

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 11TH JANUARY, 2019

Time: 2:00 pm GMT

Present:

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Prof. Eunice Obiageli Nnodu

Prof. Mahmoud Sani

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. Vivian Paintsil

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Prof. Julie Makani

Dr. Titilope Adeyemo

Dr. Flora Ndobho

Mrs. Justina Agula

AGENDA

POST ENROLMENT FORMS ON REDCap

Some amendments have been made to the post enrolment forms. In due course it will be circulated for review. It was suggested that the exact amendments, be highlighted to help with easy review.

WEEKLY REPORTS

Weekly reports have been created on REDCap so as to make verification easy. It will allow all PIs and all Site Coordinators to go onto their various electronic pages and make changes and also make it easy for PIs to have a broad overview of what goes on across all sites with ease.

VERIFICATION

Site Coordinators are encouraged to commence verification process as numbers entered onto REDCap are increasing and could be cumbersome when piled up. If anyone needs access for verification they should make it known to the study coordinator and it will be given instantly.

UPDATES ON ENROLLMENT (ENROLLMENT AGAINST TARGETS)

Accra

	Current Enrolment	Target
Adult	460	1000
Paediatric	90	500

Kano

	Current Enrolment	Target
Paediatric	305	500

Cardiologist has been trained. Adult recruitment will begin next week.

Kumasi

Slow start in uploading onto REDCap (89 uploaded). Will improve on numbers of entries in the coming weeks.

Abuja

	Current Enrolment	Target
Adult	101	70
Paediatric	101	70

STORAGE

All sites present did not have any issues with storage except the issue of urine samples taking up much space in the freezers and wanted clarification on whether samples be spun or not.

MTA's

Reminders given to sites that do not have their MTA's signed to make them available.

A.O.B

Questions about the status of the questionnaire on malaria was raised. Study coordinator will do a final circulation and adopt at the next meeting.

Webinar Series

Clarification was needed on what could/should be presented for the webinar and the study coordinator elaborated on it. It was also suggested that, the series be recorded and uploaded onto the website to make it easily accessible. It was also suggested that Project leads present first.

**MINUTES FOR SITE COORDINATORS MEETING HELD ON
FRIDAY, 25TH JANUARY 2019**

Time: 2:00 pm GMT

Present:

Prof. Eunice Obiageli Nnodu

Prof. Mahmoud Sani

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. Titilope Adeyemo

Dr. Vivian Paintsil

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Prof. Julie Makani

Dr. Flora Ndobho

Mrs. Justina Agula

AGENDA

ENROLMENT UPDATES

Accra: Accra site is having problems with recruiting in the paediatric section but recruitment will pick up soon as a new strategy has been implemented improve enrolment.

Lagos: Has begun to have issues with storage space so are suggesting that shipment of samples to Accra and Abuja should commence to create more space for additional samples.

Kano: Echo machine is functioning effectively. Urine samples are also being spun.

Kumasi: Having some difficulty accessing REDCap. Study coordinator to deal with the issues encountered.

Challenges

Some concerns were raised; shipping of samples might be expensive if it should be shipped to Accra first before going to the Biorepository. Also, the concern of difficulty in shipping samples

was expressed as some shipping companies may not be willing to ship blood samples because of the Ebola virus. The study coordinator will run all concerns by the Project Director and report to the team.

Summary of enrolment as at the last meeting

Site	Adult	Children
Accra	508	92
Abuja	110	120
Kumasi	-	158
Lagos	123	173
Kano	10	293
Total	720	936

POST ENROLLMENT E-CRF UPDATES

Dr. Anie informed the meeting that at least 100 responses of the e-CRF on a 50-50 basis from adult and paediatric sections of each site be filled out. Those with only one section can do 100. A pilot study has to be run by each site apart from Accra which has already piloted the CRF. Results of the pilot should be presented at next meeting so that dates for the commencement of the study will be set.

MTAs

MTAs for sites apart from Abuja and Dar es Salaam have been signed.

BIOREPOSITORY

Preparations in progress for the shipment samples to begin.

H3AFRICA CONSORTIUM MEETING

Preparations for the meeting almost finalised.

AOB

ABUJA: Are yet to receive second tranche of sub-award.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 8TH FEBRUARY 2019

Time: 2:00 pm GMT

Present:

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Prof. Eunice Obiageli Nnodu

Dr. Mahmoud Sani

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. William Kudzi

Dr. Vivian Paintsil

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Julie Makani

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Dr. Najibah Aliyu

Dr. Titilope Adeyemo

Mrs. Justina Agula

AGENDA

ENROLMENT UPDATES

Abuja: Has encountered problems with storage space for samples at the hospital hence have transferred samples to the IHVN biorepository in Abuja and have made payments for the storage.

Accra: Has enrolled 542 Adults and 100 Paediatrics. Strategy put in place for paediatric recruitment working and are working to improve it, to better enrolment numbers.

Dar es Salaam: Has so far enrolled 437 paediatrics and 132 Adults. They realised a number of CRFs uploaded unto REDCap were incomplete and are working on them after which the verification process will start.

Kano: Echo machine is dysfunctional hence adult enrolment has been put on hold until issues are resolved.

