

Mid-term evaluation report

NACCAP programmes first call

CoMMAL

The Hague, October 2008

Foreword

In 2004, the Dutch Ministry of Foreign Affairs (DGIS) made available € 20 M to contribute to EDCTP through the Netherland African Partnership for Capacity Development and Clinical Interventions against Poverty related Diseases (NACCAP) programme. The general aim of NACCAP is to support investment in strengthened research and development capacity of multiple locally owned and controlled health research centres in sub-Saharan Africa, capable of clinical testing of new interventions against poverty related diseases and contributing to the EDCTP objectives.

In 2005, NACCAP funded two partnership programmes (CoMMAL and INTERACT) for an initial two and a half years, with funding to continue up to 2009/ 2010 if the results of a mid-term review (MTR) to assess if the partnership programmes are indeed contributing to the objectives of NACCAP was favourable. In June 2008, a MTR was executed by NACCAP and the results of the review are presented in this report.

The MTR-committee comprised a member with expertise in the field of research and university governance structures (Prof. Jan Borleffs), a member with expertise in the field of capacity strengthening of African research institutes (Dr. Andrew Kitua); a member of the NACCAP programme committee with expertise on translating research into health policy (Dr. Irene Agyepong) as chair; and two members of the NACCAP secretariat (Dr. Judith de Kroon & Dr. Eva Rijkers) for administrative support. Written reports of CoMMAL and INTERACT were assessed, and site visits paid to Malawi and Uganda. The time frame of the MTR unfortunately did not allow a site visit to Rwanda but fortunately, members of the INTERACT Rwandan team came to meet the MTR committee in Uganda.

The MTR committee observed that on the whole both programmes appear to be generally moving in the right direction towards strengthening research and development capacity of health research centres in Malawi, Uganda and Rwanda, capable of clinical testing of new interventions against poverty related diseases and contributing to the EDCTP objectives. However, the funded programmes also have variable levels of challenge in making sure that the direction is completely right and the objectives are fully achieved if funding is extended to 2009/2010. The MTR committee concluded that none of the challenges are insurmountable such that the programmes need to be terminated. The challenges do however need to be addressed to make sure that NACCAP objectives are fully achieved with continued funding. The MTR committee therefore recommends that both programmes be funded up to 2010 but on the condition that the recommended suggestions for modifications to improve the alignment between the programmes and NACCAP objectives arising out of the MTR are implemented.

In summary, the CoMMAL programme's creativity in developing effective interventions to reverse brain drain and attract senior researchers back into Malawi as part of research capacity building, as well as the embedding of the programme firmly within the College of Medicine for long term sustainability are commendable and to be encouraged. So also is the team spirit and open collaboration that was observed within the CoMMAL programme and between the programme and other research programmes within the University and the College in general. The major observed challenges that CoMMAL needs to address are to make sure it maintains what it is currently doing and also moves fast enough with its capacity building and development efforts related to the Research Support Centre (RSC) to stay ahead of the enthusiasm and increasing demands generated by its success so that it does not become overwhelmed.

The CoMMAL programme also needs to better engage stakeholders outside the core partnership, especially within the Ministries of Health and Education in the countries in which they work and get a better buy in from these stakeholders into the work they are doing. These are stakeholders who are essential for the long term development of sustainable national research capacity and effective utilization of research for development.

Furthermore, the MTR committee would share some lessons learnt with the NACCAP Steering Committee. Both partnerships programmes thought the communication with the MTR committee very valuable. They wondered if it could be possible for NACCAP to visit the programmes more often to discuss progress and exchange views on improvements. In addition, they informed the MTR committee that it might be even more effective if NACCAP visited its funded programmes already within one year after the start of the programmes. Secondly, the MTR noted that in general there seems to be a lack of African senior scientists (capable of supervising PhD students). Therefore, the MTR committee would like to propose to NACCAP to consider pro-actively creating possibilities for (expatriated) African senior scientists (including post docs) to return to their home-countries. In addition, the MTR committee expects that the (two) partnership programmes funded by NACCAP stand to benefit by visiting and learning from each other. Therefore, the MTR committee would like to advise NACCAP to organise a joint meeting with all these partnership programmes.

Last, but not least, the MTR committee wishes to express its appreciation to the CoMMAL team for their hospitality, welcome, cooperation and open discussions and interactions with the committee. Without the efforts they put into facilitating the MTR, it would not have been possible to achieve so much in so short a time. The MTR committee commends the teams for the work already done, and looks forward to seeing continuously growing and improving international standard, strong health research and development capacity and institutions within the three countries.

Yours sincerely,

Irene Agyepong,
Chair of the MTR committee

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PART A: GENERAL INTRODUCTION

1. Background information: EDCTP

In 2002, the Member States (MS) of the European Union, Norway and the Developing Countries (DCs), particularly sub-Saharan Africa, came together to establish a sustained partnership to reinforce research into the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis. This resulted in 2004 in the European & Developing Countries Clinical Trial Partnership (EDCTP), the first programme financed by the instrument of Article 169 of the 6th Framework Programme of the European Commission. The mission of EDCTP is to accelerate the development of new clinical interventions to fight HIV/AIDS malaria and tuberculosis in, particularly, sub-Saharan Africa and to improve generally the quality of research in relation to these diseases. The main objective of EDCTP is to contribute to the integration of European research in these fields. Within its mission, EDCTP aims at the establishment of a sustained research partnership between Europe and DCs in the fight against the three diseases.

In 2004, the Dutch Ministry of Foreign Affairs (DGIS) made available € 20 M to contribute to EDCTP. Because at that time the implementation strategy of EDCTP was not clear, the Dutch ministry decided to contribute to EDCTP through the NACCAP programme; the Netherlands-African partnership on Capacity strengthening and Clinical trials against Poverty-related diseases; a research and capacity strengthening programme managed by NWO/WOTRO.

2. Background information: NACCAP

The general aim of NACCAP is to provide an impulse to the investment in, and development of, **African owned** and controlled health research centres aimed and **capable of clinical testing** of new interventions against poverty related diseases. As a result, the position and contribution of African institutes in EDCTP will be strengthened, supporting **partnerships** in **joint R&D** activities to fight poverty related diseases in Africa. NACCAP aims at **transferring responsibilities** for sustained developments to the supported African centres: for this, the centres (2-5) strengthened should become **part of an African Network of R&D centres** capable of **collaborating with EDCTP** in clinical trials.

