Site Visit:
Abuja, Nigeria
26-27 August 2019

Site lead: Prof Obiageli Nnodu
Site Visit Leader: Dr Raphael Sangeda (SPARCo Hub, Tanzania)
Site Visit Team: Mr Mario Jonas (SADaCC, South Africa), Dr Jack Morris (SADaCC, South Africa), Dr Raphael Sangeda
Project Coordinators: Dr Hezekiah Isa (SPARCo, Nigeria), Dr. Victoria Nembaware (SADaCC, South Africa), Dr Malula Nkamyenka (SPARCo, Tanzania)

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Summary: CERSTA

The site visit to CERSTA (with Professor Obiageli E. Nnodu as site lead) at the University of Abuja Nigeria was undertaken by the Database (DB) Working Group led by Dr. Raphael Sangeda (SPARCo Hub, Tanzania) and DB members Dr Jack Morrice and Mr Mario Jonas, both from SADaCC. The site visit was conducted on Monday, 26 August 2019, with a Data Quality and Analysis Workshop conducted on Tuesday, 27 August 2019 (See *Appendix: SickleInAfrica Data Workshop, Nigeria 2019*).

The focus of the visit was firstly to verify the existing server infrastructure to assess the feasibility of expanding the server and data storage. Secondly, an assessment was done on the extent to which data quality checks are enforced and that the Data Resolution Workflow is implemented as was suggested in the Database Working Group.

The site visit team was re-acquainted with existing CERSTA members, as well as introduced to new members. Following the visit to CERSTA, the team visited the ICTS centre of UniAbuja and attended a meeting with the Head of ICTS, Professor Olumide Owolabi, Dean of the Faculty, Dr Maxwell Mwegbu as well as Systems Administrator, Mr Samuel Osagie (More complete meeting minutes in *Appendix: ICTS Meeting Minutes*).

Subsequent to the ICTS meeting and lunch, a data quality audit was completed (See **Database/REDCAP issues arising at Abuja Site Visit**) on 26 August 2019.

DISCUSSION, RECOMMENDATIONS AND CONCLUSIONS

Data quality and Audit:

It is the opinion of the site visit team that SPARCo Abuja has implemented site-wise data quality checks at the point of data entry via validated Excel data fields. The challenge to address is to ensure site compliance to these implementations. Furthermore, the site appears to have implemented recommendations from previous meetings as well as the previous site visit with regards to e.g. consistent date formats.

During the training workshop, mobile data capture was demonstrated and two mobile devices (with REDCap Mobile) were used by participants to assess mobile data capture. The ease-of-use and interface of the data capture instrument received generally positive reviews from participants. An official review of these mobile devices for data capture still needs to be completed. It is hoped that data capture via mobile devices will inprove data quality even more.

Given the technical experience CERSTA personnel has, it would be suggested that an additional REDCap Systems Administrator be identified and equipped. This

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redundancy in roles 1) speaks to capacity building, 2) ensures continuity of service (in the event of the unavailability of one REDCap Admin) as well as 3) means of succession planning.

Computer infrastructure support

Optimal solutions to power and networking should ideally be implemented within 6 to 12 months. Although networking, power and storage issues at the Abuja site are not ideal, this should not prevent the security and stability of implementing a server solution to serve the needs of the SPARCo site provided the following interventions can be assured:

Power: Sufficient time to shut down server infrastructure securely

- Intervention: Provision of a UPS that will at the very least allow server equipment to be shut down properly either manually by the systems administrator or through a software solution

Networking: Stable network connection for a pre-determined time period

- Intervention: network connectivity must be secured during regularly schedule data uploads to the Sickle in Africa Data Coordinating Centre (CC); a continuous, stable network connection to the CC is not needed at this time

CERSTA: Welcome and Introductions

Upon Arrival at CERSTA, Prof Obigael Nnodu introduced her site staff

- Mr Ikechuckwu Collins Udeozo: *Data entry ASH - accounting person*
- Mr Ruben Chianumba: *SPARCO data entry*
- Dr Eno-Abasi Etuk: *Clinician SPARCO Program officer*
- Mrs Juliet Iyabosa: *Research Nurse, Doris Duke and Imperial College* projects
- Mr Chisom Okparaugo: *Science Laboratory Technologist (Biochemistry)Lab assistant for ASH NBS Project (Curretnly research assistant on Doris Duke. Imperial College Screening Project.*
- Dr Adewole Adeyefa SGA Coordinator
- Mrs Yaceenu Thomas: *Technician involved in NBS*
- Mr Isaac Olanrewaju: *e-Lab computer specialist*

