

Memorandum of Understanding

between

The Tigrai Health Bureau (THB),

The MU/Health Sciences College (MU), and

The ISS of Rome, Italy (ISS)

**to jointly conduct a 3-years operational intervention
and a research study on HIV/AIDS treatment and care in Tigrai**



A. INTRODUCTION

The THB, together with national and international partners, has been doing, since the beginning of the epidemic in Ethiopia, a very fruitful epidemiological and operational work for HIV/AIDS in all hospitals and health centers of Tigrai. However, the THB concurs that the situation of HIV/AIDS in Tigrai deserves a sustained monitoring and evaluation, particularly on the clinical outcomes and impact of Antiretroviral Treatment (ART) programs and considers important to conduct further operational research, clinical training and laboratory capacity building.

The scope of this MoU, which substitute all previous MoU, is to define rules and responsibilities for an operational project (**Ethiopia HIV-Care**) which also includes a clinical prospective cohort study (**CASA**). The project will be conducted, with the supervision of the Tigrai Health Bureau, through a partnership between the ISS and the MU.

The final beneficiaries will be people with HIV/AIDS referring to the Health Facilities participating to the project. They should gain medium and long term benefits in terms of both a reduced probability of clinical events, improved ART monitoring and overall improvement of quality of life. The most vulnerable population sectors with respect to the dynamics of poverty and social marginalisation (for example women and children) will be the subject of particular attention in all phases of the project.

Other beneficiaries of the project will be the health sector workers (physicians, nurses, laboratory technicians and health officers, etc) of the health facilities participating to the project. They will be able to improve their competency in the clinical care of HIV/AIDS patients, both through the specific training activities and through the scientific information derived from the results of the longitudinal clinical cohort study.

The project will start in five to seven health centers and MU/Ayder Referral Hospital.

Additional health facilities, can be included, as per suggestion by the Tigray Health Bureau, in subsequent years. The Tigrai Health Bureau, the MU and all participating health facilities will be the ultimate owners of the products of the project.

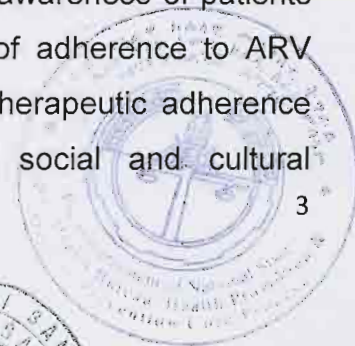


B. ACTIVITIES

The project will have a duration of at least 3 years and will include 3 specific activities:

a. Education and Training

- The training activities will have the objective of reinforcing the competency of the local Health Care Workers (physicians, nurses, health-officers, laboratory technicians) in their diverse care functions, also using the train-the-trainers methodology.
- The scope, objectives and format of the training activities will be jointly agreed by the MU and the ISS, and may fall into diverse typologies: a. intensive - up to 1 week – residential training courses (3 courses/year) organized at the Coordinating Institution; b) focused in loco training at different health facilities; c) participation to national international meetings or conferences on HIV/AIDS; etc).
- Adequate and specific training will also be provided for the conduct the clinical cohort study (ARV monitoring, data management, clinical monitoring, data analysis and statistics).
- The ISS will also provide ad hoc educational material and access to scientific literature.
- In agreement with by MU, the ISS will also support periodic exchanges of medical personnel, through the ISS partnerships with Specialty Medical Schools in Infectious and Tropical Diseases and with the Italian Society of Infectious and Tropical Diseases (SIMIT).
- As part of the education activities, the project also foreseen a program for the “therapeutic education” of HIV/AIDS patients through the organization of periodic specific patient-oriented seminars aimed at improving the awareness of patients of the efficacy of the treatment and of the importance of adherence to ARV therapy. These seminars will deal with the problems of therapeutic adherence and retention in care, also addressing the role of social and cultural



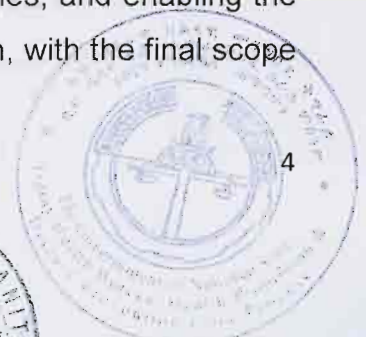
determinants. To facilitate contacts and improve the level of communications with patients, the project further foresees the involvement of patient associations (where present) and of the HIV community.

b. Laboratory equipment

- All Health Facilities participating to the project will be adequately provisioned with missing basic equipment, including furniture and software/hardware.
- The improvement of laboratory services is planned to reinforce the monitoring of ARV treatment and of its potential side effects. This provision will include CD4 lymphocyte counting machines for all health care facilities, and the provision of viral load (HIV-RNA) quantification machine in the MU/Ayder referral Hospital laboratory. The provision of laboratory instruments will also include training of laboratory technicians and apparatuses maintenance.

