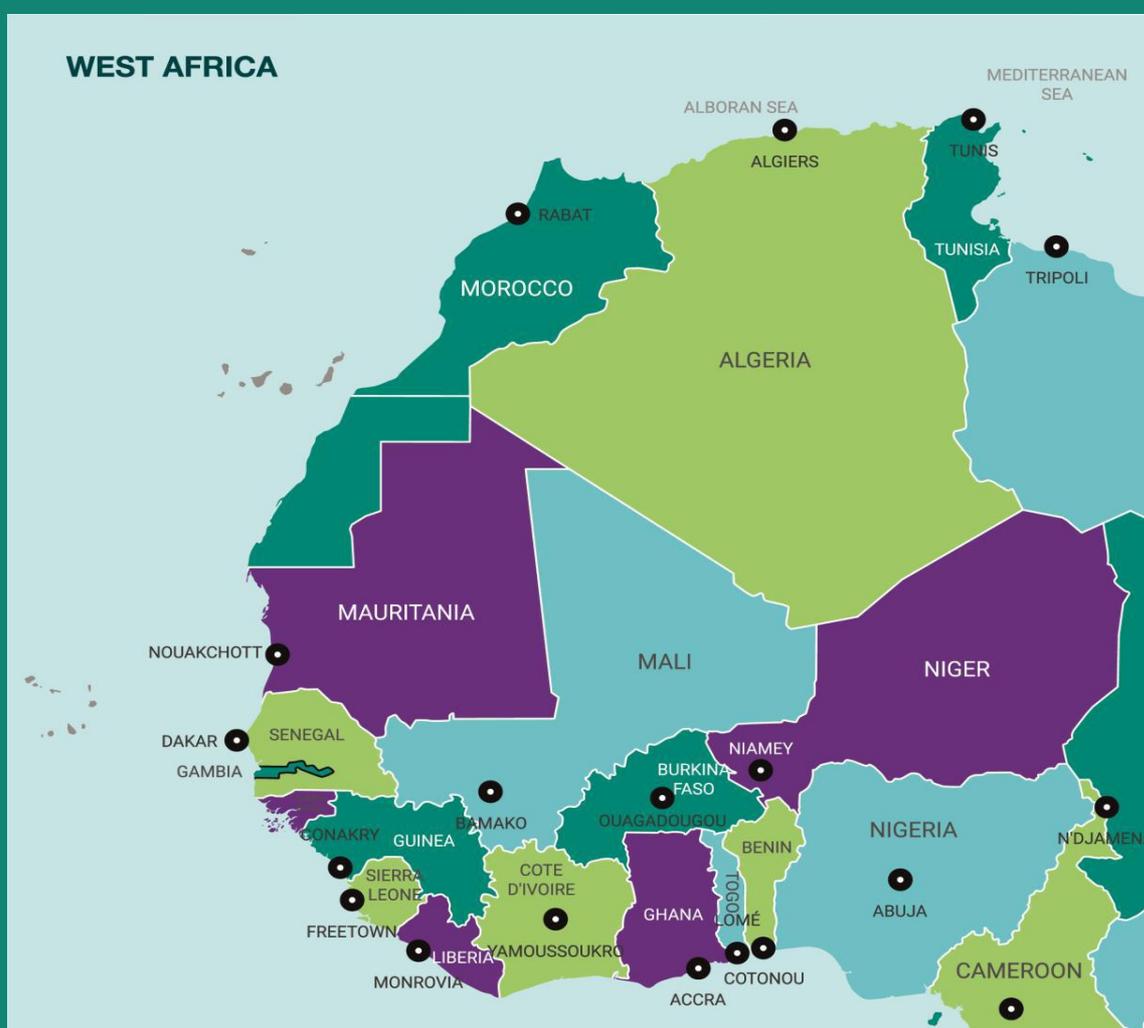


CEPI Lassa Fever Study Pre-Study Site Analysis

GCP Assessment of
Clinical Trial Study
Sites in West Africa



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2. List of Abbreviations and Definition of Terms

Abbreviation	
CCC/Walter Reed	Centre for Clinical Care and Research/Walter Reed Program Nigeria
CEPI	Coalition for Epidemic Preparedness Innovation
CITI	Collaborative Institutional Training Initiative
CNRFP	Centre National de Recherche et de Formation sur Paludisme
CRO	Clinical Research Organization
CRSN	Centre de Recherche en Sante de Nouna
CRU	Clinical Research Center
CVD	Center for Vaccine Development
EC	Ethics Committee
EDC	Electronic Data Capture
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Authority
FORS/IRCB	Fondation pour La Recherche Scientifique and Clinical Research Institute of Benin
GcLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practices
GRAS	Groupe de Recherche Action en Sante
IATA	International Air Transport Association
ICH	International Council on Harmonization
IHVN	Institute of Human Virology
IP	Investigational Product
IT	Information Technology
IWRS	Interactive Web Response Systems
Jos	Jos University Teaching Hospital

LASV	Lassa Fever
LMHRA	Liberian Medical Health Product Regulatory Authority
MOH	Ministry of Health
MRTC	Malaria Research and Training Center
NGHTN	Nigeria Global Health Trials Network, National Hospital
NHREB	The National Ethical Review Board
NIAID	National Institute of Allergy and Infectious Disease
NIMR	Nigerian Institute of Medical Research
NPHIL	Liberia-US Clinical Research Partnership Reference Laboratory
PBSL	Pharmacy Board, Sierra Leone
PCR and RT-PCR	Polymerase Chain Reaction – Real Time
PI	Principal Investigator
PPE	Personal Protective Equipment
QA	Quality Assurance
SBEE	Société Beninoise d'Énergie Electrique
SOP	Standard Operating Procedures
UNCCT	University of Nigeria Center for Clinical Trials
UPS	Uninterruptible power supply
USB	Universal Serial Bus
WHO	World Health Organization

3. Introduction

3.1 Background and Overview

In preparation for the Coalition for Epidemic Preparedness Innovation's (CEPI) clinical trials of candidate vaccines against Lassa Virus (LASV) in 2019-2020, potential clinical trial sites were mapped across affected countries in West Africa. More than 40 clinical trial sites were identified, and an initial site assessment was conducted by an online survey to categorize sites in terms of readiness to conduct GCP (Good Clinical Practice) compliant clinical vaccine trials.

Verification of the information and capacity gap identification through site visits commenced in late 2018 by CEPI and was subsequently assumed by ICON GPHS in April 2019 and carried out through to end October 2019. A total of 33 sites have been assessed. A detailed and site-specific report was prepared for CEPI and its partners. As CEPI feels this valuable data should be made available to a wider audience, the anonymised data are herewith shared.