ICTS Meeting

Prof Obiageli Nnodu took us to ICT centre to meet the Director of ICTS, Prof. Olumide and his team. (For more complete minutes, see *Appendix: ICTS Meeting Minutes*)

It was established that ICTS has existing infrastructure and expertise to manage proposed computer server resources. Challenges do exist in the area of 1) stable power supply and 2) Internet connectivity. It is the opinion of the team that neither of these

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2 elements should prevent the provisioning of CERSTA server infrastructure to be housed at ICTS of UniAbuja.

Both stable power supply and Internet infrastructure is at planning stage at the University level and it is foreseen that this be implemented in the next 6 to 12 months.

Database/ REDCAP issues arising at Abuja Site Visit

ENSURING CONTINUITY BETWEEN "OLD" AND "REVISED" CRFS

We need to distinguish between the hard-copy CRF as completed during patient visits and the REDCap CRF which is the electronic data capture implementation of the hard-copy. SPARCo Nigeria has revised their hard-copy CRF during a training workshop coinciding with the first Nigerian Site Visit in November 2018 and implemented this revised CRF at the various sites. Data was historically captured using the "old" and, subsequently, the revised (hard-copy and REDCap) CRFs.

It was noted that the new REDCap CRF needs to be implemented to replace old REDCap CRF, taking care to maintain the integrity of data historically captured in the old one.

The following procedure to implement the above was discussed with the data coordinator Mr Olenrewaju and the data clerk, Mr Chianumba as follows:

- Create an old data dictionary export to excel
- Create a new data dictionary export to excel
- Create a merged data dictionary
- Organize the new dictionary, taking care that no variables with data are removed
- Add new variables, if any, at the end (these can be moved to appropriate positions later)
- Delete unwanted columns
- You can remove fields with 100% data missing (check using SPSS or R)
- Dealing with importing excel data
    - Make sure all the fields present in Excel are **definitely** in REDCap Data dictionary
    - Make sure the Excel data format corresponds to the REDCap format and codes; you may use the "find and replace" feature
    - Align all Excel to the Import templates; note the format for repeating instruments (Note that this can be done in a separate copy of the project to avoid problems with the existing data)
- Contact SPARCo hub and SADaCC for discussions on these steps

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REGARDING DATA QUALITY

- It was agreed that the data coordinator will run quality rules and when they find any discrepancy raise queries using the query resolution workflow feature of REDCAP
- The data clerk on the other hand can run data quality rules, however the data clerk's main responsibility needs to be responding to the data quality queries raised by the data coordinator and then to close these queries after resolving them
- The data resolution report will be discussed at the workgroup meetings to track the progress

REGARDING DATA RESOLUTION WORKFLOW:

- It was agreed that the SysAdmin/REDCap enable the feature by going to "Additional customizations" in project Setup (Figs 1 and 2)
- Then change from comments Log to "Data Resolution Workflow" in the section Enable Field Comment Log or Data Resolution Workflow (Data Queries)

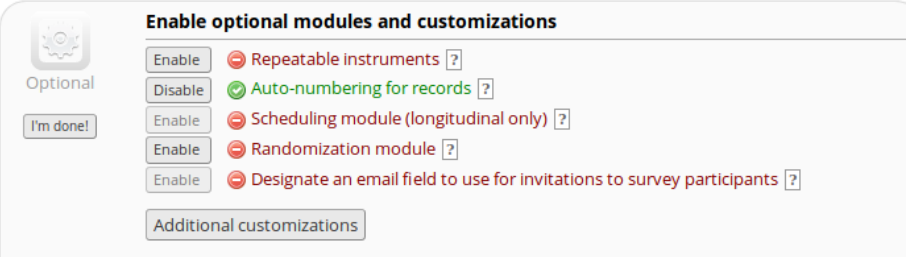

Figure 1: "Additional Customizations" under "Project Setup"

