of Health-RI activities:
  - *Operational:*
    - Operationalize a platform that provides an overview of all available content (data, samples, images, tools, facilities, etc.) and connect contributors and users to provide access
    - Be the landing zone of Dutch health research infrastructure nodes such as BBMRI-NL, EATRIS-NL, and the health parts of ELIXIR-NL, NL-Biolmaging and others
    - Provide shared services directly to users (from existing initiatives BBMRI-NL, TraIT, ELIXIR-NL and EATRIS-NL)
  - *Tactical:*
    - Provide education and training on common themes - e.g. FAIR\* and ELSI\*\*

## Act as a collective voice on the research infrastructure

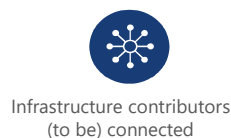
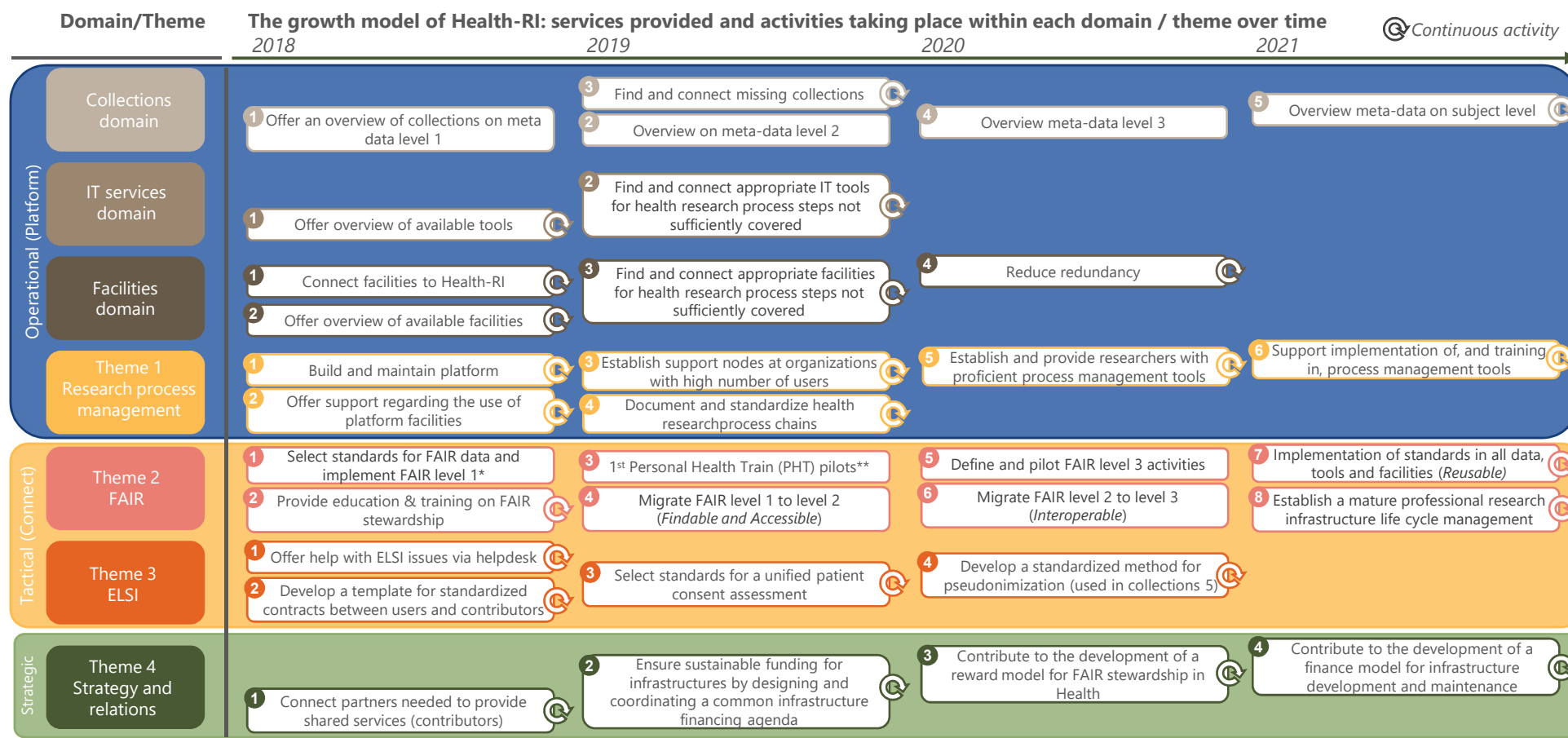