Kumasi: As at time of meeting has entered 270 enrolled patients into REDCap. They plan to move samples from KCCR to the School of Medical Sciences, hence are putting measures in place to ensure this is done.

UPDATES ON POST ENROLLMENT E-CRF PILOT

Accra and Kumasi have run their pilot while others are yet to.

MTAs

MTAs for all sites have been signed. Waiting for Dar Es Salaam to return copies of theirs and that will complete the process and enable shipment processes to commence.

VERIFICATION

Numbers of entries on REDCap that have been verified has gone up. Some coordinators still have issues with verification processes. The study coordinator will sort them out.

SAMPLE SHIPMENT

Samples obtained from all sites are to be divided into three copies; i.e. one for the site, one to be shipped to Accra and one for storage at the Biorepository. Concerns were raised about the contamination of samples if they have to be split into three.

H3AFRICA CONSORTIUM MEETING

Preparations for the meeting almost finalised. Delegates advised to ensure that they have all registered and filled out forms to start their Visa application process.

INTRODUCTION OF DR. KUDZI

Dr. William Kudzi has been put in charge of sample analysis on the project. Machine for sample analysis has arrived and trail samples are being run and analysed.

AOB

Community engagement liaison person of Lagos passed away.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 22ND FEBRUARY, 2019

Time: 2:00 pm GMT

Present:

Prof. Mahmoud Sani

Dr. David Nana Adjei

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. Vivian Paintsil

Dr. Flora Ndobho

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Eunice Obiageli Nnodu

Prof. Julie Makani

Prof. Gordon Awandare

Dr. Titilope Adeyemo

Prof. Ellis Owusu-Dabo

Dr. Olayemi Edeghonghon

Mrs. Justina Agula

AGENDA

UPDATES ON ENROLMENT

Kano: Has so far enrolled 387 paediatrics and 33 adults. Due to the dysfunction of the echo machine adult recruitment is on hold but and would commence as soon as GE representative arrives in Ghana for machine to be fixed. Concerns were raised on Bio repository MTAs with all sites, to facilitate sample shipment. Study coordinator indicated that for now focus will be on shipping of samples to Accra before sending them to the Bio repository hence all attention should be given to that.

Dar es Salaam: Has so far enrolled -- paediatrics and 179 adults. So far has not run the post enrolment CRFs but will do so in the coming week.

Kumasi: As at time of meeting has entered 270 enrolled patients into REDCap. They plan to move samples from KCCR to the School of Medical Sciences, hence are putting measures in place to ensure its moved.

POST ENROLMENT STUDY

So far 42 post enrolment forms have been filled and uploaded unto REDCap. Coordinators are encouraged to work on them and upload.

H3AFRICA CONSORTIUM MEETING

Preparations for the meeting finalised. Delegates advised to ensure that they have all registered and filled out forms to start their Visa application process.

VERIFICATION

Study coordinator advised site coordinators to speed up the verification process as numbers entered unto REDCap have increased.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 8TH MARCH 2019

Time: 2:00 pm GMT

Present:

Prof. Julie Makani

Prof. Eunice Obiageli Nnodu

Prof. Mahmoud Sani

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. William Kudzi

Dr. Titilope Adeyemo

Dr. Najibah Aliyu

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Dr. Vivian Paintsil

Mrs. Justina Agula

AGENDA

UPDATES ON ENROLMENT

Kano: The echo machine arrived in Kano as agreed on. However, after the first trial it is dysfunctional and this has resulted in halting of recruitment and they are awaiting a technician from GE to arrive in Kano to fix machine. Five (5) of the post enrolment CRFs for both adults and paediatrics have been put on REDCap. They have enrolled 423 children and 33 adults. Adults are yet to be put on REDCap. They have requested the adult CRF for aim three (3) to be uploaded on REDCap so they can start inputting the information they have collected on REDCap.

Dar es Salaam: Six hundred and eighty-three 683 patients have been enrolled. Five hundred and nine (509) paediatrics and 174 adults. They have been able to run four (4) post enrolment CRFs for adults.

Accra: About 600 adults and 106 children have been enrolled. Paediatric recruitment is still slow but have included Saturdays to help in increasing recruitment numbers.

Lagos: Has so far enrolled 230 children and 175 adults.

Abuja: Has so far enrolled 252 patients and have run five (5) of the post enrolment CRFs for community engagement.

POST ENROLMENT SURVEY

So far 53 post enrolment forms have been filled and uploaded onto REDCap. Study coordinator suggested to Dr. Anie that some work could be started with information gathered so far to have a better understanding of post enrolment challenges.

VERIFICATION

Study coordinator advised site coordinators to speed up with the verification processes as numbers entered onto REDCap is steadily increasing.

AOB

Malaria Project Two

Concern was raised about the CRF for the malaria project. Study coordinator made available the final CRF to all.

Julie wanted to know where information about malaria episodes of patients enrolled on the study will be done; whether from the wards or the clinics and whether they will be done on a daily or weekly basis.

Najibah stated that it would be ideal to have nurses on the project visit the wards every week to check if there are any patients enrolled on the study admitted and get their records and it will be dependent on the information demanded on the CRFs.

