Driving value for patients and the Belgian healthcare system

Pact for strategic investments
Report of the Health Working Group[1]

September 2018

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[1] For an overview of the members of the Health Working Group, see Annex 1.

Table of Contents

EXECUTIVE SUMMARY

Overall, the Belgian healthcare system scores highly: according to the Health System Performance Assessment[2], a large majority (78%) of the Belgian population reported that they were in good health, above the average of the EU15. The Belgian system has plenty of capacity, a broad range of services on offer, accessible services and strong funding. The healthcare sector is also a key plank of the Belgian economy, employing around 14% of the workforce, and the pharmaceutical industry is strongly export-focused, thereby contributing more than EUR 7 billion to the national trade balance. Nevertheless, the system is now faced with a massive challenge: the effects of demographic ageing and technological progress will exert growing pressure on our social fabric in the next quarter-century. The growing occurrence of complex, chronic conditions (multiple morbidity) that will need to be treated among an ever older population will only make that challenge greater. Between 2020 and 2030, the percentage of over-65s in the population will grow from 19% to 23%; by 2050, it is expected to be as high as 27%. This will exert further pressure on healthcare costs on the one hand and on people's capacity to pay on the other. To keep costs in check and to safeguard quality, the system is going to have to become more outcomes-focused and will have to make use of modern technologies and innovations to improve the population's wellbeing and to help ratchet up participation in the workforce and productivity. To achieve this, we are going to need the courage to think radically about adaptations to the structure of healthcare provision.

In making the requisite investments in major healthcare innovations, Belgium boasts several trendsetting companies and excellent, world-class centres of research, in such domains as oncology, vaccination and gene and cell therapies. The country's many biopharma clusters are a key driver of the Belgian economy and competitiveness, providing work to over 35,000 people and representing 11% of the country's exports. However, continuing investment is called for in ecosystem services, research and innovation if the country is to retain this robust competitive position against rival life-science clusters elsewhere.

A key trend both in healthcare and the biopharma sector is digitisation. As in other industries, digitisation also offers healthcare new opportunities to boost system effectiveness and efficiency, but currently Belgium is lagging behind in uptake. For instance, few Belgian doctors say they feel involved in digital healthcare, and little use is being made of remote healthcare tools, such as remote diagnosis. Nor is the country's data infrastructure as a whole integrated yet, which means that not much data is being shared between institutions.

Investment priorities

Based on the trends identified above, the Strategic Committee discerns three key areas to focus on in the next few years: a) Developing an ambitious system for data integration; b) Reorganising healthcare by introducing the right new technologies; and c) Fostering innovation by continuing to expand ecosystems. Combined, these projects will be good for approximately EUR 7.5 to 9.5 billion for the years up to 2030, about 30% of which will come from private investment.

The individual projects falling under these umbrellas will give rise to a positive feedback loop. Patients, healthcare providers and companies alike will note the many benefits of having an integrated data system to improve service provision and to make research more efficient and of higher quality. Moreover, a healthy cross-fertilisation will arise between these healthcare innovations and the knowledge centres in industry. This will enable Belgium not only to meet the challenge of the changes which the sector is facing but indeed to excel as an innovator and a trailblazer in the domains selected for focus.

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[2] KCE report 259 (2016). Performance of the Belgian Health System — Report 2015. A Health System Performance Assessment (HSPA) is a process that allows the healthcare system to be assessed holistically, based on measurable indicators.

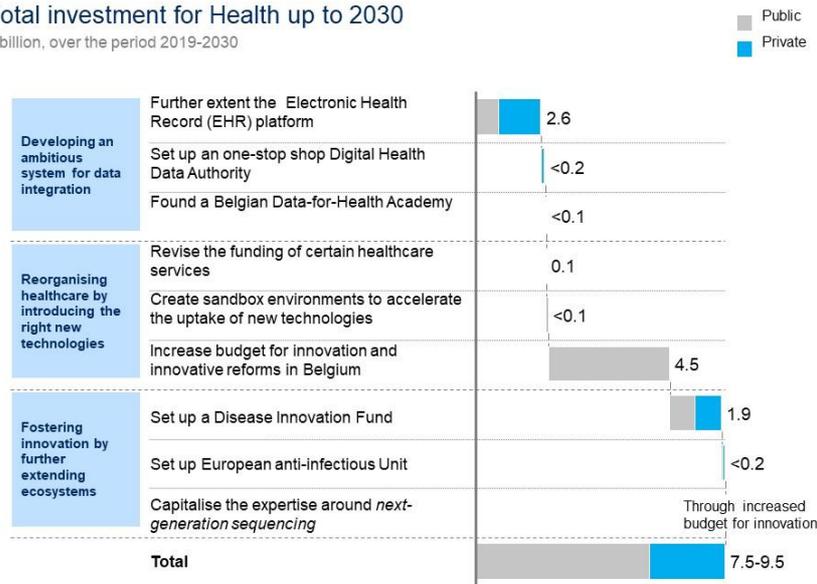**Total investment for Health up to 2030**
€ billion, over the period 2019-2030

Legend: Public (grey), Private (blue)

Category	Item	Value
Developing an ambitious system for data integration	Further extent the Electronic Health Record (EHR) platform	2.6
	Set up an one-stop shop Digital Health Data Authority	<0.2
	Found a Belgian Data-for-Health Academy	<0.1
Reorganising healthcare by introducing the right new technologies	Revise the funding of certain healthcare services	0.1
	Create sandbox environments to accelerate the uptake of new technologies	<0.1
	Increase budget for innovation and innovative reforms in Belgium	4.5
Fostering innovation by further extending ecosystems	Set up a Disease Innovation Fund	1.9
	Set up European anti-infectious Unit	<0.2
	Capitalise the expertise around *next-generation sequencing*	Through increased budget for innovation
	Total	7.5-9.5

Source: National Pact for Strategic Investments.

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Figure 1: The health working group's "investment asks"

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1) Developing an ambitious system for data integration

Given priorities B and C, there is a requirement for better availability and integration of outcome data. As things stand, most Belgian hospitals and research centres have proprietary data systems and platforms, yet there is little exchange or collaboration between these institutions. This is causing Belgium to lose out on great potential in synergies and competitiveness.

To shape an integrated Belgian data system, several interventions will be required. The Committee proposes three specific ideas:

- **Investment priority #1:** Further extend the *Electronic Health Record (EHR) platform*, being developed by Health Minister Maggie De Block, to encompass all patient data in structured fashion, including the integration of other data, even extra-mural data (e.g. existing registers, biobanks, academic research, etc.). This will require additional hardware provision (e.g. data storage capacity, servers) and analytics applications (e.g. suitable software), and capacity.

- **Investment priority #2:** Set up a *one-stop shop Digital Health Data Authority* as a watchdog for privacy and proper use of patient data as per GDPR legislation (see above), by means of fitting governance and a well-written mandate. This body will be the only and the central access point for data, and will operate under a specific access model. Denmark's Health Data Authority, *Sundhedsdata Styrelsen*, can serve as a model for the new Belgian authority.

- **Investment priority #3:** Found a Belgian *Data-for-Health Academy* to serve as a *centre of expertise*. This academy should be one that brings together data and healthcare experts to facilitate optimum use of the available data, to steer the system, and to maintain and extend it. This way, the academy should also be able to bundle knowledge and expertise, allow for cross-fertilisation and even to provide training courses.

To enable these projects, the Committee estimates that approximately EUR 2.6 billion in investment will be needed. More than 90% of that sum should be allocated to a beefed-up Electronic Health Record (EHR) budget (which would thus de-facto be tripled). Most of the remaining few per cent would be needed for the setting-up and servicing of the one-stop shop.

These initiatives ought to have a large-scale impact on the Belgian economy in practice. As well as making the state of Belgian healthcare more transparent to all and enabling the system to have clear healthcare targets to work to, this will also boost companies' competitiveness and allow for better, more up-to-date

applications for the patient. These improved healthcare services would, for example, be able to yield an estimated EUR 330 million annually in productivity gains in the treatment of chronically ill patients alone. In addition, research centres' competitiveness will be boosted, as they will have readier access to more data and will be able more rapidly to trawl for and recruit clinical trial participants. Hospitals will be able to work together more easily on rare disease care, and the transparent, accessible data will allow for more competition between healthcare institutions, since patients will be in a position to make informed choices.

2) Reorganising healthcare by introducing the right new technologies
Healthcare must be reorganised such as to foster quality, efficient healthcare provision. To achieve this kind of outcome-focused system, a reorganisation of services is required, with features such as more out-of-hospital care — which will be enabled by new technologies. For the introduction of these new technologies, speeded-up testing and evaluation is called for before they are launched in the system, beginning with remote healthcare apps and wearable tech, which have shown promising results so far. For this migration to a more outcome-focused system, we at the Committee make three specific proposals:

- **Investment priority #4:** The funding of certain healthcare services should be revised to allow for new and more efficient technologies in Belgian healthcare. Moreover, the savings so gained should be used to create co-ordinating roles in the healthcare system to act as change agents to accomplish the rest of the transition. For instance, patient hospitalisations can be shortened by bringing the lists of daily admissions up to date, thereby providing useful financial stimuli to use new technologies that enable a shortened hospital stay.

- **Investment priority #5:** Create sandbox environments to accelerate the uptake of new technologies in healthcare, both by putting in place speeded-up procedures for certain technologies and by setting up test environments to which an adapted legislative framework, innovative reimbursement schemes and clear KPIs apply. The ambition here ought to be to make Belgium Europe's "access sandbox", where innovative models of access to healthcare allow relatively small-scale testing of new technologies in a protected environment.

- **Investment priority #6:** Allow health insurers more budgetary leeway to develop innovations and innovative reforms in Belgium. If Belgian patients are given more access to valuable innovations, this will enable, in addition to improved health, more and better data collation and innovation. Various reforms by government will also accompany the temporary, conditional investments in innovation, transition management and institutions. This budgetary increase is in line with the investment trends in healthcare in neighbouring countries.

The estimated investments required to achieve these improvements are forecast at around EUR 4 to 5 billion.

The most significant direct impact will, of course, be the savings achieved for society as they have fewer healthcare costs to bear. For instance, considerable savings could arise from shortened hospitalisation periods, based on the better use of already-existing technologies. Thanks to productivity gains and the use of better technologies, Belgian healthcare providers will be able to offer an even higher level of service for affordable prices. The introduction of new, digital technologies will also allow Belgium to profile itself as *Europe's access sandbox*, allowing Belgian patients more rapid access to medical innovations.

3) Fostering innovation by further extending ecosystems
In several therapeutic domains — such as oncology, cell and gene therapies, and vaccination — Belgium is an absolute world beater in research and development. However, currently the opportunities to promote this kind of research are too fragmentary and there is a lack of focus on investing in knowledge centres. What is more, there is a worldwide tendency to cluster research activities strongly to build dense ecosystems which more readily attract talent, funding and fresh ideas and which provide a more nourishing climate. Consequently, the Strategic Committee urges that Belgium make every effort to set up these centres of excellence to position the country as the world number one. To do so, the Committee proposes three ideas:

- **Investment priority #7:** Set up a *Disease Innovation Fund*, which should focus on Belgium's life-sciences ecosystem and should largely invest in start-ups and SMEs working on rare diseases, cell and gene therapies, increasingly prevalent diseases and personalised medicine. More specifically, the Fund ought to concentrate on connecting research with healthcare. Apart from this fund, a *one-stop shop* should also be set up under the purview of the Belgian Medicines Agency, FAGG, allowing start-ups easy access to guidance and information on issues such as legislation and regulation.

- **Investment priority #8:** Set up a *European Anti-Infectives Unit*: public-private partnership (PPP) should enable the funding of a specialist infrastructure in which phase 1 clinical trials, such as human challenge studies, can be carried out in ideal conditions. The expertise that there already is in Belgium with regard to vaccines and tropical medicine would thus be reinforced, and it would allow Belgium to make more of a splash as Europe's "clinical trials hotspot", attracting many pharmaceuticals, medical and biotech firms. The expertise accrued can then be applied directly and scaled up in the Mobile Global Health Lab, which specialises in rapid-application solutions to epidemics as they break out. The experts who comprise it could be lured to Belgium from abroad to add to the country's talent pool. Strains of identified viruses could be kept in a virus bank in Belgium and subjected to further research.

- **Investment priority #9:** Capitalise the expertise around *next-generation sequencing* by providing adequate means for the requisite investments in data capacity, innovative pilot schemes, artificial intelligence for analysis of the data, and recoup the costs of tests which will enable predictive, personalised medicine.

The total investment in these projects would comprise approximately EUR 2 billion, of which about EUR 1.9 billion would be for the Disease Innovation Fund. The rest of the budget covers the investments to be made for the Mobile Global Health Lab and Anti-Infectives Unit, and for the genomics revolution that is just around the corner.

