

BL 2

Business Plan

2008-2013

Empowerment

**Harnessing DEC excellence and leadership for
effective application of health research**



Business Plan for JCB

May, 2007

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EXECUTIVE SUMMARY

Needs and Opportunities

Research capacity in disease endemic countries (DECs) has grown over the last decades and several countries are committing more of their own resources to health research. However, there remains a major need for expanded capacity strengthening, especially at a more strategic level and in support of priority setting and research planning. Strong health research leadership is needed in DECs to inspire innovation and direct high quality research programs that address national and regional priorities. Such leadership requires competent individual leaders, as well as a facilitating environment and interaction with health decision makers. Increasingly the international research community seeks the development of partnerships with local, national and regional institutions in DECs. To be effective, these partnerships require strong and competent leadership within the DEC health research communities. There is therefore a great need to enhance capacity for innovation and product development in DECs, to build national capacities for basic, clinical and implementation research, and to enhance research capacity in control programmes and strengthen national commitment to health research.

Overall Objective

To develop excellence and leadership in health research and decision making so that high quality institutional and national systems can identify and manage research priorities.

Specific Objectives

1. To support the development of responsible health research leadership in DECs at individual, institutional, and national levels.
2. To enhance the quality and relevance of health research in developing countries within the context of institutional and national frameworks by:
3. Promoting strong links between research, academia and control institutions
4. Promoting best practices for research and associated decision making
5. To leverage TDR's role in health research by fostering national and regional initiatives established to promote and empower local researchers to meet their own health research priorities.

Activities

The activities will support both individual researchers and institutions through a variety of mechanisms. Individuals will have access to research grants, scholarships, fellowships, re-entry grants and WHO regional office managed small grant schemes. Institutions will be encouraged to support their researchers and be provided with ongoing strategic advice and financial support. Databases on TDR researchers, institutions, research networks, ethics

committees, research policies and methodologies will be set up as key linking resources. Special attention will be given to female researchers and to countries where English is not a primary language.

Health research management courses will emphasize the need for ethical and high quality in research and decision making, for both laboratory and clinical research. This will be backed up by a process that helps countries recognize and document the achievements of researchers and institutions and facilitates transition of research into practice. TDR will also support, through a networking approach, focused curriculum development required to sustain research in priority areas of neglected infectious diseases.

‘Satellite’ business lines for national and regional initiatives will be developed that are operated and funded locally. Technical support and quality assurance will be provided from TDR until such initiatives are self-sustaining.

End-Products

- Leadership by DEC researchers and research institutions
- Research leaders in DECs with internationally recognized research projects of high quality.
- DEC universities effectively managing high impact research and generating high quality PhDs.
- Inventory of TDR researchers and research institutions in DECs, including alumni, experts and recognized laboratories and institutions, so that their expertise can be utilized.
- Short courses and masters courses established in research and management topics, maintained and sustained in DECs.
- Enhancing the quality and relevance of health research within national frameworks.
- Networks of DEC researchers, research institutions and control partners involved in discussions on national research needs and facilitating transfer of research results into practice.
- Guidelines and associated database developed on topics to inform the implementation and adoption of best practices. Internationally recognized standards increasingly being met by laboratories and researchers, human subjects protection programmes, ethics committees and data management centres.
- Concept of health research quality systems established at national level and developed.
- Regionally based 'satellite' business lines/networks on specific research activities established to address unmet needs, operating under local ownership and with sustainable locally generated funding.

Comparative Advantage

TDR is a global leader in capacity strengthening for health research in DEC countries. It has partnered with many agencies, academic and non-academic institutions and networks to support human resources and research infrastructure development. It has fostered capacity building in biomedical and health research programs for more than 30 years, and has a critical understanding of the needs of disease endemic countries and countries in transition regarding empowerment for health research leadership. TDR is itself engaged in all aspects of biomedical and clinical research, which provides it with a hands-on understanding of the need for research capacity, leadership and ethical decision-making. Since its inception, TDR has supported the training of 1,400 DEC scientists, 70% as PhDs and 20% at Masters level, with remaining 10% supported post-doctoral or short-term specialized training. Brain-drain has been minimal due to careful selection of candidates, long-term follow-up, and assistance to re-entry in the home institution. It has a track record of initiating self-sustainable regionally based activities, such as the Strategic Initiative in Developing Capacity for Ethical Review (SIDCER) and the Forum for African Medical Editors (FAME).

