

INTERNATIONAL RESEARCH CENTER OF EXCELLENCE/ INSTITUTE OF HUMAN VIROLOGY NIGERIA
CLINICAL TRIAL SITES PROFILE

Established cohort: Well-characterized cohorts relevant for HIV vaccine, prevention, and treatment studies have been established across the clinical trial sites (CTS) and are summarized below. These developed cohorts include key populations such as men who have sex with men (MSM); HIV positive pregnant women engaged in PMTCT services; and HIV sero-discordant couples.

IRCE Abuja Clinical Trial Site (IAB-CTS)

Years of experience	8
Thematic areas	HIV, TB, Malaria, Non-communicable diseases and Lassa fever
Number of trials	2
Trial phases	Phase 3 and 4
Laboratory certifications	ISBER certification
Research team members	Prof Abimiku Alash'le, Dr. Eriobu Nnakelu; Dr. Okpokoro Evaezi; Ms. Maryam Almuftaba, Dr. Gbenga Kayode; Dr. Elima Jedy-agba, Pharm Avong Yohanna, Ms. Uzoamaka Oguama, Ms. Osa-Afiana Chinye, Ms. Osawe Sophia and Dr. James Onyemata
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Description of clinical trial site	This site has the following: 2 large clinical rooms, 3 cubicles of moderate size (i.e. for vital signs, vaccination and sample collection) 1 board room and 1 conference room, office workspaces, pharmacy, IT support services, data center, reference laboratory services and 1 ISBER certified biorepository.
Laboratory infrastructure	Well-equipped reference laboratory and biorepository that is ISBER compliant for long term storage of serum, plasma and viable cells. There are several -20 and -80 degrees celsius freezers with 24hrs monitoring for temperature excursions.
Data storage and security	There is a dedicated data center at IAB-CTS where regulatory binders and case report forms are stored in fire and waterproof cabinets. These rooms are securely locked. Also, there are dedicated pass-worded tablets installed with e-case report forms for electronic data capture.
IT infrastructure	There is 24-hour dedicated internet service. The telephone system connects via IP. Full video and teleconferencing facilities are available at the IAB-CTS.
Field operations	To access the participants, the IAB-CTS has at its disposal 20 on-site vehicles, comprising 5 pick-up vans, 13 SUVs and 2 buses.

Power, back-up systems and security	The site is equipped with a standby generator and inverters. In case of a power failure, the inverter switches on automatically pending when the generator comes on. The security architecture of IAB-CRS is outsourced to a security firm that provides 24 hours coverage. There are over 10 security officers on duty at any point in time. In addition, the IAB-CTS has the premises monitored by closed-circuit television (CCTV) cameras. All entry doors at IRCE are access controlled.
Examples of Trials completed	Strategic Timing of Antiretroviral Treatment (START Study) For enquires on the START study, Contact Dr. Eriobu Nnakelu Email: neriobu@ihvnigeria.org
Examples of Trials ongoing	Dolutegravir and Darunavir Evaluation in adults Failing Therapy (D2EFT study) For enquires on the D2EFT study, Contact Dr. Eriobu Nnakelu Email: neriobu@ihvnigeria.org

IRCE Jos Clinical Trial Site (IJS-CTS)

Years of experience	10
Thematic areas	HIV, TB, Malaria, Non-communicable diseases and Lassa fever
Number of trials	2
Trial phases	Phase 3 and 4
Laboratory certifications	ISO15189 accreditation
Research team members	Prof Abimiku Alash'le, Dr. Eriobu Nnakelu; Dr. Okpokoro Evaezi; Ms. Maryam Almuftaba, Dr. Gbenga Kayode; Dr. Elima Jedy-agba, Pharm Avong Yohanna, Ms. Uzoamaka Oguama, Ms. Osa-Afiana Chinye, Ms. Osawe Sophia and Dr. James Onyemata
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Description of clinical trial site	The IJS-CTS has the following: 3 clinical cubicles of moderate size, 1 conference room, office workspaces, different laboratories (ISO15189 accredited), and 1 biorepository. The clinic rooms are well ventilated and equipped with examination couch, weighing scales, thermometer, appropriate tables and chairs. The phlebotomy room is adjacent to the laboratory.
Laboratory infrastructure	Well-equipped reference laboratory that is ISO15189 accredited. It has facilities for long term storage of serum, plasma and viable cells. There are

	several -20 and -80 degrees celsius freezers with 24hrs monitoring for temperature excursions.
Data storage and security	There is a dedicated data management room in IJS-CTS where regulatory binders and case report forms are both stored in fire and waterproof cabinets.
IT infrastructure	There is a dedicated internet service that has the capacity to provide internet service for 24 hours. The telephone system connects via IP. Full video and teleconferencing facilities are available at the IJS-CTS
Field operations	To access participants, the IJS-CTS has 5 on-site vehicles, comprising 2 pick-up vans and 3 SUVs vehicles. These dedicated vehicles are serviced routinely and a maintenance record is kept.
Power, back-up systems, and security	The IJS-CTS has on-site security provided by the presence of two-day duty guards. The premises are monitored by closed-circuit television (CCTV) cameras. There is access control at the site. The site is equipped with a standby generator and inverters. In case of a power failure, the inverter switches on automatically pending when the generator comes on to ensure uninterrupted power supply.
Examples of Trials completed	Efficacy and safety of efavirenz 400 mg daily versus 600 mg daily: 96-week data from the randomised, double-blind, placebo-controlled, non-inferiority (ENCORE1 study); Second line study; Kaletra study For enquiries on the above studies Contact Ms. Osawe Sophia. Email: sosawe@ihvnigeria.org
Examples of Trials ongoing	Nil