The sites detailed in this report were selected by CEPI and assessed by ICON GPHS. The assessment report reflects site status and capacity at a particular point in time (April – October 2019). We recognize that status and capacity may change over time. The assessment information was supplied in good faith based on information which we believe, but do not guarantee, to be accurate and complete. It is not an exhaustive list of potential sites and more sites may be assessed at a future date

3.2 Countries and Numbers of Sites Assessments Conducted

Country	Number of Sites Visited	Number of Sites Unable to Visit
Burkina Faso*	4	1
Mali	2	0
Ghana**	4	1
Benin***	1	0
Liberia	5	0
Guinea	1	0
Sierra Leone	3	0
Nigeria	13	0

*Burkina Faso – Security Issues impeded a visit to this site

**Ghana - Scheduling with appropriate Medical personnel hampered scheduling

***Benin – Two sites identified were deemed one facility at the time of the assessment visit.

4. Objective of CEPI Lassa Fever GCP assessment of clinical trial sites

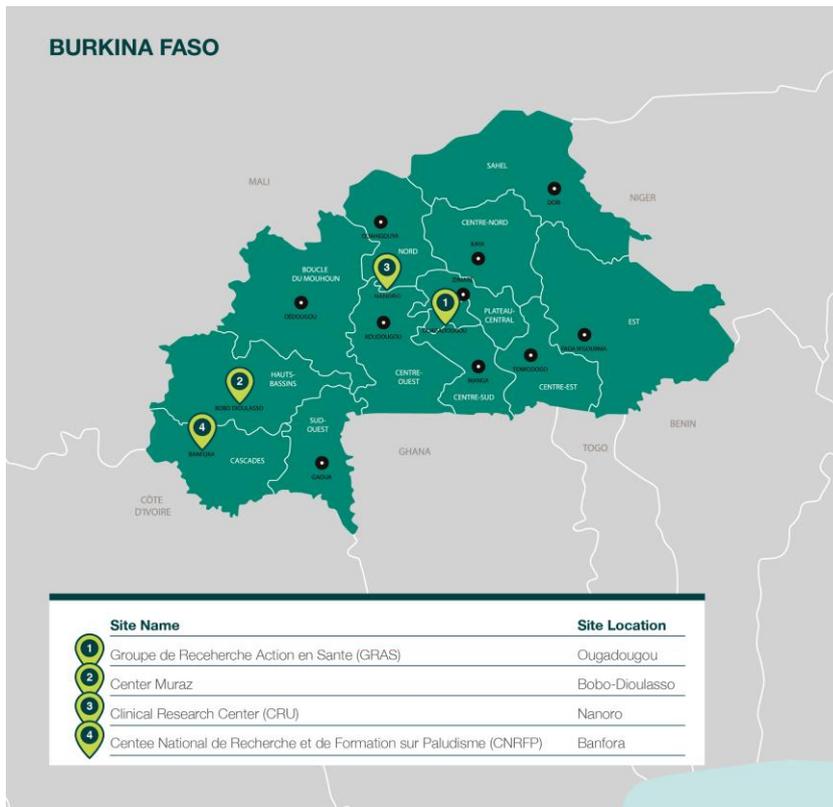
The following was agreed upon by ICON GPHS and CEPI prior to the initiation of the work:

Objective: To provide CEPI awardees with meaningful support for their clinical trial site selection and avoid competition for sites by assessing 30 sites for their ability and readiness to conduct GCP compliant clinical vaccine trials through on-site visits and identifying capacity gaps for future capacity-building support.

Outputs:

1. Detailed spreadsheet with all content as generated from the questionnaire and on-site visits conducted from April-October 2019
2. Report with site assessment findings on a country-by-country basis, highlighting capacity gaps

5. Burkina Faso



5.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
Groupe de Recherche Action en Sante (GRAS)	Ougadougou	Urban	14 July 2019
Center Muraz (Muraz)	Bobo-Dioulasso	Urban/Rural	13 July 2019
Clinical Research Center (CRU)	Nanoro	Rural	14 July 2019
Centre National de Recherche et de Formation sur Paludisme (CNRFP)	Banfora	Rural	13 July 2019
Centre de Recherche en Sante de Nouna (CRSN)	Nouna	Rural	Not available for site visit due to safety reasons

5.2 Ethical Considerations

5.2.1 Regulatory Considerations

All four sites are required to submit to the national ethics committee. The committee meets on a monthly basis and submission of documents is required two (2) weeks before the scheduled meeting. If the submission is on paper, ten (10) copies are required. If electronic, it can be submitted via Universal Serial Bus (USB). Timeline for approval is normally between one to two (1-2) months.

All four sites are required to obtain authorization from the Ministry of Health (MOH) and the Medical and Pharmaceutical Agency for import licenses to conduct a clinical trial.

5.2.2 Guardian Verification and Community Engagement

For all sites, guardians are identified by a family member. Additional consenting for female subjects may be required in some cases, but this is usually a verbal consent and it is not a formally documented process.

Approval by community leaders is not required for any of the sites.

5.3 Audits

All four (4) sites have had regulatory audits and two (2) sites have had sponsor audits.

5.4 Data Management Experience

Most sites have some data management experience.

5.5 Study Conduct and Support

5.5.1 Power Supply and Maintenance

All sites have a power supply from the national grid with back-up power systems through generators and in the case of one site, solar also.

Regular system maintenance is noted for two sites. For the remaining two (2) sites, the maintenance procedures were unclear.

5.5.2 Internet

All sites have internet access through Wi-Fi. The internet connectivity is 'relatively stable' to 'stable' for all sites. Most sites use either firewalls or controlled access for internet security.

5.5.3 Document Storage and Security

All four (4) sites have document storage areas/space available and two sites have fire and waterproof storage cabinets. All document storage areas are locked, and most sites operate using controlled/restricted access only.

5.5.4 Temperature Control

All sites have temperature control systems with back-up systems noted for most. Temperatures are measured at least twice daily at all sites, with annual calibrations conducted.

5.5.5 Investigational Product Storage and Transport

All sites have freezers, refrigerators, and ambient rooms for investigational product (IP) storage.

IP is transported using a range of methods, including isothermal bags, ice bags, cold packs, dry ice, etc. Some sites (e.g., GRAS) use sponsor SOPs for IP transportation, and courier companies may provide supplies at some sites.

5.6 Subject Recruitment

The larger hospital, involves local community leaders to discuss the study at the local level and to help with subject referral. All materials must be approved and translated into French.

A specific strategy and communication plan is developed in two centers (an SOP is in place). Community leaders are involved in this process. For all scheduled visits a reminder is carried out by field workers. Incentives, such as transport, may also be used where appropriate, e.g. for distances over 15 kms.

At one site, a communication plan may also be used to recruit subjects, depending on the indication and population of interest. Radio and newspaper advertisements are also used, and the PI may visit community leaders in the locality. Field workers and community leaders also follow-up by text or by home-visits for subjects enrolled in a study.

5.7 Site Staff

All sites have staff available to conduct research or study. Two sites have staff who are 100% dedicated to research. All site staff undergo annual Good Clinical Practice (GCP) training. Most of the sites have had additional training such as Collaborative Institutional Training Initiative Program (CITI) or National Institute of Allergy and Infectious Disease (NIAID) Learning, depending on their affiliations and studies conducted in the past.

All sites except one have their own Standard Operating Procedures (SOPs) for training. The one site without their own SOPs is working to put their own SOPs in place but were using sponsor SOPs at the time of site assessment.

