

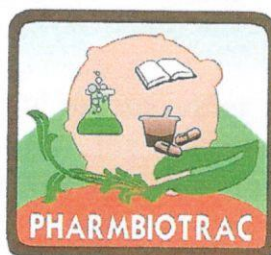
MEMORANDUM OF UNDERSTANDING

BETWEEN



Action for Natural Medicine - Anamed International

AND



**MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY (MUST),
PHARM-BIOTECHNOLOGY AND TRADITIONAL MEDICINE CENTRE
(PHARMBIOTRAC)**

**REGARDING
IMPLEMENTATION OF THE CONDUCT OF A SCIENTIFIC CLINICAL TRIAL STUDY OF
THE *Artemisia annua* L. EFFECT ON IMMUNOLOGICAL RESPONSE IN HAART HIV
PATIENTS**

F.R.

C.D. CUT

CAC

THIS MEMORANDUM OF UNDERSTANDING (MoU) is made this 13 day of May 2017 between the **ACTION FOR NATURAL MEDICINE - ANAMED INTERNATIONAL**, Schafweide 77, 71364 Winnenden, Germany, hereinafter referred to as ("**ANAMED**"), on the one part and the **MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY (MUST), PHARM-BIOTECHNOLOGY AND TRADITIONAL MEDICINE CENTRE (PHARMBIOTRAC)**, of P.O. Box 1410, Mbarara hereinafter referred to as ("**The Project Implementing Entity**") and where the context shall allow refer to its legal representatives, assignees and successors in title of the other part.

WHEREAS, ANAMED was initiated in 1986 by the German pharmacist Dr. pharm Hans-Martin Hirt and African healers. In the course of time they have been joined by many other active people in many countries of Africa and other continents. In 1994 the organisation "anamed international" was registered in Germany as the German equivalent of a charitable trust with its HQ in Winnenden to support the activities of ANAMED,

AND WHEREAS, ANAMED aim at contributing to the building of national and international networks for the exchange of information and experiences between those committed to Natural Medicine and that in every tropical country democratic and long-term groups are formed which are committed to the aims and principles of anamed,

AND WHEREAS, ANAMED run week-long seminars in the Tropics. Thus people are trained who subsequently train others and local Natural Medicine networks are developed. *Anamed* also writes, publishes and translates books about Natural Medicine,

AND WHEREAS, ANAMED promote among other topics the cultivation and use of *Artemisia annua* and Moringa, for the treatment of malaria, HIV/AIDS and malnutrition, the three main plagues of the development world,

AND WHEREAS, PHARMBIOTRAC is established at MUST as an Africa Higher Education Centre of Excellence under the World Bank's ACE II Project, aiming at strengthening quality of postgraduate training in Eastern and Southern Africa in the area of Pharm-biotechnology, traditional medicine/natural products and health sciences

AND WHEREAS, PHARMBIOTRAC is one of Uganda's leading African Centres of Excellence involved in training, research and community outreach in the fields of pharmaceutical biotechnology and traditional medicine science and technology for Societal Transformation.

AND WHEREAS, PHARMBIOTRAC's main objective is to build a critical mass of specialized and skilled human resource that can advance traditional medicine and Pharm-Biotechnology for socio-economic development of Africa, and the specific objectives include to;

PAC

- i. Strengthen capacity in the region to train highly skilled and specialized professionals in traditional medicine and Bio-pharmaceuticals,
- ii. Strengthen capacity in the region to engage in cutting edge research in TM and systems biology for health products development,
- iii. Create capacity in collaboration with private sector industry for development, production and commercialization of TM, biopharmaceuticals and nutraceuticals from research outputs,
- iv. Advance the practices of TM/TMK in the region and promote domestication and sustainable utilization of medicinal species.

AND WHEREAS, PHARMBIOTRAC has strong partnership with several local and international bodies including Universities, research organisations, government institutions, private sector and development partners.

AND WHEREAS, PHARMBIOTRAC has various initiatives including but not limited to clinical research of natural products, innovation incubation and research.

AND WHEREAS, PHARMBIOTRAC wishes to offer its skills and expertise to partner institutions to enhance the collaboration in clinical research and herbal product development.

AND WHEREAS, PHARMBIOTRAC is willing to strengthen collaboration and partnership because it has a lot in common to share.