With these investments made, Belgium would be able to maintain or gain a position as a world leader in several domains. The fostering of investment and keeping the focus on several ecosystems will not only further encourage research activity and export potential but will also attract more international talent and companies to Belgium. Setting up new innovative centres would only serve to bolster that inflow of capital and talent. Moreover, studies have shown that the return on investment (ROI) of R&D investments for the wider economy is between 10% and 30%.

The individual projects falling under these umbrellas will give rise to a positive feedback loop. Patients, healthcare providers and companies alike will note the many benefits of having an integrated data system to improve service provision and to make research more efficient and of higher quality. Moreover, a healthy cross-fertilisation will arise between these healthcare innovations and the knowledge centres in industry. This will enable Belgium not only to meet the challenge of the changes which the sector is facing but indeed to excel as an innovator and a trailblazer in the domains selected for focus.
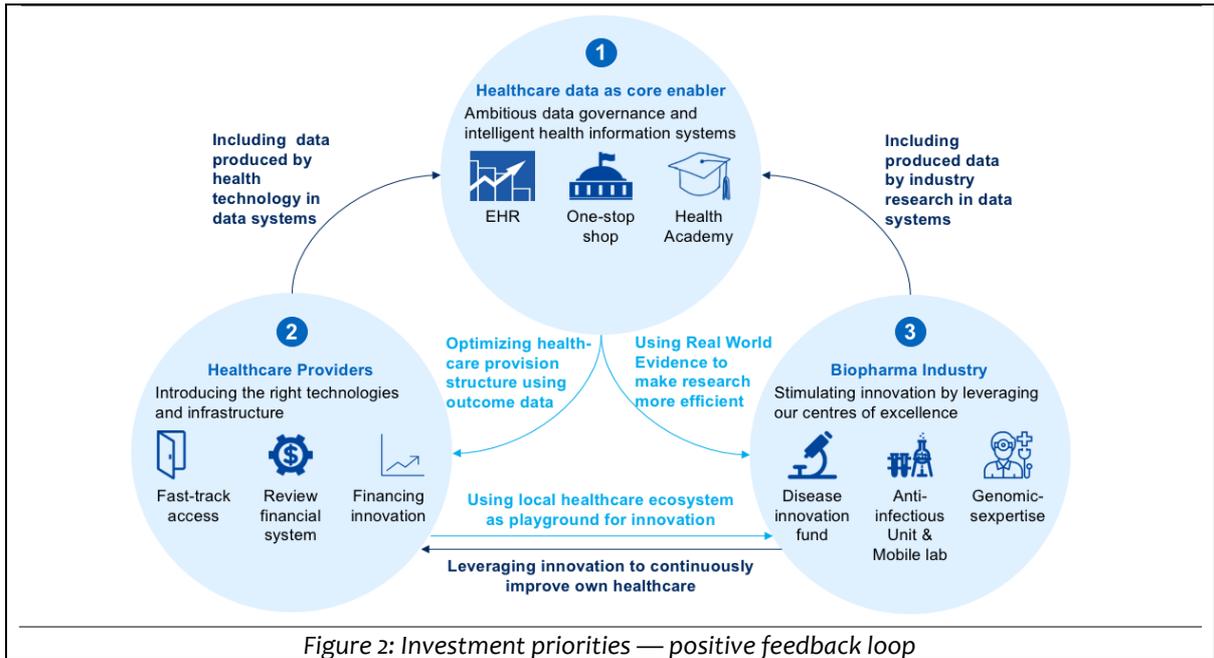
Figure 2: Investment priorities — positive feedback loop

Today, health-related activities in Belgium provide a remarkable contribution to the welfare of citizens and to the country's economic potential. This outcome relies on two strong pillars: an excellent and broadly accessible healthcare system on the one hand, and excellent biopharma and medtech clusters on the other hand.

An efficient, high-quality and widely accessible healthcare system

Health and healthcare are key for people's wellbeing. The Belgian system is highly appreciated by citizens. According to the latest Health System Performance Assessment[3], Belgium is doing relatively well: a large majority (78%) of the Belgian population reports being in good health, which is a better result than the EU15 average. The Belgian population also reports satisfactory experiences with the health system, especially in ambulatory care. This positive perception is mainly driven by excellent accessibility and the range and reach of the services provided. Overall, the efficiency of the healthcare system is considered high, with lower healthcare spending than in other Western European countries on average, although the variability in quality and outcomes of healthcare services remains large[4] and the system's input-oriented funding system slows innovations that may help to improve patient outcomes.

The economic impact of the healthcare system is twofold:
- An effective healthcare system contributes to improving the health status of the population, thus providing a productive labour force in all sectors of the economy. In this respect, it is worth noting that the numbers claiming disability insurance have been growing steadily for twenty years. At the end of 2016, 390,000 people were recorded as disabled workers, representing 5% of the Belgian population in the 15–64 age bracket. Admittedly, socio-economic, education and cultural characteristics also play a large role in people's health status.
- In a more direct way, employment in healthcare or long-term care activities is a growing trend. In 2016, it accounted for 14% of all employment in Belgium. This growth is set to continue, in view of the population ageing and the resultant growing care needs.

A world-renowned biopharma & medtech cluster

Besides a good healthcare system, Belgium has a strong, diversified and internationally oriented biopharma & medtech cluster. It is spread across different parts of the country, with a mix of big players such as Janssen, GSK and IMEC, established biotech firms such as Celyad and Bone Therapeutics, and small health data start-ups such as Bloom!, Ontoforce and many more, who work closely together with our top-flight healthcare providers and academic centres.

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[3] KCE report 259 (2016). Performance of the Belgian Health System – Report 2015.
Health System Performance Assessment (HSPA) is a process that allows the health system to be assessed holistically based on measurable indicators.
[4] State of Health in the EU, Belgium Country Health Profile 2017, European Commission and OECD.
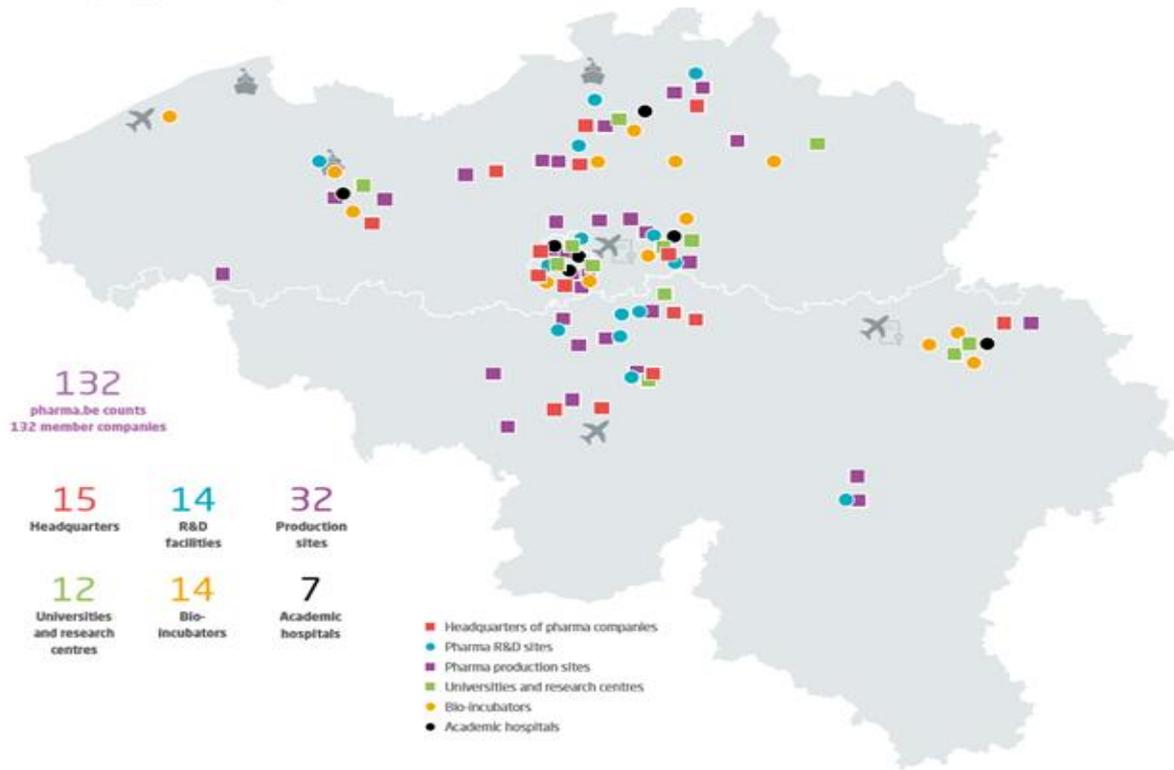
Figure 3: Belgium's biopharmaceutical and medical ecosystem
Source: pharma.be

Over the last 40 years, the biopharma & medtech sector has developed into a major sector of the Belgian economy and become a biopharma & medtech hub within Europe, with a wide range of activities covering the whole value chain: from basic research through clinical trials to production, distribution and marketing. In doing so, it benefits from the presence of leading universities, research centres and academic hospitals, creating a favourable climate for innovation. In particular, the regulatory framework for clinical trials offers a fast approval procedure, based on harmonised assessment methods and consistent evaluation of new applications. More generally, the sector also benefits from Belgium's central location in Europe and good transport connections with a high-income hinterland, good-quality human capital and openness to trade, ideas and (high-skilled) personnel.

Building on those assets, the direct economic footprint of the biopharma & medtech sector is significant and expanding, as seen by different metrics:
- In 2016, more than 35,711 people were employed in research, production or distribution activities, biopharma & medtech being one of the few industrial sectors where the number of jobs is trending upwards.
- Biopharma & medtech is Belgium's top sector for innovation, both in terms of number of researchers and in terms of R&D investments.
- Exports of vaccines and medicines from Belgium reach key markets in Europe and further afield, such as North America and Asia, reflecting both the global orientation of Belgian producers and a strong biopharma & medtech-related logistics hub function. As a result, the net trade balance came to €7.2 billion in 2016, contributing to a sound external position for the economy.

Beyond the biopharma & medtech cluster itself, the interplay between a strong healthcare system, biopharma & medtech and life science industry, medical research institutes, and universities with centres of excellence in life science, creates a strong ecosystem in which the health industry at large can thrive. This has maintained Belgium's consistent positioning in the top ten of European life science clusters by various rankings, and provides a strong source of income and competitiveness for the Belgian economy.

Opportunities and challenges ahead

Looking ahead, both healthcare and the biopharma & medtech sector will face important challenges for maintaining or further improving their position, ranging from the looming rapid population ageing to pressures from new technologies and the emergence of new actors and new business models around the globe.

The ageing trend will unfold rapidly over the coming 25 years. This will affect the healthcare system in various ways. According to official projections for Belgium (Study, Committee on Ageing), the number of people aged 65 and over will increase by 1.1 million between 2017 and 2060. An increase of half a million people aged 85 and over is projected, this being an age group at increased risk of acute and chronic healthcare or long-term care needs. The public budgetary cost resulting from healthcare and long-term care has already risen from 5.9% of GDP in 2000 to 8.1% in 2018, and is expected to grow further to 10.1% of GDP by 2060, with most of the increase already occurring by 2040. Ageing will have another effect: the complexification of care, as older people will be facing several chronic conditions at once (multiple morbidity).
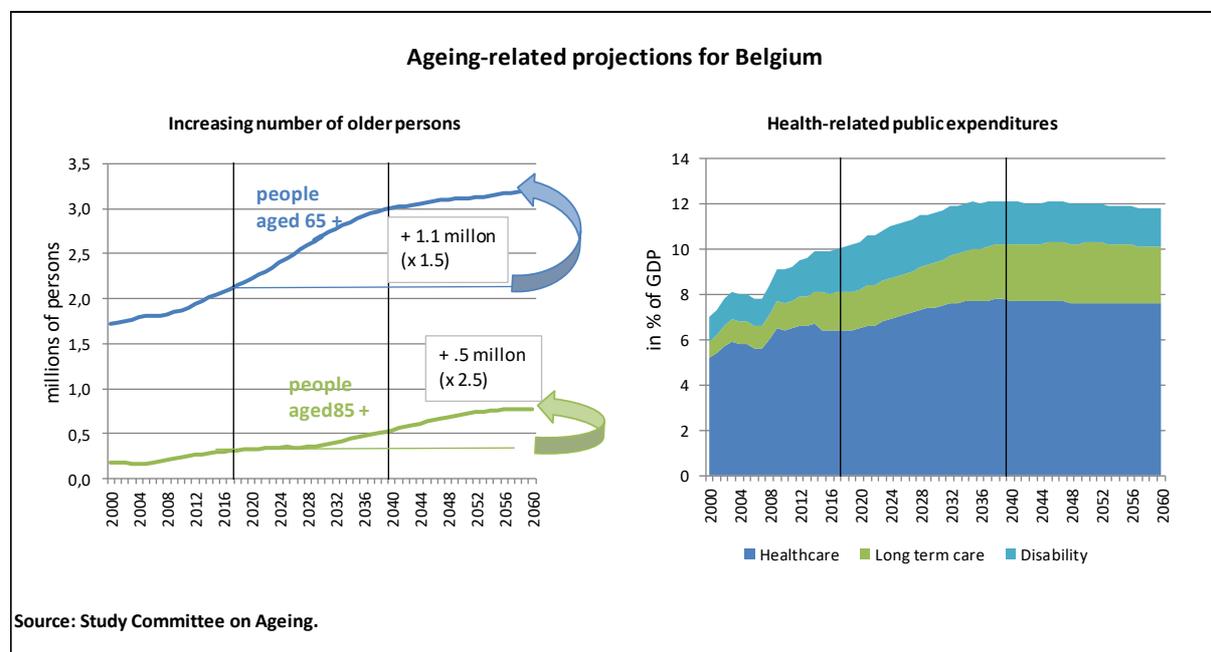

Figure 4: Ageing-related projections for Belgium

Besides demand factors, the healthcare sector will be affected by supply-side effects, as the availability of (ageing) human capital will be constrained. Both the healthcare and long-term care sector and the biopharma & medtech sector — being a high-tech profession — are already facing difficulties in recruiting professionals.

