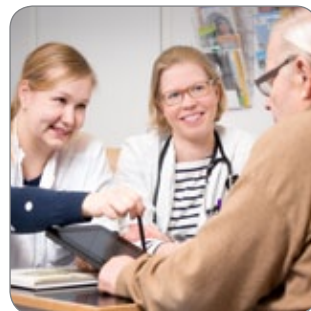


# Innovating together

Health Sector Growth Strategy  
for Research and Innovation Activities  
Roadmap for 2016–2018



# Health Sector Growth Strategy develops the entire innovation ecosystem and operating environment

## Target

Finland is an internationally known pioneer country in research and innovation, investments and new business in the health sector

## As a pioneer, Finland is

- A source of and able to utilise the high-level scientific research and innovations that are born out of that
- A dynamic operating environment for growth companies in the sector
- A model country for matching the health services system and innovation activities
- An attractive co-operation partner and a target country for investments in the health sector
- A forerunner in personalised health care and utilisation of genome data

## Key action areas

New forms of public-private co-operation

Strengthening of the competence base

Funding research and innovation

Research infra-structures

Commercialising of research

Innovation friendly policy and regulation

Enabling utilisation of health data in research

Marketing Finland's assets

## Enablers for growth and renewal

Demand and user driven approaches, networked ecosystem, co-operation across industry sectors and fields of science, digitalisation, innovative public procurement and an ability to combine data resources in research and innovation activities

## Building on our assets

Biobanks, genome data and health data registers

Versatile and high-level scientific research and expertise base

Networked university hospitals and high quality social welfare and health care services

ICT competences and start-up environment

### Abbreviations

MEC = Ministry for Education and Culture  
MEE = Ministry of Employment and the Economy  
MSAH = Ministry for Social Affairs and Health

HEI = Higher education institutions  
Tekes = the Finnish Funding Agency for Innovation

## To the reader

The health sector in Finland has grown and become more international at a faster pace than many other sectors in recent years. Health technology has turned into a high-tech export sector and a provider of employment of national importance. The growth in exports and research investments has not taken place by accident. Long-term investments in education, research, innovation and research infrastructures of this sector have been made in Finland. We have versatile multidisciplinary expertise, and the quality of the Finnish health care system is among the best in the world.

The Health Sector Growth Strategy for Research and Innovation Activities published in 2014 was prepared in collaboration by three ministries (Ministry of Employment and the Economy, Ministry of Social Affairs and Health, and Ministry of Education and Culture), funding providers for research and innovation i.e. Tekes and Academy of Finland as well as health sector actors. The Growth Strategy aims for expertise-driven improvement of citizens' health and well-being, for example, by using the possibilities created by the advancement of science and technology. At the same time, we can promote our country as an internationally renowned forerunner in health sector research and innovation, investment and new business.

Finland has every possibility of developing into a pioneering country and inter-

nationally desired partner for health care, top-class research and global business that utilise genome data. Strong coordination at the national level and common actors are a prerequisite for the full utilisation of the unique social welfare and health care data resources, sample resources of the biobanks and genome data. In order to achieve this pioneering position, the government has decided to invest in the necessary infrastructures, to set up the national organisations enabling the utilisation of genome data, and to intensify cooperation between the actors. In the drafting of new legislation, the citizens' fundamental rights, data protection and a research and innovation friendly operating environment will be taken into account.

The current Roadmap for 2016–2018 adds detail to the priorities and investments of Prime Minister Sipilä's government in order to accelerate the implementation of the Health Sector Growth Strategy for Research and Innovation Activities. By developing the operating environment for health sector research and innovation, we are investing in expertise, strengthening our assets to enable growth of exports and to attract investments. At the same time, we aim to utilise latest research and innovation to provide high quality of health care and social welfare for our citizens also in the future.

June 2016

**Sanni Grahn-Laasonen**  
Minister of Education and Culture

**Olli Rehn**  
Minister of Economic Affairs

**Hanna Mäntylä**  
Minister of Social Affairs and Health

**Juha Rehula**  
Minister of Family Affairs and Social Services

# Health Sector Growth Strategy for Research and Innovation Activities: Key Action Areas<sup>1</sup>

1. Universities and cities with university hospitals agree on action plans to develop hospital cluster research and innovation ecosystems and related cooperation with companies.
2. The profiles and research foci of higher education institutions, research institutes and university hospitals will be reinforced when developing the international competitiveness of competence clusters.
3. The health sector research community formed by research institutions and higher education institutions will increase their collaboration to maximise the impact and to better serve decision-making and society (participation of the private sector included).
4. Higher education institutions and research institutions in the central university cities will strengthen collaboration in technology transfer and commercialisation with a particular aim to reinforce sectoral cooperation on national level.
5. Through cooperation between Tekes and the Academy of Finland, funding instruments will be developed further, taking the special features of the health sector into consideration in order to facilitate the utilisation of research.
6. The state capital investment activities (Teollisuussijoitus Oy and Tekes) will consider the needs for risk capital in the health sector.



7. The Academy of Finland, Tekes and other public operators will consider the development of the health sector when strengthening their strategic and operational models for cooperation.
8. a) Access to personal health data and patient documents will be enabled for research purposes.  
b) National genome centre will be established, including legislation and guidelines for the utilisation of genome data.
9. A joint operation model will be drawn up to reinforce the work of relevant ministries and the business sector for exerting influence in the EU.
10. Introduction of innovative solutions will be encouraged when renewing health technology and pharmaceutical regulation as well as in the strategies of the health sector institutions. Innovative public procurement will be supported.
11. To support market entry of small and medium sized companies developing health technology and pharmaceuticals, training and advisory activities for regulation as well as standards will be enforced.
12. Systematic activities (Team Finland Health) will be initiated to attract foreign industry investments. An annual marketing plan for the sector will be prepared and implemented in cooperation with the sectoral associations and areas.



