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Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

1 Center names and contacts

Clinical Research Center, Butembo, Nord-Kivu, DRC (CRC, Butembo, DRC)	Dr. E. Kanza, kanzavira1@yahoo.fr , kanzaeric@gmail.com Dr. K. Kasonia, mbalekasonia@yahoo.fr ; Dr. S.L. Masembe; drsmasembe@yahoo.com ; safari_masembe@yahoo.fr Dr. M. Mumbere; mupjahman80@yahoo.fr
Centre de Recherche en Maladies Tropicales de l'Ituri (CRMTI, Rethy, DRC)	Dr. Michel Mandro Ndahura <i>Chef de Bureau Inspection&Contrôle et Associé de Recherche Clinique, Division Provinciale de Santé de l'Ituri</i> mandhura@yahoo.fr Dr. Tony Ukety, tony.ukety@gmail.com
Liberia Institute for Biomedical Research, Clinical Research Center, Bolahun, Liberia	Dr. F. Bolay director.libr@gmail.com , bolayf@yahoo.com ,
Onchocerciasis Chemotherapy Research Center, Hohoe, Ghana (OCRC, Hohoe, Ghana) NOW: School of Public Health, University of Health and Allied Sciences Research Centre (UHASRC)	Dr. N. Opoku University of Health and Allied Sciences Research Centre (UHASRC) Hohoe, Volta Region, Ghana opokuopn@hotmail.com OCRC was established in 1976. For more information on the research conducted since, see below and search pubmed for publications by Dr. Kwablah Awadzi and Dr. N. Opoku.

2 Other Sources of Information

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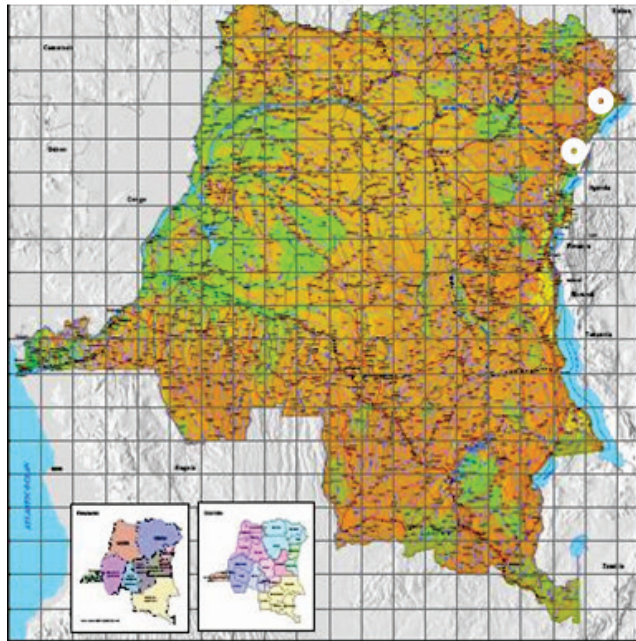
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3 Center locations

Rethy, Ituri Nord, DRC
Butembo, Kivu Nord, DRC



Bolahun, North West Liberia



Hohoe, Upper Volta Region, Ghana



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4 Infrastructure

4.1 Major equipment common to all sites

Clinical evaluation equipment	12 lead ECG (with backup) Sphygmomanometers Stethoscope Emergency medical kit (Statkit 900)
Ophthalmological equipment	Visual acuity chart (illiterates) Binocular loupe Direct ophthalmoscope Indirect ophthalmoscope Slit lamp Tonometer FDT perimeter (visual field assessment)
Laboratory equipment	2 Hematology analyzers 2 Serum biochemistry analyzers 2 electrolyte analyzers 2 Clinitek® 50 Urine Chemistry Analyzers 2 Olympus compact inverted microscope binocular (11BF) with 10, 40 100 objective 2 Olympus CX21 FS, 1-2 Kit microscope binocular, with 10, 40. 100 objectives 1 Electronic analytical balance, 320g, 0.1mg 1 Benchtop centrifuge (unrefridgerated) 3 Cold boxes for sample transport 1 Water purification system (Reverse osmosis) 2 340 L reffridgerator (with out of range alarm) 2 100 L reffridgerator (with out of range alarm) 2 96 L Freezer to -25 C (with out of range alarm)
Office	1 Scanner-photocopier-printer 1 scanner 1 printer 1-2 lab top computers 3-4 desk top computers 1 LCD projector
Communication	Satellite dish with wired and wireless access to internet Codan HF radio Satellite phone

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Other	Voltage stabilizers 'UPS' Solar lighting kit Portable generator Back-up generator
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4.2 Other infrastructure characteristics

	Clinical Research Center, Butembo, Nord-Kivu, DRC (CRC, Butembo, DRC)	Centre de Recherche en Maladies Tropicales de l'Ituri (CRMTI, Rethy, DRC)	Liberia Institute for Biomedical Research, Clinical Research Center, LIBR CRC Bolahun, Liberia	Onchocerciasis Chemotherapy Research Center, Hohoe, Ghana (OCRC, Hohoe, Ghana)
Number of beds	24 - 30	50	15 - 20	20 – 25
Laboratories	Hematology / Biochemistry Parasitology	Hematology Biochemistry Parasitology	Hematology / biochemistry Parasitology	Hematology Biochemistry Parasitology Bacteriology In vitro
Other	Patient examination rooms Pharmacy for trial drug storage and dispensation	Patient examination rooms Pharmacy for trial drug storage and dispensation	Patient examination rooms Pharmacy for trial drug storage and dispensation	Patient examination rooms Pharmacy for trial drug storage and dispensation Minor surgery theater Emergency treatment room
Electricity provision	Public, with back-up generators	Public, with back-up generators	Generator (two) Building equipped for AC as well as DC current	Public, with 1 100KVA back-up generator
Transport	2 Toyota Landcruisers 1 Toyota pick-up 2 motorcycles	2 Toyota Landcruisers 5 motorcycles Ca. 10 bicycles	3 Toyota Landcruisers (one close to 'write off') 1 Toyota pick-up 10 motorcycles	3 Toyota Landcruisers 1 Volvo XC 90
Communication	Mobile phone net	Mobile phone net	Mobile phone net	Fix line phone and fax Mobile phone net
Conference room	Yes	Yes	Yes	Yes
Secure document storage	Yes	Yes	Yes	Yes
Water storage	Yes	Yes	Yes	3000 gallons water storage.