In 2004 EDCTP took of as a research-funding organisation that awarded separate, small grants, focussing on collaborative EU-African research rather than on capacity strengthening¹. However, the NACCAP Steering Committee (SCO) thought this was not the optimal way to achieve the objectives and therefore decided to announce a call for proposals on its own, with the aim to fund African-Dutch partnerships consisting of integrated multidisciplinary R&D projects which contribute to institutional capacity development of African research centres. In addition, because NACCAP aims at strengthening centres that can collaborate with EDCTP in clinical trials, preferably the awarded partnerships included researchers from other European countries (N-N networking).

¹ During the course of 2005 the interpretation of article 169 was further developed and in 2006 EDCTP changed its strategy into a strategy more in line with the NACCAP approach.

3. Goal of the midterm review

As a result of this first call, three partnership programmes (INTERACT, CoMMAL, APRIORI) were selected for funding for 2,5 year and funding will continue up to august 2009-2010 on the condition that the results of a mid-term review are favourable.

Two of the partnership programmes, INTERACT and CoMMAL started December 2005 and were reviewed in June 2008. The third one (APRIORI) started in October 2006 and will therefore be reviewed in December 2008.

The **goal** of the mid-term review is to assess if the partnership programmes are indeed contributing to the objectives of NACCAP and specifically to the objective of the first NACCAP call, i.e:

- Strengthened research & development capacity of multiple, locally-owned health research centres in Sub-Saharan Africa contributing to the EDCTP objectives.

Since the funded partnership proposals were selected on the basis of the quality of capacity strengthening, scientific quality and governance (including equality of the partnership and African ownership), progress with regard to these aspects are specifically being reviewed.

3. Methodology of the Mid Term Review

For the mid term review, a specific Mid Term Review (MTR) committee is composed, consisting of 2 experts, one in the field of research and university governance structures and one in the field of capacity strengthening of African research institutes. The MTR committee is chaired by an expert on translating research into health policy, and assisted by the NACCAP secretariat.



*The MTR committee:
from left: Irene Agyepong, Andrew Kitua and Jan Borleffs*

Composition of the MTR committee:

Chair: Dr. Irene Agyepong (NACCAP Programme Committee, Director Ghana Health Service Greater Accra Regional Health Directorate, Accra, Ghana;

Members: *Capacity Strengthening*: Dr. Andrew Kitua, Director General, National Institute for Medical Research, Dar es Salaam, Tanzania;
Science: Prof. Dr. Jan Borleffs, Dean Education and Director Post-Graduate School of Medicine, University Medical Centre Groningen, The Netherlands;
Secretariaat: Dr. Judith de Kroon & Dr. Eva Rijkers, NACCAP secretariat

Met opmaak: Nederlands (standaard)

Tasks of the MTR committee:

The tasks of the MTR committee are:

Prepare MTR:

- 1 Take note of the background documents:
 - original NACCAP background document;
 - first call text;
 - the original partnership proposals;
 - site assessments (before start of the partnership programmes) reports;
 - annual reports of the partnership programmes 2006 and 2007;
 - overview of the NACCAP comments on the annual reports;
 - MTR form, including testable goals;
 - preliminary SWOT (by NACCAP).
- 2 If necessary, adjust testable goals that will also serve as the programme outlines for presentations to be held by partnerships;
- 3 Discuss testable goals with programme co-ordinators of partnership programmes;
- 4 If necessary, adjust testable goals and ask programme co-ordinators to complete the MTR form;
- 5 Formulate specific review questions;
- 6 Propose a list of participants / stakeholders whom the MTR committee would like to interview during the site-visit;

Visit the partnership programmes:

- 7 Take note of the MTR testable goals form, completed by the co-ordinators of the partnership programmes and formulate review questions;
- 8 Visit the partnership programme sites in Africa and meet with the main African participants of the partnership programmes. For this a meeting will be organised by the partnerships;
- 9 Interview individuals (programme participants, other stakeholders) to answer specific questions of the committee;

Contribute to the report:

- 10 Write a report and formulate conclusions, including recommendations for improvements/ future activities;
- 11 Discuss the report with the coordinators of the partnership programmes for comments and if relevant, adjust the report accordingly;
- 12 Present the (adjusted) report to the NACCAP Programme Committee.

Based on the report, the NACCAP Programme Committee will formulate recommendations with regard to improvements to be made and continuation of funding to the NACCAP Steering Committee who will decide.

5. Contents of the report

The reportage of the MTR of CoMMAL (Part B) is included in this report and are composed as follows:

Chapter 1 of each reportage includes a short summary of the conclusions and recommendations of the MTR committee. In **chapter 2**, a short description of the partnership programme and the environment in which it

operates is described, followed by **chapter 3** that provides the results of the site MTR including the progress of the partnership programme. For this, the testable goals are taken as a lead. Progress with regard to each testable goal is followed by a preliminary conclusion of the MTR committee and its recommendations. **Chapter 4** includes some bottlenecks for the future identified by the partnership programmes. Furthermore, the annexes provide some detailed information on the partnership site visit programmes (annex 1: CoMMAL) and abbreviations used (annex 2).

PART B: CoMMAL

Reportage of the MTR of the College of Medicine, Malawi-Amsterdam-Liverpool partnership for Research Capacity Development through the establishment of a Research Support Centre in the College of Medicine, University of Malawi (CoMMAL)

1. Summary

The CoMMAL partnership programme, and especially the growing commitment for a cross-cutting supportive role of RSC is regarded very promising. Specific strengths of CoMMAL are the achievements in creating a favourable institutional and research environment, resulting in the ability to attract highly qualified Malawians from abroad and a close co-operation with and commitment of affiliated partners and CoM. The capacity building approach of the CoMMAL programme whereby institutional capacity to support research is being developed through the establishment of the Research Support Centre within the College of Medicines and attracting back into the College of Medicine from outside Malawi, highly trained Malawian researchers is working well. Individual research capacity building through PhD training and short course in GCP, GLP is also on track

This success already does and in future may even more attract international funding organisations and other partners. Currently, the increasing attractiveness of the support offered by the RSC threatens to outpace the rate of RSC development and distract CoMMAL and the already highly burdened staff of RSC from their core objectives and hinder the sustainability of RSC. In general the CoMMAL team recognises the need to stay in control in this phase of fast growth and expansion. RSC should make sure that it remains focussed in strengthening CoM so that it can develop its own Malawian research agenda. For this, RSC needs the commitment of external funders and partners but at the same time should remain independent. In addition, highly qualified (trained or re-gained) core staff must be retained. Core funding (by the Malawian government and by income generating activities) therefore is crucial.

