A Model for Genetic Data Exchange and Sovereignty

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Executive Summary

Over the past decade, significant breakthroughs in DNA sequencing have accelerated our capacity for genetic research and created new disciplines of precision medicine, promising a generation of novel therapies for previously incurable ailments. However, with an influx of vast amounts of genetic data, another challenge arose: the problem of data stewardship and governance. As of today, an individual who has their DNA analyzed through consumer-focused products like 23andMe or Ancestry.com, or through their personal healthcare provider has no promise of knowing where the genetic data goes or how it will be used. This historical lack of transparency has had cascading consequences across the industry- from disincentivizing participation in programs that would benefit from sharing genetic or health data, to driving a profound lack of genetic diversity in clinical trials. We believe that a blockchain tool, leveraging non-fungible tokens, can enable a degree of transparency and traceability to allow individuals to become informed stewards of their own genetic data. By doing so, we strive to build guardrails for privacy and security around the exchange of genetic data, thereby regaining the trust of participants, and encouraging our community to drive a thriving genetic data marketplace for the greater good of society.

I. The Problem

A: Individual Privacy

There are currently two principal objectives for patients and consumers who share their genetic information with third parties. The first pertains to the patient's immediate medical needs, and can be used to inform a diagnosis or therapy. The other is for personal interest, where an individual has shared their genetic data in order to learn about their ancestral background or biomarkers related to future health and disease risks.

In the case of personal interest, most individuals will readily recognize the names 23andMe and Ancestry.com, both of which are direct-to-consumer (DTC) genetic genealogy testing companies that provide a range of information from geographic ancestral lines to notable health indications. In the year 2017, the number of consumers purchasing geneology tests more than doubled, leading to over 12 million genomes sequenced by the end of the year through these services.[1] Subsequently, in 2018, consumers purchased just as many DNA tests as were purchased in all of 2012-2017 combined. By the end of November, 2018, Ancestry.com had 14 million genomes, with 23andMe following closely at 9 million genomes.[2]

When consumers or patients share a sample of their genetic data to be sequenced, the collector or lab requires the patient to sign an agreement stating what can be done with the data. 23andMe, for example, states that "Giving consent... means that you agree to let 23andMe share your de-identified individual-level data with approved researchers outside of 23andMe… [which may] range from academic institutions and non-profit organizations to pharmaceutical

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[1] Regalado, Antonio. 2017 was the year consumer DNA testing blew up. Technology Review. Feb 12, 2018. https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/

[2] Bursztynsky, Jessica. More than 26 million people shared their DNA with ancestry firms, allowing researchers to trace relationships between virtually all Americans. CNBC news. Feb 12, 2019. https://www.cnbc.com/2019/02/12/privacy-concerns-rise-as-26-million-share-dna-with-ancestry-firms.html

and diagnostic companies."[3] In the summer of 2018, they announced a partnership with pharmaceutical giant GlaxoSmithKline to aid in the development of new medicines, using 23andMe's repository of genetic data in exchange for a $300 million investment.[4] This was not their first major collaboration with the pharma industry -- 23andMe had already partnered with companies like Pfizer, Genentec, and others by 2015,[5] and launched in 2009 what is now the world's largest genetic study of Parkinson's disease.[6] Furthermore, they received FDA authorization in 2018 to test for genetic risk factors for 10 diseases, such as specific BRCA gene mutations associated with breast cancer.[7]

23andMe is quick to refer the public to their updated list of scientific publications, white papers, and conference presentations on their site, and consumers may even be happy to know that information from their saliva can support a greater cause.[8] However, this fails to capture the full extent of how their data and data from similar companies are shared and used.

One such customer of DTC sequencing services was subsequently denied life insurance coverage because the test returned a positive BRCA gene mutation, associated with heightened risks for breast cancer. Protections in existing legislation- the Genetic Information Nondiscrimination Act (GINA)- do not apply to life insurance, disability insurance, or long term care, and few consumers realized that such genetic tests would be used against them in the first place.[9] Furthermore, the US military is exempt from GINA protections, and as more research has suggested a pattern of inaccurate results from DTC testing services, even Pentagon

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[3] https://www.23andme.com/about/individual-data-consent/
[4]https://mediacenter.23andme.com/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/
[5] https://blog.23andme.com/23andme-research/23andmes-recent-research-collaborations/
[6] https://www.23andme.com/pd/
[7]https://www.fda.gov/news-events/press-announcements/fda-authorizes-special-controls-direct-consumer-test-reports-three-mutations-brca-breast-cancer
[8] https://research.23andme.com/publications/
[9]https://www.fastcompany.com/3055710/if-you-want-life-insurance-think-twice-before-getting-genetic-testing

leadership urged restraint. Commander Sean Robertson emphasized the need for service members to understand the risks of such testing services, suggesting that in addition to exposing personal and genetic information, the unintentional discovery of genetic markers could influence service members' careers.[10]

Earlier in 2018, the Golden State Killer was famously identified over 40 years after his first crimes with the help of a small genealogy site.[11] Though this was considered a resounding success for law enforcement, such media attention helped to hide other cases where law enforcement used genetic information to frame innocent individuals for murders they did not commit.[12] With the proliferation of DNA testing services, such companies long denied collaboration with law enforcement, but FamilyTreeDNA in Houston was recently outed for sharing its database of over 2 million genetic records with the FBI during 2018,[13] which adds to growing suspicions that other genealogy services are doing the same. Already, Canadian law enforcement has been using such Ancestry services to assist in identifying the nationalities of migrants and facilitate their deportation.[14]

Human rights advocates have argued that arming American law enforcement agencies with genetic capabilities can be abused to conduct unethical and unlawful surveillance and intimidation. The New York Police Department has already amassed an imposing database of DNA profiles through controversial door-to-door "knock-and-spit" swab tests in low-income

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[10] Murphy H, Zaveri M. Pentagon Warns Military Personnel Against At-Home DNA Tests. New York Times, Dec 24 2019. https://www.nytimes.com/2019/12/24/us/military-dna-tests.html

[11] https://arstechnica.com/tech-policy/2018/04/genealogy-websites-identify-rape-suspect-who-eluded-police-for-40-years/

[12] Worth, Katie. Framed for Murder By His Own DNA. The Marshall Project. April 19 2018. https://www.themarshallproject.org/2018/04/19/framed-for-murder-by-his-own-dna

[13] Haag, Matthew. FamilyTreeDNA Admits to Sharing Genetic Data With F.B.I. New York Times. Feb 4, 2019. https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html

[14] Hopkins, Andrea. Canada Using DNA, ancestry websites to investigate migrants. Reuters, July 27, 2018. https://www.reuters.com/article/us-canada-immigration/canada-using-dna-ancestry-websites-to-investigate-migrants-idUSKBN1KH2KF

neighborhoods, in addition to other non-consensual collection methods using coffee cups, water bottles, and cigarette butts from detained individuals.[15] Unlike the tightly regulated national FBI database, county-level administrators enjoy a greater degree of freedom- New York City's Local DNA Index System is now approaching 100,000 genetic profiles, and they permanently store this data even if the 'donors' are cleared of any wrongdoing.[16] We can anticipate more police departments rapidly building their own unregulated databases, as federal legislation from 2017 has been equipping law enforcement offices across several states with the tools to make collecting genomes as routine as fingerprints.[17] Currently, US Customs and Border Protection agents are preparing to dramatically expand the collection of DNA samples from immigrants and asylum-seekers at the US-Mexico border. Under the direction of the Justice Department, this is expected to target over 700,000 migrants annually and feed into an FBI database, with countless questions of individual consent and privacy left outstanding.[18]

