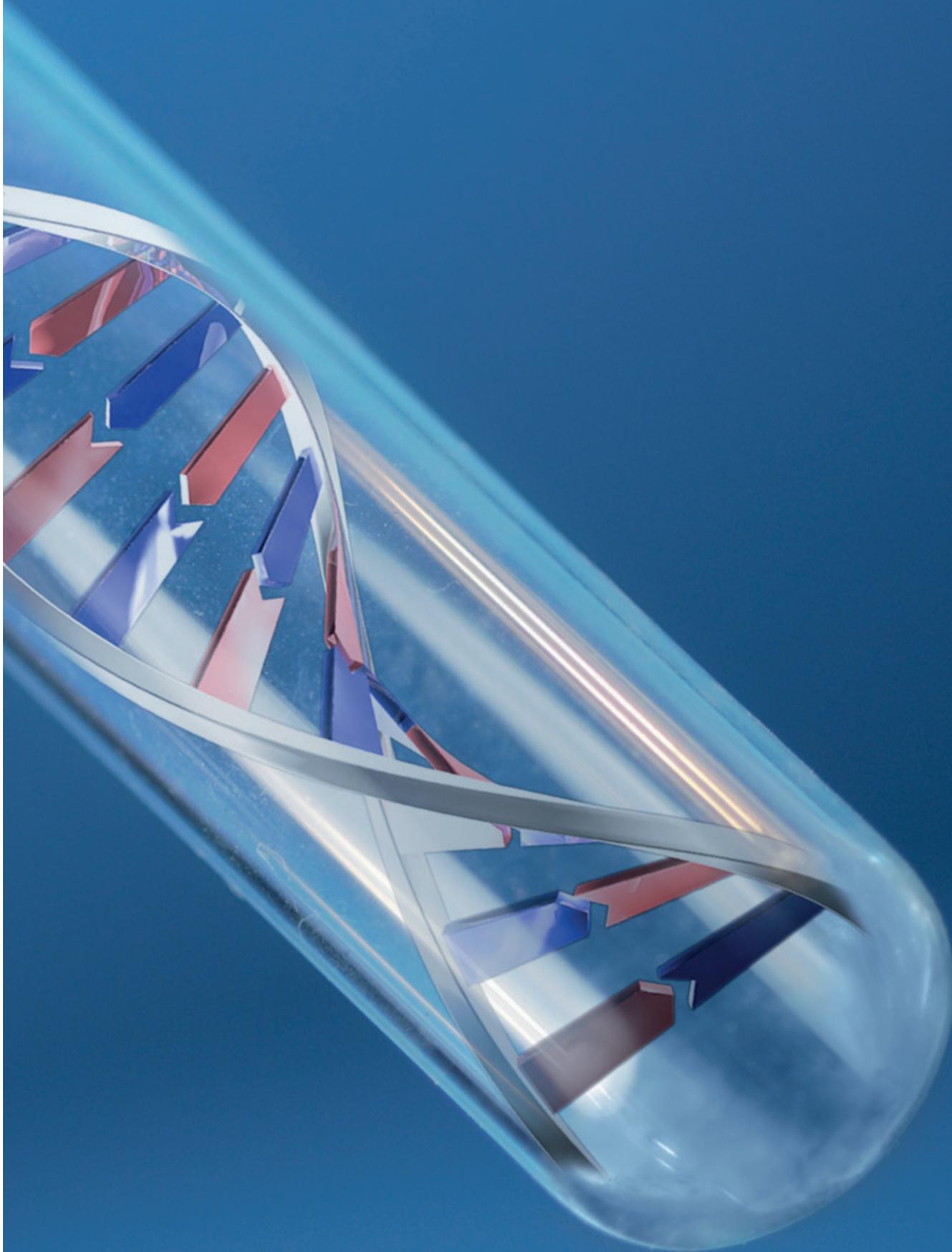


SITRA

# Direct-to-consumer genome data services and their business models





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Direct-to-consumer  
genome data services and  
their business models

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# Contents

	Foreword	4
	Abstract	5
<b>1</b>	<b>..... INTRODUCTION .....</b>	<b>7</b>
	Direct-to-consumer genome data services	8
	What are the services?	
	What kinds of services are available?	
	Description of the business	10
	What does a business model mean?	
	Overview of the market	11
	Development and history of the business operations	
	Offerings on the market	
<b>2</b>	<b>..... BUSINESS MODELS .....</b>	<b>12</b>
	Business model 1:	
	<b>Comprehensive genomic tests for consumers and as genome data bank material</b>	13
	Company example:	
	<b>23andMe</b> – Genetic tests as entertainment and as a data collection means	14
	Company example:	
	<b>DNADTC</b> – Sequencing of the entire genome	15
	Business model 2:	
	<b>Genomics as part of individual health planning</b>	16
	Company example: <b>MD Revolution</b> – Genome data as part of the overall service	17
	Business model 3:	
	<b>Services based on comprehensive genetic testing</b>	18
	Company example: <b>Genetrainer</b> – Genome data as a service platform	19
	Business model 4:	
	<b>Medical precision tests for consumers</b>	20
	Company example: <b>Myriad Genetics</b> – Medical precision testing	21
	Business model 5:	
	<b>Restricted trait tests</b>	22
	Company example: <b>Genecodebook Oy</b> – Individual tests for curious consumers	23
	Summary of the business models	24
	Comparison of the business models	25
	A case of the ownership of genome data: Icelandic experiences	26
<b>3</b>	<b>..... DEVELOPMENT AND FUTURE OF THE SECTOR .....</b>	<b>28</b>
	Market outlook	29
	Business enablers	32
	Glossary	33

# Foreword

**HUMAN HEALTH AND WELL-BEING** are affected by genome, environmental factors, individual choices and chance. The identification and utilisation of factors based on the genome will revolutionise healthcare and medicine as well as the possibilities people have of affecting their own wellbeing. In the future, healthcare will be increasingly based on personalised medicine. Risk factors and strengths can be identified in advance, and the prevention, diagnosis and treatment of diseases can be targeted to have the best effect on each individual. With regard to the national economy, it is about the possibility of significantly improving the productivity of healthcare.

On an individual level, it is about improving the quality of life and increasing the chances of individuals to have an impact on their own lives. In principle, people should own their own health data, including their genome data. The use of genome data always requires the permission of the patient. However, it is each individual's personal choice how much they wish to know about their genome affecting their health and wellbeing, for example, possible risk factors.

This review discusses direct-to-consumer services based on genome data, and their business models. Five business models were identified during the study:

- **comprehensive genomic tests for consumers and as genome data bank material**
- **genomics as part of individual health planning**
- **services based on comprehensive genome tests**
- **medical precision tests for consumers**
- **restricted trait tests.**

On the genomic map, Finns are a unique people. Finland possesses extremely high-level research and know-how in healthcare and genomics as well as comprehensive patient information systems. Even from an international perspective, this combination is an exceptionally great starting point for the launch and utilisation of services based on genome data.

The business models presented in the study form a precis of the current dynamic situation in the field. This report does not discuss the medical utilisation of genome data. During the preparation of the report, several experts in different fields were interviewed, providing valuable information. We would like to extend our warmest thanks to everyone who participated in the preparation and commenting of this report.

With the rapid development of genome data, a national genome strategy is required in order to guarantee healthcare for the citizens in the future as well without endangering their legal protection and fair treatment. The Finnish Innovation Fund Sitra is prepared to participate in preparing a strategy that promotes the wellbeing of all Finns.

For more topical information on the development of the genome data sector, see Sitra's website at [www.sitra.fi](http://www.sitra.fi).

**Antti Kivelä**

Director

# Abstract

## The study identified and assessed five general business models:

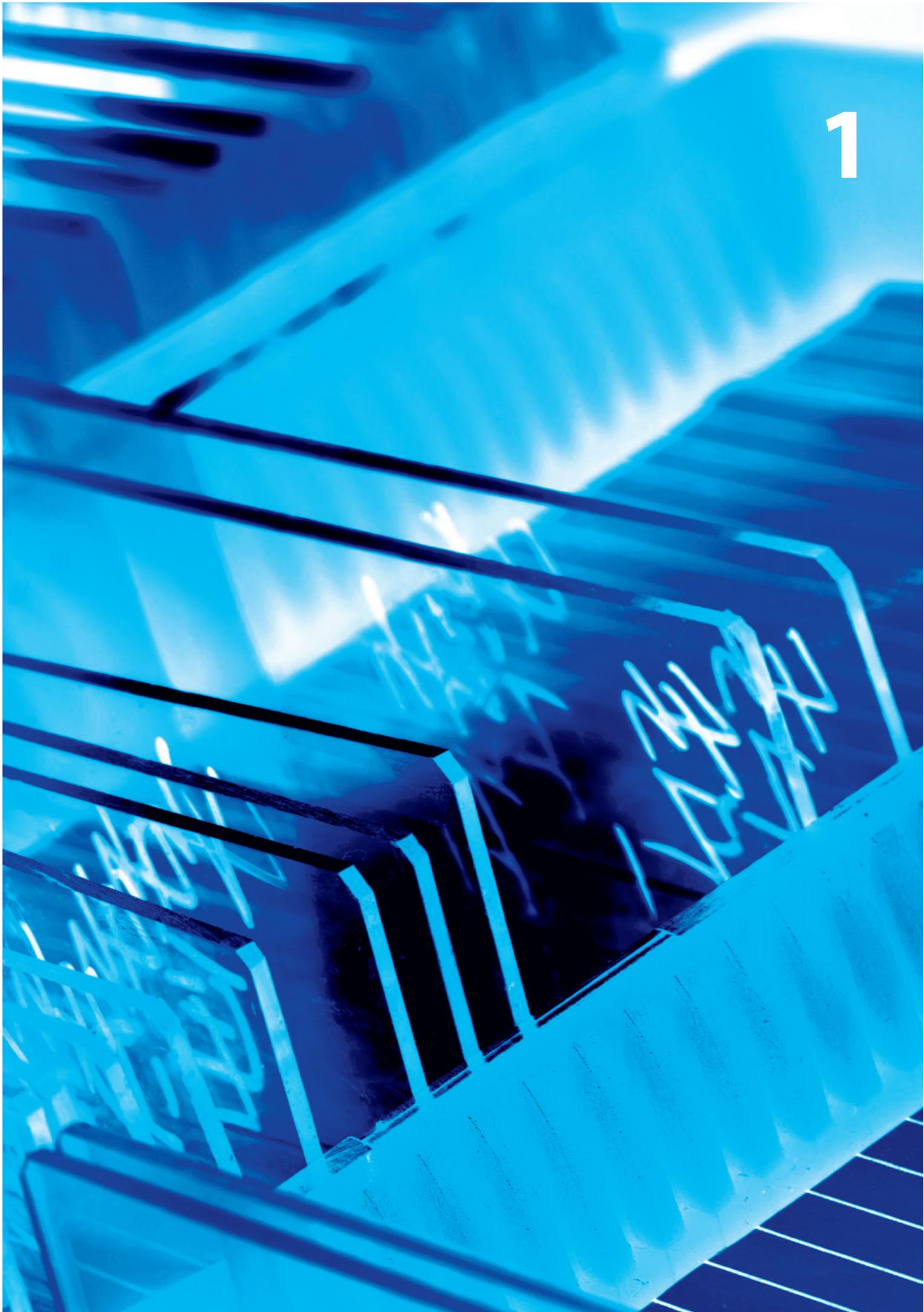
**DIRECT-TO-CONSUMER GENOME DATA TESTS AND** services have become more common with the bioboom. Today, many different kinds of companies are active in the field. The purpose of this study is to describe various business models used by genome data companies offering services directly to consumers and to present viewpoints into the future of this rapidly developing field.

