IMPROVING HEALTH THROUGH THE USE OF GENOMIC DATA

Finland´s Genome Strategy
Working Group Proposal

MINISTRY OF
SOCIAL AFFAIRS AND HEALTH

ABSTRACT

Recent advances in genomic research are leading to a new era in medicine. In the next few years, the use of genomic data in healthcare will rapidly increase. In the future, decisions regarding the prevention and treatment of diseases will be increasingly based on an individual's genetic makeup. This major change in medicine requires careful preparation.

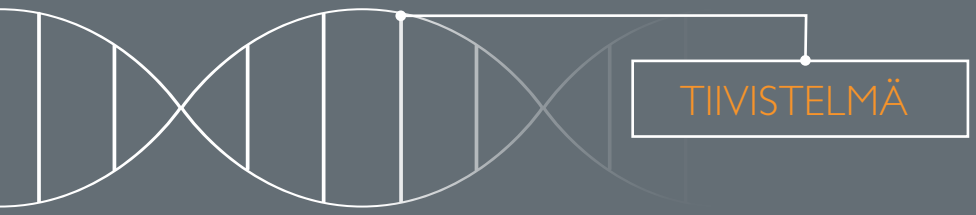
The National Genome Strategy sets key measures for ensuring that, by 2020, genomic data will be effectively used in healthcare and in the promotion of health and wellbeing. Achieving this objective will require development of a Finnish national reference database of genomes to be used in clinical care and research. The capacity of healthcare professionals to apply genome-based information should be strengthened, and people need to be empowered to improve their own health by effective use of genomic information.

The working group proposes the establishment of a national genome centre that would bring together all parties within the field of genomics. The centre will have the responsibility for development of the national reference database and for implementing many of the actions included in the genome strategy. A legal framework should be developed for the genome centre, and government funding for the centre needs to be secured. A strong tradition of genetic research in Finland, the existing comprehensive health registers and population databases, and the high quality sample collections in biobanks are valuable assets that provide a solid basis for implementing the proposed actions.

Finland has the potential to grow into an internationally interesting partner in genomics research and genomics-related enterprise. This objective can be achieved through closer cooperation between the relevant stakeholders in Finland and by entrusting the national genome centre with the negotiation of contracts on behalf of the Finnish partnership network. A national service point at the genome centre would enhance genomics research and innovation, benefiting directly both Finns and Finland's health services. However, the window of opportunity for exploiting Finland's strengths will be open for a few years at best.

KEY WORDS:

DATA PROTECTION | DATA SECURITY | GENE TESTS | GENES | GENOME | GENOMICS
PERSONALISED MEDICINE | PHARMACOGENETICS



TIIVISTELMÄ

Perimän tutkimuksessa saavutetut edistysaskeleet johtavat uuteen aikakauteen lääketieteessä. Genomitiedon eli ihmisen koko perimästä saatavan tiedon käyttö terveydenhuollossa yleistyy lähivuosina. Tulevaisuudessa terveyden edistäminen ja sairauksien hoito suunnitellaan usein yksilöllisesti perimästä saatavan tiedon perusteella. Tähän muutokseen on valmistauduttava huolella.

Kansallisessa genomistrategiassa esitetään keskeiset toimenpiteet, joilla varmistetaan genomitiedon tehokas hyödyntäminen terveydenhuollossa sekä terveyttä ja hyvinvointia edistävässä päätöksenteossa vuonna 2020. Tavoitteeseen pääseminen edellyttää kansallisen genomitietokannan perustamista ja tietokannan hyödyntämistä potilaiden hoidossa ja tieteellisessä tutkimuksessa. Lisäksi on vahvistettava terveydenhuollon ammattilaisten valmiuksia käyttää genomitietoa sekä ihmisten kykyä tehdä terveyteensä liittyviä päätöksiä.

Työryhmä esittää kansallisen, kaikki toimijat yhdistävän genomikeskuksen perustamista. Sen tehtävänä on vastata valtakunnallisen genomitietokannan kehittämisestä ja useiden genomistrategiaan sisältyvien toimenpiteiden toimeenpanosta. Genomikeskuksen perustamisesta olisi säädettävä lailla ja sen kansallinen rahoitus olisi varmistettava. Suomen vankka osaaminen geenitutkimuksessa, kattavat terveystietojen tietovarannot ja biopankkien korkealaatuiset näytekokoelmat muodostavat huomattavan kansallisen pääoman, johon perustuen ehdotetut toimenpiteet voidaan toteuttaa.

Suomella on kaikki edellytykset nousta kansainvälisesti tavoitelluksi yhteistyökumppaniksi genomitutkimuksessa ja genomiikka-alan yritystoiminnassa. Tämä tavoite saavutetaan tiivistämällä toimijakentän yhteistyötä ja antamalla genomikeskukselle valtuudet valmistella keskitetysti sopimuksia suomalaisen yhteistyöverkoston puolesta. Kansallisen palvelupisteen luominen genomikeskukseen tehostaisi suuresti genomitutkimusta ja alan kehitystoimintaa, joiden tulokset hyödyttäisivät suoraan suomalaisia ja suomalaista terveydenhuoltoa. Aikailuun ei kuitenkaan ole syytä. Aikaikkuna Suomen vahvuuksien hyödyntämiselle on korkeintaan muutama vuosi.

ASIASANAT:

FARMAKOGENETIIKKA | GEENIT | GENOMI | GEENITESTIT | GENOMIIKKA | PERIMÄ
TIETOSUOJA | TIETOTURVA | YKSILÖLLISTETTY LÄÄKETIEDE

SAMMANDRAG

Framstegen inom genomforskningen håller på att inleda en ny tidsera inom medicinen. Användningen av genominformation, dvs. information om människans hela arvsmassa, kommer under de närmaste åren att öka inom hälso- och sjukvården. I framtiden kommer hälsofrämjande och vård av sjukdomar ofta att planeras individuellt utifrån den information som fås från genomet. Den här förändringen måste man omsorgsfullt förbereda sig inför.

I den nationella genomstrategin föreslås centrala åtgärder genom vilka det kan säkerställas att man i Finland år 2020 effektivt använder genominformation till godo för människornas hälsa inom hälsovården och i beslutsfattande som främjar hälsa och välmående. För att målet ska uppnås krävs det att det inrättas en nationell genomdatabas som det är möjligt att utnyttja i vården av patienter och i vetenskaplig forskning. Det kunnande som yrkespersoner inom hälso- och sjukvården har att använda genominformation och den förmåga som människor har att fatta beslut som berör den egna hälsan behöver stärkas.

Arbetsgruppen föreslår att det inrättas ett nationellt genomcentrum som förenar alla aktörer och som ska svara för utvecklandet av den nationella genomdatabasen och genomförandet av flera av de åtgärder som ingår i genomstrategin. Förslaget innebär att det föreskrivs genom lag om inrättande av ett genomcentrum och att den nationella finansieringen säkerställs. Finlands gedigna kunnande inom den genetiska forskningen, de heltäckande datalagren för hälsodata och de högkvalitativa provsamlingarna i biobankerna bildar ett betydande nationellt kapital som genomförandet av de föreslagna åtgärderna kan grundas på.

Finland har alla förutsättningar för att bli en internationellt eftertraktad samarbetspartner inom genomforskning och företagsverksamhet inom genomikbranschen. Detta mål kan uppnås genom ett tätare samarbete mellan de olika aktörerna och genom att genominstitutet ges befogenheter att centralt bereda avtal på det finska samarbetsnätverkets vägnar. Inrättande av ett nationellt serviceställe vid genomcentrumet skulle i stor grad effektivisera genomforskningen och utvecklandet av branschen, och resultaten av denna verksamhet kunde komma till direkt nytta för finländarna och den finländska hälso- och sjukvården. Tidsramen för utnyttjandet av Finlands styrkor är dock högst några år.

NYCKELORD:
ARVSMASSA | DATASEKRETESS | DATASÄKERHET | FARMAKOGENETIK | GENER | GENOM
GENOMIK | GENTEST | INDIVIDUALISERAD MEDICIN

FOREWORD

Within the next few years, recent advances in genomics technology will enable wide-ranging use of genomic data in clinical care and in the prevention of diseases. Comprehensive planning is required to prepare for this change. The development of such a plan was included in the recommendations of the national Strategy for Growth in Research and Innovation in the Health Sector, published in May 2014 (MEE reports 12/2014).

