AC^{3}T Online Profile
September 2019

Driven by Africa - for Africa - the African Access Initiative (AAI) is a partnership of companies, governments, healthcare providers, and nonprofit organizations focused on building sustainable access to cancer treatments. Using data generated at the country level by African hospitals and governments, AAI is expanding access to cancer medicines and technologies, strengthening healthcare infrastructure, and building clinical oncology capacity in Africa.

Under the purview of AAI, BIO Ventures for Global Health (BVGH) launched the African Consortium for Cancer Clinical Trials (AC^{3}T) to foster and implement cancer clinical trials led by African investigators. AC^{3}T is designed to build clinical trial capacity, address the cancer data gap in Africa, and improve access to prioritized cancer diagnostics, medicines, and quality treatment for African patients.

This document was developed to survey African institutions' clinical trial capabilities – with a focus on cancer. The results of each institution's survey will be condensed into an online profile, which will be published on a publicly-accessible website managed by BVGH. This website, and the profiles contained therein, will be promoted to pharmaceutical and biotechnology companies, academic researchers, and oncology experts to encourage those organizations to conduct clinical trials of their innovative cancer products at one or more of the profiled African institutions.

Please complete the following form to the best of your ability. If you or anyone at your institution has questions, please do not hesitate to contact BVGH at dseymour@bvgh.org. Thank you for participating in the AC^{3}T program.

Section #1: Institution Information

	Institution name	
	Address	
	City	
	Province, state, or territory (if applicable)	
	Postal code (if applicable)	
	Country	
	Institution representative last (family) name	
	Institution representative first (given) name(s)	
	Institution representative title(s) (e.g., Head, Oncology Department)	
	Institution representative email address	
	Institution representative phone number (with country code)	
	Institution representative fax number (with country code)	

Institution type:

☐ Public hospital
☐ Private hospital
☐ University or academic center
☐ Government research institution
☐ Private research institution
☐ Other (please specify): _____

Therapeutic areas addressed by institution (check all that apply):

☐ Cardiology
☐ Ear, nose, and throat
☐ Gastroenterology
☐ General surgery
☐ Gynecology
☐ Hematology
☐ Microbiology
☐ Neonatology
☐ Nephrology
☐ Neurology
☐ Nutrition
☐ Obstetrics
☐ Occupational therapy
☐ Oncology
☐ Ophthalmology
☐ Orthopedics
☐ Pain
☐ Physiotherapy
☐ Urology
☐ Other (please specify): _____

Number of patients served per year (if applicable)	
Regions served by institution (define the patient catchment area at the sub-national, national, or international level)	
Number of beds at institution (if applicable)	
Number of staff members at institution	Clinical staff: _____ Administrative staff: _____ Support (facilities, security, etc.) staff: _____

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Section #2: Institution Clinical Trial Experience

	Past clinical trials conducted at institution (Please list and provide details for up to three clinical trials that have recently been conducted at your institution)	**Clinical Trial #1** Indication: _____ Intervention: _____ Study phase: _____ URL to online study documentation: _____ URL to published results and/or references: _____
		Clinical Trial #2 Indication: _____ Intervention: _____ Study phase: _____ URL to online study documentation: _____ URL to published results and/or references: _____
		Clinical Trial #3 Indication: _____ Intervention: _____ Study phase: _____ URL to online study documentation: _____ URL to published results and/or references: _____
	Institution is affiliated with a network, site management organization (SMO), clinical research organization (CRO), etc.?	☐ Yes ☐ No
	List of networks, SMOs, and CROs affiliated with your institution.	1. _____ 2. _____ 3. _____
	Institution has received research grant(s) from national funders	☐ Yes ☐ No
	Institution has received research grant(s) from international funders	☐ Yes ☐ No
	Sponsors for past clinical trials conducted at institution (select all that apply): ☐ Academic ☐ Government ☐ Industry ☐ Investigator-initiated ☐ Other (please specify): _____ ☐ None ☐ Not applicable	
	Types of past clinical trials conducted at institution (select all that apply): ☐ Behavioral ☐ Epidemiological ☐ Diagnostic ☐ Drug ☐ Observational ☐ Surgical ☐ Vaccine ☐ Other (please specify): _____ ☐ None ☐ Not applicable	
	Study phase capabilities at institution (select all that apply)	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ None
	Institution has pediatric research capabilities (if applicable)	☐ Yes ☐ No ☐ Not applicable

