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The DNA Data Marketplace

An analysis of the ethical concerns regarding the participation of the individuals

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Content

Abstract

Personal genomic data and the related health data are valuable resources for both public-funded research, and for-profit entities in development of new drugs, therapies and diagnostic tests. In order to access to large datasets, pharmaceutical and biotech companies have developed partnerships with public and private entities such as Direct-to-Consumer (DTC) genetic testing companies to buy genomic and health related databases collected from research participants and customers. Although individuals mainly support data sharing for research purposes, the for-profit nature of such data sharing raises some questions regarding the rights of the data subjects and fairness in sharing benefits. In response, a new generation of sequencing and data sharing startups such as Nebula Genomics, LunaDNA and EncrypGen are emerging which aim for leaving the ownership and data control in the hands of each individual customer. In particular, such so called “DNA data marketplaces” allow individuals to receive various types of monetary incentives to sequence their genome and share it with interested commercial parties. This paper aims to provide an exploratory and critical review of the ethical challenges related to establishing such marketplaces for genomic and health data sharing. In the view of the growing number of startups developing such marketplaces, a thorough analysis of the relevant ethical concerns is timely and needed.

Introduction

Personal genomic data and the related health data are valuable resources for both public-funded research, and for-profit entities in development of new drugs, therapies and diagnostic tests. In response to this need, pharmaceutical and biotech companies have developed partnerships with public and private entities such as Direct-to-Consumer (DTC) genetic testing companies to buy genomic and health related databases collected from research participants and customers (Stoeklé et al., 2016). For instance, in 2018, GlaxoSmithKline, the pharmaceutical company, announced investing 300 million dollars in the 23andMe and thus establishing an exclusive drug development stake within a 4 year-collaboration (Tirrell, 2018), showing the value locked in genetic data.

Most of the customers of DTC companies opt-in to participate in research activities of the service providers and the downstream data sharing by the companies for research purposes. As reported by 23andMe, 80% of more than 5 million customers have given their consent to share their data (Hirschler, 2018). The existing studies with customers have revealed that the underlying reasons for such consent are mainly out of altruistic motivation to participate in research and help advancement of science (Goodman et al., 2017; Trinidad et al., 2010). However, the for-profit nature of sharing customers' data by DTC companies has been perceived objectionable by some customers (Skloot, 2015). Notably, by giving consent to research, customers should accept that they acquire no rights to research, products or profits that are made and may link to their DNA (Ducharme, 2018). This is viewed as unfair where a clear asymmetry in sharing benefits and interests is witnessed (Skloot, 2015).

Moreover, the active participation of the individuals in managing sharing and access to their own genomic and health data in the framework of the current data sharing models is not fully supported. The importance of this matter is recently pronounced by the European Data Protection Supervisor in their statement: "In principle, individuals should be able to decide whether and with whom to share their personal information, for what purposes, for how long, and to keep track of them and decide to take them back when so wished" (Boothby, 2018).

In response, a new generation of startups are emerging which propose, among others, to leave the ownership and data control in the hands of each individual customer (Rosenbaum, 2018). These so-called "DNA data marketplaces" propose that people can share their data with companies that are interested to have access to their data for various research leading to product development (Harris, 2018). A monetary compensation or incentives will thus be offered to customers in exchange for their data

(Jones, 2018). Although offering direct incentives to individuals to engage them in genomic data sharing may seem beneficial, this has been seen as a sensitive issue drawing a lot of attention in the area of research ethics. The concerns can be intensified in the view of existing questions regarding adequacy of independent ethics oversight on genomic data sharing by for-profit startups.

In an effort to address the associated concerns with DNA data marketplaces, this paper provides an exploratory and critical review of the associated ethical challenges related to participation of the individuals through analysis of different arguments discussed in academic papers and gray literature. We illustrated our discussions by referring to three examples of such startups, namely Nebula Genomics, LunaDNA and EncrypGen, which aim for establishing such DNA data marketplace.

DNA data Marketplace: Three examples

In order to illustrate our discussion, we reviewed the information provided in the websites of three startups namely Nebula Genomics, LunaDNA and EncrypGen, which enable individuals to share their genomic data and related health information and receive various monetary incentives. We also consulted the information published in other websites in relation to the visions, policies and strategies of these startups.

a. Nebula Genomics

Nebula Genomics is a startup established by George Church, plans to “upend the usual way genomic information is owned”, claiming that the current system applied by DTC companies is “very paternalistic” (Harris, 2018). Nebula established a partnership with Veritas, a company that is offering whole genome sequencing (Morris, 2018).