Genome data services are currently living a renaissance after the slump of the early 2000s. The offering can be divided into two subtypes: mere genome tests that produce raw data, and interpretation services, which refine the raw data into meaningful information. Both are often offered together. The price of genome testing has seen a sharp decrease, and the market is concentrated in the hands of just a few companies. The utilisation of genome data continues to be imperfect, but several companies are being born around the creators of raw data and increasing research information.

1	<b>Comprehensive genome tests for consumers and as genome data bank material</b>	<i>Consumers are offered genome data and some interpretation services. The company's genome data bank is useful for research. Price is rapidly decreasing and the market is concentrated in the hands of strong operators.</i>
2	<b>Genomics as part of individual health planning</b>	<i>A lifestyle intervention planned with the help of genome data is promised to provide medical precision. A new operating model.</i>
3	<b>Services based on comprehensive genome tests</b>	<i>Mobile and other interpretation services built on genome data. This model has experienced plenty of traction due to startup companies.</i>
4	<b>Medical precision tests for consumers</b>	<i>Individual tests that offer medical-grade testing to consumers. This high added value service thrives with a high price and believability.</i>
5	<b>Restricted trait tests</b>	<i>Individual tests with which consumers may examine their genetic traits. The market situation is difficult due to the price competition from more extensive tests.</i>

The genome data market is rapidly changing. Based on expert interviews, the number of genome data services is growing but, on the other hand, more and more companies target their products at the healthcare sector.

Finland is in an excellent position for genetic research and the development of new solutions. The enablers for the development of new business comprise the increase in research data, development of genome data platforms, suitable legislation and piloting for verifying the benefits. In particular, Finnish operators can create added value in the combination of high-level information technology and genome data services.



# Introduction

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**GENETIC TESTS ARE RAPIDLY BECOMING MORE COMMONPLACE.** Consumers now have access to services that were only available to the most affluent research groups and universities just a couple of years ago. Public discussion concerning the appropriateness, benefits and harm of consumer genome tests has also arisen. However, not much information on the operations of the companies offering genome tests has been available.

This study describes the most common business models of direct-to-consumer genome data services. The objective of the report is to help the reader understand this new sector and the different ways the companies in the field do business. This report will not discuss genomic tests used during treatment in healthcare.

The report describes the contents of the direct-to-consumer genome data services, and presents a method of dividing these services. Services based on genome data are used for a multitude of reasons. A large part of the services are offered for a medical purpose, but several services appeal to the consumers' hobbies, such as genealogy, willingness to learn, curiosity or lifestyle endeavours.

The business models identified in the market are described one by one in this report. Each description includes

an analysis of the different business sub-areas and an assessment of the strengths and weaknesses of the model. A company example is also presented for each business model with the purpose of illustrating the model in practice. The report offers general information on the market, its development and future outlook.

This study was completed with the help of expert interviews, information searches and by finding information on the companies in the field. In the report, information from the Internet, scientific papers and other sources is combined to create a picture of the current situation of the market and its future prospects.

The descriptions of the companies and their operations are based on content found on the Internet, which means that the information is as accurate as the sources. Although the study has been carefully prepared, assessing the accuracy of the sources, the authors of this report will not assume responsibility for any information that is inaccurate or has changed after the completion of the report (June 2013). ■

# Direct-to-consumer genome data services

Direct-to-consumer genetic services have become more common with the rapid development of the bio sector. Consumers can now purchase many different kinds of services that are based on their personal genome data and were previously available for professional use only.

## What are direct-to-consumer genome data services?

Direct-to-consumer genome data services refer to genomic tests marketed and sold to individual consumers, and services related to the data produced by the genomic testing.

These services are also referred to as DTC genome data services, DTC GT (direct-to-consumer genetic testing), consumer genomics or consumer genetics. Genomic testing may refer to just a laboratory analysis of DNA, producing DNA raw data, or additionally, services related to interpreting that data.

## In this report, direct-to-consumer genome data services are defined as follows:

- 1 *Tests (or services) offered directly to the general public with no intermediaries between the consumer and the service provider.*  
**For example:** A genetic testing kit that can be ordered from the Internet
- 2 *Tests (or services) supplied to the general public via a retailer, such as directly from a pharmacy or via a provider of alternative treatment.*  
**For example:** A genetic test sold at a pharmacy with the help of a pharmacist
- 3 *Tests (or services) where the consumer is the customer, but a person with medical training participates in providing the service.*  
**For example:** A genetic test sold through a doctor's office and a review of the results together with the doctor

This definition is based on the Human Genetics Commission<sup>1</sup> guidelines from Great Britain, and a similar definition by Mitchell et al. (2010)<sup>2</sup>.

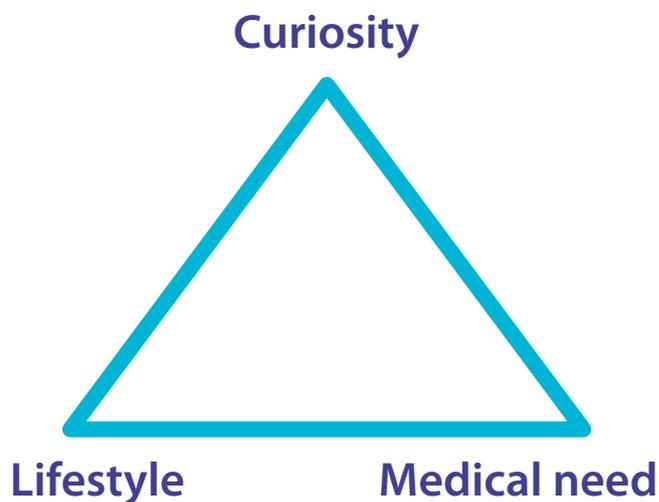
<sup>1</sup> Human Genetics Commission (2010). *A Common Framework of Principles for direct-to-consumer genetic testing services.*

<sup>2</sup> As referred to in the publication: Howard, H. & Borry, P. (2012). *Is there a doctor in the house? The presence of physicians in the direct-to-consumer genetic testing context.* *Journal of Community Genetics*, 3:105–112. DOI 10.1007/s12687-011-0062-0



### What kinds of services are available?

Genome data itself is raw information on the base sequence of an individual's DNA. The composition of DNA, or genotype, has a great effect on the traits of a person; together with environmental factors, it forms the individual's phenotype, or appearance and traits. Children inherit their genome from their parents. These factors make various direct-to-consumer services possible. ■



*The services can be divided into three categories based on the customer's need. The service can meet a need that is medical, experiential or other need for information, or related to a lifestyle change.*

## DIFFERENT GENOME TESTS FOR CONSUMERS

### Diagnostic tests

Tests with the purpose of diagnosing an illness in persons showing symptoms or having other signs of illness.

### Presymptomatic tests

Tests with the purpose of predicting a high risk of an onset of illness in a person showing no symptoms. For example, the risk of breast cancer can be predicted to a certain degree with the BRCA test.

### Carrier screening

Tests for determining whether a person carries a latent gene mutation that predisposed one to an illness or trait that may be expressed in the children of the person tested.

### Prenatal tests

Tests with the purpose of finding medical information prior to the birth of a child or to determine the sex of the child at an early stage of pregnancy.

### Predisposition tests

Tests that provide suggestions on a person's lifelong risk or risk relative to the general population of contracting a specific illness. For example, the APOE test provides information on the predisposition of getting Alzheimer's disease.

### Pharmacogenetic tests

Tests with the purpose of predicting the effects of a specific medication on an individual's system: the effectiveness and adverse effects of the medicine.

### Nutrigenomic tests

Tests with the purpose of predicting the effects of a specific nutrient on an individual, his or her metabolism, health and risk of disease (nutrigenomics).

### Lifestyle or behaviour tests

Tests with the purpose of producing information on an individual's response to exercise and other lifestyle factors to support a change of lifestyle.

### Phenotype tests

Tests with the purpose of producing information on how the phenotype of a person is caused by the genotype; for example, studying the genes causing eye colour.

### Family relation tests

Tests with the purpose of determining blood relations, for example, paternity and maternity tests.

### Ancestry tests

Tests with the purpose of producing information on an individual's genome for ancestry and genealogy.