<sup>1</sup>Health Sector Growth Strategy for Research and Innovation Activities (Ministry of Employment and the Economy Reports 16/2014)

# 1 Universities and cities with university hospitals agree on action plans to develop hospital cluster research and innovation ecosystems and related cooperation with companies.

In recent years, different public-private cooperation models have been introduced to facilitate health sector research and innovation. Interest towards Finland as a research, development and piloting platform has increased lately. By means of cooperation and division of responsibilities, the innovation potential may be maximised, and the multidisciplinary competence basis can be utilised across a broader front. Key features of the new operating models are close public-private partnerships and common goals.

By developing national competence centres and regional ecosystems and their collaboration, it is possible to increase the efficiency and impact of research, development and innovation activities as well as Finland's attraction as a preferred location for experts and knowledge-intensive companies. Regional clusters combine the players of the regions, whereas sectoral hubs bring expertise together to strengthen

national collaboration.

The development of regional competence hubs and innovation campus operating models around university hospitals has been supported e.g. through Tekes' INKA (Innovative Cities) Future Health programme that will continue until the end of 2017. New hubs and clusters of competence that intensify innovation cooperation are emerging in large cities, where multidisciplinary and cross-industry cooperation in research, development, innovation and education activities is promoted. Activities have been initiated in Helsinki (Health Capital Helsinki), Kuopio (Health Kuopio), Oulu (OuluHealth Ecosystem), Tampere (Future Health Village), Turku (Health Campus Turku) and Jyväskylä. The six host universities of Biocenter Finland have undertaken to continue jointly developing the network of seven biocenters that offer life science technology services nationally.

The significance of university hospitals as competence hubs of specialised level services in their regions will be highlighted as the health care, social welfare and regional government reform is implemented. The government's policy approach on health care and social welfare of 7 November 2015 also notes that in connection with the reform, joint support services for the future autonomous regions will be created, including research coordination, procurement and equipment infrastructure services. Some of these support services will be provided regionally, some at the national level (see key action area 2).

In addition to regional competence hubs, national clusters of competence in different fields are also emerging in the health sector as outlined in the Government Programme (see key action area 3).



## Actions in 2016–2018

1. Implementing the innovation campuses and regional ecosystem plans (actors in cities with university hospitals and the INKA Future Health programme; 2016–2018)
2. Encouraging regional ecosystems to collaborate, joint development of operating models and sharing of good practices (INKA Future Health programme; 2016–2017)
3. The health care, social welfare and regional government reform package: establishing national and regional research coordination services and equipment infrastructure services shared by the new autonomous regions (MSAH, Ministry of Finance; 2017–2018, to be specified in the implementing act)
4. Supporting the division of responsibilities between the regions and regional competence hubs that reinforce smart specialisation through the growth agreements between the central government and urban regions (MEE; 2016–2018)
5. Supporting cooperation between higher education institutions (HEI), research institutes and companies in ecosystem initiatives that provide a platform for commercialising research and competences, starting new companies, and generating international business in selected priority areas, including the health sector. (The key project on knowledge and education 5, MEE, MSAH, MEC, Academy of Finland, Tekes)

## 2 The profiles and research foci of higher education institutions, research institutes and university hospitals will be reinforced when developing the international competitiveness of competence clusters.

In all policy areas, experts are encouraged to engage in national cooperation and division of responsibilities in order to improve quality.

By utilising the resources of different actors more efficiently and with higher impact in sectoral and regional competence hubs, new competence-based growth may be created in the health sector, and the possibilities of internationalisation may be exploited. Finland has world class expertise in several areas of therapy and technology. However, international visibility and partnerships with leading international experts can only be achieved through multidisciplinary and multi-actor cooperation, coordination and division of responsibilities between actors, fields of science and sectors.

These objectives have been promoted as part of a process aiming to develop cooperation between higher education institutions (HEIs) and research institutes (KOTUMO). This process promotes, among other things, cooperation between the ministries that direct research actors and the steering process of HEIs. The funding granted by the Academy of Finland for the profiling activities of universities has also contributed to reaching the targets.

The profiling of HEIs and structural measures implemented both inside and between them as well as with research institutes will be key objectives during the HEIs agreement term 2017–2020. A funding mechanism geared to supporting profiling of the universities was launched in 2015 and transferred from the university framework to the Academy of Finland. The universities compete for this

funding (EUR 50 million/year). For example, funding has been granted to support the Helsinki Life Science Center initiative that unites life science activities at Helsinki University and the Behavioural Life Sciences initiative that supports it, the joint research, teaching and development platform for pharmaceuticals and diagnostics of the University of Turku and Åbo Akademi University, development of the focus area of health and well-being at Aalto University, as well as development of the BioMediTech Institute jointly owned by the University of Tampere and Tampere University of Technology.

Up-to-date research infrastructures play a key role for guaranteeing a high quality of research as well as for the development of research and innovation system structures. The infrastructure environment of life sciences research has undergone extensive and long-term development both in terms of central government funding to universities and research infrastructure funding from the Academy of Finland. The Finnish Research Infrastructure Committee that operates under the Academy of Finland launched a study of the university hospitals' research infrastructures that will be completed in 2016. The purpose of this study is to build up knowledge of infrastructures in research use at hospitals, to open up possibilities of utilising new infrastructures for researchers, to intensify cooperation between university hospitals in the procurement and funding of research infrastructures, and to

promote the joint use of them. This will also be encouraged by setting up a data bank of research infrastructures as part of the Open Science and Research project.

The overall reform of health care and social welfare services, the implementation of the act on health care and social welfare services reform, and the update of the Health Care Act will improve the preconditions for establishing a division of responsibilities between university hospitals and their profiling under the guidance of the Ministry of Social Affairs and Health. The objectives and measures of the strategic Government Programme's key project on knowledge and education 5 will implement this objective in the life sciences and health sector.