For more site specific information, please contact the sites.

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5 Diseases in the areas

	CRC Butembo, DRC	CRMTI, DRC	LIBR CRC, Liberia	OCRC, Ghana
Onchocerciasis	Y	Y	Y	Y
Malaria	Y	Y	Y	Y
Tuberculosis	Y	Y	Y	Y
Schistosomiasis	Y (intestinal)	Y (both)	Y	Y (urinary)
Cutaneous leishmaniasis	N			Y
Lymphatic Filariasis	N	N	Y	N
Intestinal helminths	Y	Y	Y (Ascaris, hookworm, trichuris)	Y(Hookworm)
HIV/AIDs and opportunistic infections	Y	Y	Y	Y
Other STD	Y	Y		Y
Leprosy	Y		Y	N
Buruli Ulcer	N			N
Tropical ulcer (Ulcère phagedénique)	TBD			N
Idiopathic tropical splenopathy (splénomégalie tropicale)	Y			Y
Epilepsy	Y	Y		Y
Plague	N	Y		Y
Amoebiasis, intestinal and hepatic	Y			Y
Yellow Fever	N		Y	N
Lassa Fever	N		Y	N
Glaucoma	Y		Y	Y
Malnutrition	Y			N
Diabetes	Y			Y
Hypertension	Y			Y
Hepatitis B	TBD			Y
Others	Typhoid fever Please contact site	Please contact site	Please contact site	Please contact site

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6 Site pictures

6.1 Centre de Recherche Clinique, Butembo, DRC



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6.2 Centre de Recherche en Maladies Tropicales de Ituri (Rethy, DRC)



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6.3 LIBR Clinical Research Center, Bolahun, Liberia



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6.4 Onchocerciasis Chemotherapy Research Center, Hohoe, Ghana; NOW School of Public Health, University of Health and Allied Sciences Research Centre (UHASRC)

FRONT VIEW



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6.5 Pictures of site infrastructure, equipment ...



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7 Research study related training and experience

7.1 All sites

Good Clinical Practice

Good Clinical Laboratory Practice

Informed consent with illiterate research participants

Data recording and reporting into a data base via remote data entry

Experience in writing Standard Operating Procedures (SOPs)

Standard Operating Procedures for clinical, laboratory / parasitology methods established at centers

7.2 University of Health and Allied Sciences Research Centre (UHASRC) (Formerly Onchocerciasis Chemotherapy Research Center)

The University of Health and Allied Sciences Research Centre (UHASRC) is located at Hohoe, Volta Region, Ghana, in the premises of the Hohoe Municipal Hospital. The centre was established in 1976 by the Ghana Ministry of Health in collaboration with the World Health Organization (WHO) under the name Onchocerciasis Chemotherapy Research Centre (OCRC).

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As the previous name suggests, the main focus has been on onchocerciasis research and the key objective was to conduct clinical trials to develop an effective, safe, and easy to use drugs for the control of onchocerciasis.

The centre played a major role in the development of the ivermectin (a microfilaricide) which is the drug used for the control and elimination of onchocerciasis. After completion of clinical development of ivermectin, the centre's focus shifted in 1986 to the development of a drug or drug combination with *Onchocerca volvulus* macrofilaricidal or macrofilaria-sterilizing activity and conducted Phase I-III clinical trials on the safety, tolerability, pharmacokinetic and efficacy of various drugs and drug combinations (metrifonate; furazolidone; nitrofurantoin desmethylmisonidazole; mebendazole; mebendazole-citrate flubendazole; albendazole; levamisole), including the investigational drugs amocarazine and moxidectin.

8 From OCRC to School of Public Health, University of Health and Allied Sciences, Volta Region, Ghana

With the establishment of the new University of Health and Allied Sciences in December 2011 in the Volta region, the centre has merged with the University's School of Public Health, which is currently located at the Hohoe Municipal Hospital. This has resulted in upgrading of the laboratory facilities which now includes 2 Selectra Pro M biochemistry analyzers, 1 3-count Sysmex kx-21 Haematology analyzer, 1 3-count Sysmex xs-500i Haematology analyzer, 2 Bactec Fx40 BD bacteriology machines, 3 centrifuges, 1 Fluorescence microscope, 2 inverted microscopes, 2 ordinary microscopes, 1 minus 70 degree freezer, 1 minus 30 degree freezer, 2 fridges, 2 fume cabinets. Research staff includes 2 clinicians, 2 epidemiologists, 3 biomedical scientists, 1 clinical trial specialist, 2 data managers, 2 data entry clerks, 3 laboratory technicians and 2 nurses.

As of middle of 2015, ongoing activities include a community study on the relative efficacy of ivermectin vs albendazole plus ivermectin against onchocerciasis, malaria vaccine research and Clinical Research Capacity building in Ghana in collaboration with the Noguchi Centre for Medical Research and the University of Copenhagen, Denmark. Plans underway for a Phase 2, randomised, observer-blind, controlled, multi-country study to assess the safety and immunogenicity of a single intramuscular dose of recombinant chimpanzee adenovirus Type 3-vectored Ebola Zaire vaccine in the centre.