Others also echoed the fact that it was originally understood that information gathering for malaria patients be captured at the wards.

The study coordinator mentioned that information can be gathered based on specific patient conditions/ it can be done in the wards if patient can assist and information can be extracted from their files and if not, from the community. Hence it should be an all-inclusive data collection system.

Prof Makani stated that the information be collected proactively both in the clinics and the wards. Questioners clearly state what information is needed.

Dr. Adeyemo mentioned that, per the protocol samples are to be collected again during these acute cases and are to be analysed. She suggested everyone goes back to the protocol so as to clearly define the real scope of the malaria project.

H3Africa Consortium Meeting

Prof. Makani would like to have an hour or two of everyone's time during this period to talk about aim two.

Study coordinator to update everyone on their visas once he has any updates.

Sample Analysis.

Dr. Kudzi stated that the laboratory core has been able to analyse about 480 samples so far and should be done with samples in Accra by the following week.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 22ND MARCH 2019

Time: 2:00 pm GMT

Present:

Prof. Mahmoud Sani

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. Titilope Adeyemo

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Prof. Eunice Obiageli Nnodu

Prof. Julie Makani

Dr. Vivian Paintsil

Mrs. Justina Agula

Dr. Najibah Aliyu

AGENDA

UPDATES ON ENROLMENT

Kano: Has enrolled four hundred and forty-four (444) paediatrics, but adult's recruitment still holds at thirty-three (33) as they wait for the echo machine to be fixed. The echo machine has been moved to Lagos by the GE support unit for repairs and should be back in about a weeks' time.

Dar es Salaam: Has enrolled seven hundred and twenty (720) patients. Five hundred and twenty-four (524) paediatrics and one hundred and ninety-six (196) adults.

Accra: Due to challenges with the procurement processes of the university there has been a halt in recruitment. Numbers still stand at 600 adults and 106 paediatrics.

Lagos: Has enrolled two hundred and fifty-two (252) paediatrics and one hundred and fifty. (150) adults. They are having issues with space for sample storage onto REDCap. They are having issues with space for storing urine samples.

POST ENROLMENT CRF

Dr. Anie confirmed that all sites can go ahead to run the post enrolment CRF in their various sites. The target is a hundred or more.

VERIFICATION

Most site coordinators have started the verification process and are not encountering any challenges.

OBJECTIVE TWO (2)

Study coordinator commented on the CRF for aim two and sought if there were any comments on it so it could be discussed. Concerns were however raised to the fact that Prof. Makani who is the lead of the project was not on the call and she will be needed to play an integral part in the ensuing discussions.

It was raised that the project needed more attention and that Prof. Makani come up with an SOP. CRF for aim two should be modified as it deviates mostly from the protocol. Several other concerns were raised about clarifications on the CRF.

It was suggested that the CRF developed can be piloted and used to capture information for aim 1b as overtime patients will be lost and will make it difficult to capture enough information. While waiting for project two to take off. It was also suggested that a separate CRF as well as an SOP for aim two be developed by the lead and distributed to everyone before the meeting in Tunis.

Site coordinators agreed to adjourn further discussions of aim two to when the project lead is available for a productive discussion session.

H3AFRICA CONSORTIUM MEETING

Study coordinator to update everyone on SickGenAfrica meeting schedule at Tunis during the conference.

SICKLEGENAFRICA STEERING COMMITTEE MEETING

FRIDAY 12TH APRIL, 2019

Meeting started at 3:40

Attendance

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Julie Makani

Prof. Ellis Owusu-Dabo

Prof. Mahmoud Sani

Prof. Obiageli Nnodu

Prof. Alash'le Abimiku

Dr. Olayemi Edeghonghon

Dr. Vivian Paintsil

Dr. Kofi Anie

Dr. William Kudzi

Dr. Titilope Adeyemo

Dr. Petronilla Nwadike

Dr. David Nana Adjei

1. ENROLMENT UPDATE FROM ALL SITES

Accra-Olayemi

Started recruitment in August 2018

Adults = 672

Pediatric=119

Challenges

Pediatric enrolment is below intended target.

Purchase of essential materials is slow as compared to previous purchases. This is due to the presence of a new procurement officer.

They also have some patients decline participation because:

1. Patients feel they will spend a longer time in the clinic

2. Patients who are students may miss school days

The Saturday recruitment strategy has commenced, and numbers have improved to some extent. It is however, yet to be determined if the improvement in enrolment is as a result of this strategy.

Action

A proposed meeting between Solomon, David, Olayemi and Cathy is to be held next week to look into pediatric enrolment (Monday, 15th April 2019).

Kumasi-Vivian

Migrated unto REDCap 605 patients.

DNA extraction has begun.

Kumasi now has an adult clinic

They will commence enrolment in the coming week.

Challenges

Initial DNA quality and volume was substandard, however the change in protocol has improved both quality and volume of DNA extracted.

Action

Kumasi will commence enrolment in the coming week

Abuja-Obiageli

Adult = 129

Paediatric = 146

Challenges

They are having issues finding a place for sample storage.

They have shipped some samples to IHVN as a local storage site.

Action

Improve on targets and find innovative ways of storing samples.