The Ministry of Social Affairs and Health (MSAH) set up a working group to formulate a National Genome Strategy in healthcare during the period of 1.9.2014 – 30.4.2015. The strategy will establish the conditions that are required for the effective utilisation of genomic data in Finnish healthcare. It will also promote genomics research and the development of applications for genomic data in the field of human health.

The Chair of the working group was Director Liisa-Maria Voipio-Pulkki from MSAH's Department for Social and Health Services, and the Vice-Chair was Professor Kristiina Aittomäki from the University of Helsinki and the Hospital District of Helsinki and Uusimaa's laboratory service (HUSLAB). The members of the working group are presented in Appendix 2.

In the formulation of the strategy, the Ministry of Social Affairs and Health worked closely with the Finnish Innovation Fund Sitra. The Health Section of the Advisory Board on Biotechnology acted as a consultative expert group.

During the autumn of 2014, the working group organised six workshops on different themes. More than one hundred experts from various fields participated, as did representatives of other stakeholder groups such as companies.

The working group used the views presented during the workshops to draft strategic goals and proposals for an action plan. The stakeholders gave their feedback on the proposals during a hearing and discussion held on January 12, 2015. The experts and anyone else interested in the subject were given the opportunity to comment on the proposals and the draft strategy through the Innovillage collaborative development platform and the "otakantaa.fi" service which enables people to express their views on public decisions. The feedback was taken into consideration when finalising the strategy. During the development of the strategy, an active public communications programme on the progress of the work was maintained.

Having completed its work, the working group respectfully submits its unanimous proposal for a National Genome Strategy to the Ministry of Social Affairs and Health.

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CONTENTS

1. INTRODUCTION

The novel research methods in genetics open up new possibilities to identify the causes of human health and disease, as well as to create new means for disease prevention and targeted care. The use of genomic data, i.e. information about an individual's whole genetic makeup, is rapidly increasing in healthcare. In the future, health promotion and the treatment of diseases will be increasingly based on individual genetic makeup. Genomic data will enable us to make better individualised choices, to target the screening of the diseases more precisely, to make more accurate diagnosis and to select the most effective care.

WHAT IS KNOWN ABOUT A PERSON'S GENETIC MAKEUP?

Human genetic makeup or genome has been researched for decades in order to diagnose diseases and to understand their causes. There was a significant step forward in genome research in 2000, when the full sequence of the human genome was completed. Although not perfect, it launched a technological development producing a range of methods which could be applied to genome research and were significantly more cost-effective than before.

The new genomic methods, i.e. methods that examine the entire genetic makeup of a person instead of individual genes, expand the use of genetic information to cover human health, susceptibility to diseases, and changes in the genetic makeup that are linked to a specific disease. Above all, we have seen the high level of variation in people's genetic makeup, and understood that individual differences in susceptibility to many common diseases are related to this variation. Thus we can presume that preventive methods and individual treatments can also be developed for the most common diseases. These methods would be applied especially in high risk groups.

SIGNIFICANCE OF GENOMIC DATA TO THE INDIVIDUAL AND THE SOCIETY

Data on individual genetic makeup is a key to promoting health and well-being as well as new thinking about healthcare and practices. Extensive use of genomic data is expected to produce significant benefits (Figure 1). Individuals will be able to get more effective medicines and care. It will be possible to diagnose diseases at an early stage and more accurately. In addition, we can identify individual risks of disease and prevent diseases before their onset. The use of genetic information will also enable people to take

Practical applications of genomic data

Cost-effective drug treatment with pharmacogenomic tests

Clopidogrel is a commonly used drug to prevent clotting in the blood vessels of the heart and brain. Every year about 30,000 new patients are prescribed this medication in Finland. For about 15-25% of patients the prevention of vascular events is low because the genetic changes in the CYP2C19 enzyme slow down the production of the active drug in their bodies. Therefore, in order to evaluate the effectiveness of the drug treatment, a CYP2C19 genetic test should be carried out on patients before prescribing clopidogrel.

responsibility for their own health and wellbeing, should they so wish. Since the new technologies have significantly reduced the cost of sequencing the genome, various types of genetic tests are being offered also direct-to-consumer around the world. These technologies enable anyone to obtain information on his or her own genetic makeup. The objective of the genome strategy is to create equal opportunities to health benefits brought by genomic data.

Combining information on genetic makeup with health data will continuously generate new information about the relationship of genetic makeup to diseases and the results of their treatments. This information will benefit and save the costs of healthcare, as interventions can be designed to be more preventive and cost-effective

If Finland succeeds in building an interesting research and business environment in the field of genomics, this could generate significant new scientific and commercial activities for Finland. Research will benefit from improved availability of genomic data, and commercial activities will have a point of contact for building up innovation and business around genomic data.

The systematic collection of genetic information has increased rapidly in several countries during recent years. In order for genetic information to be more widely used in healthcare, clinical research and in commercial applications, people should have confidence that their genetic information is used in an ethically responsible and legally sound manner. Genomic data are sensitive personal data. Therefore data protection regulations will have to be taken into consideration in the implementation of the strategy. Particular attention should be paid to the secure use of genomic data and the maintenance of people's trust.

Practical applications of genomic data

Prevention and targeted treatment of diabetes

Diabetes (DM) is one of the fastest growing diseases in Finland and the world. Over 500,000 Finns suffer from diabetes, and it is estimated that the number of patients could double during the next 10–15 years.

The spectrum of diabetes is complex. Molecular genetic research has also identified rare hereditary forms. There are over one hundred known genetic changes increasing predisposition to the most common form, type 2 diabetes, but there could be thousands of these changes in the genome. Therefore people belonging to genetic risk groups have a large number of modifications in their genetic makeup that make them susceptible to diabetes.

If each year 2-5% of diabetes cases could be prevented by risk profiling and preventive action, the direct savings in health care costs would be 28–70 million euros a year including the additional costs caused by co-morbidities of DM. In addition, more accurate identification of the sub-type of diabetes would help to predict the course of the disease in each patient and to select targeted treatment.

BENEFITS OF USING GENOMIC DATA EFFECTIVELY

Figure 1. The benefits of using genomic data effectively.

GENOMIC TECHNOLOGY IS TRANSFORMING HEALTHCARE

Genetic tests are already fairly widely used in healthcare. In 2012, approximately 100,000 genetic tests were carried out in Finland. Of these, about 30% were carried out to diagnose hereditary diseases and to identify high susceptibility to certain diseases. In the future, there will be no radical change in the status of these genetic tests, but they will become more comprehensive and more cost-effective.

The application in healthcare of information gained from genome research is becoming significantly more diverse. Depending on their purpose, genome-wide tests can be divided into the following groups:

Practical applications of genomic data

Genetic test reduces morbidity and mortality

Lynch syndrome is a hereditary condition causing susceptibility to cancer. It has a high risk of colon cancer, and uterine and ovarian cancer in women. The child of a carrier of the genetic defect has a 50% risk of inheriting the defect. All carriers of the genetic defect are monitored regularly by colonoscopy. Those who have not inherited the genetic defect do not need follow-up.

Through follow-up of the carriers of the defect, over 50% of the colon cancer cases can be prevented by removing the precancerous lesions during colonoscopy. The prognosis of confirmed cancer is generally good since they are detected at an early stage. Therefore genetic tests are cost-effective and reduce both morbidity and mortality caused by Lynch syndrome.

1) Diagnostic tests for defining the cause of a rare disease or for identifying high-risk susceptibility for a specific disease

2) Research into the molecular mechanisms of diseases. For example, examination of the genetic changes in a malignant tumour as a part of cancer treatment

3) Pharmacogenetic tests for the assessment of the suitability of a specific drug for a patient's treatment

4) Predicting susceptibility to common diseases by genetic risk profiling.

This kind of use of genomic data produces peronalized healthcare. It predicts risks, prevents diseases and is both customized and participatory. Participatory means that a person is more capable of taking care of his or her health by having access to comprehensive information on the factors affecting it.

2. FINLAND AS A UTILIZER OF GENOMIC DATA

The genetic structure of the Finnish population provides us with a unique possibility to function as pathfinders and early utilizers of genomic data. By combining genomic and health data we can identify connections of genetic makeup to the health of the population and the effectiveness of treatment in a manner which would be difficult or impossible elsewhere. Finland is also one of the world's leading developers of health technology and experts in information and communications technology. Finland has an opportunity to become a model country in combining genetic information, clinical data and information on personal wellbeing.

