

MINUTES FOR STEERING COMMITTEE MEETING HELD ON FRIDAY, 8TH

JANUARY 2021

PRESENT

Solomon Ofori-Acquah

David Nana Adjei

Olayemi Edeghonghon

Josephine Mgya

Mahmoud Sani

Petronilla Ozumba (IHVN)

Vivian Paintsil

Najibah Aliyu

William Kudzi

Ryan Minster

Nathan Edward Siebu

Naana Asiedu

Eunice Agyemang

ABSENT WITH APOLOGIES

Kofi Anie

Julie Makani

Melissa Nuno

ABSENT

Ellis Owusu-Dabo

Gordon Awandare

Titilope Adeyemo

Obiageli Edeghonghon

AGENDA

1. PROJECT REPORTS

- Solomon briefed Committee Members on the progress of the projects in 2020. The Chair informed members of recruiting patients in the third year to hit the target of 7000 participants. Due to COVID, the target number for patients was not met thus there was the need to decide whether to accept to work with about 6300 recruited participants or to recruit additional 200 participants to sum up to 6500 by focusing on the sites that are engaging in activities other than patients' enrolment, which are Accra and Kano.
- The committee was to embark on downstream analysis which is the quantification of the five protective proteins. DNA extraction of about 2000 samples were to be closed and then genotyping will begin. Genotyping would be done using the H3Africa array to minimize variations. Solomon, Kudzi and Ryan communicated with the DNA House in Dubai with regards to the samples.
- COVID affected the flow of reagents needed to calibrate the Nanodrop and this halted DNA extraction. The work had shifted from recruiting patients to sample analysis. DNA extraction would take place in Kumasi and Accra, and cardiovascular phenotyping in Kano.

REPORTS ON PROJECTS AND ENROLMENTS

David took the members through the various projects and enrolments.

Total Target Enrolment: 7000	
PROJECT 1	PROJECT 1B
Total Number Enrolled = 6613	Total enrolments: 67
Verified Participants = 5900	Accra = 11 (17.7%)
Total males = 3035 (45.9%)	Abuja = 45 (72.6%)

<p>Total females = 3578 (54.1%)</p> <p>Adults enrolled = 2746</p> <p>Males = 1043 (38.0%)</p> <p>Females = 1703 (62.0%)</p> <p>Accra = 1151 (41.9%)</p> <p>Abuja = 212 (7.7%)</p> <p>Dar es Salaam = 488 (17.8%)</p> <p>Kano = 697 (25.4%)</p> <p>Kumasi = NA</p> <p>Lagos = 198 (7.2%)</p> <p>Children enrolled = 3867</p> <p>Female = 1875 (48.4%)</p> <p>Male = 1992 (51.5%)</p> <p>Accra = 368 (9.5%)</p> <p>Abuja = 380 (9.8%)</p> <p>Dar es Salaam = 1112 (28.7%)</p> <p>Kano = 502 (12.9%)</p> <p>Kumasi = 1211 (31.3)</p> <p>Lagos = 304 (7.8%)</p>	<p>Dar = 5 (8.1%)</p> <p>Kano = 0</p> <p>Kumasi = 0</p> <p>Lagos = 1 (0.06%)</p> <p>Sites not stated = 5</p> <p>PROJECT 2</p> <p>Total enrolments: 4</p> <p>Accra site: 4 (100%)</p> <p>Abuja = 0</p> <p>Dar es Salaam = 0</p> <p>Kano = 0</p> <p>Kumasi = 0</p> <p>Lagos = 0</p> <p>Site not stated = 0</p>
<p>Hb Electrophoresis conducted = 3927</p> <p>Hemolysis Cytoprotective Proteins = 767</p>	<p>PROJECT 3</p> <p>Total enrolments: 667</p> <p>Males: 220 (33.0%)</p> <p>Females: 447 (67.0%)</p>

Post enrolments Survey = 767	**About 30 to 50 are yet to be uploaded onto REDCap because echoes had not been done.
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Core lab: Protein analysis was on hold. Hb electrophoresis of the Dar samples were running. 55 more DNA samples had been extracted in Kumasi.

