



Empowerment

TDR EMPOWERMENT FUNCTION (BL2)

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Table of contents

Overview and highlights	5
1. Context, strategic objectives and framework	7
1.1. Context and rationale	7
1.2. Strategic objectives	8
1.3. Strategic framework	8
2. Key stakeholders, roles and responsibilities	12
3. Implementation plan (2008–2013) and progress	14
3.1. Plans, progress and key milestones	14
3.2. Progress/delays and global context changes: implications for 2008–2013 plans	19
3.3. Activities to be implemented in 2009	20
4. Leverage, contributions to stewardship and synergies with TDR business lines	21
4.1. Leverage	21
4.2. Contributions to stewardship	21
4.3. Contributions to other TDR research business lines	22
4.4. Elements enhancing sustainability of Empowerment Function outcomes	22
5. Critical issues and suggested solutions	24
6. Annexes	25
6.1. Publications resulting from Empowerment Function or related activities	25
6.2. Scientific Advisory Committee (SAC) membership	30
6.3. Responses to specific JCB/Scientific and Technical Advisory Committee (STAC) requests	31

List of abbreviations

BL	Business Line	FERCAP	Forum for Ethical Review Committees in Asia and Western Pacific
BL1	TDR/Stewardship	MIM	Multilateral Initiative on Malaria
BL10	TDR/BL10 Visceral Leishmaniasis Elimination (for visceral leishmaniasis)	NGO	Nongovernmental organizations
BL2	TDR/Empowerment	NIAID	National Institute of Allergy and Infectious Disease
BL6	TDR/BL6 Drugs for Helminths/NTDs (for moxidectin clinical trial)	NIH	National Institutes of Health
BL8	TDR/BL8 Evidence for Treatment of TB/HIV (for TB/HAART; gatifloxacin and 4FDC)	PABIN	Pan-African Bioethics Initiative
BL9	TDR/BL9 Anti-malarial policy & Access (for malaria)	PAD	Portfolio Planning and Development
CDF	Career Development Fellowship	QM	Quality management
CDM	Clinical Data Management	QMS	Quality management systems
CIS	Commonwealth of Independent States	R&D	Research and Development
DEC	Disease-Endemic Countries	REB	Research Ethics Board
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Effort	RNAS+	Regional Network of Research, Surveillance and Control of Asian Schistosomiasis
FAME	Forum for African Medical Editors	RNSA	Research Network for Schistosomiasis in Africa
FECCIS	Forum for Ethics Committees in the Confederation of Independent States	PSSMC	Partnership for Social Sciences in Malaria Control
FLACEIS	Latin American Forum of Ethics Committees in Health Research	RSG	Research Strengthening Group of Empowerment
FOCUS	Forum for Institutional Review Boards/ Research Ethics Boards in Canada and the United States	TSC	Training Steering Committee of Empowerment
GCLP	Good Clinical Laboratory Practice	SAC	Scientific Advisory Committee of Empowerment
GCP	Good Clinical Practice	SEARO	WHO Regional Office for South-East Asia
GLP	Good Laboratory Practice	SGR	Small Grant Researchers
GRP	Good Research Practices	SIDA	Swedish International Development Agency
HAT	Human African Trypanosomiasis	SIDCER	Strategic Initiative for Developing Capacity in Ethical Review
ICMR	Indian Council of Medical Research	STAC	Scientific and Technical Advisory Committee
ICRCC	International Clinical Research Collaboration Center	TCELS	Thailand Center of Excellence for Life Sciences
IRB	Institutional Review Board	TDR	UNICEF/UNDP/World Bank/WHO/ Special Programme for Research and Training in Tropical Diseases
ISO	International Organisation for Standardisation	TOR	Terms of Reference
ITOCA	Information Training and Outreach Centre for Africa	USAID	United States Agency for International Development
IVR	WHO/HQ Initiative for Vaccine Research	WHA61.21	World Health Assembly's <i>Strategy and plan of action on public health, innovation and intellectual property</i>
JCB	TDRs Joint Coordinating Board	WIRB	Western Institutional Review Board
LDC	Least Developed Countries		
LDF	Leadership Development Fellowships		
LTG	Leadership Training Grants		
MFES	Middleton Foundation for Ethical Studies		

Overview and highlights

Overall strategy

TDR has a long and successful history of developing research capacity among institutions, individuals and networks involving poor and disease-endemic countries (DECs). Today, there is a need to build upon this foundation and support the development of not only research capacity but also research leadership. In this context, the goal of the Empowerment Function is to develop and sustain leadership in health research and decision-making so that high-quality institutional and national systems can identify and manage research priorities.

