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## 23andMe

[https://www.23andme.com/en-ca/?utm\\_source=Google&utm\\_medium=CPC&utm\\_campaign=CA%20-%20Google%20-%20EN%20-%20Search%20-%20Brand%20-%20All%20Devices&utm\\_term=&utm\\_content=23c\\_search\\_paid\\_brand&gclid=Cj0KCQjwguDeBRDCARIsAGxuU8Y2HW4Q8r2wd\\_EEnRPr-gqfzX5e2\\_XxMntnk4twWT70SLMGXRgseWgaAnHxEALw\\_wcB&gclsrc=aw.ds&dclid=ClauqvDQr94CFQO5TwodV2UK4Q&myg=true](https://www.23andme.com/en-ca/?utm_source=Google&utm_medium=CPC&utm_campaign=CA%20-%20Google%20-%20EN%20-%20Search%20-%20Brand%20-%20All%20Devices&utm_term=&utm_content=23c_search_paid_brand&gclid=Cj0KCQjwguDeBRDCARIsAGxuU8Y2HW4Q8r2wd_EEnRPr-gqfzX5e2_XxMntnk4twWT70SLMGXRgseWgaAnHxEALw_wcB&gclsrc=aw.ds&dclid=ClauqvDQr94CFQO5TwodV2UK4Q&myg=true)

- DNA analysis is performed in US laboratories that are certified to meet CLIA standards
- They have more than 5 million genotyped customers around the world
- 2 Personal Genetic services: Health + Ancestry or just Ancestry
  - Health + Ancestry (C\$249)- tells you information about your genetic health risks, carrier status, traits, wellness, and ancestry
  - Ancestry (C\$129)- helps you understand who you are, where your DNA comes from and your family story
- 23andMe also has interactive tools that let you share and compare your results with others and explore genetic similarities and differences between you and family members
- It has a tool where you can trace DNA through your family and see how different traits traveled through generations
- There is another tool that lets you find and connect with new DNA relatives and see DNA segments that you share with them

### Health

- Genetic Health Risks - Tells you how your genetics can influence your risk for certain diseases (ex. Celiac Disease, Late-Onset Alzheimer's Disease, Parkinson's Disease etc.)
  - Sample report:  
[https://permalinks.23andme.com/pdf/samplereport\\_genetichealth.pdf](https://permalinks.23andme.com/pdf/samplereport_genetichealth.pdf)
- Wellness – tells you how your genes play a role in your wellbeing and lifestyle choice
  - Information on things like deep sleep, lactose intolerance, genetic weight
  - Sample report:  
[https://permalinks.23andme.com/pdf/samplereport\\_genetichealth.pdf](https://permalinks.23andme.com/pdf/samplereport_genetichealth.pdf)
- Carrier Status – tells you if you are a carrier for certain inherited conditions (ex. Cystic Fibrosis, Sickle Cell Anemia, Hereditary Hearing Loss etc.)
  - Sample report:  
[https://permalinks.23andme.com/pdf/samplereport\\_carrierstatus.pdf](https://permalinks.23andme.com/pdf/samplereport_carrierstatus.pdf)
- Traits – Tells you how your DNA influences your facial features, taste, smell and other traits (ex. hair, taste and smell, facial features)



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- Sample report: [https://permalinks.23andme.com/pdf/samplereport\\_traits.pdf](https://permalinks.23andme.com/pdf/samplereport_traits.pdf)

### Ancestry

- Can see where your ancestors lived 500+ years ago
- Shows you your DNA breakdown across 150+ regions worldwide
- Breaks down when different ancestries were introduced into your DNA
- You can also use the DNA Relatives tool and find, connect, and message people who share DNA with you.

### How it Works

- You order a saliva collection kit on the website and send it back in
- It takes approximately 6-8 weeks to receive the results online
- Users login to their online account to see the results
- The Genetic Health Risk and Carrier Status reports meet criteria for being scientifically and clinically valid
- 23andme's lab extracts DNA from cells in the saliva sample and then processes the DNA on a genotyping chip (Illumina HumanOmniExpress-24 format chip). The genetic data is then analyzed and a personalized report is generated based on scientific and medical research
- The labs are CLIA-certified and CAP-accredited and ensures quality standards, accuracy, and reliability of results

### Privacy

- Choices users can make:
  - If they want to store their saliva sample or not
  - If they want other 23andMe members to see their account or not
  - If you want to take part in DNA Relatives tool which connects you with both known and unknown close and distant relatives
  - These decisions can be changed at anytime
- Types of information they collect:
  - Personal information (name, credit card, email etc.)
  - IP address
  - Genetic, phenotypic, and familial information through saliva
- Personal information is stored in separate computing environments from genetic information
- Registration information is stripped from sensitive information – including genetic and phenotypic data
- Genetic information is identified using a barcode system
- When used for research, genetic information is assigned a randomized research identification number