ACTION POINTS

- Majority of the activity would be centred in Kano, Accra and Kumasi.
- Mahmoud to start echo studies in Accra after completing that of Kano.
- Solomon informed the committee about an ongoing process of procuring a new echo machine for the Data Science Project with other funds.
- Two manuscripts had been submitted to be reviewed.
- Solomon to make changes on the design paper.
- Kofi to revise the community engagement paper.
- Genotyping was estimated to be completed by the end of 2021.
- After genotyping, Ryan would interrogate the genotyped data with the protein results.
- The big manuscript would be at year 5 of the project. In the interim, members were encouraged to come up with clinical demographic, descriptive papers.
- Solomon reminded members that the project was the largest cohort of the sickle cell disease globally. The nearest one in terms of size was the corporative study of sickle cell disease in the 1980s in the United States with 3700 patients enrolled.
- First shipment to be done in the middle of the year, June for 3500 samples to the biorepository.

- The Steering Committee Meeting was scheduled to take place in the first Friday of every month.



Chairman to the Committee: Prof. Solomon Ofori-Acquah

Secretary to the Committee: Eunice Agyemang



MINUTES FOR STEERING COMMITTEE MEETING HELD ON FRIDAY, 5TH

FEBRUARY, 2021

PRESENT:

David Nana Adjei

Kofi Anie

William Kudzi

Olayemi Edeghonghon

Josephine Mgya

Najibah Galadanci

Eunice Nnodu

Titilope Adeyemo

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ABSENT

Solomon Ofori-Acquah

Julie Makani

Mahmoud Sani

Gordon Awandare

Vivian Painstil

AGENDA

1. UPDATES FROM VARIOUS SITES

- **Accra:** There had not been much to update the group in terms of enrolling patients because of the lack of PPEs. The Accra site lost one of their staff (Record Officer) to COVID- 19. Much time was spent on completing verification of data. Out of 368 paediatric participants, they had been able to verify 335. They had verified 1097 out of 1151 adult data.
- **Dar es Salaam:** Apart from verification of data, they were working on queries from audit reports. With regards to community engagement, they had been supporting the health services with consultations. Fewer patients were to come to the hospital due to viral pneumonia. Online consultations were conducted for participants.
- **Kano:** Actively enrolling participants for project 3 and 1b. About 850 patients had been enrolled for project 3 but only 740 have their echoes done. For project 1b, 14 had been enrolled. Patients on REDCap had been verified.
- **Abuja:** They had enrolled 83 participants for project 1b and 3 participants for project 2. They had verified all the patients enrolled previously. For community engagement, a member with the sickle cell disease had been helpful with reaching out to patients and data entry. They had maintained active supports of the sickle cell groups they were working with. Participants were entreated not to visit the hospital but could only do so if they had a problem. Before participants would see the doctor, there was an arrangement for them to interact with the team and also get the opportunity to watch videos on sickle cell disease to encourage themselves.

- **Lagos:** They had completed project 1. For project 1b, they had a meeting on training the new nurse on how to collect data. They had not been able to enrol any participant for project 2b but had completed data verification.
- **Kumasi:** Of the 1200 sample population, they had conducted about 520 DNA extractions. William sent DNA extraction kits which were used in facilitating the work in the lab. They were reviewing the study to check for double recruitments.
- **Core lab:** COVID had affected their supplies but were waiting for Solomon to ship the reagents needed to start with sample analysis. DNA extraction was ongoing in Kumasi whilst that of Accra was on hold. Once DNA could not be extracted to be quantified, protein analysis could not be conducted. Protein analysis was only done on samples that had passed the DNA test hence, protein analysis was on hold. Hb electrophoresis of Dar samples was ongoing, and they were addressing the discrepancies with Dar site. A total of 891 samples had passed the sample QC test and were undergoing Hb electrophoresis. 120 Dar samples had been analysed. Barcoding had started on samples that had passed the QC test. DNA can then be shipped to Dubai for Ryan to start analysing the data.
- **Community Engagement:** Discussions were held earlier on how the different sites can have virtual community engagement sessions with participants. Kofi suggested that sites should hold the session virtually. David asked for research questions for publications, so Kofi sent one to look specifically into broad consent. There are a couple of interns who are master's students under WAGMC who will be undergoing community engagement projects within SickGenAfrica.

2. STATUS OF SUBMITTED PAPERS

Kofi reported that there had not been any updates on the submitted papers

3. ACTION POINTS

- Site investigators to give additional information on broad consent of participants.