In its more scientific contributions, 23andMe insists that its research "does not constitute research on human subjects," because it was performed on "anonymized data with no contact between investigators and participants" as demonstrated by their Institutional Review Board (IRB) application.[19] IRBs are created for the purpose of protecting the rights and welfare of human research subjects,[20] so this attempt to evade higher standards of privacy and security is

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[15] Whalen, Andrew. NYPD'S 'Knock-and-Spit' DNA Database Makes You a Permanent Suspect. Newsweek, Feb 11, 2019. https://www.newsweek.com/police-dna-database-nypd-swab-testing-collection-new-york-1326722

[16] Ransom J, Southall A. N.Y.P.D. Detectives Gave a Boy, 12, a Soda. He Landed in a DNA Database. New York Times, Aug 15 2019. https://www.nytimes.com/2019/08/15/nyregion/nypd-dna-database.html

[17] Murphy, Heather. Coming Soon to a Police Station Near You: The DNA 'Magic Box'. New York Times, Jan 21 1019. https://www.nytimes.com/2019/01/21/science/dna-crime-gene-technology.html

[18] Allyn B, Rose J. Justice Department Announces Plan To Collect DNA From Migrants Crossing The Border. NPR. Oct 21, 2019. https://www.npr.org/2019/10/21/772035602/justice-department-announces-plan-to-collect-dna-from-migrants-crossing-the-bord

[19] Eriksson N, Macpherson JM, Tung JY, et al. (2010) Web-Based, Participant-Driven Studies Yield Novel Genetic Associations for Common Traits. PLOS Genetics. https://doi.org/10.1371/journal.pgen.1000993

[20] Grady, Christine. Institutional Review Boards. American College of Chest Physicians. June 4 2015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631034/pdf/chest_148_5_1148.pdf

unsurprising, and when genetic data can no longer be considered de-identifiable,[21] it becomes that much more important that genetic data be held to the highest standards of privacy.

In 23andMe's complete privacy statement, they offer the "Right to be Forgotten," giving all customers the right to "delete their accounts at any time",[22] but they simultaneously cite compliance with the Clinical Laboratory Improvement Amendments of 1988,[23] which, as they state in an email, means that their labs "will retain your genetic information and a randomized identifier on their secure servers for a limited period of time, 10 years pursuant to CLIA regulations."[24] Before the GSK deal, a researcher at the University of Queensland[25] estimated that 23andMe made nearly $130 million USD from selling access to a million genotypes.[26] Today, they continue to build a strong revenue stream, sharing data with profitable pharmaceutical companies, using rich genetic data that consumers paid them to provide, while consumers are given limited visibility into how else their genetic data will be used.

In the case of medical diagnoses, select premier hospitals have built into their workflow a standardized process for consenting patients for the collection of genetic information. For example, at Memorial Sloan Kettering Hospital, a leading cancer center in New York, every patient can be sequenced as part of their care plan.[27] Alongside them are similarly renowned institutions such as Brigham and Women's Hospital in Boston and the MD Anderson Cancer Center in Houston.

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[21] https://science.sciencemag.org/content/339/6117/321
[22] https://www.23andme.com/about/privacy/
[23] Clinical Laboratory Improvement Amendments (42 USC 263a) https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf
[24] https://www.bloomberg.com/news/articles/2018-06-15/deleting-your-online-dna-data-is-brutally-difficult
[25]https://www.reuters.com/article/us-health-dna/cashing-in-on-dna-race-on-to-unlock-value-in-genetic-data-idUSKBN1KO0XC
[26]https://www.reuters.com/article/us-health-dna/cashing-in-on-dna-race-on-to-unlock-value-in-genetic-data-idUSKBN1KO0XC
[27] Juan Perrin, interview, April 18, 2019

An interview with a Memorial Sloan Kettering researcher revealed that they exclusively share data with faculty and analysts inside of the labs at their own institution. We found a similar story echoed across institutions, that patient data is generally de-identified and shared for specific purposes to third parties who request either specific data for ongoing research. For example, a pharmaceutical company might request a query across genetic databases to help estimate the population size relevant to a particular mutation, informing how they perceive a potential market for subsequent research investments.

This data sharing can be a great revenue generator for organizations. Dermot Shorten, Quest Diagnostic's Vice President of Strategy and Ventures, said his company earns in the low, single-digit millions per year from such sales.[28] However, there is no centralized marketplace to buy and sell data in the current system, with portfolios of data being requested and negotiated via email or phone calls. Seven Bridges Genomics attempted to address this "data marketplace" challenge, but described it as "complicated," where still the vast majority of transactions were left to the manual process. Another project to address this challenge is cBioPortal, which provides large-scale cancer datasets, analysis, and visualization.[29] It was originally developed at Memorial Sloan Kettering and is available via an open source license, but those interviewed agree that their data transmission format has not taken factors such as genetic testing strongly into consideration.[30]

Instead, this process is largely network-driven, based on existing relationships within the industry.[31] For example, a pharmaceutical company's director may reach out to an executive at a lab that processes genetic data. They will email or schedule calls to initiate the request, and

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[28] http://clinchem.aaccjnls.org/content/clinchem/early/2016/12/29/clinchem.2016.261479.full.pdf
[29] http://www.cbioportal.org/
[30] HL7's Version 2.x (V2) messaging standard is the workhorse of electronic data exchange in the clinical domain and arguably the most widely implemented standard for healthcare in the world. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185
[31] Scott Chapin, interview, April 18, 2019

the pharmaceutical company will define the criteria of their query for genetic information. The lab will then either query their own data to provide an answer, or depending on the engagement, will transmit the data directly to the buyer.

Once the data is gathered for a given engagement or study, pain points were uncovered through multiple interviews around storage of the data. Companies are still using traditional databases. Quest Diagnostics is one of the world's largest providers of diagnostic services, and is one of the labs used by Ancestry.com.[32] Scott Chapin, Director of Architecture and Analytics at Quest Diagnostics mentioned that they are no exception to this storage pain point- almost all of their data is held in isilon storage, a type of archival storage, accumulating hundreds of petabytes of data over time.