INTERNATIONAL OPERATING ENVIRONMENT

The opportunities for utilizing genomic data in medicine have been recognised around the world. Several countries have drawn up, or are drawing up, strategies and action plans to utilize genomic data.

For example, the British National Health Service (NHS) has launched a 300 million pound genome project with the target of reading the genetic makeup of 100,000 people. In Germany, the Ministry of Education and Research has earmarked 360 million euros to promote personalized medicine during the next three years. And in the United States, a 215 million dollar genome project has been launched. All these projects aim at utilizing the results in the healthcare sector. At the same time they generate data which can be used in developing new medicines and methods for early detection and treatment of diseases.

Also Estonia has advanced in the collection and utilisation of genomic data. The legislation on research into human genes was passed in 1999, and one year later Estonia's genome project fund was established. In Estonia, there is a specific objective to reduce the costs of healthcare by investing in the use of genomic data in the prevention of disease.

NHS compares the genome project with the construction of railways during the Victorian era. The railway did not just provide a fast and cheap way of moving from one place to another, but also increased commercial activity in many ways. The genome project is expected to promote innovation and economic activity within the health sector, which will contribute to creating welfare in the country.

Several other countries, such as Italy and Canada, have launched projects aiming at utilizing genomic data with the objective of improving national health care systems and making them more efficient. On the other hand, this can also be seen as a part of worldwide research and business. Nations that are the first to attract international partners will gain the most benefit from cooperation.

FINLAND COULD BECOME A MODEL OF GENOMIC DATA USE

Finland is particularly well placed to utilize genomic data. From a global perspective, Finland's strengths include a high standard of healthcare, uniform treatment practices, reliable healthcare registers, a long tradition of high-quality genetic research, and the willingness of the population to participate in scientific research.

Finns are genetically relatively homogenous. This provides special opportunities to combine genomic and health data. As a result, genetic mechanisms targeted by drugs can be identified in a manner that is difficult, if not impossible, elsewhere. Finland is also one of the world's leading developers of health technology. In addition, we have good skills in information and communications technology. In the future, it will be possible for individuals to collect information relating to their health and lifestyle using the My Kanta Pages service that is part of the national health data repository.

The ability of the Finnish healthcare system to utilize the new possibilities offered by genomic data depends on current information technology solutions and on the training of healthcare professionals to utilize genomic data.

There are already significant projects and programmes supporting the utilisation of genomic data in the Finnish healthcare. For example, the objective of the GeneRISK Study is to analyse how the provision of information about one's health and possible risk factors motivates people to change their lifestyles and prevent diseases. If 2 to 5 per cent of heart and vascular diseases could be prevented, this would save healthcare costs of 10–26 million euros every year.

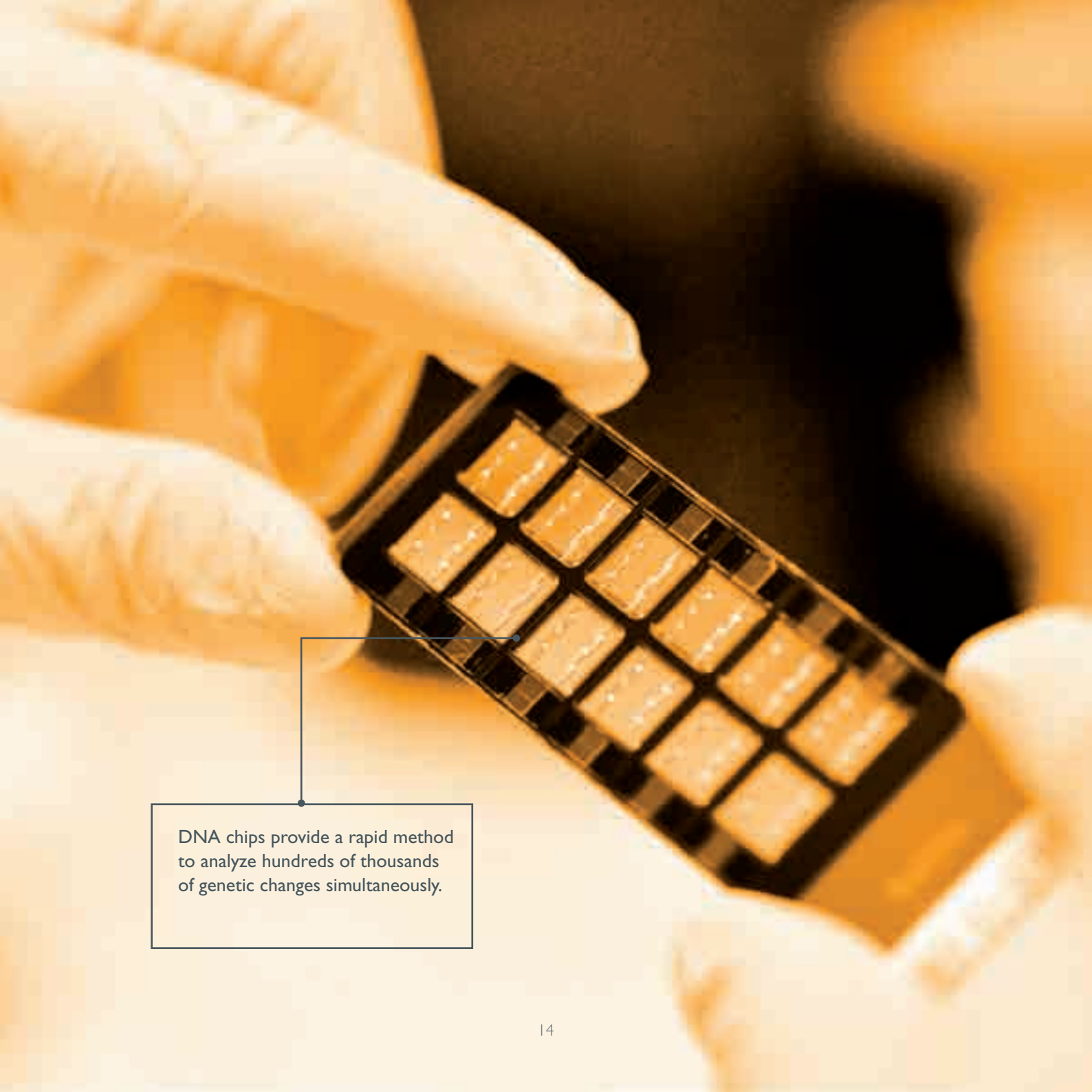
THREATS AND RISKS RELATED TO UTILISATION OF GENOMIC DATA

Everyone must have an equal opportunity to benefit from genomic data. If Finland is not well prepared to make use of this data, the development of healthcare in a more preventive and cost-effective direction may be undermined. In this case, genomic data would benefit mainly those who can acquire and utilise it on their own initiative.

A critical requirement for the collection and utilisation of genomic data is that people can trust it to be handled confidentially with sufficient security measures respecting their wishes and rights. Lack of legislation or clarity and conflicting interpretations could limit the utilisation of genomic data. In order to ensure that the data are not used against the wishes of the person or without their consent, and that all the measures are carried out according to the law, ethical and legal guidelines as well as interfaces with data security must be created.

There is a risk that the operating environment becomes fragmented and that there will be several different databases for storing genomic data. This would be particularly damaging to Finland, given its comparatively small population. There is also a risk that no new economic activity will be generated around genomic data research in Finland. In that case, potential international partners will focus their interest elsewhere.

New information technology solutions help people to use their own genetic information safely. We must ensure that genomic data are generated and processed only by organisations that have the necessary professional and scientific resources and methodologies. Surveys and interviews should be carried out at regular intervals to ensure that the use of genetic information is in accordance with the needs, expectations and concerns of the population.



DNA chips provide a rapid method to analyze hundreds of thousands of genetic changes simultaneously.

3. GOALS OF THE GENOME STRATEGY

Due to the rapid increase in genomic data, there is a need for a National Genome Strategy. This would enable healthcare to pave the way for the effective use of genomic data without compromising the legal protection and fair treatment of individuals. At the same time, we need to ensure that Finland becomes an attractive country for top level international research and innovation utilizing genomic data. A national genome centre is needed to implement the genome strategy, to coordinate cooperation and to ensure that the strategic goals are achieved.

NEED FOR A GENOME STRATEGY

The full-scale use of genomic data in healthcare requires thorough preparation. There is a need for a comprehensive strategy to respond to the many challenges. These include health technology assessment of genetic tests; quality assurance of the genetic tests and testing laboratories; equity in access to genetic testing and counselling as well as treatment based on the test results; training of healthcare staff; data protection; dealing with incidental findings; and containing the costs of genetic tests and personalized care.