The present Empowerment Function has three strategic objectives: (1) development of leadership; (2) linkage between research, academia and control institutions with best practice in research; and (3) leverage of TDR's role in health research. The Empowerment Function's activities support individual scientists and institutions in DECs to engage more fully in TDR's research business lines (as leaders or contributors) and to play leadership roles in their institutions, at national and international levels. Through its empowerment activities, the Empowerment Function promotes equity and gender equality in the development of research leaders, as well as supporting research on gender and equity issues.

Operational approach and progress

Progress achieved is described here in the context of four functional areas of activity.

1. **Capacity for research management and leadership (at individual and institutional levels).** In 2008, a more comprehensive process of selection, monitoring and evaluation of researchers and institutions was implemented. Grants were reshaped to provide for long-term sustainability, higher-quality processes and expanded partnerships.
2. **Training (sustainable quality training in DECs).** In 2008, efforts to harmonize short courses were initiated. The selection process for individual grantees was revised to include evaluation of home institutions, including site visits. A new initiative for TDR in-house Leadership Development Fellowships (LDF) was created and begins implementation in 2009.
3. **Networks.** Building upon past successes in initiating, leveraging and supporting research networks, the Empowerment Function continues to facilitate a wide range of active networks. In 2008, a planned new social science network was under development. Additionally, an information exchange database was under development to support collaborations, strategic alliances and situation analysis among networks, as well as individuals and institutions. However, the planned development of a new stakeholders' network for capacity-building was shifted to the new ESSENCE (Enhancing Support for Strengthening the Effectiveness of National Capacity Effort) initiative launched under the auspices of TDR's Portfolio Development (PAD) team and supported by the Swedish Development Agency (Sida).

4. **Quality management and evaluation.** An emphasis on quality and excellence is pivotal to the credibility of leadership development, and can contribute greatly to the sustainability of DEC health research initiatives. In 2008, quality management concepts were integrated into the various TDR processes of research, training and network activities. An introductory course on quality management is under development – the first module will be available for researchers in the first quarter of 2009.

Progress/delays: effects on 2008–2013 plans

There have been delays in the harmonization of short course curricula. Additionally, development of a new curriculum in *Social sciences research to support product research and development (R&D)* was delayed following the decision to initiate this as a short course rather than a full PhD programme. Delays in the recruitment of a quality & evaluation manager delayed the development of the quality management training curriculum and its implementation by one year.

Leverage and stewardship

All of the Empowerment Function's activities (e.g. capacity for leadership, training, networks and quality management) are undertaken in the context of research projects and thus are instrumental in leveraging a broad range of research initiatives. A key milestone this year was the signing of a cooperation agreement with Thammasat University, Thailand. Under the new agreement, Thammasat University will act as a TDR clinical coordination and training centre for health research, initiating capacity-building activities (particularly in relation to good research practice) throughout the South-East Asia and Western Pacific regions.

Also in 2008, Thailand's Food and Drug Administration enacted regulations requiring systematic ethical review to international standards for clinical research. This represents a milestone in TDR's efforts to promote discussion in the Regions about ethical aspects of research as an important research priority – and to steward such discussion into policy and practice through the activities of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

1. Context, strategic objectives and framework

1.1. Context and rationale

Despite increased investments in health research in DECs, there has been slow progress in controlling some of the most neglected diseases. Many cost-effective interventions such as bednets still are not used widely or efficiently. New drug leads for neglected tropical diseases, tuberculosis and malaria represent only a small fraction of all new chemical entities developed. There is clearly a need to improve harmonization of research and development investment and to align such investments with country priorities.

TDR has a long and successful history of developing research capacity in poor DECs, leading to significant increases in the numbers of qualified DEC researchers over the past three decades. However, today there is a need to go further and support the development of public health leadership in these same countries. Such leadership can respond to urgent national and regional health-care priorities, leading to the development of technological and methodological innovations. Fostering such leadership helps to ensure that global and regional research priorities and investments reflect the real needs of DECs and thus can lead to real improvements in health.