Disruptive progress in technologies and care models, in particular due to digital technologies, will profoundly affect business models in healthcare and in biopharma & medtech. The biopharma & medtech research model is shifting towards more integrated clusters, combining various players, technologies and services. The ability to adapt to these changes and to leverage technical opportunities into new economic activities is key.

Provided that supportive framework conditions remain in place, the existing ecosystem should be able to face and capitalise on these trends. A crucial success factor would be the development of a comprehensive and integrated system, pooling granular data and making information accessible to the healthcare system (both public and private) securely and with full respect of the patient's privacy. Individual healthcare players in Belgium have systems for collecting and storing patient data, but there is no centralised system in place for pooling data and providing wide accessibility under well-defined governance rules. This is likely to be a major priority as time progresses, riding on the wave of digitisation that is ongoing in healthcare across the world.

Trends	Description	Vision 2030
1 Integration and access to outcome data will play an increasingly important role in ensuring top quality care	▪ Developments in **data applications** will impact − **Care** by making it **more targeted, cost-efficient and outcome driven** − **Research** by providing **easier access to larger data pools** accelerating hypotheses generation and clinical trials	▪ Belgium has **most integrated and accessible longitudinal patient data pool** in the world, accessible by providers, patients, researchers, ... within adequate privacy constraints
2 Greying population and rising costs will raise need to restructure care around outcomes	▪ Belgium's care system will come under **increased strain due to demographic dynamics** − Its population is **greying**: by 2050 almost 50% of the population will be older than 50 − **Contributing share** of population will **decline** ▪ Ever-increasing demand for better care and budgetary strains will **encourage innovation with alternative settings of care** (e.g., revalidation centres) **and e-Health technologies** (enabling remote care)	▪ **Belgium is front-runner in outcome-based Healthcare** through a **restructuring of care infrastructure** around the patient journey and **adoption of the right e-technologies**
3 Cutting edge research requires increasing concentration in particular geographic clusters	▪ Worldwide **trend towards life science clustering** around centres of excellence **to fight R&D productivity drop** ▪ Belgian research clusters, such as stem cell and gene therapy, biotech and vaccine development, impacted by same trend	▪ **Belgium hosts 2-3 ecosystems of excellence that are broadly recognized as the global top in their field,** surrounded by vast and diverse clusters of incubators; finance; academics; etc.

Figure 5: How worldwide trends will affect top-flight healthcare delivery in 2030

2. The patient at the very core of our healthcare vision for 2030

These trends allow us to put the patient at the very heart of our vision of healthcare for 2030. Today's technologies enable real-time, long-term follow-up of the patient, whatever the setting, in care or otherwise. Some hospitals are today already monitoring a substantial amount of patient data through the Electronic Health Record. The gradual shift towards more *extra-muros* care, either at home or in intermediary care settings (such as rehabilitation centres), and the need and ability to follow the patient when he is not "in treatment", will require investments in and reforms of Belgium's healthcare system. Those initiatives should be twofold.

First, innovations allowing a gradual shift from hospital to alternative care settings should be encouraged where they allow for a better, more cost-effective care by using the latest technologies (such as data-capturing devices and non-invasive surgery) and where they help shorten patient stay. Also, better collaboration between first-line healthcare professionals could significantly improve health outcomes for patients and reduce some of the inefficiencies of the current system. First, this means that the first-line care and hospital funding system should provide for the right means and incentives for institutions to work together. Second, it also implies an environment where these new technologies can be tested and real-world data can be gathered for a healthcare and business case to be made, which brings us to the second important priority: investments in Belgium's e-health and health data capabilities.

A top-notch patient-focused Electronic Health Record (EHR) should come into being to link all the patient data being registered — from the molecular level to health outcomes — and communicate with other applicable contextual and bio(bank) data. Not only will such system allow for a long-term, horizontal and outcome-focused follow-up of the patient's condition, the data thus gathered will also be the key commodity for Belgium's medical and biopharmaceutical research and will serve to speed up access to medical innovations. By doing this, Belgium would be continuing to build on the commitments taken in the adapted e-Health roadmap set out by the Federal Government, and it would also be making progress on the data-for-health strategy it approved during the OECD Ministerial Meeting of January 17, 2017[5].

Obviously, patient privacy is paramount here and all investments in health data capabilities need to be GDPR-compliant. This is why the data capturing and storage technologies we recommend investing in have to be best-of-class ("privacy by design") and why the appropriate data governance structure is equally important. Not coincidentally, we recommend setting up a data one-stop shop based on Denmark's Health Data Authority (Sundhedsdata Styrelsen), and a data-for-health academy inspired by Britain's Farr Institute.

We believe Belgium would thus be building a digital health ecosystem where security of access to data fuels R&D (including access to R&D), and where the medical innovations thus developed produce unique data that will further increase Belgium's appeal for domestic and foreign investments in medical and biopharmaceutical research. The positive

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[5] https://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf

feedback loop thus created would be self-sustaining and would create value for patients, science, healthcare providers, innovators, and would benefit the Belgian social and economic fabric as a whole.
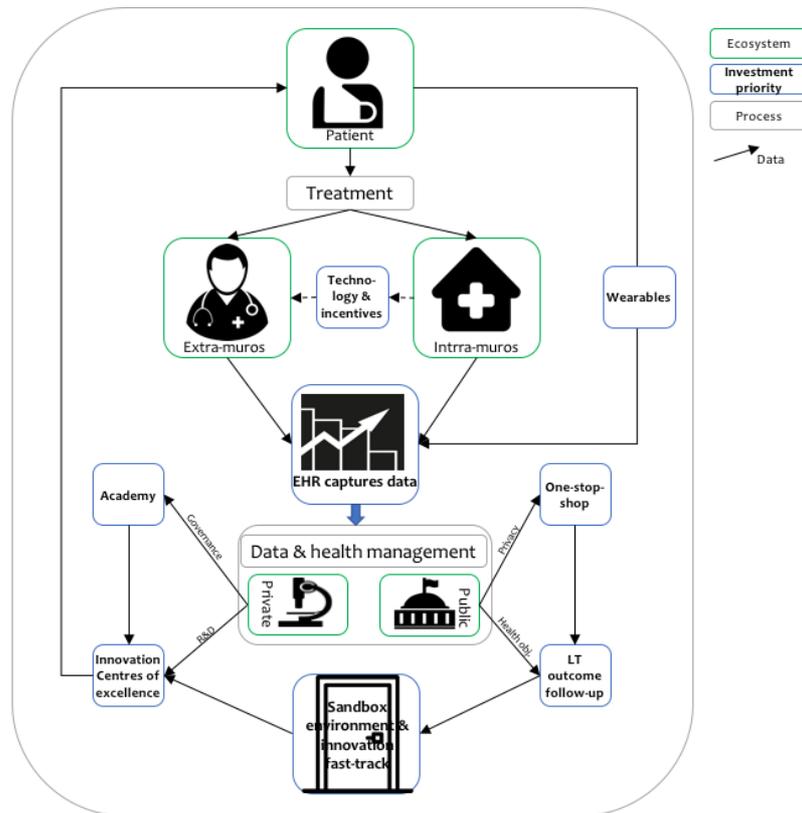

Figure 6: The patient at the very heart of our healthcare vision for 2030

This virtuous circle can be further leveraged by investing in Ecosystems of Excellence in those areas where Belgium has an edge over its competitors. These include vaccines, infectious diseases, antibacterial resistance, cell and gene therapies, and NGS in oncology. To take the latter, Belgium has the right combination of skills to be a trailblazer in next-generation genome analysis (VIB, multiple genomic academic centres, sequencing hardware capabilities at IMEC, experts in genome analysis, etc.). An investment in a multi-disciplinary project in a targeted field (e.g. diabetes or oncology) could create a world-renowned centre of expertise in Belgium. The benefit of investing in these will not only be seen in terms of better and more personalized care for patients, it will also permit a more rational use of resources and hence save money in our social security budget.

Taking as our premise this shared vision of the future of healthcare, we have identified three priority investment areas: striving for ambitious data governance and intelligent health information systems, restructuring healthcare by introducing the right technologies, and finally stimulating innovation by leveraging our ecosystems of excellence. The return on investment for these was computed using employment and productivity, public savings and business performance as our guide.

3. REFORM AND INVESTMENT PRIORITIES

3.1. Having ambitious data governance and intelligent health information systems

E-health covers the range of tools that can be used to assist and enhance prevention, diagnosis, treatment, monitoring and management regarding health and lifestyle. It is often perceived as substantially increasing productivity, and therefore as an instrument to support the reform of healthcare systems[6]. Examples of successful e-health developments include health information management and networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals. Combined with the current scope for the gathering and usage of health data, the potential of health data for patients, healthcare systems and medical research is enormous. This applies both to a treatment's discovery phase and its development during clinical trials, and to the monitoring of its effectiveness in a real-world setting, patient safety and a better understanding of the expression of a condition within a population group.

Harvesting the potential of data for health and for the benefit of the patient requires major challenges to be overcome. Although securing, linking and analysing large amounts of data are complex matters, the difficulties are mainly organisational in nature. Allowing different sectors to work together to share data, agree standards and achieve a change in data culture is a long-term task that must first and foremost be managed politically.

Belgium has numerous strengths with which to make this necessary turnaround. A great deal of data is already being collected, and some basic infrastructure is in place. In addition, we have a huge talent pool and can leverage our world-class medical and biopharmaceutical ecosystem. At policy level, quality work has been done in recent years and there are still important initiatives in the pipeline, such as the framework for mobile healthcare applications, the NGS Roadbook, the Patient Health Viewer, the data pilot projects and the accelerator for the Electronic Health Record. However, a holistic and complete vision, agreed to by all stakeholders, and additional reforms are needed. The quality of data is not always as should be: it is still under-utilised, the pooling of data is difficult, access is slow and complex, and there is a lack of overarching coordination.

These challenges can only be matched by Belgium's wealth of ambition: to lay the foundations for a health data ecosystem for the next decade, ensuring that Belgium remains one of the most attractive countries in which to carry out biopharmaceutical research and investments. Big data needs more than just data: a supporting ecosystem also provides the necessary skills, services, technical platforms, standards, legal and organisational frameworks and funding mechanisms. This is even more important now that it has become relatively simple and inexpensive to collect a great deal of data. Belgium is not yet desperately lagging behind in this respect, but it could end up that way. If one looks at what our main competitors, Denmark, Sweden, the UK and Finland, to name only a few, have achieved these past couple of years, it is hoped that policymakers and decision-makers will heed our warning.

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[6] The benefits and difficulties of e-health are documented, among other places, in the e-book edited by Wickramasinghe N, Bali RK, Suomi R and Kirn S, Editors. Critical Issues for the Development of Sustainable E-health Solutions. Springer 2012. DOI 10.1007/978-1-4614-1536-7.