Nebula Genomics is aiming for establishing a “Nebula marketplace”, where those consenting to share their genetic information can earn the cryptocurrency called “Nebula tokens” (Buhr, 2018). In Nebula marketplace, individuals are meant to acquire and store their own genomic sequencing directly from Nebula Genomics instead of obtaining the service from a personal genomics company. The Nebula's business model anticipates that companies and research organizations would be willing to pay for the cost of sequencing, in exchange to get access to key medical information of the individuals involved. Thereby customers would get their genetic sequencing for no cost. This system intends to eliminate the need for middlemen outside the Nebula system (Morris, 2018).

The CEO of the Nebula system stated that: “For far too long, companies offering genetic testing have asked their customers to simply give away their valuable genomic data, and then have sold it without their knowledge”. “We want to change this and make people feel comfortable about personal genome sequencing by enabling data sharing in a secure, transparent and equitable manner” (Morris, 2018). To this end, a blockchain platform is designed to enable customers to choose how and with whom they want their data to be shared, and to be compensated for it (Morris, 2018).

Moreover, Nebula aims for assisting pharmaceutical companies in recruiting research participants with conditions that are interesting for their current studies, by launching an anonymized search for such patients. Once contacted by the companies, the patients can decide if they will grant access to the companies to their genomic and other medical data (Harris, 2018).

b. EncrypGen

EncrypGen is a startup aiming to “bring together genomic data sellers and buyers in one platform” (Wilson, 2019) and “looks forward to solving the problem of retaining customers’ DNA data by DTC companies to be resold to research and development companies” (Matthews, 2018). EncrypGen “Gene-Chain” DNA Data Marketplace connects individual DNA data owners with data buyers and providers of other health related services. The Gene-Chain’s aim is to empower users to store and monetize their genetic data by sharing it with third parties looking to obtain genetic data such as research scientists and pharmaceutical companies (Home - EncrypGen | The DNA Data Marketplace - EncrypGen., 2018).

According to the EncrypGen’s website, the individuals are invited to contribute data: “If you have had your DNA tested you may upload your raw DNA data file and create a Gene-Chain profile now. EncrypGen de-identifies the raw DNA data file by stripping it away from name, email, and other sensitive information. DNA data buyers search Gene-Chain profiles suitable for their projects and purchase de-identified genomic data with DNA tokens” (Buy DNA Tokens - EncrypGen., 2018).

As stated by the chief executive of EncrypGen: “Until now, to buy data that is useful in research and development of new drug therapies and precision medical treatments, meant paying whatever prices the big DNA testing companies demand, and without any compensation for people whose data is being sold”, adding that the company’s platform “ensures control and payment for data owners, and creates a new resource for researchers and pharma” (Williams, 2018).

In addition, EncrypGen has announced the plans for developing partnerships “with testing companies, analytics software developers, and various parties, like employee health benefits services”, in an attempt to drive more users to the platform and monetize data (Levy, 2018).

c. LunaDNA

LunaDNA is “a community-owned platform that is created by the Public Benefit Corporation, LunaPBC”. It integrates its research platform with the Genetic Alliance’s Platform for Engaging Everyone Responsibly (PEER) (De Crescenzo, 2019). According to Genetic Alliance, PEER is used by 45 disease communities that represents more than 50,000 participants (Beach, 2019).

LunaDNA offers company shares to individuals for contributing their DNA data as well as uploading their medical reports and lifestyle health activities. Those shares entitle members to a share in the profits from medical research and development. The platform is powered by the blockchain technology and aims at flowing back the benefits to the community in the form of dividends when researchers and pharmaceutical companies pay to access the data (Tracer and Brodwin, 2018).

According to the president and cofounder of LunaDNA, the company wants to give individuals more autonomy over how their data is used, and compensate them directly for their data sharing: “You can’t say data is valuable and then take that data away from everybody […] What we’re finding is that [our early adopters are] very excited about the transparency of this model–that when we all come together and create value, that value flows down to the individuals who shared their data” (Peters, 2018).

Users are supposed to get different portions of shares depending on the data they provide. For example, if a user donates DNA-targeted genes they will receive 10 shares, but if they submit their whole DNA genome, they will receive 300 shares (Lovett, 2018).
LunaDNA provides aggregated data to researchers with data anonymization with the consent of the involved individuals (Lovett, 2018). The anonymized data, with encrypted DNA information on a blockchain (Erickson, 2019), will be shared with nonprofit institutes such as those studying rare diseases. In this case, there would be no initial financial gain but “there could be intellectual property that at some point in time is monetized, and the community would share in that”. According to CEO and cofounder of LunaDNA: “When we have enough data in the near future, then we’ll work with pharmaceutical companies, for instance, to drive discovery for those companies. And they will pay market rates” (Peters, 2018).