For a sustainable commitment of the RSC, the RSC should further develop from a project into a cross-supportive unit of CoM. This process is already being discussed and the MTR recommends CoMMAL to continue this process and to aim at transforming RSC into a position (office) that clearly demonstrates the cross cutting and coordinative nature of RSC in the CoM and is governed by a steering committee/board that includes CoM, all affiliated partners and representatives of the MoH. Involvement of the latter may also ensure better alignment of research policy with the needs of public health. Communication (shared with the university) on the added value of research for health with the ministry, NGO's, participating district hospitals and communities might add to this. In addition, the CoMMAL team should use the opportunities to link the existing expertise in operational research to their research agenda. Funding opportunities may exist in the second part of 2008 when WOTRO will start a research funding programme on health systems and health policy research.

Although courses are already self-sustainable, and there are several other opportunities to ensure financial sustainability of the RSC (data management and monitoring, two previewed tasks of RSC, could become part of each grant proposal), CoM could decide to transfer a percentage of all grants to RSC when RSC takes up the task of grant management and administration. In order to take up this challenge, RSC should ensure that financial management of RSC is highly capable to perform this task.

To retain focus and to attract additional funding for the RSC, the MTR committee recommends CoMMAL to write a business plan for the next two years that positions RSC as a cross-supportive unit, including

governance and a financial budget and to communicate this plan to the MoH, University and external funding organisations.

With regard to efficiency, the scientific progress is delayed, due to slow recruitment of patients. This will be caught up by adding two more district sites for patient recruitment. However, there is still a need for a no-cost extension of 12 months to catch up the delay in capacity strengthening. Because of the promising approach of the RSC, the MTR recommends NACCAP to agree with a no-cost extension of 12 months.



*Healthy mother, healthy baby, healthy Malawi:
banner in Thyolo district hospital*

2. The partnership programme

Description of the partnership programme

Clinical research in malaria and HIV conducted by the College of Medicine (CoM), University of Malawi, is recognized to be of a high international standard. However, its research agenda has been developed mainly by its international collaborators ("affiliated partners"), and CoM has depended on these partners for international funding. CoMMAL identified two goals: build sustainable research capacity through the establishment of a Research Support Centre (RSC) and conduct clinical trials. The RSC will assist local researchers in the design and conduct of clinical research; introduce ICH-GCP quality standards; and develop a training programme in research methodology. It is anticipated that the successful establishment of a dedicated RSC will make a sustainable contribution towards the quality and quantity of Malawian owned research and foster a high quality competitive research environment that reduces brain drain; and encourage talented Malawian post-graduates and senior scientists to return to Malawi (reverse brain drain).

The programme is developed in collaboration with other partners of the CoM from the UK (Liverpool) funded by the Wellcome Trust, and from the USA, funded by the Fogarty International Centre of NIH. The CoM has identified the RSC as high priority in their strategic development plans and proposes to take over the running costs of the RSC in incremental steps from 2007 onwards.

Although very common, the importance of anaemia and its aetiology is poorly understood in Malawi. The existing research collaboration between the CoM, the Emma Children's Hospital AMC and the Liverpool School of Tropical Medicine (LSTM) concentrated on the role of malaria, iron deficiency, and HIV in causing maternal and childhood anaemia.

The programme consists of the following 4 projects:

- Project 0: Development of a Research Support Centre within the Post Graduate Institute of the College of Medicine (CoM), University of Malawi.
- Project 1: Intermittent Preventive Therapy post-discharge (IPTpd); an innovative approach in the prevention of rebound severe malaria anaemia in young children
- Project 2: iron supplementation in HIV infected children: Is iron safe and beneficial?
- Project 3: The effect of iron supplementation on maternal morbidity in HIV-infected pregnant women (in cooperation with Fogarty/NIH)

The first project (RSC) is aiming at individual and institutional capacity strengthening and coordination, the second, third and fourth projects are clinical trials aiming more at research and scientific capacity strengthening “by doing”.

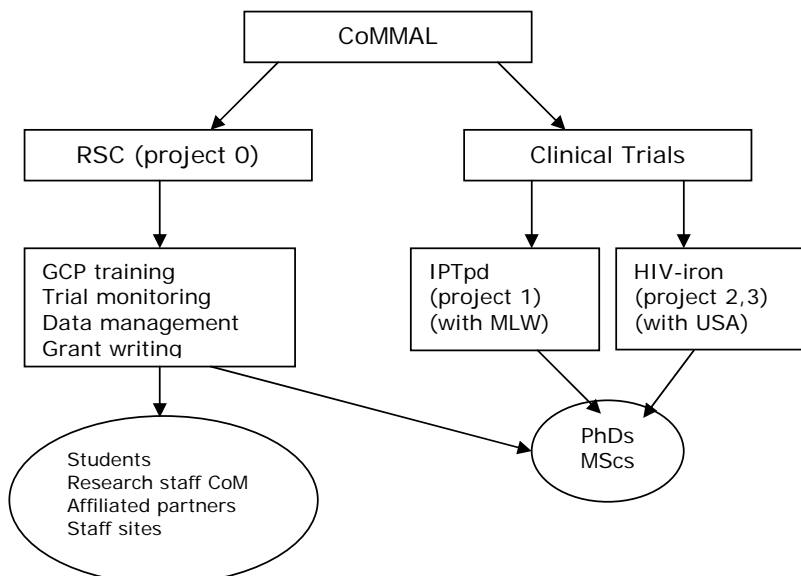
The aim of the Research Support Center (project 0) is to:

- (1) support the conduct of clinical research;
- (2) to introduce ICH-GCP quality research standards;
- (3) to provide training in GCP, study methodology, etc. and;
- (4) to develop a vibrant research climate, able to attract and retain high quality Malawian researchers from abroad.

The two research projects (1 and 2) funded by NACCAP (and a third, funded by Fogarty) aim at specific PhD and MSc skill building by executing concrete research projects (“learning by doing”).

The main applicant of the proposal is a Dutch researcher, Dr M. Boele van Hensbroek (Academic Medical Centre / Emma Children’s Hospital, Amsterdam, the Netherlands). Main partners in the partnership are prof. E. Borgstein (University of Malawi), Dr F.O. ter Kuile (Liverpool School of Tropical Medicine, United Kingdom), Dr V. Mwapasa (University of Malawi) and Dr K. Phiri (University of Malawi). The programme’s proposed subsidy period from 2006 to 2010 (60 months) was shortened to 48 months (august 2009). Total budget was set at € 1,65 M (originally proposed: € 1,8 M).