### Actions in 2016–2018

1. In cooperation between the ministries, compiling the proposals for developing the division of responsibilities and cooperation received from HEIs and research institutes in February 2016, and preparing the decisions indicated by the proposals in the relevant ministries during 2016 (the key project on knowledge and education 5)
2. Directing the resources of HEIs and research institutes at creating competence hubs and business cooperation as indicated by their profiles (players in health sector competence hubs)
3. Supporting the profiling of universities, also in the health sector (Academy of Finland, 2016–)
4. Planning and implementing measures indicated by the results of mapping the research infrastructures at university hospitals (Academy of Finland; 2016–2018)
5. Mapping the needs and experiences of companies related to joint use and funding of research infrastructures and development environments (MEE, Tekes; 2016)



### 3 The health sector research community formed by research institutions and higher education institutions will increase their collaboration to maximise the impact and to better serve decision-making and society (participation of the private sector included).

Research institutions should operate in close cooperation with university hospital campuses and biobanks and ensure that particularly personalised medicine solutions are developed in Finland and that they are integrated to primary health care and specialised health care.

Valuable collections of human biological samples and health care register databases have been accumulated in Finland for decades. As the Biobank Act (688/2012) entered into force on 1 September 2013, broader access to the sample collections and the related data has become possible.

Following the launch of biobank activities, it is necessary to intensify cooperation and agree on standard practices at the national level. To develop the activities, such as joint IT infrastructure, uniform consent procedures and solutions that ensure the quality and usability of data are required. A uniform operating model applied to customer companies and partners as well as good organisation of the activities and usability of collections may reinforce Finland's position as a sought-after partner in research and product development cooperation.

The mid-term report of the Biobank Act steering group (MSAH 2016:26) contains a review of the launch of the activities, the national and international operating environment, and needs for legislative amendments. Among other things, the planned amendments aim to simplify and specify the consent procedure to enable the use of biobanks in the introduction of personalised medicine, especially genome data.

In keeping with Government Programme objectives, internationally competitive national competence hubs are emerging in different sectors

in Finland. In the health sector, this means public-private cooperation models that combine the competence and resources of university hospitals, universities and research institutes as well as companies. The goal is to speed up the development of new medical treatments, health technology products and service concepts and getting references for companies in Finland.

The prerequisites for establishing the Comprehensive Cancer Centre Finland, FICAN, which will play a key role in the introduction of personalised medicine, have been investigated by several working groups (the latest report by MSAH 2014:13; a further working group appointed in March 2016). Regulation on the national centralisation of specialised services will be updated in connection with the health care and social welfare reform package. This will provide better preconditions for the establishment of FICAN and other similar cooperation structures, research cooperation conducted within their framework, and the development of new personalised medical treatments, diagnostics and health technology.

Research coordination services will also be developed in the so-called well-being data service operator project (see key action area 8a) and as part of national implementation of the EU Clinical Trials Regulation (536/2014) (see key action area 10).

#### Actions in 2016–2018

1. Carrying out an investigation of co-operation and mergers between public biobanks (MSAH, National Institute for Health and Welfare, MEC, biobanks; 2016)
2. Enhancing the actions of the public biobanks by harmonising their ways of working and ensuring effective co-operation with the National Genome Centre that will be established (The key project for employment and competitiveness 1, MSAH, MEE, Ministry for Justice; 2016–2019)
3. After the launch of biobank activities, making any necessary amendments in the Biobank Act (in particular, the consent procedures), (MSAH; autumn 2016)
4. Promoting the establishment of the Comprehensive Cancer Centre Finland by laying down provisions on the coordination duties of university hospital districts (in the future, regions) in the Health Care Act and the Government Decree to be issued by virtue of it (MSAH) and investigating other further measures needed for its establishment, including the funding base (MSAH, MEC, MEE, university hospital districts/ regions, the National Institute for Health and Welfare)
5. Establishing the Comprehensive Cancer Centre Finland with a coordinating role to coordinate the work of the regional centres (The key project for employment and competitiveness 1, MSAH, MEE, MEC; 2016–2020)

## 4 Higher education institutions and research institutions in the central university cities will strengthen collaboration in technology transfer and commercialisation with a particular aim to reinforce sectoral cooperation on national level.

New regional hubs and clusters of competence that intensify innovation cooperation are emerging in connection with large cities, where cooperation in research, development, innovation, technology transfer and education activities is promoted with a multidisciplinary approach (see key action area 1). By intensifying national cooperation and division of responsibilities also in technology transfer, commercialisation and business accelerator activities, significant economies of scale and international visibility could be achieved in the health sector, thus promoting the application and utilisation of research and accelerating the market access of innovations.

One of the goals of the government's key project on knowledge and education 5 is to reform the service structures, processes and career

development models that support the utilisation and commercialisation of research as part of the multiannual process aiming to intensify cooperation between HEIs and research institutes. In February 2016, the ministries requested for their proposals on developing the division of responsibilities and cooperation (see key action area 2).

Key project funding (EUR 59 million) granted to Tekes aims for faster utilisation of research results. Some of the funding will be allocated to building up the innovation and commercialisation skills of HEIs and research institutes as well as developing service processes that support commercialisation (Innovation Scout).