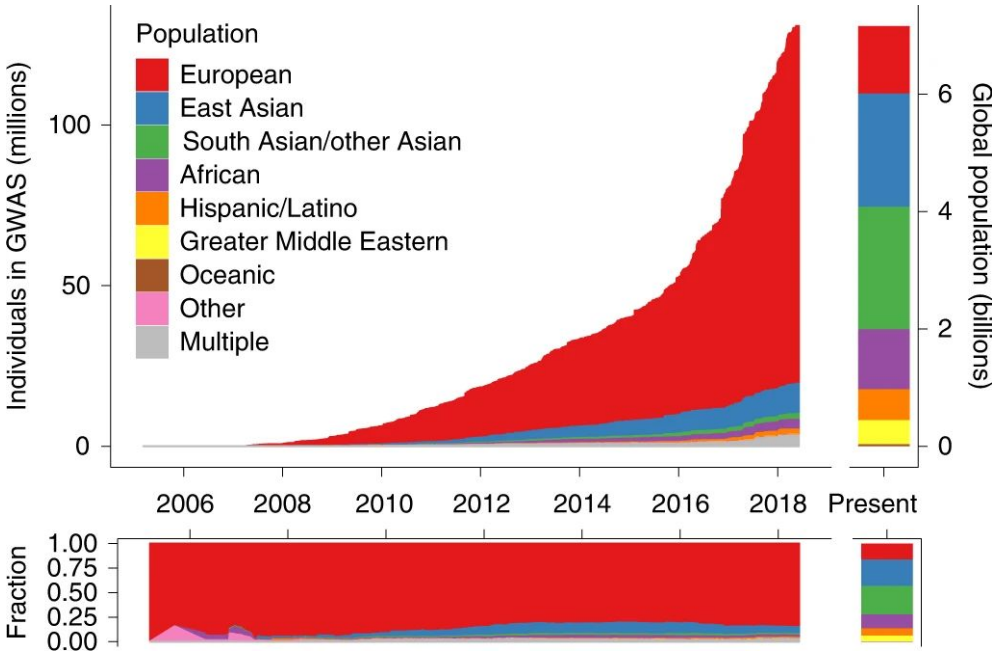
All interviews confirmed that outside of delivering the intended medical diagnosis, there is no feedback loop to the patient about what happens with their data, where it is sold, or how it is used. One industry expert stated, "It would be very valuable to have this information. The more metadata, the better, even if we don't see relevance now - where it went, what was done with it. Especially for sensitive stuff like DNA - even after being cleaned, this data is still identifiable." Furthermore, limitations of laboratory consent processes revealed that even if the lab identifies potentially dangerous or meaningful outliers in a patient's genetics, a medical lab is unable to inform the individual of the potential disease diagnosis or risk if there was no specific consent collected towards that purpose.

B: Genetic Inequity

This lack of transparency for patients has contributed to an even greater challenge pressing the medical community. A 2018 study published in Genome Biology illustrated the

[32] Fact Sheet, Quest Diagnostics, http://newsroom.questdiagnostics.com/index.php?s=30664

profound eurocentric biases of our cutting edge genome-wide association studies (GWAS), and how they fail to appropriately represent diverse ancestries. GWASs look for small variations in the genome to isolate and identify specific genes that may contribute to a patient's risk of developing a given disease.[33] From all GWAS publications- the 4,600 studies included in this assessment- 78% of participants represented individuals of European descent, with Asians comprising 11%, and Africans and Latinos combined forming <4% of study participants.[34] As a result, much of the research driving the entire discipline of precision medicine- "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person"- is failing to adequately represent our diverse population.[35]



Ancestry of GWAS participants over time, as compared with the global population

(Source: Martin AR et al. 2019).

[33] https://ghr.nlm.nih.gov/primer/genomicresearch/gwastudies
[34] https://genomebiology.biomedcentral.com/articles/10.1186/s13059-018-1396-2
[35] https://ghr.nlm.nih.gov/primer/precisionmedicine/definition

One can easily imagine a possible genetic mutation prevalent in the African-American population that changes the way certain molecules are metabolized in the body. A pharmaceutical company, relying on GWAS insights, may invest hundreds of millions of dollars to develop a new drug, but realistically may not realize until the third phase of a clinical trial that a particular mutation leads to a rapid buildup of the drug or its metabolite in the body, leading to serious harm or even death of African-American individuals. Such a scenario is not unlikely-- polygenic risk scores, or genetic risk scores, can be used to predict an individual's disease risk based upon the presence of a constellation of genetic markers.[36,37,38] As it stands, existing prediction capabilities for individuals of African descent are just marginally better than random, if at all.[39] Genetic risk scoring practices would least benefit them-- a population that already bears substantial health disparities across the world-- as long as the quality of their data remains stagnant, irrespective of other advancements in precision healthcare made in the meantime. Unless the data used is equitable in how it represents the population it aims to help, whole communities will be left out of the innovation cycle, and the research findings may lead to inappropriate diagnoses, treatments, and even patient harm.

Minority populations have long been distrustful of healthcare research and treatment services. In the early 20th century, the Tuskegee Institute and US Public Health Service notoriously engaged in a treatment study of Syphilis, but the African American population was intentionally not given any penicillin treatment, and were instead observed over 40 years to

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[36] A Cecile J W Janssens, Validity of polygenic risk scores: are we measuring what we think we are?, Human Molecular Genetics, Volume 28, Issue R2, 15 October 2019, Pages R143–R150, https://doi.org/10.1093/hmg/ddz205

[37] Sugrue LP, Desikan RS. What Are Polygenic Scores and Why Are They Important? JAMA. 2019;321(18):1820–1821. doi:10.1001/jama.2019.3893

[38] Duncan, L., Shen, H., Gelaye, B. et al. Analysis of polygenic risk score usage and performance in diverse human populations. Nat Commun 10, 3328 (2019) doi:10.1038/s41467-019-11112-0

[39] Martin AR et al. Clinical use of current polygenic risk scores may exacerbate health disparities. Nature Genetics 51, 584–591 (2019).

study the effects of the treatable disease.[40] Even at the turn of the century, peer reviewed studies found African American populations to be less trusting than white Americans regardless of their social class.[41] As it stands, they are already underrepresented in research studies for conditions like prostate cancer, for which African American men are already more likely to develop and die from than caucasian men.[42]

The historical lack of accountability, coupled with the modern lack of transparency in genetic data collection makes it extremely difficult to build trust and incentivize participation in medical research under current circumstances. One promising effort is the *All of US* Research Program, established in 2015 by the National Institutes of Health to recruit over a million individuals across all backgrounds to share their clinical and genetic health information. Just after a year of active data collection, over 250,000 participants have joined, with the majority coming from racial and ethnic minority populations.[43] However, as long as these key issues in trust and transparency are not addressed, minority populations will not believe there will be accountability, and will continue to broadly resist opportunities to drive medical research and advances in treatments for their populations.

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[40] https://www.cdc.gov/tuskegee/timeline.htm
[41] Corbie-Smith G, Thomas SB, St. George DMM. Distrust, Race, and Research. *Arch Intern Med.* 2002;162(21):2458–2463. doi:10.1001/archinte.162.21.2458
[42] https://www.auajournals.org/article/S0022-5347(17)30779-6/fulltext
[43] Devaney, Stephanie. All of Us, Scientific American 322, 1, (January 2020). https://www.scientificamerican.com/article/all-of-us/

II. A Solution

A. Current Developments

1. Non-Genomic Approaches to Permissioning and Data Ownership:

The challenges with health data ownership and exchange are hardly unique to the genomics space. The issues detailed above are seen in several other areas of the healthcare ecosystem, and many have attempted to address the inefficiencies in how we transact such health information. The use cases below illustrate a few examples of companies working to improve data exchange practices in the genomics space as well as across healthcare broadly. Reviewing the current state of such solutions and the problems they are targeting is helpful in understanding where significant innovation is happening, and consequently where opportunities for meaningful change exist.

SimplyVital

To understand SimplyVital's approach, a brief discussion of value-based payments and care coordination is useful. Reimbursement practices in healthcare are gradually transitioning from the classical fee-for-service model to a value-based care model, which shifts the focus from the quantity of care (number of procedures and services performed) to the quality of care and resulting patient health outcomes. This transition requires a high degree of coordination across a range of clinicians interacting with patients over an episode of care.