# Description of the business

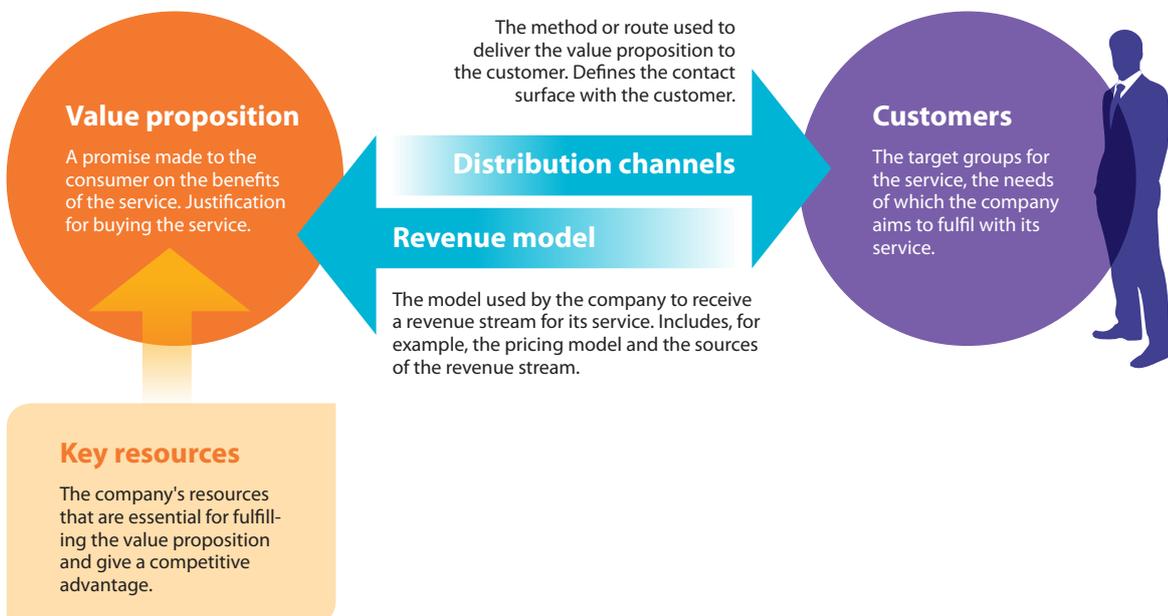
## What does a business model mean?

A business model connects the customer need and the solution offered by the company. A business model may combine many innovations and means for achieving a competitive edge. Both the company and an individual product may have a business model. The same company may use several parallel business models.

Of the business models identified in this report, the following key areas are described: value proposition, customer segments, distribution channels, revenue logic and key resources.

The purpose of this study is, in particular, to describe the operating logic of the companies with relation to the consumers.

The following pages discuss the market and recent history of direct-to-consumer genomics, followed by a description of the identified business models.



# Overview of the market

The direct-to-consumer genomics business has developed in two waves, the second of which is currently in progress. The rapid development from the 1990s to this day has been characterised by both rosy optimism and the downfall of companies.

## Development and history of the business operations

The bioboom began at the end of the 1990s and the turn of the 2000s, when the first DTC genome data services were also launched. Some companies were established mainly by academic researchers, primarily in California and some other hubs. The first wave of the bioboom ended in various bankruptcies and corporate mergers.

The early 2010s has seen the rise of a second wave of development in the field of DTC genomics, apparent from the increasing number of startup companies. The field has also seen some high-value corporate acquisitions as global bio and medicine companies reinforce their know-how. The expectations on the benefits of genetic technology are more realistic during the second wave of development than they were in the first years of the millennium.

In Finland, the total number of genetic tests per year is estimated at over 100,000<sup>3</sup>, but these comprise almost exclusively tests ordered to meet a clinical need by a doctor's

referral. There are no comprehensive statistics on tests directly ordered by Finnish consumers. Direct-to-consumer genome data services are most commonly purchased from abroad over the Internet.

Estimates on the size of the global market in consumer tests vary wildly from some tens of millions of dollars to almost one billion dollars. The value of the market is predicted to grow rapidly, as much as dozens of per cent annually. Due to, for example, the rapid development in the field and the legislation only just being developed, the size of the industry and the emphasis of the market are difficult to predict reliably.

The profitability of companies offering DTC genomics has been poor thus far, which has driven several operators into divestment, bankruptcy, or making their testing services available solely to the healthcare sector.

<sup>3</sup> Vierula, H. (21.2.2013). *Geenitieto kaipaa turvallista varastoa. Lääkärilehti*. Online publication available: [http://www.laakarilehti.fi/uutinen.html?opcode=show/news\\_id=13122/type=1](http://www.laakarilehti.fi/uutinen.html?opcode=show/news_id=13122/type=1) [Referred to on 6.6.2013]

## Offerings on the market

Genome data services can be roughly divided into two subtypes which have different market situations. The types are presented in the illustration below.

Many of the current companies offer services of both types as a single product. There are, however, indications of diversification: the US company GeneByGene has begun offering the sequencing of the entire genome, or DNA genotype, as a separate product. The raw data of the other tests offered by GeneByGene is also available, allowing

the customer to easily analyse his or her own health situation. On the other hand, the start-up company Genetrainer is building its service offering on the data produced by the extensive genomic test of the 23andMe company.

Service providers of different types are differently profiled and generate their revenue from different sources. The following pages present five business models that have been identified with the help of the service type, positioning on the market, and the different factors of the business model. ■

### Genetic testing or genome reading

Collection and laboratory analysis of an individual's DNA sample in order to produce raw data.

The rapid development of testing technology is lowering the prices and making the competition tighter. Testing is becoming commonplace and cheap.

The market is concentrated between only a few operators.

### Interpretation and utilisation of genome data

Explanation of DNA data and its conversion into health information or other useful information.

The understanding of what genome mean to people is improving gradually, but with a constantly increasing speed. Interpretation know-how remains a scarce resource.

The market is developing, with numerous new entrants.

# Business models

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## BUSINESS MODEL 1

# *Comprehensive genomic tests for consumers and as genome data bank material*

Testing services ordered from the Internet offer the consumers an easy way of receiving individual genome data. However, the company might have more use for the data than the consumer who purchased the service.

## Service and value proposition

The service allows a consumer to have his or her genome tested fully or partially. The data allows the profiling of the relative risk of contracting several diseases, personal traits, information related to ancestry, or risks related to medication. The test usually produces suggestive data. Information on the customer's health and traits may also be collected. The services may include the use of social media for sharing the results.

The services promise the consumers a lot of information on their genome, a better understanding of their health and the related risks, and many kinds of information satisfying their curiosity. The service helps the consumers understand their family history; some services allow the customers to find their genetic relatives.

## Distribution channels

The Internet is essentially the sole distribution channel: the products are ordered online and the results are reported online. A courier service delivers the sample. Additionally, the company may offer a telephone consultation service, either as a fixed part of the service or as an optional service for an extra fee.

## Revenue logic

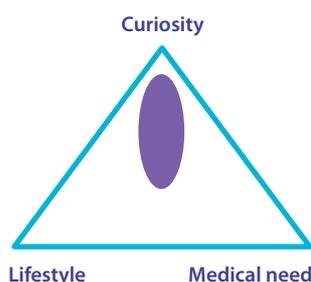
The consumer pays a one-time fee for the test, in exchange for which the genetic sample is analysed and the information reported over the Internet. A monthly charge for using the service is also possible. The majority of the revenue comes from direct sales to consumers, but not through health insurance. Another part of the revenue comes from the sales of the collected genome data and research services to public and private research unit for genetic and medicine research. The revenue logic may include a plan for a market exit, with the intention of increasing know-how and the genome data bank for a corporate acquisition. The company may be running a loss, but assume the service value of the genome data to be very high.

## Customer segments

Consumers that desire an easy way of finding out information on their genome. Often first mover consumers or enthusiasts, more rarely persons seeking an answer to a specific medical question.

## Genome data as a key resource

Genome data is a critical key resource. Companies strive to collect a genome database that is as extensive as possible in order for it to be attractive to research units and pharmaceutical companies. The genome data of individuals can be compared and shared further.



## STRENGTHS

- + Plenty of potential customers.
- + Consumer curiosity and trends increase demand.



## WEAKNESSES

- Profitability is challenging when selling just to consumers.
- Reaching a critical customer mass is extremely important.
- Regulatory pressure is high.

## COMPANY EXAMPLE

## 23andMe

## Genetic tests as entertainment and data gathering

### Amount of personal contact



### Source of revenue stream



### Experientiality



### Operating area



### Importance of genetic data in the service



*23andMe is currently the most popular company offering comprehensive genomic testing services directly to customers. The company's objective is to gain one million users with the help of the revenue stream and venture capital. The genome data of the customers can be used for research purposes on a group level.*

**23ANDME** was founded in 2006 in Mountain View, California. The company offers consumers a genome test that can be ordered online. The test examines roughly one million spots in an individual's DNA and helps in the assessment of relative risks of disease and traits.

23andMe is expanding its operations with the help of ample funding (including Google and Google founders), and aims to increase its user base from the current number of around 350,000 to one million. The price of the test has fallen from around USD 400 in 2008 to USD 100. The company's previous competitors have either ceased to exist or have been acquired.

In the company's value proposition, the consumer receives extensive information on his or her relative health risks, ancestry and learning resources for familiarisation in genomics. 23andMe emphasises the significance of the tests in advancing science and personalised medicine, and appeals to the consumers' desire to participate in work that is meaningful.

23andMe's sole distribution channel is an online sales and service. Both ordering and the reporting of the results are done at a Web portal. The Web portal and software are the company's key resources in addition to the genome data.

The service is targeted at the general public. The service, easy-to-use in practice and based on scientific knowledge, appeals in particular to those interested in technology and health and the first mover segment. The service also competes with individual tests.

The company's revenue logic is based on a customer base that expands due to aggressive pricing. 23andMe is trying to achieve a dominant market position, and has already achieved it to some degree, at which point services based on genome data would begin to build around the 23andMe testing as an ecosystem (for example, Genetrainer). On the other hand, the genome data collected from the customer volume can be utilised through the resale of anonymous cohorts. The genetic data is the company's critical key resource with regard to both producing the service and generating a revenue stream through the resale of the data.