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Report Site Visits

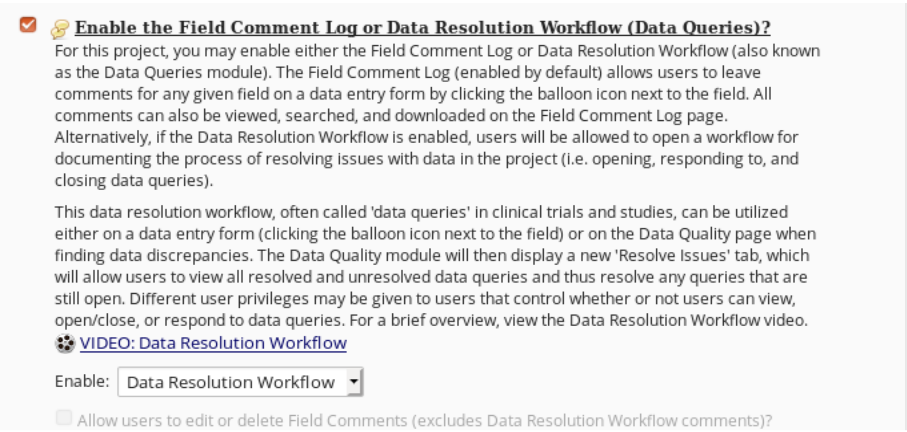

Figure 2: Enabling the Data Resolution Workflow

REGARDING THE REDCAP MOBILE APP MODULE:

- It was agreed that the SysAdmin/REDCap admin enable all users to allow data entry using mobile app. This is done under user rights
- For REDCap mobile capture, it would be our strong suggestion that each element be mandatory when completing data instruments, providing proper branching logic in the event that information for a data element is not present.

The meeting was adjourned at 5pm to allow team to prepare for the upcoming workshop in the next day, 27 August 2019.

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FOLLOW-UP ACTIONS

- Monthly meetings to track the data quality and data workflow resolutions
- Focus on data analysis and manuscript development in the upcoming workgroup meetings
- Make sure the CRF is updated on REDCap in Draft mode to implement the newly designed form
- For example, the field blood pressure needs to be split to diastolic and systolic fields
- Height needs to be entered in "cm" only and allow decimal points
- Matching of old and new CRF to identify the amount of data recoding required before re-importing data into the new design
- When doing the draft mode data instrument design focus on the adding new fields and editing existing ones, but avoid deleting fields as much as you can
- **Good practice**: The Database is running in "production" mode which prevents accidental renaming/changing of the data instruments and breaking of the existing data integrity

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Appendix: ICTS Meeting minutes

Present: Rueben Chianumba, Eno-Abasi Etuk, Mario Jonas, Jack Morrice, Maxwell Mwegbu, Obiageli Nnodu, Isaac Olanrewaju, Samuel Osagie, Olumide Owolabi, Raphael Sangeda.

Meeting commenced at approximately 9:30. Prof Nnodu introduced the SPARCO/SADaCC and the SickleInAfrica Consortium and the reason for regular site visits

- 22 sites in Nigeria (See *Appendix: Satellite sites*)
- A number of issues were discussed focusing on server infrastructure capacity: current and planned
- Other issues include:
    - set up of REDCap and issue of mobile App: which the site considered positively and urgent to reduce missing data happening. The site visit team insisted that this is NIH requirement that was raised at the April meeting in Tunisia. The site visit team proposed that the site implement the data quality and data resolution workflow to honour the funders and advisors' proposal of data quality assurance
    - Consequently, a data workshop planned for the next day would also focus on data quality issues
- Also informed that Nigeria modified its case report form in Nov 2018 after adapting the SPARCO/SADDAC template
- Multisite capacity building in Nigeria
- Network level in Nigeria, will help to answer question whether variation in Sickle cell phenotypes might exist due to the Geography of Nigeria (Sahel-North, Savannah in the middle belt , Rainforest in the southern parts) in addition to the environmental and psychosocial effects –typically Nigeria has Benin haplotype
    - So after collecting data across the country, what is the distribution of phenotype
    - Fine tune the process of data collection, do regression of data from multi-regional data (*Elements of this research questions were discussed in Data Workshop in 27 August*)
- No in-house capacity to handle the data analysis within SPARCO Nigeria thereby justifying needs for data management and data analysis training

SADaCC plan

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SADaCC reaffirmed its commitment to provide solutions. Server survey was done at this time (See attached completed Server Survey).