- The chair informed members about the drafted site-specific video waiting for approval from Solomon before distributing to sites.
- William to do a voice-over with regards to laboratory analysis
- Kofi to do a voice-over on community engagement
- Solomon to do an introductory and concluding voice-over with regards to the video
- Publications committee to review and approve research questions from the various sites.
- Sites to formulate research questions to be submitted to the publications committee for approval.

Chairman to the Committee: Dr. David Nana Agyei



Secretary to the Committee: Eunice Agyemang



MINUTES FOR STEERING COMMITTEE MEETING HELD ON FRIDAY, 5TH

MARCH 2021

PRESENT

David Nana Adjei
Eunice O. Nnodu
Olayemi Edeghonghon
Kofi Annie
Mahmoud Sani
Najibah Galadanci
Josephine Mgya
Minster Ryan
Titilope Adeyemo
William Kudzi
Vivian Painstil
Melissa Nuno
Naana Asiedu
Eunice Agyemang

ABSENT

Solomon Ofori-Acquah-With permission
Julie Makani
Gordon Awandare
Petronilla Ozumba
Ellis Owusu-Dabo
Nathan Siebu

AGENDA

1. UPDATES FROM VARIOUS SITES

- **Accra:** They were unable to recruit new participants because the space available in the clinic was inadequate. Had been able to complete most (80%) of the verifications of participants recruited. Out of 1100 recruited participants, about 50 participants were yet to be verified. For project 1b, a lot of patients were reluctant to seek medical treatment and they only visited the hospital when they experienced crisis. Most of the patients refused to be admitted at the hospital.

- **Abuja:** The clinic for the paediatric patients had been closed because many doctors became infected with the coronavirus. Had not been able to make progress with project 1b and project 3.
- **Lagos:** Experienced skeletal clinical services. For project 1b, they were going to do a follow up on 18 participants. They had completed verifications.
- **Kano:** The echo machine broke down, so they had to stop enrolling participants for project 3. They had been able to enrol 702 participants for project 3. They had enrolled about 50 participants for project 1b.
- **Dar es Salaam:** Clinics were running. They had been able to follow up on patients under project 1b. An evaluation of the number of patients admitted at the medical and paediatric wards was conducted and it turned out they were about 157. Sickle cell patients were about 10%. They could not recruit any participants for project 2. Verifications were ongoing. Had started preparations for shipping clear data samples.
- **Kumasi:** Still experiencing the ill effects of COVID because most of the doctors and nurses became infected with the coronavirus. As a result, they moved into the laboratory aspect of the project. They had not recruited any participants for project 1b. Had been working on biodata and almost done with all verifications. About 50 more participants were yet to be verified due to double enrolments. Had shipped about 1179

samples to Accra to undertake some tests. DNA extraction was ongoing, and they had extracted 507.

- **Core lab:** They had received some of the reagents and started working on recalibrating the machines with the reagents for quality control. About to start the lab and protein analyses. In the interim, they had been analysing Hb electrophoresis on Dar samples and was still ongoing. Kumasi samples had been shipped to Accra with serum samples, 807 plasma, 507 DNA and 1179 Red cells. There were not enough buffy coats to extract DNA from some of the samples. After extracting DNA, quality control needs to be done and the samples must pass 3 quality controls to be acceptable for downstream analyses on sequencing.

2. PROJECT 3

Had a total of 772 participants enrolled for project 3 but not all of them were on the system. Had a problem with the echo machine and was in the process of solving the problem. They had not been recruiting participants for the project and had planned to complete 1000 recruitments in May.

3. PUBLICATIONS

- There were two issues with the paper. The community engagement paper was awaiting a final decision from the editor and the other thing was about another possible publication which was based on the proposal Kofi

submitted to the Publications Committee. Under community engagement, they were tackling ethical issues. Within H3Africa, there were ethics in community engagement and there had been a lot of discussions with regards to broad consent in relation to some issues like commercialization of aggregate data. Kofi suggested in the proposal that because there was data on participants who did not give broad consent, the site coordinators and team members should be interviewed on why participants did not give consent.