All sites have Principal Investigators (PIs) with research experience.

5.8 Laboratory Training, Medical Emergency Procedure

Laboratory trainings are available on file for most sites and job descriptions are available. Personal Protective Equipment (PPE) is not reusable and transport via vehicle with temperature monitoring is used. Two sites have International Air Transport Association (IATA) certification for the transportation of hazardous materials/human samples. IATA was not referenced at the remaining two sites.

Medical emergency trollies are available for medical emergencies at all sites, with SOPs in place. Maintenance is documented at one site.

5.9 Vaccine Experience, Lassa Fever Experience

All sites have vaccine trial experience. No site has Lassa Fever trial experience to date.

5.10 Burkina Faso: Summary and Capacity Gaps and Capacity Gaps

All four (4) sites assessed in Burkina Faso are clinical research (and specifically vaccine research) experienced. Neither site has Lassa Fever trial experience. They have dedicated research staff who undergo annual GCP training. All sites apart from one (1) have SOPs in place and training is tracked. All four (4) sites have been audited.

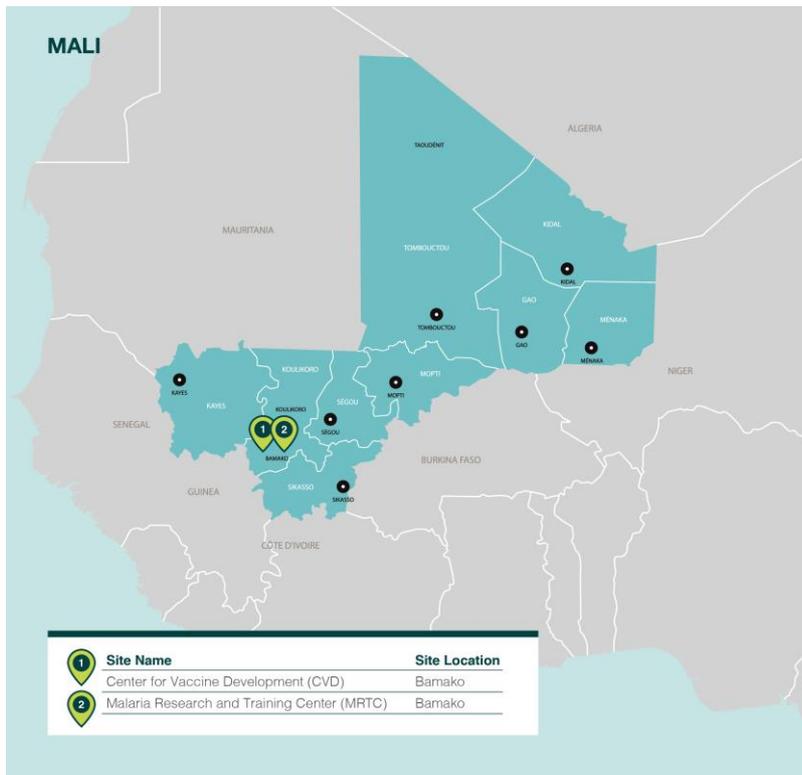
Most sites have data management experience and all sites have robust data storage and security. Laboratory training records are available at most sites and job descriptions are in place. Two sites have IATA certification. All sites have a good IP storage and transport facilities with temperature controls and monitoring in place.

All sites have medical emergency trollies and SOPs governing medical emergencies. Isolation areas were available at two (2) of the four (4) sites.

All sites have good power supply from the national grid with back-up systems. Internet is present and stable to relatively stable at all sites.

Most sites have a communication strategy for engaging subjects in their studies and work with local communities and community leaders to recruit and retain study subjects.

6. Mali



6.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
Center for Vaccine Development (CVD)	Bamako	Urban	28 June 2019
Malaria Research and Training Center (MRTC)	Bamako	Urban	28 June 2019

6.2 Ethical Considerations

6.2.1 Regulatory Considerations

A national ethics committee (EC) is in place in Mali (Comite d’Ethique National). It normally takes about six (6) months for review and approval.

Documents to be approved must be submitted one (1) month in advance of the next ethics committee meeting. Submission can be in paper or electronic format.

6.2.2 Guardian Verification and Community Engagement

For both sites, guardianship is verified by a family member and/or a community leader. Additional consent for females may also be sought.

6.3 Audits

The National Ethics Committee (Comite d' Ethique National) audited both sites in 2017. Additionally, both sites were audited by a sponsor in 2018 and a CRO in 2019.

6.4 Data Management Experience

Both sites have Interactive Web Response Systems (IWRS) experience.

6.5 Study Conduct and Support

6.5.1 Power Supply and Maintenance

Power supply is provided through the national grid and supported by generators at both sites. Each site has at least one generator. Equipment at both sites is also supported by uninterruptable power supply (UPS) which usually lasts for 8 hours. Both sites check equipment daily and have personnel on-site 24/7.

6.5.2 Internet

Both sites have internet and Wi-Fi, and the internet service is stable. There is an Information Technology (IT) manager at each site who is designated to provide and monitor access.

6.5.3 Document Storage and Security

Documents at both sites are stored in cabinets that are fireproof but not waterproof. Both paper and electronic document storage is used at both sites. The document storage areas are locked with limited/restricted access.

6.5.4 Temperature Control

Both sites have monitored temperature control systems with back-up systems.

6.5.5 Investigational Product Storage and Transport

Both sites have freezers (-20°C, -80°C and -180°C) and refrigerators.

Both sites have experience with transporting IP with a variety of methods used for transport.

6.6 Subject Recruitment

For subject recruitment in more remote areas, posters, radio and newspaper advertisements, and village conferences with community leaders are used. All methods of recruitment must be approved by community leaders. Materials used may need to be translated to Bambara.

Site subject retention is supported by text message and phone call reminders, home visits, and incentives as subjects may have to travel up to 100kms to come to the sites.

6.7 Site Staff

Both sites have staff who are fully dedicated to research and both have training SOPs in place.

- One site has mandatory GCP training and uses CITI training.
- The other site has GCP training in place and training in general is captured in training logs for sponsor audit readiness and site daily activities.

Site PIs are GCP trained. Both sites have clinical research experience.

6.8 Laboratory Training, Medical Emergency Procedure

Both sites have non-reusable PPE. IATA is not referenced at either site.

Both sites have a medical emergency trolley available, however, regular maintenance is not documented, and associated SOPs are unavailable.

Subject isolation areas are available.

6.9 Vaccine Experience, Lassa Fever Experience

One site has vaccine research experience. Neither site noted any experience with Lassa Fever.

6.10 Mali: Summary and Capacity Gaps

Both sites assessed in Mali are clinical research experienced. Neither site has Lassa Fever experience. They have dedicated research staff who are GCP trained. Both sites have SOPs in place and training is tracked. Both sites have been audited.