STRATEGIC AIM

The aim of the strategy is to make Finnish healthcare more effective. This will be achieved by providing people with better and more targeted care. Healthcare professionals will gain access to more comprehensive genomic data for application in clinical care. Researchers, for their part, will have entirely new opportunities for utilizing genomic data in scientific research. Society may benefit from a containment of healthcare costs and better allocation of resources. In addition, the aim is to transform Finland into an internationally attractive environment for research and business in the field of genomics.

IMPROVING HEALTH THROUGH THE USE OF GENOMIC DATA

The strategic vision is:

> **"In 2020, genomic information will be effectively used in Finland to achieve population health benefits". The guiding principle of the strategy is "Improving health through the use of genomic data."**

The strategy is limited in scope to the promotion of human health and wellbeing. It does not address other significant spheres of application of genomics nor specific treatments. The aim is to implement the strategy by 2020.

The genome strategy is aligned with the Health Sector Growth Strategy for Research and Innovation Activities and the national eHealth and eSocial Strategy. The implementation of the genome strategy should rely as far as possible on existing structures.

A particular focus of the strategy is on data utilisation. The aim is that Finland would concentrate on using genomic data to produce high added value. Another area of focus is creating a single body, a genome centre, for the management of genomic data and to serve as a national service point for stakeholder groups using genomic data.

Figure 2. The goals of the genome strategy.

STRATEGIC GOALS

The genome strategy has seven main goals, four of which are enabling goals and three are ultimate goals (Figure 2).

By achieving the enabling goals, the necessary conditions will be created for the full-scale use of genomic data in healthcare, research and commercial activity as well as in people's own lives. The enabling goals are related to ethical principles and legislation, the integration of genomic research into healthcare, the ability of healthcare professionals to apply genomic data, and the development of information systems that will enable the efficient utilisation of the data.

The ultimate goals are built on the foundation of the enabling goals. The actual benefits of genomic data use for individuals, Finnish healthcare and the society will be obtained through the attainment of the ultimate goals.

A national genome centre is needed for the implementation of the genome strategy. The genome centre will develop and maintain a national reference database of genomes and a database of genomic variants. It will provide a single point of contact for research institutions and companies needing research, contractual and commercialisation services.

In the following chapters, each goal and the proposed activities to achieve them are described.

3.1 ETHICAL PRINCIPLES AND LEGISLATION GOVERN THE RESPONSIBLE USE OF GENOMIC DATA

Advances in genomic technology raise ethical and legal issues relating to people's privacy and the predictive nature of genomic data, among other things. In order for genomic data to be used effectively in healthcare, research and in commercial activities, the use of data related to the human genome must be safe and governed by law and guidelines.

Genetic tests generate data on the genetic makeup of both the individual and his or her biological relatives. The data can be used to predict disease by identifying whether the person has a genetic change that will cause a disease or protect the person from it. It is important that people get enough information about the significance of genomic data.

Because of the sensitive nature of information about a person's genetic makeup, it is necessary to ensure that the data are not used in a way that would harm that person or other people. Everyone should have the right to manage one's own genomic data. New information technology solutions make it easier for people to monitor and use their genomic data. This has to be ensured through legislation. Everyone can decide for themselves whether they wish to be informed about their genetic makeup and susceptibility to diseases. Everyone should also be given the opportunity to receive counselling on the implications of the findings of genetic tests.

The interests and welfare of the individual should always have priority when investigating the human genome. Discrimination based on genetic makeup is prohibited in many international agreements, declarations and recommendations to which Finland is committed. The Council of Europe's Convention on Human Rights and Biomedicine allows predictive genetic testing for health purposes only, or for health-related scientific research. Thus genetic tests cannot be carried out, for example, for insurance purposes. Finland's criminal code prohibits discrimination in employment on the grounds of genetic characteristics.

The use of genomic data involves the handling of sensitive personal data. Consequently, data protection regulations will have to be taken into account in the implementation of the strategy.

Information systems must be developed so that genomic data are stored and used securely. Privacy must be protected and misuse of information about an individual's genetic makeup prevented. In the case of data about a person's entire genetic makeup, conventional precautionary measures cannot completely eliminate the possibility of the person being identified. Therefore genetic data linked to an identifiable person and stored for scientific research or any other purposes must be held confidential.

ACTIVITY 1

– Confirm the ethical principles concerning the use of genomic data

Establish a multi-disciplinary working group to draw up ethical principles and working practices which respect the rights of the individual and for the responsible use of genomic data in healthcare, research and product development. International recommendations should be taken into account when drawing up the principles. Promote the adoption of these principles and working practices through training.

ACTIVITY 2

– Prepare legal framework for the use of genomic data

The needs for revision of the legislation are identified and the necessary regulatory amendments are prepared.

The applicable data protection regulations are mapped out, and the purpose of collecting and using genomic data, among others, is defined.

3.2 GENOMICS RESEARCH IS CLOSELY INTEGRATED INTO HEALTHCARE

The Finnish public healthcare system has broad responsibility for the citizen's health. This has enabled to establish large databases related to healthcare. This data together with genomic information, other public registers and our specific population history, create exceptionally good conditions for the use of genomic data in research and healthcare.

Valuable sample collections have been put together in Finland, such as the National Institute for Health and Welfare's population research material that has been collected over decades. A large part of the sample collections is being transferred to wider use under the terms of the Biobank Act. These collections of samples and the possibility to combine them with register data have placed Finland, like other Nordic countries, in the position of being an internationally interesting centre for genome research.

Even on a global scale, Finland's national registers provide a rare opportunity to link collected samples to long-term monitoring data. This increases the value of the collections considerably. The goal is that in the future, all patient data and national register data can be combined with genomic data.

For scientific research and healthcare there is a need not only for international reference databases but also data about the genome of the Finnish people and its variations. Finns relate positively to scientific research. As a result, the collection of samples needed to create a reference database can be carried out as part of healthcare visits.

ACTIVITY 3
– Create a national reference database of genomes

A national reference database of genomes will be established. Genomic data produced by various organisations will be stored in the database, and the linking of health data with genomic data will be made possible. In addition, the necessary links to international databases should be set up.

Plan and implement the collection and management of the consents required for the use of genomic data. Consent can be given during a healthcare visit, taking into account the individual's informed right to decide.

ACTIVITY 4
– Identify the procedures and create the conditions for using scientific data effectively and efficiently in healthcare

Subject to authorisation, it has been possible to use healthcare data in scientific research that utilises genomic data. The transfer of genomic data in the opposite direction, from scientific research to patient care has been considerably less common. However, high quality genomic data generated in research would be useful, for example, in the selection of certain drug treatments. In addition, procedures should be created to evaluate which incidental findings revealed by research should be communicated to people and how.

The long-term goal is to use reference databases in planning healthcare services and in targeting them at

the population and individual level. In addition, it must be ensured that healthcare units have the right to access data in order to promote appropriate and cost-effective care. The unit providing care should have at their disposal all available, relevant information.

3.3 HEATHCARE PROFESSIONALS HAVE THE KNOWLEDGE AND SKILLS TO USE GENOMIC DATA

In the future, primary and specialised care providers must have knowledge of genomics and skills to apply genomic information in service planning and clinical care. The need for genetics services is increasing. Fair access to services can only be ensured through adequate training of healthcare personnel.

The education and training of healthcare professionals must be developed to ensure that the personnel has up-to-date knowledge and skills in genomics and on the use of genetic information and its limits. The personnel needs to know where they can access new information related to genomics and how genetic tests and information can be used in healthcare. Training in the use of genomic data should be tailored for each professional and specialist group. Training curricula must be updated regularly.

ACTIVITY 5

– Reinforce and update genetics education in the curricula of healthcare professionals

Enhance genetics education by mainstreaming it in the initial professional education of doctors and other healthcare professionals. The goal is that during basic training the student acquires adequate knowledge about genetics and the use of genetic information.

ACTIVITY 6

– Develop and implement a training programme for the current healthcare workforce

Develop a training programme on genomics for the continuing professional development of different groups of healthcare professionals. The programme should be versatile and utilize online training.