Section #3: Institution Regulatory/Research Ethics Committee

	Institutional review board (IRB)/independent ethics committee (IEC) name or entity that performs this function	
	How often does the IRB/IEC meet?	

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	Local or Central IRB/IEC	□ Central □ Local □ Other (please specify): _____
	IRB/IEC application approval turn-around time (in weeks)	
	IRB/IEC in compliance with ICH E6(R2) (in terms of composition, functions, and operations guidelines)	□ Yes □ No
	Institution and/or local regulation mandates the distribution of study safety reports (e.g., development safety update report [DSUR], suspected unexpected serious adverse reactions [SUSAR]) to the IRB/IEC for review	□ Yes □ No
	If no, who reviews study safety reports?	
	Average total time from receipt of the final protocol to review and approval of a study by relevant committees (in weeks)	
	Brief description of other committee(s) (if any) that must review a clinical trial at your institution prior to approval	

Section #4: Institution Staffing Resources

	Institution has staff member(s) that performs study site coordination and manages daily operational activities	□ Yes □ No Title (e.g., Research Coordinator): _____ If yes, number on site:_____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has staff member(s) that prepares and administers study drug (i.e., maintaining study blind)	□ Yes □ No Title (e.g., Research Nurse): _____ If yes, number on site:_____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has staff member(s) that collects and processes study data and maintains data integrity	□ Yes □ No Title (e.g., Research Data Manager): _____ If yes, number on site:_____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has staff member(s) that monitors site processes and ensures quality	□ Yes □ No Title (e.g., Quality Assurance Manager): _____ If yes, number on site:_____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)

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	Institution has biostatisticians on site	□ Yes □ No If yes, number on site: _____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has database programmers on site	□ Yes □ No If yes, number on site: _____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has epidemiologists on site	□ Yes □ No If yes, number on site: _____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has pathologists on site	□ Yes □ No If yes, number on site: _____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Institution has pharmacists on site	□ Yes □ No If yes, number on site: _____ □ At least one has experience with clinical trials □ At least one has formal training in Human Subjects Protection (HSP) □ At least one has formal training in Good Clinical Practice (GCP) □ At least one has formal training in Good Clinical Laboratory Practice (GCLP)
	Staff members with experience conducting clinical trials as a lead investigator	Staff member #1 name: _____ Staff member title: _____ Staff member email address: _____ Brief description of staff member's expertise: Brief description of staff member's recent clinical trial experience:
		Staff member #2 name: _____ Staff member title: _____ Staff member email address: _____ Brief description of staff member's expertise: Brief description of staff member's recent clinical trial experience:

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		Staff member #3 name: _____ Staff member title: _____ Staff member email address: _____ Brief description of staff member's expertise: Brief description of staff member's recent clinical trial experience:

Section #5: Institution Diagnostic Capabilities and Equipment

	Institution has laboratory on site	☐ Yes ☐ No
	Institution sends diagnostic samples to external laboratory	☐ Yes ☐ No If yes, which external lab(s): _____
	Does your institution have personnel capable of performing diagnostic biopsies?	☐ Yes ☐ No
	Which of the following are performed at your institution? (check all that apply)	☐ Pleural tap ☐ Abdominal tap ☐ Lumbar puncture (spinal tap) ☐ None
	Institution's laboratory accreditations (check all that apply)	☐ College of American Pathologists (CAP) ☐ Clinical Laboratory Improvement Amendments (CLIA) ☐ Good Laboratory Practices (GLP) ☐ International Organization for Standardization (ISO) ☐ Other (please specify): _____ ☐ None
	Institution's laboratory has been inspected or audited	☐ Yes ☐ No If yes, date of last inspection or audit: _____ Frequency of inspections or audits: _____ Entity that performs inspections or audits: _____
	Institution's laboratory conducts complete blood count (CBC) with differential	☐ Yes ☐ No
	Institution's laboratory conducts comprehensive metabolic/chemistry panel (CMP)	☐ Yes ☐ No
	Institution's laboratory conducts routine urinalysis	☐ Yes ☐ No
	Institution has the following imaging capabilities (check all that apply):	
	☐ Computed tomography (CT) ☐ Magnetic resonance imaging (MRI) ☐ Positron emission tomography (PET) ☐ Nuclear imaging ☐ Ultrasound	☐ X-ray ☐ Pediatric imaging ☐ Other (please specify): _____ ☐ None ☐ Not applicable
	Institution can perform the following diagnostic laboratory tests (check all that apply):	
	☐ Histology ☐ Immunohistochemistry (IHC) ☐ Antibiotic sensitivity ☐ Flow cytometry	☐ Microscopy ☐ Bacterial culture ☐ None ☐ Not applicable

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	Institution has the following functional laboratory equipment (check all that apply): □ Autoclave □ Autostainer □ Centrifuge □ Refrigerated centrifuge □ Clinical chemistry analyzer □ Cyrostat □ Dry ice supply □ Flammable storage cabinet □ Flow cytometer □ Freezer (-20 to -30°C) with daily temperature monitoring □ Freezer (-70 to -80°C) with daily temperature monitoring □ Fume hood □ Grossing station □ Hygrometer □ Incubator (30L, up to +80°C) □ Lab oven □ Laboratory analyzer □ Microscope □ Microtome □ Microwave □ PCR and/or RT-PCR machine □ Refrigerator (+2 to -8°C) □ Rotator □ Spectrophotometer □ Tissue culture hood □ Tissue embedding unit or station □ Tissue processor □ Water bath	
	Institution has functioning IV infusion pumps	□ Yes □ No
	Institution has functioning basic life support equipment (crash cart)	□ Yes □ No
	Institution has functioning electrocardiogram (EKG)	□ Yes □ No
	Institution's equipment is calibrated and maintained per manufacturer's guidelines	□ Yes □ No
	Institution's equipment calibration and maintenance is documented	□ Yes □ No
	Institution's laboratory has a secure, limited access biological specimen storage area with daily temperature monitoring	□ Yes □ No
	Institution's laboratory has a backup power source, with alarm, sufficient to run necessary equipment, refrigerators, freezers, etc.	□ Yes □ No
	Institution maintains and uses a diagnostic imaging protocol manual	□ Yes □ No
	Laboratory maintains and uses a laboratory protocol manual?	□ Yes □ No
	Does your institution have a policy for documenting all procedures conducted and the corresponding results?	□ Yes □ No

Section #6: Institution Cancer Treatment Capabilities and Equipment

	Institution treats cancer patients	□ Yes □ No
	Institution performs surgical excisions to treat cancer patients	□ Yes □ No
	Institution has the ability to administer chemotherapy to treat cancer patients	□ Yes □ No
	Institution uses radiation therapy to treat cancer patients	□ Yes □ No
	Institution has the following radiotherapy machines on site (check all that apply)	□ Linear accelerator □ Cobalt 60 □ Brachytherapy machine □ Other: _____
	Institution has a protocol for managing anaphylactic shock	□ Yes □ No

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	Institution has a blood bank	☐ Yes ☐ No
	Institution carries out blood transfusions for patients that need it	☐ Yes ☐ No ☐ Not applicable
	Availability of banked blood at institution	☐ Always available ☐ Occasionally available ☐ Rarely available ☐ Not applicable
	Institution performs the following routine blood screening tests on banked blood (check all that apply): ☐ HIV ☐ HBV ☐ HCV ☐ HPV ☐ HTLVI ☐ HTLVII ☐ Syphilis ☐ Other: _____ ☐ None ☐ Not applicable	