The Health Working Group puts forward three specific investment proposals that will allow Belgium to fully capitalise on the potential of data (especially big data) for the benefit of patients, the healthcare system and medical research alike:

1. Generalization of data gathering and use & development of new top-notch features => **top-notch EHR**	Regulating & granting appropriate access for public & private research => **one-stop-shop**	Analysing data and interpreting results through integrated healthdata ecosyst. => **academy**

Figure 7: Data-for-health investment priorities flowchart

Investment priority #1: Top-flight Electronic Health Record

"Electronic health records (EHRs) provide opportunities to enhance patient care, embed performance measures in clinical practice, and facilitate clinical research." [7] Certainly, concerns have been raised about the increasing recruitment challenges for clinical trials, the difficulties of collecting data of high quality, and the relevance of the results. EHRs can counterbalance these trends, using them "as the primary data source for […] observational studies, embedded pragmatic or post-marketing registry-based randomized studies, or comparative effectiveness studies. Advancing this approach to randomized clinical trials, electronic health records may potentially be used to assess study feasibility, to facilitate patient recruitment, and streamline data collection at baseline and follow-up. Collaboration between academia, industry, regulatory bodies, policy makers, patients, and electronic health record vendors is critical for the greater use of electronic health records in clinical research." When EHRs are linked with *extra-muros* data, complemented with artificial intelligence for decision support and pattern detection, and serving as the blueprint for genetic sequencing and data collection, they truly become the most powerful instrument for healthcare quality and effectiveness, patient safety and cutting-edge research.

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[7] Clin Res Cardiol. 2017; 106(1): 1–9.

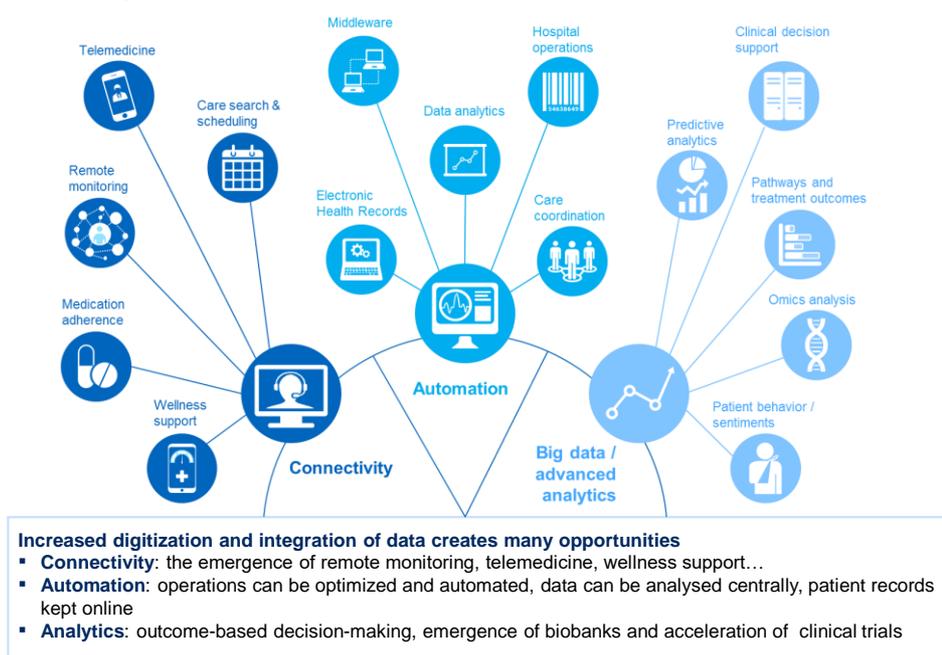Data consolidation becomes increasingly important to leverage digital technologies and improve competitiveness

Figure 7: The importance of an effective health information system

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Text box

Data as an enabler of a better care model

The benefits of a powerful exchangeable e-health data system, allowing appropriate information sharing among healthcare practitioners and patients, can be illustrated with the following example, extracted from the European Commission document[8] on investments in health:

E-health project example: benefit to practitioner and patient

"The delivery of e-prescriptions in Sweden is a joint initiative between each county council and Apoteket, Sweden's national pharmacy. Via Sjunet, the Swedish Information and Communication Technologies (ICT) network for healthcare, or using web-based prescriptions, 42% of all prescriptions are electronically transferred from the doctor to the pharmacy[9]. E-prescriptions increased the security and quality of prescriptions and reduced medication errors by 15%. They also enabled healthcare providers to save a lot of time. Patients benefited from a dedicated drug information hotline which improved their knowledge and safety and their flexibility to obtain their drugs in any pharmacy. The economic evaluation of the case-study on e-prescriptions in the Stockholm region showed that this electronic service generated an estimated annual net economic benefit of over € 95 m in the eight years of its implementation. Five years after planning and development began, the net benefit was approximately €27 m. This is impressive, given the relatively low spending on ICT of less than €4 m for the whole period of eight years. Healthcare provider organisations get 80% of the benefits, mainly from time savings and avoided costs of providing the same timeliness, convenience and reduction in errors without e-health. Citizens get the remaining 20%, chiefly through more safety thanks to correctly issued prescriptions and better adherence to treatment."

From the same Commission document, the *potential profits* are illustrated using an example in diabetes:
"Health status of individuals and labour market participation: example of diabetes type 2. A striking example of how prevention can increase labour market participation is the avoidable negative effects of diabetes type 2, which currently affects 7% of Europeans. A French longitudinal study found that diabetes type 2 patients lost an estimated mean time of 1.1 year in the workforce between the ages of 35 and 60. More generally

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[8] Investing in health, European Commission Staff Working Document, Social Investment Package, February 2013

[9] As of June 1st, the use of e-prescription will be compulsory in Belgium.

available statistical data60 seem to show that chronic conditions have an important impact on several dimensions of social inclusion. Comparing to a healthy individual, the impact of diabetes type 2 for a 50-year old single man is significant. It represents almost 3% of career lost (in terms of years of working life). It also has significant individual consequences, as it shortens the lifespan by 2.3% and increases the chance of being at risk of poverty by more than 5%."

Extrapolated to Belgium, we would estimate the number of diabetes patients to be approximately 800,000. An integrated and updated set of electronic patient health records, shared among healthcare practitioners, will provide the opportunity for adequate patient follow-up, moving from healthy status to sub-clinical disease, diagnosed disease, treatment installation and monitoring of health outcomes. It would optimise the interaction between health promotion, prevention, treatment and long-term follow-up. It would reduce the instance of medical and biopharmaceutical errors and would enhance early detection of disease and co-morbidities. If, by optimal use of patient follow-up, one can avoid the development to confirmed diagnosis, which may lead to additional severe comorbidities such as hypertension, cardio-vascular disease or neurological symptoms, the net benefit is to the patient — remaining in better health — and to society, which obtains monetary savings related to the delay in disease progression. If, by acting effectively and efficiently, we might reduce the workforce time lost by just 10%, we would save in Belgium the equivalent of approximately 80,000 workforce years, an estimated saving of €90 million[10] per annum.

This is a tremendous potential impact; similar figures might be investigated for other chronic diseases, as we know that nearly 23.5% of those currently in employment suffer from a chronic condition and have impairment in their daily activities. The savings resulting from an integrated EHR may be ploughed back in the healthcare sector for the development of new technologies, be they related to promotion, prevention, diagnosis or treatment and cure.

Understanding its potential and seeing that by 2018 only one-third of Belgian hospitals would be equipped with an Electronic Health Record system, the Health Minister, Maggie De Block, put together an accelerator program to have an EHR for every hospital bed in the country by 2022, investing €80 million annually as of 2016, half of which came from the healthcare budget. What the "EHR accelerator" funds is a basic HER, which was the necessary, first step.

However, looking at what is happening in countries competing for investments in biopharmaceutical and medical research and the tools researchers will need in the future, we have to face the fact that this program will not suffice. The use of a well-performing EHR needs to be generalized, and new features of the EHR of the future — compatible between every hospital in the country — progressively developed. Generalising the use of the EHR will demand investments in training and incentives among healthcare professionals (cf. "Recommended reforms" below). These training programmes could be designed and developed by the Data-for-health Academy (Investment priority #3) as could a strategy formulated to help attract the necessary (health) data scientists.

Israel, for example, recently approved a plan to invest 1 billion shekels ($275 million) to digitise the personal health records of its nearly 9 million citizens to help develop new drugs.[11] According to a statement, the Israeli government expects the plan to attract foreign investment and encourage partnerships with local entrepreneurs. "At the heart of the project will be Mosaic, a national information infrastructure initiative that will include

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[10] Impact calculation detailed in appendix.
[11] https://www.bloomberg.com/news/articles/2018-03-25/israel-to-invest-275-million-in-digital-health-project

a digitized sample bank for research purposes. The project could eventually lead to the establishment of a national centre for genetic sequencing", the statement reads.

Estimated cost[12]	Funding source	Estimated impact
▪ €240 million per annum ▪ €2,400 million by 2030[13]	• Min. 1/3 from Federal government	*Qualitative:* • Real-time, longitudinal follow-up of patients • Integrated Artificial Intelligence for decision support • Decrease in adverse events • Reduction of unnecessary examinations • Best-in-class genetic database infrastructure *Quantitative:* min. €330 million saved per annum due to decreased productivity loss for patients with diabetes and other chronic diseases

Some experts also advocated investing more in Belgium's cloud capacity to optimise the technology. As this investment priority was put forward by the Digital Working Party, it will not be covered here.

Investment priority #2: The data-for-health one-stop shop

Access to health(care) data is a delicate and sensitive matter, and rightly so. To protect patient privacy, the infrastructure must have the appropriate technical features (privacy by design[14]) and the right governance and access model has to be in place. Only by doing so will we be able to reconcile healthcare data's potential with patient privacy.

The Danish Health Data Authority (Sundhedsdata Styrelsen) does just that. Since November 1st 2015, it has served as a one-stop-shop for access to health data for public and private researchers. Finland has introduced legislation that should be approved by the summer, copying the Danish model. Applications can be processed in a uniform manner within a statutory, predetermined period (of 1 month in Denmark). The Authority discusses the research protocol, and once approved, grants access to all the necessary linked data and assists in its interpretation. Once the results are in, the dataset is destroyed.

Text box
The potential of data and DNAlytics
DNAlytics, a spin-off of UCL at the University of Louvain-la-Neuve, develops molecular patient stratification applications to inform the choice of available treatment options. An example would be rheumatoid arthritis (RA), for which the national healthcare association RIZIV spends over €140 million a year on anti-TNFs. Academic research has shown us that in a considerable number of cases, anti-TNFs are insufficient as a treatment of RA. To be able to analyse when this is the case, however, one needs access to the trial-and-error treatment iterations. This presupposes that there is the means to provide secure access to Tardis (the RA register for anti-TNFs), IMA and HER data to allow empirical objective

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[12] All cost and impact estimates can be found in the annexes.

[13] Use 2019 to define features and formulate generalisation strategy.

[14] "For instance, differential privacy gives you provable privacy guarantees on queries, homomorphic encryption allows you to run computation on encrypted data, while private set intersection allows you to safely combine datasets. None of these are perfect or a silver bullet, but combined they allows you to build robust privacy-preserving systems such as i2b2 in Switzerland for genetic data," Yves-Alexandre de Montjoye of MIT and Imperial College London recently wrote in *L'Echo*.

determination of treatment iterations. "Having access to Tardis and IMA database would allow us to precisely characterize the patient's iterations from one treatment to another, [and] estimate the costs related to this therapeutic [iteration], even before a single patient is recruited in a clinical study", as the founder himself, CEO Thibault Helleputte, says.

Estimated cost[5]	Funding source	Estimated impact
▪ €10–15 million per annum ▪ €100–170 million by 2030	• 10% public • 90% private	*Qualitative:* Fast, simple and secure access to health data for research. *Quantitative: comparable to EHR system impact*

Investment priority #3: The data-for-health academy

"When it comes to the road ahead," a recent report from Stanford states,[15] "it will be absolutely vital that all players in the health care community, in both private and public sectors, come together to overcome these challenges." The experts therefore advocate setting up a data-for-health academy as the final piece of our investment priority for Belgium's ambitious health information system.

The objective and mandate of the organisation, which could be integrated in the healthdata.be platform, should be to facilitate the optimal use of data to be able to improve care for patients through innovation, with utter respect for patient privacy. The Academy should be a platform in which the various actors — representatives of data providers, patients, industry (biopharma, medtech), IT, universities, administrations, etc. — can participate, have a permanent dialogue and thus get to know and respond to each other's (diverse and changing) needs. A first test case could be articulated around defining the further technical specifications of the state-of-the-art EHR advocated above, the functioning and governance of the data-for-health one-stop shop, and the design and follow-up of the recently-launched big data pilot projects in healthcare. The Academy platform would also serve to allow the centralisation of knowledge, the provision of training, and as the contact point between policymakers. Britain's Farr Institute can serve as a source of inspiration.