NOW THEREFORE THIS MOU WITNESSETH AS FOLLOWS:

Article 1: General

The parties agree to partner and collaborate in the area of a randomised clinical study of the *Artemisia annua* L. effect on immunological response in adult HAART HIV patients in Uganda who after at least one year of antiretroviral treatment still have a low immunity with a CD4 value of 350 or less. The study will be a three arm placebo controlled trial. The control group will continue standard antiretroviral treatment. There will be one experimental group where *Artemisia annua* as capsules will be added, in the second experimental group *Artemisia annua* as capsules and Moringa leaf powder will be added to HAART. All patients will be treated for one year. The *main* objective of the study is to determine the effect of *A. annua* powder on the CD4 cell count and other immunological indices in HAART HIV patients with low immunity after at least one year of antiretroviral treatment.

a) Anamed International transferred the responsibility for the scientific study (mentioned in Article 1a) to Dr. Felicitas Roelofsen, resident at Grüner Weg 34, 50825 Köln, Germany. She is a retired cancer surgeon and has experience in coordinating scientific studies as a member of the Gastro Interstinal Tract Cooperative Group of the EORTC (European Organisation of Research and Treatment of Cancer),

b) Clinical studies of the *Artemisia annua* L. effect on immunological

response in pre-HAART HIV patients in Uganda will be conducted by a team of researchers/professionals from Mbarara University of Science and Technology under the overall coordination of Dr. Patrick Engeu Ogwang who is the Deputy Center Leader/Principal investigator of the Pharm-BioTechnology and Traditional Medicine Centre (PHARMBIOTRAC) Mbarara University of Science & Technology (MUST),

- c) The study protocol will be prepared by both the parties. It will be submitted for ethical approval and registration in Uganda by the Project Implementing Entity at MUST, and after ethical approval be registered at clinicaltrials.gov
- d) The study will be conducted at MUST, in Uganda; the local scientific investigators of the study guarantee the ethical scientific procedures,
- e) Anamed International is committed to financing the study in agreement with the planned expenses to the tune of United States Dollars (US \$ 170 000) (Equivalent to around 155 521Euro) according to the revised budget as of May 13, 2017.
- f) PHARMBIOTRAC shall commit up to (US\$) 50,000 (fifty thousand dollars) in support of this research with a PhD student assigned to this study and expenses for professional experts.

As the value of currency may change over time, the calculation will be in Dollar and Anamed will pay accordingly. The money will be given in 3 tranches, the first given as an advance, the others sent only after reporting the scientific processes and accountability for the first installment provided. The expenses of the money will be audited by the Internal Auditor of the MUST following Public Finance Management Act of the Republic of Uganda.

- g) The results of the scientific study will be evaluated in Uganda and be submitted to Prof. Iris Burkholder of the University of Saarbrücken for further back up of the statistical work.
- h) The results of the scientific study will be published in a highly cited international peer reviewed scientific journal. The draft manuscripts of the publications will be made jointly by both parties. Anamed International will be acknowledged as the financial supporter of the scientific work.

Article 4: Obligations of ANAMED.

- a) Financing the mentioned study according to the agreement and sending the tranches in US currency after receiving the information of the finished work,
- b) Keeping confidential any and all communication and information whether provided in the course of or as a result of the discharge of its obligations under this agreement and all information relating to any report, recommendation of advice given by ANAMED to PHARMBIOTRAC in pursuance of its obligations. ANAMED shall not at any time disclose or publish any information relating to

PHARMBIOTRAC to a third party without the prior written consent of PHARMBIOTRAC.

Article 5: Obligations of PHARMBIOTRAC

These shall include:

- a) Jointly undertaking research and development activities between ANAMED and PHARMBIOTRAC as determined by both institutions especially the research mentioned in Article 1 and collaborating with Dr. Felicitas Roelofsen as indicated in article 1a,
- b) Provide technical expertise and laboratory capacity to conduct research and product development,
- c) Keeping confidential any and all communication and information whether provided in the course of or as a result of the discharge of its obligations under this agreement and all information relating to any report, recommendation of advice given by PHARMBIOTRAC to ANAMED in pursuance of its obligations. PHARMBIOTRAC shall not at any time disclose or publish any information relating to ANAMED to a third party without the prior written consent of ANAMED.

Article 6: Commencement, Duration

This MOU shall enter into force and effect on the date of last signature by the last party signing and shall remain until the publication of the mentioned study.

Article 7: Renewal of this MOU

Another MOU may be signed if a further scientific study (for instance in malaria prophylaxis) is planned.