- Expandable server
- Additional storage capacity
- Set-up will be replicated at all current SPARCo sites as well as at Coordinating Centre; with more computing power to allow centralised consortium when needed

Prof Olumide gave a response to the questions raised

- There is a dedicated room in current ICTS building with access limited to only authorized staff
- New ICT/Data Centre is set in UniAbuja
- Existing server rack from current server room will be placed in new data room at the new Data Center in building adjacent to existing ICTS centre
- There is currently limited Internet bandwidth; move to fibre and layout of fibre is in planning stage with the VC of UniAbuja; expected implementation in 6 to 12 months
- Power:
  - generator in every building for backup power. New solar power project is in planning stage; commissioned by World bank
  - Power in all IT equipment there is UPS
  - So what is needed is the 24 power autonomy to be achieved
- Plan to set up local cloud: to allow moving when the local server is unavailable
- Need to promote sharing – SADDAC recommendation
- The Systems Administrator (Mr Samuel Osagie)
  - Anonymization for data security is done
  - Security is an important agenda item
  - VPS: dedicated to university managed by Sysadmin for last 5-6 years
  - Regular downtime is in place
  - Create REDCap user with only limited access to projects; data privacy is realized by team.
  - The site visit asked if the REDCap installation/instance is available to others at UniAbuja. The answer was only projects: 2 major the CESRTA project and the Cardiovascular project. Site visit team urged to encourage training for other teams to comply with REDCap consortium licencing requirement for institutional support of REDCap and thus suggested to invite researchers to create projects and grow local REDCap community.

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- Site visit team highlighted the need for Tablets: Mobile devices used for data capture to be kept in secure place and with PINs not disclosed
- Storage of devices needs to be secure and labelled with serial numbers
- The SysAdmin affirmed to continue granting a fine-grained Permission is done in rule-based fashion.

Meeting was adjourned at approximately 11:30 and the team inspected the server room. The team returned to CESRTA and continued afternoon discussions around local data management issues below.

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Appendix: Site Assessment Checklist

IDENTIFICATION

Full site name	University of Abuja	Date	26 Aug 2019
Brief site name	UniAbuja	DAG name	nigeria

DESCRIPTION & LOCATION

Physical address		CESRTA, University of Abuja, Main Campus, Airport Road, Abuja, Nigeria
Postal address		CESRTA, PMB 117 Gwagwalada
Location of main site		University of Abuja, Main Campus, Airport Road, Abuja, Nigeria
Distance from airport		14km
What is the road condition? (e.g. dirt, tarmac)		Good tarmac road from airport to University, Tarmac road on University with some potholes, but reasonably good.
Location(s) of satellite site(s)		See *Appendix: Nigeria Satellite Sites*
Web page		https://cesrta.uniabuja.edu.ng/
Type of site	Hospital	☐ Private
		☑ Provincial/Regional
		☑ Referral / Teaching
		☐ Military
	Other	☐ Clinic (not part of hospital or university)
		☐ Clinical Research Unit (CRU) e.g. at university

CONTACTS

Mark the Primary Contact Person with a *

Include email address and phone numbers where possible.

Site PI	Prof Obigael Nnodu
Other Investigators	Prof Samuel Asala, Prof Nash Oyekanmi, Dr Hezekiah Isa, Dr Maxwell Nwegbu
Research Site Coordinator	Dr Hezekiah Isa assisted by Dr Etuk Eno-Abasi
Data Coordinator	Prof Nash Oyekanmi and Prof Olumide Owolabi, assisted by Mr Isaac Olanrewaju
Data Capturer(s)	Mr Reuben Chianumba
Research Assistants	Mr Ikechuckwu Collins Udeozo, Ms Juliet Iyabosa, Mr Chisom Okparaugo, Mrs Yaceenu Thomas
IT Representative	Samuel Osagie
Other Key Staff (e.g. Bioinformaticist, Infectious Diseases Physician)	Clinicians: Dr. Biyaya Nwankwo, Dr Vivian Kwaghi