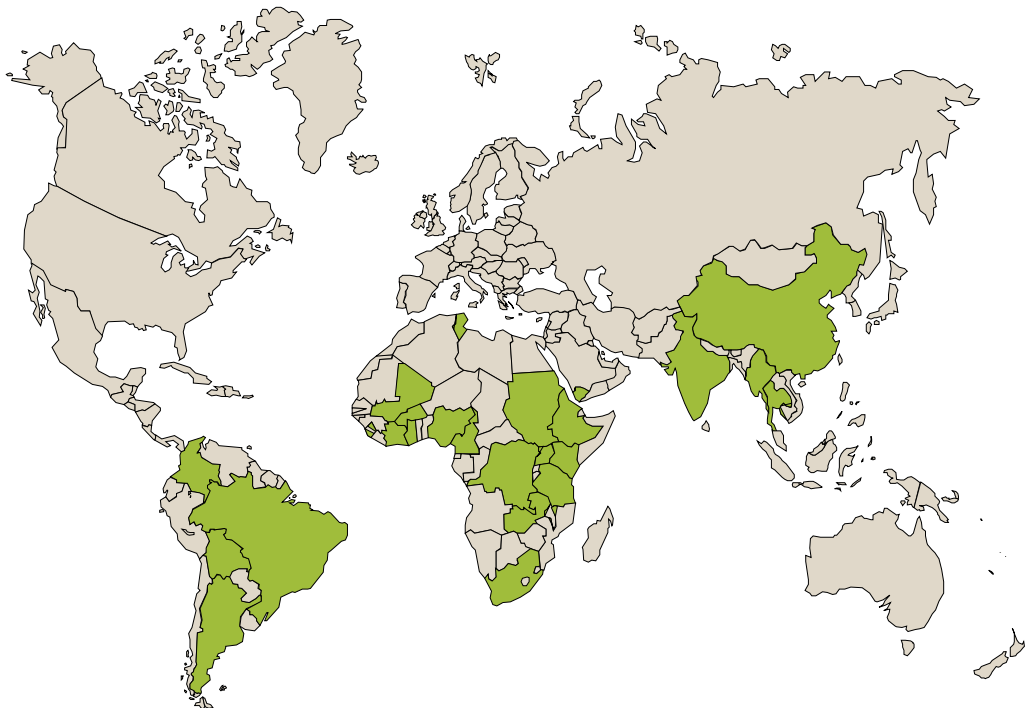


Fig. 1. Global distribution of current Empowerment activities

In line with this, BL2 is refocusing its activities on *developing the research management and leadership skills* of researchers and their institutions in an integrated manner. Through support of appropriate research training and research activities, investigators will be identified and positioned to engage with TDR research business lines and to play leadership roles in their institutions at national and international levels. Intensive support for individuals will cover both technical skills and competencies in research management. The capacity of the individuals' institutions will be strengthened concurrently so that individual research initiatives flourish alongside the broader professional development of relevant institutional staff, while also ensuring the provision of adequate infrastructure and systems for quality management.

1.2. Strategic objectives

The overall goal of the present Empowerment Function is to develop and sustain leadership in health research and decision-making so that high-quality institutional and national systems can identify and manage research priorities. Three strategic objectives aim to further this goal:

1. **Leadership** – to support the development of responsible health research leadership in DECs at individual, institutional and national levels.
2. **Quality of health research** – to enhance the quality and relevance of health research in developing countries within the context of institutional and national frameworks by promoting:
 - strong links between research, academia and control institutions; and
 - best practices for research and associated decision-making.
3. **Leverage** – 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.

1.3 Strategic framework

Strategic approach

The three main end products by 2013 and their expected outcomes and impact within the global health context are presented in **Fig. 2**.