The partners visualize this approach as follows:



Environment

Organisational environment

The CoM is part of the University of Malawi, initiated in 1986 and founded in 1992. The most important source of income is the Government of Malawi (Ministry of Educational Sciences & Technology and Ministry of Health by its SWAP budget) and through the government, funding from the Global Fund, Norway, Sweden, and the Netherlands. CoM runs as an autonomous single faculty unit with its own administration and management system and is able to a large extent to establish its own direction and goals. The college has its own buildings and campus adjacent to the Queen Elisabeth Central Hospital in Blantyre, which is the main teaching hospital. The main task of CoM is learning and teaching. Undergraduate students pay a relatively small fee. Post-graduate training was only started in 2005 when the Post Graduate Institute (PGI) was set up in order to build capacity and attract qualified professionals willing to be involved in conducting research to meet the needs of the country. In general, PhD students are funded by research grants and work within one of the research programmes of the affiliated partners of CoM.

The affiliated partners of CoM are also housed at the campus and have their own buildings, funded by international funding organisations. The main affiliated partners relevant for the CoMMAL partnership are: the Malaria Alert Center (MAC, financed by Gates, in partnership with LSHTM); the Blantyre Malaria Project (BMP, financed by Fogerty in partnership with Michigan State University and University of Maryland); the Malaria Liverpool Welcome Trust Programme (MLW, financed by Wellcome Trust and DFID in partnership with the Liverpool School of Tropical Medicine) and the Rotavirus Vaccine Programme (financed by Glaxo Smith Kline GSK). Furthermore, CoM and its affiliated partners work together with regional health care centres and district hospitals, of which Chikwawa, Zomba and Thyolo are relevant for the CoMMAL partnership programme.



*One of the CoMMAL partners:
the Malaria Alert Centre at the campus of the College of Medicine*

The presentations for the MTR as well as individual interviews (for programme and interviewed individuals see annex 1) took place at the campus of the University of Malawi in different buildings of different affiliated partners of CoM. All these affiliated partners are very well housed and equipped including research laboratory facilities. The CoMMAL research projects use these research facilities of the affiliated partners while the partners also provided housing of the RSC. The Post Graduate Institute is yet housed at a department of CoM. Recently, the RSC moved from a room within the Rotavirus Vaccine Programme into a floor of a new building of CoM, located near the ICT and library department of CoM.

Timing

CoM was set up in 1992, with the PGI in 2005. Soon, it was recognised that a platform should be established in order to be able to coordinate the research needs of CoM and the needs and activities of international funders and foreign partners in order to be able to take the lead in a better organising of Malawi's own research policy and agenda. While international funders mainly are looking for opportunities for clinical trial research, the CoM is also interested in translational research, with a focus on anaemia and iron studies. The PGI realised that Malawian clinical capacity for this was lacking. When at the first years of the new Millennium the foreign policy of UK and USA changed with less hospitality for researchers from abroad, CoM identified this as an opportunity to attract Malawian expatriates back to their home country. Thus, the NACCAP call in 2005 with a focus on capacity strengthening was a timely opportunity that aligned with the need to build Malawian capacity in clinical trials and with the need to 'build' a research capacity co-ordinating structure ("platform") able to integrate external funding possibilities into a Malawian owned research agenda.

3. Progress

• **Testable goals**

In order to measure progress, several testable goals and related review questions were formulated by the MTR committee and approved of by CoMMAL. In summary, the testable goals are:

- Relevance (with regard to individual, institutional and environmental capacity strengthening, and with regard to science);
- Governance (contributing to equal partnership and/or African ownership and embedding while safeguarding transparency and accountability);
- Efficiency (is progress on schedule);
- Effectiveness

In addition, the partnerships identified some challenges for the future of CoMMAL.

• **Results**

1. Relevance

a) contributing to strengthened research & development capacity of a locally-owned health research centre in Sub-Saharan Africa.

The Research Support Center (RSC) aims at strengthening research capacity at the individual level as well as at the institutional level.

Individual level

The RSC provides individual support (research training) consisting of one-to-one support including research methodology, ethics, statistics, epidemiology and proposal writing & submission. Furthermore, short courses are given in ICH-GCP, basic and clinical research methodology. This support is not only available for the staff and students who are included in the CoMMAL partnership, but open to everyone who needs support. As such, 23 students received one-to one support on the different aspects. The courses on data management attracted over 40 applicants ranging from students to representatives of NGO's. Five GCP courses provided 108 individuals (students, study site staff including scientists, CRO's, nurses and data managers, ethics committee members) training in ICH-GCP. In addition, the RSC managed to gain external funding to broaden its curriculum towards a course on basic research methodology that educated 25 students and lectures. The courses are not closed by an exam. All the trainees (of which 35 clinical staff) now use their knowledge in practice.



Research technician Thyolo district hospital

Institutional level

Institutional support consists of providing ICH-GCP quality control, trial monitoring services, data management and data analysis support. Furthermore, the RSC provides information on funding & training opportunities, conferences, dissemination of research results, research database, publication tracking and opportunities for collaboration with (international) partners.

Seven GCP trainers were trained by Kendle/GSK in 6 courses. These trainers will take over the ICH-GCP training. The trainers include not only employees from RSC but also from the MLW and from the Centre for Bioethics (MoH). The course is closed by an exam. RSC now has developed its own GCP material for the courses and Kendle will accredit the course (since an international accrediting body does not exist). The course on GCP has been included as a module of the Masters of Public Health programme at CoM. Furthermore, RSC with help of Kendle, has trained three clinical research associates (CRAs) who are monitoring 3 clinical trials executed by different affiliated partners. For the future, it is previewed that the RSC team can operate as a self-sufficient Site Management unit.

The data management team of RSC is trained by MLW and assists in providing services to research projects within 12 different research programmes (of the MLW clinical research programme and of other programmes executed by (affiliates of) CoM). Courses on data management have been developed and will start in 2008. Data management is expected to become one of the income-generating services of RSC.

These capacity strengthening activities have led to an upgrade in the level of the African clinical trial capacity, which at the moment is as indicated in table 1.