Estimated cost	Funding source	Estimated impact
• €3–5 million per annum • €30–50 million by 2030	• 50% private • 50% public	*Qualitative*: • Facilitate the optimum use of data, permanent dialogue to monitor evolutions, centralisation of knowledge, data capacity analyses and training • Contact point with policymakers *Quantitative: comparable to EHR system impact*

Recommended reforms

Because of its crucial importance for the future of healthcare management and medical research and development, the experts advanced additional data-related reforms:

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[15] Harnessing the Power of Data in Health (2017), Stanford Medicine 2017 Health Trends Report.

Building block	Description of the hurdle	Description of the actions
Data culture and quality	• Some uncollected data remains • Information systems used at multiple points of care differ in their semantics and structure • Data owner might be reluctant to share information with supra-entities	1. The blind spots in our health data landscape must be identified with the help of all parties involved. 2. A standard clause must be included in the conventions that the administrations sign with care providers, ensuring the access of third parties to this data in the execution of their legal assignments. 3. investigate and define common language for certain data types, such as the FAIR guidelines, which could be introduced into Belgian legislation
Semantic interoperability and data ownership	• Complex procedure to couple data • As for biobanks, a lack of standards hampers usability of data	1. Use the unique identifier to connect databases more easily 2. Partly through big data pilot projects, it is determined which data linkages are a priority. The ongoing pilot projects will also help defining a minimum set of standards. 3. Data standards and language are harmonised as much as possible and will be mandatory for new and future databases.
Infrastructure needs	• Lack of real outcome measurement and infrastructure • Lack of coordination for infrastructure investments • Lack of clear incentives	1. Need infrastructure to measure outcomes 2. Investment in state-of-the-art infrastructure so that data from EHR can be consolidated, shared, connected and re-used. 3. In order to provide the right additional priority infrastructure, the government operates as a facilitator, as it has done highly effectively for the Belgian Meaningful Use Criteria and the EHR accelerator.
Access to data	• Pay-per-act does not cover or guarantee communication, collaboration and use of technology, and therefore there is a lack of a holistic vison on data and health data governance • Access to data is rarely possible and complex (not least due to huge variation in access protocols), with a significant lag	1. There should be a publicly accessible and continuously updated metadata catalogue of existing data(bases) in Belgium. 2. For data that can already be accessed, the possibility of improving the existing procedure is being examined, as in the case of the IMA, where access to data is difficult and is only possible by entering into an ongoing reimbursement procedure under Article 81. 3. For data that is not yet accessible today, and for future databases, a clear, simple and uniform yet comprehensive master protocol will be established to ensure secure access for epidemiological, scientific, R&D and reimbursement purposes at a competitive cost. 4. The mandate of healthdata.be will be adapted in consultation with healthcare professionals so that researchers have access to data without having to request authorization from each individual institution. 5. In the Danish and soon-to-be-adopted Finnish model, applications can be processed in a uniform manner within a statutory, predetermined period. The objective is to develop into a one-stop shop, high-quality service provider with regard to access to health data.

Data governance	• Complex coordination • Many unconnected initiatives • No place where all stakeholders meet and where gradual building of trust can begin	A data-for-health academy and one-stop shop should be developed — see under Investment Priorities.
Create an ecosystem	• Belgium needs to do what others are not doing, so as to find test cases where it can stand out • If we succeed in turning our country into a health data valley, the resulting positive feedback loop — where top biopharmaceutical research feeds into the health data flow and the data thus collected attracts investment in R&D — would transform Belgium into a unique high-tech ecosystem.	Two innovative test cases could be set up: a. How can health data help to improve current treatment pathways for rheumatoid arthritis, which are estimated to be inadequate for a substantial amount of patients using Tardis? b. Long-term follow-up of patients with RSV and how they respond to different treatments.

3.2. Restructure healthcare by introducing the right technologies

The second priority must be to shape an environment that will foster the introduction of the right technologies and organisational models to allow for better, more cost-effective care. This is possible through the use of, for example, point-of-care diagnostics, a shift from residential to ambulatory care and coordinated transmural care (such as out-of-hospital rehabilitation centres), and by facilitating the introduction of new technologies, such as non-invasive surgery. The experts have identified three specific building blocks to shape that technology-prone environment: first, reviewing specific features of the current funding system; then developing a Health Technology Assessment sandbox environment that allows for access to fast tracks; and third, adequately funding healthcare innovations.

Investment priority #4: Review specific features of the funding system and use margin to create new coordination roles

Innovations allowing the gradual shift from hospital to alternative care settings should be encouraged where they allow for better, more cost-effective care. Better collaboration between the first-line healthcare professionals could indeed significantly increase health outcomes for patients and reduce some of the inefficiencies in the current system. That means, first and foremost, that the first-line care and hospital funding system should provide for the right incentives for institutions to work together[16] and to use the latest

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[16] By:
1. funding coordination functions between the different lines of treatments/care setting
2. jointly agreeing on health objectives in a multidisciplinary way and rewarding them if reached

technologies (such as data capturing devices and non-invasive surgery) and to work towards shortening patient stay.

The funding of in-patient stays penalises the transition from conventional care to innovations that shorten the in-patient stay (e.g. novel surgical approaches allowing substantially shortened in-patient stays for THP. Keeping the patient in hospital for less than 2 nights — although possible from a medical perspective — does not allow the hospital to justify the stay (based on the average LOS)). Innovative surgical approaches increasingly allow for one-day surgery and have been widely implemented throughout the surgical community. Hospitals that have not adopted these innovations and still perform techniques that require in-patient stays for the same indications are, however, not always disincentivised to do so.

As a means to start recalibrating the funding system to be technology-favourable, we recommend reviewing specific features of the funding system for short outliers and updating the compulsory one-day surgery list. This should be done in collaboration with the scientific community and could be used as an inspiration for other, similar collaborative initiatives.

Estimated cost	Funding source	Estimated impact
• €1–2 million for extra administrative capacity	100% public	Qualitative: • Better, less invasive care for patients • Scope to shorten hospital stay and treat patients at home (comfort and savings) • More cost-effective care for healthcare providers and system alike • Data gathering of new technologies Quantitative: €2–5 million

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- Flu vaccination: if, in a given district, the benchmark for vaccinating the targeted population is achieved, both the GP and the biopharma & medtech company receive an incentive (regardless of who the vaccinator was).
- Asthma: a pilot project on the good use of medicines is currently already under way, with very satisfying results. The collaboration of GPs with the local biopharma & medtech company is working well. If, in a given district, the number of hospital admissions for asthma crisis is decreased, both the GP and the biopharma & medtech company earn an incentive.
- Diabetes/obesity: health targets could include stopping the increase of diabetic amputations by keeping the population under the HbA1c threshold. This is achieved through broader diagnosis and earlier treatment, thanks to a more coordinated approach and tailored interventions by healthcare workers.
- Osteoporosis: Intense (targeted) patient education at several levels to protect older patients from falling. Where the number of wrist and hip fractures is reduced, the GP and the biopharma & medtech company are to be incentivised.
- Heart failure: Intensive education (including on therapeutic adherence) at several levels can reduce the number of hospital readmissions within the year for patients new to therapy (measurement of the rate of re-hospitalisation within the year).
- Hepatitis C: education on therapeutic adherence is crucial for successful treatment. Number of post-treatment patients with complete eradication as a measure to incentivise the local GP and biopharma & medtech company.

The resources thus freed up should be invested in healthcare coordination functions. The thus re-engineered healthcare model will allow for better healthcare delivery and improved patient outcomes.

Investment priority #5: Faster access to innovation

Despite the presence of a world-class biotech and health technology ecosystem in Belgium, penetration (speed) of health innovations is mediocre and relatively slow compared to other countries (Health Consumer Index, 2017). A faster technology adoption will not only benefit patients who will have access to the best and latest treatments; the data thus collected will also serve Belgium's health R&D agenda. It is therefore crucial that health technology penetration in Belgium improves.

Today, health technology assessments are being done at the level of NIHDI in the competent committees, such as the CTG/CRM for drugs, TGR/CMT for medical equipment and technologies, and CTIIMH/CRIDMI for implants and invasive medical technologies. Although these have been professionalised over the past couple of years (and will continue to be, according to Pact for the Future (2015) and the Medtech Pact (2016)), important challenges remain. Questions arise as to the quality of some evaluations and their isolated approach with regard to other health technologies. Some committees are not bound by strict deadlines, and due to this, some dossiers take years to be addressed. The timeframes that do exist, such as in the case of the CTG/CRM, are considered slow in comparison to other countries. Once approved by EMA, a new drug takes about 3 months to recoup its costs in Germany and the UK, 6 months in Sweden, Norway and Switzerland, but 15 months in Belgium. Illustration: some drugs developed in Belgium will only be accessible to Belgians one year after they have gone on the market in Germany!

The expert working group therefore recommends mandating the existing Access to Innovation platform to investigate:

1. **Fast-track access procedures**
   - How to capitalise on existing expertise and align HTA procedures, for those technologies where such procedures do not yet exist;
   - Seek maximum synergies with European Union initiatives, such as the proposed European HTA proposed by the European Commission, and hence avoid overlapping and reinventing the wheel on a national level;
   - Further simplifying and professionalising access procedures[17];
   - Strengthening the focus during the CRM procedure on the scientific clinical evaluation by simplifying the voting on the therapeutic added value and by bringing this step forward to earlier on in the procedure;
   - Identifying evaluation fast tracks, as has recently been done for paediatric drug indications, by:

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[17] For example:
- By introducing strict assessment and decision deadlines for all medical technologies;
- The economic assessment (biopharma & medtech company economic evaluation has been a legal criterion for reimbursement since 2002) is being undertaken without there being any health economist at the European Commission or supporting the NIHDI evaluator team.

o leveraging new data gathering possibilities (cf. also the next priority domain);
o pre-approving the use of some technologies within certain guidelines, and by so doing, developing adaptive reimbursement pathways[18];
o developing temporary reimbursement authorisations, especially in the area of Unmet Medical Needs and Orphan indications.

2. **Create sandbox environments**
   - Together with all stakeholders involved, develop sandbox environments and legislation for experimental technologies;
   - Develop and operationalise innovative reimbursement schemes, such as indication-based contracts, annuity systems and pay-for-performance systems (and combinations of all of the above) to ease access to the new wave of biopharmaceutical innovation (ATMPs, CAR-T, RNAi, etc.). Belgium could thus position itself as "Europe's access sandbox" and thus become a top-tier country for medical innovations, benefiting patients and innovators alike;
   - Define KPIs to evaluate quality and speed of access to medical innovations in Belgium and to provide overview reports on CRM activity, from submission to decision, on timelines, approval percentages, use of managed entry schemes etc. (which is done in other EU member states already, including the Netherlands, Germany and France).

Estimated cost	Funding source	Estimated impact

• €5–10 million per annum
 • €55 110 million by 2030
	100% public	*Qualitative:*
		 • Fast, simple and secure access to health technologies for Belgian patients
		 • Attractiveness of Belgium as a launchpad for medical technologies, so as to become "Europe's access sandbox" and a top-tier country
		 • Data gathering
		 • Expertise building
		 • Attractiveness of Belgium as a place to do R&D in medical technologies
		
		 Quantitative — first-order estimates:
		 • For the public:
		    o by seeking maximum synergies with European initiatives: €0.25 million
		    o by a better assessment of the therapeutic value: €17–32 million per annum
		 • For the private sector, due to simplified and harmonised procedures: €1–3 million per annum

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[18] As the government has done with its innovative Unmet Medical Need procedure, which still needs to be improved if it is to take off properly.

Investment priority #6: Better patient outcomes through an adequate funding of healthcare innovations

If we want Belgians to have access to innovations and the system to change and gather the necessary data, and our **innovators to have access to the Belgian market**, the current funding of innovative healthcare service delivery and innovations does not suffice.

Directly investing in innovation such as innovative medicines and technologies will result in saving lives and improving quality of life and public health as it enables the tackling of a broad range of chronic and rare diseases. Investing in innovative medicines and technologies also leads to reductions in other sources of healthcare spending, and has a key role to play in making the healthcare system more sustainable.

Moreover, several reforms put forward by the government, such as the hospital funding and hospital landscape reorganisation, will also require **temporary and conditional investments in innovation, in transition management** and in **institutions accompanying that change**. Making sure that the structural reforms put forward in the government agreement and the several deals the government concluded with the healthcare sectors actually materialise is considered an absolute priority for the Health Working Group.

Finally, better access to innovation in Belgium should incentivise data gathering from cutting-edge technologies developed domestically, specialisation, and the creation of ecosystems: keenness to develop healthcare innovations in Belgium, yet being overly reluctant to grant access to those same technologies, cannot be a sustainable strategy. We therefore recommend investing €375 million annually in innovative healthcare service delivery and innovations through the health insurance, whilst earmarking the sums necessary to accompany the healthcare reforms.