- On behalf of all stakeholders, Health-RI will represent the health research ecosystem on topics where a collective voice is needed to achieve changes that support the research process. This requires bringing the different stakeholders together. Stakeholders will be represented in the Health-RI governance.
- Health-RI will provide this collective voice on both tactical and strategic level. Examples of Health-RI activities include:
  - *Tactical:*
    - Drive and connect to the development of international data standards
  - *Strategic:*
    - Set a collective infrastructure financing agenda together with stakeholders and influence them to commit to the agenda
    - Align the Health-RI strategy with developments in healthcare infrastructures, for example, electronic patient files and MedMij, to create the possibility of connecting data that, for example, supports citizens to live a healthy life

\*FAIR: Findable, Accessible, Interoperable, Reusable

\*\*ELSI: Ethical, Legal, Social, Impact

# The Health-RI infrastructure will grow over time along seven domains/themes



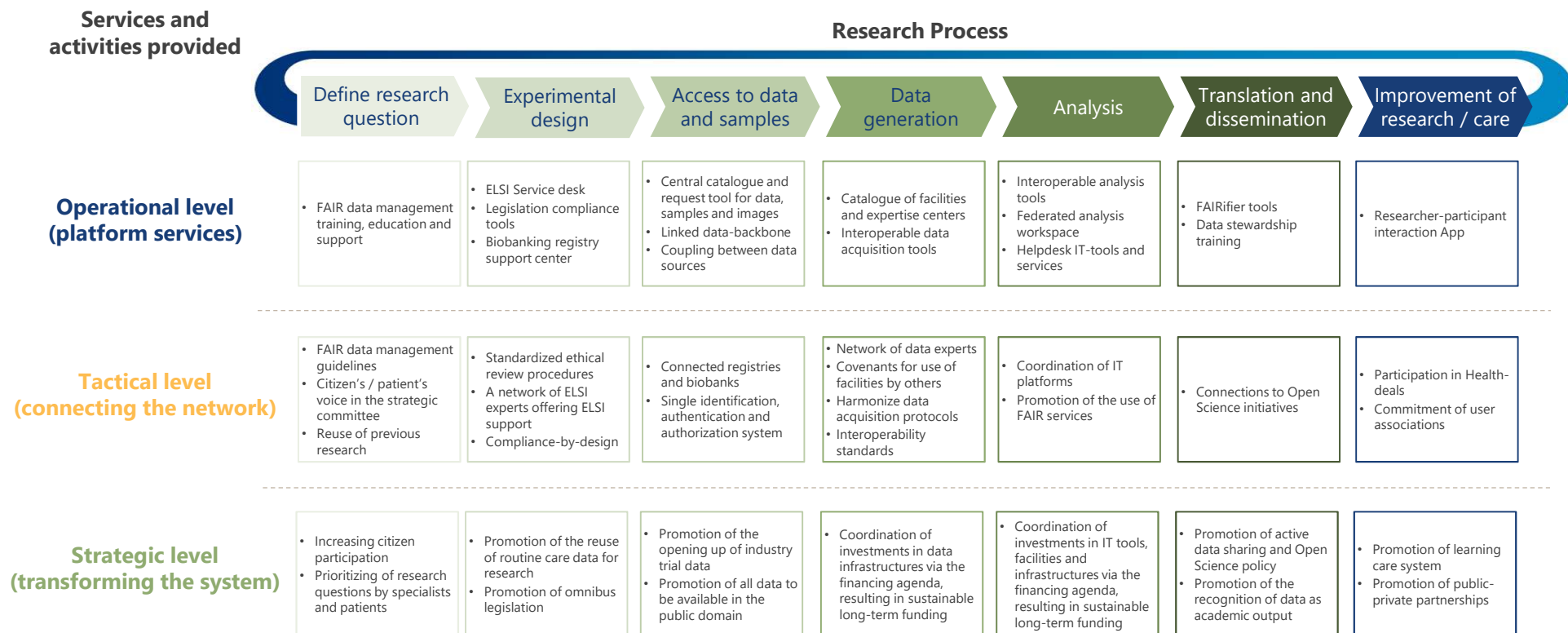
Connection of partners is not projected over time and overview of partners is not exhaustive

\* FAIR level 1 is the current TraIT office suite level, \*\* Pilot FAIR level 2: <https://www.dtl.nl/fair-data/personal-health-train/>



# Health-RI services and activities will lead to an infrastructure that facilitates the entire research process

## Health-RI activities at different steps in the research process (non-exhaustive)



The Health-RI platform will offer researchers solutions-on-demand for each step of the research process. By simultaneously operating on the tactical and strategic level, Health-RI will connect the needs of researchers and other stakeholders (funders, society, etc.) transforming the total health research system.