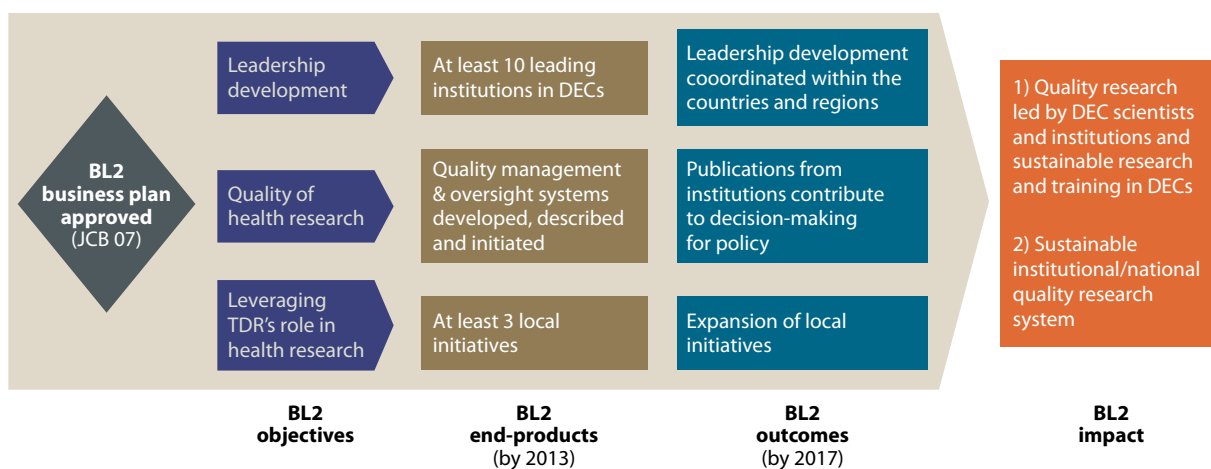


Fig. 2. BL2 strategic approach

TABLE 1. INDICATORS FOR END-PRODUCTS AND OUTCOMES

Objectives	End-products	Indicators for end-products	Outcomes	Indicators for outcomes
Leadership development and sustainability	New research institutions in DECs recognized by international research stakeholders (by 2013)	Total number of institutions (at least ten) that establish and lead health research initiatives in alignment with, or in response to, country research plans	Leadership development coordinated within countries and regions (by 2017) Publications from these research institutions contribute to decision-making for policy (by 2013)	Total number of regions with leadership development model replicated Percentage increase in the number of collaborative research publications used to support decision-making
Quality health research	Quality management systems (QMS) and oversight system developed, described and initiated in developing countries	Number of institutions/ countries that integrated QMS into their research activities (at least 10 by 2013)	Institutions are requested to provide opinions to address policy issues at different stages (by 2015)	Numbers of policy committees in which institute members participate
Leverage	Functional locally established initiatives	Number of initiatives leveraged from TDR's roles in health research	Expansion of local initiatives by countries	Number of local initiatives

Leadership development programmes for TDR grantees are designed around a four-step process of advancement: (1) established researcher; (2) advanced researcher; (3) researcher leading partnerships; and (4) health research leader.

Grants available in the first three steps include: (1) leadership training grants (LTGs); (2) career development fellowships (CDFs); and (3) leadership development fellowships (LDFs) (Fig. 4).

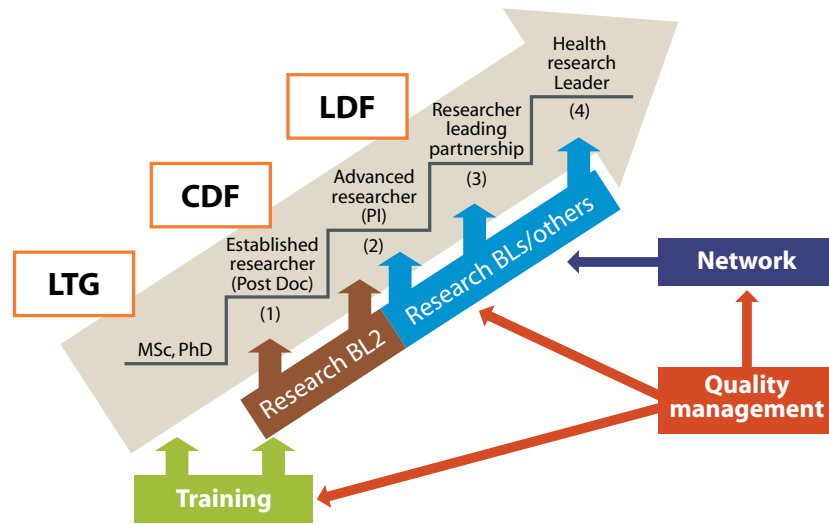


Fig. 4. Four stages of leadership development.

LTG: leadership training grant; CDF: career development fellowship; LDF: leadership development fellowship.

2. Key stakeholders, roles and responsibilities

The Empowerment Function interacts directly with grantees, stakeholders in DEC countries and institutions, and TDR/WHO and its partners. In the past, many of TDR's collaborations with institutions, networks and groups have been informal, e.g. through joint meetings and jointly-funded projects. The new strategy aims at greater formalization of these relationships along the lines of the following functions and activities. The major categories of stakeholders are listed below; their roles and responsibilities are detailed in **Table 2**.

Academic institutions and training networks

Academic institutions play the major role in hosting, supporting and sustaining training activities globally and at national and regional levels. The Empowerment Function interacts with dozens of academic institutions (in Asia, Africa, the Americas and the Western Pacific and Eastern Mediterranean Regions) and with developed country institutions to design, initiate and expand training programmes to address special needs and gaps (e.g. health economics, social sciences, bioinformatics) and to train the general public health workforce. The Empowerment Function provides researchers working on infectious diseases of poverty with opportunities to gain new skills and to strengthen collaboration and networking. Partnerships with networks of academic institutions also are formed around certain training activities such as good clinical practice (GCP), good clinical laboratory practice (GCLP), clinical data management (CDM), good laboratory practice (GLP) and planning and evaluation.