- Kofi reported that there were about 20% participants who did not give broad consent. The interns at WAGMC would work on extracting the demographics of the 20% and then develop questionnaires to be administered to all the sites.
- David reported that he had submitted all the research questions and titles to the Publications Committee Chair. After the Committee approves the research questions, data would be extracted. The committee would make decisions on data extraction and samples to be communicated to members. A template was sent to the Chair of the Committee for approval to be distributed.

4. REDCAP

REDCap was updated which resulted in some features not functioning properly. The problem had been resolved. The current version of REDCap

had more enhanced features to make data entry and uploads more efficient. The new update would also enhance the data collection process. In the next meeting, there would be a discussion on experiences from the various sites.

Chairman to the Committee: Dr. David Nana Adjei



Secretary to the Committee: Eunice Agyemang



MINUTES FOR STEERING COMMITTEE MEETING HELD ON FRIDAY, 7TH

MAY, 2021

PRESENTS

David Nana Adjei

Solomon Ofori-Acquah

Vivian Paintsil

Olayemi Edeghonghon

Ryan Minster

Najibah Galadanci

Titilope Adeyemo

Kofi Anie

William Kudzi

Obiageli Nnodu

Emmanuel Jonathan

Gordon Awandare

Melissa Nuno

Nathan Edward Siebu

Eunice Agyemang

ABSENT WITH PERMISSION

Josephine Mgaya

ABSENT

Mahmoud Sani

Ellis Owusu-Dabo

Julie Makani

Petronilla Ozumba

Naana Asiedu

AGENDA

1. REPORTS FROM VARIOUS SITES

- **Accra:** Had some challenges in recruiting participants due to the COVID outbreak, although the initial plan was to recruit participants at the beginning of the year. Had recruited 20 adult participants with 7 uploaded onto REDCap, and 4 participants recruited under Project 1b. Had not received the documentary for participants but was in the process of counselling and interacting with participants concerning their well-being when they visit the clinic.
- **Kano:** Had started enrolling for Project 1 and 3. Had enrolled a total of 782 participants. Due to the breakdown of the echo machine, 700 had their Echos done. All data on REDCap had been verified and participants who had not undergone echo were not uploaded onto REDCap.
- **Abuja:** Were not actively enrolling patients in the clinic. Had a total of 95 participants for Project 1b and 19 for Project 2. For Project 1, they had enrolled and verified 592 participants. Enrolling participants for Project 2 was a bit difficult because SickGenAfrica patients were not showing up to be recruited. They were in the process of uploading all data onto REDCap.
- **Lagos:** Had completed enrolment and verification for Project 1. For project 1b, they had recruited 23 participants, with 5 outstanding data yet to be uploaded onto REDCap. They had recruited 1 participant for project 2.

- **Kumasi:** Had completed enrolment and verification for Project 1. The Kumasi site had moved into the laboratory aspect of the project and concentrated more on DNA extraction. They had extracted and sent 138 DNA samples to Accra. In total, 723 DNA samples had been extracted, with a remainder of 300 samples to be extracted. All samples had been stored in a -80 freezer at the School of Public Health.
- **Core lab:** In the process of writing a report for Solomon. In the biorepository, there were 5541 patient samples including red cell lysate, plasma, buffy coats, and urine. They had three (3) freezers, with two of them full and the third one, half full. The fridges are monitored twice a day to make sure the temperatures were within expectations.

Total distribution in CoreLab:

Accra: 1519 samples (1151 adult samples, 368 paediatrics), 26%

Kumasi: 1302 (all paediatrics) 23%

Lagos: 500 (200 paediatrics, 300 adults) 9%

Abuja: 582 (372 paediatrics, 210 adults) 10%

Kano: 859 (490 paediatrics, 369 adults) 50%

Dar: 979 (689 paediatrics, 290 adults) 17%

Hb Electrophoresis:

Had analysed all the red cell lysates from Lagos, Kano, Abuja, and Dar es Salaam.

Had analysed 1144 samples from Accra. In the process of estimating the Hb

Electrophoresis of Kumasi samples, and had done 368 samples for Kumasi.

DNA Extraction

Had extracted DNA from Accra and Kumasi samples. Kumasi samples had undergone quality checks, both photometric and spectrophotometric.

Accra

Total adult sample collected: 1151

DNA extraction: 1117 samples

925 out of 1117 samples had passed the quality control test.

