



Direct-to-consumer genetic testing

Opportunities and risks in a rapidly evolving market

Winning with technology series

The global direct-to-consumer genetic testing market is growing, fuelled by a rise in awareness, an emerging culture of consumer empowerment, and the demand for increasingly personalized services. However, companies offering these services face increasing concern over data privacy and scientific validity. We advise existing and potential players to focus on building consumer trust, to tailor services to maximize consumer satisfaction, and to work together with regulatory bodies if they hope to thrive in this market.

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A big idea

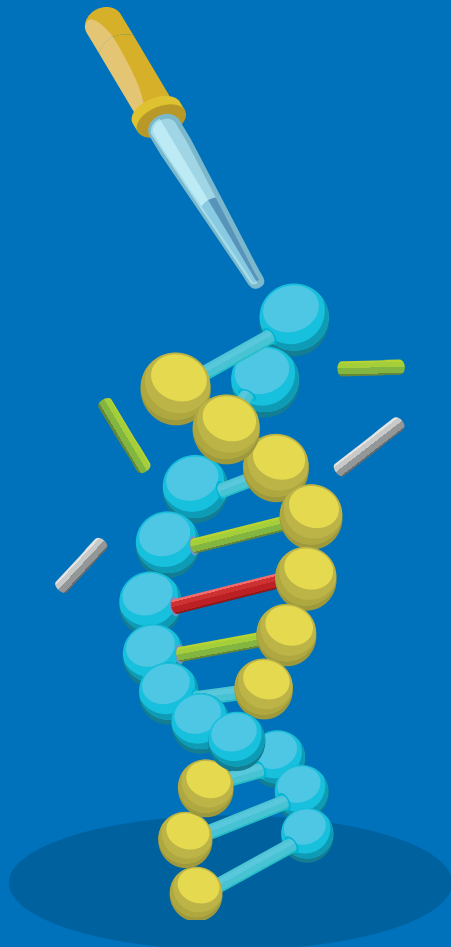
Direct-to-consumer genetic testing: an exciting market, but not without its challenges.

Once purely the domain of healthcare institutions, rapid technological advancement over the last decade has made it possible for genetic testing to be undertaken cheaply, quickly and directly by consumers.

The global direct-to-consumer genetic testing (DTC-GT) market is forecast to grow steadily to be worth over US\$1bn by 2020¹, but commercial success for new and more established players is not guaranteed. A set of wide-ranging challenges are likely to become more acute as regulation tightens. For example, growing concerns over data privacy, scientific accuracy, and the psychological impact on consumers demands careful consideration.

Genomic data is special, since it encodes not only our blueprint, but that of our family and children. The continuing privacy and the security of people's genetic data, both immediately, and into the long term, is of paramount importance.

– Caroline Rivett, Digital, Security and Privacy Lead,
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About this paper

KPMG professionals have undertaken a proprietary survey of 2,000 people to understand their views on direct-to-consumer genetic testing. Respondents answered a number of questions on issues like willingness to use such a service, expectations of genetic testing providers, and concerns over reliability of results, data security and privacy. In this summary, we look at the results, as well as the market demand and risks that need to be considered by companies entering this space.

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Demand is growing

Continued expansion of the DTC-GT market is predicted.

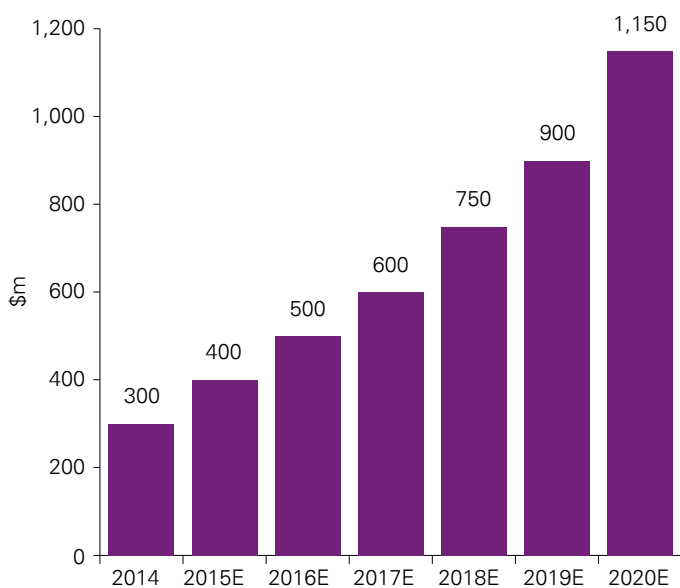
Over the past decade, technological advances have enabled us to decode, and make sense of, the information contained in our genes at ever faster speeds and lower costs. Until relatively recently though, the principal application of this technology was in hospital-based diagnostic equipment.