Kano-Mahmoud

Adults- 33

Pediatrics - 467

Challenge

Malfunctioning of Echo machine. Machine has however been repaired and was delivered last Thursday.

Action

Start using Echo machine this Thursday.

Protect machine from power surges.

Dar es Salaam-Julie

Started recruitment in August 2018.

Total - 683

Pediatrics - 509

Adult - 174

Health education talks are given on Clinic days

They have started extracting DNA

Challenge

None

2. UPDATES ON OBJECTIVE 2-Julie

Project 2

Julie believes more resources will be needed to implement active surveillance on SCD malaria patients. Mahmoud is of the opinion that the CRFs we have now, adequately address objective 1b and not objective 2. This was supported by all the other site coordinators. Solomon emphasized the need for project 2 to use the same approach as Project 3; have a separate and different CRF. Equal efforts should be put into each project by the staff at the various sites. Site coordinators should integrate project 2 into existing processes in their various sites to ensure smooth implementation. All site coordinators requested that a protocol be developed for objective 2 to enable them implement.

Action

1. David will circulate draft CRF of objective 2 for final comments
2. Julie should finalize those comments to create separate CRF for objective 2 by 17/04/2019
3. Julie should develop a protocol for objective 2 as soon as possible for the project to commence by 19/04/2019.
4. Solomon suggested the Steering Committee take a look at the study protocol of objective 2 to determine if it has to be modified or remain the same.
5. Find other methods to boost enrolment since there will be a slump on enrolments at some point.

3. UPDATES ON OBJECTIVE 3-Mahmoud

Project 3 will be running in Kano and Accra. Lagos may be considered in the future.

Echo machine is now at Kano and adult enrolment will commence this Thursday.

Action

1. David to upload CRF for objective 3 before Monday.
2. Mahmoud to pilot the CRF by next week.

4. SAMPLE SHIPMENT-Alash'le Abimiku

Samples

(Aliquot) will split three ways:

1. The site keeps one
2. The Biorepository in Abuja
3. Cape Town for Genotyping

Training

Should there be the need for trainees to return to Abuja for further training, it would not be an issue.

DNA Extraction & Training

David is to arrange a follow up with all participants of the Biorepository training in Abuja with Alash'le and all Site Coordinators in attendance to discuss the underlisted;

1. What they are doing?
2. How many samples they have extracted
3. What is the yield?
4. Quality of the samples
5. Standard operating procedures
6. How many think they need additional training

Not all sites are meant to extract DNA. Mahmoud mentioned the budget of Kano may not permit them to extract. Each site has made some investment in terms of equipment and capacity.

IHVN has money allocation from NIH for storage of samples, therefore no payment has to be made for space. Few batches will be shipped to Alash'le, to confirm quality before full cycle shipment is implemented.

5. SUB AWARDS

Subawards are almost ready to be sent to the various sites. PIs and site coordinators should have a look and insert what they have tabled for Solomon to consider while keeping in mind their budget.

6. PUBLICATION POLICIES AND GUIDELINES

Publication Policy

Ellis presented draft publication policy.

Every publication will be reviewed by the Steering Committee. Alash'le suggested we develop a matrix for the publication of papers. Ellis will ensure the SickleGenAfrica publication policy does not contradict H3Africa publication policy. Everyone will be included on the author list of the design paper and project specific papers will be based on the traditional method of authorship; i.e. who contributed, what they did etc. Every publication will end with; "and the SickleGenAfrica Network", but footnote will depend on the paper.

7. NIH REPORT

Everyone on the steering committee is to submit just 2 pages of report per the guidelines in the mails sent earlier. Solomon emphasized that he is available for clarification if need be. A new Program Manager has been assigned to NIH after Norma Lerner retired.

8. AOB

A female candidate is needed to serve on the advisory board. Julie Makani will provide a nominee. Steering Committee members are also welcome to suggest names.

Meeting closed at 6:15pm.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 26TH APRIL 2019

Time: 2:00 pm GMT

Present:

Prof. Eunice Obiageli Nnodu

Prof. Ellis Owusu-Dabo

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. William Kudzi

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Julie Makani

Prof. Mahmoud Sani

Prof. Gordon Awandare

Dr. Titilope Adeyemo

Dr. Vivian Paintsil

Mrs. Justina Agula

AGENDA

ENROLMENT UPDATES

Kano: Has enrolled five hundred (500) children, but adult recruitment still holds at thirty-three (33) as they are yet to restart recruitment.

Accra: Has enrolled seven hundred and forty-one (741) adults and one hundred and forty-nine (149) children. Children recruitment has seen significant improvement over the past weeks.

Abuja: Has enrolled two hundred and eighty-five (285) patients; one hundred and fifty-six (156) children and one hundred and twenty-nine (129) adults. They halted recruitment due to issues with storage space however recruitment will resume soon, as 50% payment has been made for storage space at the biorepository.

Molecular Haematology Core: Reagents for the analyser have arrived. The core is well equipped as it awaits samples to be shipped from various sites for analysis. So far results from samples that have been analysed are good.