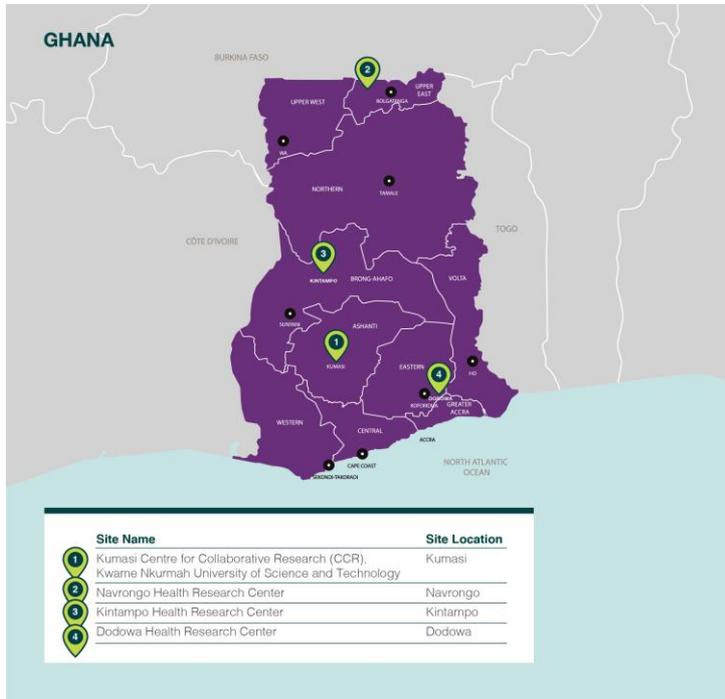
Both sites have some data management experience and have robust data storage and security. Laboratory training is not routinely tracked and neither site has IATA certification. Both sites have IP storage and transport facilities with temperature controls and monitoring in place.

Both sites have medical emergency trollies but SOPs governing medical emergencies were not in place. Isolation areas are available.

Both sites have good power supply from the national grid with back-up systems. Internet is stable at both sites and both sites have an IT manager who monitors access and controls.

Both sites work with local communities and community leaders to recruit and retain study subjects.

7. Ghana



7.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
Kumasi Centre for Collaborative Research, Kwame Nkumrah University of Science and Technology (Kumasi)	Kumasi	Urban	8 July 2019
Navrongo Health Research Center (Navrongo)	Navrongo	Rural	9 July 2019
Kintampo Health Research Center (Kintampo)	Kintampo	Rural	8 July 2019
Dodowa Health Research Center (Dodowa)	Dodowa	Rural	10 July 2019
Komfo Anokye Teaching Hospital (Komfo)	Kumasi	Rural	Not available for an evaluation

7.2 Ethical Consideration

7.2.1 Regulatory Considerations

Ethics Committee (EC) review/approval is provided by the Ghana Food and Drugs Authority (FDA). Review packages need to be submitted to the EC one (1) month ahead of the next meeting. Submissions can be in paper or electronic format.

7.2.2 Guardian Verification and Community Engagement

Guardians are determined by the family for all four (4) sites. At one site, community leaders can also verify guardianship. Additional consent may be required for female participants at all four (4) sites.

Community engagement is required for all four (4) sites.

7.3 Audits

All study sites have gone through one or more audits with no major findings reported. Audits were conducted by the Ghana Food and Drug Authority (FDA) and sponsors.

7.4 Data Management Experience

Most sites have IWRS experience.

7.5 Study Conduct and Support

7.5.1 Power Supply and Maintenance

In all four (4) sites power is provided through the national grid and supported by two (2) heavy duty automatic generators (except in one site which has three (3) auto-switch generators). Equipment is also supported by uninterruptible power supply (UPS) systems in all sites.

Power maintenance is available at all sites. Two sites perform daily equipment checks.

7.5.2 Internet

All sites are equipped with stable internet connection with no connectivity issues.

Internet in Ghana is very reliable, and sites also use dongles as back-up in case of power failure.

7.5.3 Document Storage and Security

All four (4) sites have document storage cabinets which are both water and fireproof.

All sites have controlled/restricted access to the document storage area.

7.5.4 Temperature Control

Air conditioning is available at all the sites and temperatures are monitored.

7.5.5 Investigational Product Storage and Transport

- All sites have refrigerators and freezers in place. All sites have -20°C and -80°C freezers, and in addition either a -150°C or a -170°C freezer. At most sites, temperatures are measured daily on a manual basis, with a 24-hour temperature monitoring device also in place.
-

Each piece of equipment must be certified by the Ghana Food and Drugs Authority (FDA) before a trial starts and all site equipment is marked “certified by Ghana FDA”. This is specific to Ghana.

Dry shippers, ice packs, and dry ice are used for IP transport at all sites. All four (4) sites have experience using other transport systems also.

7.6 Subject Recruitment

All four (4) sites are well known in the local communities and subject recruitment is done with the help of community and village chiefs. Referrals are also made from within the hospitals themselves.

Radio and newspapers advertisements also help to recruit from within the local communities.

All materials used are required to be approved.

7.7 Site Staff

Research staff are available at all sites. It is mandatory for all investigators to be GCP trained every two (2) years (Ghana Food and Drugs Authority (FDA) requirement). Site training SOPs are available at three sites. One site did not have any site training SOPs noted.

PIs at all four (4) sites documented the requirement of the Ghana Food and Drugs Authority (FDA) to be GCP trained every two (2) years.

7.8 Laboratory Training, Medical Emergency Procedure

Laboratory trainings are available and on file for all sites. PPE is not reusable and transport via vehicle with temperature monitoring is followed. IATA certification was not referenced at any of the sites apart from one site.

Medical emergency trollies are available for medical emergencies at all sites, but SOPs for maintenance or maintenance itself are not documented.

7.9 Vaccine Experience, Lassa Fever Experience

Only one site is reported to have an isolation area, however there is no separate entrance indicated. There are no isolation areas or separate entrances for infectious disease patients for any of the other three (3) sites.

No vaccine or Lassa Fever experience was noted for any of the sites.

7.10 Ghana: Summary and Capacity Gaps

All four (4) sites assessed in Ghana are clinical research experienced but none of the sites have Lassa Fever clinical research experience. They all have research staff who are GCP trained (every two (2) years). Training SOPs are in place at three (3) out of the four (4) sites and training is tracked. All sites have been audited.