However, DTC-GT – in which customers order sampling kits directly – is a rapidly expanding, and potentially attractive industry. The autonomous and relatively straightforward transaction permits genetic tests to be accessible to anyone willing to pay for them.

There are already over 250 companies offering customers DNA tests in applications including forensics, ancestry, health, pharmacogenomics, fitness and nutrition. The global DTC-GT market value is expected to be valued in excess of US\$1bn by 2020.²

Inevitably, as the market grows, associated challenges arise. Being aware of these challenges can allow companies to manage their impact proactively.

Figure 1: DTC-GT market, 2014-2020E^{3,a}



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Drivers of growth

Consumers are increasingly driven by self-curiosity and empowerment, reflected by an increase in awareness of services offering genetic testing and follow-on advice.

Rising public awareness

Public awareness and acceptance of genetic testing is steadily growing; a national survey revealed that awareness in the US grew from 31% to 38% between 2007 to 2014⁴, and a social media survey found that 47% of users were familiar with the DTC-GT concept.⁵

Consumer empowerment

The shift from passive to empowered customers has provided opportunities for businesses to respond across a number of sectors, including those in the genetic testing sphere. The inherent accessibility of DTC-GT is a major benefit, allowing consumers free access to their own genetic information and access to personalized insights and recommendations.

A sense of empowerment is a key driver of DTC-GT uptake – 80% of early adopters of DTC-GT services report a sense of empowerment from their results, and claim ‘curiosity’ as a primary motivation.⁶ In response, 90% of DTC-GT companies use the emotional appeal of ‘empowerment’ in their marketing strategies.⁷

Service personalization

Across many sectors there is a clear rise in customers seeking tailored products and experiences, with an increasing willingness to pay for the identification and addressing of unique needs. Pharmacogenetics, in which genetic variants guide the choice of pharmaceutical treatment, is currently the most established example of gene-based personalization. However, similar manifestations for consumers in health, fitness and nutrition-centered DTC-GT services have the potential for a much wider impact on the general population.

In the nutrition space, 30% of individuals in a recent EU survey felt strongly that personalized advice would be much more effective at improving their dietary behavior, and crucially felt it worth paying for.⁸ Companies such as My Inner Go and DNAFit attempt to meet this demand by providing tailored fitness and weight management advice.

Case study: DnaNudge

The British company, DnaNudge, has developed an easy to-use DNA sampling and processing device allowing rapid and affordable ‘in retail’ lab free DNA testing with a profiling and interpretation service connected via a mobile app. The app then generates personalized nutrition and associated shopping advice based on the customer’s genetic information.

DnaNudge has adopted a range of strategies to overcome core barriers to market access and maximize customer value of their DTC-GT services:



Own your own data

In retail DNA processing places the genetic data ownership in the customer’s hands, thereby helping to overcome data protection regulatory barriers and privacy fears.



‘Nudge’

The point-of-decision technology is centered around a ‘nudge’ approach: small, actionable recommendations that customers can easily adopt to facilitate improvement.