POST ENROLMENT CRF (COMMUNITY ENGAGEMENT)

The Study Coordinator encouraged all site coordinators to verify all data captured from their sites and upload onto REDCap all the FBC results as the number of uploaded forms and verified information are low.

NOMINATION OF MEMBERS OF THE PUBLICATION SUB-COMMITTEE

After deliberations the following was arrived at;

- A six-member committee will be set up.
- Ellis will share current paper to nominated committee members to review and decide on whether they think the paper should go on and decide whether they would want to be a part of the paper.
- David was tasked to share an email with all nominated members of the committee to officially inform them of their membership as everyone was not on the call.

The underlisted persons were nominated as members of the committee;

Ellis - Chairman

David - Secretary

Olayemi - Member

Obi - Member

Julie - Member

Mahmoud - Member

NOMINATION OF MEMBERS OF THE INTERNAL ADVISORY GROUP

Deferred to next meeting.

**MINUTES FOR SITE COORDINATORS MEETING HELD ON
FRIDAY, 24TH MAY 2019**

Time: 2:00 pm GMT

Present:

Dr. David Nana Adjei

Dr. Titilope Adeyemo

Dr. Vivian Paintsil

Dr. Olayemi Edeghonghon

Dr. Kofi Anie

Dr. William Kudzi

Mrs. Justina Agula

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Julie Makani

Prof. Mahmoud Sani

Prof. Eunice Obiageli Nnodu

Prof. Ellis Owusu-Dabo

Dr. Najibah Aliyu

Dr. Flora Ndobho

ENROLMENT UPDATES

Accra: Has enrolled seven hundred and ninety-five (795) adults and two hundred and ten (210) children. Enrolment for children over the past week has halted due to strike action by the laboratory scientists of the hospital.

Lagos: Has enrolled four hundred and eighty-two (482) patients; three hundred (300) children and one hundred and eighty-two (182) adults. Adult enrolment is usually low because most adults do not meet enrolment requirement.

Molecular Haematology Core: Awaiting delivery of the protein analyser so as to kickstart protein analysis and also await samples from collaborating sites to run analysis. A number of DNA samples extracted will be shipped to South Africa for quality analysis. Study Coordinator to train Dr. Kudzi on REDCap functionalities.

Kumasi: Has migrated onto REDCap seven hundred and sixty-four (764) children. Are not facing any setbacks so far.

VERIFICATION

The Study Coordinator encouraged all site coordinators to verify all data captured from their sites on REDCap so data set can be cleaned and checked for errors.

SITE VISIT TO NIGERIA

Deferred to next meeting.

ACTION ITEMS

Check with Solomon if DNA samples from Kumasi should be added to samples from Accra going for analysis in South Africa.

Study Coordinator to go onto REDCap to resolve any issue associated with the verification interface.

Study Coordinator to share CRF of project 1b with Gordon so he can review and draft something for project two and share.

**MINUTES FOR SITE COORDINATORS MEETING HELD ON
FRIDAY, 24TH MAY 2019**

Time: 2:00 pm GMT

Present:

Dr. David Nana Adjei

Dr. Titilope Adeyemo

Dr. Vivian Paintsil

Dr. Olayemi Edeghonghon

Dr. Kofi Anie

Dr. William Kudzi

Mrs. Justina Agula

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Julie Makani

Prof. Mahmoud Sani

Prof. Eunice Obiageli Nnodu

Prof. Ellis Owusu-Dabo

Dr. Najibah Aliyu

Dr. Flora Ndobho

ENROLMENT UPDATES

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SITE VISIT TO NIGERIA

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ACTION ITEMS

Check with Solomon if DNA samples from Kumasi should be added to samples from Accra going for analysis in South Africa.

Study Coordinator to go onto REDCap to resolve any issue associated with the verification interface.

Study Coordinator to share CRF of project 1b with Gordon so he can review and draft something for project two and share.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 7TH JUNE 2019

Time: 2:00 pm GMT

Present:

Prof. Gordon Awandare
Prof. Eunice Obiageli Nnodu
Prof. Julie Makani
Dr. David Nana Adjei
Dr. Olayemi Edeghonghon
Dr. Najibah Aliyu
Dr. Kofi Anie
Dr. Titilope Adeyemo
Dr. William Kudzi
Mrs. Justina Agula
Miss. Zoey Fiaxe
Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah
Prof. Ellis Owusu-Dabo
Prof. Mahmoud Sani
Dr. Vivian Paintsil
Dr. Flora Ndobho

AGENDA

ENROLMENT UPDATES

Accra: Has enrolled Eight hundred and Twenty-Three (823) adults and two hundred and Thirty-Six (236) children. Enrolment for children has been picked up once again as strike action by the laboratory scientists of KBTH hospital has been called off. The post enrolment survey for Accra has begun and so far, thirteen (13) participants have been enrolled.

Kano: has enrolled Sixty-Eight (68) adults. Due to a long string of public holidays in Nigeria, recruitment has been put on hold but should be picked up in the coming week. Paediatric enrolment for the first year has been concluded as target for the year has been met. The post enrolment survey is being run and the target for a hundred participants will be met over the next weeks.