23andMe may be on its way to becoming the de facto standard of the extensive genetic tests in consumer genomics. Major companies in the bio sector have acquired 23andMe's earlier competitors deCODE (Iceland, the first DTC genetic test company) and Navigenics, that have discontinued sales to consumers.

### Other companies operating under a similar business model

#### Counsyl (USA)

The company offers an extensive trait and carrier testing for future parents.

[www.23andMe.com](http://www.23andMe.com)

## DNA DTC

## COMPANY EXAMPLE

# Sequencing of the entire genome

*DNA DTC is a sequencing service of the entire genome offered by the GeneByGene company. Some companies offered sequencing in earlier years, but GeneByGene has brought the service to the market during the new wave. DNA DTC offers genetic data to the customers in a raw format, allowing the consumer to separately choose and purchase added-value generating services. Sequencing the entire genome produces substantial amounts of data that may reveal important things to the individual.*

**GENEBYGENE** started in 2000 as the first company offering commercial genealogy tests (Family Tree DNA). Today, the company based in Houston, Texas also offers trait tests (DNA Traits), family relation tests (DNA Findings) and, as its latest offering, the sequencing of the entire genome, mitochondrial DNA and the exome, or the active part of the genome, for consumers (DNA DTC). Additionally, training services are available. GeneByGene's division Family Tree DNA provides The Genographic Project's genetic testing. This extensive project charts the prehistoric migration routes of the human race. GeneByGene aims to become the world's leading genetic testing and genetic diagnostics company and is very active on the corporate acquisition front.

DNA DTC's value proposition is to produce raw data of the base sequence of an individual's DNA accurately and reliably. The product does not include analysis or genome interpretation, and it is mainly intended for research purposes. The consumer receives the raw data that he or she can use to acquire interpretation information from the desired location in the sequence.

Ordering the sequencing offered by DNA DTC, and the data delivery, both take place in an online service. The customer must take and deliver the blood sample required in the test, so a healthcare professional may be required during the ordering process.

In the first phase, the target group comprises genome field experts, researchers and affluent people interested in the subject. The scarcity of interpreting services limits the wide-scale sales of the test.

The current consumer price for testing the entire genome is USD 6,995. The company's revenue logic also includes the utilisation of the collected genome data in research and development purposes. The ownership of the genetic data remains with the customer, but GeneByGene reserves the right to use the data to acquire revenue.

DNA DTC is one of the rare companies that have taken the leap to sequencing the entire genome for consumers, so it has the chance of becoming the dominant actor in the field. The greatest obstacle is the small added value the customer gains from just the raw DNA data: interpreting the large mass of data is difficult and the high price is difficult to justify. The situation may change rapidly, if consumer-targeted automatic interpreting services become more prevalent. Interpretation software targeted at researchers is already available (for example, Knome and Complete Genomics).

Customers can also receive a more limited set of genome data via GenebyGene's Family Tree DNA. The customer can then analyse the data using, for example, the Promethease online tool, also used by professionals.

[www.genebygene.com](http://www.genebygene.com), [www.dnadc.com](http://www.dnadc.com)  
[www.familytreedna.com](http://www.familytreedna.com)

## Amount of personal contact



## Source of revenue stream



## Experientality



## Operating area



## Importance of genetic data in the service



### Other companies operating under a similar business model

#### Illumina

The company is a leading supplier of genetic testing equipment and technology. Illumina offers the sequencing of the entire genome to interested parties via a genome sequencing conference.

## BUSINESS MODEL 2

# Genomics as part of individual health planning

In the business model, individual genome data is used as a part of a more extensive health service package. The company's aim is to stand out in the market in particular due to genetic testing.

## Service and value proposition

The service often includes individual health planning based on genome data and the collected lifestyle information, and personal guidance in changing one's lifestyle.

Particular areas of application include lifestyle changes for persons suffering from chronic illnesses or as a preventive measure. The services aim to appear medically credible.

Genome data is promised to generate added value by enabling the planning of an entirely individual lifestyle programme in order to achieve optimal health results. The service can comprise, for example, the following segments:

- diet optimisation with the help of genomics, *nutrigenomics*
- identification of disease risks
- identification of personal exercise type and an evaluation of the risk of injury.

## Distribution channels

This comprehensive service is most commonly offered as a multiprofessional contact service. The service may be expanded by means of mobile applications and remote connections.

## Revenue logic

The service is sold as an entire package that includes individual planning, visits, and genetic and other tests. Service products of different sizes and scopes may be available.

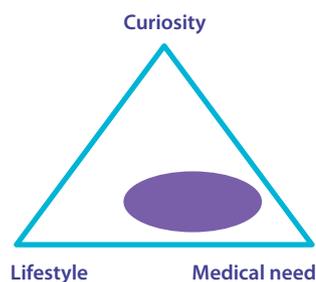
The one who pays for the service may be an insurance company (USA) or the consumer him or herself. Insurance companies may have an incentive to utilise a proven preventive approach, preventing expensive complications.

## Customer segments

Persons who have chronic illnesses or belong to a risk group and wish to change their lifestyle.

## Genome data as a key resource

Genome data forms a part of the service, and it is treated as the other medical patient data. The genetic testing is often outsourced. The genome data is usually not utilised other than for producing the service, but the use of the genome data helps the company to stand out from the competition due to its scientific nature.



## STRENGTHS

- + The need and the benefits are evident.
- + A change trend where persons assume more responsibility for their own health.



## WEAKNESSES

- The market is not yet mature for genetics-based preventive healthcare services.
- The attitude of insurance companies towards preventive healthcare services.

## MD Revolution

COMPANY EXAMPLE

# Genome data as part of overall service

*The San Diego based MD Revolution is a nascent company offering individual medicine services based on genome data. In the service, a preventive lifestyle plan is customised for the customer, including tracking that supports the change. The company utilises genome data, multiprofessionality and mobile solutions to create a new kind of a service model.*

**MD REVOLUTION** is a company established by doctors, offering personal health plans utilising genetic testing and a mobile health tracking application. The service includes nutrigenomics, disease predisposition charting and prediction of drug response, particularly for cardiovascular diseases. MD Revolution outsources the actual genetic testing to the Pathway Genomics testing company.

The starting price of the health programmes is around USD 900, including medical supervision from 90 days to one year. The different-level service packages are given an all-inclusive price based on the duration and intensiveness of the service.

MD Revolution's value proposition is better health and prevention of disease through individual and comprehensive health guidance. The company emphasises personal support in lifestyle change and the medical foundation of the plan. Several distribution channels supporting each other have been chosen for fulfilling the value proposition: face-to-face meetings, remote connection solutions and the mHealth solution built on a mobile platform.

MD Revolution's potential customers include persons who are concerned for their health and are at risk of a lifestyle disease, and persons who have already become ill. The impulse for using the service may originate from the person's circle of acquaintances or from elsewhere in the healthcare system.

The company asks for an all-inclusive price either directly from the consumer or via an insurance company. The pricing model is strongly conducive towards the overall package, and the service parts are not itemised.

Genome data is used as a means of improving individual health planning, but it forms only a part of the overall service. Genetic testing is also a powerful way of differentiating from the other competitors offering lifestyle change services. The actual usefulness of the data produced by genetic testing in personal health planning still remains scientifically unproven.

MD Revolution's offering is promising, and is following the trend of healthcare becoming more individualised, emphasising the patient's own role as the crucial factor in one's own health. The service promise is likely to achieve its real potential only once the interpretation of genome data is developed and mainstream healthcare adopts the use of genome data services and recommends it extensively.

### Amount of personal contact



### Source of revenue stream



### Experientiality



### Operating area



### Importance of genetic data in the service



### Other companies operating under a similar business model

#### Health Puzzle (Finland)

This Finnish startup is creating a mobile platform that combines genetic data and lifestyle monitoring in order to enable individual health planning.

#### 1eq

A nascent company developing a digital platform, combining genetic, lifestyle and health data. The service is currently in the beta-testing stage.

[www.mdrevolution.com](http://www.mdrevolution.com)

## BUSINESS MODEL 3

# Services based on comprehensive genomic tests

Comprehensive genetic tests produce data on top of which other companies can build their own service offering. Interpretation services help genome data to gain a practical meaning.

## Service and value proposition

In this business model, the company utilises individual genome data produced by a different party in order to offer its service. The company does not perform the genetic testing itself; it uses data produced by a genetic testing company as a platform. Genomic advice services can also be considered to be business that uses genome data as a platform. Different service types may include lifestyle services or genealogy services. The services are often differentiated from medical services in order to avoid the regulation related to the field.

The provider promises to produce individual and personalised information from the genome data, for example concerning exercising habits and nutrition. With the help of the service, the customer may achieve his or her best genetic potential, choose a correct diet and other facets of a lifestyle in order to gain better health, or just receive interesting information on these issues. The value proposition is based on a deeper understanding of the genome data and a more extensive utility value for the earlier test.

## Distribution channels

A player in the field can offer a genome data interpretation service and related plans either fully electronically or as a neighbourhood service. In the fully electronic solutions, an interpretation of the genome data received online is output as a report that is delivered to the customer via the online service. The interpretation service can also be provided over the telephone or during a personal visit.

## Revenue logic

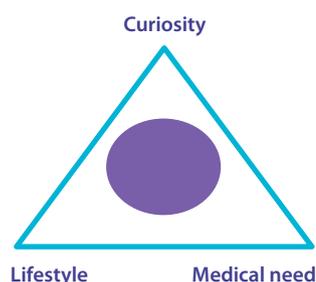
The consumer pays either a single payment for the service (individual report), a monthly fee, or an hourly rate (genetic advice services). The pricing aims to be affordable, as the consumer must separately acquire the genetic testing. Following the early software investments, electronic services have the benefit of being extremely scalable.