The successful recovery of a 55-year-old, overweight male following a complete knee replacement, for instance, involves several clinicians- the orthopedic surgeon, the pharmacist, the physical therapist, nurses, technicians, and even the patient's primary care provider.

Communication among these providers, while crucial for successful patient recovery (in turn, for provider reimbursement under the value-based care model), is still tremendously inefficient.

Providers use siloed electronic medical records (EMRs), fax machines, excel spreadsheets, and other tools to record and communicate aspects of patient care that the patient above may have received, and any information lost between the points of care contribute to large cost burdens. One study of the administrative burdens related to billing and reimbursement practices at an academic healthcare system found that these costs can measure up to 25% of professional revenue.[44] Processes or tools that increase communicative efficiencies are therefore significant assets in this value-based care framework that financially incentivizes sharing of medical data amongst providers.

An interview with SimplyVital's CEO highlighted two solutions that the company is building. The first of these aims to solve the problem of inefficient data exchange between disparate providers by storing episodes of care as data points on the blockchain. Care coordinators and providers that are associated with said patient's care are notified every time the patient receives care from a provider within their care management team. Subsequently, transaction receipts for both- the episode of care taking place, and notification of the care coordinators and providers- are hashed and stored on the blockchain. Providers can then use this product and SimplyVital's underlying Ethereum based protocols (HealthNexus) as an audit trail for any episode of care, providing documentation for filing reimbursements in the value-based care model.

Where SimplyVital's first product illustrates a key example of breaking down data silos and decentralizing an archaic model of data ownership, the company is developing another solution that is focused on improving data accessibility. This product is still in its early stages,

[44] https://jamanetwork.com/journals/jama/fullarticle/2673148

but from the aforementioned interview with the SimplyVital CEO, the focus is to simply make data accessible for buyers and sellers- SimplyVital is agnostic to the type of data that will eventually be transacted (although they concede that genomics and oncology are intriguing).[45,46]

The company believes in the future need for a third-party marketplace to connect parties that have stores of data- presumably hospital systems and providers- to parties that desire data, such as insurers or pharmaceutical companies for research. SimplyVital plans to use its own token- HealthCash- and incorporate fiat to crypto exchange capabilities.[32]

Though SimplyVital's solutions do not shift the current data ownership paradigm- as care providers are still owners of health information rather than patients- its solution demonstrates the potential for blockchain-based permissioning[47] and its role in creating an efficient exchange of data. The company's roadmap illustrates how provider permissioning between trusted stakeholders can drive increased revenue in the value based care model and can enable a marketplace for medical data.

MedRec

MedRec was a whitepaper prototype published by the MIT Media Lab and Beth Israel Deaconess Medical Center (BIDMC) in 2016. Where SimplyVital's focus is on provider-provider and provider-industry data sharing, MedRec brings patient agency over their own data to the center of its proposed solution. To understand MedRec's value proposition, a quick review of the dominant issues with EMRs is helpful. It is widely agreed upon that EMRs in the current state suffer from:

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[45] https://crushcrypto.com/wp-content/uploads/2018/03/HLTH-Whitepaper.pdf

[46] Interview With David Akers, SimplyVital (March 11, 2019)

[47] Permissioning is defined here as an efficient and safe way for one party to grant another party access to information that the former party is holding. This can be for purposes of information validation (occurrence of an episode of care) or for transaction of value (HealthCash traded for medical data).

1. *Fragmented and slow access*- Current EMR design promotes fragmented storage across multiple healthcare settings as patients change providers or move geographically. This results in a loss of past medical information as the patient is no longer the steward of their own data.[48] HIPAA privacy rules also promote a slower exchange of data, allowing providers up to 60 days to respond to requests for access (and edits to) past medical records.[49]
2. *System interoperability*- Historically, EMR systems lacked incentives to design frameworks for facilitating quick and efficient data transfers from one hospital network to another. For years, many have argued that preventing such data transfers actually resulted in significant benefits for EMR companies, reinforcing market incentives that have impeded progress in interoperability.[50] The Center for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology proposed new rules to penalize these "Information Blocking" practices.[51] However, notable stakeholders such as the College of Healthcare Information Management Executives and the American Medical Association responded with comment letters detailing concerns with the methods and requirements, and it's likely that consensus will remain a dynamic target for years to come.[52,53]
3. *Lack of availability of research data*- it is notoriously difficult and time intensive for researchers to mine EMRs for studies, given variations in data collection and

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[48] "Who Owns Medical Records: 50 State Comparison." Health Information and the Law. George Washington University Hirsh Health Law and Policy Program. Aug. 20, 2015. [Online] Available: http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison

[49] https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html, See 45 CFR 164.524(b)(2)

[50] https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

[51] https://www.hhs.gov/about/news/2019/02/11/hhs-proposes-new-rules-improve-interoperability-electronic-health-information.html

[52] https://chimecentral.org/wp-content/uploads/2019/05/CHIME-letter-to-CMS-and-ONC-on-interop-FINAL.pdf

[53] https://www.ama-assn.org/system/files/2019-06/executive-summary-onc-proposed-rule.pdf

management practices. Additionally, patient groups, care providers, and regulatory agencies have noted an increasing interest in wanting to contribute to research, but currently lack efficient ways to do so.[54]

MedRec's suggested prototype proposes a solution to these problems by employing a private blockchain where the block content represents data ownership and viewership permissions determined by members of a peer-to-peer network. They also employ Ethereum's smart contracts[55] to create a representation of medical records on individual nodes, and these contracts in turn contain metadata on record ownership, permissions, and data integrity.[56]

Several other cryptographic properties build out the proposed prototype and result in a theoretical system that offers patients a decentralized, immutable record of their health data across distinct providers and treatment sites. This system also allows providers and patients to securely offer research entities access to their health data (anonymized and aggregated).

While this model is different from SimplyVital's vision of a healthcare data marketplace, it illustrates a similar principle of how Blockchain may enable secure patient and provider permissioning and facilitate robust clinical research. More importantly, the MedRec prototype offers a distinct change in the current data ownership model, with patients as stewards of their own data, not hospitals or care providers.

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[54] Kish, Leonard J., and Eric J. Topol. "Unpatients [mdash] why patients should own their medical data." Nature biotechnology 33, no. 9 (2015): 921-924

[55] Smart contracts are self-executing contracts with the terms of the agreement between buyer and seller being directly written into lines of code. The code and the agreements contained therein exist across a distributed, decentralized blockchain network.

[56] https://www.healthit.gov/sites/default/files/5-56-onc_blockchainchallenge_mitwhitepaper.pdf

2. Incentives focus on monetary or personal gain

There is no consensus around the best practice for motivating individuals to donate their genetic data. What has become clear, however, is that the lack of both privacy and traceability of genetic data is inspiring consumers to question and even regret their decision to give away their genetic information.[57] In an effort to address this concern, a number of companies are exploring strategies to re-incentivize patients to share their genetic data.

A few active incumbents in this space- Foundation Medicine, LunaDNA, and Nebula Genomics- all have similar revenue models. They each have a database of customers' health and genetic data. Commercial organizations such as pharmaceutical or biotech companies, laboratories, and other institutions pull queries from these databases for medical research, which can be used for drug development. These queries are revenue-generators for Foundation Medicine, LunaDNA, and Nebula Genomics. They hope to attract more customers to donate genetic or health data, as more data increases the likelihood for commercial organizations to return with additional queries. Data are each of the company's unique competitive advantages. What is different amongst all of the three companies, however, is their approach in attracting customers to donate genetic data.