c. Operational Research Study

- The project will set up a long-term prospective cohort (CASA) of adult HIV+ patients attending the five participating health facilities. The cohort will follow, for 3 years, all new patients that had not previously started ARV.
- The study is aimed at measuring short, mid and long term clinical and laboratory outcomes, and assess the impact of ART, including issues of adherence, toxicity, immunological and virological response, HIV drug resistance and quality of life of patients.
- The results of this operational study will support local health facilities and regional program makers to take decisions for the improvement of the overall management of People Living with HIV/AIDS (PLWH) in Tigray. The CASA project is aimed at optimizing patient management through the empowerment of the local health staff and the upgrading of local health facilities, and enabling the conditions to expand health interventions to the entire region, with the final scope of improving the quality of life of PLWH in Tigray.



- Clinical and laboratory data will be collected in all participating institutions, using the official ART case report forms. ISS will support local data input (local data clerks) and data monitoring.
- The scientific direction of the CASA study will be a joint responsibility of the ISS and of the MU, in partnership with the other participating health facilities.
- The CASA Central Data Base will be based at MU and duplicated at the ISS.
- The CASA study shall undergo appropriate review from the ISS Ethical Committee and from the MU Review Board.

C. DUTIES AND RESPONSIBILITIES

The THB will provide legal support to ISS, the permission to access clinical data charts at the Health Facilities and to build and analyze the Central Database, which will be based at MU. The database shall be fully accessible to the ISS, to monitor the progress of data collection, check the quality of the data, produce the queries, and provide periodical study reports in collaboration with participating health facilities.

The ISS will appoint and hire a local ISS representative to act as local study coordinator. THB and MU will recognize the ISS local representative, and will give him the appropriate powers to act on his behalf.

MU will contribute with the skills and expertise of its staff to mentor health facilities staff. MU will assure office space for the coordination of the study, for the ISS representative and for ISS staff. MU will also provide, as needed, some administrative support for which it will consider a reasonable overhead cost.

The project will be financially supported, for three years, by the DGCS (Italian Directorate for Foreign AID) and by the ISS. The project is expected to start Q1 2012 and will continue for at least 3 years.



ISS will provide the expertise of his researchers and the appropriate financial support for all project activities: training and education, laboratory equipment, data collection, management and analysis, Information Technology.

As per the local personnel involved in the project, the ISS will support the work of 3 part-time project monitors (1 week/month), jointly selected by the MU and by the ISS. ISS will also support the as needed extra work of existing local data clerks at participating facilities. ISS will financially support the participants to the training courses (both the teachers and the pupils).

Any scientific publication or technical report will have to be authorized and agreed upon by all partners of the project, both in terms of content and authorship.

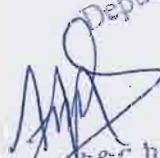
Signed Dec 23, 2011

For the THB


Yalem Tsegay Assfaw
/RN.BSC.MPH/
Deputy Bureau Head



For the MU


ዓብዱልካዲር ክዳር (Ph.D)
Abdulkadir Kadir (Ph.D)
Vice President for
Research and Community Services



For the ISS

STEFANO VELLA MD, Director,
Department of Therapeutics
ISS - The Italian National Institute of Health
Viale Regina Elena 299 - 00161 Rome - Italy
Phone: +39 06 49906015 / Mobile: +39 348 2650598 / Mail: stefano.vella@iss.it



MoU_ETHIOPIA_HIV_PROJECT_CASA



ADDENDUM:

The **ISS** (ISS) is the principal technical-scientific organ of the Italian National Health Service. It is a public body which merges research and consultation activities, training and control applied to public health protection. The ISS has been committed to the fight against HIV/AIDS since the beginning of the epidemic, with particular reference to therapeutic aspects, to prevention interventions campaigns, and to epidemiological monitoring. The ISS has strong links with the Italian Ministry of Health, the Ministry of Scientific Research and Education, and the Ministry of Foreign Affairs, from whom it receive funding for national and international research programs. The ISS has been involved in Global Health work for more than two decades. Such work includes basic research, clinical trials, cohort studies and operational, implementation research projects. Principle areas of activity have focused on HIV/AIDS, TB, Malaria, Hepatitis, pandemic communicable diseases and primary care and health systems strengthening. Current projects include research into the prevention and treatment of HIV/AIDS and other poverty-related diseases, health system capacity building, health information technology and technical support for national public health authorities. The ISS is committed to improving healthcare systems and healthcare delivery globally and coordinates, since many years, international research projects at the global level, in full partnership with local authorities and clinical and research institutions. All ISS Global Health Projects are guided by the belief that the practice of global health transcends the perspectives, concerns and interests of individual nations and emphasizes transnational health determinants, promotes interdisciplinary collaboration and combines population-based prevention with individual clinical care¹. The ISS work is guided by the principles of equitability and local ownership, human right focus, local sustainability, alignment with National Programs, accountability and commitment to evidence and results.