Lagos: Has enrolled four hundred and eighty-eight (488) patients; three hundred (300) children and one hundred and eighty-eight (188) adults. Paediatric recruitment which has exceeded the years target is currently on hold so as to focus on adult recruitment. They hope to conclude enrolments for the first year by the end of the month.

Abuja: Has enrolled a total of three hundred and three (303) patients exceeding their target for the first year; One hundred and sixty-nine (169) children and one hundred and thirty-four (134) adults. Has so far enrolled six participants in the post enrolment survey.

Molecular Haematology Core: Still awaiting delivery of the protein analyser so as to kickstart protein analysis. Seven hundred (700) samples from Accra have gone through the Hb analysis.

VERIFICATION

Abuja wants some variables on their REDCap interface changed; David to effect the changes.

David will go onto REDCap to resolve any issue associated with the verification interface

PROJECT 1B

CRF was first test run in Accra.

The 1B CRF was relatively easy to administer. There was difficulty in getting some patients to participate and issues with the time frame in obtaining laboratory results- Olayemi.

David to give access to all the other sites to test run.

PROJECT 2

Gordon provided an updated version of the project 2 CRF. David shared it and advised that all coordinators review and get back with comments immediately so final amendments can be made and updated on REDCap so sites can test run, for project to commence latest by the end of the month.

PROJECT 3

CRF for the project is ready and has been reviewed by Mahmoud. David will finalise CRF and upload it onto REDCap, so that details of enrolled participants can be entered onto REDCap

NOMINATION TO ADVISORY BOARD

Obi suggested a professor from the university of Florida. Further discussions have been deferred to next meeting.

ACTION ITEMS

With regards to project 2 all investigators are to review the CRF and compare to the standard of care in their regions and indicate on the CRF what is covered and what is not covered before the next meeting, so an adequate scope of the standard of care for all sites can be captured in amendments to be made.

Site coordinators were asked to present budgets for the community engagement events to be run and their sites immediately to be approved and processed.

NOTES

DNA extraction in Accra is currently on hold but should be picked up in the coming week.

Logistical arrangements have to be made for effective function of project 2.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 21ST JUNE 2019

Time: 2:00 pm GMT

Present:

Prof. Mahmoud Sani

Prof. Eunice Obiageli Nnodu

Dr. David Nana Adjei

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. William Kudzi

Dr. Titilope Adeyemo

Mrs. Justina Agula

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Prof. Julie Makani

Dr. Vivian Paintsil

Dr. Olayemi Edeghonghon

Dr. Najibah Aliyu

AGENDA

ENROLMENT UPDATES

Dar es Salaam: Has enrolled Eight hundred and Ninety-Five (895) patients in total. Six hundred sixty-one (661) children and two hundred and forty-four (244) adults. Enrolment for adults is on the low end as few adults come to the clinic. The post enrolment survey has begun and so far, thirty-seven (37) participants have been enrolled. No patients have been enrolled unto project 1b.

Kano: Has enrolled eighty-five (85) adults and five hundred (500) children. Mahmoud wants a number of his staff to be given access unto REDCap; he will share their emails with David so they can be granted access to enter data collected unto REDCap.

Lagos: Has enrolled four hundred and ninety-one (491) patients; three hundred (300) children and one hundred and ninety-one (191) adults.

Abuja: Has enrolled a total of three hundred and six (306) patients; One hundred and sixty-nine (169) children and one hundred and thirty-six (136) adults. They have also had access to the CRF for project 1B but are yet to run it.

Molecular Haematology Core: Still awaiting on delivery of the protein analyser so as to kickstart protein analysis. Eight hundred (800) samples from Accra have gone through the Hb analysis and four hundred and sixty (460) of the results have been uploaded unto REDCap.

TRIP TO NIGERIA

All sites have submitted their budgets for the focused group community engagement, scheduled to take place during the visit. All sites will be required to hand over all receipts of payments made to David so as to ensure funds are duly retired.

Kofi will be sending the itinerary for focused group discussions to site coordinators.

VERIFICATION

David will create a new list that will show only patients who have not been verified so as to help site coordinators identify and track their progress and ease the verification process.

PROJECT 1B

CRF was first test run in Accra.

The CRF for 1B was relatively easy to administer. There was difficulty in getting some patients to participate and issues with the time frame in obtaining laboratory results-Olayemi.

David to give access to all the other sites to test run.

PROJECT 2

Gordon will come up the list of necessary logistics to make Project 2 functional and have a discussion with site coordinators and PIs.

PROJECT 3

CRF for the project is ready and has been finalised. Mahmoud in a few weeks will start inputting the data collected unto REDCap

NOTES

Plans are being finalized for the migration of samples across sites.

DHL will be consulted to pick up the samples and ship them from sites.

Each site has to acquire containers to package samples so DHL's only bit will be to ship to Accra.

Samples in Abuja have been deposited at the IHVN Biorepository hence shipment will be made from that end. Abuja also has all the logistics ready to package samples to facilitate shipment.

An MTA will be signed between Accra and the IHVN when all samples have been moved to the biorepository.

Shipment will be enforced soon after site visit to Nigeria and an SOP will be developed to brief site coordinators on how to prepare samples for the shipment.