1. OBJECTIVES

1.1 OVERALL OBJECTIVE

The overall objective of this business line is

to develop excellence and leadership in health research and decision making so that high quality institutional and national systems can identify and manage research priorities.

No other major international health research institution has undertaken this challenge so comprehensively. TDR has a long and successful history of developing research capacity in poor, disease endemic countries. This has led to significant increases in the numbers of qualified researchers working in these countries. Today, there is a need to build on this and help develop more extensive public health leadership, so that research priorities can be set locally and research results used for new or improved health policies and changes.

This Business Line proposes to maximize TDR's strong past experience and expertise, as well as that of key partners in health research development: researchers, academic and health institutions, sponsors and regulatory agencies. This will be done through fostering and building leadership capacity within countries and regions that can respond to immediate and urgent national and regional healthcare needs and can also lead in the development of new technological and methodological innovations in the future. This new genre of leaders will also be supported in developing a quality-based health research system.

By synergizing with the other business lines of the new TDR strategy (notably on stewardship), by engaging the appropriate international parties across society and across sectors, and by targeting this business line directly at the needs of the researchers for leadership development, TDR is in a position to assist focused, results-oriented research approaches that empower countries and communities for appropriate decision-making.

1.2 SPECIFIC OBJECTIVES

1. To support the development of responsible health research leadership in DEC's at individual, institutional, and national levels.
2. To enhance the quality and relevance of health research in developing countries within the context of institutional and national frameworks by:

- a. Promoting strong links between research, academia and control institutions
 - b. Promoting best practices for research and associated decision making
3. To leverage TDR's role in health research by fostering national and regional initiatives established to promote and empower local researchers to meet their own health research priorities.

2. NEEDS AND OPPORTUNITIES

2.1 NEEDS

The need for enhanced health research leadership in many disease endemic countries (DECs) is pressing and urgent. Research capacity in DECs has grown over the last decades and several countries are committing more of their own resources to health research. However, there remains a major need for a more strategic level in priority setting and research planning, so that these countries play a leading role in setting and participating in the international health research agenda. Strong health research leadership in DECs can identify cost effective, appropriate priorities and inspire local innovation that can lead to sustainable health and economic development.

It should be recognized that health research leadership development in DECs cannot be viewed only as individual knowledge and skills, or just a technological transfer from North to South or South to South. Health leadership development depends crucially on the quality of the institutions where the researchers work and the enabling environment -- the structures and systems in the countries in which they are embedded. It needs to be developed within the context of effective biomedical, behavioural and health research programs, and integrated into national decision-making procedures for research prioritization and for health policy implementation and development.

In developing countries and societies in major economic, social, or political transition with limited infrastructure and capacity for research, appropriate oversight is not well established, particularly around the protection of people in health research. Leadership is needed to anticipate and protect the health needs of the populations being researched within sound scientific, ethical, and social frameworks.

Systems for acknowledging, recognizing and strengthening research excellence are necessary for motivation and building strong programmes. This recognition can also help funding institutions and relevant development partners at the international level identify DEC leaders for inclusion in strategic international health planning as equal partners. There is a clear and present threat that the research agenda is being driven by organizations whose interests, however well meaning, may not fully align with those of the country.

Increasingly, however, the international research community seeks the development of partnerships with local, national and regional institutions in DECs. To be effective, these partnerships require strong and competent leadership within the DEC health research communities. There is therefore a great need to enhance capacity for innovation and product development, to build national capacities for clinical, policy, implementation and social science research, to enhance research capacity in control programmes and to strengthen national commitment to health research. By focusing not just on individual excellence, but on

systems that can encourage, support and sustain such excellence and its utility, it is anticipated that DEC's can more rapidly develop and play leading roles in national as well as international scientific debate.

2.2 OPPORTUNITIES

Increasing health research leadership must be addressed globally by organizations with the vision and foresight to undertake a comprehensive program that links individual, institutional and national needs through technically sound and ethical decision-making in health research.

There is an increasing recognition of the link between improved health outcomes and economic development. The belief that investment in science and technology across all sectors is a prerequisite for economic development may result in increased funding to tertiary education institutions and research institutions in general, with positive consequences for health research.

Against this backdrop, four major empowerment challenges and opportunities have been identified to best utilize this expanded funding.