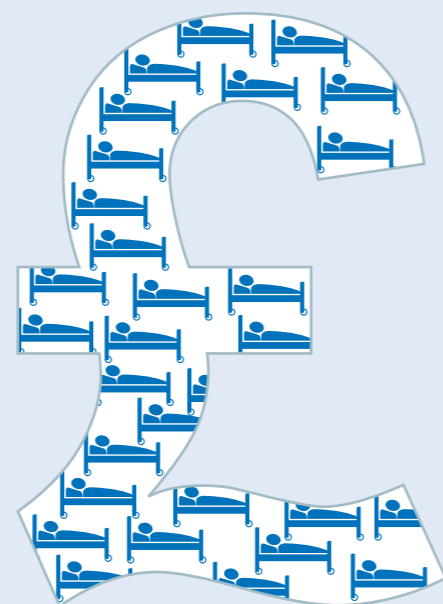
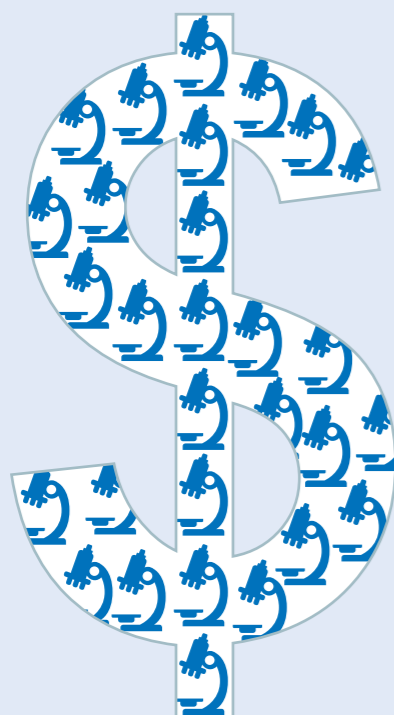
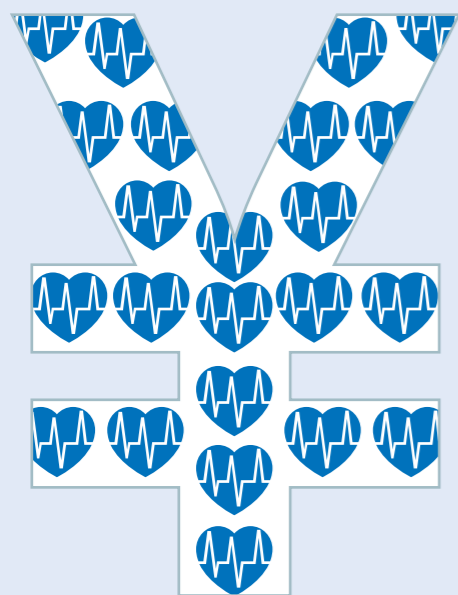
The role of the National Institute for Health and Welfare in the emerging health sector ecosystem is also becoming clearer. The Institute has investi-

gated data policies that enable the efficient use of data and the possibilities of cooperation. It commissioned a study on the legal conditions of business cooperation and its societal acceptability, and together with the Ministry of Social Affairs and Health, it is carrying out a further examination of business cooperation as internal development work.

### Actions in 2016–2018

1. By means of steering and public funding, encouraging HEIs to engage in research cooperation and to enhance the impact and commercialisation of research results, ensuring that they become strategic choices for HEIs and that ambitious targets are set (Key project on knowledge and education, MEC, MEE; 2016–2017)
2. Encouraging health sector actors to take up Innovation Scout funding (service processes and commercialisation competence) (Tekes; 2016–2017)
3. Reforming the service structures, processes and career development models that support the utilisation and commercialisation of research as part of the multi-annual process of intensifying cooperation between HEIs and research institutes (Key project on knowledge and education, MEC, MEE; 2016–2017)
4. Encouraging health sector actors to pilot the implementation of research organisations' joint commercialisation and innovation services (MEE, MEC)





## 5 Through cooperation between Tekes and the Academy of Finland, funding instruments will be developed further, taking the special features of the health sector into consideration in order to facilitate the utilisation of research.

Researchers and research teams will be encouraged to develop further ideas that have international growth potential into inventions that lend themselves to commercial utilisation.

The high-level research in the health sector in Finland could be utilised considerably better to bolster growth and competitiveness and to support decision-making. Compared to other sectors, a long and capital-intensive phase between research results and commercialisation or market entry is a typical characteristic of the health industries.

In the funding for health sector research provided by Tekes and the Academy of Finland and in the development of mutually complementary funding instruments, key objectives include increasing the impact of research and enabling the utilisation of research results.

Networking between researchers and companies can enable the creation of new and even radical innovations. Research of an internationally high standard and bold experiments in its utilisation create opportunities for research and business life alike.

In 2015, Tekes and the Academy of Finland piloted their funding cooperation in the so-called plug-in experiment that promoted interaction between business life and top level health sector research funded by the Academy, and the commercial utilisation of scientific results. All 12 research projects that were funded were of a high standard. Most of them were launched in autumn 2015. The experiences gained in this experiment that targeted the commercialisation of leading edge research will also be utilised in other areas of research.

The cooperation between Tekes and the Academy of Finland aiming to promote the utilisation of research has been reinforced by such means as organising the funding for key projects as an interoperable and mutually complementary mechanism. In keeping with the key project on knowledge and education, Tekes' current instruments that support the commercialisation of research will be developed, and new funding instruments (EUR 59 million) will be introduced to improve the matching of public research to business life needs as well as to raise awareness among scientists of the commercial potential of research and entrepreneurship, also in the health sector. The key project funding (EUR 30 million) of the Academy of Finland will be allocated to research projects that have already been highly rated and especially geared towards early-career researchers for cooperation between HEIs and business life to bring innovations to the market.

### Actions in 2016–2018

1. Scientists and research teams in the health sector will be encouraged to identify internationally competitive ideas and develop them into solutions that lend themselves to commercial utilisation, and to make use of key project funding (Key project on knowledge and education 5, Academy of Finland, Tekes; 2016–2018)
  - Challenge Finland: targeted at solving societal challenges in joint projects of companies and research organisations – carried out as a competition (Tekes)
  - Research Benefit: targeted at the commercialisation of the most promising research results in joint projects between companies and research organisations (Tekes)
  - Innovation Scout: targeted at reinforcing the innovation and commercialisation expertise at HEIs and research institutes as well as the development of service processes that support commercialisation (Tekes)
  - Key project funding: support for the utilisation of research results, funding, geared towards early-career researchers (Academy of Finland)



## 6 The state capital investment activities (Teollisuussijoitus Oy and Tekes) will consider the needs for risk capital in the health sector.

The greatest problem related to growth funding lies in the scarcity of private capital. Numerous legislative obstacles restrict the availability of private capital for the growth and internationalisation of companies. Removing these obstacles and restrictions would create a possibility to increase growth funding for companies while promoting the development of the risk capital market. The market value of investment assets held by Finnish foundations and non-profit organisations is some EUR 20 billion. By targeting only a few percent of these investments at growth enterprises, hundreds of millions of euros of new capital could be released in the market, also serving the needs of health sector growth enterprises.