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 19TH JULY 2019

Time: 2:00 pm GMT

Present:

Prof. Eunice Obiageli Nnodu

Prof. Mahmoud Sani

Prof. Julie Makani

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. Flora Ndobho

Dr. Vivian Paintsil

Dr. Titilope Adeyemo

Dr. William Kudzi

Mrs. Justina Agula

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Mrs. Petronilla Ozumba

Absent:

Prof. Solomon Ofori-Acquah

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

AGENDA

ENROLMENT UPDATES

ALL sites including the molecular haematology core reported improvements in their enrolment and number of samples analysed. Study Coordinator encouraged all to keep the momentum.

SHIPMENT

The first batch of two hundred (200) samples from Lagos have arrived in Ghana and are being processed.

Petronilla of the IHVN wanted to know if all DNA extractions will take place in Ghana; David confirmed that extractions will be done in Ghana.

She further suggested that the MTA between Ghana (University of Ghana) and Nigeria (IHVN) be drafted and signed so as to hasten shipment process from Ghana to the Biorepository when DNA samples are ready.

Action

Petronilla to send the H3Africa MTA template to David to aid in the drafting of the agreement between the Network and the Biorepository as well as the other collaborating sites.

PROJECT 1B

Some of the patients enrolled unto the study visit private hospitals when they have a crisis making data collection somewhat impossible. All research nurses employed unto the project will in such cases have to trace patients to the hospitals they are admitted in and collect the necessary data needed - David

Collecting data from the other hospitals may be difficult since we do not have any form of agreement with them – Vivian

The Accra site has an instance where a patient is on admission in a different hospital. They are looking at engaging the patient to help fill out the CRF over the phone and also request that she brings along her hospital folder and lab results on her next visit so as to extract additional data. Olayemi will brief us on how it turned out and how operational it was.

PROJECT 2

Project 2 CRF has been uploaded unto the REDCap platform.

Comments with regards to logistics needed for initiating the project was raised; i.e. how to confirm malaria cases on the study and the costs involved. David stated that after discussions with Solomon, it was decided that all suspected cases of malaria will be tested first and confirmed before patients are added unto the study and the project will bare costs for the tests ran. Once all sites coordinators come to an agreement to logistics needed for the project, it would be made operational across all sites by the end of July.

Julie brought to our attention that Gordon is currently the lead for project 2, hence all submissions in relation to the project be directed to him.

Action

David to send out a mail to all site coordinators to test run Project 2.

PROJECT 3

Deferred.

David and Kofi confirmed that on their visit to Kano project 3 was running smoothly.

POST ENROLLMENT SURVEY

About 360 post enrolment CRFs have been uploaded unto REDCap on the last count.

NOTES

- Petronilla asked to be given an estimated timeline by which all DNA extractions will be completed so as to ensure readiness by her team; William asked for a few weeks to make a comprehensive assessment of the extraction process and give feedback to that effect.

AOB

- Funds for year two yet to be received – Abuja.
- Funds for year two to reach various project accounts early next week - Justina

MINUTES FOR SITE COORDINATORS MEETING

FRIDAY, 2ND AUGUST 2019

Time: 2:00 pm GMT

Present:

Prof. Eunice Obiageli Nnodu

Prof. Mahmoud Sani

Dr. David Nana Adjei

Dr. Olayemi Edeghonghon

Dr. Najibah Aliyu

Dr. Kofi Anie

Dr. William Kudzi

Dr. Vivian Paintsil

Mrs. Justina Agula

Miss. Zoey Fiaxe

Mr. Nathan Seibu

Absent:

Prof. Solomon Ofori-Acquah

Prof. Julie Makani

Prof. Gordon Awandare

Prof. Ellis Owusu-Dabo

Dr. Flora Ndobho

Dr. Titilope Adeyemo

AGENDA

ENROLMENT UPDATES

Abuja: Has enrolled a total of three hundred and sixty-two (362) patients; Two hundred and fourteen (214) children and one hundred and forty-eight (148) adults. They have also enrolled sixty-three (63) patients onto the post enrolment survey. Had issues with recruitment over the past week but have rectified the situation and have commenced recruiting again.

Lagos: Has completed enrolment. They are ready to ship remaining samples in the coming week. There are still issues filling out the project 1B CRF for adults (patients still go to private hospitals

during acute crises). They plan to remedy this by asking patients to visit immediately after discharge from the hospital with lab results to fill out CRF. The paediatric unit has however reported some acute cases.

Accra: Has enrolled nine hundred and thirty-four (934) adults and two hundred and ninety-two (292) paediatrics. They have also enrolled ninety-six (96) patients onto the post enrolment survey. With regards to project 1B, they have records two patients who had acute crises

Kumasi: Have uploaded nine hundred and eighty-five (985) paediatric patients onto the REDCap platform. They have also enrolled sixty-eight (68) patients onto the post enrolment survey.

Kano: Has enrolled one hundred and forty-nine (149) adults and seven hundred (700) paediatrics. They have also enrolled one hundred (100) patients onto the post enrolment survey. They have commenced data entry for the echo project (project 3) onto REDCap.

Molecular Haematology Core: First batch of samples shipped in from Lagos have all gone through the Hb analysis and has been entered onto REDCap. William advised that all site coordinators should ensure that all samples to be shipped are properly cross checked.