ACTIVITY 7

– Assess the need for professionals in clinical genetics

In Finnish healthcare, the genetics professionals working in the clinical setting are doctors specialised in genetics and genetics nurses who have been trained on the job. In many countries, there is also a third category of health professionals, genetic counsellors, who are trained in genetic counselling. The need for all three professional groups in Finland should be assessed and the number of trainees should be adjusted based on identified needs. If necessary, a curriculum for genetic counsellors should be introduced.

3.4 FINLAND HAS INFORMATION SYSTEMS ENABLING THE EFFECTIVE USE OF GENOMIC DATA

The extensive use of genomic data requires seamless data connections across information systems and interfaces. Finland must develop a comprehensive IT architecture for managing genomic data.

Historically, the emphasis in the development of information systems in the health sector has been on the collection and local utilisation of data within organisations. As a result, data transfer between organisations is not seamless at the moment. The national eHealth and eSocial Strategy shifts the emphasis of development work from collecting and transferring data to ways of using data efficiently in the promotion of personal wellbeing, in the clinical setting and in healthcare management. The objective is also to use the data to support research, innovation and commercial activities.

The special features of genomic data are the large size of storage required, the need for a national reference database and the wide range of applications of genomic data in different areas and levels of healthcare. For the utilization of genomic data it is important that the information technology solutions are implemented using open and secure interfaces.

The utilisation of genomic data should not be seen simply as an information technology project, but as part of the development of an ecosystem for public and private services. In the future, various kinds of services and applications can be built around genomic data. For example, there will be a need for more genomic data interpretation services. Even if an individual's genome does not change, it will be interpreted several times either as a whole or in part as understanding of the influence of genomic data increases. Interpretation of this data requires a broad base of comparison material (reference and variation databases).

The informatics requirements for the use of genomic data should be taken into account in the development of national IT solutions in order to avoid creating double structures.

In addition to national solutions, it is extremely important to adhere to international standards. This will ensure that genomic data produced in Finland are internationally comparable.

The efficient use of genomic data will bring significant benefits to healthcare and research. The greatest benefit is gained when genomic data are combined with other healthcare and wellbeing information such as clinical patient data as well as information about lifestyle and environment. Existing solutions will be heavily relied on for the collection, storage, combining and utilizing the data. In addition, a service operator enabling the efficient use of data is being planned. It will play an important role in the processing of data for scientific and other purposes (Figure 3).

There are several electronic services in Finland that people are familiar with and value. These could be used more widely in healthcare. New information needs should be kept in mind when developing data

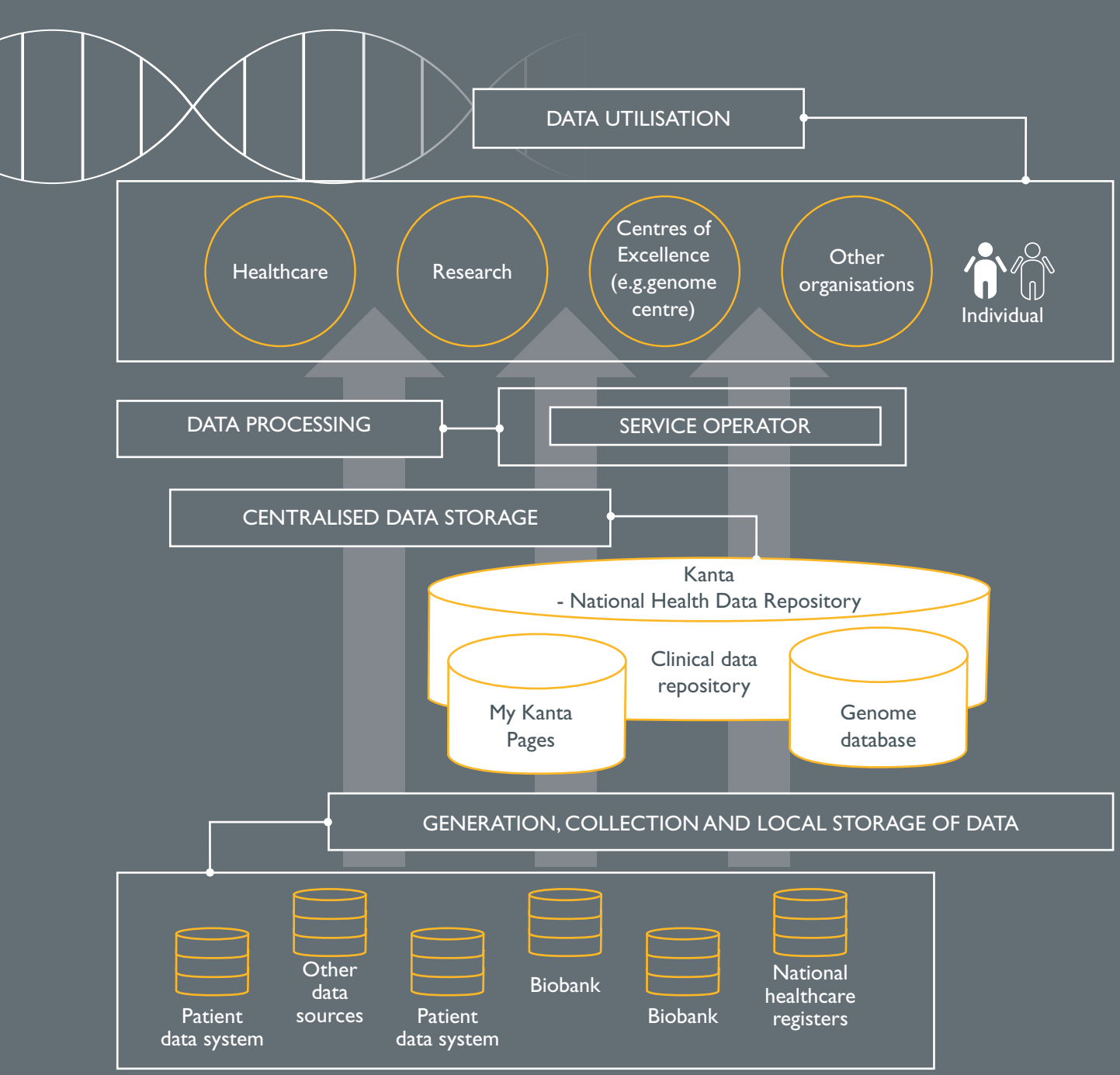


Figure 3. High-level design of the architecture for the generation, storage, processing and utilisation of genomic data.

management systems. For instance, in the future information about an individual's genetic makeup could be included in decision support tools and other self-treatment services used by individuals. People must have the right to manage, prevent or limit the utilisation of their genomic and health data. On the other hand, there must also be a possibility to provide, subject to the individual's consent, anonymous data to commercial operators, for example to be utilized in the development of new medicines.

This component of the genome strategy focussing on information technology will be implemented jointly with the national eHealth and eSocial Strategy. During implementation, the genome strategy will capitalise on the results of other ongoing Finnish projects that are related to the genome strategy such as the Finnish Innovation Fund Sitra's service operator project and research projects coordinated by the Institute for Molecular Medicine Finland (FIMM), the Finnish Funding Agency for Innovation (Tekes) and SalWe Ltd.

ACTIVITY 8
– Develop an IT architecture for genomic data

Define the aims for utilizing genomic data, especially with regard to operational needs. Identify the national and international standards and conceptual models to be followed in storing, transferring and utilizing genomic data. One of the first tasks is to decide on a common data storage format. This will ensure that the data are stored in a structured manner and that data generated using different definitions can be utilized in a reliable way.

The building of a comprehensive structure will also include developing national guidelines on data security and protection as well as on the management of consents and refusals. There will also be a public platform for the storage and utilisation of genomic data where people can manage and control their own health information in order to promote their personal wellbeing.

3.5 GENOMIC DATA ARE WIDELY USED IN HEALTHCARE BASED ON INDIVIDUAL AND POPULATION NEEDS

The use of genomic data can improve diagnosis and enhance the targeting of treatment. With genetic risk profiling, screening can be focussed more precisely on susceptible subgroups of the population. The efficient utilisation of genomic data must be equally available to the entire population. In addition, empowering people to use their own genetic information as an aid in health planning will contribute to the prevention of diseases and enable many to live a healthier life.

ACTIVITY 9

– Ensure that sufficient genetic testing is performed on patients to determine the cause of diseases, and that test results also benefit family members and other relatives

Genetic tests for inherited diseases and high-risk susceptibility will become increasingly important. In the future, decisions regarding treatment and monitoring will be based to a greater extent on information on the location of mutations in genes and the type of mutations. Identification of family-specific mutations is essential for identifying risk of disease or for ruling it out in family members and relatives. It will also result in a more efficient allocation of resources. It is important to ensure equitable access to genetic testing in the Finnish healthcare system. Genetic tests are particularly valuable in the investigation of inherited diseases and high-risk susceptibility in situations where the test results have relevance to several family members.