1. Historically, health policies have often been developed apart from research evidence, and researchers have often developed research questions and studies apart from control needs. The consequence is that new drugs and other tools developed are sometimes not used because their design and implementation was not fully cognizant of, or attuned to, local and regional health circumstances, while other needy areas are left unmet. Building a policy/research interface in countries is critical to prevent this for the future. Lessons learned from these links can be implemented, leading to the development of a quality research culture within ministries of health and partnerships with research institutions and academia that is more efficient and cost effective. Research into interventions, implementation and social issues plays a critical role. Such an emphasis on the practical outcomes and value of research for national development will enhance public and media trust and help realign research planning and investment with more efficient and accountable public health outcomes.
2. Increased funding of science and technology is leading to multiple players and projects. There is a need for collaborative and pragmatic coordinated approaches. Areas where such coordination can occur include the development of networks and innovative courses, promoting best research practices, strengthening input and advocacy from national authorities on their research priorities and linking between the public and private sectors.
3. There are several groups that need specific attention. Least developed countries (LDCs) have academic and research infrastructures that are very weak. Special assistance is required to facilitate the development of appropriate research capabilities

in these groups of countries. In addition, special attention must be devoted to countries where English is not a first language of academic instruction or use in the institutions. Enhancing the role of women in research within the broader context of gender perspective in health research is also critical.

4. New partnerships are beginning between donor countries and institutions with local, national, and regional institutions in DECs. There is an opportunity to ensure that there is equality within these partnerships and that the needs of the DEC countries and institutions are fully taken into account by research programmes and outside funders. Such partnerships cannot be fully effective if the leadership and technical expertise within the DEC health research communities is not well developed and efficient. This efficiency and excellence must be at all levels - individual, institutional and national. International partnerships should be fully utilized to build sustainable, long-term capacity in disease endemic countries. There are also increasing opportunities for new regional and sub-regional initiated networks and partnerships that can play a strong role in developing research based mechanisms and solutions for regional needs.

3. COMPARATIVE ADVANTAGE

3.1 TDR COMPARATIVE ADVANTAGE

TDR provides global leadership in the development of strategies for addressing major diseases affecting large populations in disease endemic countries. It has partnered with many agencies, academic and non-academic institutions, research centres and networks to support human resources and research infrastructure development.

As a WHO-based program with links and coordinating potential across other major UN and international agencies, TDR's leading position in biomedical and health research is unique. In addition, TDR has fostered capacity building in biomedical and health research programs for 30 years and has a very strong reputation for international leadership in this area with high credibility and loyalty among the DEC researchers and institutions. Its experience has provided it with unparalleled insight into pragmatic empowerment and leadership approaches for disease-endemic countries and countries in transition. Crucially, TDR is itself engaged in all aspects of biomedical and clinical research, which provides it with a hands-on, upfront, and practical understanding of the need for leadership and ethical decision-making in health research.

Although several international cooperation programmes have supported capacity building, few, if any, match TDR's core expertise, staff scope and the range of activities combining R&D and capacity development at individual, institutional and country level. The leverage potential of TDR activity makes this area of endeavour particularly appealing. This business line, in combination with TDR's overall strategy and range of activities, seeks to make TDR among the most comprehensive leverage programmes on human resources and research environment for tropical disease research development in disease endemic countries.

3.1.1 Proven technical and field experience

Since its inception over 30 years ago, TDR has supported approximately 1,400 DEC young scientists (35% female) who have received formal degree training, PhD (70%) and Master's (20%), with the remaining 10% supported for post-doctoral or short-term specialized training. Through continued support, many of these individuals have risen to positions of significance in their countries and have gained international recognition. Costs have been minimized by negotiating study programmes with partners and increasing the training capacity of regional and national institutions. Within the TDR alumni, brain-drain has been minimal due to careful selection of candidates, long-term follow-up, and assistance to re-entry in the home institution. This legacy represents a major contribution of TDR towards the development of in-country and regional leadership in health research.

TDR has also initiated several projects in the area of best practices in experimental, pre-clinical and clinical research, research ethics and project management, and has set internationally accepted standards for supported projects. Many of these activities are now ready for institutional and system wide implementation.