Teollisuussijoitus Oy is a state capital investment company that promotes Finnish entrepreneurship, employment and economic growth through private equity investments and international networking. It invests in private equity funds and directly in Finnish companies.

### Actions in 2016–2018

1. Continuing the implementation of the Industrial Renewal programme (Teollisuussijoitus Oy)
2. Ensuring that early-stage research-driven companies in the health sector are not overlooked by the venture capital funds that Tekes Pääomasijoitus Oy is investing in (Tekes; 2016–2018)
3. Investigating neutral tax treatment of investments made in private equity funds by foundations and non-profit organisations in order to increase the offer of private growth funding (2017)

Teollisuussijoitus Oy's Industrial Renewal programme launched in 2014 is directed at growth-seeking Finnish SMEs. The investments are made on market terms, mainly as minority holdings. The goal of the programme is to invest EUR 100 million in industrial enterprises. Health technology is one of its priority areas.

Tekes Pääomasijoitus Oy invests in venture capital funds which invest in companies in their early stages of development. The investments of equity funds are managed by private management companies, and the funds are invested in Finnish early-stage companies, including health sector companies.

As part of key project funding, EUR 20 million have been allocated to Tekes Venture Capital for private equity funds that provide risk finance for early-stage, research-driven companies, also in the health sector.



## 7 The Academy of Finland, Tekes and other public operators will consider the development of the health sector when strengthening their strategic and operational models for cooperation.

The most significant public funding providers for research and innovation in the health sector are Tekes and the Academy of Finland. Their close strategic and operative cooperation in the funding of health and well-being research, in the utilisation of its results and in networking will increase the impact and commercialisation potential of research. As part of processing key project applications submitted to the Academy of Finland, Tekes assesses their potential for business and need of support for achieving commercial success. This is done for applications by projects that meet the scientific quality criteria of the Academy and are funded by it.

Health and well-being are focal areas in the activities of both Tekes and the Academy of Finland. The Academy provides over EUR 40 million of funding for health sector research annually (EUR 41.6 million in 2014). In addition, almost EUR 10 million is channelled to support research in this sector through funding for research infrastructures. The research programme "Personalised Health – From Genes to Society" will provide funding amounting to EUR 10 million for health sector research in 2015–2019. One of the themes selected by the Strategic Research Council at the Academy of Finland for 2016–2019 is health, well-being and lifestyles.

Tekes funding in the area of health and well-being totalled some EUR 90 million in 2015. Tekes programme Bits of Health (2014–2018) aims to turn Finland into a significant operating environment and ecosystem of digital health where internationally successful companies emerge and

evolve and where funding is granted to needs-driven research and research organisations network with companies. The estimated total volume of this programme is EUR 100 million, and Tekes' total funding will be EUR 50 million.

Tekes and the Academy of Finland will work together, in particular to promote the internationalisation of personalised medicine and research that uses genome data. The "Personalised Health – From Genes to Society" research programme of the Academy of Finland is building an international dimension in collaboration with the NSF, a key finance provider for science in the United States.

### Actions in 2016–2018

1. Launching the COHORT research programme that will improve the efficiency of cohort and biobank utilisation and the coordination of cooperation (Academy of Finland; 2016)
2. Continuing the implementation of the "Personalised Health – From Genes to Society" programme (Academy of Finland; 2016–2019)
3. Funding health sector research under the Strategic Research Council's theme of health, well-being and lifestyles (Academy of Finland; 2016–2019)
4. Continuing Bits of Health programme implementation (Tekes; 2016–2018)
5. Investigating the possibilities for closer Nordic research and innovation cooperation in the health sector, for example, through the EU's Baltic Sea Region programme and NordForsk's Health and Welfare programmes (MSAH, MEE, Academy of Finland, Tekes)

## 8a Access to personal health data and patient documents will be enabled for research purposes.

The goal of the “Information to Support Well-being and Service Renewal, eHealth and eSocial Strategy 2020” (MSAH; 2015) is to expand the utilisation of well-being and health data in social welfare and health care, research and product development, as well as to provide easier access to this data and to ensure that the data is safe and reliable.

Well-being and health data on individuals and, above all, information on the use of social welfare and health care services, is collected in a number of national and local systems. More advanced applications and technologies have given individuals better possibilities of collecting information related to their personal well-being. By combining health and well-being data and information on service use, an information basis of international significance in terms of its quality and scale can be compiled for the benefit of citizens, customers, the social welfare and health care system, research institutes and companies alike.

The Ministry of Social Affairs and Health has made a decision to expand the citizens’ My Kanta pages, which are a part of the Kanta service, so that individual citizens can save their personal health and well-being data

in it. An innovation platform will be developed in collaboration with other actors that will enable the utilisation of this data and the development of applications that serve the health and well-being of individual citizens.

The plan is to harness these data resources, which are unique by international standards, for more extensive use and utilisation closer to the individual. Information from different sources should be offered smoothly, following the so-called one-stop shop principle.

The legislation on the secondary use of customer and patient data needs to be modernised to facilitate the utilisation of both social welfare and health care data as well as the well-being data collected by the citizens themselves, and also to enable the smooth interoperability of these data sources in research and innovation activities.

Enabling legislation will create preconditions for a new kind of well-being service operator. The operator will be able to combine health and well-being data from different sources and registers and to serve those in need of this information through a single access point, an electronic service, safely and reliably.

The Ministry of Social Affairs and

Health is drafting legislation that will enable the use of social welfare and health care data, and Sitra (the Finnish Innovation Fund) launched a project in autumn 2015 to prepare for the establishment of an organisation focused on gathering and coordinating well-being data. The working title is Isaacus – the Digital Health Hub. This service operator could be tasked to provide, through a single access point, data related to well-being (e.g. patient, demographic and lifestyle data) and open data gathered from various registers and sources. This work would be carried out in broad-based cooperation with the public, the private and the third sector. The aim is that the service operator could enable the use of the data for research focusing on the development of the service and the associated ecosystem, and for development, innovation, management by information, product development and digital solutions.