ACTIVITY 10

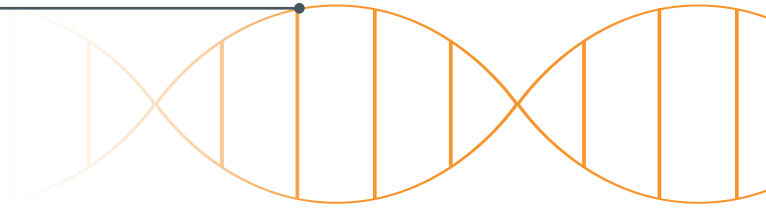
– Develop a procedure for the systematic evaluation and adoption of genetic tests

As genomic data changes, it is impossible for every healthcare professional to monitor the changing field in sufficient detail and apply their professional skills. That is why a body is needed to prepare and monitor the effectiveness and efficiency of genetic tests used in Finland's healthcare system. The guidelines must take into account international recommendations, international developments in the field and the availability of services, particularly in other EU countries. This expert role would be a natural fit for the national genome centre.

ACTIVITY 11

– Promote the use of genetic risk profiling in the prevention of diseases

As genomic data becomes more precise, it will be possible to identify susceptibility to disease better. That opens up new possibilities for the prevention of diseases. Guidelines and a databank will be created for service providers and healthcare professionals. It will be easy to retrieve information about gene research from the databank as well as information on how to make decision based on the results and how the results can be used in practical work. Risk profile-based prevention could be based on medical treatment and changes to lifestyle, and to be successful there would also be a need for support services for individuals.



Practical applications of genomic data

Genetic information helps prevent sudden death

A 56-year-old woman developed sudden chest pain which was found to be caused by a rupture of the ascending aorta. She survived after an emergency operation. Further examination of the family revealed that the risk of rupture of the aorta was inherited in a dominant pattern, and the underlying genetic defect was identified.

All those at risk need to be monitored. During genetic counselling, genetic testing was performed on the patient's four siblings. One of the siblings had the genetic defect, and therefore genetic counselling and testing of the children was necessary. The genetic defect was also identified in the patient's son who already had an enlarged aortic root. An elective operation was carried out thus avoiding the risk of sudden death from a rupture of the aorta. Since three siblings did not have the genetic defect, they and their children did not need any follow-up.

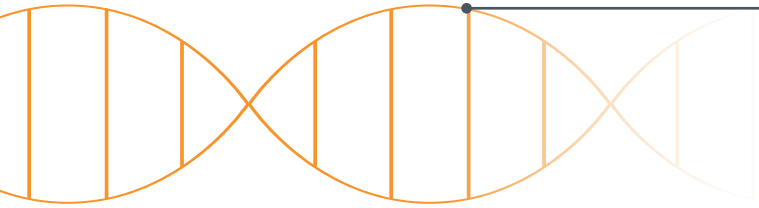
Practical applications of genomic data

From cardiovascular disease risk assessment to prevention using genomic data

Several thousand Finns unknowingly suffer from familial hypercholesterolaemia where cholesterol levels are very high due to an inherited genetic defect. Without treatment their risk of cardiovascular disease is several times higher than in the average population. Their increased susceptibility could be easily detected with a genetic test and taken into account in lifestyle choices and medication from early childhood.

The common variation in the genome of the population influences our risk to develop cardiovascular disease. Half of the difference in individual risk can be explained by inherited characteristics. Compared to the average Finn, almost a million Finns carry changes in their genome that double the risk of heart disease.

In health promotion and prevention of cardiovascular events, there is a need for data on changes in the genome and their significance as well as for guidelines on how to apply genomic data in healthcare. The use of genomic data can reduce morbidity and mortality and lead to more cost-effective healthcare.



Practical applications of genomic data

Genetic test enables targeted treatment of cancer

Genetic changes in cancerous lesions guide the development of cancer. Identification of these changes enables the targeted treatment of cancer.

In the example case, the patient had cancer of the colon removed by surgery, and he underwent chemotherapy because the cancer had spread to lymph nodes. After one year the patient was found with liver metastases which could not be surgically removed due to their size and number.

In tests for KRAS and NRAS oncogenes, no mutations were found in the cancerous tissue, and targeted antibody treatment against EGFR was started. The response to treatment was positive and the patient was operated to remove the liver metastases. There was no recurrence of the cancer during follow-up. If a mutation would have been found in the KRAS or NRAS oncogenes, the treatment would have been ineffective or even harmful.

ACTIVITY 12

– Provide healthcare professionals with a clinical decision-making support tool based on genomic data

Risk profiles for diseases are generated from a large number, usually several tens, of variations in genetic makeup which are combined with other information about the patient. This is possible with electronic decision-making support. These kinds of information technology solutions have to be developed as tools to support healthcare professionals. The most effective solutions will be discovered through pilot studies.

ACTIVITY 13

– Analyse the costs and benefits of making use of genomic data

Even though many kinds of genetic tests are possible, the use of all of them is not necessarily cost-effective. On the other hand, it is possible to concentrate on effective treatments on the basis of genetic tests and to avoid the costs of ineffective or harmful treatments. Not all tests are associated with possibilities for interventions that promote health or prevent diseases either. The cost-effectiveness of the use of genomic data will have to be assessed at a national level and monitored as part of the operations of the genome centre.

3.6 INDIVIDUALS ARE ABLE TO MAKE USE OF GENOMIC DATA IN THEIR OWN LIVES

Currently genomic data is mainly used to diagnose diseases and to guide the selection of treatment. In the future, genetic risk profiling will be increasingly available as a preventive intervention or as part of a personal health plan. This opportunity together with the necessary support services must be equally available to all.

More and more Finns are interested in maintaining and promoting their health through lifestyle choices. Information about individual genetic makeups will be critical in the future when we assess lifestyle risks and make lifestyle choices. Healthcare needs common guidelines on the use of genome-wide tests. At the same time we must consider the availability of such tests from the perspective of those who want to know about their own genomic data. The provision of services must not lead to unequal treatment of patients.

In Finland, genome-wide tests have not been availave to consumers. Some Finns have bought these services via the Internet from companies based abroad. In such cases, data about individuals' genetic makeup cannot be used in domestic research or in the development of new services even after it has been anonymised. The data are also not stored as part of the Finnish genomic database.

Legislation must be developed so that people have the right to use their genetic information and decide on how it is used through consent management. The individual should also have the opportunity to acquire information about their genetic makeup and on the other hand, the right to share it with others.

ACTIVITY 14
– Provide guidelines for people on services related to genetic testing

A clear health service pathway and guidelines have to be developed for people on what types of genetic or genomic tests are available and where. The pathway will also indicate which organisations offer interpretation of results, what tests can reveal and what advice related to the results is provided to support health planning. People must also be given reliable comparative data about services provided by the private and third sector that are aimed at consumers. The use of services must always be voluntary and based on the individual's desire to know. Resources should be directed towards solutions that promote the nation's health. These kinds of applications are particularly associated with disease risk profiling, evaluation of the suitability of drugs and the prevention of disease through lifestyles that promote health.

It should be ensured that people receive up-to-date and reliable information about using genomic data in promoting their own health.

ACTIVITY 15
– Provide individuals with access to genomic data tools

Provide people with general guidelines on the use of genomic data in promoting health and create related services to support decision making. Create a genome portal which would provide the public with information about genetics as well

as online tools to utilise information about their genetic makeup. In addition, investigate the opportunities to provide people with virtual health services related to the use of genomic data on an experimental basis. This could be achieved, for example as a virtual clinic service by combining the individual's consent with his or her wellbeing, patient and genetic information.

ACTIVITY 16

– Build in secondary education the capability to use genomic data

Develop secondary education curricula to build students' capability to apply genomic information to make informed decisions about their own health. Teaching about genomic data would be a natural part of health education for example.

3.7 FINLAND IS AN INTERNATIONALLY ATTRACTIVE RESEARCH AND BUSINESS ENVIRONMENT IN THE FIELD OF GENOMICS

Finland has invested a considerable amount of public funds in health-related research. As a result we have become one of the leading countries in science, including in genetics research. However, society has not been able to fully benefit from research investment, nor has the investment sufficiently generated economic activity or produced enough added value. There are significant opportunities for business, commercial growth and employment especially in the development of drugs and in digital healthcare research.