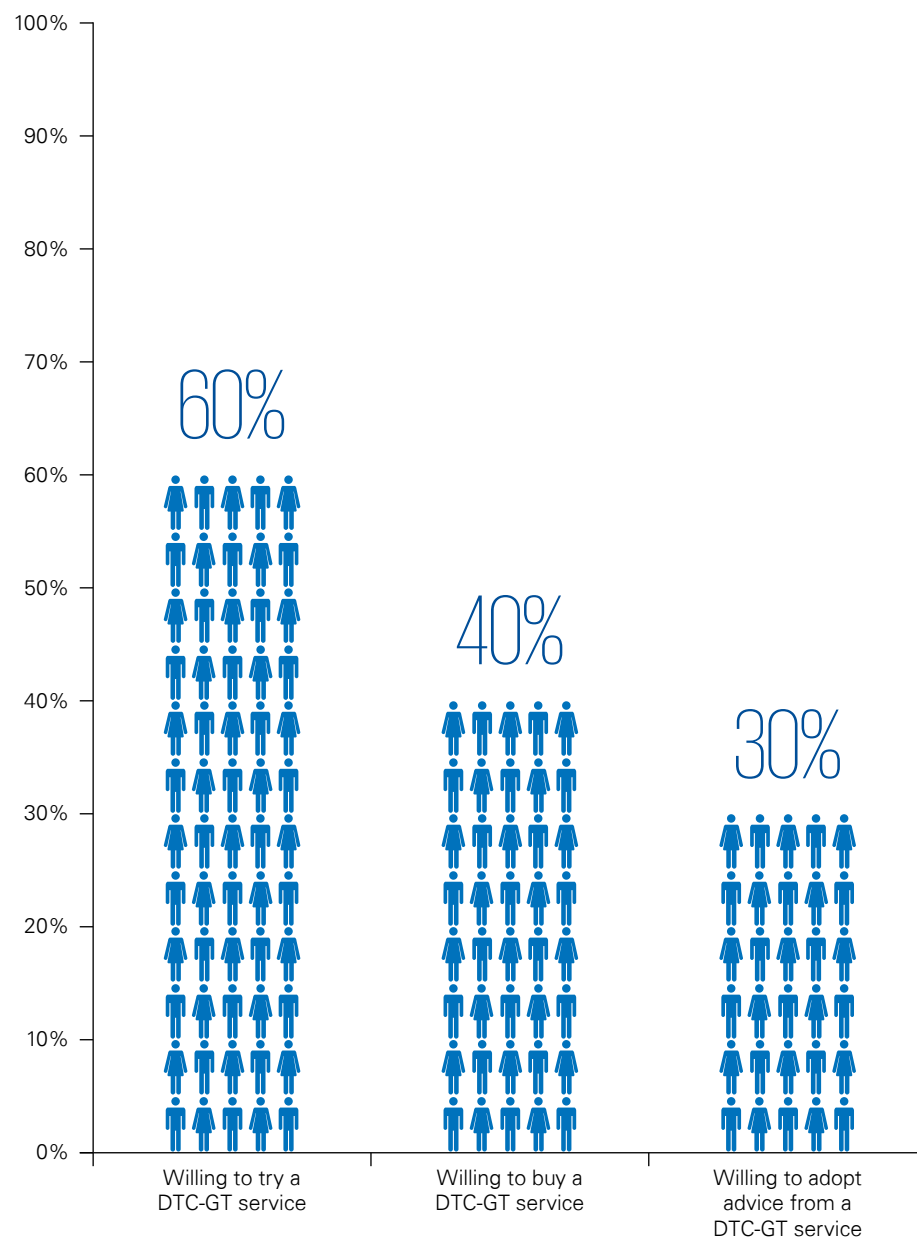
Closing the loop

Provision of follow-up services generates continued value for the customer and revenue-generating opportunities beyond the initial DNA profiling stage.

Willingness to use DTC-GT is high...

An amenable consumer population presents an opportunity that has sparked investor interest.

Figure 2: Percentage of survey respondents willing to try, buy and adopt at-home DTC-GT services⁹



Customers are expressing a willingness to undergo testing and pay for genetic testing services. According to a recent survey of a nationally representative¹⁰ sample of 2,000 participants:

33%



of individuals stated that they would be willing to pay for and use advice provided by a DTC-GT company.