## Customer segments

The target group includes persons who have already acquired a genetic test or acquire one encouraged by the service. At the initial stage, these persons include, for example, special groups or enthusiasts interested in their own lifestyle, but as genetic testing improves, the target groups may expand.

## Genome data as a key resource

Genome data is a requirement for the service. The ownership of the data usually remains with the customer, but this is very dependent on the company's data protection agreement. In contrast with the aforementioned business model #2, in this model genome data is a critical requirement for service.



## STRENGTHS

- + There is high demand for interpretation services and a lot of possible applications.
- + Depending on the distribution model, either excellent scalability or low fixed expenses.
- + Lower regulatory pressure.



## WEAKNESSES

- The market is still young.
- The scientific knowledge required in the interpretation remains incomplete in many ways.

## Genetrainer

## COMPANY EXAMPLE

# Genomic data as a service platform

*Genetrainer is a British startup that has attracted a lot of interest with the product it has developed. The company promises to offer a personalised exercise plan within a couple of minutes based on, for example, genetic data from the 23andMe service. Its business is based on the interpretation of genome data, software and algorithm development, and scalability.*

**GENETRAINER** is a service company established in 2013, still at its developing stage, promising to draw up a personal fitness plan for its customers based on genetic data. The company is currently raising venture capital and assembling a co-operation network. Its partners include the heart rate monitor manufacturer Polar and the GPS locator company Garmin.

Genetrainer's value proposition is an individual and optimal fitness plan that enables the achievement of one's personal exercise goals as efficiently as possible. Genetrainer promises to deliver the report within a couple of minutes from receiving the genetic data. The company is aiming at the global market, thus utilising an online service as its sole distribution channel.

The company profiles itself in the same target group as many fitness services: sufficiently affluent population interested in its health. Genetrainer utilises the current quantified self and self-hacking trend, where individual wellbeing is attempted to be optimised with scientific precision.

The revenue logic is based on extremely good scalability: Genetrainer's core comprises software algorithms and reporting automation, which enable fast analysis of the input genetic data and reporting it to the customer. The pricing model or consumer price of the service has not been published yet.

Genetrainer receives its genetic data from commercially available direct-to-consumer genetic testing services such as 23andMe and Family Tree DNA. The service also supports the genetic data of companies that have already gone out of business (deCODEme and Navigenics). Genetic data forms the foundation of the service, and it is possible that it will be used to further develop the service.

Genetrainer seems to represent the birth of a business ecosystem based on genome data. In practice, 23andMe acts as the ecosystem platform, but in the future, it could be any party performing wide-scale genomic testing or sequencing of the entire genome. The business model also enables a rather light way of starting to do business, as the service in question is based on a software product and is easily scalable. The basic requirements of this model are parties efficiently producing individual genomic testing and sufficient research data. The progression might follow the birth of mobile ecosystems, where a lot of business grows on top of strong mobile platforms such as Android.

[www.genetrainer.com](http://www.genetrainer.com)

## Amount of personal contact



## Source of revenue stream



## Experientiality



## Operating area



## Importance of genetic data in the service



### Other companies operating under a similar business model

#### Genetic Genie (USA)

A free service that performs a limited metabolism analysis based on 23andMe raw data.

#### Promethease (USA)

Promethease offers a genome data interpretation service on the Internet. The basic level of the service is free, and an improved version of the service can be purchased for a fee (a so-called 'freemium' model).

## BUSINESS MODEL 4

# Medical precision tests for consumers

A person concerned with his or her hereditary diseases can have an accurate targeted test done, producing clinical information on the risk of disease or the person's carrier status.

## Service and value proposition

Through testing, a customer can get an answer to a certain question concerning his or her health. The tests are medical although they are offered to private consumers. In most countries, medical tests are mainly performed as part of public healthcare.

Interpretation of and support for the test results by a medical professional are always involved in consumer testing. The most well known test types are tests for rare genetic diseases and carrier status tests for prospective parents. Paternity and prenatal testing can also be considered to belong into this category. The BRAC genetic test predicting risk of breast cancer can be offered to customers concerned with their own risk of developing breast cancer.

The service promises to give the buyer the required information reliably and accurately and to communicate the results in a manner understood by the customer. The information allows the customer to make life choices that may have a great impact on his or her health.

## Distribution channels

The distribution channel used is almost solely either healthcare professionals in a public healthcare system or specialised clinics. In the United States, genetic testing is marketed directly to consumers, but the order itself is most often placed through professionals in order to ensure the necessary support. The use of medical professionals as the distribution channel increases the legitimacy of the tests in the eyes of the consumers.

## Revenue logic

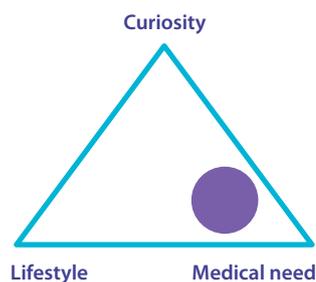
The testing services are often expensive, but consumers are willing to pay a high price for medical accuracy and expert help. The one paying can be the consumer or an insurance company.

## Customer segments

Consumers with a need for specific information, for example, due to a hereditary disease appearing in the family, and who can afford the service.

## Genome data as a key resource

Genome data makes the service and further development of the tests possible for the company offering the service. Genome data is an essential and fixed part of the service.



## STRENGTHS

- + A high-profile service allows for the asking of a high price.
- + As medicine develops, the use of the tests will become more common.



## WEAKNESSES

- Specific tests are vulnerable to competition, if patent protection practices change.
- The sequencing of the entire genome may make individual tests unnecessary.

# Myriad Genetics

## COMPANY EXAMPLE

### Medical precision testing

*Myriad Genetics is a US company developing and selling genomic tests for medical purposes. Actress Angelina Jolie, for example, was a customer of Myriad Genetics before her decision to have a preventive mastectomy. The company's gene patenting has raised wide-scale discussion on the operation of genetic testing companies.*

**MYRIAD GENETICS** was founded in 1992 for the development and commercialisation of medical genetic tests predicting risk of cancer. The company has patented, for example, the so-called BRACAnalysis test that is used to study hereditary risk for breast and ovarian cancer. Myriad Genetics attempted to patent the BRAC breast and ovarian cancer gene, but the United States Supreme Court decided in June 2013 that human genes cannot be patented.

The company's value proposition is medical accuracy and high-level risk assessment with the help of genetic testing. Myriad Genetics is clearly profiled as a healthcare partner. The company currently offers around ten targeted products.

Tests are distributed through healthcare professionals who can order a test directly from an online service. Myriad Genetics is actively promoting the consumers' own activity as the party asking for a genetic test. Healthcare as the distribution channel enables the use of insurance compensation to a certain extent and ensures that the customer will receive support in interpreting the test results and making any treatment decisions. Myriad also produces a lot of training material to support its customers.

The revenue of Myriad Genetics is based on its own product development, patent protection and the high price asked for the medical products. The one who pays for the test services can be the customer him or herself or a health insurance company. Competition in medical testing is limited by rigorous regulation and the strictness of the approval procedures.

The company uses significant amounts of genome data in its product development. The data produced by the tests is medical, and the company almost certainly uses it in its own product development.

The number of medical targeted tests will likely grow notably over the coming years, and business in the field will develop. The biggest threat to the business model of companies offering individual tests is the sequencing of the entire genome becoming cheaper – instead of performing an individual test, you can read the entire DNA. The importance of genome interpretation expertise will then grow even further.

In the short term, the decision by the United States Supreme Court to prohibit the patenting of human genes may reduce the interest of investors in medical tests. However, the testing technology is specialised and can be protected, and the expertise required in high-level genome data services is difficult to attain, so in the long term, the limitation of gene patents is more likely to make the creation of alternative technologies possible.

[www.myriad.com](http://www.myriad.com)

#### Amount of personal contact



#### Source of revenue stream



#### Experientiality



#### Operating area



#### Importance of genetic data in the service



#### Other companies operating under a similar business model

##### Kimball Genetics (USA)

The company (part of Labcorp) sells many targeted genetic tests directly to consumers.

##### Medichecks (UK)

The company sells a very extensive selection of laboratory tests, including several genetic testing products.

## BUSINESS MODEL 5

*Restricted trait tests*

Consumers may find out limited parts of their genome for their own purpose. The need is often on the level of 'nice to know' or a desire to lead a healthier lifestyle.

**Service and value proposition**

A mixed bag of lifestyle tests are available. Individual tests can be used to find out the form of the lactose intolerance gene or the bitter taste gene, seek help for improving nutrition or identify the best form of exercise. The services are often connected by the focus on fulfilling one need. The tests rarely include personal consultations concerning the test results.

The value propositions of the services are related to improving the quality of life; not so much preventing diseases or other medical needs. Different providers may promise, for example, genome data helping slow down aging, better athletic performance through the understanding of one's own genome, or understanding of one's personal traits.

**Distribution channels**

The distribution channels try to get close to the consumer. In addition to direct online sales, pharmacies, alternative treatment clinics and beauty salons can market and resell the tests in addition to their own services.

**Revenue logic**

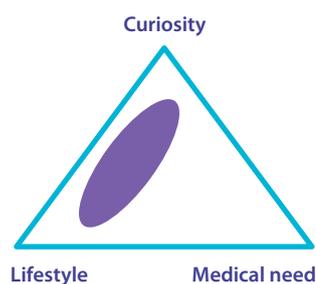
A one-time payment is often made for the test and the service. The consumer always pays for the test him or herself. The prices of individual tests range from around EUR 50 to 200, including the testing package, laboratory analysis and a report in a specified form.

**Customer segments**

The often high price relative to the specificity of the service limits the number of buyers: the customers are enthusiastic about a certain issue and are sufficiently affluent. For example, the customers for the exercise test can be health enthusiasts.

**Genome data as a key resource**

Genome data is almost solely used in the production of the service, and the collected data rarely has other uses. The main reason for the genetic testing is differentiation on the market. The genome data produced during the testing may end up at the subcontracting laboratories, depending on the company.