These investments would also serve to grant patients access to the latest technological developments. Maximally capitalising on the soon-to-be-operational horizon scanning unit (for drugs), and based on a genomic technological growth curve (Investment priority #9), predictions could be made as to what needs we should expect to see, and in what priority therapeutic fields. These insights could then serve to develop a new "drug pact for the future" and a "new medtech pact" where the flanking reforms would be put forward. Finally, payment of expenses could be made conditional on a performance monitoring system. The annual investment of an additional €375 million through health insurance would also serve to fund investments put forward later in the report (Investment priority #9).

Estimated cost	Funding source	Estimated impact
• €375 million per annum • €4.5 billion by 2030	100% public	*Qualitative:* • Access to innovative treatments and healthcare solutions • Data gathering • Facilitates structural reforms if made temporary and conditional • Better health tracking and hence reduced productivity loss of working population

		• Stimulates specialisation and the creation of ecosystems
		Quantitative If we assume a multiplier of 4.3, as was the case for cross-national public healthcare spending in the EU25 countries from 1995 to 2010, we would have a generated output of EUR 18 billion after 11 years.[19]

3.3. Stimulating innovation by leveraging our ecosystems of excellence

The health Working Group puts forward three specific Ecosystems of Excellence propositions that will take the logic of healthcare innovation and international attractiveness a step further.

In the global competition to attract life science investments, Belgium scores reasonably well but lags bigger countries such as the UK, Germany and France, which can benefit from solid economies of scale, both in the life-science market and in research funding and infrastructure. Since Belgium cannot compete on all fronts, it must select several key areas of expertise, combining its current strengths with the biggest areas of relevance and opportunities. Lacking size, Belgium can build on the existing high-quality interactions between the academic world and the footprint biopharmaceutical industry, and could focus on quality of research, diagnosis, treatment and healthcare system efficiency. Because Belgium is relatively strong in life science research, we propose building a strong "health outcomes" system (and even becoming best-in-class in some of the major therapeutic domains, such as oncology).

The small size of the population, its highly skilled workforce, the dense network of first-line healthcare providers, the proximity of world-class hospitals and the closeness of interaction with the academic world make Belgium the perfect location to develop an approach that is based on a long-term vision of evidence- and population-based health outcomes. If Belgium manages to take on a global leadership role in creating an infrastructure for standardising, measuring and attaining health outcomes, this will attract investments for both private and public partners. One of the prerequisites for this is to have a long-term vision that addresses the responsibilities of the Belgian regions for research, prevention and education, together with the federal responsibilities of healthcare and social affairs.

We propose to focus on three initiatives:
1. a Disease Innovation Fund
2. a European Anti-infectives (including Vaccines) Unit for human challenge trials
3. capitalising on the potential of genetics, at home and abroad

Investment priority #7: The Disease Innovation Fund

Our first recommendation would be to set up a structure for the improvement and promotion of the country's Medical & Life Science ecosystem, with specific attention paid to SMEs working on rare diseases, cell and gene therapies, emerging diseases, and

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[19] https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-9-43

personalised medicine. Specifically, we suggest developing further the current Innovation Office of the Federal Agency for Medicines and Health Products (FAGG/AFMPS) into the **one-stop shop for these SMEs**, helping them on regulatory topics ranging from clinical research to questions regarding price and reimbursement issues for all health products (medicinal products, medical devices, in-vitro diagnostics, medical technologies, etc.).

The second recommendation is setting up a **Federal Disease Innovation Fund**, as a public-private partnership (PPP), to advance insights into major diseases and health problems and to bridge the gap between research and treatment, and conversely to gather health data that could steer further research. The purpose of this Fund should be to stimulate this ecosystem by strengthening the collaboration between all Belgian-based stakeholders (academic centres, research centres, biotech/healthtech, and biopharma & medtech) in topics ("calls") that are relevant to the improving of healthcare in Belgium. The idea is not to replace the existing regional research funds, but to fund bridging initiatives that have a direct impact on the health of citizens.

The calls will be evaluated by a scientific board with representatives of the various stakeholder groups sitting on it.

Estimated cost	Funding source	Estimated impact
• €27 million per annum for innovative approached to diseases • €300 million by 2030	• 50% private (in kind) • 50% public	*Qualitative:* • Health benefits from improved treatment and available medicines • Highlighting of expertise of Ecosystems of Excellence to the global market • Export benefits from products developed *Quantitative:* • ROI of up to 27% for cancer and cardiovascular research

Investment priority #8: Unique Belgian capabilities to fight infectious diseases

After clean water and adequate nutrition, vaccines have had the greatest impact on human health globally. This has been clearly recognised by the Belgian government through the establishment of the "Pact of the Future" in 2015, agreed between the Belgian biopharmaceutical industry and the Minister of Social Affairs and Health, which includes the set-up at the Federal Agency for Medicines and Health Products (FAMHP) of a "Vaccines Centre of Excellence" as the spearhead of what should become the reference body for Europe.

Although vaccine development has been a success story, there are still many challenges, including R&D preparedness and response, to prevent epidemic emergencies from becoming humanitarian crises (viz. Ebola, Zika, SARS), and there is an important role for human challenge studies in the evaluation of the efficacy of potential vaccine candidates. The challenge organism worked on may be close to wild-type and pathogenic, adapted and/or attenuated from wild-type with less or no pathogenicity, or genetically modified

(GMO) in some manner, which may require specific biosafety conditions for the conduct of the clinical trial.

Within Europe, Belgium has been shown to be very attractive as a host for the conduct of clinical trials in general and for those conducted through Belgian universities and research centres for vaccine trials. Amongst other universities, the University of Antwerp has long-standing experience in the conduct of vaccine trials, and recently ran a trial with genetically modified polio-vaccine-viruses held under contained conditions (in the "Poliopolis" infrastructure), with support from the Bill and Melinda Gates Foundation (BMGF). The trial has gained much interest from the BMGF, which is willing to participate further in this endeavour, as is the Coalition for Epidemic Preparedness Innovations (CEPI), with Peter Piot as its Vice-Chair, whose remit is to fund and coordinate vaccine development against emerging infections with epidemic potential. The University of Antwerp is currently engaged in an initial CEPI project to perform a non-human challenge Phase I study, with more work to follow.

Building further on the existing expertise and network, this project seeks to address these challenges through the set-up of a Public-Private Partnership investment to build an infrastructure (similar to Poliopolis, but a permanent facility) providing the appropriate settings for the conduct of Phase 1 vaccine trials and human challenge studies for vaccines requiring various different biosafety conditions, including a "contained" facility allowing for residence of up to 15 volunteers and specifically equipped with controlled access to the facility; controlled under-pressure, HEPA filtration of exhaust air; an autoclave for waste destruction; and specialist collection of waste water for subsequent decontamination.

The envisaged infrastructure will be a unique facility of about 3,200 m^2 comprising a unit for the conduct of vaccine trials with GMOs under "contained" condition; a unit for the conduct of vaccine trials with vaccines that do not require containment; biosafety level 1, 2 and 3 laboratories specifically equipped for handling of clinical materials and vaccine candidates according to the required containment level; and a biobank unit compliant with the latest Royal Decree of 9 January 2018 on biobanks. Needless to say, the construction of the facility will be undertaken in close collaboration with the Service for Biosafety and Biotechnology (SBB) of Sciensano and the Federal Agency for Medicines and Health Products to ensure that all (bio)safety and regulatory requirements are met.

The close vicinity to the site of the Institute of Tropical Medicine, with its outstanding experience and expertise in tropical infectious diseases and healthcare, combined with the University of Antwerp's expertise in infectious diseases and vaccines, makes Antwerp the preferred place for hosting this unique infrastructure and to anchor the activity in Belgium, thereby supporting the mission of the "Pact of the Future" to have a "Vaccines Centre of Excellence" as outlined above.

To ensure the facility can operate at full capacity, it is the intention to share the facilities with fellow researchers, but also with biopharma and medtechceutical partners, pairing the potential excess of capacity with the need and desire for great flexibility.

These investments, which would truly put Belgium on the map, would trigger more investments, especially with the moving of the European Medicines Agency from London. The Vaccines Centre of Excellence at the FAGG/AFMPS, together with the Phase 1 clinical trial unit for anti-infectives that is to be developed, could turn Brexit into an opportunity for Belgium by functioning as an "expertise magnet". Many companies are indeed considering new venues for their regulatory activities and continuous batch releases, and with its Vaccines CoE and Phase 1 unit, Belgium would be in pole position to benefit. This could, however require additional investments in qualified personnel at the FAGG/AFMPS.

Investing in these capabilities will also serve Belgium's position and reputation in the world. When global epidemics erupt, there is a need for fast intervention by medical staff and experts in virology to ascertain which strains of the virus are responsible for the infection. Recently, the Praesens Foundation,[20] founded by ex-Biocartis CEO Dr. Rudi Pauwels and chaired by Pr. Dr. Peter Piot, created a Mobile Health Lab for urgent epidemic outbreaks (Ebola, etc.) as a pilot scheme in Senegal. Its goal is to implement the use of easy-to-use, yet high-quality, patient diagnostics in resource-poor settings, including molecular diagnostics capabilities for the rapid detection and monitoring of infectious diseases. These solutions should improve epidemic preparedness, surveillance and rapid deployment where there are disease outbreaks in areas regularly affected by epidemic and endemic diseases. Once further developed, it will also serve as an expertise magnet for Belgian molecular diagnostics and will reinforce Belgium's reputation for scientific excellence in this field. Given sufficient funding, this Global Mobile Health Lab could be deployed in other areas of the world and also be able to combat local anti-microbial resistance directly on the ground. Diagnostic teams could identify what the best treatments are for the strains identified. Research teams will thus more easily be able to take samples and collect virus strains for further research. The viruses collected will help enable the setting-up of a Belgian research library.

Estimated cost	Funding source	Estimated impact
Phase 1 clinical trial unit for anti-infectives ▪ €5–9 million per annum • €60–101 million[21] by 2030	• 50% private • 50% public	*Qualitative:* • New cooperation clusters • Leveraging of Belgium's strength, to build up expertise and reputation • Economic benefits from knowledge and export of products *Quantitative:* • IRR of 5–7% for R&D in drug development
Global Mobile Health Lab • €6 million per annum • €66 million by 2030	• 1/3 private • 1/3 philanthropic • 1/3 EU (DG ECHO)	*Qualitative:* • Help remote communities • Contributes to containing infectious diseases • Reputation and capability building • Expertise & knowledge development and greater attractiveness • Potential for drug development and upscaling

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[20] www.praesenfoundation.org
[21] Start-up funding of €30 million (50% private, 50% public), then yearly funding of €3 million for trials on neglected diseases (not for industrial trials).

Investment priority #9: Capitalising on the potential of genetics

One of the most significant evolutions in healthcare is the convergence of genetics, molecular biology, medicine and outcomes data generation, allowing us to track health progress from early diagnosis to health outcomes, forwards and backwards. The emerging population health needs truly challenge existing study designs. Large, population-based prospective cohorts, providing high-quality geno-/phenotyping and long-term follow-up are required to ensure sufficient statistical power to better understand the role of various personal, social, and physical environmental factors and their interaction with complex traits.

Population-based cohorts provide insights into pathways of disease/ill-health development, more specifically the interaction between drivers and societal challenges, models for identifying individuals at increased risk of developing major diseases, multiple morbidity, the evaluation of markers for early detection of disease, assessing drivers for socio-economic disparities in health, and studying health determinants. Furthermore, they provide new information on the impact of major determinants of health, and provide a sound base for targeted policy, policy follow-up, and evaluation of the healthcare and social security systems.

An integrated approach will allow an increased overall efficiency of the system, to gain insights in the real-world effectiveness of treatments. This way, patients will receive the best possible treatment based on their genetic make-up, and superfluous costs and ineffective treatments will be avoided. At the same time, clinical insights will be generated that can be of use at an international level. Indeed, setting up an integrated data structure from genetic screening to outcomes evaluation will make Belgium even more attractive as a venue for clinical research. Recent reports by the Belgian Healthcare Knowledge Centre (KCE) on the potential of collecting population-based genetic information, and by the Cancer Centre (WIV) on Personalised Medicine, could serve as the conceptual framework to integrate data along the patient journey.