The following TDR competencies are highlighted:

- strong convening and networking power and experience with a wide range of organizations;
- extensive knowledge of, and good relationships with, scientific groups globally and in DEC's;
- access through WHO and the UN to DEC government structures and national/international public health programmes and research institutions;
- excellent credibility and response from the academic community and policy makers;
- good knowledge of constraints and needs of DEC's, reinforced by the expertise and presence of regional and country offices of WHO, other co-sponsors and stakeholders;
- flexibility in designing strategies, partnerships and grant systems responding to the evolving research environment in tropical diseases;
- scientific and financial leverage of DEC's' research groups to help them access significant research grants;
- the development of standards for best practices and standard operating procedures in health research;
- the implementation of programmes in ethics for decision-making in health research;
- training and positioning DEC health researchers to take on positions of responsibility with TDR research activities; and
- developing quality systems for health research focusing on ethical and technically sound decision-making.

3.1.2 Demonstrated stewardship

Researchers have trusted TDR to lead human resource and institutional development for 3 decades. TDR has assumed leadership in areas such as best practices in pre-clinical and clinical research, research ethics, project management and community-directed interventions, setting internationally accepted standards for supported projects. Tutorial materials and guidelines have been prepared and adopted by training institutions in DEC's, enabling endemic countries to test new tools as they become available.

A major initiative was undertaken within TDR to address ethical issues in health research by building capacity across all parties engaged in ethical decision-making in such research. The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) was formed,

composed of a network of independently established regional forums for ethical review committees and health researchers and invited partner organizations with an interest in the development of ethical review. This international network provides a voice for human subjects research issues in national, regional, and international healthcare settings. It has also developed into a platform for promoting health research leadership within the field of ethical review.

Another example is the establishment of the initiative FAME (Forum of African Medical Editors) for improving the quality of medical journals in Africa. FAME trains medical editors and potential authors in DECs. A train-the-trainers course on scientific writing was carried out and several courses conducted for local journals. The impact of these activities is enhanced recognition and use of the journals, their articles and the scientists that are authoring them.

More recently, TDR has stewarded the expansion of public health training capacity in Africa by partnering with University of Cape Town and University of the Witwatersrand to promote doctoral level training programmes in priority disciplines of health economics, health policy and epidemiology. Masters courses, including in social sciences, have been developed.

There are many networks developed with a focus on South-South cooperation complemented by North-South partnerships. The Multilateral Initiative for Malaria (MIM) task force activity is one high profile example, but many other largely self-sustaining networks are promoted and supported.

The underlying principle behind all these activities is that ownership, and hence sustainability, transfers as soon as possible to disease endemic country institutions.

3.2. SYNERGIES WITH OTHER ORGANIZATIONS

TDR already has well-established synergies with DEC researchers that are leaders in their field of expertise and practice. There are also existing and developing strong synergies with government health institutions and universities, public and private organizations, and public-private partner (PPP) initiatives to develop relevant indigenous training programmes. Several national and regional agencies and networks have already associated with TDR in capacity development. This will expand considerably, bringing a distinctive regional priority perspective linked to an understanding and development of broader research systems. TDR also works with international agencies such as the Fogarty International Center of the National Institutes of Health (NIH) and the Wellcome Trust that have a very strong mission and mandate to build research capacity for tropical disease research in disease endemic countries. There are specific areas of synergy that can be developed at the international level, also, with the Global Forum for Health Research and COHRED.

4. ACTIVITIES AND END PRODUCTS

Capacity building and empowerment will be embedded within all the business lines of TDR. The activity of this BL provides a specialized focus and will seek to support and assist other BL's in their capacity building and empowerment endeavours.

In all three objectives, there will be particular emphasis on gender issues. It will redress the under-representation of women in tropical disease research and training by offering - wherever appropriate and through designated funding mechanisms - special grant opportunities (research training grants, re-entry grants and fellowships) to female researchers and their career development. The BL will further support regional and global networking opportunities that empower women scientists in their careers. Specific attention within regional/national initiatives will address structural factors inhibiting women scientists in advancing their careers or making best use of their acquired leadership capacities.

Special attention will be given to least developing countries (LDCs). Attention will also be paid to countries for which the first language of operation is not English.

DEC researchers and institutions will have responsibility and authority to deliver on the short-term goals of projects and to transform the activities and support into self-sustainable, DEC owned and led activities.

It is critical that attention be paid in the initial start-up phase of the business line to the development of appropriate frameworks and networks that will be necessary to strategically realize the institutional and national level of capacity building and empowerment.

4.1 KEY ACTIVITIES

Objective 1. To support the development of responsible health research leadership in DECs at individual, institutional, and national levels.

This objective is developed across three major activities that group specific programs and initiatives. These three activities are inter-related, providing for mutual support and horizontal movement of specific engagements. They consist of targeted funding for capacity strengthening for leadership development, information exchange and decentralized management strategies.