Responding to these drivers, investors have already shown an interest in the market, with individual funding steadily increasing over the last 5 years from <US\$20m in 2011 to >US\$100m in 2016.¹¹

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...But privacy is a concern

Central to all applications of DTC-GT is the issue of information privacy and security.

In submitting a sample for processing, individuals provide sensitive information not only about themselves, but about family members with whom they share a genetic link. There is no requirement for family members to give their consent, a point worth considering given that digital data on individuals can be held forever and can affect people who are children now, or as yet unborn. Leakage of such data could negatively impact these individuals across a range of areas including employment prospects, relationships and insurance premiums.

Cybersecurity breaches – database password and server hacking, storage device theft, and human error or oversight by data custodians themselves – represent a threat here. Crucially, there are concerns too around data sharing that does not result from unauthorized activity, but via the exploitation of legal loopholes.

65% of individuals willing to use an at-home DTC-GT service reported privacy as one of the main concerns; specifically, the potential sharing of data with third parties including consumer health, pharmaceutical, and insurance companies. Almost all of the respondents willing to use the service had concerns about a company owning their DNA profile.¹²

For example, while 23andMe states they do not share individual-level genetic information without a customer's consent, their policy leaves them free to share information that has "been anonymized or aggregated so that you cannot reasonably be identified as an individual." However, there are suggestions that anonymization of genetic data is not sufficiently robust; several publications report the ease at which data de-identification (i.e. removal of the individuals' names) can be reversed.^{13,14}

Furthermore, whilst companies provide only specific genomic information to the applicant, they can retain the full genetic sequence on the DNA they have collected, leaving open the potential to digitize and retain the data, either for future use, or to increase the overall company valuation on a future sale. Additionally, if information is stored and processed by branches of the company or its service providers residing in another country, the initial privacy agreement of the customer may become subject to differing jurisdiction requirements.

Data Protection Laws such as the US Genetic Information Non-discrimination Act (2008) provide customers with a level of comfort by disallowing results to impact health insurance policies and employment. However, the law does not cover life insurance, long-term care insurance or disability insurance.¹⁵ In the UK, Belgium and Italy, the legislation similarly falls short, with current regulatory regimes failing to cover DTC-GT in its entirety or at all (in the case of Italy). This contrasts the situation in countries including France, Germany, Portugal and Switzerland, where genetic tests can only be conducted by medical professionals. Medical device regulations typically only cover at-home DNA sample collection, and with approximately 56% of companies offering tests in more than one category, standardized regulation of the industry is a complicated affair. In the absence of regulation, DTC-GT companies dictate their own contracts, the terms of which are often difficult to navigate and heavily biased in their favor. The new EU General Data Protection Regulation (GDPR) legislation will force companies to consider carefully how they handle customer data. While this may provide some reassurance for potential customers, the reality of implementing costly adherence processes poses a risk to survival for smaller DTC-GT companies.

Results can be difficult to interpret...and accept

Companies offering DTC-GT face a range of concerns from both consumers and healthcare professionals.

Scientific accuracy and utility

It is important to consider when an increase in knowledge is valuable and when it serves only to confuse and worry. Not all genetic variants need raise concern, or require actionable recommendations. Offering such recommendations on all test results can make it difficult for consumers to judge where they should have genuine concerns.

Healthcare professionals cannot always provide reassurance, as they do not necessarily feel confident commenting on the results – 80%-95% of primary care practitioners stated this in surveys conducted across the US, Australia and New Zealand.^{16,17,18} This may in part be because of the range of possible meanings attributable to the results. Studies comparing the genetic results of the same individuals generated through tests from different companies showed a disparity in risk predictions and sometimes reported contrasting results.¹⁹ For example, a recent study found that false positive results – that is, stating an individual possessed a certain gene variant when they did not – occurred at a rate of 40%.²⁰ Similarly, a study evaluating disease risk prediction of DTC-GT services in Japanese individuals revealed mismatches in disease risk prediction, highlighting the need for a non-Caucasian evidence base and standardized ethnicity adjustment.²¹ This is particularly pertinent for the Indian population, where local companies such as Positive Bioscience have seen a 15-fold increase in uptake since 2014.²²