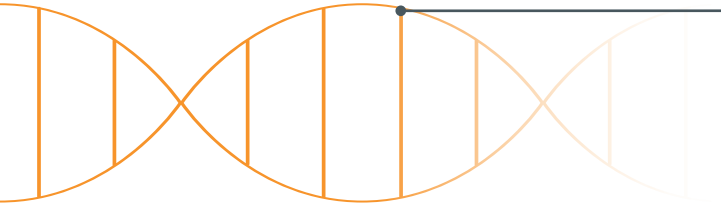
Finland has a strong tradition of genetic research, comprehensive health databases and high-quality sample collections in biobanks. All of this combined with genomic data amounts to a considerable national capital which is of interest to international research and investors. Investments are needed to promote genomics research and development in the field. The results of such research and innovation activities are of direct benefit to Finns and the Finnish healthcare system.

In Finland, the law governing biobanks already allows cooperation in research between the public sector and companies. Biobanks are allowed to deliver samples and their data to companies for research and development projects. However, the objective is not to pass the samples to research organisations and companies, but to generate knowledge. This will enable targeted and individualised study designs which are essential for drug development.

A national service point, the genome centre, is needed for research organisations and companies interested in cooperation. The role of the centre is to provide centralised services for research projects and agreements. It must have the authority to make contracts on behalf of the Finnish cooperation network. The service point could also function as the national coordinating body for international cooperation projects.

In the case of health technology solutions, the development of a product typically takes years before it is ready for the market. That is why funding is a bottleneck for many small companies. In particular, start-up businesses with international aspirations need long-term funding. Finland's risk and capital investment markets should be further developed to support the growth and internationalisation of companies. Tekes is one organisation that has reacted to the situation by creating a new funding instrument in 2014 to amend shortcomings in early-stage funding for companies.

The national Health Sector Growth Strategy for Research and Innovation Activities was completed in the spring of 2014. It defines the essential measures needed in order for Finnish health sector to be internationally successful. The objectives will be reached only by bringing together the fragmented field of actors to cooperate, and through seamless cooperation between the public and private sectors. These are also the preconditions for Finland to become an interesting partner in genomics research and commercial activity in the genomics sector.



ACTIVITY 17

– Establish a national service point that offers companies and research organisations centralised services related to research, agreement and commercialization matters

From the point of view of companies, an actor the size of Finland must be able to provide a broad range of services from a national service point. Research organisations would also benefit from a centralised legal service with experience in drafting research agreements that are aligned with Finnish legislation. An entity providing a single point of contact would also function as a coordinating body for international cooperation projects.

ACTIVITY 18

– Develop a national operating model for cooperation between the public and private sector that enables utilisation of genomic data, and the health data linked to it, in research and product development projects

Develop common operating principles and procedures to be followed in Finnish genome research. In this way, partners will not have to negotiate the models of cooperation agreements with every service provider and research group separately. The operating model must be flexible, and the authorization and ethical evaluation processes should be streamlined.

ACTIVITY 19

– Provide access to genomic data and health information compiled from the data sources of various organisations for use in research and development activities

From the perspective of many international companies, Finnish organisations are small players. Combining genomic and other health data produced by various organisations in the same database would also be in those organisations' best interests. It would enable research across a broader range of areas than any organisation would be able to carry out alone.

ACTIVITY 20

– Establish a funding, productisation and commercialisation programme

In order to strengthen Finnish competitiveness in the international market and to support innovation in healthcare, there is a need to set up a programme for the development of funding instruments and for building productisation skills. The objective is to speed up and facilitate the introduction of innovations to international markets. The programme would not concentrate solely on genomic applications, but the significant role of genomics should be taken into account in the programme.

4. ROADMAP FOR IMPLEMENTATION AND MONITORING

Genomic and other health data must be put to effective use, avoiding fragmentation in data management. There is a clear need to set up a body to coordinate activities at the national level and to provide research institutes, healthcare organisations and companies a single point of contact for services relating to genomic data.

We need a genome centre. Its role would be to oversee the implementation of the genome strategy, serve as a single point of contact for stakeholders needing research, contractual and commercialisation services, and develop a national reference database of genomes. Other responsibilities of the genome centre would include: standardize and streamline the ethical evaluation of research projects, promote networking and collaboration of various actors in the sector, and facilitate Finland's participation in international collaborative projects. The genome centre should enable the storage of genomic data, data integration and interfacing with other services such as biobanks, healthcare systems, research data and reference materials as well as ethical review committees. It will take several years to build and develop the genomic data services. New opportunities will be created around the genomic data services with the potential to generate new business, new professions and an entire ecosystem.

RESPONSIBILITIES OF THE GENOME CENTRE

(to be elaborated on during strategy implementation)

- Develop a national reference database of genomes and a database of genomic variants
- Serve as a single point of contact for research, contractual and commercialisation services
- Evaluate at the national level the validity and utility of genetic tests
- Promote ethical practices in the use of genomic data
- Standardize and streamline ethical evaluation of research projects
- Promote networking and collaboration between the various actors in the sector
- Initiate and stimulate public debate on the utilisation of genomic data
- Facilitate Finland's participation in international collaborative projects

The working group recommends that the genome centre be a permanent body governed by law and that national funding be secured for it (possibly a dedicated budget line in the government budget). The drafting of legislation regarding the genome centre should start immediately.

While the legislation is being prepared, other activities proposed in this strategy can be carried out with a view to achieving the set goals by 2020. A tentative implementation schedule is provided in the roadmap below (Figure 4). A working group should be set up to plan the establishment of the genome centre.

The estimated costs of implementing the genome strategy by 2020 are EUR 50 million. Most of this funding is required for establishing the genome centre. The centre will need between 15 and 20 employees including 10 to 15 high-level experts.