1. Capacity strengthening towards excellence and sustainability

This element of the business plan represents the major funding component and provides direct support to specific individuals within their institutional context. It develops responsible researchers who are accountable and responsible for research, understanding and acting

according to good research practice, as well as responsible institutions that are accountable and responsible for quality and sustainable research/training. The activities include:

- Facilitating and supporting researchers to address local/regional health and ethical issues through the Multilateral Initiative on Malaria (MIM), re-entry grants, regional small grant schemes and research in other business lines.
- Developing/strengthening PhD/MSc training of individuals and the capacity of DEC institutions to conduct such training.
- Facilitating the establishment and development of training programmes/courses to be based in DEC institutions (e.g., Masters courses and short courses in immunology, research methodology, statistics, data management, project management, social science, health economics, good clinical practice, good laboratory practice, ethics, etc.) for researchers and associate researchers across different disciplines, managers, ethics committee members and other public health stakeholder groups as appropriate (including patients/participants in studies).
- Developing centres of expertise (e.g. data management, social sciences, course development, etc.) as focal points for regional capacity development.

2. Information exchange

The activities will involve the collection, collating, and updating information on:

- Existing TDR researchers, TDR alumni, TDR networks in biomedical research (including bioinformatics, molecular biology), investigators, sponsors, Data Safety Monitoring Boards (DSMBs), regulatory agencies, patients and other organizations. The investigators and institutions listed may thus be readily contacted by other organizations and national institutions.
- Best practices (e.g., clinical, laboratory, ethical review committees, management, scientific writing and editing).
- Critical capacity development issues, research policies as appropriate, laws, regulations, and guidance.

The information dissemination and utilization will be through the TDR web site and knowledge management framework.

3. Decentralized management strategies for research and training capacity development in DECs

This is a new Modus Operandi to facilitate the decentralization of some BL2 activities through local people and institutions who take responsibility for the ongoing management of these activities and networks. The WHO Regional Offices will be involved where appropriate, enhancing TDR collaboration with its regional and national counterparts. This is an important mechanism to develop DEC leadership, country-relevant agenda, and eventually

promote decision-making empowerment. A common management system for the networks will be introduced to monitor and evaluate the activities and ensure operational consistency in the networks. The activities include the following:

- Convening a stakeholder meeting to further develop the activities of BL2 within TDR, WHO regional offices and with external partners and DECs to identify needs, synergies, processes and activities for research and training capacity development in DECs.
- Developing strategic alliances with other stakeholders (e.g., the Global Forum, COHRED, Wellcome Trust, bilateral organizations, etc.) to promote advocacy and fundraising for empowerment in national and international capacity building agenda.
- Developing a Quality Management System (QMS) with reference to the international standards and guidelines for quality management for the project policies, processes and procedures required for this core aspect of BL2. QMS enables BL2 to identify, measure, control and improve the various core BL activities that will ultimately lead to improved performance.
- Identifying and developing thematic networks, including local leadership in priority areas, and convening initial meetings to implement networks and introduce QMS.
- Developing focused networks around certain knowledge disciplines to build on funded activities and help build and sustain regional capabilities.
- Promoting and facilitating interaction between different fora and networks in different regions, discipline, technologies, institutions, universities and the public sector group.

Objective 2. To enhance the quality and relevance of health research in developing countries within the context of institutional and national frameworks by:

- a. Promoting strong links between research, academia and control institutions
- b. Promoting best practices for research and associated decision making

This objective is developed across three major activities that build and promote sustainable national and regional systems.

1. Health research quality assurance system

This is a system designed to develop quality health research and policy practices based on local and national health research needs. The activities include:

- Developing a concept and program on Quality and Ethical Decision Making in Health Research as a basis for developing health research leadership.

- Promoting networks for discussion and dialogue on mechanisms that determine health research priorities, ensure high quality research, and assess evidence for policy at the country level.

2. Good practices programme

- Further develop guidelines on best science and scientific management practice.
- Support the further development of appropriate practices in countries to ethically review research, ensure appropriate human subject protection and ensure quality standards in biomedical research at laboratory and clinical research levels.
- Build and support the development of appropriate accreditation programmes (such as SIDCER ethics committee recognition programme) to recognize and promote good practice.
- Link to databases for information exchange on best practices.