The objective is that, during the current government term, a single joint organisation will be established in Finland that may be contacted by researchers and companies considering research investments and cooperation and that will provide the services they need.

### Actions in 2016–2018

1. Continuing the implementation of the Information to Support Well-being and Service Renewal, eHealth and eSocial Strategy 2020 (MSAH)
2. Developing the My Kanta service and its ecosystem (MSAH, Tekes, Social Insurance Institution, National Institute for Health and Welfare; 2016–2017)
3. Preparation of the legal framework, operating principles and funding alternatives for the national service operator for well-being data (MSAH, Ministry of Finance, MEC, MEE, the Isaacus project/Sitra; 2016-6/2017)
4. Updating the legislation on secondary use of social welfare and health care system customer and patient data (MSAH; 2016–2017)



## 8b National genome centre will be established, including legislation and guidelines for the utilisation of genome data.

Progress made in genome research heralds a new era in medicine. In the future, health promotion and the treatment of illnesses will frequently be planned individually, based on information obtained from the genome. The use of genome data, or data on the entire human genome, in health care will become more widespread over the next few years, and national preparedness for this is needed going beyond the biobank activities.

The Ministry of Social Affairs and Health, Sitra and the stakeholders prepared a proposal for a National Genome Strategy in 2015. It sets out key measures for ensuring that in 2020, genome data will be used in Finland efficiently to improve human health in the health services and in decision-making that promotes health and well-being. Preconditions for reaching this target include the establishment of a national genome

The use of genome data will increase in health care

database and the possibility of using it in patient care, scientific research and innovation activities.

Because of the great business potential of research and product development that utilise genome data, Finland will invest in establishing the necessary infrastructures. High-quality

biobanks, information systems and health care registers as well as the homogeneous nature of the genome are Finnish strengths that the international pharmaceutical industry as well as diagnostics and health technology companies are interested in utilising.

The first measure will be drafting legislation on the use of genome data. The establishment of the National Genome Centre to administer the Finnish genome database and its use will greatly promote people's possibilities to benefit from their personal genome data, improve the

efficiency of scientific research in the field and facilitate development activities. The results will directly benefit Finnish people and increasingly personalised health care in Finland. According to the General Government Fiscal Plan, EUR 17 million of funding has been earmarked for the establishment of the National Genome Centre and the Comprehensive Cancer Centre Finland, and for the harmonisation of biobank activities in 2017–2019.

The utilisation of genome data will be promoted by the harmonisation of biobank activities, establishment of the Comprehensive Cancer Centre Finland as well as the instigation of an actor that will focus on gathering and coordinating well-being data (see key sets of measures 3, 8a).

### Actions in 2016–2018

1. Starting National Genome Strategy implementation with the formulation of ethical principles. Launching preliminary work on an act on the National Genome Centre and the use of genome data in health care and scientific research on health (MSAH, Ministry of Justice; 2016–2017). The government bill could be completed in autumn 2017
2. Investigating the preconditions for establishing the National Genome Centre, with special reference to biobank cooperation, information management solutions and the funding basis (Key project for employment and competitiveness 1, MSAH, MEC, MEE, the universities, biobank actors and research institutes, CSC; 2016–2017)
3. Establishing the most effective methods of utilising Finnish biobanks and health databases in pharmaceutical development in the precompetitive stage. Enabling stepwise progress to companies' research investments (MSAH, National Institute for Health and Welfare, MEE, MEC, biobank actors, universities, hospital districts/autonomous regions, CSC; 2016–2018)



## 9 A joint operation model will be drawn up to reinforce the work of relevant ministries and the business sector for exerting influence in the EU.

The majority of health sector regulation comes through the European Union. EU Regulations and Directives have an impact on the development and take-up of innovations in the pharmaceutical and health technology sectors, both directly and through national legislation.

Topical examples of trends that have an impact on the innovation environment include the work to update the regulation on medical devices and in vitro diagnostics as well as the EU General Data Protection Regulation.

Development efforts that play a significant role for the competitiveness of the health sector are also carried out at the EU level in the context of research infrastructures, standards, funding instruments and programmes alike.

Finland and Europe can be lead markets in health sector

By working more closely together, the ministries can proactively influence the development of the operating environment. The goal is to promote the prerequisites of the health sector to be a lead market both in Finland and in Europe.

The Academy of Finland and Tekes are working closely together to promote Finnish participation in the funding applications related to the health challenge (Health, Demographic Change and Well-being that is part of the EU Framework Programme for Research and Innovation, Horizon 2020.

In 2014–2015, Finnish actors have bagged a total of EUR 17.2 million of this funding for health-related research and innovation activities carried out in Finland.

The agenda of the second programming period of the EU's Innovative Medicines Initiative (IMI2, 2014–2024) features several Finnish areas of strength, including eHealth, personalised health care, diabetes and multidisciplinary research in ageing. Tekes and the Academy of Finland have actively brought up views collected from Finnish stakeholders on the scientific priority areas of the programme and, together with the IMI, encouraged Finnish SMEs and small research organisations to engage in cooperation with an extensive international network of companies and experts. Finnish actors have submitted 37 applications to IMI2 funding rounds (1–6) in 2014–2016.

Academy of Finland and Tekes actors promote the possibilities of Finnish health sector research in the EU by influencing at various levels such as with national EU actors, European Commission and EU policy-makers.

### Actions in 2016–2018

1. Identifying key EU projects of the next few years that have major significance for the preconditions of health sector growth in Finland. Agreeing upon cooperation and division of responsibilities between the branches of administration, using the resources of the relevant sections of the government, and engaging in dialogue with business life and other stakeholders (MEE, MEC, MSAH, Academy of Finland and Tekes, 2016–2018)
2. Striving for a bigger impact on EU work programmes and health-related themes. Supporting participation in application processes (MEE, MEC, MSAH, Academy of Finland and Tekes)
3. Raising awareness of health sector EU programmes and the possibilities of utilising them; activating Finnish companies and research organisations to take advantage of them. Continuing the consultation work related to the Innovative Medicines Initiative and applications (Tekes; 2016–2018)



# 10 Introduction of innovative solutions will be encouraged when renewing health technology and pharmaceutical regulation as well as in the strategies of the health sector institutions. Innovative public procurement will be supported.