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ON-SITE FACILITIES

Which of the following are available **at the site**?	Yes	No	N/A	Comment
Data management office/area	✓			
Designated study document storage area available on site (e.g file room)	✓			
Printer/Photocopy machine	✓			
Scanner	✓			
Long-term document archiving facilities **on-site**	✓			
Long-term document archiving facilities **off-site**		✓		
Meeting room	✓			
Teleconference capability	✓			
Administrative support office	✓			

DATA MANAGEMENT-RELATED COMPUTING

Which of the following does your data management staff **primarily** use?		Yes	No	N/A	Comment
Computer types	Laptops	✓			
	Desktop computers	✓			
	Mobile devices (e.g. tablets or cellphones)	✓			
Operating system	Microsoft Windows	✓			
	Apple Mac		✓		
	Linux operating system		✓		
Internet connection	Institutional WiFi	✓			
	Private WiFi connection	✓			
	LAN connection	✓			
	Mobile internet connection		✓		
Databases	Microsoft Excel	✓			
	Microsoft Access	✓			
	REDCap	✓			
	Other software (specify)		✓		
Data location ('live' data)	Individual computer(s)				
	Network drive				
	Own server	✓			Cloud VPS
	Institutional server				
Backup storage	Individual computer(s)				
	Network drive	✓			
	Own server	✓			
	Institutional server				
	Flash drive / memory stick				

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Which of the following does your data management staff **primarily** use?		Yes	No	N/A	Comment
	External hard drive	✓			Occasionally
	CDs / DVDs				
Security	Computers require password on start-up	✓			
	Usernames and passwords are **unique** to each individual person (i.e. not shared)	✓			
	UPS for desktop computers/servers	✓			Mostly

OWN SOPS/GUIDELINES

For which of the following does the site have its own SOPs/guidelines?		Yes	No	N/A	Comment
Systems	Setup/Installation				
	System Maintenance				
	Contingency plan (in event of failure of computerised system)				
Data Management	Database design				
	Data collection and handling	✓			
	Data quality control/assurance		✓		
	Data backup		✓		
	Data recovery		✓		
	Data transfer		✓		
	Database lock & archiving		✓		

SADACC SOPS/GUIDELINES

Which of the following SOPs have been implemented at the site, and which have the site personnel been trained on?	Trained & implement-ted	Trained	Not yet provided at site	Comment
Username & Password Management			✓	
User Rights & Data Access Groups Management			✓	
Data Recording			✓	
Data Receipt, Entry and Validation			✓	
Database Design & Build (incl. Longitudinal setup)			✓	

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Database Backup, Lock, Export & Archiving			✓	
Data transfer from SPARCO sites to SADaCC			✓	
Remote data quality monitoring			✓	
Recruitment & Informed Consent Process			✓	

What is working particularly well at your site?
Data are entered into REDCap after collection from sites across Nigeria. Most of the data is captured using the modified CRF with some sites sending data in data-validated Excel format which is then reformatted for import into REDCap. The PI performs virtual inspection of records and marks data entry as "complete" where appropriate.
What is not working so well at your site, if anything?
Would like to capture data at the satellite sites directly to REDCap. Implementation of Mobile App data capture in REDCap is being planned.
What can we do to help?
Enforce Mobile data collection, data quality checks &data resolution workflow

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Appendix: Nigeria Satellite Sites

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Appendix: Server Survey

Personal Details					
Institution:	University of Abuja, Nigeria				
Callers Name:		**Sys Admin Name:**	Prof. Olumide Olowabi		
PI Name:	Prof. Obiageli Nnodu	**Date:**	26 Aug. 2019	**Time:**	9:40-11:30 am

Physical Infrastructure	
Questions	Comments
1. Do you already have servers? a. If yes, what are you using them for?	Current servers run virtual environment and houses: • REDCap • Website • All the University Student Portal. Runs Cent OS
2. Do you have a dedicated room for your new server? a. Do you have a server room? b. If no dedicated server room, i. is there a lockable room that can be used to house the new server? ii. Do you have a rack to install the server into?	• Dedicated server room has lockable with a key. • Current rack is a 42u unit
3. Would the server be co-hosted? a. i.e. would the server be housed in a shared facility such as your institutions server room or any other equipment room?	Server is co-hosted at the ICT center at University of Abuja, Main Campus
4. Is there a server rack in the server room?	Yes
Access Control	
1. Is the room the server will be housed in alarmed?	No
2. Does the room require a physical key, pin code or swipe card for access?	Physical key access
3. Do any opening windows in the room have burglar bars?	Yes, there is a small window (~1 ft^2) with burglar bars.

