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

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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  
Chef de Bureau Inspection&Contrôle et Associé de Recherche Clinique, Division Provinciale de Santé de l'Ituri  
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

Annette C. Kuesel  
UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases  
Phone: +41 22 791 1541  
Mobile: + 41 79 596 5718  
e-mail: kuesela@who.int
Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Equipment</th>
</tr>
</thead>
</table>
| 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 (unrefrigerated)  
3 Cold boxes for sample transport  
1 Water purification system (Reverse osmosis)  
2 340 L refrigerator (with out of range alarm)  
2 100 L refrigerator (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 |
## Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

<table>
<thead>
<tr>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage stabilizers</td>
</tr>
<tr>
<td>'UPS'</td>
</tr>
<tr>
<td>Solar lighting kit</td>
</tr>
<tr>
<td>Portable generator</td>
</tr>
<tr>
<td>Back-up generator</td>
</tr>
</tbody>
</table>

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

5 Diseases in the areas

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

Please contact site
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6 Site pictures

6.1 Centre de Recherche Clinique, Butembo, DRC
Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

6.2 Centre de Recherche en Maladies Tropicales de Ituri (Rethy, DRC)
Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

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)
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6.5 Pictures of site infrastructure, equipment …
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).
Profiles of Clinical Research Centers which conducted the Phase 3 study of moxidectin

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 (mefloquine; furazolidone; nitrofurantoin; desmethylmisonidazole; mebendazole; mebendazole-citrate flubendazole; albendazole; levamisole), including the investigational drugs amocarzine 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 Hoohoe 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.