Article 8: Amendment and termination

This MOU shall be amended and be of force and effect if reduced to writing and signed by the authorized signatories and may be terminated by one party giving six (6) months written notice to the other.

Article 9: Law Applicable

This MOU shall be read and construed according to the laws of the Federal Republic of Germany.

Article 10: Settlement of Disputes

Any disputes arising out of the operation and or interpretation of this MOU shall be settled through mutual and amicable discussion and agreement, failure of which, any such disputes shall be referred to arbitration in accordance with the Arbitration and Conciliation Act Cap 4 of the laws of Germany.

Article 11: Force Majeure

EAC

Neither party shall be liable for any delay or default if such delay in performance or other failure to perform their respective obligations under this MOU is the result of an event of Force Majeure, which includes, but is not limited to, acts of God, government restrictions, wars, floods, strikes, fire.

Article 12: Intellectual Property Rights

Intellectual property rights will be in accordance with accepted international standards, but not limited to African Regional Intellectual Property Organization (ARIPO),

- a) All scientific data, materials, publications and other related information (files, records, documents and other work materials, including those on computer disks arising out of or connection with the joint activities) generated as a result of the activities is the joint property of all the parties to this MOU,
- b) Ownership of any intellectual property (including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights) developed or created by the students and faculty during the course of this Agreement shall be vested in both parties to this MOU,
- c) Any publication regarding such intellectual property shall only be possible with the prior written consent of both parties, with the understanding that such consent should not be unreasonably withheld,
- d) This MOU will not permit the use or dissemination by either party hereto of intellectual property belonging to the other party, without the prior written consent of the party owning the said intellectual property.

Article 13: Miscellaneous Provisions

- 13.01 (a) Any notice request, approval, information, declaration or further Agreement between the parties, permitted or required by this Agreement shall be in writing and shall be deemed to have been duly given, made or sent when it shall be delivered by hand or by mail, telex or telegram, to the party to which it is required or permitted to be given or made at the address of such party specified below or at such other address as such party shall have designated by notice to the party giving such notice or making such requests:

FOR THE ANAMED

Dr. Felicitas Roelofsen, representative of **ANAMED INTERNATIONAL**,
Grüner Weg 34,
50825 Köln, **GERMANY**.
Mobile: +49-177-7643957
E-mail: dr.felicitas@gmail.com

FOR PHARMBIOTRAC (MUST)

ACE II Center Leader/ Director



Pharm-BioTechnology and Traditional Medicine Centre
(PHARMBIOTRAC)

Mbarara University of Science & Technology (MUST),

P. O. Box 1410, Mbarara, **UGANDA**.

Tel. No: +256-485-660540; Fax. No: +256 485420782

Mobile: +256 772 837055

E-mail: tolocas@must.ac.ug

Website: <http://www.must.ac.ug>

(b) Any action permitted or required to be taken and any document permitted or required to be executed under this Agreement may, on behalf of PHARMBIOTRAC (MUST) be taken or executed by the Vice Chancellor or such other person as he/she shall designate in writing.

13.02. This Agreement may be executed in several counter parts of each of which shall be an original.

13.03. This Agreement shall not be amended, supplemented, varied or rescinded except with the consent and approval of the ANAMED and the Project Implementing Entity.

IN WITNESS WHEREOF, the parties hereto, acting through their duly authorized representatives have caused this Agreement to be signed in their respective names and delivered as of the day and year above written.



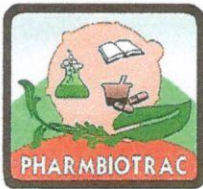
Dr. med. Felicitas Roelofs

Dr. Med. Felicitas Roelofs, Representative OF ANAMED INTERNATIONAL

THE COMMON SEAL of Mbarara University of Science and Technology


EAC

C.UT




.....
Prof. Celestino Obua, VICE CHANCELLOR, MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY

Witnesses


.....
**Dr. Casim Umba Tolo FOR AND ON BEHALF OF THE ACE II CENTER LEADER/
DIRECTOR PHARM-BIOTECHNOLOGY AND TRADITIONAL MEDICINE CENTRE
(PHARMBIOTRAC)**


.....
Dr. Esther C. Atukunda, Department of Pharmacy Local Principal investigator


.....
Dr. Ogwang Patrick Engeu, PROJECT OVERALL COORDINATOR/LEAD SCIENTIST