# Health-RI has clear benefits for all stakeholders in the health and medicine research field



## Health researchers and research organizations

Researchers will be enabled **to perform excellent research** via:

- Better access and easy use of IT tools and facilities
- User support (for tools, ELSI\*, FAIR\*\* issues, etc.)
- Better access to (high-quality) FAIR data through standardization and harmonization of data, tools and processes



## Citizens and patients

**Better healthcare quality and access to personalized health** will be within reach for citizens and patients, because Health-RI:

- Offers the research scale needed to drive the understanding of personalized indicators of health and disease
- Connects stakeholders to accelerate translation of knowledge into (preventive) treatments
- Gives patients and citizens a voice to ensure that the infrastructure that is built addresses society's concerns



## Funders

Funders will obtain **optimal return-on-investment**, because Health-RI will:

- Enable and stimulate reuse, translation and dissemination of research data and outcomes
- Help to ensure the efficient use of available infrastructure funds by coordinating the financing agenda with all stakeholders involved
- Facilitate adoption of standards by researchers, leading to better reproducibility (and quality) of research and compliance-by-design



## Government and society

The Netherlands will **consolidate its leading role in the global healthcare field** because Health-RI will:

- Act as a 'launch pad' for excellent health research
- Facilitate translation of research into practice

For the government and society, this will lead to increased return-on-investment, healthier citizens, and a significant increase in the economic contribution of the Dutch health research field



## Private parties

Innovative companies will be able **to accelerate development of solutions in (personalized) medicine and health**, because Health-RI will:

- Provide a platform to connect to research data and researchers
- Empower researchers to perform research that meets standards and regulations

Health insurers will be able **to service their clients better**, because Health-RI:

- Supports research targeting the development of personalized healthcare and improvement of healthcare quality



## Contributors

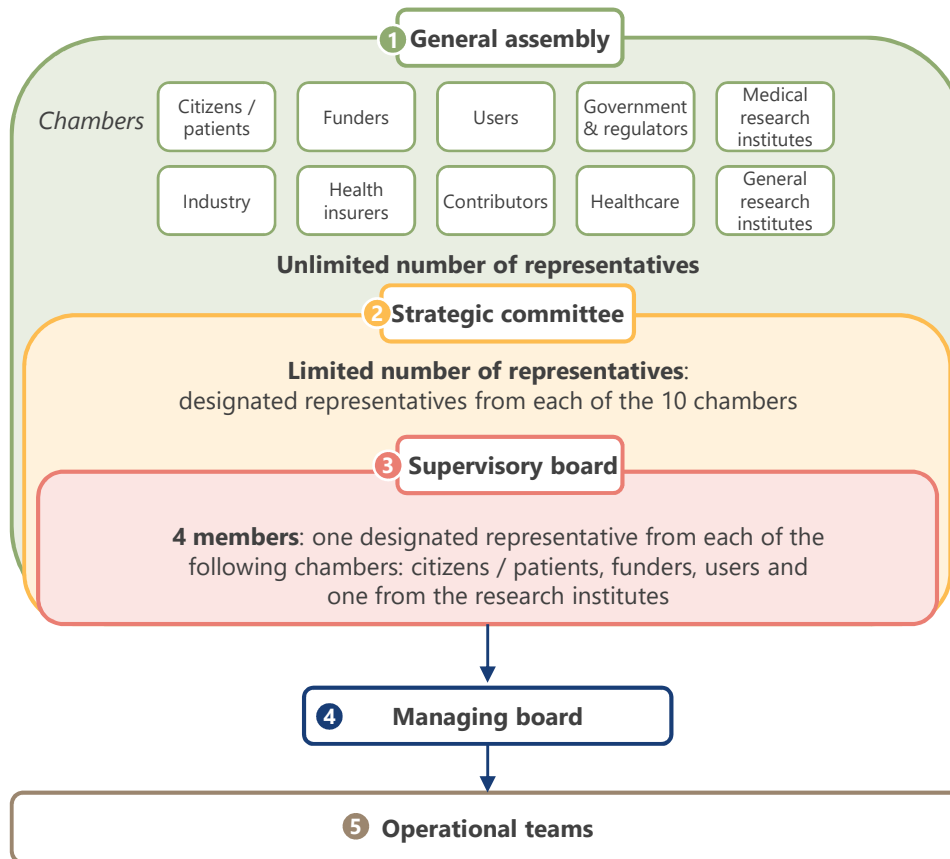
Infrastructure contributors will become **more effective organizations** because Health-RI will:

- Increase the visibility of their offering and its use by researchers
- Commit to design a structural financing agenda for infrastructures

Data contributors will be able to generate **more knowledge from their data** because Health-RI will enable standardization and interoperability of content, thereby increasing its suitability for use by other researchers

# The Health-RI governance is inclusive for all stakeholders

The governance structure of the Health-RI organization is efficient, effective and supported by its stakeholders



**1** All stakeholders can join **the general assembly**, which is informed at least once a year by the managing board. All ten chambers of stakeholders will be present in the general assembly. Each chamber appoints their representative in the strategic committee.