Foundation Medicine connects physicians and patients to personalized treatment modalities in exchange for the patient consenting to share their data with Foundation Medicine for analysis. The patients in return are given recommendations on potential treatments and therapies most appropriate to their disease pathology. In this business model, patients have the incentive to share their data because their donation can directly help them find proper diagnosis and treatment.

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57 https://thewestsidestory.net/the-23andme-deal-with-glaxosmithkline-raises-privacy-and-ethics-questions/

LunaDNA is a community-owned health data platform where patients can anonymously share health data on one platform to help advance medicine. Every member of LunaDNA who shares their genetic information receives shares of LunaDNA, giving them a sense of ownership. Commercial organizations from the pharmaceutical or biotech industries can pull queries from LunaDNA's central database of health data, which in return generates revenue for LunaDNA. After deducting expenses, all proceeds are returned to shareholders, which consists of the members who have provided their data. LunaDNA's current incentive structure encourages customers to become stewards of their own data and give back to the medical community in a practice more broadly known as "citizen science," a concept explained in more detail in the next section.

Nebula Genomics is exploring ways to incentivize customers by focusing on privacy, transparency, and micropayments. When customers get their whole genome sequenced through the Nebula kit, customers will receive raw genetic data, have access to a Nebula blockchain that stores the genetic data, and receive an ancestry report. Furthermore, Nebula Genomics is looking to shift sequencing costs to researchers and enable participants to get compensated for data sharing.

Foundation Medicine, LunaDNA, and Nebula Genomics have explored these incentives to attract customers who may be willing to donate genetic and health data. It remains to be seen what will truly motivate customers and what incentive is executable, but we believe there is a different way to incentivize customers while improving their data's traceability and privacy in a more effective way.

B. Our Proposal

1. Citizen Science, NFTs, and Zero-Knowledge Proofs

We propose optimizing for transparency in the genetic data sharing process, enabling a greater degree of trust in the system that can encourage participation, increasing the volume of genetic data available for research. Using distributed ledger technology, our proposal addresses the general public's distrust of the security and traceability of their donated data. By using zero knowledge proofs and non-fungible tokens (NFTs) in tandem, which few others have accomplished, we can build a secure feedback loop to the data provider that can serve as an incentive to contribute to a broader citizen science community for genetic data.

Citizen Science, also known as participatory science or crowd-based science, is a movement where amateur volunteers collectively contribute to and support the process of scientific inquiry. This could involve "citizen scientists" being instructed to collect air samples throughout a city for public health research, or taking pictures of certain plants or animals when spotted for crowd-sourced field data. The movement has capitalized on a swelling population of activist-minded individuals concerned with helping advance societal issues in the small ways they are able to contribute. As a result, the movement highlights the potentially immense benefits of democratizing participation in research, which is why its application is particularly relevant for genetic research.

The first "blockchain game," CryptoKitties, introduced the idea that consumers might pay to own and keep track of a digital item that has meaning to them. Activists began to wonder if this concept could be used to aid environmental initiatives. In July 2018, Axiom Zen, the company behind CryptoKitties, partnered with NGOs Ocean Elders and ACTAI Global to create "Honu," a sea turtle-inspired CryptoKitty. The groups put the digital sea turtle up for auction to

raise money for sea turtle conservation efforts, and the auction closed at $25,000.[58] This notable event opened the door for new digital assets to be transacted, “tokenized” on the blockchain with a unique digital signature, to be utilized for citizen science initiatives.

A CryptoKitty, or a crypto sea turtle, is considered “non-fungible,” meaning that each represents something unique, and they are not interchangeable. In contrast, something that is “fungible” is completely interchangeable with other assets like it. A non-fungible token is a special type of unique, not interchangeable cryptographic token. This is in contrast to a fungible token like Bitcoin, meaning any Bitcoin can be exchanged for another, similar to standard currency.

Proof of Impact (PoI) also incorporates NFTs in their model to shape the current state of social capital markets. PoI has several financial investment models tailored to individual use-cases, but all are built on the premise that investors (buyers) can purchase impact events- real world actions that range from childhood vaccinations to carbon credits. When a seller performs an impact event, such as delivering 2,000 vaccines, they deliver data to prove the completion of the impact event which is then verified on the public ledger. After this, a NFT corresponding to this impact event is created and can then be sold to buyers. In this philanthropic case, the individual buying the token would know that their donation funded a discrete number of vaccines for a specific region- PoI gives buyers full visibility into the details of the impact event they contributed to and the real-world effect it had.[59]

Another cryptographic concept is the zero-knowledge proof, a practice used when two parties want to prove that they both know some information without revealing the information itself. For example, certain authentication processes do not involve an exchange of passwords,

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[58] https://news.mongabay.com/2018/07/how-blockchain-gaming-could-benefit-wildlife-conservation/
[59] *Proof of Impact Whitepaper: Unlocking the Intrinsic Value of Impact through Global Impact Capital Markets*, March 2019
https://drive.google.com/file/d/1gDqxorF_Ie4WU1TNt8RYWGqkp23EWqQJ/view?usp=sharing

which is protective because the passwords cannot be intercepted and stolen during an exchange, but both parties still need to verify their possession of the information. The term “Zero-Knowledge” stems from the fact that zero information is revealed, but the verifying party is correctly convinced that the proving party knows the secret.

One use case that brings together NFTs and zero-knowledge proofs is GunClear. David Noble, its creator, stated in an interview that he was inspired by a desire to take the idea of CryptoKitties and build thick layers of privacy around it. Subsequently, GunClear’s mission is to enable the sale of a firearm from one party to another, but enhancing the transparency by having a clearly traceable history of gun ownership. “Ownership tokens” can be transferred to signify a sale with “zero knowledge” exchanged about the buyer and seller. Only the gun’s serial number is made public and used to identify the gun being sold. This is the first project that we are aware of that layers NFTs and zero knowledge proofs together.

Exploring the use cases for these technologies outside of healthcare has helped to define the potential for novel workflows within it. With a unique digital signature, NFTs can help address the uncertainty around where donor data has been transacted. Furthermore, it could unlock the donor’s ability to permission access to their own data, removing another barrier to participation and enabling new applications of citizen science to support research.

Transparency and Traceability

One critical aspect not being addressed by existing players is the traceability of customer genetic and health data. Under current practice, once genetic or health data are given to a consumer company or a healthcare provider, customers are not informed of how their data are used, when it is provided to industry and third parties, or for what purposes the third parties pull queries from their data. We believe that utilizing a blockchain to facilitate the transaction of

genetic data, we can provide traceability to the customer through a consistent feedback loop where the individual can permission specific ways their genetic data can be used. By doing so, customers not only feel more secure about providing their data, but they can also actively engage in the process of advancing charitable causes such as medical research.

A simple way to understand this concept is to consider sharing an online photo on the website of a major social network. Imagine Person A (Alice) posts a group photo on her profile page. Person B (Bob) who also happens to be Alice's friend, decides to share the image that Alice posted. Alice may be notified. Then, Charlie, who is Bob's relative, sees the post on Bob's wall, and decides to share the photo again. Unfortunately, Charlie is not an acquaintance of Alice. Therefore, Alice is completely unaware of Charlie sharing her photo, and has no way of finding out how her photo has been exposed to a completely new network. While existing social media services and similar programs provide users with a limited range of options for controlling the visibility of their data, distributed ledger technology can enable a far greater degree of personalized control for data sharing, addressing how data is shared, with whom, for how long, and more.