Nongovernmental organizations (NGOs) and NGO-supported networks

NGOs have played a major role in the development and capacity building of networks for ethical review. Key NGO stakeholders with which the Empowerment Function interacts include the Middleton Foundation for Ethical Studies (MFES)

as well as the TDR-initiated SIDCER network, including its regional forums – Forum for Ethical Review Committees in Asia and Western Pacific (FERCAP); Pan-African Bioethics Initiative (PABIN); Forum for Ethics Committees in the Confederation of Independent States (FECCIS); Latin American Forum of Ethics Committees in Health Research (FLACEIS); and Forum for Institutional Review Boards (IRBs)/Research Ethics Boards (REBs) in Canada and the United States (FOCUS). Other NGO-supported networks with which the Empowerment Function interacts include the Joanna Briggs Institute (for systematic review); AuthorAID; Forum for African Medical Editors (FAME); Information Training and Outreach Centre for Africa (ITOCA); Regional Network of Research, Surveillance and Control of Asian Schistosomiasis (RNAS+); Research Network for Schistosomiasis in Africa (RNSA); Partnership for Social Sciences in Malaria Control (PSSMC); HAT Consortium; Bioinformatics Net and Vector Genomics Net.

Private sector

Private-sector institutions such as Roche Pharmaceuticals and the Western Institutional Review Board (WIRB) have played a major role in supporting TDR-initiated ethical review training and GCP, as well as training in the management of ethics committees.

Public sector

Key stakeholders include the Indian Council of Medical Research (ICMR) and the National Institutes of Health (NIH)/Fogarty International Center.

Donors (public and private)

In addition to the donors that provide undesignated funding to TDR as a whole, the United States Agency for International Development (USAID), National Institute of Allergy and Infectious Disease (NIAID) and ExxonMobil have provided designated support to the Empowerment Function's activities.

TABLE 2. FUNCTIONS OF EMPOWERMENT FUNCTION STAKEHOLDERS

Stakeholders	In-kind contribution	Facilitator	Support activities	Advocacy
Academic institutions and training networks		✓✓✓	✓✓✓✓	✓✓✓
NGOs: MFES, SIDCER, regional forums	✓✓✓	✓✓✓ ✓✓✓	✓✓✓ ✓✓✓	✓✓✓
Public sector: ICMR, NIH/Fogarty		✓✓✓ ✓✓✓	✓✓	✓✓✓ ✓✓✓
Private sector	✓✓✓		✓✓✓	
Other networks		✓✓		
Local initiatives	✓✓✓	✓✓✓	✓✓✓	✓✓✓

3. Implementation plan (2008–2013) and progress

3.1. Plans, progress and key milestones

The overall plan, including key activities and milestones, is presented systematically in **Table 3**. Highlights of progress (by functional area) during 2008 are described below.

Capacity for research management and leadership

A key feature of the 2008 business plan was the development of a more comprehensive process of selection, monitoring and evaluation of researchers and institutions. This process is now 70% complete and is expected to be finished in 2009. Changes in the processes put into place so far have included: (1) refocusing Empowerment Function research grants on specific TDR research needs; (2) making institutional support integral to the grantee selection process so as to enhance the sustainability of research efforts; (3) addressing equity issues systematically in the mechanism for grantee selection – in 2008 the female-to-male grantee ratio was 8:4.

Additionally, in accordance with a Joint Coordinating Board (JCB) recommendation from June 2008, a strategy for providing support to least-developed small countries was initiated and piloted in Guinea, Nepal and Bhutan. The project, which commenced in fall 2008, involved a comprehensive needs assessment that yielded recommendations and support for capacity-strengthening in three national research institutes, conditional upon full country institutional partnership.

Training

The implementation plan for 2008 focused on the facilitation, promotion and quality assurance of training programmes in DEC institutions globally and the harmonization of short courses in good research practices. In terms of progress, harmonization was completed in GCLP and GCP courses and is ongoing in six other areas. The International Organisation for Standardisation (ISO) training standard (ISO 10015) was used as a guide for the revision of curricula.