To make a reality of these ambitions, the experts urge action on the following points:
- Molecular markers and genetic tests should be evaluated within reasonable deadlines and evaluated by the best experts (Investment priority #5) so as to obtain access.
- To be able to start the investments and data registration as quickly and efficiently as possible, specific regulations about infrastructure security, standards, etc., need to be agreed.
- The health data profession will have to develop new software to create a Molecular Register of Genomic Test Data. As this plank of the project is highly complex and will demand an entirely new approach and organisation at the level of both healthcare providers and government, significant investment will be needed to integrate these and the forthcoming new 'onomics' structurally into Belgian healthcare. However, experts fear that the €2.5 million that will be freed up annually by reimbursement of tests (and for capturing associated data) will not suffice, given that the new indications (and the associated patient numbers) and

the technological developments which are currently on their way to maturity. This budget should be raised on the basis of on a "technological growth curve", whose details should be worked out with the healthcare sector. Even the €5 million foreseen for the development of guidelines, pilot schemes, software and hardware will probably fall short if not made structural. Moreover, this would allow remarkably promising and intriguing pilot schemes to be elaborated, such as KardioKompassi in Finland[22]. The KCE report 240C on "Next-generation sequencing gene panels for targeted therapy in oncology and haemato-oncology" provides an estimate of the number of tests needed in France: the French cancer centre (INCa) estimates the number of NGS panel tests for somatic mutations needed at 40,000 to 60,000 per year. This estimate would translate to an annual need for the Belgian population of about 7,000 to 10,000 tests. Therefore, the Working Group proposes that, in anticipation of the technological growth curve, current budgets be doubled every two years.

- In line with developments in other countries, Belgium will need a cohort[23] of its population as a research infrastructure, with the following objectives:
    1. To be an open epidemiological platform, accessible to the whole research community. It could be used as a tool to develop large-scale research projects at reduced costs through nested studies.
    2. To serve as an instrument for scientists and researchers. The cohort is meant as research tool for a wide range of research and policy questions.
    3. To serve as an instrument for policymakers. It could be used as a tool for epidemiological surveillance in domains that are currently not or insufficiently

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[22] KardioKompassi is FIMM's first preventative healthcare pilot project utilising personal genetic risk information and returning it to the participants. The aim of KardioKompassi project is to study ways of providing people with health-risk information based on genetic research data, the ways this information is used in preventive healthcare, and its usefulness with respect to individual health behaviour. In this project, the transfer of genetic information to an individual's personal online health account was also being tested for the first time in Finland. The results of the follow-up survey showed that participants receiving their genome information, and how their health behaviour influenced their risk profile, had an impact on participant's behaviour for at least 1.5 years after the project. The application developed during the project is further developed and will be used in the FinnGen study, which plans to tap into 500,000 unique blood samples collected by a nationwide network of Finnish biobanks over a period of 6 years, securing funding of €59 million. The research project is based on a public-private partnership between Finnish universities, biobanks, hospital districts, and several international biopharma & medtechceutical companies, to drive research, implementation, and economic development in the field of personalised medicine. The data created during the study can be used for prioritising drug targets based on genomic information, thus enabling more efficient drug development pipelines and better individually-tailored drug treatment choices. It will boost the activities of Finnish biobanks by speeding up sample collection and enabling enrichment of samples with genomic data. The aim is to persuade up to 500,000 Finnish individuals to participate in the study. FinnGen will manage anonymous health registry and genomic data without compromising the privacy and integrity of participants. The genomic data produced during the project will be returned to Finnish biobanks, providing the basis for new industrial partnerships, drug trials, monitoring studies, and other private-public projects.

[23] The cohort will generate new data (from molecular (e.g. NGS/WGS), to health status, health care use, etc.) and will maximise the use of existing data: from patient-focused EHR to existing administrative data. In 2018, Sciensano initiated a two-year study into the feasibility of starting up a Belgian health cohort (N=200,000, follow-up 30/40 years). Sciensano will work in partnership with Belgian universities, academic centres and researchers, and administrative stakeholders to develop the business and funding plan, including the road map, protocols and governance structure of the consortium that will lead the research infrastructure. The cost of an initial set-up (a five-year period) can be estimated at about €45 million.

covered. It will allow for the providing of indicators in a large set of policy domains and will contribute to the understanding of drivers of health and the interactions of these with policy-setting and evaluation.

- There is a great deal of movement at EU level, too. For instance, thirteen member states (including Sweden, Finland and Estonia) signed an accord on April 10th 2018 to link their genome data banks together and to provide each other with secure access to them. The aim is that by 2022, there should be access to 1 million genomes, which can thus serve to unlock the potential of investments already made in biobanks, gene sequencing and data infrastructure. Given that the European Commission has been playing a supportive and facilitating role in this development, it is remarkable that Belgium has not (yet?) joined in this initiative. Doing so might make it easier to obtain co-investment from European Union funds, especially in light of the initiatives which the Investment Pact proposes.
- A roadmap needs to be developed to integrate all the necessary expertise and to increase collaboration with a common purpose to increase our knowledge of genomics and other 'onomics' data, linked to phenotype data, disease and healthcare utilisation data.
- Moreover, this genetic data collection and the ensuing therapeutic focus should be expanded to the population-based generation of outcomes data. The aforementioned INCa estimates for France assume a rapid market uptake of whole-exome sequencing, as is illustrated in their figure reproduced below:
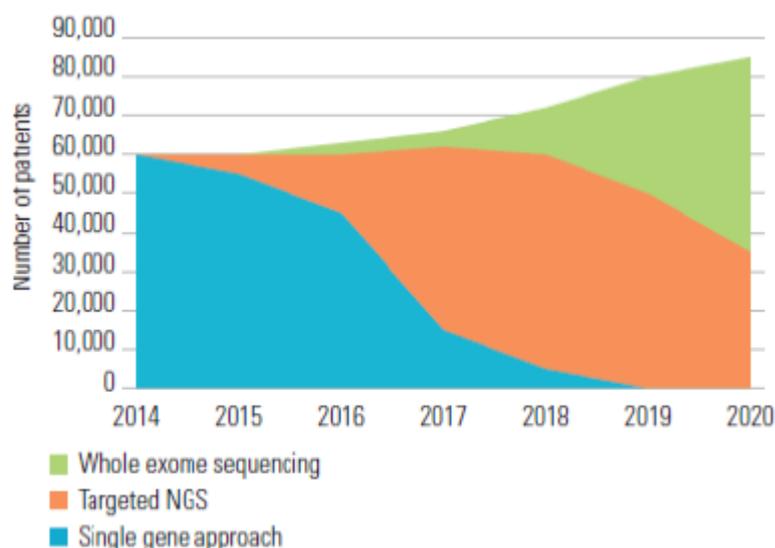
Figure 8: Evolution of the number of patients benefiting from genomics in France
Source: Institut National du Cancer, France

Estimated cost	Funding source	Estimated impact
NGS & WGS €292.5 million by 2030	• 100% public through investments in innovations — hence no additional cost	*Qualitative:* • New data generated • Better use of existing data • Better, more targeted patient care • Expertise and capability building

		• Social Security savings through more targeted use of drugs *Quantitative:* • At least €330 million[24]

Text box

Where data, access to the newest technologies and ecosystems of excellence could all come together: Real-World Evidence in home care

As we have seen throughout the document, big data and Real-World Evidence (RWE) offer significant opportunities to increase the efficiency of research and health systems. Today, the whole world is struggling with the sustainability of healthcare systems, and countries that have taken leadership roles will generate international attention and appeal. What we propose is to set up a system in Belgium to see how the systematic capture of health data, done with the same rigour as in randomised clinical trials (RCT), could shed light on which therapies work best in a natural setting. The objective is to verify to what extent the efficacy as presented in clinical trials is actually matched by the treatment's effectiveness in a real-life situation.

These RWE studies can even be conducted prior to registration or in the context of "adaptive pathways", i.e. the fast-track approval for promising innovative drugs to treat diseases with a high unmet medical need. The legal and regulatory framework to do this already exists. It has also been put into practice pre-registration for some disease domains in other EU countries (the UK, accepted by the EMA).

Belgium might strategically invest in qualitative disease registries. Oncology, immunology, neurodegenerative and rare diseases could be focus areas. Regarding immunology, there is already the Tardis registry in treating RA, which could serve as a model.

Belgium is a good location for clinical research. Adding a more structured and organised approach to Real-World Evidence will significantly increase Belgium's attractiveness as a destination for clinical trial investments. This approach could apply for interventional and observational studies. Within this context, the Belgian Federal Agency for Medicines and Health Products (FAGG/AFMPS) should play a critical role in helping to organise the system, as should healthdata.be.

The impact could be significant and might improve the current generation of health and treatment data, and these could be linked to other parameters such as lifestyle and behaviour, thereby allowing Belgium to become one of the world's most attractive countries for health research, in both clinical and real-life settings.

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[24] Computation for lung cancer alone, based on OncoDNA input. See Annex for detailed computation.

4. CONCLUSION

The individual projects falling under these umbrellas will give rise to a positive feedback loop. Patients, healthcare providers and companies alike will note the many benefits of having an integrated data system to improve service provision and to make research more efficient and of higher quality. Moreover, a healthy cross-fertilisation will arise between these healthcare innovations and the knowledge centres in industry. This will enable Belgium not only to meet the challenge of the changes which the sector is facing but indeed to excel as an innovator and a trailblazer in the domains selected for focus.
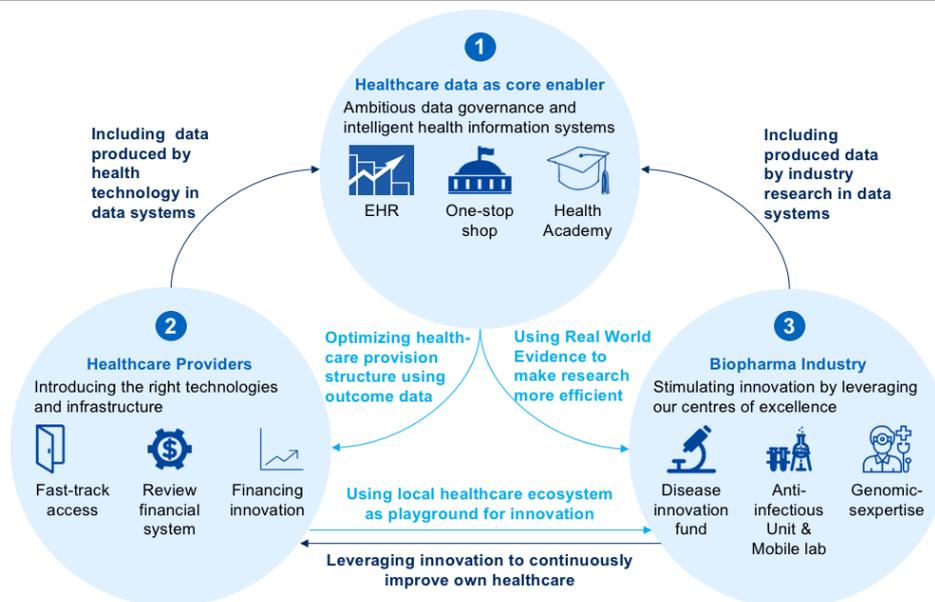
Figure 2: Investment priorities positive feedback loop

To make a success of the investment projects outlined above, various actors in the world of healthcare will have to mobilise:

- *Government*: The competent Health Ministers and others involved will have a key role to play in implementing these investment priorities. They will have to guide through the implementation and follow-up. Government bodies will also have to earmark extra budgetary resources for healthcare to fund the necessary stimuli provided for in the Pact (e.g. in private funds, academia, one-stop shops, etc.). In some domains, the legislative framework will have to be amended to make the proposed investments legal — as regards, for instance, the funding and reimbursement model. In addition, government will have to make the available data accessible in conformity with GDPR legislation.

- *Hospitals and other care providers*: All healthcare institutions are going to have to make serious work of integrating patient data and research data into the extended Electronic Health Record (EHR) platform. In addition, they are going to have to create a culture of exchanging data and collaborating; a culture where innovations are actively put to work in their offerings of service provision — to drive down hospitalisation periods, for instance.

- *Industry, start-ups, universities, research centres*: All parties involved in research and innovation in the healthcare sector will have to make their share of the

investments to keep Belgium an absolute world-class player in research and development.