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- They state they will not sell, lease, or rent individual's information (genetic information with personal info attached) to a third party BUT they do share genetic information that has been stripped of personal/registration information to perform business development and research
- They also state that while they do their very best to protect all information, they cannot fully guarantee against breaches in security
- When a customer passes away, their account information will only be given to those who are legally authorized to make decisions on their behalf – these people must complete a authorization form and provide evidence and legal documentation
- They mention that under certain circumstances, information may be disclosed to law enforcement or the government – if they are required by law to comply
- 23andMe will not provide personal data (genetic and non-genetic) to an insurance company or employer
- Full privacy report: <https://www.23andme.com/en-ca/about/privacy/>

<https://www.youtube.com/watch?v=zeo7zPzZwIk&feature=youtu.be>

- Users get personalized reports that provide insight into their health and ancestry
- They simply order a kit from 23andme.com and provide a saliva sample back
- They will then be notified when their online report is ready

[https://www.youtube.com/results?search\\_query=23andme](https://www.youtube.com/results?search_query=23andme)

- 23andMe has partnered/sponsored many Youtubers to try out their kit and announce their results on their channel

<https://www.sciencenews.org/article/review-genetic-tests-23andme-veritas-genos-health-comparison>

- A molecular biology writer wrote about his experience with 23andMe and other similar kits
- The company only tests for a small subset of all potential single nucleotide polymorphisms. Therefore, even if you get “variants not detected” it only means they didn't detect any of the variants that the kit tests for
- 23andMe does provide a clear explanation of what it does and doesn't test for and lists other factors that contribute to the diseases risk
- They do a better job then other companies like Genos or Veritas of explaining what having specific genetic variants mean
- This means, DNA may need to be retested as new genetic discoveries are made

<https://medicalfuturist.com/top-companies-genomics>

- The most popular genetics company – established in 2006
- They have built up the biggest databased of patients' DNA information – more than 5,000,000 customers and 1 billion phenotupics data points



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- Originally, the company offered services whether they told anyone their likelihood to get certain diseases and information about their family tree but in 2014, the FDA restricted their operations because the health information services were not clear enough for customers
- So, the company scaled back their activity – they now mostly provide information about ancestry (building family trees)
- In April 2017, FDA re-approved 23andMe's services, which tell people to which diseases they are susceptible, based on their DNA

<https://www.businessinsider.com/23andme-launches-drug-development-2015-3>

- 23andMe is backed by Google
- In 2015, it launched its drug development unit
- Richard Scheller, former Genetech executive, is the chief scientist who leads the company's research. He recently retired from a 14 year career at Genetech, a pioneer of biotech cancer drugs
- Drug research has always been the foundation of their business model
- 23andME, licenses the data from its DNA database to researchers
- They have more than 20 partnerships with drug companies, as well as with the government and academic researchers
- They aim is to improve drug development efforts by targeting research efforts towards patients with specific genetic markers
- In November of 2013, the FDA ordered the company to stop marketing personalized health reports which tell customers if they are genetically predisposed to more than 250 diseases and medical conditions
- In Feb. 2015, they cleared a test for carriers of a genetic mutations that causes Bloom syndrome.

<https://www.businessinsider.com/dna-testing-delete-your-data-23andme-ancestry-2018-7>

- At-home genetic testing companies like 23andMe frequently sell data to drugmakers
- On July 25<sup>th</sup>, 2018, a large UK pharmaceutical company called GlaxoSmithKline announced that they were acquiring a \$300 million stake in 23andMe and will be entering into a 4-year drug-development collaboration with the company
- As part of the 4 year deal, GlaxoSmithKline has bought the rights to use 23andMe's genetic data to look for potential new drugs to develop and use the data to select patients for clinical trials
- When users submit their spit sample to 23andMe, they are kept anonymous
- However, experts caution customers there is a chance that their personal data and information can be leaked



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- After registering your spit sample online, 23andMe will ask whether you would like them to store your saliva or not. BUT they do not ask what you would like to do with your genetic data, the DNA that is extracted from the spit
- It is still unclear exactly what 23andMe does with your DNA
- If your spit or DNA is stored, the company can hold onto it for up to 10 years
- You can put in a request and ask the company to discard your spit and close your account

<https://www.businessinsider.nl/why-gsk-invested-300-million-in-23andme-genetic-drug-discovery-collaboration-2018-7/>

- Using 23andMe's data, GSK is working on an experimental drug to treat Parkinson's disease in patients with a particular mutation
- 23andMe has also partnered with major pharmaceutical companies like Lundbeck and Pfizer → both company's hope to use 23andMe's data to develop their own drugs
- These companies are looking to use the genetic information gather from 23andMe users to develop new drugs and therapies
- People who give consent to share their information (about 80% of users) are asked to answer survey questions about their health and habits
- In 2015, 23andMe also started getting into drug development on its own
- If certain genes stand out, 23andMe can target it to create a drug
- VP of business development shared that their goal is to discover drugs based off of data from human beings rather than animal models
- On July 25, 2018, 23andMe announced that they have made progress identifying new drugs since 2015 but there is a long way to go
- Similar collaborations have happened elsewhere as well – in June of 2018, Swiss drug giant Roche acquired the rest of Foundation Medicine, a company that collects genetic data from samples of cancer tissue or blood for \$2.4 billion. Roche also acquired Flatiron Health, another cancer data company, for \$1.9 billion.