3. Enhanced training capacity for DEC's through establishment of partnerships

Networks within countries and between countries and across disciplines will be promoted and facilitated to coherently develop knowledge-based infrastructures and platforms for common learning. TDR will leverage these activities, involving numerous partners to assist their individual and collective contribution to training and appropriate capacity building.

- University networks to discuss appropriate curriculum developments to promote innovative responses to, and control of, infectious diseases, e.g., postgraduate curricula on product R&D, social science.
- International fellowship programs for basic, product R&D and social, behavioural and clinical research in neglected diseases, and research ethics.

Objective 3: To leverage TDR's role in health research by fostering national and regional initiatives established to promote and empower local researchers to meet their own health research priorities.

1. Satellite business lines

- A number of opportunities exist for TDR to technically assist and quality assure regional and sub-regional initiatives that address priority health research issues for which funding can be generated locally within the region. TDR can provide international credibility to the activity, assure its relevance and advise on best practices of governance and management.
- The concept of a 'satellite' business line has been coined to describe this concept. Through this activity, TDR will support initiatives that address regional concerns and facilitate networking and outreach. Due diligence will be undertaken to ensure activities are of appropriate quality and relevance.

4.2. END PRODUCTS

The major end-products of this BL will be excellence in the human and institutional resources to provide DEC leadership in health research.

Objective 1. To support the development of responsible health research leadership in DECs at individual, institutional, and national levels.

1. Capacity strengthening towards excellence and sustainability

- At least 10 additional health research leaders implementing international good practices in their institutional and national research (Q4 2013).
 - a. At least 20 additional internationally recognized quality research projects in DECs.
 - b. At least 5 of these projects addressing national public health issues through a public organization or report that is used for policy implementation.
- At least 3 additional universities/research institutions that develop a PhD or equivalent training programme in an unmet health research area (Q4 2013).
- At least 15 additional universities/research institutions with demonstrated ability to provide sustainable training in Africa, South America and Asia, leading to responsible research within country and region.
- At least 3 additional universities effectively managing high impact research and generating internationally recognized high quality PhDs (Q4 2013).
- At least 5 clinical data management centres established and functional in Africa (Q4 2013).

2. Information exchange

- Inventory of existing TDR researchers, research institutions/networks in DECs, TDR alumni and universities (offering PhD training and other short courses or workshops), experts in TDR diseases, recognized research laboratories, ethics committees, researchers, national accredited laboratories, and research supported by TDR (Q4 2009).
- Functional inventory with reference to the rate of exchange information on the website, utilization of expertise and expansion of networks of different disciplines (Q4 2013).

3. Decentralized management strategies for research and training capacity development in DECs
 - Detailed five year activity plan in SEARO and EMRO (Q4 2008), AFRO and WPRO (Q2 2009).
 - Forum of capacity strengthening stakeholders formed and functional with a common goal of promoting advocacy and fund raising for developing country empowerment in national and international capacity building agenda (Q2 2009).
 - Management and oversight of capacity building activities developed and embedded in all BL projects, national and regional institutions (academic, research and public health) Q4 2008.
 - Networks developed through TDR related activities spanning research activities, clinical monitoring, ethical review and other best practices created and utilized in strategic dialogue on stewardship/capacity building/ empowerment needs (2 years, end of Q2 -2010).

Objective 2: To enhance the quality and relevance of health research in developing countries within the context of institutional and national frameworks by:

- c. Promoting strong links between research, academia and control institutions
 - d. Promoting best practices for research and associated decision making
1. Health research quality assurance system
 - Networks of researchers and institutions (academic and public health) in developing countries actively involved with discussion on national and regional research needs (Q2 2010).
 - Publications of national guidelines and Standard Operating Procedures (SOPs) for ethical review and researchers from at least five countries in each WHO region involved, through TDR established network in ethics -- SIDCER, (Q4 2013).
 - Concept of quality health research system developed, described and initiated in at least 10 developing countries (Q4 2013)
 - Health research protections programme established in at least 5 countries (Q4 2013).
 2. Good practices programme
 - At least 25 research institution laboratories and 50 researchers recognized as meeting international standards, through certification or recognition programme (Q4 2013).

- At least 20 national ethics committees in regional forums (Forum in Asia and Western Pacific, Eastern Europe, Latin America, Africa and Middle East) are SIDCER recognized ethics committees (Q4 2013).
 - National ethic committees accreditation programme established at least in five developing countries (Q4 2013).
 - Recognition systems in biomedical research explored and, if appropriate, developed in several disease endemic countries.
3. Enhanced training capacity for DEC's through establishment of partnerships
- Networks operating with committed partners to facilitate exchange and training of researchers (Q2 2011).