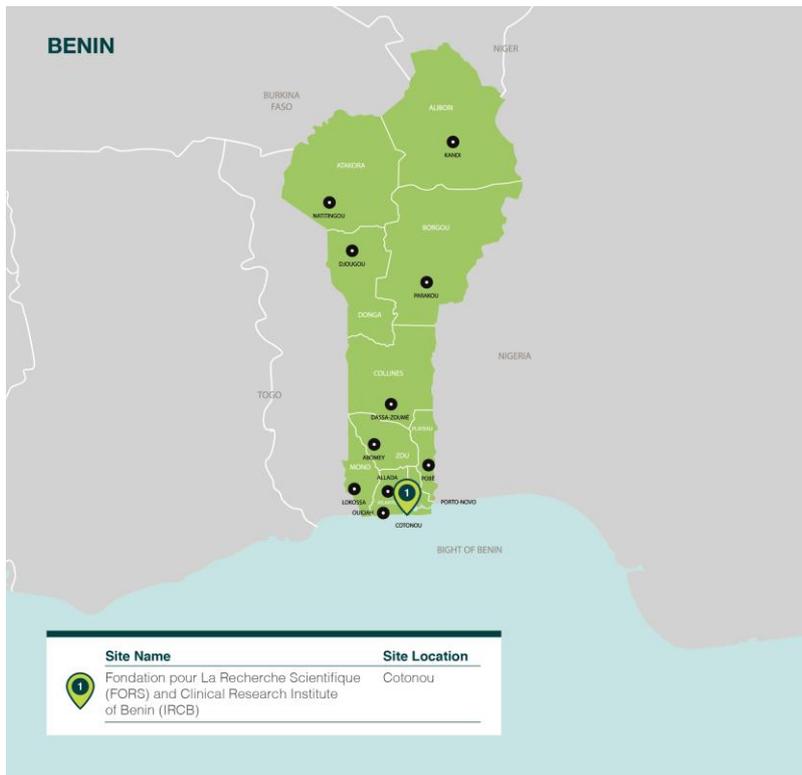
All sites have some data management experience and have good data storage and security. Laboratory training tracked at all sites but only one site references IATA certification. All sites have good IP storage and transport facilities with temperature controls and monitoring in place. All equipment is required to be certified by the Ghana FDA prior to use on a study.

All sites have medical emergency trollies but maintenance records and SOPs governing medical emergencies were not in place. Only one (1) site has an isolation area.

All sites have good power supply from the national grid with back-up systems. Internet is stable at all sites.

All sites work with local communities and community leaders to recruit and retain study subjects.

8. Benin



8.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
Fondation pour La Recherche Scientifique and Clinical Research Institute of Benin (FORS/IRCB)	Cotonou	Urban	4 July 2019

8.2 Ethical Considerations

8.2.1 Regulatory Considerations

There are several ethics committees (EC) in place at a national level. There is no local EC for this site. The National EC requires two to three (2-3) months for review and approval. Timelines may vary depending on whether it is a country or site-specific submission, and periodicity of meetings occur depending on the number of review/approval requests. Documents must be submitted three (3) months in advance, in electronic and paper format.

8.2.2 Guardian Verification and Community Engagement

Guardianship is verified by family or community members. Community approval is required.

8.3 Audit

Various site audits were performed in 2016, 2017 and 2018 by various sponsors and CROs. In addition, several site assessments have been carried out on behalf of sponsor and academic institutions.

8.4 Data Management Experience

There is a data manager available on site.

8.5 Study Conduct and Support

8.5.1 Power Supply and Maintenance

Power is supplied by the national supplier, Société Beninoise d'Énergie Electrique (SBEE). There are two generators available for the laboratory. Power goes off about three to four (3-4 hours) per month and there is a UPS backup system available. Power maintenance checks are performed daily.

8.5.2 Internet

Stable internet and Wi-Fi are available through several internet providers, with a UPS back-up system, although connectivity is usually reliable. Internet protocols are in place for password security and computer access configuration.

8.5.3 Document Storage and Security

Fireproof/Waterproof locked cabinets are present on site. SOPs on document storage and access are also in place. Document storage is secured with restricted access granted only to essential personnel. Long term storage is available both on and off site.

8.5.4 Temperature Control

Temperature control is available at site and an automatic monitoring system is in place.

8.5.5 Investigational Product Storage and Transport

Freezers (-20°C, -40°C, -80°C and -150°C) are available for sample and vaccine storage, biological materials and tools (biochemistry tools, PCR tools, etc.) are available. A cold room is also available. An automatic temperature control and monitoring system with email alert is used twice per day (morning and evening, including at weekends) by the research team.

8.6 Subject Recruitment

The Ministry of Health (MOH)'s Demographic Surveillance System (through the National Institute of Public Health Department of Epidemiology), and health surveillance of borders, ports and airports are used to recruit subjects, together with newspapers and radio advertisements with assistance from community leaders. For reminders to and retention of subjects, phone calls, home visits, and text messages are used.

8.7 Site Staff

This site has a large range of staff available including: seven (7) physicians; four (4) infectious disease specialists; one (1) pharmacist; four (4) epidemiologists; eight (8) nurses; two (2) data managers; five (5) statisticians; two (2) clinical research coordinators; one (1) quality assurance officer to other staff (e.g. laboratory scientists and technicians, field workers, data entry and support staff).

Staff training is by role and is documented in study files for example IATA, GCP every two to three (2-3) years. Site SOPs on multiple training topics are available.

The site PIs have medical backgrounds and are GCP trained, having worked on various clinical research studies.

8.8 Laboratory Training, Medical Emergency Procedure

Training for Good Clinical Laboratory Practice (GcLP) (every two to three (2-3) years), Real Time - Polymerase Chain Reaction (RT-PCR) and Enzyme-Linked Immunosorbent Assay (ELISA) is available. There are non-reusable PPE in use and SOPs for laboratory training are in the process of revision.

There is no medical emergency trolley on site but an SOP on medical emergencies is in place.

8.9 Vaccine Experience, Lassa Fever Experience

This site has been working in clinical research for more than 10 years but does not have Lassa Fever research experience. There have been four (4) cases of Lassa Fever at this site in the three (3) years preceding the site assessment.

An isolation area is available.

8.10 Benin: Summary and Capacity Gaps

This site is clinical research experienced but does not have Lassa Fever experience. There are research experienced staff on-site who are GCP trained (every two to three (2-3) years). Training SOPs are in place and training is tracked. This site has been audited several times in recent years.

This site does have some data management experience and has a data manager on-site. It has good data storage and security governed by SOPs. Laboratory training is tracked and GcLP is carried out every two to three (2-3) years. The site has good IP storage and transport facilities with temperature controls and monitoring in place.

The site does not have a medical emergency trolley but does have an SOP governing medical emergencies in place and it does have an isolation area.

This site has a good power supply from the national grid with back-up systems and daily maintenance checks. Internet is reliable and has monitored access.

In addition to working with local communities and community leaders to recruit and retain study subjects, this site also works with the MOH Demographic Surveillance System and health surveillance of borders, ports and airports to recruit subjects.

9. Liberia



9.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
NPHIL The Liberia- US Clinical Research Partnership - JFK	Monrovia	Urban	25 July 2019
NPHIL The Liberia- US Clinical Research Partnership – Dupont Road	Dupont Road, Monrovia	Urban	27 July 2019
NPHIL The Liberia- US Clinical Research Partnership - Redemption	Redemption Hospital, Monrovia	Urban	25 July 2019
NPHIL The Liberia- US Clinical Research Partnership - ELWA	ELWA, Monrovia	Urban	28 August 2019
NPHIL The Liberia- US Clinical Research Partnership - Reference Laboratory	Monrovia	Rural	24 July 2019

Of note, one site is the central reference laboratory and as such was not assessed as a stand-alone research site.

9.2 Ethical Considerations

9.2.1 Regulatory Considerations

The National Ethical Review Board (NHREB) meets quarterly. Approval is generally given within three (3) months. Submissions are made in paper format with ten copies per submission required.

9.2.2 Guardian Verification and Community Engagement

Interviews and identification cards are required for guardian verification for all sites.