Table 1: Level of Partnership programme at this moment: level at the review moment is printed bold				
Level	1	2	3	4
Components	<i>Epidemiological relevant population and interested investigators</i>	<i>Identified cohort and follow-up capability</i>	<i>Sites with some clinical trial capacity (indicate phase)</i>	<i>Fully capable site for phase I-III trials</i>
1. Investigators	Lacks GCP	GCP exposure	GCP qualified with limited experience	GCP qualified with experience
2. Subjects	Target population identified	Demonstrated ability to follow-up. Community involvement	Demonstrated ability to follow-up. Community involvement formalis	Demonstrated ability to follow-up. Community development programme
3. Ethics	IRB not yet established	IRB National ethics committee exists	IRB National guidelines for clinical trials exist	IRB National guidelines for clinical trials exist
4. Laboratories	Access to laboratory facilities	GLP exposure	GLP qualified with limited experience	GLP qualified with experience
5. Clinical facilities	Ability to measure clinical outcomes	Access to facilities with staff	Adequate facilities and qualified staff	Excellent facilities with qualified staff
6. Data management	Data collection field staff	Some computer infrastructure and basic data-processing skills	Sufficient computer hardware and software Experienced data-processing staff.	Biostatistics, sufficient computer hardware and software. Experienced data-processing staff
7. Sample repository	absent	Some, but temporary/ sporadic	Part of laboratory	Available (cold) chain
8. IPR skills	absent	External qualified advisor available	Some internal qualified skills available	Experienced qualified personnel available within centre
9. Administration	Basic administrative capability	Basic administrative capability	Accounting and administrative systems available	Well established and audited accounting and admin systems

GCP/GLP= Good Clinical Practice/Good Laboratory Practice; international quality standards for clinical/laboratory practice.

IRB= Ethical review Board; independent committee of (local) stakeholders and experts who review proposed work plans for ethical implications and whose approval is required prior to start

Staff turnover

CoMMAL has been able to attract senior, expatriated Malawians (1 from UK, 2 from USA) to return to their home country. In addition, a Zimbabwean director for the RSC was employed. These scientists receive a core salary from CoM which is being topped-up by the externally funded grants. In addition, a senior epidemiologist is employed and several senior employees (data manager) are shared between affiliated programmes and CoMMAL. Still vacant is the position for a senior statistician, which hopefully will be fulfilled by a Malawian senior scientist now working in Belgium. Furthermore, 3 African PhDs and 1 Dutch PhD have been attracted to the programme. For each local trial site a CRO, 2 nurses, a data manager, field officer and lab personnel are employed. All

employees are trained. There seems to be little turn-over of employed staff. All together make an open and enthusiastic team that has a good relationship with the Post Graduate Dean and the Principal.

Environmental level

CoMMAL contributes in different ways to capacity strengthening at the environmental level: in the first place, the RSC project of the CoMMAL programme adds to a favourable research environment, by providing courses open for all partners and overall clinical trial services and by harmonization of the different GLP courses that existed within CoM and its affiliated partners. As such, RSC contributes to collaboration between and harmonization of different research programmes. Furthermore, PhD students (n=3) of CoMMAL and specific expertise of different affiliated partners of CoM are shared, resulting in cross-fertilisation of specific expertise. For example, MLW educates RSC on data management so that finally, data management of MLW can be handled to RSC. A biostatistician will be shared between MLW and RSC while the health economist of MAC assists RSC in setting up an educational programme on health economics. Individual interviews with all affiliated partners show that all are prepared to hand over their specific expertise to the RSC and support the RSC to become the cross-cutting supportive centre, providing ICH-GCP courses, trial monitoring, data management. In addition, grant management & administration, now done by all affiliated partners separately, was identified as a major task of RSC that needs capacity strengthening and central co-ordination within CoM. This willingness of the fairly autonomous affiliated partners of CoM to strengthen RSC for the sake of better performance of all, shows that the RSC answers to a need of the different research stakeholders. Furthermore, CoM has been asked to assist in setting up a similar RSC-like structure in Zambia and Zimbabwe. CoM through RSC is also a partner in a consortium formulating a proposal on Networks of Excellence for EDCTP, aiming at embedding CoM into a regional research network on clinical trials. This clearly shows that CoMMAL contributes to collaboration of CoM with EDCTP.

With regard to creating a favourable public health environment, some added value exists but is less obvious. Research projects are executed in collaboration with local health services. The added value of CoMMAL for these services include an upgrade of the quality of care because CRO's, nurses, data managers, field workers and laboratory personnel are trained in ICH-GCP. In addition, better data management and a supportive environment attracts medical personnel to these local sites that originally were not very attractive to work for. In some of the research projects, collaboration exists with international non-governmental HIV care programmes (MSF, DIGNITAS). However, in general, national non-governmental organisations that settle at the campus seem to last only two-three years and therefore are hardly regarded as sustainable partners. Informal links exist with the Ministry of Health, but more structural involvement of the Ministry of Health seems to be low. Similarly, CoMMAL research projects work within the context of the national Aids programme (including PEPFAR) and the national malaria programme (by the Malaria Alert Centre (MAC), but research linkages do not seem to be very strong. MAC focuses on operational research and has good expertise in health economics. Although MAC is willing to assist RSC in educational activities on health economics, operational research activities are hardly taken into account by the CoMMAL programme.

Conclusion and recommendations of the MTR committee:

The CoMMAL partnership is relevant with regard to capacity strengthening as is shown by a clear contribution of RSC to individual, institutional and environmental research capacity strengthening of CoM. In general, RSC, which started of as a project, now has developed into a virtual and even physical coordinating and supportive centre not only for CoM but also including its affiliated partners.

Links with the MoH and NGO's are less clear and there is no clear strategy on how to align the research agenda with the needs of the MoH and on how to improve translation of research results into health policy/practices.

The MTR therefore recommends the partnership to

- *continue to position RSC as a cross-cutting, supportive organisational unit of CoM, independent of external funding organisations and to put in place (in addition to or by extending the current advisory committee) a Steering Committee for the RSC, composed of the different stakeholders, chaired by CoM and with the RSC director as secretary;*
- *make sure that courses developed and organised by RSC are accredited by international recognized organisations in order to safeguard quality control of courses and (as a consequence) of the educational curriculum of CoM;*
- *strengthen the linkage with Ministry of Health in order to encourage research agenda setting on the basis of the Malawian public health needs. For this, the MoH could be invited to become member of the board/steering committee of RSC (and if not feasible hospital directors could represent the MoH). Secondly, RSC could offer services to translate the needs of the MoH into the research agenda of CoM and to incorporate this research agenda into the SWAP of the MoH;*
- *invest in communicating the added value of research projects for improving the quality of care within the health services to the MoH because part of the core budget for CoM is provided by the MoH (through the SWAP support). In addition, CoMMAL could encourage upgrading the quality of care for all patients, not only for the ones participating in a research project. In this way, the community will be aware of the project, will advocate the project and as such it will be more difficult to lower the quality of care after the project has ended.*

b) Relevance with regard to science

The scientific part of the programme focuses on the relationship between anaemia and malaria treatment (children) and anaemia treatment and HIV (children and pregnant women). The projects include a clinical trial in malaria treatment and thus is at the core of the scientific objectives of EDCTP. The research projects on HIV do not exactly focus on interventions for HIV but on improving the treatment for anaemia in HIV infected persons and therefore, aiming at improvement of clinical care for HIV patients. However, where the first research question was inspired by EDCTP, the second aligns with the research agenda of CoM itself, and focuses on severe anaemia and iron supplementation.