Ethical Concerns

Participation of the individuals in for-profit data contribution startups raise a number of ethical concerns for the rights and interests of the individuals and society in general. While some of these concerns are related to the impact of incentives strategies that such startups utilize on consent and participation in research, the other concerns are related to potential privacy concerns that may arise from use of emerging technologies such as Blockchain.

1. Consent-related concerns

Informed consent is a fundamental principle in research ethics, and an essential pre-requisite before the initiation of study with human subjects. The informed consent is obtained to protect the participants autonomy and to inform them about the risks and benefits of being involved in a specific research (Smith-Tyler, 2007). For an informed consent to be ethical and valid, several crucial elements should be present and employed, including voluntariness, disclosure of information and decision making capacity (del Carmen and Joffe, 2005; Griffith, 2009; Gupta, 2013; Meisel et al., 1977). Concerning the participant free decision-making and voluntariness of consent, a number of ethical concerns arise when incentives are offered in return to participation. In the context of DNA data marketplace and collection of genomic and other health related data for future research and product development purposes, the impact of monetary incentives on validity of consent should be thoroughly investigated. We will discuss the consent-related issues here under two major concerns of undue influence and withdrawal of consent.

1.1. Undue influence

Informed consent must be obtained from participants under circumstances that minimize the possibility of coercion or undue influence (CFR - Code of Federal Regulations Title 21- Protection of human subjects., 2004). According to the standards of the 1947 Nuremberg Code, there should not be any kind of persuasion or pressure put on participants (Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10. Nuremberg, 1949). It is important to evaluate whether or under what research circumstances financial incentives might affect a subject’s judgement, and to what degree the payments induce people to participate while having deep objections (Grady, 2005).

Incentives are employed as a common strategy in many fields and are widely seen in everyday life. They possibly range from bonuses to offers and rewards in trade or school systems and are widely accepted by the community as long as they are achieving objectives of public policies. However, when it comes to research with human subjects, there is substantial sensitivity to the debate over the application of incentives as a tool to encourage participation (Grant and Sugarman, 2004).

Research ethics committees and other entities involved in research oversight are usually concerned that financial incentives may coerce potential research participants and thus compromise the voluntariness of their consent (Dickert et al., 2002). In fact, the offers of payments can threat the validity of the consent under circumstances that compromise the participant's ability to respond reasonably, therefore his/her participation can be unduly induced (Wertheimer and Miller, 2008). According to the official Instituional Review Board (IRB) guidebook published by the US Office for Human Research Protections (OHRP), "an offer is troublesome if it is so attractive [that it] may blind prospective subjects to the risks or impair their ability to exercise proper judgment'' (U. S. Department of Health and Human Services).

Moreover, provision of monetary incentives may undermine altruistic participation in research, which may be prevalent among healthy research participants. For instance, the previous studies have reported that offering remunerations may negatively impact the participation of altruistic subjects, as they may see this in contrast with their virtuous values (Deci et al., 1999). That said, one might argue that participation in research is not always based on altruistic motives. This is particularly pertinent in case of participation of patients or their family members in research with a goal of accelerating finding cure/diagnosis for their or family members health condition (Joffe, 2006). Regardless, it is crucial to investigate how both patients and healthy participants, with various socio-economic backgrounds respond to the financial incentives in personal data sharing.

1.2. Consent withdrawal

Research participants should be aware that they have the right to freely withdraw their consent at any time during the research (Edwards, 2005), and voluntary terminate their participation in research (Gabriel and Mercado, 2011), without necessarily providing reasons (Goldfarb, 2011). Notably, when the samples and data collected from the participants are already used in research, the withdrawal of the consent will be valid for the future use.

Offering financial incentives to individuals for sharing their genomic data could be a barrier to consent withdrawal. In particular, the questions arise about whether individuals can withdraw their consent after receiving various types of financial incentive, such as tokens, shares, or free sequencing (Roberts et al., 2017). Will the companies ask the participants to return the tokens, shares, etc. that they have received in exchange for the withdrawal of their consent? The procedure of withdrawal could be much more complex when individuals are already exchanged access to their data in return to free sequencing of their genome by interested companies.