Section #7: Institution Pharmacy

	Institution has pharmacy on site	☐ Yes ☐ No
	Institution's pharmacy has secure, limited access storage area with daily temperature monitoring and backup generator	☐ Yes ☐ No
	Institution's pharmacy has standard processes in place to ensure proper receipt, handling, and storage of investigational study drug and comparators	☐ Yes ☐ No
	Institution's pharmacy has standard processes in place to ensure proper dispensing	☐ Yes ☐ No
	Institution's pharmacy has standard processes in place to ensure proper labeling that maintains the study blind (if applicable)	☐ Yes ☐ No
	Institution's pharmacy has standard processes in place to ensure proper drug accountability, retrieval, and return or destruction of unused product	☐ Yes ☐ No
	Institution has a secure, limited-access investigational drug (test article and comparators) storage area with daily temperature monitoring	☐ Yes ☐ No
	Institution's pharmacy has a backup generator sufficient to run necessary equipment, refrigerators, freezers, etc.	☐ Yes ☐ No

Section #8: Institution Research Systems, Recordkeeping, and Data Management

	Institution adheres to informed consent processes compliant with ICH E6(R2)	☐ Yes ☐ No
	Institution follows ICH E6(R2) for collection and storage of source documentation for paper and/or electronic records	☐ Yes ☐ No
	Institution stores patient records/source documents (paper/electronic) in a secured, limited access location during and after the trial	☐ Yes ☐ No

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	For source documents collected via electronic data capture, institution has a validated system and site procedures that follow ICH E6(R2) 5.5 guidelines (including providing an audit trail for all entry and modifications, maintaining a list of personnel authorized to make data changes, and safeguarding blinding)	□ Yes □ No □ Not applicable
	Institution has process in place for proper storage, archiving, and retrieval of essential study documents per ICH 8.1 (including document identification, version history, search, and retrieval)	□ Yes □ No □ Not applicable
	Institution study monitors have full access to source documents or certified copies of source documents (if electronic) if direct access can't be obtained	□ Yes □ No
	Institution has the ability to process, store, and ship biological specimens	□ Yes □ No
	Institution study staff that prepares or transports dangerous goods has training that meets the International Air Transport Association (IATA) (USA) or other countries' hazardous training requirements for shipping dangerous goods	□ Yes □ No
	Institution has a finance administration team	□ Yes □ No
	Institution undergoes routine financial audits	□ Yes □ No
	Institution uses satellite sites (other patient treatment sites where the trial primary investigator and/or sub-investigator will conduct the research trial)	□ Yes □ No
	Institution has a study drug shipment, transport, and storage SOP in place for satellite sites	□ Yes □ No □ Not applicable
	Institution has a primary investigator oversight process in place at satellite sites	□ Yes □ No □ Not applicable

Section #9: Additional Institution Information

	Institution's additional areas of strengths (e.g., effective recruitment methods, specializing in pediatric oncology, etc.)	

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Permission and Submission

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Prior to publishing an institution's information online, BVGH will share a draft of the online profile with the institution's primary representative. The institution will be asked to review the profile and to provide feedback or requested changes within one week of receiving the draft profile.

To ensure the accuracy of an institution's information, BVGH will conduct annual reviews of the institution's profile, and may contact the institution's primary representative for updates as necessary.

Typing your institution and name below and submitting this form constitutes an electronic signature, wherein you confirm that:

- You are authorized to sign on the behalf of your institution and agree to be your institution's primary representative for AC^{3}T
- Your institution has read and agrees to the contents of this document
- BVGH has permission to publish your institution's AC^{3}T questionnaire information on the public AC^{3}T website
- A representative of your institution will provide BVGH with updates, as necessary, to information covered in the AC^{3}T online profile

Institution Name: _____

First and Last Name: _____

SUBMIT

If you or anyone at your institution has questions, please do not hesitate to contact BVGH at dseymour@bvgh.org. Thank you for participating in the AC^{3}T program.