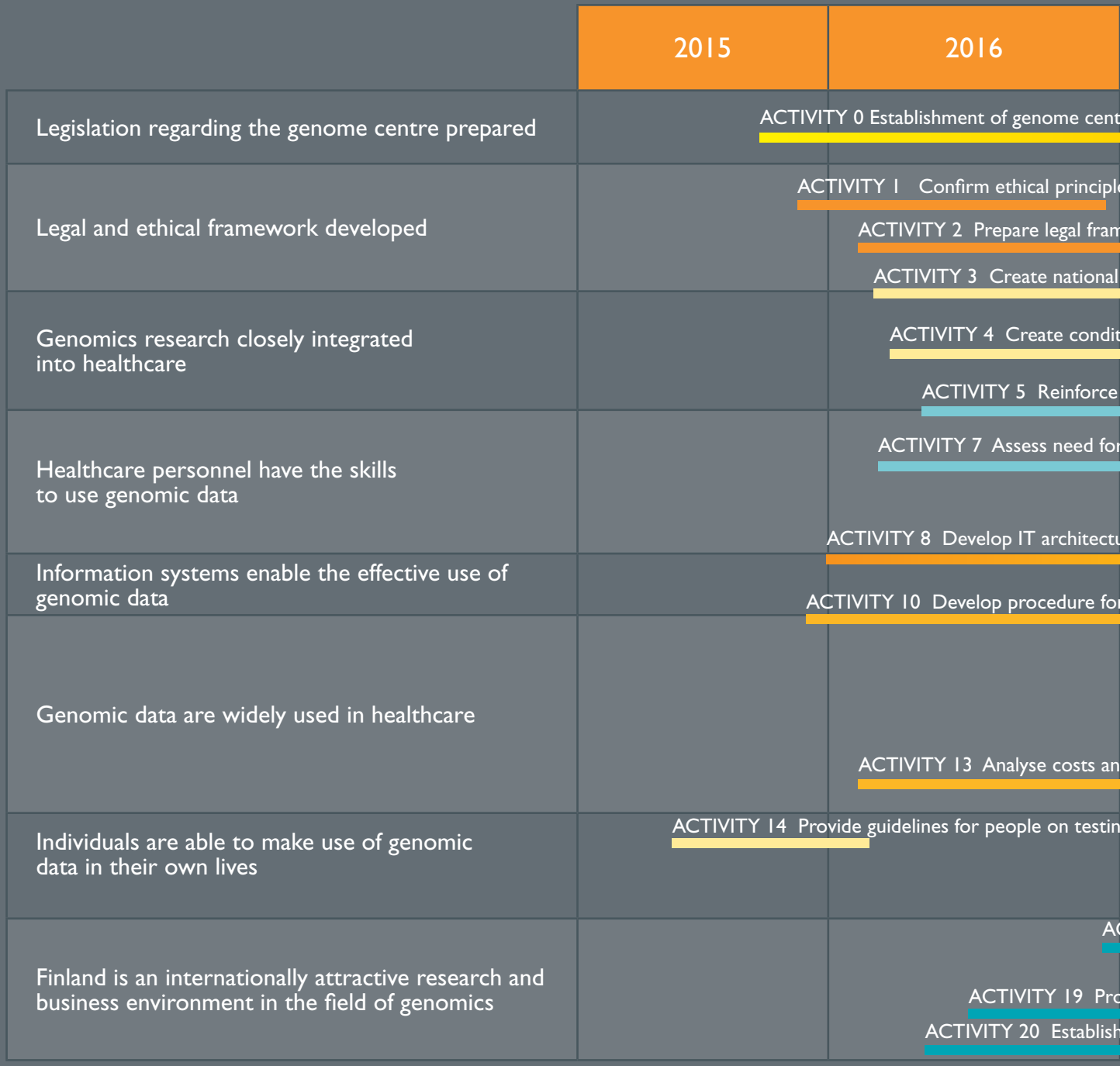
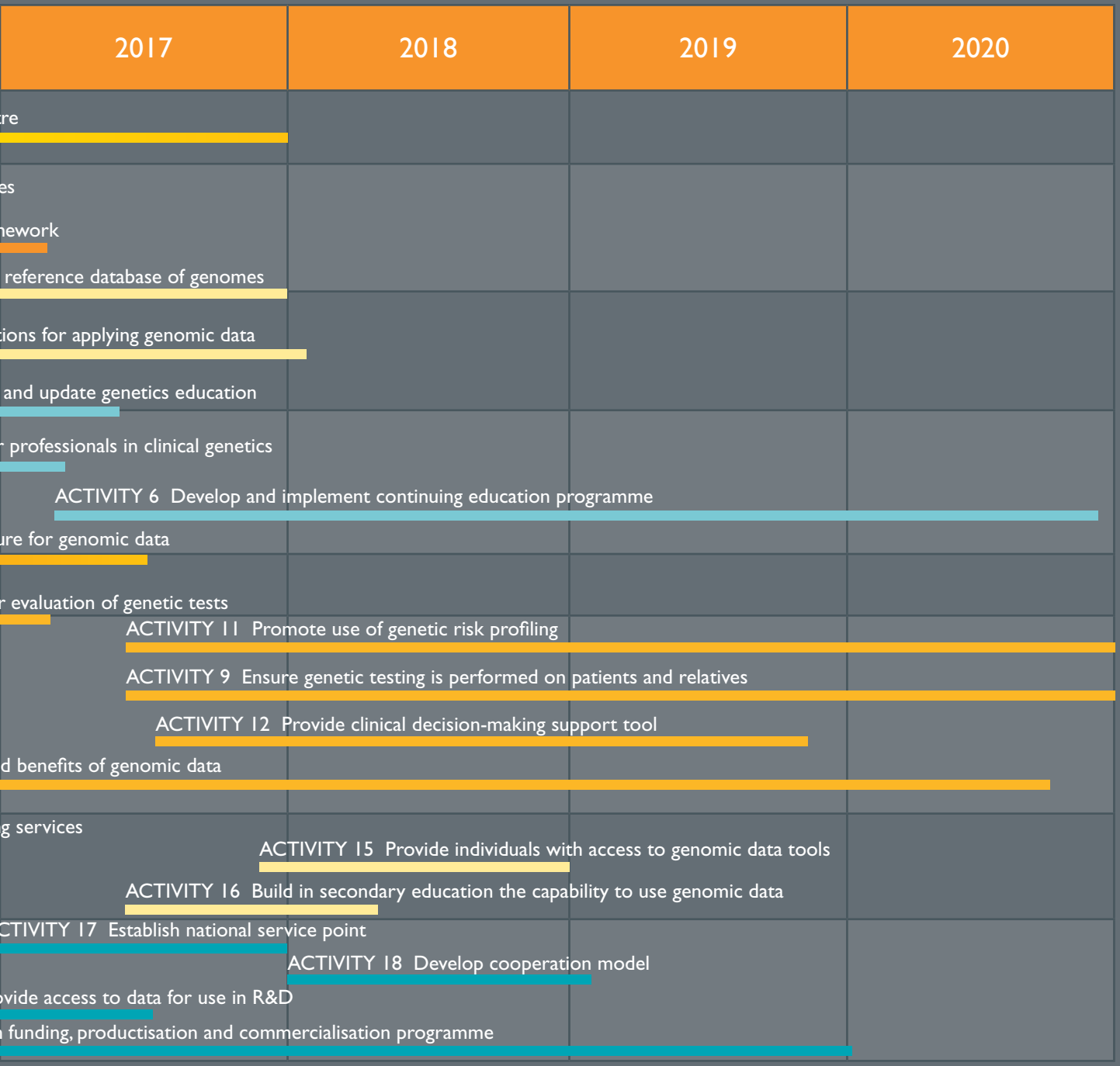


Figure 4. Proposed roadmap for the implementation of the genome strategy.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ACTIVITY 6 Develop and implement continuing education programme
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evaluation of genetic tests
ACTIVITY 11 Promote use of genetic risk profiling
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ovide access to data for use in R&D
funding, productisation and commercialisation programme

USEFUL LINKS

American Society of Human Genetics	http://www.ashg.org
British Society for Genetic Medicine	http://www.bsgm.org.uk
Center for Genetics and Society	http://www.geneticsandsociety.org
Council of Europe	http://www.coe.int/t/dg3/healthbioethic/default_en.asp
European Alliance for Personalised Medicine	http://euapm.eu
European Society of Human Genetics	http://www.bsgm.org.uk
Genomics England	http://www.genomicsengland.co.uk
Global Alliance for Genomics and Health	http://genomicsandhealth.org
Human Genome Organisation (HUGO)	http://www.hugo-international.org
Human Genome Variation Society	http://www.hgvs.org
HumGen International Database on the Legal and Socio-Ethical Aspects of Population Genomics	http://www.dtcgenetest.org
International Genetic Epidemiology Society	http://www.geneticepi.org
Nuffield Council on Bioethics	http://nuffieldbioethics.org
OECD	www.oecd.org/sti/biotechnology/genomics
Public Health Genomics European Network	http://www.phgen.eu/typo3/index.php
World Health Organization	http://www.who.int/topics/genomics/en

APPENDIX 2

GENOME STRATEGY WORKING GROUP MEMBERSHIP

CHAIR:

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Jari Porrasmaa, Senior Adviser, *Ministry of Social Affairs and Health*
Anneli Törrönen, Ministerial Adviser, *Ministry of Social Affairs and Health (until 1 December 2014)*
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IN ADDITION, THE FOLLOWING PERSONS PARTICIPATED TO THE MEETINGS OF THE WORKING GROUP AND TO THE FORMULATION OF THE NATIONAL STRATEGY:

Antti Kivelä, Director, *Finnish Innovation Fund Sitra*
Lauri Salmivalli, Health Care & Life Science Industry Leader, *Deloitte Finland*

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Finland´s Genome Strategy Working Group Proposal

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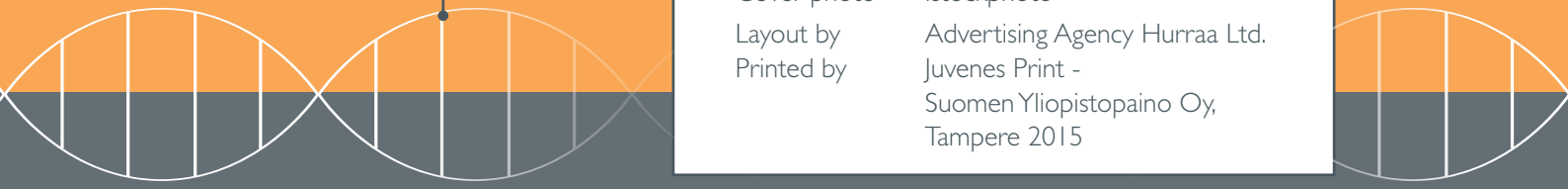

MINISTRY OF
SOCIAL AFFAIRS AND HEALTH

SITRA