For instance, the LunaDNA consent policy informs patients that: “Your continued consent to LunaDNA’s use of your Shared Data is required for your continued ownership of any shares in LunaDNA issued to you in connection with the contribution of that Shared Data. If you elect to purge Shared Data for which you were issued ownership shares in LunaDNA, LunaDNA will redeem (i.e., cancel) those shares, and may also elect to cancel certain other shares that may have been issued to you. […] If you revoke your consent or delete your account, LunaDNA will redeem all shares issued to you. We believe this is the best way to be fair to other members of LunaDNA who have not revoked access to their data” (LunaDNA, 2018). The other two startups however have not provided any information on this matter on their website.

It is highly recommended that these emergent startups establish clear policies regarding consent withdrawal and communicate that to the participants.

2. Blockchain-based platforms and privacy concerns

Sharing personal genomic data raises considerable privacy and security concerns, due to unique nature of genomic data that contains identifiers which make the complete de-identification of the data hard if not impossible (Wang et al., 2017). In addition, genomic data can reveal a wide range of sensitive health and non-health related data about the individuals and their family members (Genomeweb, 2018). For example, in a study analyzing Y-chromosome haplotypes together with combining data from genealogical registries, researchers were able to predict the surnames of a number of anonymized participants in the dataset (Gitschier, 2009).

That said, the utility of genomic data for the researchers can be increased if personal genomic data are linked to other medical and life-style information from the individual (Angrist, 2013). Therefore, it is crucial to adopt privacy-preserving technologies that facilitate access to personal data while mitigating the risks of breach of privacy.

As it is reported above, some of the startups aim for implementing blockchain technology as an approach to better protect genomic and health data, while allowing participatory control on access to the data. Blockchain is an emerging technology of a decentralized, digitized database medium and a public ledger of all transactions in the network (Ozercan et al., 2018). The key feature of a blockchain is the distributed database where the database is present in many copies across several computer systems creating a peer-to-peer network indicating that there is no longer a centralized body controlling access to data (Duan et al., 2016; Han et al., 2014). Arguably, Blockchain-based platforms can help to solve the governance problems in sharing genomic data by using technical solutions. These platforms promise their customers to provide distributed data stewardship and control together with provision of effective ways for strengthening data access and ownership agreements (Shabani, 2019). In terms of the security of the networks, although blockchain use is expected to improve data encryption (Weintraub, 2018), no technology is infallible and concerns about possible hacking and breaching of the blockchain system have been noticed by the experts and the platform developers (Erickson, 2019).

Nebula Genomics privacy policy includes that they take a number of organizational, technical and physical measures to protect the personal information they collect, both during transmission and once received. However they note that, “no security safeguards are 100% secure and we cannot guarantee the security of your information”(Privacy Policy, 2018).

Moreover, the questions remain about the compatibility of using such technologies with applicable data protection regulations in different jurisdictions. As Rebecca Herold notes: “Implementing blockchain does not fit neatly within most legal and regulatory compliance requirements that exist, and those working to meet compliance are likely new to blockchain and may not realize all the associated compliance issues […] Validating the security and privacy of blockchain is not a simple goal to accomplish” (Price, 2018).

Finally, the possibility of access by third parties such as for law enforcement purposes should be investigated (Weintraub, 2018). The Nebula Genomics privacy policy includes the possibility of such access: “We may disclose information about you to government or law enforcement officials or private parties as required by law, and disclose and use such information as we believe necessary or appropriate to comply with applicable laws and lawful requests and legal process, such as to respond to subpoenas or requests from government authorities” (Privacy Policy, 2018). In principle, this could be seen at odds with the rational behind blockchain technology, which restricts access to data for those who are not part of the network.

3. Other associated concerns

3.1. Education and awareness of the potential risks

Individuals should be encouraged to carefully weigh the benefits and risks of getting engaged in a DNA data marketplace. Moreover, raising awareness regarding the implications and possible consequences of personal genomic data sharing for the individuals and their family members is essential (Shabani and Borry, 2015). Currently, the potential concerns regarding genomic data sharing in the conventional research settings are being investigated. Some of the studies such as “Your DNA, Your Say” are also prepared educational videos in an attempt to familiarize general public with the potential benefits and concerns of data sharing (Middleton et al., 2018). However, the similar studies and educational materials in the context of data sharing in DNA data marketplace are missing.

Previously, in the context of Personal Genome Project (PGP), following educational videos are being required for those who agreed to share their genome publicly. In addition, the requirements such as higher level of education has been expected from volunteers of PGP (Reuter et al., 2018). Although this can be seen as one way to mitigate the concerns regarding awareness about the associated risks with such data sharing, but it may lead to biasing the sample of participants and work against diversity.