Total paediatric sample collected: 368

Had extracted DNA for all 368 samples.

295 samples passed the QC test

Kumasi

A total of 477 samples passed the QC test. They had to reconcentrate the DNA samples to pass the test. Olayemi to rebleed 180 patients because they failed the QC test and did not have enough buffy coats to extract DNA samples. In total, 180 adult samples and 36 paediatric samples were needed to undergo DNA extraction from Accra site.

Protein analysis

Samples that passed the QC test were selected to undergo protein analysis. Had analysed 4 proteins for Accra: haptoglobin, hemopexin, alpha-micro globin and ferritin for 752 adult samples and 166 paediatric samples. Had planned to collect the remaining samples from all the sites. In the process of procuring kits to start DNA extraction in other sites.

Community engagement

80% participants had given broad consent and 20% had not. Interns did not have to interview all the sites because the sites who had a 100% broad consent were probably about half the number, so they only had to interview a few sites. They had representatives in terms of investigators nominated from two sites. The Kano and Dar site had given someone to be interviewed. The interview questions would be

shared in advance for review and, the interns would be introduced to committee members.

- Malaria samples were collected as part of Project 1b

SUGGESTION

- Lab scientists from the various sites to work with William in the Core Lab.
- David to follow up on the draft video
- William and David to check with Site Coordinators for a reconciliation on samples.

VERIFICATION

- Most of the sites had verified about 80% of data entered onto REDCap. For project 1, site coordinators were asked to verify data and check out for validity.
- Site coordinators to select 'yes / no / non-applicable' when entering data onto REDCap for running data analysis.
- A timeline would be set for verification.

PUBLICATION

- The Publication Committee was formed last two years, and Ellis was nominated the Chair.
- The Committee had its first meeting on 30th April 2021 to enable members to quickly work on the Article titles and research questions submitted.
- A google document link was created and shared to allow committee members work on the article titles and research questions. It was requested that committee members share their comments.

- After approval, site coordinators would be asked to write a proposal of not more than five pages to be submitted to the publication committee. The proposal template was structured to include specific objectives, data, and what to be extracted.
- An active google document would be created and shared with committee members to check on projects by the various sites to prevent duplication.

AOB

- Solomon updated committee members on grant renewal. They had a meeting with the NIH.
- A company in Dubai to start with DNA genotyping.

Chairman to the Committee: Dr. David Nana Adjei



Secretary to the Committee: Eunice Agyemang



MINUTES FOR STEERING COMMITTEE MEETING HELD ON FRIDAY, 4TH

JUNE, 2021

PRESENT

Solomon Ofori-Acquah

David Nana Adjei

Olayemi Edeghonghon

Gordon Awandare

Josephine Mgya

Kofi Anie

Najibah Galadanci

Julie Makani

Obiageli Nnodu

Titilope Adeyemo

William Kudzi

Emmanuel Jonathan

Melissa Nuno

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ABSENT WITH APOLOGIES

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ABSENT

Mahmoud Sani

Ellis Owusu-Dabo

AGENDA

1. UPDATES FROM VARIOUS SITES

- **Kumasi:** Work was ongoing with regards to the biodata on REDCap. They had uploaded 1229 onto REDCap. The Kumasi site had a complete data set for 1193 participants and was working on duplicated data. They were working on getting the full blood count of some participants to complete data verification of the 1229 samples. Some samples have been transported to Accra. The site has planned to ship 1503 aliquots of samples to Accra. Over 1000 DNA samples had been extracted and 507 have been transported to Accra.
- **Accra:** Had recruited 1168 adult participants for project 1. Out of these, 1109 had a complete record and had been validated. They had 1 unverified record and 58 incomplete records. With paediatrics, 368 had been recruited. About 17 out of the 1168 adult participants were recruited this year and had been uploaded onto REDCap. They had not recruited any paediatric participants this year. For project 1b, they had recruited 5 participants in 2019, 6 participants in 2020 and 19 participants in 2021, making a total of 30. They were not actively recruiting participants for Project 2 and had so far recruited 2 participants. Currently experiencing challenges with staffing.
- **Kano:** They were still enrolling for Project 1 and 3. For Project 1b, they had enrolled 60 participants. A total of 782 participants were enrolled for Project 1a and 3. Many of the samples had their echoes done. The echo machine is functional, and the cardiologist is currently doing echoes for pending samples. All data uploaded onto REDCap had been verified.