Also in line with quality management integration, the RTG programme was revised to emphasize institutional development alongside individual training potential and to reinforce linkages between researchers and policy-makers. In line with this new emphasis, the grant programme was renamed – it is now known as the LTG. A site visit to home institutions was incorporated into the grantee selection process of individuals, allowing assessment of potential and opportunities for institutional strengthening. The TDR CDF programme has obtained new support (US\$ 3 million over three years) from the Bill and Melinda Gates Foundation. This will support the development of clinical scientists' capacity to manage clinical trials and the establishment of a network among fellows, post-training. Meanwhile, a new in-house initiative has led to the creation of a TDR LDF programme that will bring DEC researchers together with TDR research business lines. Implementation is set to begin in 2009. Each fellow, under supervision, will participate in a curriculum for leadership training best suited to their needs.

TABLE 3. IMPLEMENTATION PLAN 2008–2013 AND PROGRESS

Activities (2008–2013)	Milestone and target dates	Progress made	Revised dates
Objective 1. Leadership development – research			
Funding research projects	1.1 Quality management components incorporated in all steps of the (grant candidate) review processes (2009)	1.1 70% of quality management integration process has been completed	On track
Development of ethics review processes	1.2 Functioning SIDCER regional networks (2009)	1.2 PABIN is facing difficulties with functionality due to governance structures. This needs to be resolved via constitutional amendment. A PABIN assembly is planned for this purpose (late 2008/early 2009)	Despite delays, process of bringing PABIN to full functionality should be completed within 2009 framework
Development of individual and institutional research management systems	1.3 Definition of required quality standards for researchers and institutions developed (2009)	1.3 Definition of standards for researchers and institutions in the context of a four-step leadership development process has been completed and endorsed by the TSC. Assessment of needs is complete. Development of quality research management systems now proceeding in institutions in Guinea, Cameroon, Bhutan and Nepal	On track
Development of quality for laboratory	1.4 Functioning laboratory network (2009) 1.5 Required quality standards for laboratory established (2008)	1.4 GCLP laboratory network in Asia established and institutionalized locally. Development of a GCLP laboratory network in Africa is ongoing 1.5 GCLP standards established. Basic laboratory standards being developed	1.4 Development of African network, led by Cameroon and Guinea, on track 1.5 Basic laboratory standards expected to be defined by mid-2009

Activities (2008–2013)	Milestone and target dates	Progress made	Revised dates
Objective 2. Quality health research –training			
Individual and institutional capacity development	<p>2.1 Quality management components incorporated in all steps of the review processes (2008)</p> <p>2.2 Need updated database of training requirements in terms of expertise and skill mixes (2008)</p> <p>2.3 Need updated database of research institutions that meet the critical mass of expertise (2009)</p>	<p>2.1 Completed – RTG changed to LTG</p> <p>2.2 Completed – LDF programme developed; CDF programme scaled up. Supported by Bill and Melinda Gates Foundation</p> <p>2.3 Ongoing</p>	<p>2.1 On track</p> <p>2.2 On track</p> <p>2.3 On track</p>
Training programmes and curriculum development	<p>2.4 Analysis for unmet research area (from network function and BL1 analysis – 2009)</p>	<p>2.4 Needs analysis in 2007 recommended development of short course in social sciences research to support product R&D. Proposed curriculum has been sent to host university for approval. However, delays in development make it unlikely that course can be initiated in 2009</p>	<p>2.4 University agreement to cosponsor and host a short course in social sciences research to support product R&D is expected at the end of 2009. First course planned for 2010</p>
Training centres	<p>2.5 Established framework for formal university/ institution engagement and participation in TDR-promoted training, capacity building and empowerment activities (2009)</p>	<p>2.5 Ongoing</p>	<p>2.5 Ongoing</p>

TABLE 3 (CONT). IMPLEMENTATION PLAN 2008–2013 AND PROGRESS

Activities (2008–2013)	Milestone and target dates	Progress made	Revised dates
Objective 2. Quality health research – networks			
Capacity-strengthening stakeholders' network	2.6 Capacity-strengthening stakeholders' forum formed (2009)	2.6 Activity cancelled. Focus shifted to work closely with newly established ESSENCE initiative	
Existing researchers, institutions networks	2.7 List of forums to be established with structures and TORs (2008) 2.8 Common strategic plan with BL1 to facilitate expert networks' participation in discussion on health research priorities and capacity needs (2009)	2.7 Ongoing 2.8 Awaiting analysis report from BL1 in 2009	2.7 Forum TORs are delayed and expected to be completed mid-2009 2.8 No change
Focused SEB network	2.9 Network of social scientists formed with TORs (2009)	2.9 Ongoing	2.9 No change
Focused WHO regional small grant researchers (SGR) network	2.10 SGR network formed with TORs (2009). 2.11 CDF network formed (2011)	2.10 Ongoing 2.11 Not yet initiated	2.10 No change
Information exchange	2.12 Information exchange database established (2009)	2.12 Compilation of information on TDR-trained researchers (expertise, discipline, country/ region and gender) completed. Database construction is ongoing	2.12 On track