All sites engage with communities through meetings with local chiefs, elders, local government and opinion leaders to inform and to request permission to reach out to the community.

9.3 Audit

Three of the sites have been audited by the Liberian Medical Health Product Regulatory Authority (LMHRA). Audits by sponsors or other entities were not noted.

9.4 Data Management Experience

All sites have a data management group under the remit of the research team.

9.5 Study Conduct and Support

9.5.1 Power Supply and Maintenance

All sites have a power supply and generators, with solar/UPS back-ups available. Power maintenance is performed at all sites except one.

9.5.2 Internet

All sites have internet available through a reliable Wi-Fi connection, except one site where it is noted to be unreliable.

Internet security is maintained with access by password authorized personnel only, except for one site.

9.5.3 Document Storage and Security

Document storage is access-controlled, and in locked cabinets with only authorized personnel granted access for most of the sites. Oversight is by the data manager at all sites apart from one site where the site manager performs the oversight.

9.5.4 Temperature Control

Air conditioning is used to control temperatures at all sites.

9.5.5 Investigational Product Storage and Transport

All sites have refrigerators for biological sample storage.

All sites have -20°C and -80°C freezers.

All freezers and refrigerators have a thermometer attached to them.

IP is transported using cooler boxes, and/or containers with thermometers. Dry ice is not easily available.

9.6 Subject Recruitment

Flyers, posters, radio jingles, talks shows are used for recruiting at most sites.

Retention is supported through participant trackers, home visits, texts, calls, and provision of transport as an incentive.

9.7 Site Staff

Full time staff are available at all sites. All relevant staff are required to be GCP trained.

Site SOPs are available for all except .

9.8 Laboratory Training, Medical Emergency Procedure

Laboratory training is in place; however, no laboratory certifications are available at any of the four (4) sites.

Three sites have medical emergency trollies but there is none in one site.

Medical emergency SOPs are in place in the three sites with emergency trollies, but maintenance is not consistently documented.

9.9 Vaccine Experience, Lassa Fever Experience

Two have vaccine experience. No site has had Lassa Fever experience up to the time of site assessment.

9.10 Liberia: Summary and Capacity Gaps

All four (4) sites assessed in Liberia are clinical research experienced and two (2) sites have vaccine research experience. No site has Lassa Fever experience. All sites have research staff who are GCP trained. Training SOPs are in place at three (3) out of the four (4) sites and training is tracked. All sites have been audited.

All sites have data management experience with a data management team in place and all have robust data storage and security. Laboratory training is in place at all sites, but no certification was available. At any site. All sites have IP storage and transport facilities with temperature controls in place.

Three (3) sites have medical emergency trollies and SOPs governing medical emergencies in place but routine maintenance is not documented. Only one (1) site has an isolation area.

All sites have good power supply form the national grid with back-up systems. Internet is reliable at all sites apart from one (1).

All sites work with local communities and community leaders to recruit and retain study subjects.

10.3 Audit

No audit experience. This site has never carried out clinical research.

10.4 Data Management Experience

There is a data manager on site in addition to two (2) computers dedicated to data collection.

10.5 Study Conduct and Support

10.5.1 Power Supply and Maintenance

The laboratory uses solar and batteries (Goalzero and UPS). There are two (2) generators in the event of power outages. No power maintenance process is in place.

10.5.2 Internet

The site does have internet, but the network is limited (often offline and unstable) and does not work effectively on Electronic Data Capture (EDC) or, IWRS. No internet security procedures are in place.

10.5.3 Document Storage and Security

Currently, there is a room in use for document storage, with AC, but secure document storage cabinets are not available. There are no document security procedures are in place.

10.5.4 Temperature Control

There is no temperature control procedure in place.

10.5.5 Investigational Product Storage and Transport

The site has a +4°C refrigerator and the laboratory has two (2) -80°C back-up freezers and two (2) generators for back-up power supply as noted above. IP can be transported within controlled temperatures using iceboxes, Credo Cubes, etc. as needed. Site staff have been trained in IATA and have valid certificates.

10.6 Subject Recruitment

Recruiters interact with community leaders and advertise via radio or the news. In addition, the hospital has a good network of social workers who are based in local villages. The hospital also works closely with remote health centres with nurses employed from the surrounding villages.

10.7 Site Staff

Site staff present includes: two (2) physicians; three (3) pharmacists; one (1) epidemiologists; one (1) laboratory scientist; eight (8) laboratory technicians; eight (8) other technical staff and two (2) support staff together with a laboratory QA person, a safety officer and a stock manager. No site SOPs were available.

10.8 Laboratory Training, Medical Emergency Procedure

The laboratory follows Strengthening Laboratory Management Toward Accreditation (SLIPTA) quality management with support from Centers for Disease Control (CDC). All staff are trained on biosecurity and biosafety, and GcLP. Several staff members are trained on RT-PCR (2-10 staff members), and ELISA (6 staff members)

No medical emergency trolley is available, however, an SOP for medical emergencies is in place.

10.9 Vaccine Experience, Lassa Fever Experience

This site does not have vaccine or clinical research experience. It does have access to CTEP, which has an isolation room, screening areas and a total capacity of 24, and can increase capacity for an outbreak. There have been two lethal Lassa fever cases at this site.

10.10 Guinea: Summary and Capacity Gaps

This site is not clinical research experienced but does have some Lassa Fever experience. There is a range of staff on-site but clinical research and GCP knowledge and experience are lacking. Training SOPs are not available. This site has not been audited.

This site does have a data manager in place but does not have adequate data storage facilities or security. Laboratory training is in place for lab staff, including GcLP and IATA certification. There are some IP storage and transport facilities in place. No site temperature control and monitoring are in place.

This site does not have a medical emergency trolley but there is an SOP governing medical emergencies in place. It does not have an isolation area.

The laboratory uses solar and batteries for power with back-up generators. No power maintenance process is in place. Internet is unreliable.

This site works with local communities and community leaders to recruit and retain study subjects and utilises a network of health centres in local areas for referrals.

11. Sierra Leone



11.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
34 Military Hospital	Wilberforce, Freetown	Urban	16 May 2019
Connaught Hospital College/College of Medicine and Health Sciences	Freetown	Urban	11 June 2019
Kenema Government Hospital	Kenema	Rural	21 June 2019

11.2 Ethical Considerations

11.2.1 Regulatory Considerations

A national ethics committee (EC) is in place. The timeline for approval is about one to three (1-3) months and submission is required three (3) weeks before the review meeting. The Pharmacy Board, Sierra Leone (PBSL) is also required to provide authorisation and import licenses, etc.

11.2.2 Guardian Verification and Community Engagement

In all sites, a family member can verify guardianship while in one site a community leader can verify guardianship. At one site, community engagement is required prior to starting a study, at one it is preferred and at a third site it is not required..

11.3 Audit

Two sites have been through audits with two sponsors. One site has had only site assessments.

11.4 Data Management Experience

One site has some data management experience, however there are no SOPs in place.

The other two sites have data management experience but do have data entry personnel.

