



54gene Frequently Asked Questions

1. How exactly will 54gene impact the quality of Healthcare in Africa?
 - We will impact the quality of healthcare in Africa by increasing access to genomic data from African populations to promote inclusive research and development, which will lead to
 - optimized treatment and diagnostic outcomes for the African population, as well as
 - power drug discoveries that will not only treat Africans, but also treat all people
 - Presently, most genomic data used for development research is from Europe, United Kingdom and North American
 - Our mission is to address the fact that only 2% of genomic data available is African - therefore the company is building the world's largest pan-African biobank to address this gap and the need to include underrepresented racial and ethnic minorities research.
 - Increasing access to genomic data from African populations can:
 - improve the responsiveness of products to the health of African people and
 - power drug discoveries that can treat people of all races
2. How do you measure the impact you are making?
 - We can measure the impact from the researchers and product development companies that come to partner with us, using the existing data from our biobank.
 - Publications using our resources will be required to acknowledge the source of data, which would let us know the increased inclusion of genomics data from African populations.
3. What is 54gene's goal?
 - Our goal at 54gene is to significantly improve diversity of genomic data used for discovery, diagnosis and by increasing the availability and access to genomic data from African populations.



4. What does 54gene do? Is it a lab?

- 54gene is an African genomics company.
- It was founded to significantly improve the inclusion of African populations in genomics research leading to discovery, diagnosis and treatment that would be more responsive to African populations.
- We collaborate with health and research institutions in African countries to conduct research to generate primary data and biospecimen.
- We have a state-of-the-art biobank, which is a facility that helps to store biospecimen in the right conditions so that it retains its quality for when it is needed for secondary use.
- Our modern / new laboratory has the capacity to conduct tests needed for disease diagnosis and to support research collaborations.

5. Can I conduct any research in your lab?

- Our laboratory has modern equipment with skilled medical consultants and laboratorians to ensure the quality of the tests we conduct.
- At present we are scoping and mapping needs against our capacities, and as a result are unable to open our laboratory to the public for diagnostics and research partnerships.



6. What do you plan to do with the samples you are collecting?
 - With permissions given by the participants, we can share the collected data and biospecimen with researchers and development research organizations for discovery and knowledge generation, diagnosis and treatment solutions.
 - Shared samples are devoid of any information that can be used to identify the individuals from whom it was taken.
 - We manage our data in accordance to the regulations of the Data and Sample Access Committee.
 - The sharing of our data is based on the terms of a fully executed Material Transfer Agreement, that would have been endorsed by the Nigeria National Health Research Ethics Committee.
 - In all instances, people who have contributed specimens to the 54gene biobank are able to ask to withdraw their samples and destroy such specimen, where there is still some stock left, 54gene will honor such requests.

7. How does 54gene monetize the work?
 - 54gene de-identifies, stores and adds genetic information to the samples. The samples are then aggregated in large cohorts or groups that provide statistical significance, something an individual or a few samples alone cannot provide. Companies developing therapeutics or diagnostic tests pay 54gene for their efforts to collect, de-identify and aggregate high quality genetic data.

8. Does 54gene work with any local manufacturers? Why/why not?
 - 54gene is open to collaborate with development research institutions in and outside Africa.
 - We are interested in evaluating all partnership opportunities as they arise.

9. What kind of studies do you run with the samples we collect? / What have we done so far?
 - 54gene is currently focused on genomics studies related to non-communicable diseases. Specifically, we are interested in studying and supporting development research in cancers, endocrine disorders, cardiovascular diseases, neurodegenerative diseases and sickle cell disease.