Activities (2008–2013)	Milestone and target dates	Progress made	Revised dates
Objective 2. Quality health research – quality management			
Development of quality management (QM) system	2.13 QM curriculum defined (2008) 2.14 Strategies defined for developing in-country health research quality systems (2009)	2.13 Draft curriculum completed 2.14 Ongoing	2.13 Complete curriculum should be finalized by end 2009 2.14 On track
Development of management and oversight of capacity building and research activities	2.15 Quality requirements, quality control, quality assurance for BL2 activities defined (2008) 2.16 Auditor trained for TDR standard operating procedures (2008) 2.17 Clinical monitors and regional clinical coordinators trained according to TDR standards of practice (2008)	2.15 Activity delayed, requirements for research, training and network defined but not yet completed 2.16 Completed 2.17 Completed	2.15 Activities will be completed mid-2009
Objective 3. Leveraged activities			
Satellite business line	3.1 At least three local initiatives established (2013)	3.1 Two initiatives established: (1) International Clinical Research Collaboration Center (ICRCC) with Thailand Center of Excellence for Life Sciences (TCELS) and (2) Nagasaki–Thammasat University’s diploma course on product R&D	3.1 On track

Networks

The Empowerment Function continues to facilitate a wide range of research-related network activities, building upon its past experiences initiating, leveraging and supporting such networks both regionally and globally. In line with the 2008 implementation plan, a network information exchange database is being developed to support collaborative efforts, strategic alliances and situation analysis for TDR-supported networks, as well as institutions and individuals. Originally, the 2008 implementation plan also called for the creation of a capacity strengthening stakeholders' network in 2008 in the context of the Empowerment Function. However, this initiative has now been shifted to Portfolio Planning and Development (PAD), which is leading the development of ESSENCE (Enhancing Support for Strengthening the Effectiveness of National Capacity Effort). ESSENCE is supported by the Swedish International Development Agency (Sida) and hosted by TDR.

Quality management and evaluation

The 2008 implementation plan places an emphasis on the integration of quality management systems, standards and processes into research, training and network activities, including those directly managed by the BL2 function and by TDR or other stakeholders more generally. As an initial step in that process, there is ongoing development of an introductory course in quality management for health researchers. The first curriculum module (*Introduction to quality management*) will be piloted in a training course for researchers in a DEC institution in the first quarter of 2009. A completed course, including 14 curriculum modules, is to be finalized by the end of 2009. A textbook and web-accessible materials are also under development.

3.2. Progress/delays and global context changes: implications for 2008–2013 plans

Delayed recruitment of quality management staff delayed a number of activities; in addition, the 2009 budgets cut will delay further the training for and implementation of quality management systems in DECs. The plan to create a PhD programme in social sciences research for product R&D was amended and a short course is now being developed. This change in concept and format means that the first course is now expected to be launched in 2010 instead of 2009.

The other substantive change in the implementation plan is the decision to shift leadership of the capacity stakeholder network to PAD, in the context of the new ESSENCE initiative.

3.3. Activities to be implemented in 2009

Research management

- 1) New selection and monitoring process for research projects will be implemented for all grants awarded.
- 2) Ethical review processes will be strengthened in all institutions that received funding from MIM and RSG, beginning with all 2009 grant awards.
- 3) Laboratory capacity will be strengthened in all institutions involved in laboratory-related research grants, beginning with all 2009 grant awards.
- 4) Empowerment will work proactively with small countries to strengthen research capacity and establish quality management systems.

Training

- 1) New monitoring and evaluation process for the LTG programme will be implemented, beginning with all 2009 grant awards.
- 2) New LDF programme will be launched: 12 fellows will be trained at TDR including at the WHO South-East Asia Regional Office (SEARO); and at the TDR Clinical Coordination and Training Centre in Bangkok (calls for application in January 2009).
- 3) Harmonization and institutionalization of short courses for GRP will continue.
- 4) Development of a new short course curriculum on social sciences research for product R&D will be completed in 2009, with the first course scheduled for 2010.
- 5) Technical assistance and quality assurance will be provided for regional initiatives (ie. ICRCC and product R&D for health research – started 2008).