Moreover, the associated risks with sharing data through DNA data marketplace are not fully known yet. It is expected that some of the concerns such as those related to risks for privacy emerge only in the future and due to technological advances. The participants therefore should be aware of unknown risks.

3.2. Broader impact on biomedical research and data sharing

There is a growing concern about the impact on public-funded research not offering incentives. How will individuals respond towards research that does not offer incentives in the future? Will people donate their DNA for research when in the meantime they can sell it?

In fact, encouraging more individuals to participate in research through offering incentives may be seen as a strategy to increase the recruitments and engagement of the individuals in genomic data sharing. However, the downside is the financial offers may have an unfavorable impact on research not offering incentives due to an overall reduction in intrinsic motivation to participate (Zutlevics, 2016). Wilkinson and Moore underlined the concerns about research offering inducements and its foreseen detrimental effects on participants dis-favoring to engage in research not offering incentives and ultimately leading to research commercialization (Wilkinson and Moore, 1999).

Another sensitive concern is about the quality of the data. There is a potential that rewarding users for sharing their data could impulse the users’ provision of flawed or misleading health information (Curtis and Hereward, 2018), particularly in answering surveys related to medical history or lifestyle information .

Conclusion

The emerging DNA Data marketplaces are promising to introduce a fair model of data sharing among individuals and the interested parties such as pharma and biotechnology companies. They encourage the individuals to directly take part in sharing their data and practice their ownership rights regarding their DNA information. However, our analysis showed that developing DNA data marketplace raises concerns for consent and privacy and may have externalities for public-funded research that do not offer incentives.

One of the main arguments of developing DNA data marketplace is to empower individuals to directly share their data and control who can have access to data. In essence, empowerment of the individuals by enabling them to actively involve in management of their personal health information has recently received an increasing attention.

For example, The European Data Protection Supervisor published in October 2016 an Opinion on this subject and recognized the potential of Personal Information Management Systems (PIMS) as one approach for effectively implementing citizens' rights on their personal data at the practical level. PIMS "allow individuals to manage their personal data in secure, local or online storage systems and share them when and with whom they choose." Such tools are developed by commercial entities that aim to benefit from enabling novel data flows and also by 'data cooperatives', which are the entities co-owned by the individuals using the service (European Data Protection Supervisor, 2016).

DNA data marketplace could be seen as an example of such approach, aiming for involving individuals in managing how to share their health data and with whom. However, in order to truly empower patients and individuals, it is crucial to ensure that they are adequately informed about the limitations on controlling their data once have been shared and accessed by companies and interested parties. In addition, the companies should develop fair and transparent policies on issues related to consent withdrawal in the view of offering tokens, shares, etc. in exchange for data.

In addition, the success of data collection through such marketplaces is hinged on attracting a large number of participants, otherwise it would be hard to foresee a significant impact on the current way the medical research has been performed. As the director of Mount Sinai's Center for Biomedical Blockchain Research puts it: "My biggest concern from an entrepreneurial standpoint is that these marketplaces are only valuable once they get to huge numbers. Anything less than 100,000 genomes probably isn't going to be useful to anyone" (Molteni, 2018). It should be noted that currently some of other non-profit data sharing platforms such as DNA.Land that enables individuals to share their own genome- succeeded in collecting more than 150,000 genomes (DNA.LAND). Therefore, the scalability of DNA data marketplaces may be seen as an achievable goal. Moreover, developing DNA Data Marketplaces and recruiting individuals directly may be considered as a solution to the problem of lack of diversity among study groups in biomedical sciences. The future studies are needed to survey the participants in such marketplaces and examine the level of diversity in terms of nationality, ethnicity, gender, and the like.

Finally, the use of the terms such as data ownership, buying and selling data, and data control in the context of personal genomic and health data should be thoroughly scrutinized, as such claims are surrounded by legal and practical uncertainties (Blasimme et al., 2018). One pertinent question is how the monetary value of DNA data can be estimated, and how this can be ethically and legally enforced (McNulty, 2018). EncrypGen declared that the price of access to data would be decided by the open market, while LunaDNA proposes different pricing for non-profits and corporations (Curtis and Hereward, 2018). This calls attention to the necessity of developing adequate guidelines, policies and regulations in order to ensure both ethical and legal underpinnings of DNA data marketplaces as well as transparency and fairness of the procedure.

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