Outcome variability has resulted in the DTC-GT market garnering considerable negative media attention, both in terms of the efficacy and validity of results, with key experts actively discussing their skepticism of the products.²³

Psychological impact

Where results do genuinely flag a concern, companies need to consider their possible psychological impact. Learning about one's own genetic impairments can be highly distressing, not least as there is no way to alter these, at least given our current technology. Indeed, according to a survey, 34% of individuals willing to use the service showed concern about discovering something about their genetic profile they would rather not know.²⁴ It may be important, therefore, either to provide adequate genetic counseling services before and after taking the test, or to consider leaving the testing of sensitive topics to medical professionals within settings that can offer support, should the test results be of a difficult nature. There are now numerous companies offering such counseling services, either independently or through partnerships with the DTC-GT companies themselves, such as InformedDNA – the advice service recommended by 23andMe. Companies should consider working collaboratively with such providers.

Further, the sharing of genetic information with family members may lead to a much wider psychological impact than that reasonably covered by genetic counseling. Hence, it may be important to consider the wider impact of DTC-GT results.

Market entry considerations

Adapt to the evolving regulatory landscape, focus on building trust, and tailor services to maximize customer satisfaction.



Working with regulators as the industry develops

To thrive, companies will need to enter early into dialogue with regulators to ensure evolving dynamics are understood, and a timely, appropriate response undertaken. Indeed, in joining the conversation, companies can contribute to shaping the regulatory landscape rather than reacting as it develops.

For example, a review of 23andMe measures to validate accuracy and scientific utility of their tests has led to a more streamlined regulatory pathway for approval in the US.²⁵ The FDA announcement in April 2017 rendered 23andMe tests exempt from premarket review after submitting a single premarket notification – pathing the way for emerging companies offering similar services.

Companies looking to expand globally will need to tailor approaches towards each individual market to address the sheer diversity of regulatory and consumer attitudes within the respective countries. Europe represents a particularly fragmented market, with countries possessing no specific laws for DTC-GT services (e.g. Italy) sitting alongside others either only allowing their use under certain circumstances (e.g. the UK) and those disallowing it altogether (e.g. France).

DTC-GT providers looking to access EU markets may also benefit from working together to address GDPR requirements; implementing measures and monitoring adherence is both time-and-resource-costly, so pooling knowledge and support provision may be the only way to survive in the EU market.





Highlight consumer empowerment

Marketing communications of DTC-GT providers would benefit from emphasizing customer empowerment. By highlighting the potential control resulting from access to, and understanding of one's own genetic data, companies could attract customers whilst mitigating data privacy concerns.



Offer wraparound provision

In order to maximize customer satisfaction, DTC-GT companies should consider offering actionable recommendations to complement the test results. This approach addresses the customer drive to seek personalized services – potentially a key selling point.

In addition, combining tangible action plans with associated outcome measures to track improvement may open up further commercial opportunity; DTC-GT companies offering follow-up suggestions and services could see benefits in the form of customer retention and possible follow-on business, such as a bolt-on, paid for, diet or exercise tracking.

Where it is not possible to offer follow-up services internally – for example for applicants whose results indicate a likely medical condition requiring genetic counseling – companies may consider partnering with other providers to set up a network within which customers can be referred.



Address privacy concerns proactively

Companies should consider how they wish to address the privacy concerns that dominate current customer opinion. By successfully communicating a privacy strategy suitable for the evolving regulatory landscape, companies serve to gain a significant competitive edge.

For example, the DTC-GT company Guardiome puts the customer in sole charge of their genetic data by erasing all traces of the information from their systems following delivery of results. Interpretation and guidance of lifestyle choices is then undertaken at home autonomously, with the aid of custom-made software.

Reader comments

Actions:

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- a. Figures based on US market analysis and extrapolated to a global estimate

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