**STRENGTHS**

- + Lower regulatory pressure due to a precisely specified service targeting.
- + Consumer curiosity and trends increase demand.

**WEAKNESSES**

- The usefulness of the genome data is often unclear.
- Customers may include only a small special group.
- Genome-wide tests offer much more data at a cheaper or the same price.

# Genecodebook Oy

COMPANY EXAMPLE

## Individual tests for curious consumers

*The Finnish Genecodebook Oy offers precision tests targeted at consumers. The Oulu-based company sells its selection of five tests through an online store and pharmacy retailers. The tests produce health information or phenotype information. It is difficult for individual tests to compete with genome-wide tests.*

Founded in Oulu in 2010, **GENECODEBOOK OY** offers five consumer tests that are based on the analysis of one or a couple of base pair variations (SNP, "snip") in the sample. The tests can be used to study, for example, taste, lactose intolerance, and certain disease risks. The company also plans to expand its service offering to clinical operators in both the private and public sectors.

The service includes a genetic testing package, laboratory analysis and an interpretation of the results via an online service. The value proposition depends on the test: either knowledge of the risk for an individual disease, which might make the customer seek screening, or, in the case of the taste test, plain entertainment and satisfaction of curiosity.

Genecodebook Oy's distribution channels are the online store and pharmacies. The company is trying to get as close to the consumer as possible. In addition to the online report, the service does not include genetic consultation. In the case of pharmacy sales, the pharmaceutical staff can offer advice according to their level of expertise.

The price of individual tests varies between EUR 96 and 169, and the revenue model is based on one-time payments made by the consumers. Genecodebook Oy does not sell or disclose the genome data produced during the tests, but as with the other genetic testing companies, it may use the mass of data in the development of its own services.

Testing is targeted at either persons concerned with the risk of contracting a specific disease, or for entertainment use, such as a gift for a wine enthusiast. The tests sold via pharmacies can attract affluent impulse buyers.

Genecodebook Oy's business model is challenging. In 2012, the company ran a loss of over EUR 80,000 with a very small turnover. The company has not introduced new tests on the market after 2011.

Individual tests face the toughest competition from genome-wide tests, the price of which has fallen significantly. A genome-wide test commissioned at the same price can produce more than a thousand times the amount of data when compared to a restricted genetic test. Genecodebook Oy's tests may find a niche in the customer base found through pharmacies.

### Amount of personal contact



### Source of revenue stream



### Experientality



### Operating area



### Importance of genetic data in the service



### Other companies operating under a similar business model

#### GenePlanet (Slovenia)

GenePlanet, operating in Europe, offers a selection of a few dozen genetic tests for different purposes.

#### CoolGenes (UK)

In the near future, the company will begin sales of several non-medical genetic tests to consumers in an online store.

# Summary of the business models

The table presents the key points of the identified business models of direct-to-consumer genome data services, and an assessment of the strengths and prospects of the business models.

	1	2	3	4	5
	<b>Comprehensive genomic tests for consumers and as genome data bank material</b>	<b>Genomics as part of individual health planning</b>	<b>Services based on comprehensive genomic tests</b>	<b>Medical precision tests for consumers</b>	<b>Restricted trait tests</b>
<b>Value proposition to consumers</b>	Understanding of health risks, entertainment and possibility of familiarisation with genomics.	A health plan drawn up with the help of genome data and comprehensive support for a change in lifestyle.	Individual lifestyle service with the help of outsourced genetic testing quickly and easily.	A reliable and accurate answer to a medical question a customer asks.	Fun and useful information on a person's specific trait.
<b>Distribution channels</b>	Remote ordering and reporting through a Web portal.	Face-to-face, via a remote connection and on a mobile platform.	Online report of the customer's data.	Usually through healthcare, online ordering also supported.	Usually through healthcare, online ordering also supported.
<b>Customer target groups</b>	First movers, those interested in genomics and certain special groups, depending on the service.	Persons seeking a lifestyle change, technology-oriented persons, persons suffering from lifestyle diseases.	Persons interested in their lifestyle, fitness enthusiasts, quantified self enthusiasts.	Affluent persons interested in their own risk of disease.	Enthusiastic and affluent first mover customers.
<b>Revenue logic</b>	Affordable consumer price and a large number of customers. Research use of the genetic data.	The price charged for the genome-wide service is rather high. Medical service and possibility of insurance compensation.	Attractive pricing and a strong push for benefits of scale. There is also an hour-based revenue model.	A concerned customer pays a premium for the reliability of a medical test. Possibility of insurance compensation.	One-time payments made by consumers.
<b>Key resources</b>	Genome data is a critical key resource and one source of revenue. The value of the collected data is significant	Genome data forms a part of the creation of the service offering. The professionals and the software are the key resources.	Genome data is the foundation of the service offering. Software know-how is a critical resource.	Genome data is a critical resource for product development.	Genome data is a critical resource for product development. The resale value of data collected from the customers is poor.
<b>Assessment of the business model</b>	<b>The business model requires a strong position in the market. Some of the players in the field have become testing providers for healthcare.</b>	<b>This model is on the rise, but the incomplete understanding of how to interpret the genome data will continue to hinder the model for some years yet.</b>	<b>Large potential once the interpretation of genetic data improves. Launching a software-based service is relatively quick.</b>	<b>Functional model with increasing demand. The sequencing of the entire genome may completely change the business model.</b>	<b>A challenging model, with difficulty in price competition with genome-wide tests.</b>

Companies offering genome data services may also offer clinical services to healthcare, but the business model is different with regard to these. Genetic tests used in healthcare during treatment are outside the scope of this review.

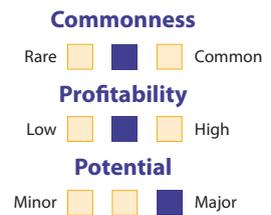
# Comparison of the business models

Between the identified five business models, there are large differences in how common and functional they are and what their future potential is. The fast increase of research data, individual lifestyle trends, patenting approaches and regulation guide the business operations.

1

## Comprehensive genomic tests for consumers and as genome data bank material

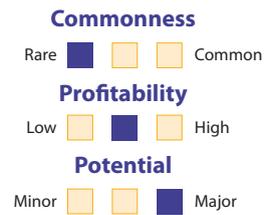
There are only a small number of companies operating under this business model, but the players have already become rather established. The regulation of laboratories and the volume advantage are likely to continue to concentrate the market to fewer players in the future. Testing costs are decreasing extremely rapidly. The profitability of the model in consumer sales is currently weak or fair, partially based on income from the research use of the genetic data.



2

## Genomics as part of individual health planning

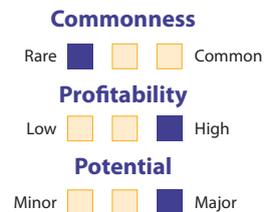
There is a clear and justified need for the services. There are currently only a few players in the field, most of them are at the startup stage. The number of companies will likely increase, and the business models will develop into new forms. The profitability of the model is potentially good. Scalability depends entirely on the balance between personal service and digital solutions.



3

## Services based on comprehensive genomic tests

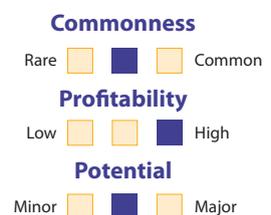
A small number of nascent companies operate in the field, but a large number of new companies are likely to be founded. The business model will greatly benefit from the extensive genetic tests and genome sequencing becoming cheaper and more common. The model enables the development of many services with high added value and good scalability.



4

## Medical precision tests for consumers

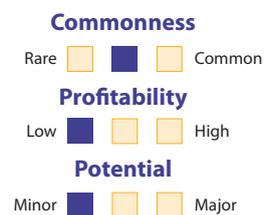
Pricey but accurate tests are likely to retain and increase their position as the awareness of the consumers increases. Drivers of change are regulation and the genome sequencing becoming cheaper, making single tests more difficult to justify. Many companies are likely to become service providers solely for healthcare. Profitability is based on the price premium gained from the medical reliability.



5

## Restricted trait tests

The number of companies offering individual tests mainly for entertainment purposes has increased during the last couple of years. The greatest threat this model faces is price pressure from more extensive tests. The profitability of restricted trait tests requires large volumes, and thus far, their profitability has been low. It is difficult to predict a bright future for this business model.



## Icelandic genome data

*deCODE Genetics was a pioneer of direct-to-consumer genome data services that attempted to take advantage of the special nature of the genome of the Icelandic people. However, this promising company ran into financial difficulties, ending up as a part of a major multinational bioindustry company through several intermediaries. The transfer of the genome data along the corporate acquisition raises legal, ethical and moral questions with regard to the ownership of the data.*