11.5 Study Conduct and Support

11.5.1 Power Supply and Maintenance

All sites have power supply through national providers, however, all sites experience frequent power outages.

One site has two (2) back-up generators available and has daily maintenance checks, but no written procedures.

The other two sites have no reliable power back-up systems available.

11.5.2 Internet

Wi-Fi or a dongle is unreliable in two of the sites, while one site does not have internet access used for internet access, however it is unreliable.

11.5.3 Document Storage and Security

One site has some fireproof and waterproof document storage available, with controlled/restricted access, in addition to some long-term storage facilities.

One other site has some fireproof and waterproof document storage available with controlled/restricted access, but no long-term off-site storage.

There is no specified document storage area available at the third site.

11.5.4 Temperature Control

Two sites were in the process of setting up temperature control systems with monitoring logs at the time of the site assessment. There is currently air conditioning at both sites with regular temperature checks.

There is no temperature control system in place at one site.

11.5.5 Investigational Product Storage and Transport

One site has a dedicated temperature-controlled IP storage area with regular checks. It has three (3) freezers and two (2) fridges. A triple packaging system is used with ice packs as back-up for transport.

At the other two sites, little information exists in relation to IP storage.

One site uses ice packs for transport.

One site does not have an IP transport system in place.

11.6 Subject Recruitment

One site has no routine recruitment strategy in place, but they use radio, religious and community leaders to help with recruitment from the locality. For retention, community and religious leaders follow up with participants, who may also be given cell phones.

Neither of the other two sites have a recruitment plan in place. One site uses phone calls for follow-up of study subjects.

11.7 Site Staff

All three sites have a wide range of staff available including: physicians; infectious disease specialists; pharmacists; epidemiologists; nurses; data entry officers; clinical research coordinators; and other staff (e.g. laboratory scientists and technicians, field workers, and support staff).

At two sites there are some training SOPs and logs available, however, no SOPs or trainings logs are available at one of the site.

All three sites have researchers with experience in clinical research.

11.8 Laboratory Training, Medical Emergency Procedures

At one site, the World Health Organization (WHO) guidance for PPE is followed. There are some sponsor SOPs available together with IATA and RT-PCR certification.

There is also PPE training available at one of the other sites, but no SOPs are in place.

There is a medical emergency trolley available at one site, however no availability at the other two sites.

11.9 Vaccine Experience, Lassa Fever Experience

One site was involved in a Lassa fever study at the time of the site assessment.

One site has limited experience in vaccine research or in epidemics.

One site was involved in an Ebola trial during the Ebola outbreak.

11.10 Sierra Leone: Summary and Capacity Gaps

All three (3) sites assessed in Sierra Leone have some clinical research experience and some vaccine experience. One site has Lassa Fever experience. Training SOPs are in place at two (2) sites (some SOPs at one of these sites), including for GCP, and training is tracked. Two (2) sites have been audited.

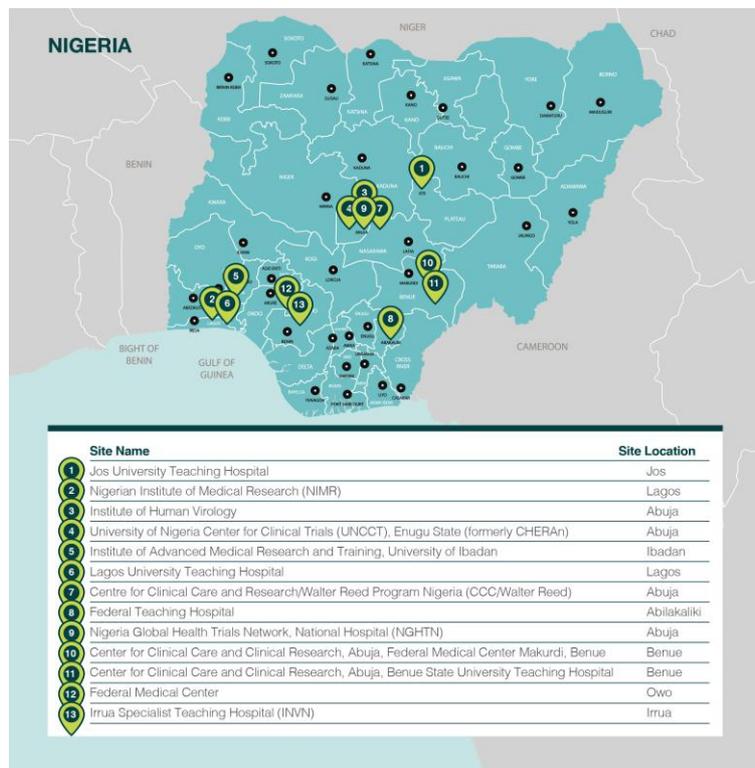
One (1) site has some data management experience (but no SOP) and does have some data storage and security. Neither of the other two (2) sites have data management experience (one of these does have some data storage and security in place). Laboratory training SOPs are present at one (1) site as is IATA certification. This site also has some IP storage and transport facilities. Two sites were in the process of setting up temperature controls and monitoring procedures at the time of assessment.

One (1) site has a medical emergency trolley. Only one (1) site has an isolation area.

All sites have a power supply from the national grid, but it is unreliable. Internet is available at two (2) sites but it is unreliable, and the third site does not have internet.

Only one (1) site noted a strategy for recruiting subjects.

12. Nigeria



12.1 Study Sites and Visit Date

Site Name	Site Location	Site Type (Urban/Rural)	Site Visit Date
Jos University Teaching Hospital (Jos)	Jos	Urban	13 June 2019
Nigerian Institute of Medical Research (NIMR)	Lagos	Urban	22 May 2019
Irrua Specialist Teaching Hospital (Irrua)	Irrua	Rural	19 June 2019
Institute of Human Virology, Abuja (IHVN)	Abuja	Urban	11 July 2019
University of Nigeria Center for Clinical Trials (UNCCT), Enugu State (formerly CHERAn)	Abuja	Urban	27 June 2019
Institute of Advanced Medical Research and	Ibadan	Urban	17 June 2019

Training, University of Ibadan (Ibadan)			
Lagos University Teaching Hospital	Lagos	Urban	3 July 2019
Centre for Clinical Care and Research/Walter Reed Program Nigeria (CCC/Walter Reed)	Abuja	Urban	24 June 2019
Federal Teaching Hospital (Federal Abilakaliki)	Abilakaliki	Urban	17 July 2019
Nigeria Global Health Trials Network, National Hospital (NGHTN)	Abuja	Urban	2 October 2019
Center for Clinical Care and Clinical Research, Abuja, Federal Medical Center Makurdi, Benue (Federal Benue)	Benue	Urban	27 May 2019
Center for Clinical Care and Clinical Research, Abuja, Benue State University Teaching Hospital (Benue, Abuja)	Benue	Urban	28 May 2019
Federal Medical Center, Owo, Ondo State (Owo)	Owo	Rural	9 September 2019

12.2 Ethical Considerations

12.2.1 Regulatory Considerations

Ethics committee review processes and bodies vary from site to site with most sites having a three (3) month approval timeline.