PROJECT 2

David has given access to CRF for all sites on the REDCap platform. David awaits feedback from Gordon for project to kickstart test run. SickGenAfrica to cover malaria tests for all patients enrolled in the project

NOTES

- Kofi had some discussions with Olayemi prior to the meeting with regards to the 2nd year community engagement activity in Accra. They agreed on Friday, 13th September, 2019 as a suitable date and preferably an afternoon session.
- Obi raised concern on the effect the lopsided ratio of adult recruitment to paediatrics in the Accra can affect our finally data analysis. Olayemi spoke on the difficulties with paediatric recruitment in the site and also mentioned that the high paediatric numbers from the Kumasi site will help balance the proportions in the long run.
- Plans for the 2nd year community engagement in Dar es salaam will be put together- Kofi
- Registrations for the 14th H3Africa conference ongoing. David to update members on plans for the SickGenAfrica meeting during the conference.

**MINUTES FOR STEERING COMMITTEE MEETING HELD ON
FRIDAY, 16TH AUGUST 2019**

Time: 2:00 pm GMT

Present:

Dr. David Nana Adjei
Dr. Olayemi Edeghonghon
Prof. Eunice Obiageli Nnodu
Prof. Mahmoud Sani
Dr. Najibah Aliyu
Dr. Kofi Anie
Dr. Flora Ndobho
Prof. Julie Makani
Mrs. Justina Agula
Miss. Zoey Fiaxe
Mr. Nathan Seibu
Dr. Ryan Minster

Absent:

Prof. Solomon Ofori-Acquah
Dr. Titilope Adeyemo
Prof. Gordon Awandare
Prof. Ellis Owusu-Dabo
Dr. Vivian Paintsil
Dr. William Kudzi

AGENDA

ENROLMENT UPDATES

Dar es Salaam: Has enrolled a total of nine hundred and ninety-four (994) patients; seven hundred and twenty-three (723) paediatrics and two hundred and seventy-one (271) adults. Enrolment for project 1b still stands at three patients. They have also enrolled fifty-seven (57) patients onto the post enrolment survey.

Abuja: Enrolment still stands at a total of three hundred and sixty-two (362) patients; Two hundred and fourteen (214) paediatrics and one hundred and forty-eight (148) adults. They have also uploaded details of sixty-three (63) patients enrolled in the post enrolment survey onto REDCap.

They are still facing issues on enrolling patients onto project 1b; they are working on getting an MOU signed with local health facilities where patients often visit to make data collection less cumbersome.

Kano: Enrolment for paediatrics has been concluded with a total number of five hundred (500) patients, also one hundred and sixty (160) adults have been enrolled onto project 3. They are focusing on enrolling more patients onto project 3 before they commence enrolling patients onto project 1b. They have also enrolled one hundred (100) patients onto the post enrolment survey.

Accra: Has enrolled nine hundred and forty (940) adults and three hundred and six (306) paediatrics. They have also enrolled one hundred and one (101) patients onto the post enrolment survey. With regards to project 1b, they have fully enrolled one patient.

POST ENROLMENT SURVEY

Numbers uploaded so far onto REDCap (508) is close to the target set for the survey. Core lead (Kofi) is hoping the target is met before the H3Africa consortium meeting in Ghana.

SHIPMENT

- The Study Coordinator urged all site coordinators to ensure that samples are well labelled before they are packaged for shipment to prevent mixed samples; samples should be labelled on the side and at the top of all tubes.
- As much as possible, site coordinators should ensure that no spaces are left in the boxes while packaging to avoid the destruction of some samples.
- Each package should come with a cyro map to make identification of samples easy.

COMMUNITY ENGAGEMENT

Second round of community engagement for Accra will take place on the 13th of September 2019. Participants of the engagement will be patients recruited onto the study.

Tentative dates (16th, 17th or 18th September, 2019) were suggested for the 2nd round of community engagement in Dar es Salaam. Flora will check the sites' schedule and get back to Kofi with the most appropriate date to work with.

PROJECT 1B

The Study Coordinator urged all sites to share their experiences with this project so that together we can brainstorm and adopt a strategy that will work across all sites.

PROJECT 2

David has given access to CRF for all sites on the REDCap platform. David urged all sites to kickstart the test run and make available any comments so necessary changes can be made, as the 1st week in September is projected as the start date for the project.

Dar es Salaam has not been able to access CRF for the project. David would give Flora access after the meeting.

PROJECT 3

Julie suggested that sites that would be recruiting onto project 3 be made to use echo machines available in the hospitals they operate from to prevent any delay the movement of the echo machine from one site to another may cause. A standard protocol should be developed and followed by the said sites. David would run this by Solomon and Mahmoud and give feedback.

H3AFRICA CONSORTIUM MEETING

SickleGenAfrica would be sponsoring a number of our team members to the 14th consortium meeting in Ghana. Justina has contacted members who will be attending.

NOTES

- Julie suggested that all sites write a simple methods paper documenting their experience with regards to collection of samples, packaging and shipment.
- We are using the H3Africa kidney group DHL shipment account to ship our samples from Nigeria to Ghana.