10. At 54gene do you sell patient data to pharma companies?
 - The purpose of all biobanks is to provide access to data and biospecimen for secondary use by other researchers.
 - At 54gene we are open to support both academic and development research. When we are supporting development research, we do not sell data or biospecimen to the development research institutions like the pharmaceutical companies, but rather they would pay us for our efforts (the work we carry out to collect, curate and store data and biospecimen).
 - As part of our corporate social responsibility, we have identified a fund management scheme that will ensure whenever we collaborate with development research institutions, like the pharmaceutical companies, and we receive proceeds from their use of the data and biospecimen in our biobank, a reasonable proportion of such proceeds will be administered to support systems strengthening the institutions we collaborate with in each country.
11. What does commercial biobanking mean?
 - A commercial biobank operates solely for the purposes of collecting, curating, storing and sharing of data and biospecimen with commercial and non-commercial entities. This may be for health or non-health related uses.
 - At 54gene we are interested in collaborating with commercial and non-commercial entities that are working to develop diagnostics and treatment solutions to improve human health.
12. When clients submit their samples to the 54gene lab - are those samples used for research?
 - At 54gene, our biobank resources – specimen and data are available for use by academic and development research institutions. A data and sample access committee will review and make decisions to provide access to data and samples based on availability and objectives of the proposed research use.
13. Are all samples that are received in the 54gene lab biobanked?
 - At 54gene, we only accept and biobank specimen for which we have the consent of the participant to bank. In our database, all biospecimen are matched against the consent received by the participant.



14. With 54gene's laboratory being both a diagnostic and research lab. How are ethical guidelines followed especially when dealing with diagnostic samples?
 - The 54gene laboratory seeks to support both diagnostics and research aims.
 - When used for diagnostics, we would conduct specified tests and share the results with our clients. Specimen used to conduct the tests will be disposed in line with standard good laboratory practice. There are instances where doctors who collect specimen for diagnostics have also received consent to either biobank and/or use diagnostic data for research purposes. 54gene is happy to collaborate with such clients to help in banking the samples and associated data where the fully signed informed consent is shared with 54gene. 54gene will not biobank any specimen, not accompanied by a copy of the consent from the person

15. At 54gene, do you pay doctors for samples? if so, why?
 - Research collaboration is an established professional endeavor. It entails a relationship between an organization that is providing the funding for research, institutions/communities in which the research will be conducted and the researchers that will conduct those studies.

 - People who are engaged as researchers receive remuneration for their efforts in planning and implementing the study at the sites assigned to them, which is usually the hospital where they are working.

16. When you provide samples for research to companies, do they have the identity of the patients? what happens to those samples afterwards?
 - In our biobank, each specimen is accompanied with some information about the person from whom the specimen was collected, but which cannot be used to tell who that person is.

 - The samples are stored in a de-identified manner in our biobank. A portion of the sample will have genetic information added and then the data is aggregated with tens of thousands of other samples.

 - In all instances, people who have contributed specimen to 54gene biobank are able to ask to withdraw their samples and destroy such biospecimen, where there is still some stock left. Any information derived from said sample is also deleted.



17. Is a participant's permission required before samples are biobanked, used for research?

- At 54gene, we only accept and biobank specimen for which we have the consent of the participant to bank. Our informed consent describes the use of samples for research. The consent terms and conditions refer to the samples being used in Nigeria or overseas. In our database, all biospecimen are matched against the consent received by the participant.

18. If research is done by 54gene or a pharma company that 54gene gave samples and a new drug is discovered that leads to millions of dollars - how will this benefit the participants? Will they have any share of this money?

- Genomics research is exploratory by nature and not interventional. For this reason it is difficult to have a direct correlation between genetics research and intervention.
- The genomics research - drug discovery journey includes many interim discovery steps. 54gene's research currently involves the earliest of stages of the drug-discovery journey. 54gene data will be combined with many other sources of data and it is highly unlikely to attribute any discovery to such data.
- We do not give or sell samples we have collected. In the event 54gene collaborates with a development research organization and receives some proceeds for providing access to data with commercial purposes in mind, a percentage of the proceeds, decided on a case by case basis, will be deposited in a dedicated fund for use to benefit societies where we are operational.
- If 54gene were to be involved in a development research collaboration, which is determined ab-initio to hold high promise of potentially leading to a new drug discovery, we will work with authorities in the relevant country to agree on a policy to provide reasonable access to such drugs for a defined population set in those countries in line with best practices, such as CIOMS recommendations.



19. What is the benefit to the patient?

- Because of the nature of genomics research, there is no direct benefit to participants. However, there is a potential for long term benefit to society by ensuring inclusion of Africans in research and development of therapeutics.
- Each person's sample contributes to our biobank and as part of our corporate social responsibility, we have identified a fund management scheme that will ensure whenever we collaborate with development research institutions, like pharmaceutical companies, and we receive proceeds from their use of the data from our biobank, a reasonable proportion of such proceeds will be will be deposited in a dedicated fund for use to benefit societies were we are operational.