The first step to enabling users to become stewards of their own data is to improve the traceability of said data and a degree of control for its owner. Fortunately, blockchain provides the technical backbone to bring both improvements to fruition.

2. Technical Details

In this proposal, we outline a high level system concept. We highlight the key technical requirements to satisfy the system, while some of the more detailed specifications are left to be determined by the context of specific business, implementation, or roll-out requirements.

Traceability and Privacy via NFTs and Zero Knowledge

The primary idea behind this proposal is to allocate a unique NFT as an identifier for a specific source of genetic data. Recipients of the genetic data can then use the NFT as a reference, in order to append a log of activities in such a way that the original owner of the data can trace the activity, without needing to know any actual information about them.

The NFT is effectively the focal point for logging and tracing of how a piece of data is used and passed through the system. Being able to trace where and how data is used is a critical component to this proposal. However, only the original data owner should be capable of viewing the trail of their data. Therefore, in order to ensure the privacy of this process, zero knowledge proofs would be used to hide the true value of each NFT, so that it remains private between the parties.

The exact implementation of zero knowledge proofs can vary depending on specific requirements. It could be as simple as a hash[60] involving the NFT and its message, which clients can recompute to verify knowledge of the NFT. Or, it could be as involved as leveraging zk-SNARK[61] to prove authenticity before a message is even accepted onto the blockchain. Either way, the NFT value would remain private, and should never be publicly disclosed on the blockchain.

Furthermore, any time the data is shared with additional parties, a new derivative token would be generated to ensure that each party is able to transparently report their uses of the data, without being able to themselves trace who is using said data and how that data is being

[60] A one-way function designed to convert any data into an output of a fixed size.

[61] zk-SNARK stands for “Zero-Knowledge Succinct Non-Interactive Argument of Knowledge,” and refers to a proof construction where one can prove possession of certain information, e.g. a secret key, without revealing that information, and without any interaction between the prover and verifier. https://z.cash/technology/zksnarks

used by others- only the original token owner would be able to reconstruct the full trail of their data.

The zero knowledge proofs and derivative tokens are both important to ensure that the messages are authentic- they originate from a recipient who does indeed have the actual data (the NFT). They also make sure that 3rd party observers should not be able to reconstruct or correlate the flow of any piece of data. Although the NFTs do not, in themselves, have any information that can identify an individual, data in aggregate can be used to infer additional information associated with the data.[62] Therefore, we want to ensure that only the original data owner is provided with full traceability of where and how their data is used.

Example of Future State Proposal: Alice and Bob[63]

To help illustrate the potential future state for the exchange of genetic data, we describe a step-by-step approach to exchanging such data on the blockchain. Alice gives her genetic information to Bob, which is then allocated token T. Bob can log events for Alice to trace via a zero knowledge proof Zk(T). When Bob shares data with Charlie, he generates another token T' for Charlie to use. Charlie can log events for Alice to trace via Zk(T'). However, Charlie cannot trace any of Bob's Zk(T) messages (or any other tokens bob may have given to other partners). Meanwhile, Eve is watching the whole chain but cannot distinguish or correlate any of Bob's or Charlies messages.

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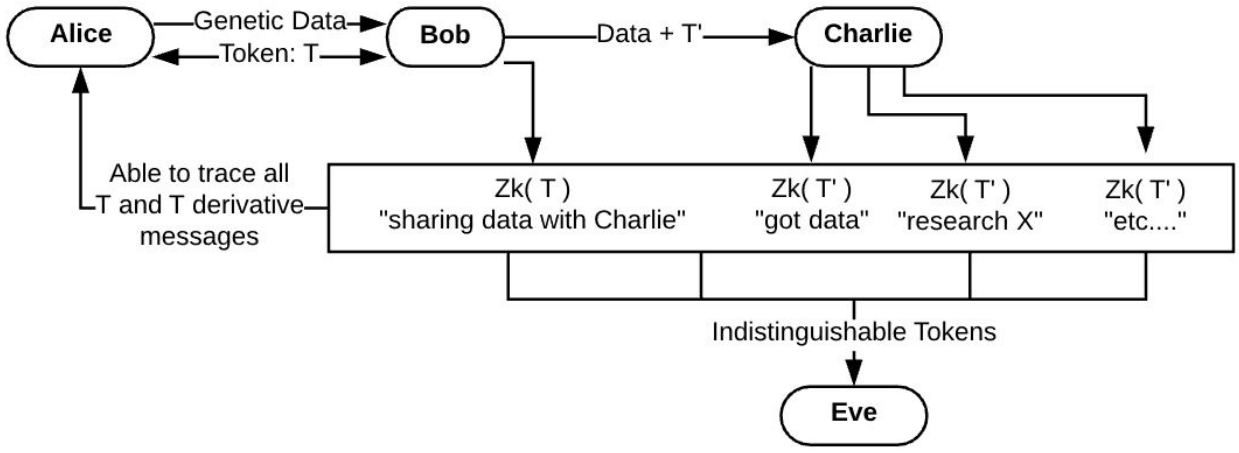
[62] L. Sweeney, Simple Demographics Often Identify People Uniquely. Carnegie Mellon University, Data Privacy Working Paper 3. Pittsburgh 2000.

[63] Alice and Bob are the world's most famous cryptographic couple. http://cryptocouple.com/



3. Why Blockchain

We believe the use of a blockchain offers specific advantages that contribute to the success of this proposal. Although the interactions involved between parties and the actual data stored is simple, the need for a delicate balance of transparency and privacy can only be satisfied with a fully transparent and verifiable ledger. A traditional database cannot offer the same level of transparency, accessibility and auditability needed to make this a success.

That is not to say, however, that the system must be run on a public blockchain. The specific operation could be implemented to run on an existing chain (ex: Ethereum), or as a small permissioned and private blockchain.

Integration into the Existing Healthcare Ecosystem

In today's healthcare environment (Figure 1), genetic data is generally gathered in one of two ways: first, through a consumer company like 23andme or Ancestry.com; or second, through a healthcare facility for medical testing. In either case, the sample is sent to a lab to sequence, and the results are returned to the patient. From there, depending on the terms and

conditions that patients often consent to without having read the text[64], the lab may provide that data in anonymized form to third parties who request it based on certain criteria. We believe the most appropriate place to pilot our proposal is a vertically integrated collection and lab system (Figure 2). This way, when the sample is collected, it can be "tokenized," with a feedback loop including the consumer-facing entity, the patient, the lab, and any third party buyers requesting the data.

Hospitals, clinical environments, and producers of consumer products could enlist their users onto our blockchain, where users would receive a token assigned to the digital signature of their genetic data. Patients and consumers would see in their user interface that the hospital, consumer company, and/or diagnostic lab have access to their data, and they would be able to send permissions to other companies, clinics, and organizations to view their data. Subsequently, pharmaceutical companies would send queries requesting access, or alternatively, users could participate in ongoing research pools with open permissions where verified industry and research participants can query the data. There may be opportunities to form digital links with existing biobanks and genetic repositories that have historically been the predominant drivers of genetic research, augmenting their capabilities. For the user, their dashboard would show the historical trail of all instances in which their genetic data was accessed, by whom, and potentially annotated with a description of the study that was supported. Lastly, the ledger would also enable a pathway to payment, where beneficiaries may directly reward participants based on the number of studies supported or the value of their data that was provided.