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4. If housed in a normal office, is any of the outside facing walls made of drywall?	Dedicated server room has only brick wall
Climate Control	
1. Does the room have an air conditioner or fan installed?	Yes, a 2hp air conditioner unit is installed
Power Supply	
1. Is there a dedicated power point with its own circuit breaker?	Yes
2. Do you have a UPS for the new server?	No
3. Is there any other backup power other than UPS?	Power generators Yes there is power generator (80KVA)
4. Do you experience power interruptions? a. If yes, how frequently? b. How long do they typically last?	There are regular power interruptions About 3 times every other day. It takes about 15 minutes each time for power backup to start up.
Network Infrastructure	
1. Internet Connection a. What type of internet connection do you have (ADSL, 3G, LAN)? b. Is there a firewall or proxy? c. If yes, who manages this resource? d. Who owns or pays for this internet connection? e. Is it capped or uncapped?	a. LAN b. Proxy c. ICT Networking Unit d. University e. Capped
2. If you have an existing infrastructure, what network speeds do you have? (1GB or 10GB)	1GB
3. Would you need a network switch for your new server?	Yes
Storage	
1. What storage do you currently have?	Whogohost: MainOne Data Centre REDCap:
2. What existing backup policies do you have? a. Backup software used? b. Frequency? (daily, weekly, monthly c. Type of backup? (full, incremental) d. Retention periods?	a. None b. Weekly c. Full d. Infinite
Anticipated use of new server	

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1. Please describe the type of use anticipated for this new server	REDCap, processing and backup
2. Do you have a dataset that you can start processing right away?	Yes
3. If you have an existing server and we gave you a dataset; are you able to start right away?	Yes
Systems Administrator	
1. Do you have a systems administrator?	Yes
2. If yes, who is your system administrator	Prof Olumide Olowabi, Mr Samuel Osagie
3. Is this system administrator SPARCo funded?	No
4. Is this person on-site full time?	Yes
5. Is this person assigned to the node, university or academic	University
6. Does this person have other clients / responsibilities?	Yes
7. Are you planning on sending the systems administrator to a systems administrator course? a. If not, do they have adequate experience? b. Who will this person be?	The system administrator is quite experienced. It will be nice, however, to provide further training. b. Mr. Samuel Osagie

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Appendix: SickleInAfrica Data Workshop, Nigeria 2019

Venue: University of Abuja Teaching Hospital (CESRTA)

Date: 27th August 2019

Time	Session	Instructors: **Lead**, support
8:30 - 9:45	Welcome, Introduction and SPARCo Overview	Prof. Obiageli. Nnodu
9:45 - 10:30	REDCap refresher	Dr. Raphael Sangeda
10:30 - 11:00	Coffee break	
11:00 - 11:30	Current CRF and Code book (Data Harmonization)	Mr. Mario Jonas
11:30 - 11:45	Feedback for Nigerian sites on CRFs	Nigerian Site
11:45 - 13:00	Data quality	Mr. Arthemon Nguweneza (presenting remotely from South Africa)
13:00 - 13:30	Lunch	
13:30 - 15:30	Hands-on Data Analysis (Nigeria Data)	Dr. Jack Morrice
15:30 - 16:00	Coffee Break	
16:00 - 17:00	Data Analysis continued	Dr. J. Morrice
17:00 - 17:30	Data collection using mobile application	Mr. M. Jonas, Dr. R. Sangeda
17:30 - 17:45	Building a platform for genomics of SCD in Nigeria	Toyin
17:45 - 18:00	Wrap up	Dr. Madu/ Prof. O. Nnodu

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