The research projects are well integrated, sharing health services sites for recruiting patients for different research questions while all projects are linked to relevant projects of affiliated partners and sharing expertise with those partners. Multidisciplinary approaches however, and especially the involvement of social sciences are lacking. Although multidisciplinary was beyond the scope of the original proposal, it might be a lost opportunity since the research questions do offer great opportunities for combining clinical sciences with social sciences. For example, the affiliated MAC partner has a lot of expertise and has shown sincere interest in linking clinical and operational research.

Conclusion and recommendations MTR committee

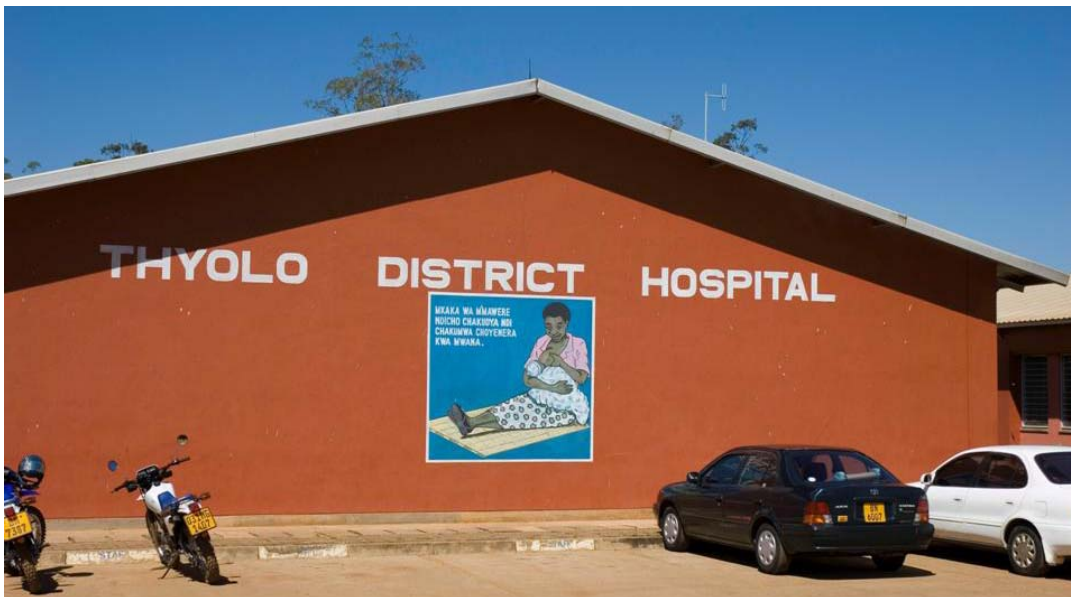
The partnership programme is relevant with regard to scientific aspects and integration between the different CoMMAL research projects exists. These projects are also well integrated in the research programmes of the affiliated partners. However, the research activities are limited to clinical research.

The MTR committee recommends CoMMAL to

- *improve the integration of the different research projects by providing the possibility for all participating sites to meet and discuss best practices and obstacles. In addition, such a possibility might create better ownership of the sites for the research projects they are part of;*
- *explore the possibilities to link up with the research questions and expertise on health economics of the MAC.*

2) Efficiency

Although the programme started successfully, there is a 4-6 months delay. This delay is due to difficulties with recruiting senior Malawian staff, slow release of funds due to lengthy contract discussions and slow patient recruitment for the malaria treatment study due to drought. Most of these problems have been solved; a senior researcher was attracted from Zimbabwe, and now is director of RSC with the establishment of RSC back on schedule. Patient recruitment has been accelerated by including two more local sites (Thyolo, Zomba) which resulted in 50% of the total patient recruitment foreseen. The second project (HIV-iron) is approved of by the ethical committee and scheduled for June 2008 as was planned. However, it is expected that a 12 months no-cost extension is needed in order to reach all programme milestones and to successfully complete sustainable embedding of the capacity strengthening part of the CoMMAL programme into CoM.



Thyolo District Hospital: one of the two new study sites

Conclusion and Recommendations MTR committee

Although the partnership had a slow start, the delay in capacity strengthening has been caught up while research project (1) still shows a delay of 6 months. This delay is adequately being addressed.

The MTR therefore recommends NACCAP to

- *allow the CoMMAL programme a no-cost extension up to 2010.*

3) Effectiveness

After 2 years, the RSC plays a modest role model in attracting highly qualified African scientists from abroad (n=3) and in encouraging young Malawian students to take up a research career. It is anticipated that the RSC that started as a project within the Post Graduate Institute will be fully integrated into and taken over by CoM in

2010. CoM already contributes to RSC by paying part of the core salaries (2 staff members). This commitment is also shown by the housing of the RSC; first being located in a small office within the GSK building of the rotavirus vaccine project, now moving to and occupying a floor of a building of the CoM itself. However, in order to really establish a sustainable, cross-cutting supportive position of the RSC, RSC should be positioned as a cross-cutting office of CoM, independently from external funding and owned by the stakeholders.

At the moment, CoM is already discussing the transformation of RSC from a project towards a department of CoM with tasks that include grant administration and management. Being a department will embed RSC into the CoM with the director of the RSC a member of the board of CoM. However, CoM does not yet have a budget line available and although staff will be core funded by CoM, RSC should earn its own budget for the development of courses, training for staff and development of a research agenda. RSC indeed has possibilities to earn its own budget by providing (monitoring) services to affiliated partners (already self-sustainable) while courses could become self-sustainable as well. Expansion of the tasks of RSC with grant management and -administration may add to its income generating possibilities.



A sign directing visitors to the previous office of Research Support Centre (just vacated at the time of the visit)

Additional partnerships and grants have already been established during the first 2,5 years of the partnership programme. For example, with Kendle/GSK (€ 20,000), MSF (training fees), The Swiss Tropical Institute (€ 410,000), Malawian Medical Journal (US\$10,000 – supporting 25 participants fees for basic research methodology course) and NIH (Gates grant € 96,000). RSC also has generated some income with courses and one-to one support (€ 8,000). CoMMAL also has applied for new grants: Welcome Trust grant with LSTM and Barts University, EDCTP grant on malaria treatment (pending), while the first steps to set up a RSC-like structure in Zambia and Zimbabwe together with SA have been made (EDCTP and WT grant pending). Effectiveness of research activities is still modest with all PhD's identified, ethical clearance obtained and only 50% recruitment of all trial participants needed and under spending of the budget.