ANNEX 1: MEMBERS OF THE HEALTH WORKING GROUP

Nom	Prénom	Fonction	Email	Organisation
Stephenne	Jean	Chairman	jeanstephenne@yahoo.com	OncoDNA
Bonheure	Kenneth	Partner	Kenneth.bonheure@mckinsey.com	McKinsey
Rutten	Catherine	CEO	cr@pharma.be	pharma.be
Brabants	Julien	Government Affairs director	julien.j.brabants@gsk.com	GSK Belgium
Heylen	Stef	Managing Director	sheylen@its.jnj.com	Janssen Pharmaceutica
De Cock	Jo	Administrateur-generaal	jo.decock@riziv.fgov.be	RIZIV
Facon	Pedro	Directeur-Generaal	pedro.facon@gezondheid.belgie.be	FOD Volksgezondheid / SPF Santé Publique
De Cuyper	Xavier	Administrateur-Général	xavier.decuyper@fagg-afmps.be	FAGG/AFMPS
De Ploey	Wouter	CEO	wouter.deploey@zna.be	ZNA
Ethgen	Olivier	CEO	o.ethgen@serfan.eu	SERFAN Innovation
Kips	Johan	Administrateur-délégué	johan.kips@erasme.ulb.ac.be	Erasme
Legrain	Olivier	CEO	olivier.legrain@iba-group.com	IBA
Mazy	Renaud	Administrateur délégué	renaud.mazy@uclouvain.be	Cliniques universitaires St-Luc
Van den hove	Luc	President and Chief Executive Officer	luc.vandenhove@imec.be	IMEC
Van Hoof	Chris	Senior Director Connected Health Solutions	Chris.VanHoof@imec.be	IMEC
Van Oyen	Herman	Director	Herman.VanOyen@sciensano.be	Sciensano
Van Damme	Brieuc	Managing Partner	brieuc@baerecraft.com	Baere Craft Consulting
Steurs	Geert	Chief Economist	gs@pharma.be	pharma.be
Van Wilder	Philippe	Health Economist	philippe.van.wilder@ulb.ac.be	ULB

Investment priority #1: State-of-the-art Electronic Health Record system

Cost

In the Israeli case example, a budget of €275 m was spent to digitise the personal health records of nearly 9 million citizens. Extrapolating this cost to a population of 11.35 million generates a minimum annual cost of €32 m per annum, or €350 m over 11 years. This is taken as the minimum investment needed to obtain a top-flight Electronic Health Record system.

To estimate the maximum investment need for expanding the Electronic Health Record system, the budget freed up by the Minister of Health, Maggie De Block, for building the basic EHR system is doubled to €120 m (an addition of €80 m). Public expenditure is only 33% of the funding source, since 67% is expected to come from the hospitals themselves or from private investors. This brings us to a total net maximum investment need of €240 m per annum, or approximately €2.4 billion over 10 years.

This last value is more in line with the study by Gartner, which demonstrates that an additional €440 million should be spent. According to that study, Belgian hospitals spend about 2.5% of their revenue on ICT. Also, according to Gartner, the 75th percentile in ICT spending by a US healthcare provider is 5.7% of revenue. According to the latest MAHA study (Belfius, 2017), the revenue of the Belgian hospital sector is about €13.7 billion. To catch up with the 75th US percentile on ICT spending, Belgian hospitals would therefore have to spend an additional €400 million annually until 2030.

Impact

The impact calculations for the data governance and health information systems initiatives are based on a cost analysis of the productivity loss of diabetes patients. Assuming 60% of the 800,000 diabetes patients (7% of Belgian population) to be in the workforce, a productivity loss of 5.6% is applied to these patients, owing to mild or severe physical work restrictions or doctor's appointments. The Electronic Health Record system could indirectly reduce workforce time lost by 10%, which means that €90 million per annum could be saved (based on a net cost to society of €33,443 per unemployed person). Extrapolating this value to the entire population suffering from chronic diseases (23.4% in the case of Belgium), a direct total saving of €331 million per annum is possible by investing in better patient tracking, care and follow-up through investments in e-health, and health information systems. This value does not even take into account all the additional benefits of an e-health system, such as improved research efficiency, patient treatment, medicine administration, etc.

Investment priority #2: The data-for-health one-stop shop

Cost

The Danish Health Data Authority, Sundhedsdata Styrelsen, on which this investment recommendation is based, employs 220 people[25]. If this can serve as a benchmark (although there are half as many Danes as there are Belgians, and knowing that Denmark is already years ahead of Belgium with regard to health data, thanks to its overarching biobank structure and registers that cover 100% of the population, among other factors)

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[25]https://sundhedsdatastyrelsen.dk/da/om-os

and assuming a pooling of the health data capacity of the current healthcare administrations (foreseen in the redesign of the federal healthcare administrations known as "Task 5 Data & Health Research System"), we estimate the number of FTEs required to be around 70. That gives the following cost estimate (also inspired by previous government initiatives, such as the Publicly Funded Clinical Trials Unit at the KCE):

Management team	FTEs	Cost per unit	Annual cost
PMO director (Band 4)	1	€200,000	€0.2 m
Office manager B3	10	€50,000	€0.5 m
Legal experts A2	10	€60,000	€0.6 m
Data and medical experts A4	50	€130,000	€6.5 m
Other expenses (ICT, offices, campaigns, etc.)			€3.2 m
TOTAL	71		€11 m

The initial investment for setting up the data-for-health one-stop shop — for the first year, for argument's sake — would have to be borne by the federal government. After that, the operational costs would be covered by user fees. Considering that the period in mind is 10–11 years, this means that only 10% of the investment would be considered public.

Impact
[Same as Investment priority #1]

Investment priority #3: The Data-for-health Academy
Cost
Besides its seven directors (including deputy directors) mandated from the partnering academic centres, Britain's Farr Institute has a staff of ten.[26] Using this as a benchmark, we arrive at the following cost estimate:

Management team	FTEs	Cost per unit	Annual cost
Coordinator	1	€100,000	€0.1 m
Office manager (B3)	2	€50,000	€0.1 m
Experts (A2)	30	€60,000	€1.8 m
Other expenses (ICT, offices, campaigns, etc.)			€1.0 m
TOTAL	8		€3.0 m

Impact
[Same as Investment priority #1]

Investment priority #4: Review funding system and use margin to create new coordination roles
Cost
€0 (zero euros).

Impact
The objective is to avoid missing out on the benefits of new technologies that enable reductions in the length of stay (LOS) in hospital entailed by surgical procedures. Given a

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[26]http://www.farrinstitute.org/about/teams-and-leadership

funding mechanism which is based on the justified LOS per procedure, it may be worthwhile to identify stays with short LOS outliers and which still are not included on the list of surgical interventions with obligatory one-day reimbursement of stay.

The current list of obligatory one-day surgeries includes 32 DRGs. The relevant stay criteria that occasion an obligatory one-day fee:
- in-patient stays with a LOS $\leq$ 3d
- scheduled intervention
- SOI of 1
- age < 75 years
- patient alive

To estimate the budgetary impact, it is crucial to identify the volume of hospital stays corresponding to the above criteria and not belonging to 1 of the 32 DRGs. Unfortunately, this information is not readily available; data from the Technical Cell is relevant, but one cannot link the information to the patient relevant criteria (scheduled intervention, age and SOI). In Belgium, the ULB-École de Santé Publique (ESP) has experience with hospital data of patients attending the Erasmus hospital and about 15 associated hospital sites.

The ESP provided a report, based on a sample of the hospital data, identifying primary diagnoses for which the median length of stay was close to one day. The following diagnoses were identified, among others:

Primary diagnosis	Median LOS	Minimum LOS
42731 Auricular fibrillation	2.4	0.0
5409 Acute appendicitis, no peritoneal inflammation	2.6	0.4
57410 Lithiasis and cholecystitis	2.1	0.9
5921 Ureteral lithiasis	1.8	0.4
V5811 Antineoplastic chemotherapy	2.3	0.8

Selecting from this list of DRGs and primary diagnoses those stays which comply with the aforementioned criteria resulted in a total (BE-extrapolated) of more than 6,200 relevant stays. This illustrates that, were it to be medically and clinically indicated, replacing the actual funding approach in these 6,200 stays with a fixed one-day surgery approach would bring estimated savings of nearly 5,000 hospitalisation days.

Investment priority #5: Faster access to innovation
Cost
We estimate the number of experts at federal level currently working on assessing and granting access to health technologies to be around 50, and we think we would need to double that number to achieve the ambitious agenda put forward here.

Management team	FTEs	Cost per unit	Annual cost
PMO director (Band 4)	1	€200,000	€0.2 m
Office manager B3	8	€50,000	€0.4 m
Legal experts A2	5	€60,000	€0.3 m
Access experts, data and medical experts A4	37	€130,000	€4.8 m
Other expenses (ICT, offices, etc.)			€2.3 m
TOTAL	50		€8.0 m

Impact

The assessment of the therapeutic value (ATV) is different in the three countries: if the outcomes are recorded on a binary scale (added value 'yes' or 'no'), the agreement between two countries is close to 70% and drops to 50% between three countries. This last figure indicates that in nearly one submission in two, there will among three countries be one divergent opinion. Importantly, in any of these countries, a request for price premium is only acceptable if there is ATV. Put otherwise, in one in every two submissions, one country will pay either more or less than the others do. This probably means that either public money is being wasted or the applicant is not receiving value for money. The median budget impact (NIHDI perspective) of innovative medicinal products (2010–15 time window), as provided by the applicant, is estimated at €2.7 m. Accordingly, the diversity in the outcome of the ATV assessment may have a budgetary impact exceeding €10 m (if six products are misclassified) on an annual basis.

The average NIHDI workload per assessment of a class 1 product or OMP is probably 6 months at 20% to 40% FTE; a median of 21 dossiers per year will require approximately [21 x 0.5 x (20% or 40%)] 2 to 4 FTEs for those product assessments only. The applicant will need a fourfold increase in these resources and will spend perhaps €50,000 on consultancy services. The annual private and public investment may be estimated to reach €1 to 2 million; more harmonisation across all 28 EU member states might be expected to reduce the efforts to probably > 50% of these estimates.

Investment priority #6: Better patient outcomes through adequate funding of healthcare innovations
Cost
1.5% of €25 billion = €375 million annually

Impact
Qualitative assessment only

Investment priority #7: The Disease Innovation Fund
Cost
A. SME one-stop shop

Management team	FTEs	Cost per unit	Annual cost
Coordinator	1	€100,000	€0.1 m
Office manager (B3)	2	€50,000	€0.1 m
Experts (A2)	5	€60,000	€0.3 m
Other expenses (ICT, offices, campaigns, etc.)			€0.2 m
TOTAL	8		€0.7 m

B. Fund
Based on what both Biowin in Wallonia and VIB in Flanders have invested in biopharma & medtechceutical research during the past 10 years, it seems that a fund of at least €300 million, half of which is to be public money, is required.

Impact
Public investment in biomedical and healthcare research could generate a positive return on investment of up to 27%. In concrete terms, this number is generated by two types of

gain: health gain and GDP gain. The health gain is the (net) monetised health benefit of people living longer and having healthier lives. The GDP gain is the benefit to the wider economy arising from public- and consequent private-sector biomedical and health activity, including private-sector R&D spending. It has been estimated in the UK that the rate of return on cancer research is 10% and for cardiovascular research 9%. Additionally, an annual rate of return for the GDP gain of 17% has been measured. When combining both effects, a total rate of return of 27% is obtained.[27]

Investment priority #8: Unique Belgian capabilities to fight infectious diseases
Cost
A. Phase I Unit
The University of Antwerp is committed to providing the land for the construction of the facility, contributing up to €2 million to the project.
The total cost of the facility is roughly estimated to mount up to €25 million (excluding the land), comprising:
- "contained" facility of 1,200m^2 allowing residence of up to 15 volunteers (€10-12 m)
- Phase 1 clinical trial unit — 1,200m^2 (€2.5–3 m)
- BSL2 laboratory — 200 m^2 (€0.5 m)
- BSL3 laboratory — 200 m^2 (€5–6 m)
- Biobank — 400 m^2 (€2.5–3 m)
- Yearly public funding for trials in neglected diseases (€2.5–3 m)

B. Mobile Health Lab and Library
See Investment priority #9

Impact
Internal rates of return (IRR)[28] ranging between 5% and 7% have been observed for drug research and development.

Investment priority #9: Capitalising on the potential of genetics
Cost[29]

Year		19	20	22	24	Techno-logical growth curve	26	28	30	TOTAL
NGS & WGS	Reimburs.	0	2.5	5	10		20	30	40	107.5
	Invest. Incl. cohort	0	23	28	38		38	38	38	185
Mobile health lab & library	DG Echo	2	2	2	2		2	2	2	22
	Private	2	2	2	2		2	2	2	22
	Philanthropy	2	2	2	2		2	2	2	22
TOTAL		6	13.5	21	36		46	56	66	**268.5**

All public expenses could be covered by the additional investments of €375 million in health insurance with regard to the NGS & WGS reimbursements and investments, and the financial support of the European Commission (DG ECHO) with regards to the Mobile Health Lab and the Library.

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[27]   https://blogs.biomedcentral.com/on-medicine/2016/02/24/public-medical-research-funding-stimulates-private-rd-investment, April 2018
[28] McKinsey Perspectives on the Biopharma & medtech R&D Environment, 2013
[29] In million EUR

Impact

With an investment of €3 million per year in lung cancer diagnostics alone, the NIHDI budget could save €30 million annually:

Figure 9: Illustration of the potential of genomics for cost-effectiveness of healthcare
Source: OncoDNA