As part of the Health Sector Growth Strategy, a study was commissioned in 2015 that charted the views of companies and research and innovation actors on regulations or their implementation practices that groundlessly slow down or hamper health sector research and innovation activities. Scope for improvement was found, among other things, in the permit processes related to research, utilisation of health care registers, agreement practices related to research cooperation as well as market access for innovations.

The government has set the target at five percent of all public procurements being innovative in nature. As the health care, social welfare and regional government reform package is implemented, innovative new solutions will be needed to support the renewal of activities, enabling increased productivity and impact. The domestic market could serve as a development environment and reference for innovative solutions. In this context, innovative public procurements are a resource for generating new jobs, business and also exports. The Ministry of Social Affairs and Health and Tekes together with the hospital districts have launched

a project aiming to promote competence related to innovative public procurement.

The results of the study on regulation will also be utilised in on-going



drafting and development efforts (legislation on secondary use of social welfare and health care sector customer and patient data, implementation of Regulation 536/2014 on clinical trials of medicines as well as an assessment of needs to update the Act on the Right in Inventions Made at Higher Education Institutions).

The EU Regulation on clinical trials on medicinal products (536/2014) was published on 27 May 2014. As far as is known at the moment, the regulation will be applied at the latest from October 2018. The Ministry of Social Affairs and Health has prepared for the regulation's entry into force, and a working group on the rearrangement of ethical reviews and more detailed preparation was appointed in August 2015. Our current ethical review system does not meet the requirements of the regulation, as it is unlikely that we can adapt it to the stringent criteria concerning schedules contained in the new regulation. In the national implementation of the EU Clinical Trials Regulation, the solutions must be streamlined, serve the actors and thus support attracting research to Finland.

The joint procurement unit to be set up in connection with health care, social welfare and regional government reform package will centralise competitive bidding, perform joint procurement functions, and provide support in cooperation with the current areas with special responsibilities on specialised care and the future autonomous regions (2017).

## Actions in 2016–2018

1. Monitoring progress made in the areas pinpointed by the study on regulation (MEE; MSAH, Ministry of Justice; 2016–2018)
2. Implementing the EU Regulation on Clinical Trials and, in this connection, reforming and improving the national ethical review system for research projects to make it more streamlined (MSAH; 2017–2018)
3. Developing competence related to innovative public procurements and promoting the sharing of good practices in the health sector (Ministry of Finance, MSAH, Innokylä innovation community, MEE, Tekes; 2016–2017)
4. Encouraging cities to utilise innovative public procurements to generate international level references, both within the framework of the growth agreements between the central government and urban regions (2016–2018) and under the auspices of the INKA Future Health programme (2016–2017)

# 11 To support market entry of small and medium sized companies developing health technology and pharmaceuticals, training and advisory activities for regulation as well as standards will be enforced.

There are plenty of standards and regulation in the health sector, and they change rapidly both in the EU and the global environment. Shortcomings in mastering regulations and standards may hamper and delay the market access of innovations. In particular, start-ups and SMEs need timely support and advice.

By improving companies' awareness of regulation and standards, market access of innovations can be speeded up. On request, the supervisory authority in the medicines sector (Finnish Medicines Agency, Fimea) provides scientific advice for researchers and pharmaceutical companies (especially small start-ups). Advice may be requested in relation to planned or completed studies and analyses of the documentation of the quality, potency and safety of medicinal products intended for humans or animals. European medical regulatory authorities also work together to provide advice related to medicines. The "EU Innovation Network" developed by Fimea is a model where the medical regulatory authorities of small countries work together to provide advice related to the research and development



of pharmaceuticals. These activities are coordinated by the European Medicines Agency EMA. Fimea is actively involved in the European advisory cooperation and disseminates information on the possibilities of academic researchers and pharmaceutical companies to avail themselves of confidential advisory services. Centralising and developing competence supports Finnish research in medicines and the market

access of innovations. Advice may also be provided for foreign actors and funding providers, either in Finland or elsewhere.

Health technology companies' awareness of regulation and standards has been raised by means of a health technology regulation guide and e-learning package produced jointly by Tekes and The Finnish Health Technology Association (FiHTA) at [reguloiko.fi](http://reguloiko.fi).

## Actions in 2016–2018

1. Developing and continuing advisory activities offered for scientists and pharmaceutical companies (Fimea, universities, pharmaceutical companies; 2016–)
2. Updating the health technology regulation guide and e-learning package (Tekes, FiHTA; 2017)
3. Producing a pharmaceuticals sector regulation guide as well as a communication and training package. The guide will mainly be intended to support start-ups and growth enterprises in improving their competitiveness and to offer support for networking and internationalisation (Tekes, Fimea; 2016)

# 12 Systematic activities (Team Finland Health) will be initiated to attract foreign industry investments. An annual marketing plan for the sector will be prepared and implemented in cooperation with the sectoral associations and areas.

Thanks to Finnish competence, innovations, research and developing operating environment, Finland is well placed to benefit from international growth in the health sector. Finland has a multidisciplinary skills base in the areas of health technology and medicine. However, this know-how has not been marketed adequately to the rest of the world.

The objective of the Team Finland Health growth programme administered by Finpro is to build and reinforce Finland's recognisability as a pioneer of health sector research, education, innovations and business and an interesting object of investments as well as to promote the growth of exports by

We need to build awareness of Finland's offering together

Finnish health sector companies.

The international visibility of the health sector requires a marketing angle that is wider than that of a single area, product or company. Team Finland Health growth programme raises Finland's profile in the health sector, as well as lays a foundation and creates models for cooperation in attracting investments and supporting SME's international growth and exports.