Conclusions and recommendations of the MTR committee

The CoMMAL partnership has shown to be effective in capacity strengthening of CoM and as such in providing a role model for highly qualified Malawian scientists. The strengthening seems to be promising in terms of

sustainability as is shown by the commitment of CoM to take up the ownership of RSC, by the expressed need and commitment of affiliated partners and by generating income from external funders. Regarding scientific effectiveness is less obvious, but is expected to accelerate in the years to come.

The MTR committee recommends CoMMAL to

- include a budget for data management and monitoring in all CoM grants for reasons of financial sustainability of RSC;
- take up the challenge to co-ordinate grant management and-administration. Part of the overhead costs of future research grants could then be assigned to RSC to cover capacity strengthening services.

4) Governance, administrative & financial aspects

An advisory board governs CoMMAL, and includes representatives of all three partners (Malawi University, College of Medicine, Liverpool School of Tropical Medicine and the University of Amsterdam, AMC/Emma Children's Hospital) plus the director of RSC. The Dean of PGI of CoM reports to the Academic Board of CoM, supervised by the Principle of CoM. CoM has autonomy but is part of the University of Malawi. Project progress is monitored by the project advisory boards of each project who report to the CoMMAL advisory board. The CoMMAL team closely works together and shares expertise and facilities and services with affiliated partners. At the level of the capacity strengthening activities of the RSC, a leading role clearly exists for the Malawian staff. The staff is supported by the Post-graduate Dean (Dutch) and the Principal of CoM (UK) who have a leading role in safeguarding alignment of the RSC with the policy of the CoM.² Although the Dutch PI of CoMMAL serves as the main communication channel for NACCAP, strategies are discussed and decided upon by the whole team. In general, CoMMAL seems to have a transparent policy on improving African ownership which is illustrated also by the affiliated partners of CoM; they all state that their aim is to increase African ownership and reckon to be able to do even more so once the RSC is functioning fully operational. Three African PhD's and one Dutch PhD execute the research projects, supervised mainly by African senior scientists that re-entered Malawi from abroad. At the moment, expatriates however still take the lead in grant writing. It is anticipated that with the capacity built by the RSC, Malawian researchers will soon be able to take the lead in this aspect as well.

Financially, the NACCAP grant is managed by AMC, but transfers are handled by the grant office of CoM which is responsible for disbursement of the grant to the separate bank accounts of the different projects. The CoM grant office is paid 10% for overhead. An internal auditor for the University of Malawi audits accounts regularly and KPMG does annual audits for all the accounts. Project co-ordinator and financial manager have to approve of procurement of items costing more € 5000 or more.

In the future the RSC might handle research grant management and administration. This might be a good idea since the grant office of CoM already has a major task in handling the University accounts and lacks staff and specific expertise for handling different donor grants that all have different accountability demands. For this, capacity of the financial expertise of RSC need to be strengthened.

Conclusion and recommendations MTR committee:

² The governance of RSC now is being revised (in line with the development of RSC from a project into a supportive department of CoM, like the Library and ICT department). Discussions are taking place to install a research committee that could govern RSC (and is composed of all affiliated partners and CoM) next to the educational committee that advises the PGI. As such, RSC will be directly under the governance of the Academic Board.

CoMMAL responsibility is skewed to the European partners, but with the assignment of African senior experts there is ample room for a more balanced African-European partnership. This equality already exists at project governance and execution level. CoM seems to have in place an accountable financial administration, but the core task of the grant office is the handling of University accounts. Expertise in handling grants from different partners that all put different conditions is scarce. In addition, it is unclear how the contributions of different affiliated partners to the CoMMAL partnership are administrated by CoM. Therefore, the MTR committee wonders if the responsibility of the overall financial administration of CoMMAL already can be transferred from the European partners to the African partners. The MTR committee advises to

- start with strengthening the financial capability of the RSC in order to be able to handle external grants according to international accountability standards. For this, CoMMAL should explore the opportunities of EDCTP-calls on individual capacity strengthening.

5) Communication and dissemination

The CoMMAL programme is communicated at the RSC web site and newsletter by announcements on training and course possibilities. The web site has had 300 hits in 2008 from 20 countries and 100 new hits each month are registered. Most visited pages are the ones on courses. The 2-weekly newsletter reaches mainly stakeholders inside the University, as does the newsletter of CoM where announcements on RSC are published as well. In addition there is an alumni list serve and CoMMAL (RSC) is represented at the annual research dissemination days of CoM. Twice, CoMMAL has presented RSC at an EDCTP Forum, while the MLW has presented the added value of RSC at several donor conferences. The CoMMAL team expresses the importance of not putting a funders flag on the CoMMAL programme, because this may hinder the CoM ownership of CoMMAL. Communication with the MoH and non-scientific stakeholders (NGO's, services) is scarce (see under relevance capacity strengthening of environment). Currently MLW has employed a science communication officer and has made this officer available to assist RSC with its communication and public engagement activities. For the future, RSC is planning to employ a communication officer with MLW and located him/her at RSC.

Conclusion and recommendations of the MTR committee

The communication and dissemination activities of CoMMAL are mainly focussed on advertisement for courses and vacancies within RSC. Research results are not yet available, but lessons learnt in strengthening institutional capacity might be equally interesting at least for donors and (national and international) policy makers. Opportunities provided by international funding organisations to disseminate the RSC approach on institutional capacity strengthening are materialised but a more pro-active strategy is lacking. The MTR committee recommends to

- integrate the communication (instruments) of RSC with those of CoM;
- set up and implement a strategy to advocate RSC targeted at the MoH of Malawi, and at the embassies of donor countries such as the embassy of the Netherlands, Norway, Sweden, UK and USA;
- involve communities and NGO's in this strategy by showing them the added value of research by improving the quality of care (see relevance capacity strengthening environmental level).