[64]http://uk.businessinsider.com/deloitte-study-91-percent-agree-terms-of-service-without-reading-2017-11

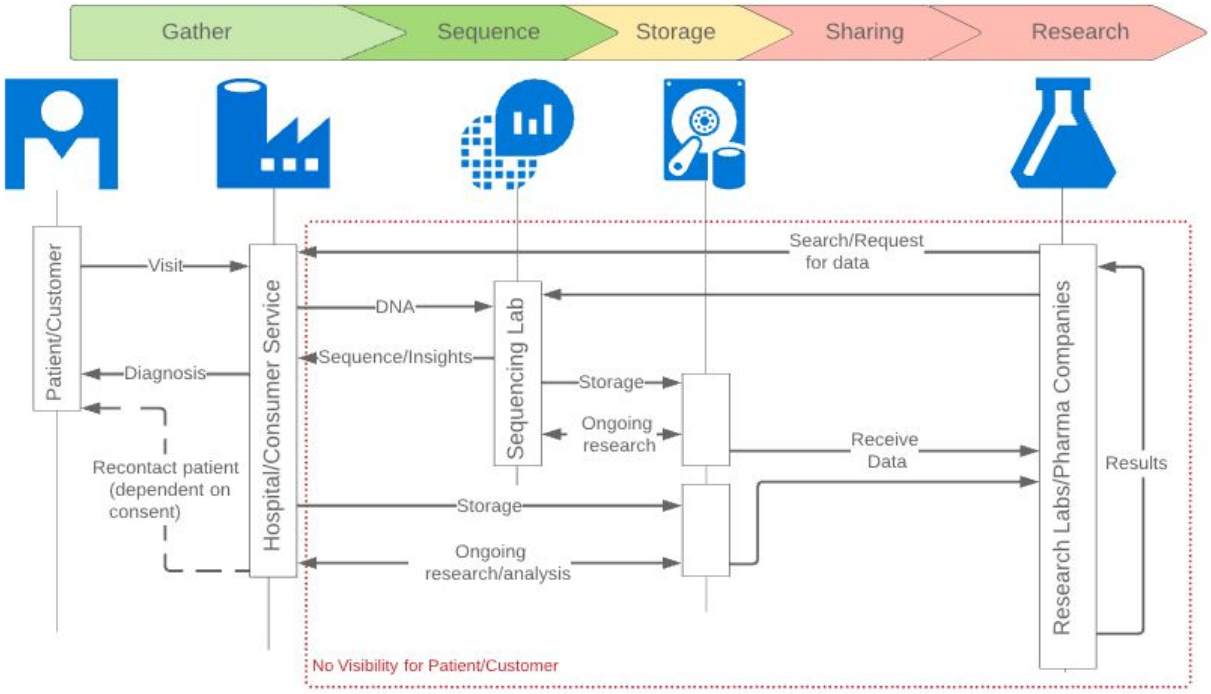


Figure 1: Current State of the Flow of Genetic Information in the Healthcare Ecosystem

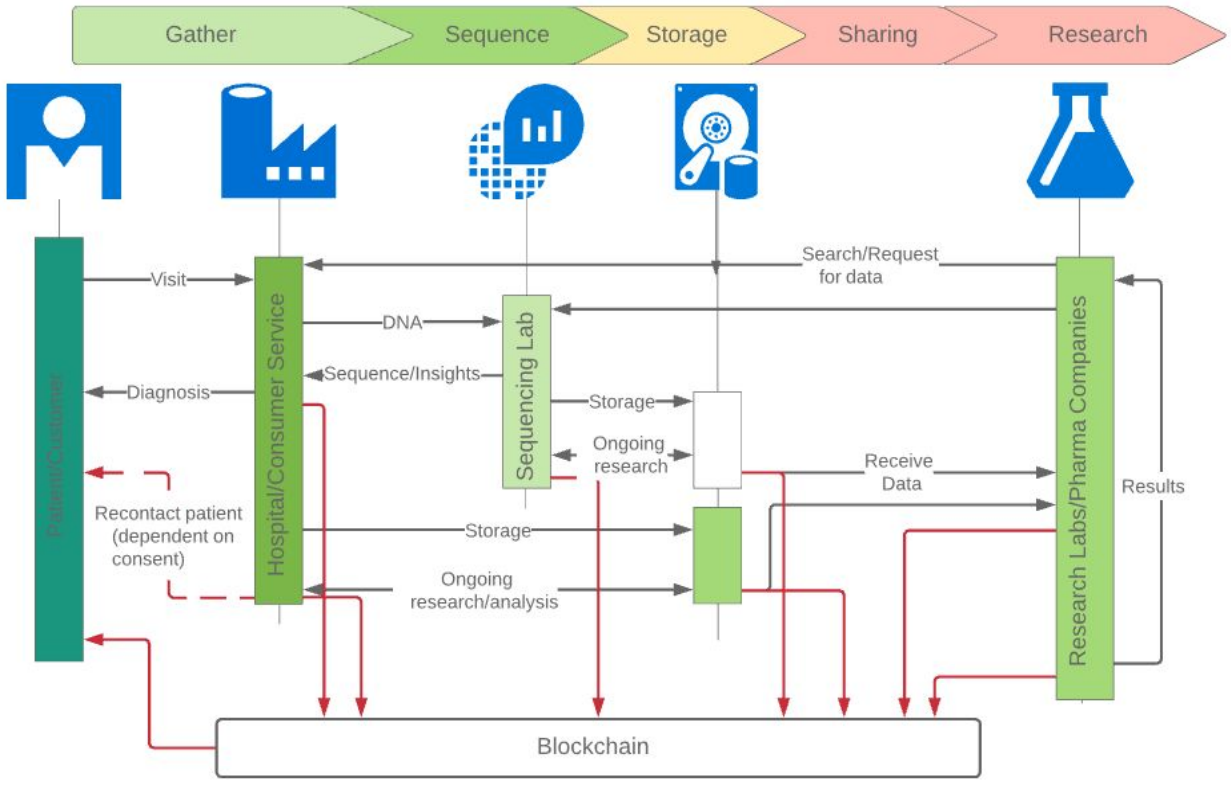


Figure 2: Proposed Future State of Flow of Genetic Information in the Healthcare Ecosystem

4. A Value Proposition

The business model for such a tool is clear for both institutions and consumers. Unlike large academic health centers and research institutions, the smaller labs, hospitals, academic facilities, and private research groups may not have sufficient resources or appropriate expertise to create a centralized infrastructure to gather patients' genetic data, nor a sufficient pool of patients to gather data from. By inviting small organizations into the genetic-data sharing blockchain ecosystem, such a model would offer them a partnership to gain access to a blockchain infrastructure without building one in-house, with visibility over a greater pool of patients they would not have been able to attract otherwise. In parallel, consumers may prefer to join in such a model because of the added visibility and control over how their genetic data is used. Our revenue model will be one where we are providing software as a service (SaaS)--access to a platform and data while providing an opportunity for consumers to be stewards of their own data.