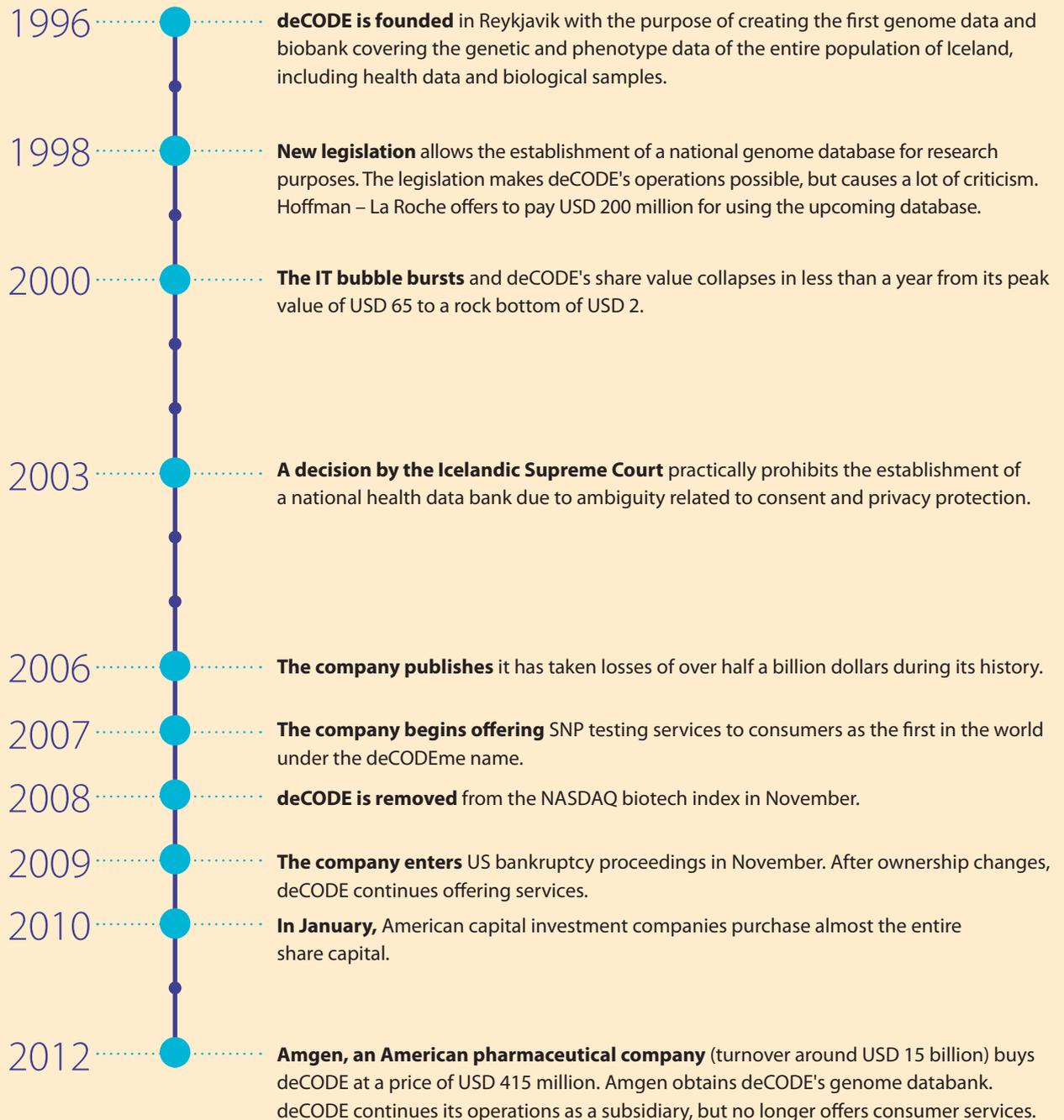
deCODE Genetics succeeded in many ways in its goal of enabling medical development with the help of the homogeneous genome of the Icelanders: the company identified gene alleles affecting several serious diseases, and the work is still ongoing as part of Amgen, a US company.

The extensive gene bank was based on as many as 140,000 Icelanders who promised, at the turn of the millennium, to donate their health data and genetic samples in order to promote research, and the desire of the politicians to see Iceland rise into prominence as a genomics superpower. As deCODE began making deals on selling the right to use the genome data to pharmaceutical companies, the public opinion began to turn. A lawsuit raised against the company, where a private person wished to prevent his deceased father's data from being handed over to deCODE, halted the collection of data. There is no precise public information on the number of Icelanders from whom the company had already collected data and samples.

Leveraging the expertise it had attained and the data produced by the gene bank, deCODE began offering consumer testing under the deCODEme brand. Soon, 23andMe and Navigenics entered the field as competitors. From this trio, 23andMe emerged as the winner, backed by the Google background. The pharmaceutical industry made generous offers for the two others in order to obtain the valuable genome data. A group of investors managed to acquire deCODE after the 2009 bankruptcy at a fraction of the price that Amgen paid for it three years later. The biological samples remain on Icelandic ground in accordance with Icelandic law.

deCODE continues its operation as a subsidiary of Amgen, but it no longer offers direct-to-consumer tests. The deCODEme consumer test has been unable to compete in pricing with the largest player in the field, 23andMe.

Many Icelandic small investors lost the money they invested and the genome data collected from volunteers ended up being merchandise. On the other hand, the corporate acquisition is believed to secure that deCODE continues research operations in Iceland. The case proved the value of genetic data to the pharmaceutical industry, and also showed that free market economy countries have very limited means of controlling the sale and transfer of genome data once the tested person has given a sufficiently broad consent for research use.



A close-up photograph of the control panel of a medical ultrasound machine. The panel is light-colored with various buttons, knobs, and a large white handle. In the background, a person wearing a white lab coat is seated at a desk, looking at a computer monitor. The scene is brightly lit, likely in a clinical or laboratory setting.

3

Development  
and future  
of the sector

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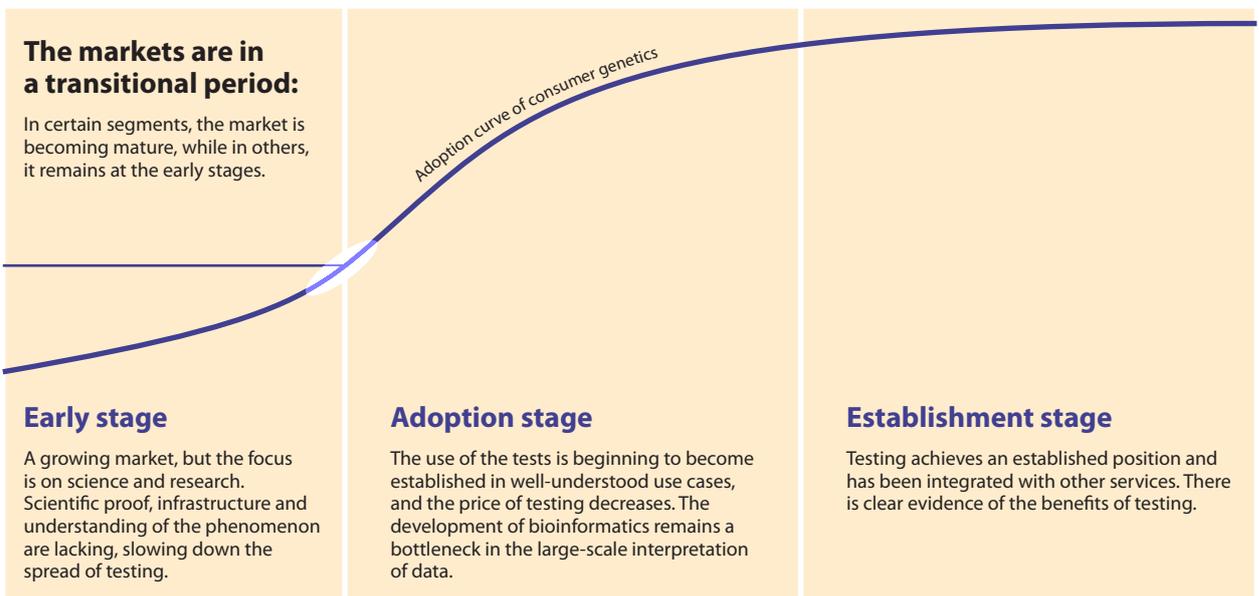
# Market outlook

We interviewed Finnish and international experts on the future prospects of direct-to-consumer genome data services and Finland's position in the development. The sector is still finding its bearings, but change is very rapid.

## The consumer genomics market is just developing

All interviewees judged that the market for direct-to-consumer genome data services is young and still finding its bearings. In DNA testing, the offering has already concentrated to a large extent, but the development of services based on genome data is only beginning.

*In the maturity model of the field presented below, consumer genomics can be estimated to be positioned in the middle ground between the adoption stage and early stage.*



# 9,000

*Finns have been sequenced and*

# 50,000

*have been genotyped.*

## QUANTIFIED SELF

Quantified self is a lifestyle movement that began at the turn of the decade in United States, pursuing better health and wellbeing. The most common quantified self methods are collecting lifestyle data from, for example, food, exercise, sleep, time use, weight, fat percentage and mood. The data is used in an attempt to optimise one's own lifestyle. Biohacking is a closely related movement, where lifestyle experiments are used to pursue peak performance, superhumanity.

Biohackers endeavour to justify their lifestyle changes with collected personal health data and scientific studies, but a lot of material that has not been scientifically proven is also used as a source. Quantified self is not part of the medical mainstream.

In the quantified self ideology, an individual's genetic data is also very important in health planning. Many of the practitioners have themselves tested by a consumer service such as 23andMe. In particular, genetic data is used in the planning of nutrition (nutrigenomics) and exercise.

Quantified self groups are active in over 30 countries. In Finland, the movement has around 200 followers who communicate via a Facebook group and a recently opened website (quantifiedself.fi).

The interviews were reviewed to identify factors that currently appear to impact the formation of the market and business models:

- The CLIA genetic laboratory standard in the USA is driving the sector towards larger testing laboratories.
- In many countries, regulation is still incomplete and under development.
- Healthcare professionals have reservations towards consumer genomics, which restrains their adoption.
- The price of genetic tests is falling more rapidly than Moore's Law predicts, but interpreting the data remains difficult.
- Services producing genomic testing data offer an open interface through which the consumer can directly share the genome data with third parties, which allows for many kinds of additional services.
- The awareness of both healthcare professionals and consumers on the usage methods and significance of genome data remains low, which causes suspicion and slow adoption.
- Personal health management is a rising trend (e.g. quantified self), but those who are most enthusiastic are already living healthily anyway. There is still only a little data on the added value of genome data.

The consumer market as a whole is characterised as most difficult for new companies. This view is supported by the changed operating models, unprofitability and bankruptcies of several companies that have operated in the field.

## The services will be directed towards medical testing and guiding lifestyle changes

Scientific knowledge of the significance of genetic alleles is constantly improving. Insofar as the effectiveness of genome data can be verified, the interviewees estimated that it will become a part of healthcare – just like other treatment, screening and diagnostic procedures. Many genome data companies offering health data services have moved from marketing directly to consumers to finding customers in the healthcare system.

On the other hand, other use cases such as identifying one's ancestors, genealogy or paternity tests will continue and expand. Demand for services outside medical testing and lifestyle change services may remain low. The experts estimate that applications producing the most value will be seen in the fields of lifestyle changes, preventive medicine and treatment of diseases.