4. Future of CoMMAL

The CoMMAL team indicated several specific challenges for the future of CoMMAL and specifically for the future of RSC:

RSC staffing:

- the individual support programme of RSC now has become so popular that the RSC staff is overloaded. The team is exploring possibilities to attract an additional Malawian statistician from Belgium to help out with organising group courses and one-to-one support;
- trial monitoring already is self-sustainable, but the work load takes much of the time of the RSC;
- many requests to join multi-centred research initiatives are received that may result in additional grants but absorb a lot of staff time;
- grant management could add to strengthen the position of RSC, but as yet sufficient capacity to handle and (financial) administration of grants is lacking;

Position of RSC (activities):

- Kendle/GSK now supervises ICH-GCP courses. RSC has developed its own courses but these need to be accredited in order to safeguard quality and international recognition. Then these courses should be fully embedded into the curriculum of the CoM and attract applications from the region;
- governance of RSC as a department of CoM owned by all partners but independent from them will require a thoughtful approach and sustainable ownership of CoM;

Infrastructure:

- for data management, RSC still lacks sufficient ICT infrastructure like open source software. Since data-management could become an important income generating activity, a reliable infrastructure should be in place;
- for undergraduate students, research projects need to be sought in order to allow students to use their newly acquired skills.

Conclusion and recommendations MTR committee

The CoMMAL partnership thus far has made a very good start in shaping the probabilities of strengthening CoM to become a African owned and controlled health research centre aimed and capable of clinical research, but its success may become a thread for the sustainability of RSC. Therefore, the MTR committee recommends to

- *focus on positioning RSC as a cross-cutting office of CoM, strengthen its expertise on cross-cutting activities and invest in income generating relationships for these activities. With regard to developing new research partnerships and projects it might be advisable for the coming two years to leave such activities to the affiliated partners of CoM;*
- *to formulate a business plan for RSC covering the next two years and describing the core objectives and activities of RSC as well as its anticipated positioning as a department of CoM. The business plan should include information on governance and a budget proposal for core-financing by all the partners on the basis of additional needs and related costs and might also serve to guide additional fundraising for RSC staff support.*

Annex 1: MTR programme CoMMAL

Monday 2^{de}		
<i>Presentations, Interviews & Site visit</i>		
09.00-09.10	Welcome and General introduction	Exnevia Gomo (Director RSC)
09.10-09.30	Project 1: 'Intermittent Presumptive Treatment – post discharge (IPTpd)'	Kamija Phiri, P.I.
09.30-09.50	Project 2: 'HIV and Iron in children'	Michael Esan, P.I., PhD student
09.50-10.10	Project 3: 'HIV and Iron in pregnancy'	Victor Mwapasa,,P.I.
10.15-10.45	Travel to Thyolo	----
10.45-11.00	Coffee break	
11.15-11.45	Evaluation study site and hospital	Ernest Nkhoma, in charge Thyolo
11.45-12.30	Presentation & Interview	Thyolo research team
12.30–14.00	Travel to Blantyre & Lunch break	
14.00-14.30	Visit College of Medicine (CoM) & interview	Erick Borgstein, P.G. Dean
14.30-15.00	Visit Malawi-Liverpool-Wellcome T (MLW)	Victor Mwapasa, Dep. Director MLW
15.00-15.30	Overview RSC activities, training and capacity building	Exnevia Gomo, Director RSC
15.30-16.00	Thee break	
16.00-17.30	Open slot	MTR committee
7 pm	Dinner at CoM guest-house Invitees: PhD and MSc students and other Malawian trainees	

Tuesday 3^{de}		
Research Support Centre 'Progress and milestones'		
09.00-09.30	GCP and trial monitoring	Atu Ngwira / John Chabuka
09.30-10.10	Courses and individual training	Linda Kalilani
10.10-10.30	RSC data management service	Reuban Ndindi
10.30-10.45	Coffee break	
Research Support Centre 'College of Medicine perspectives'		
10.45--12.30	Group discussion on: 1) 'RSC and Post Graduate training' 2) 'Grant management in the CoM' 3) 'RSC research Centre of excellence'	CoM representatives: 1) J. Mfutso Bengo, dep. P.G. Dean 2) C. Trigu, CoM Registrar 3) R. Broadhead, Principal
12.30-13.30	Lunch break	
Research Support Centre 'View from Collaborating institutes'		
15.00-15.30	Group discussion at MAC with: 1) Malaria Alert Centre 2) John Hopkins Institute 3) BMP-Michigan State University project	Representatives: 1) Don Matanga, Director 2) Newton Kumwenda, Director 3) Terrie Taylor, Director
15.30-16.00	Thee break	
16.00-16.30	COMMAL Summary and future directions	Michael Boele van Hensbroek, P.A. COMMAL programme
16.30-17.30	Feed back on visit	MTR committee
7 pm	Dinner with 'COMMAL representative group'	

Annex 2. Abbreviations

AMC/CPCD	Academical Medical Centre / Centre for Poverty Related Diseases
BMGF	Bill and Melinda Gates Foundation
BMP	Blantyre Malaria Project
CoM	College of Medicine
CoMMAL	Partnership programme between College of Medicine, AMC/Emma hospital and Liverpool School of Tropical medicine
CRA	Clinical research assistant
CRO	Clinical research officer
DC	Developing Country
DGIS	Directorate General International Cooperation (ministry of Foreign Affairs, The Netherlands)
EDCTP	European Developing Countries Clinical Trials Partnership
EU	European Union
FoM	Faculty of Medicine
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GSK	Glaxo-Smith-Kline
HAART	Highly active anti-retroviral therapy
ICH	International Conference on Harmonisation (WHO)
ICT	Information and Communication Technology
IDI	Infectious Disease Institute
INTERACT	Partnership programme AMC/CPCD, Makerere University, TRAC
IPT-pd	Intermittent Preventive Therapy- post discharge
IPR	Intellectual Property Rights
KCC	Kampala City Council Clinics
LSHTM	London School of Hygiene and Tropical medicine
LSTM	Liverpool School of Tropical Medicine
MAC	Malaria Alert Centre
MLW	Malawi Liverpool Wellcome Trust research programme
MS	European Member States
MSc	Master of Science
MTR	Mid-Term Review
NACCAP	Netherlands-African partnership for Capacity strengthening and Clinical trials Against Poverty related diseases
NGO	Non-Governmental Organisation
N-N	Nord-Nord (networking)
NWO/WOTRO	Netherlands Organisation for Scientific Research/ Science for Global development
PGI	Post Graduate Institute
R&D	Research and Development
RSC	Research Support Centre
SC	Steering Committee (NACCAP)
SIDA	Swedish International Development Cooperation Agency
SOP	Standard Operational Procedure
S-S	South-South (networking)
SWAP	Sector Wide Approach Policy
SWOT	Strengths, Weaknesses, Opportunities, Threats
TB	Tuberculosis
TRAC	Treatment and Research Aids Centre