Objective 3: To leverage TDR's role in health research by fostering national and regional initiatives established to promote and empower local researchers to meet their own health research priorities.

1. Satellite business lines
- At least three satellite business lines established (Q4 2013).

4.3 INTERIM IMPLEMENTATION MILESTONES

Objective 1

- Information exchange database established (1 year Q4 2008).
- A framework for operation of focused grant mechanisms, e.g., MIM, re-entry grants and small grants established (2Q 2008).
- A list of forums to be established and their structure and terms of references set up, e.g., researchers, patients and DSMB forum (Q4 2008).
- A framework for more formal university/institution engagement and participation in TDR promoted training, capacity building and empowerment activities (Q2 2008).
- Document regionally relevant empowerment agenda for developing research capacities in areas of high priority with a clear understanding of the roles of each partner and management responsibility for the proposed activities (Q4 2008).
- Committee for quality management system formed (Q1 2008).

Objective 2

- Establishment of expert group to discuss and define strategies for assisting national health and research authorities with the development of in-country health research quality systems, including national guidelines and requirements for health research for infectious diseases (Q2 2008).
- Required quality standards for the lab and researchers established (Q3 2008).
- Quality standards developed and published for TDR investigators, monitors and Data Safety and Monitoring Boards (Q4 2008)

5. FUNDING

5.1 RESOURCE REQUIREMENTS

US \$ x 1000

Objective	Description	2008	2009	2010	2011	2012	2013
1	Health Research Leadership	4,478.0	5,055.0	6,277.0	6,827.0	7,027.0	7,027.0
1.1	Responsible Capacity Strengthening	3,878	4,555	5,677	6,127	6,327	6,327
	HR for Institutional Strengthening	1,350	1,555	2,149	2,149	2,149	2,149
	Training Capacity	300	425	450	450	450	450
	LDC institutions	300	350	750	750	750	750
	Immuno Centers	450	430	449	449	449	449
	Short course Training	300	350	500	500	500	500
	Research	2,428	2,900	3,428	3,878	4,078	4,078
	MIM (Mixed fund)	1,728	1,700	1,728	1,728	1,928	1,928
	Small Grant	300	450	400	450	450	450
	Re-entry Grant	300	500	1,200	1,600	1,600	1,600
	Ethical Issues Research	100	250	100	100	100	100
	Regional networks	100	100	100	100	100	100
1.2	Information Exchange	200	100	100	100	100	100
1.3	Management strategies	400	400	500	600	600	600
2	Quality of Research	850	900	1,050	1,100	1,100	1,100
2.1	Quality programme	400	400	500	500	500	500
2.2	Recognition programme	300	400	400	400	400	400
2.3	Academy (Training Partners)	150	100	150	200	200	200
3	Regional / National Initiatives	100	150	100	100	100	100
	Regional / National Initiatives	100	150	100	100	100	100
	Activities	5,428	6,105	7,427	8,027	8,227	8,227
	Personnel Costs	2,627	2,627	2,627	2,627	2,627	2,627
	No. of professional staff	8	8	8	8	8	8
	No. of support staff	7	7	7	7	7	7
	Total	8,055	8,732	10,054	10,654	10,854	10,854

6. RISKS

There is a need for full participation and commitment of responsible research institutions in these activities. Without it, full empowerment cannot be realized. The poor research career path and limited capacity of many DEC's to make full use of highly qualified professionals are possible threats and may result in brain drain. It is anticipated that by better engaging top scientists and policy makers in national dialogues that this threat may diminish.

Science and technology and national health research systems are frequently underdeveloped in DEC. They are fragile and unable to compete with more immediate needs for resources. The introduction of a research culture within health systems and the appropriate use of new knowledge and evidence for policy should be developed at the same time as human and institutional resources.

This plan requires a concerted effort supported by all projects and business lines across TDR. Failure to achieve support and synergistic input from across TDR will limit potential success.

This BL structure and activities have been developed to bring clear focus and structure in the areas of information, education, and quality. In addition to this, a Quality Management System incorporating periodic external review will constantly monitor and evaluate the business line in order to ensure that the outcomes are in keeping with the objectives and that any negative outcomes are avoided or, should they occur, be immediately corrected.