<https://www.fastcompany.com/3040356/what-23andme-is-doing-with-all-that-dna>

- While the company's services were restricted in the US by the FDA, they expanded their Personal Genome Service to Canada and the UK
- Their 2 main services:
  - Analyzing saliva to determine some 100 risk factors for a number of diseases, inherited conditions, and adverse responses to certain drug therapies
  - Ancestry service
- Users can opt to share their genetic information and 23andMe can then share or sell this data to their partners
- Once the company has the DNA data, they become the Google of personalized health care → they want to become a central storehouse for genetic data
- In July 2015, the company received a \$1.4 million grant from the National Institute of Health to help expand its genotype database



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- The company was founded by Anne Wojcicki, who is married (but separated from) Google co-founder, Sergey Brin
- Using 23andMe's data based allows drug companies to eliminate recruitment times, minimize cost, and reduce the amount of time it takes to conduct research
- Pfizer partnered with them to study the genetics of inflammatory bowel disease
- Genetech paid the company to help it find breast cancer patients who had taken its drug Avastin
- In 2015, the company raised \$126 million
- The company has not revealed how much they charge partnering companies
- Since 2011-2015, 23andMe published or contributed to 22 peer-reviewed papers about a range of areas – allergies, asthma, hypothyroidism, myopia, and breast cancer
- A large number of users are actively engaged in answering questions every month
- In their Parkinson's research community, when they had 3,400 patients they were able to identify 2 new genetic associations for the disease and publish the findings all within 18 months

<https://www.businessinsider.com/23andme-meet-your-genes-nyc-pop-up-2018-10>

- On October 13 and 14 2018, 23andMe opened up an interactive pop-up exhibition in Manhattan as part of their new ad campaign
- Their goal was to show consumers what information they can get from the report
- It included posters about what DNA is and what it can tell you
- Each stall was decorated in the theme of one specific gene and its associated traits – it also provided information on what each gene does

<https://www.bustle.com/p/selma-blairs-23andme-test-sigaled-her-ms-diagnosis-years-ago-she-says-in-a-new-instagram-post-12989659>

- Actor Selma Blair announced in a Instagram post that she has Multiple Sclerosis and that when she took the 23andMe test a couple year ago, it had warned her that she showed a higher susceptibility to the disease

<https://www.businessinsider.com/23andme-gets-approval-tests-gauge-response-to-antidepressants-other-medications-2018-10>

- The CEO and founder of 23andMe announced at the beginning of October that she wanted to a new health offering that allows users to see how they process medications, including those for depression, cardiology, and infectious disease
- On Oct 31<sup>st</sup>, the federal regulators gave the company the green light to offer this type of pharmacogenetic test
- 23andMe's test will be the first of its kind to get FDA clearance to be sold directly to consumers



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- Albertsons pharmacies and Color Genomics currently offers the same type of test for \$250-\$750 and they require referrals from a doctors or psychiatrist
- The new test however cannot provide information on a patient's ability to respond to any specific medication and cannot provide medical advice
- They also advise patients to consult their doctors and not make medical decisions solely based off the test
- When 23andMe first released their product, they included a test for depression medication but in 2013, the FDA forced the company to stop selling this product
- Then, when the DA gave the company to sell some of its health screenings again in 017, they put out a limited selection of some of its original products
- The most recent addition to their product is a test for some genes involved in the risk of developing breast cancer known as BRCA1 and BRCA2 genes
- Scientists have however warned customers against services by 23andMe because when they began offering breast cancer genetic screening, the test only looked at a small number of genetic variants involved in disease
- They have not yet disclosed when the test will become available to customers

<https://markets.businessinsider.com/news/stocks/23andme-granted-the-first-and-only-fda-authorization-for-direct-to-consumer-pharmacogenetic-reports-1027678324>

- As part of the authorization process of the new pharmacogenetic test, 23andMe had to demonstrate the accuracy of its testing and consumer comprehension of the testing information
- Studies showed that more than 97% of users understood that they should not use the report to make changes to treatment without consulting their doctor
- The test reports on variants in multiple genes that impact how well a person metabolizes more than 50 other commonly prescribed and over-the-counter medications
  - The report tells customers if they are predicted to be fast or slow metabolizers based on their genetics, if they may experience reduced efficacy or have an increased chance of side effects
- FDA has gone through an extensive review process where 23andMe was required to submit studies demonstrating that their reports were scientifically valid, reliable, and understandable for users
  - They showed its test have greater than 99% accuracy and 90% user comprehension of key concepts communication in the reports

<https://www.scientificamerican.com/article/23andme-is-terrifying-but-not-for-the-reasons-the-fda-thinks/>

- Some say 23andMe is just like Google in that they are a front end for a massive information-gathering operation → they are the Google of personalized health care
- The company even lowered the price of their kit from \$299 to \$99



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- Some people also point out that in the early years, Google also made promises like 23andMe – that they would not sell personal information without consent, however, they have repeatedly proven that they are willing to break this promise