III. Limitations and Additional Considerations

The model we present in this paper is specifically built to provide a secure platform for recording transactions of consent for sharing genetic data. As such, we do not address in our proposal the best practices for exchanging the genetic data itself. There has been some literature produced around the appropriate infrastructure and policy for enabling the sharing of genetic data.[65,66,67] However, the industry would benefit greatly through continued discussion and

[65] Raza S, Hall A. Genomic medicine and data sharing. Br Med Bull. 2017;123(1):35–45. doi:10.1093/bmb/ldx024. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5862236/
[66] ACMG Board of Directors. Laboratory and clinical genomic data sharing is crucial to improving genetic health care: a position statement of the American College of Medical Genetics and Genomics. Genet Med Nature Publishing Group. 2017;19:721–722. https://www.nature.com/articles/gim2016196
[67] Knoppers BM, Harris JR, Tassé AM, et al. Towards a data sharing Code of Conduct for international genomic research. Genome Med. 2011;3(7):46. 2011 Jul 14. doi:10.1186/gm262 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3221544/

collaboration, ideally with the participation of stakeholders including hospitals, researchers, laboratories, and consumers, as appropriate to the available technical capacities for the participants and their respective institutional and federal privacy requirements.

Another consideration we chose not to detail is the importance of effective user interface design. For users, regardless if they are patients in a hospital or consumers at home, the determination of whether they feel empowered to control and direct the movement of their genetic data will depend less on the technical architecture behind the product, and more on how they interact with the tool itself. There has been exhaustive literature over the past few decades, long before the proliferation of Electronic Health Records, highlighting the need for iterative design and improvement of user interfaces, sensitive to the "information requirements, cognitive capabilities, and limitations of end users."[68] Recent reporting reveals how non-intuitive user interfaces can actually be disempowering, invite errors and even cause harm.[69] As blockchain technologies boast the ability to preserve the integrity of patient consent, developers must be equally conscious of the design of their tools, and ensure that users are able to engage in informed consent, where the users can feel confident that their decisions were based on the disclosure of sufficient and comprehensible information. Respecting existing ethical and legal standards, the information for users must be accurate, accessible, comprehensive, and relevant, and the burden rests on vendors to ensure their products meaningfully demonstrate this for users.[70]

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[68] Patel, V L, and A W Kushniruk. "Interface design for health care environments: the role of cognitive science." Proceedings. AMIA Symposium (1998): 29-37. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2232103/

[69] Schulte F, Fry E.Death by 1,000 clicks: Where electronic health records went wrong. Kaiser Health News; March 18, 2019. https://khn.org/news/death-by-a-thousand-clicks/

[70] Satyanarayana Rao KH. Informed consent: an ethical obligation or legal compulsion?. J Cutan Aesthet Surg. 2008;1(1):33–35. doi:10.4103/0974-2077.41159. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840885/

If a model such as the one we detailed here were to successfully improve the sorely lacking volume of diverse genetic information being used for research, stakeholders would need to be wary of not magnifying other inequities in how human populations are represented for research. For example, a recent genome study from the UK Biobank identified 30 independent genetic loci, or points on a chromosome, that have been associated with household income.[71] If users who choose to join the platform come from different, previously underrepresented genetic ancestries, it will improve the ethnic diversity of data; but if among them, only the wealthy participate, there will remain in the data potential gaps in representation. Furthermore, if the user interface enables consent mechanisms for participation in individual trials of genetic research, users may be able to selectively decline participation in trials for specific diseases or pharmaceutical companies. Both of these are examples of potential selection bias. As a result, deliberate collection and study of detailed demographic data will be necessary to ensure that patterns of user participation and consent do not inadvertently misrepresent the population intended for analysis.

Beyond our proposal, there are some additional considerations that merit discussion. The Genetic Information Nondiscrimination Act (GINA) of 2008 was the first and only of its kind, attempting to build a "a national and uniform basic standard... to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."[72] While GINA was considered a success, promising protection from discrimination in employment and health insurance, it failed to include explicit protections for the purchase of life, disability, or long-term care insurance. Furthermore, the protections only apply to those without manifest

[71] Hill, W.D., Davies, N.M., Ritchie, S.J. et al. Genome-wide analysis identifies molecular systems and 149 genetic loci associated with income. Nat Commun 10, 5741 (2019) doi:10.1038/s41467-019-13585-5. https://www.biorxiv.org/content/10.1101/573691v1

[72] https://www.eeoc.gov/laws/statutes/gina.cfm

disease, suggesting that as soon as an individual begins to develop symptoms of their genetic condition, GINA no longer applies and the individual is left vulnerable to discrimination. In one ongoing study of whole-genome sequencing, 25% of the participants who declined to participate cited “fear of insurance discrimination as the primary reason, after a consent process in which they were specifically educated about GINA.”[73] This presents additional barriers to participation for any genetic data marketplace, regardless of the technologies deployed, and such gaps in policy would likely require federal legislation to correct.

For gene sequencing technologies instrumental in extracting this data, addressing financial considerations can accelerate the diversification of participants included in research efforts. Data collected by the National Human Genome Research Institute tracks how the sequencing cost per genome has dramatically fallen by orders of magnitude, nearly $100,000 at the turn of the century to under $50,000 by 2010, and falling below $2,000 in 2015.[74] Researchers may explore additional methods of preparing genome studies that limit the array density or sequencing depth and reduce the computational cost burden without meaningfully reducing the strength of associations found.[75] Such practices would bring down financial barriers for both researchers to include more study participants and consumers to purchase over-the-counter sequencing services, making the product more accessible to diverse populations.

Further user research is needed to determine if additional incentives would be necessary to increase the transacted volume of genetic data. Non-fungible tokens and blockchain technology open the door for micropayments as an incentive in the future. Exchange of data is

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[73] Green RC, Lautenbach D, McGuire AL. GINA, genetic discrimination, and genomic medicine. N Engl J Med. 2015;372(5):397–399. doi:10.1056/NEJMp1404776

[74] https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data

[75] Gilly, A. et al. Very low depth whole genome sequencing in complex trait association studies. Bioinformatics https://doi.org/10.1093/bioinformatics/bty1032 (2018).

tracked via the digital ledger, from patient to hospital or DNA collector, to laboratories, pharma, and biotech companies. By having transactional evidence, customers can be paid for each individual contribution to research. However, uncertainties still remain. Dedicated research and interviews can help characterize the populations who would opt-in to this model, as well as the magnitude of the payments that would be feasible to companies and attractive to consumers. More technical research is also needed to ensure privacy and anonymity of the patient while allowing the payment to be made to the correct party.

Appendix – Interview List

Collectors
George Church, Founder Nebula & Veritas
Kamal Obbad, CEO and Dennis Grishin, CSO Nebula Genomics
Andrew Hessel, CEO Humane Genomics
Bob Kain, CEO LunaDNA

Labs and Industry
Scott Chapin, Head of Systems Architecture Quest Diagnostics
Juan Perrin, Director Memorial Sloan Kettering
John Halamka, CIO Beth Israel
Max Duffy, Associate Director Foundation Medicine

Technical Interviews
Kat Kuzmeskas, CEO and David Akers, Senior Blockchain Engineer Simply Vital
Sophie Meralli, zkLedger

NFT and Citizen Science Interviews
Arnold Waldstein, NFT Expert
David Noble, CEO Gunclear