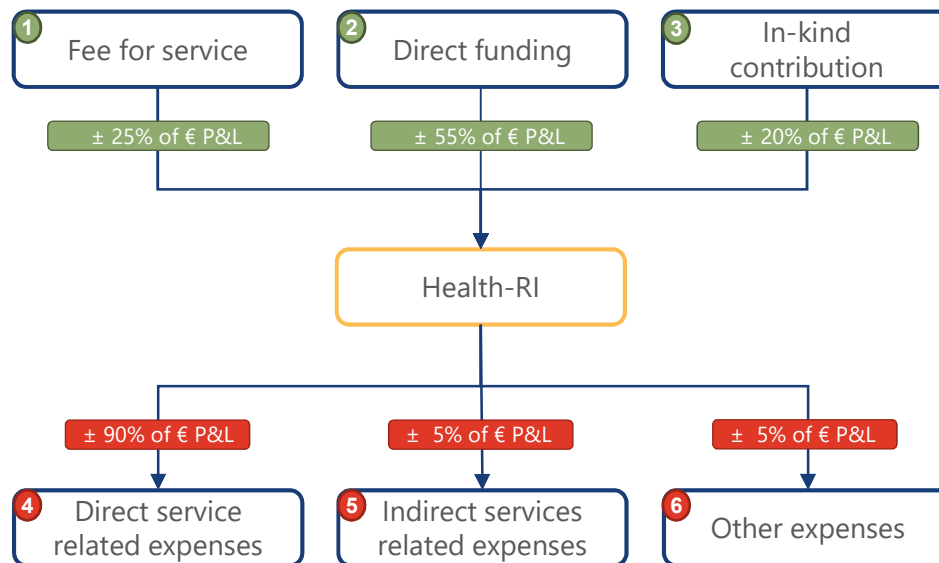
**2** The **strategic committee** will consist of designated representatives from each of the ten chambers. The strategic committee will set the strategic agenda and infrastructure agenda. Furthermore, they will advise on the five members that sit on the supervisory board.

**3** The **supervisory board** will consist of four designated individuals chosen from the representatives of the chambers of citizens / patients, funders, users, medical research institutes and general research institutes. The supervisory board will supervise the managing board on the execution of the strategic and infrastructure financing agenda, and will appoint and discharge the members of the managing board.

**4** The Health-RI organization will consist of the **managing board** and the **operational teams**. They will be responsible for the daily operations of Health-RI. The managing board will consist of a Chief Data Science, Chief Health & Medicine and a Chief Executive Officer. They will connect all disciplines within Health-RI to ensure effective execution. The structure of the operational teams will be flexible, because they have to execute a strategic agenda that will change over time.

# Three income sources for the Health-RI organization ensure a sustainable and effective execution of the strategy

## Income and expenses of the Health-RI organization



The Health-RI organization is expected to have an annual turnover (P&L) of around € 20-25 million in 2022.

We differentiate three income sources:

- 1 **Fee for service** is income generated by users paying for services offered on or via the platform.
- 2 **Direct funding** by the government, knowledge institutes or private parties like health funds. Sustainable income is needed for Health-RI to connect and represent stakeholders in the Health-RI ecosystem and to offer certain shared services.
- 3 **In-kind contribution** (FTE) from data contributors, *e.g.* contact points within each UMC and university to be able to deliver our services locally.

We differentiate three expenses categories:

- 4 **Direct services related expenses** that are connected to the offering of Health-RI services and the related activities.
- 5 **Indirect services related expenses** that are not directly related to the provided services and cover strategic and tactical activities.
- 6 **Other expenses** that include participation fees to connect with European hubs and unforeseen expenses.

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# List of definitions and abbreviations used in summary

## Definitions used in the business plan

Term	Definition	Term	Definition
Data contributor	Partner organizations that can provide researchers with data, samples or images for research. They provide this content via the platform	Personalized medicine & health research	Research related to gaining a better understanding of human health and disease and to developing or improving the prevention of disease or the treatment of disease. This ranges from fundamental research to research into societal practice covering all phases of human life, and can be related to healthcare, drug development, technological advances, food and lifestyle research, social research, etc.
Health gap	The gap between the actual health of an individual and their health-potential	Partner	Organization connected to Health-RI, either via the Health-RI network or the Health-RI ecosystem
Health-RI ecosystem	All stakeholders in the field of medicine & health	Research environment	The surrounding (involved parties, total euro's, etc.) in which health research is performed
Health-RI network	The community of partners that execute infrastructure tasks coordinated by Health-RI and funded from the collective Dutch health research infrastructure budget	Users	Individual researchers, research groups and research organizations who make use of services on or via the platform
Infrastructure contributor	Partner organizations that can provide researchers with expertise, tools and other services to perform research. They provide these services via the platform		
Innovation gap	The current lack of translation of research results into healthcare practice		
Learning healthcare system	A system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.		