Health-conscious people are increasingly eager to also purchase genome information, and wish to take responsibility for their own health.

## Genomic tests. What then?

The biggest question the experts have at this time concerns the added value generated by genome data: Does information change people's behaviour? What good does it do to know your risk of contracting a disease for which no form of treatment exists yet? Do the consumer genetic tests cause more worry and harm than actual benefit? These questions require more research data and public discussion that is only just beginning in Finland.

Gathering scientific data is arduous and slow, but several countries have invested strongly in research. In the United States, the intention is to map the genome of one million war veterans and combine the data with health data. Wide-scale genetic mapping projects are under way in Canada and Great Britain. Closer to home, promising projects are occurring in Estonia and the Faroe Islands.

The rapidly increasing research data is powerfully altering the field, enabling both healthcare savings and interesting consumer services.

## Finland and the future of genome data business

The interviewed experts were nearly unanimous on Finland having globally excellent chances of being a trailblazer in the use of genome data. The biggest factors are:

- **The unique Finnish genome and the carefully collected healthcare data: gene forms and diseases or traits can be connected much more easily than in a population with more genetic diversity. This advantage is lost if the projects in the other countries collect ten or one hundred times more samples.**
- **There is a sufficient amount of high-level expertise in genomics and genetics in Finland.**
- **IT know-how in Finland is top-grade.**

A large part of the collection of samples required for the genomic research is well on the way in Finland. According to FIMM, 9,000 Finns have been sequenced and 50,000 have been genotyped. A large part of the collected samples is still unstudied. The production price of genomic tests in Finland is competitive with other countries and commercial companies thanks to the advanced technology. Almost the entire genomic variation in Finland is present in the samples, which enables the effective identification of genes.

## Obstacles and prospects

The conversion of research, know-how and enthusiasm into business is not self-evident and requires investments, but the economic effects may be huge: a recent report<sup>4</sup> estimated that genomics and the Human Genome Project have had an effect of almost 1,000 billion dollars on the US economy, with the employment effects exceeding four million person-workyears.

The validation of data of a basic research nature through piloting both privately and in the public sector can open the door for business operations. The interviewees were

adamant in emphasising that the piloting should be done in Finland, if the money from the business operations is to remain here.

In the spring and summer of 2013, there were some pilot projects under way in Finland concerning the utilisation of genome data: for example, a lifestyle guidance mobile solution based on genome data in private healthcare, and the use of genome data to support a doctor's decision-making in public healthcare.

The California region is very attractive to startup companies: it is difficult to find as many companies in the field from Finland, and the specialised community in the Silicon Valley is able to offer a startup company high-quality and constructive feedback.

Business operations are likely to develop largely outside the consumer market, for example in genetic analytics, healthcare solutions, information systems and decision-making support.

## The Government officials and a suspicious general public hinder development

The interviewees described the attitudes of decision-makers and government officials as reserved and overly cautious. The risks of the use and proliferation of genome data dominate over the benefits in regulatory discussions. The largest threats are considered to be the additional load consumer tests would cause the healthcare system and an increase in gene-based discrimination. The public discussion during the summer of 2013 even described a development of a genetic class society. The discussion taking place in Finland proceeds along very similar lines as those in the United States, Great Britain and the rest of Europe.

The discussion concentrates on risks and threats instead of solutions on how to control them. One of the interviewees described the attitude of the legislative power as repressive and negative, although the need for clear legislation that would also enable research activities begins to be apparent. In the United States, legislation has already prohibited the unequal treatment of insurance customers based on genome data.

Concerning the threat of increased healthcare costs, one of the interviewees suggested a Web portal similar to the "Käypä hoito" and "Terveystietokeskus" portals that would provide information on genome data and direct those who have had genetic tests made to seek treatment or not seek treatment.

The interviewees are aware of the need for regulation of consumer genomics, but they also emphasised that regulation has its price: unrealised businesses, more difficult research and fewer jobs. The benefits for public health and individual wellbeing could also be very large. ■

<sup>4</sup> Battelle Technology Partnership Practice & United Medical Research. June 2013. *The Impact of Genomics on the U.S. Economy*. Referred to on 24 June 2013.

Available: [http://www.unitedformedicalresearch.com/advocacy\\_reports/the-impact-of-genomics-on-the-u-s-economy/](http://www.unitedformedicalresearch.com/advocacy_reports/the-impact-of-genomics-on-the-u-s-economy/)

# Business enablers

## Enablers for the development of genome data business

Based on the review, the development of private genetic business in Finland requires the following things:

<p><b>More research data</b></p>	<p><i>New services related to the interpretation of genome data can already be created rather cheaply for the better interpretation of the produced genome data. Genome data can be researched in parallel by companies and publicly funded researchers.</i></p>
<p><b>Platform for service development</b></p>	<p><i>Genome data services develop around companies and players producing genetic tests efficiently. Genome data banks enable the improvement of interpretation data, and product development.</i></p>
<p><b>Suitable and sufficient regulation</b></p>	<p><i>Regulation must ensure sufficient freedom for the consumer, but also build sufficient rules covering, for example, the handling of surprise findings for the healthcare system. New biobank legislation is an important factor in the birth of research and business operations.</i></p>

Change in the field is very rapid. The immediate business potential may be modest, but the understanding and applications of genome data may be at a surprising level after just a short time.

In the development of the genome data field, the innovations concerning the healthcare system and the consumer market are developed in parallel, and solutions may transfer from consumer sales to the use of the healthcare system, and vice versa.

# Glossary

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**CLIA** (*Clinical Laboratory Improvement Amendments*)

The US national guidelines and standards for clinical laboratories, including genetic laboratories. The standards define the test analysis, quality assurance and the requirements for employee competence. Laboratories can acquire a CLIA certificate or accreditation.

**DNA** (*deoxyribonucleic acid*)

A nucleic acid that is the substance containing and transferring the hereditary information of an organism's (human, animal, plant, etc.) cell. Mainly located in the chromosomes, and forms a double-stranded helix. Humans have around three billion base pairs in each of their cells.

**DTC** (*direct-to-consumer*)

Targeted directly at consumers, i.e., citizens.

**DTC GT or DTC PGT** (*direct-to-consumer (personal) genetic testing*)

Genetic testing services targeted directly at the consumer. The service and testing can be ordered and delivered, for example, through a website.

**Epigenetics**

Epigenetics refers to the operating instructions of genes to which the environment can cause changes and that are inherited from the cell to the daughter cells, possibly also from one generation to another, without changing the base structure of the genetic material. Epigenetics links the genotype and diseases. For example, changes caused by nutrition on the system may be inherited even if no genetic change is caused. This phenomenon is still poorly known.

**Exon**

A region coding for a protein in the structure of a gene.

**Phenotype**

Appearance. The collective whole of an individual's characteristics, resulting from the interaction of the genotype and the environment. *Cf. genotype.*

**Gene**

A DNA sequence controlling a hereditary trait, containing the information for manufacturing a protein or an RNA molecule. Genes are thus composed of DNA. A human has around 24,000 genes.

**Genetic test**

A laboratory test where DNA is analysed, and genes or gene mutations are identified in the genome (synonym: DNA test).

**Genome**

The entirety of hereditary information. The complete set of an organism's DNA; instructions for the operation and building of the system. The genome has a lot of individual variation, some of which makes the organism susceptible to diseases. The genome also contains a lot of DNA that does not code for protein synthesis.

**Genetic or hereditary susceptibility**

The hereditary, increased risk of contracting a certain disease, or genetic susceptibility, does not take into account the effects of the environment and the lifestyle, so it does not give the actual total risk.

**Genotype**

The genetic makeup of a cell or an individual. *Cf. Phenotype*

**Full genome sequencing**

A method where the base sequence of an individual's entire genome is determined

**mHealth** (*mobile health*)

The use of mobile technology in healthcare and health promotion.

**Mitochondrial DNA, or mtDNA, or mDNA**

The genetic material located in mitochondria that handle the energy production for cells, different from the chromosomes located in the cell nucleus. Children inherit mitochondrial DNA through the mitochondria in the mother's ovum, which means that it indicates the individual's maternal line.

**Nutrigenomics**

Research on the interaction between nutrition and genes; the use of individual genome data in diet planning. Nutrigenomics attempts to find individual response to nutrients, identify the harmful and beneficial foodstuffs, and optimise the diet to be as healthy as possible.

**Personalised medicine**

The planning of medical treatment and prevention from personal starting points based on, for example, individual lifestyle, genotype and personal drug response. The goal is to achieve more effective treatment and reduced side effects.

**Quantified self**

A lifestyle movement, where the practitioner aims to measure and monitor his or her lifestyle and change it to be as healthy as possible based on scientific and other data.

**SNP, or "snip"** (*single nucleotide polymorphism*)

A variation of one base pair in the genes, also known as a "point mutation". A variation of one base pair may increase the risk of disease, but it often has no significance.

**Y chromosomal DNA, or Y-DNA**

The DNA contained by the male sex chromosome. The Y chromosome is inherited from the biological father to the son, which means that it indicates the son's paternal line.



*Consumers show increasing interest in genomic testing. The genome data services aim to fulfil various needs, which means that the companies operating in the field are also using different business models. It is difficult to predict which model will emerge victorious, but some indicators can already be seen: Genome data collected from the consumer is valuable to the pharmaceutical industry. Consumer services built on data produced by genomic tests will become more common.*

*Although the field has not been the moneymaker it was assumed to become only a decade ago, its potential is globally significant. Innovations are developed parallel to consumer services; they can give birth to new healthcare or industrial companies.*

*Finland's prospects in business based on genome data are good. The rising public discussion on the privacy effects, threats and opportunities of genomic testing is welcome, but is sorely in need of precise information. Developing the legislation to protect the consumer but, on the other hand, enable new business, would be to everyone's benefit.*

*This review describes the methods used by companies operating in the field and views on the outlook of the field. We hope that the presented information will foster discussion on the future of the genome data business.*