- **Dar es Salaam:** Had been following up on patients admitted in the ward. Patients recruited for Project 1a had not been admitted. Sample verification was ongoing. There were some queries on the samples that were shipped to Ghana and were in the process of resolving the issue of incomplete data. They were in the process of verifying samples collected after the first shipment.
- **Abuja:** Had recruited 92 participants for Project 1a, 95 participants for Project 1b and 19 participants for Project 2 and these had been uploaded onto REDCap.
- **Lagos:** Had recruited 1 more participant for Project 1b making a total of 28.
- **Core Lab:** Hb electrophoresis was completed for the following sites: Kumasi, Accra, Lagos, Abuja, and Kano. All data had been uploaded onto REDCap. Were in the process of completing samples in the biorepository in Accra. Protein analysis were done for DNA samples that had passed the three levels of quality checks. They had completed protein analysis for all samples from Accra site. They were in the process of starting protein analysis for Kumasi samples. In total, 1800 DNA samples from Accra and Kumasi sites had undergone quality checks and available for shipment. They calculated the DNA yield in blocks of 10. In Accra, 313 paediatric DNA samples and 979 adult DNA samples had been extracted and quality checked. In Kumasi, 508 samples had been quality checked. In Accra, 209 adult samples were below 10 micrograms. 770 samples were above 10 micrograms. Kumasi had 131 samples below 10 micrograms and 377 above 10 micrograms.
- **Community engagement:** Regarding broad consent refusal, some interviews had been conducted and were ongoing. Interns were using the Interview Schedule to conduct the interview.

2. DATA VERIFICATION

All site coordinators gave an update on data verification. There was an average of 80% of verified data across all the sites. Due to the covid 19 pandemic, data verification had delayed. Site coordinators were encouraged to work on verifying data by close of June so that verified data would be extracted with dates for publications.

3. PUBLICATIONS

David was reported that a Google document has been created with all the research titles and research questions from the various sites for the Publication Committee to approve or reject. The Chair to the Publication Committee to update site coordinators on decisions taken. Some research questions were common to some sites and as a result, those sites will be requested to work together.

Publication committee to screen the research questions in relation to the database. Questions that were posed as part of the application was not to be in the list, for instance echo cardiovascular phenotype of patients in Kano was part of project 3 and must not be in the research questions. Also, the committee was encouraged to investigate the questions with no information on REDCap for examples alloimmunisation.

4. NIH REPORT

Had submitted the fourth-year report to the NIH on 14th May 2021. That was the final progress report to the NIH and was done with the Federal Financial Reporting by the University of Ghana Grant Administration. The focus for a couple of years was to recruit patients, analysing patient samples and Project 3. The focus for the next year was to clean the data for nearly 7000 patients enrolled and begin to prepare a Manuscript. Also, it was the plan of the committee to scale up the DNA extractions for the cohort. The committee wanted to be in the position of shipping 2500 DNA samples to the H3Africa biorepository in Abuja because it was a condition of the NIH. Had

already completed the Material Transfer Agreement (MTA) between the committee and Abuja. Had completed the paperwork and was in the process of deciding the quantity of DNA samples to be shipped to Abuja as a committee. The genotyping house in Dubai requested the committee to give 2.5 micrograms of DNA.

With respect to individual projects, the committee wanted to complete the haemoglobin electrophoresis for the entire cohort for Project 1, and to complete the measurement for the four haemolysis cytoprotective protein, cytoglobin, hemopexin, alpha globin and ferritin which would occupy 50% of the cohort (3500 patients).

The committee reported some success with Project 2 and is planning to optimise a concept known as Flow Fish which would allow visualising malaria parasites within red cells. For Project 3, the echoes would be completed for patients in Kano in the next three to four months. The plan for Project 3 was to begin echo in Accra. The committee was awaiting response from the NIH about the Progress Report.

ACTION POINTS

- Site coordinators to provide research questions data on REDCap to support them and research questions that were not part of the core objectives of SickleGenAfrica.
- DNA to be shipped to Dubai in the next three to four months.
- Committee to scale up the DNA extractions for the cohort

For Chair: Dr David Nana Adjei 

Secretary to the Committee: Eunice Agyemang 