12.2.2 Guardian Verification and Community Engagement

Methods of guardian verification mentioned include identification cards, questioning minors about their relationship, consulting community leaders, subject interviews, etc.

All sites noted that community engagement is required. Calls to community chiefs and/or leaders, government and local leaders are made and permission requested to contact local subjects.

12.3 Audit

Nine sites have been through at least one or more audits.

12.4 Data Management Experience

Most sites have some data management experience, but none was noted for three sites. IWRS experience varies.

12.5 Study Conduct and Support

12.5.1 Power Supply and Maintenance

Eight (8) of the thirteen (13) sites assessed get their power supply from the national grid with back-up generators and/or UPS.

At one site, power is supplied by an independent power supplier and back-up generators are also in place. At four sites, power is supplied by generators.

12.5.2 Internet

All sites except two have internet availability.

Passwords and firewalls are used for internet security at most sites.

12.5.3 Document Storage and Security

Most sites store documents in fire and waterproof document storage cabinets with controlled/restricted access.

Three sites did not have information on document storage and security.

12.5.4 Temperature Control

Temperature is controlled using air conditioning at most sites. Some sites have temperature monitoring in place.

12.5.5 Investigational Product Storage and Transport

IP storage varies across sites, but all sites have refrigerators and a range of freezers available.

IP transport is primarily done using cool boxes, ice boxes and couriers.

12.6 Subject Recruitment

In general, sites rely heavily on community engagement using various tools such as flyers, referrals, community awareness and field workers.

Retention is supported using tracking, telephone calls, incentives and text message reminders.

12.7 Site Staff

Only one site has full-time dedicated research staff. All other sites have a range of staff available but on a part-time basis only, with time allocation varying from 12.5–25 hours a week.

Most of the sites have an experienced PI with detailed knowledge of GCP and research experience.

12.8 Laboratory Training, Medical Emergency Procedures

Laboratory certification is not present or lacking at many sites. GCP training is available for most sites. Not all sites have training SOPs available.

Medical emergency trollies are available at all sites; however, maintenance procedures and medical emergency SOPs are not routinely in place.

12.9 Vaccine Experience, Lassa Fever Experience

Only one site has Lassa Fever experience.

Five sites noted vaccine experience while eight reported none.

12.10 Nigeria: Summary and Capacity Gaps

Five (5) sites assessed in Nigeria are vaccine research experienced (one (1) of these was a mock vaccine trial). One site has Lassa Fever experience. They all have research staff who are GCP trained but only one (1) site has full-time dedicated research staff. SOPs are in place at nine (9) out of the -thirteen (13) sites. Eight (8) out of the thirteen (13) sites have been audited.

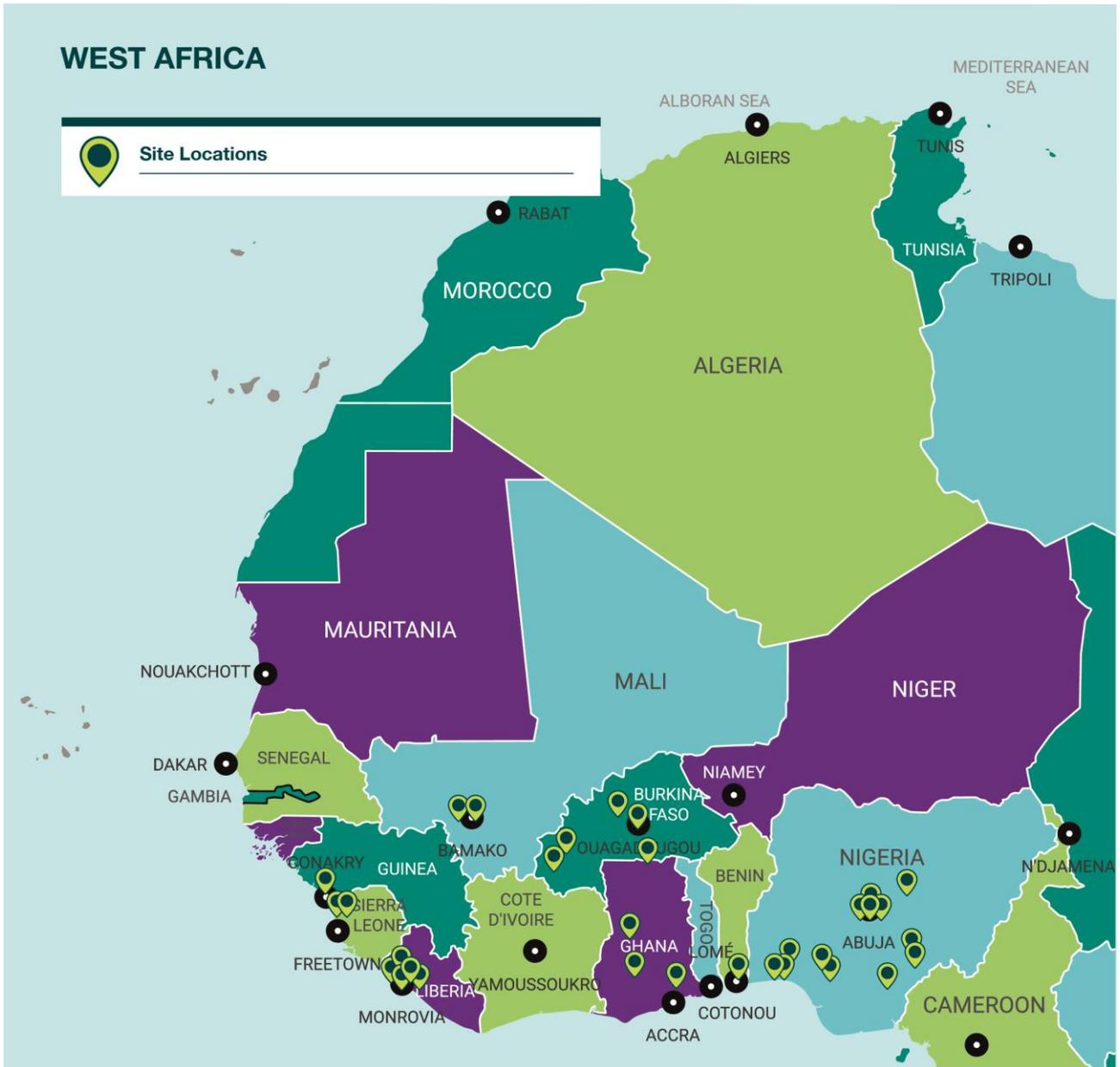
Most (ten) sites have data management experience and nine (9) have good data storage and security. Laboratory training tracked at all sites but four (4) sites do not note any certification. All sites have some form of IP storage and transport facilities. Temperature controls and monitoring are in place at most sites.

All sites have medical emergency trollies but maintenance records and SOPs governing medical emergencies were only in place at some sites. Only one (1) site noted an isolation area.

Eight (8) sites have good power supply form the national grid with back-up systems. Internet is available at all sites but two (2).

All sites work with local communities and communities to recruit and retain study subjects.

Appendix 1: Map of West Africa with All Sites



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