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What went wrong at 23andMe? Why the genetic-data giant risks collapse

At-home DNA testing is no longer in high demand — and critics have raised concerns about unreliable tests and privacy.

By Diana Kwon

23andMe analyses DNA in saliva provided by customers to product genealogy information and health-risk predictions. Credit: Tiffany Hagler-Geard/Bloomberg via Getty

The once-thriving consumer genetic-testing company 23andMe is struggling to stay afloat — raising concerns about what might happen to its customers' data and the broader industry.

The decline marks a fall from grace for a pioneering company once valued at US$6 billion. Over the past few years, the firm has faced mounting challenges, including financial losses and a huge data breach, although this did not involve DNA data. In September, most of the company's board resigned, and in November the firm said it would cut 40% of its workforce and halt its therapeutics division, which had drugs in clinical trials.

Founded in 2006, 23andMe built its business by asking paying customers to send samples of saliva, from which it extracts and sequences DNA to analyse for information about ancestry, family traits and potential health risks. Some 15 million people have sold their DNA to the company, based in Sunnyvale, California. Of those, around 80% consented to have their genetic information used for research.

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DNA testing kits are a one-time product

One key issue is that DNA-testing companies are selling a single-use product. "Once somebody has done it, they don't need to do it again," says Hank Greely, a lawyer and bioethicist at Stanford University in California.

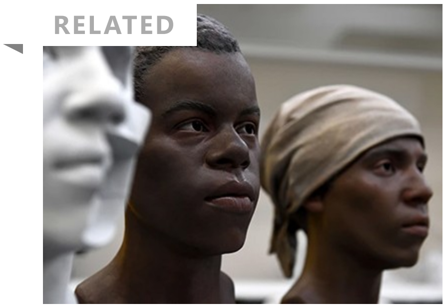
Starting in around 2016, sales of direct-to-consumer genetic tests soared, with 23andMe and Ancestry in Lehi, Utah, securing the lion's share of customers worldwide. But by 2020, sales had declined, and both firms began cutting staff.

People flocked to these products for the genealogical information they provided: a breakdown of the potential geographical origins of your ancestors. Companies, including 23andMe, also offered customers the opportunity to connect with relatives worldwide. "The market for genealogical information is large, but it's not infinite," Greely says. "Some of the companies will try to upsell you with the newest, fanciest version, but the fanciest version can tell you whether this person is probably a third cousin or a fourth cousin. Who cares?"

Health-risk predictions posed problems

In a bid to add to their offerings, companies such as Ancestry began selling access to historical records and photographs to give people extra genealogical information. One of 23andMe's main offerings has been health information — but this has drawn criticism.

Experts have long raised concerns about providing consumers with predictions of disease risk based on consumer tests. In its early days, 23andMe offered a test with information on the risk of 240 health conditions. But in 2013, the US Food and Drug Administration (FDA) ordered it to stop, citing a lack of information on the safety and efficacy of the assessments. In 2017, the company received FDA approval to tell customers if they had genetic mutations linked to ten conditions, including Parkinson's and coeliac disease. Since then, 23andMe has expanded this to more than 50 conditions.



But despite such consumer tests winning FDA approval, clinicians have continued to question their reliability and utility. False negatives might reassure a person that they don't have a disease-causing mutation that they actually have, and false positives might lead people to seek preventive interventions, such as surgery to reduce cancer risk, that they don't need.

Ancient DNA reveals the living descendants of enslaved people through 23andMe

A spokesperson for 23andMe says that the company has "demonstrated over 99% accuracy and reproducibility for the variants we test for in our genetic health reports" and that it has worked closely with regulators to ensure that the company provides accurate and meaningful genetic information to consumers. The spokesperson also says that 23andMe's products do have clinical utility, adding that its health reports help to identify at-risk individuals and motivate healthy lifestyle choices, among other things.

Anneke Lucassen, a clinical geneticist at the University of Oxford, UK, remains sceptical about 23andMe's tests. "Their product was always very limited in what it could tell you about tendencies to disease," she says, in part because common diseases are the product of more risk factors than can be measured by 23andMe.

Some are pessimistic about the overall future of consumer DNA tests for health care. "The medical side never really caught on," Greely says. "And to the extent it would catch on, it should be moving into regular medicine."

Genetic data present privacy concerns

If 23andMe folds, the fate of its customers' genetic information is a major worry. Concerns include the possibility of sensitive health-related information, such as disease risk, being revealed, or law-enforcement bodies searching DNA databases for suspects — although the company has stated that it does not allow such investigations.

In the United States, customers of genetic-testing companies aren't protected under laws such as the Health Insurance Portability and Accountability Act, because these firms lie outside health care, for which there are strict controls over genetic data.

Anne Wojcicki, 23andMe’s chief executive, has said that the company is not open to takeover. Credit: Jordan Vonderhaar/Bloomberg via Getty

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“What is 23andMe going to do with the data that they still have possession of?” says Ellen Clayton, a medical ethicist at Vanderbilt University in Nashville, Tennessee. “Are they going to try to sell access to it in order to generate funds?”

Anne Wojcicki, 23andMe’s chief executive, has said publicly that the company is not open to a takeover by another firm. And according to a 23andMe spokesperson, even if it were sold, the terms in the existing privacy policy would continue to apply to data. The spokesperson adds that 23andMe has “strong customer privacy protections”, such as security protocols and data encryption — and customers can decide how their data are stored and used, and when they are destroyed.

But the worries about 23andMe’s data becoming publicly available might also make it more difficult for researchers to collect genetic data, says Greely. “Research projects are governed by different rules than a direct-to-consumer company, but if people are spooked about genetic privacy, not all of them are going to make a careful distinction."

A massive, but limited, research resource

23andMe's DNA collection is one of the biggest in the world. The company offers these data, for a price, to universities and pharmaceutical companies for research — and it has been a co-author on 276 research articles since 2010.

"23andMe has the largest cohort of genotyped people in the world used for research," says Abraham Palmer, a behavioral geneticist at the University of California, San Diego, who is in an ongoing research partnership with the company to study people who have used prescription opioids. The data set "has allowed us to do things that you could not have done any other way". A key advantage of working with 23andMe is its platform, which allows researchers to contact users to gather more information, Palmer says.

The company's biggest industry partnership has been with the drug giant GlaxoSmithKline (GSK) in London, which led to the discovery of drug candidates, including a cancer drug now in trials.

But the 23andMe database also has limitations. One is that the health data are almost entirely self-reported — whereas other similar collections, such as the UK Biobank and Finland's FinnGen, contain information from electronic health records. Such drawbacks might be one reason why few other pharmaceutical companies have made deals with the company.

"Over the past several years, there have been newer, shinier objects that that have captured pharma interest and attention," says Matt Nelson, the vice-president of genetics and genomics at Deerfield, a health-care investment firm in New York, who was previously at GSK and involved in setting up the company's partnership with 23andMe.

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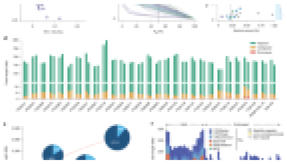

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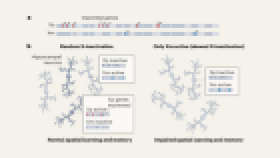

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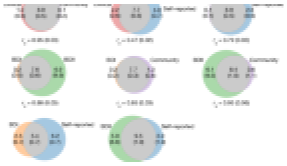

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