When planning investments, a predictable operating environment is an important criterion. The health industries are one of the strategic priority areas of the government's growth policy. Investments are being

made in Finland in systematic development of the health sector research, education, infrastructures and health data. To ensure that the stakeholders are aware of the strengths of the operating environment and the active efforts made to improve it, it is important to offer up-to-date information about the priorities and implementation of the Health Sector Growth Strategy.

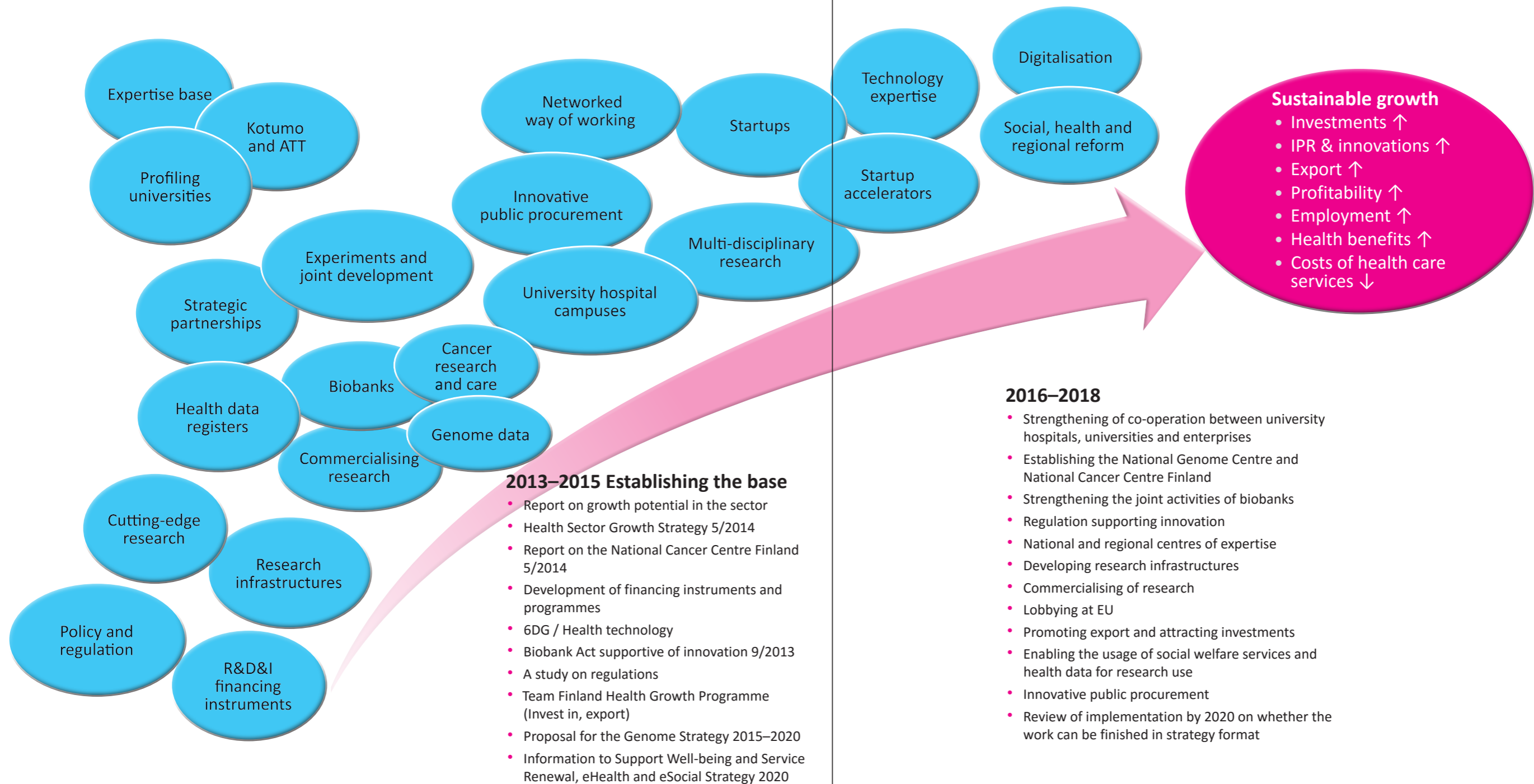
The international operating environment is developing rapidly. By engaging in regular dialogue with different players in the ecosystem, both in Finland and internationally, it is possible to account for and anticipate international trends that are essential for the development of the operating environment in different phases of strategy implementation.

## Actions in 2016–2018

1. Implementing Team Finland Health growth programme (Finpro; 2016–2017)
  - Mapping the Finnish assets, key competences and the strengths of the operating environment from investment point of view (2016)
  - Building a digital window of assets for the Finnish health sector, [www.finlandhealth.fi](http://www.finlandhealth.fi) (2016) and utilising it in marketing Finland (2016–2017)
  - In cooperation with key regional and national players, preparing an annual marketing plan for the sector (2016–2017)
  - Support SMEs in internationalisation by facilitating presence of Finnish companies to international health sector events, delegation trips. Organise customer and partner visits and consider bringing international events of the sector to Finland (2016–2017)
  - Supporting Finland's visibility in international health sector markets (2016–2017)
  - Organisation of investment-focused business visits to Finland (2016–2017)
2. Intensifying dialogue between public actors and business life (MEE, MSAH, MEC, Tekes, Academy of Finland, Team Finland actors and sectoral organisations; 2016–2018)
3. Communicating about the Health Sector Growth Strategy in individual projects and as a whole (MEE, MSAH, MEC, Tekes, Academy of Finland, Team Finland actors; 2016–2018)



# Health Sector Growth Strategy for Research and Innovation Activities – Roadmap



More information on the Health Sector Growth Strategy for Research and Innovation Activities:  
[www.tem.fi/terveysalan-kasvustrategia](http://www.tem.fi/terveysalan-kasvustrategia)

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