Network function activities

- 1) Collaborative framework for ESSENCE will be established together with PAD (2009).
- 2) Networks will be established and/or formalized for researchers, institutions, social scientists, small grants researchers and CDF fellows, with defined

terms of reference and activities for both existing and newly established networks (2008–2009).

- 3) PABIN's function as a resource for ethical review committees in Africa will be strengthened (2009-2010).
- 4) Information exchange database will be established through the TDR web site (2009).

Quality management and evaluation function activities

- 1) Quality management manual for all BL2 operations (research, training, networking) will be developed.
- 2) Quality management systems for research institutions and training centres in DECAs will be developed.
- 3) Quality management system for BL2's own activities, as well as TDR-supported research more generally, will be developed.

4. Leverage, contributions to stewardship and synergies with TDR business lines

4.1. Leverage

All Empowerment Function activities (e.g. capacity for leadership, training, networks and quality management) are undertaken in the context of actual neglected diseases research projects, and thus are instrumental in leveraging a broad range of research initiatives. This year, a key milestone was the signing of a cooperation agreement with Thammasat University, Thailand, in which the university was designated as a TDR clinical coordination and training centre for health research. In this role, Thammasat will leverage capacity-building activities (particularly those for GRP) throughout the South-East Asia and Western Pacific Regions. A similar coordination centre, planned to open in Ethiopia in 2009, is expected to expand TDR's leverage of such activities in the African Region.

In terms of training activities, TDR's successful extension of the diploma programme (R&D of products to meet public health needs) from Nagasaki University to Thammasat University will help leverage developing country capacity to conduct product R&D in the future. The creation of this new diploma programme also acts as leverage for the recently approved World Health Assembly's *Strategy and plan of action on public health, innovation and intellectual property* (WHA61.21), calling for the development of research capacity in DEC countries.

Through its networks, TDR also has leveraged opportunities for training researchers. For instance, two researchers from the Guinea National Research Institute were funded for studies abroad

at institutions with which TDR collaborates: one for PhD studies in Japan; the other for training in bioethics and ethical review at the WIRB, Washington. The latter funds DEC researchers to spend six months in the United States of America to learn about ethical review of research.

4.2. Contributions to stewardship

The creation of SIDCER provides an example of how TDR has stimulated global and regional stakeholder dialogue, as well as exchange and cooperation, on ethical issues related to research. SIDCER's activities have spun off to regional networks in Asia, the Western Pacific Region, Africa, the Americas and Commonwealth of Independent States (CIS) countries, leading to grass-roots pressure for improved ethical review standards, regulations and capacity at national level.

As a result of the SIDCER initiative, in 2008 Thailand's Food and Drug Administration adopted regulations requiring systematic ethical review of clinical research at internationally acceptable standards. WHO's SEARO office now relies upon a SIDCER-sponsored committee (FERCAP) to conduct routine ethical review of planned WHO-cosponsored clinical research. The adoption of such policies and practices represents the fruits of TDR's stewardship insofar as TDR initially stimulated discussion around ethical issues, needs and priorities.

4.3. Contributions to other TDR research business lines

The Empowerment Function provides support to all TDR research business lines through its training grants and fellowships; as well as through programmes of training in good research practices and quality management (Table 4). In 2008, in particular, the Empowerment Function provided support to the following activities.

- **Training and monitoring in GCP, GCLP and other aspects of good practice.** TDR principal investigators were trained for, and monitored in, trials conducted under the auspices of BL6 (moxidectin); BL8 (TB/HAART; gatifloxacin and 4FDC); malaria (BL9); and visceral leishmaniasis (BL10).
- **Surveys and assessment of three Ethiopian ethics committees.** Conducted in coordination with BL8, this contributed to TDR's clinical trials of TB 4-drug fixed-dose combination therapy (4FDC) while also building national capacity for ethical review.
- **Strengthening of regional and national ethics committees.** Empowerment Function initiatives are ongoing. They improve capacity for TDR research lines to undertake research throughout the world.
- **Strengthening and development of laboratory staff capacity in national research institutions.** Institutions in Cameroon and Guinea achieved international standards as part of a new Empowerment Function Small Country Development initiative.

4.4. Elements enhancing sustainability of Empowerment Function outcomes

The Empowerment Function has implemented a partnership model whereby countries must actively participate in investment in capacity training and development. This enhances country and institutional ownership and thus the sustainability of outcomes and impacts. For example, in actions to strengthen laboratory capacity (e.g. in Cameroon and Guinea), the country institutions both organize and fund the training activities taking place. TDR provides the expert staff or consultancy to assess capacity-strengthening needs both in hardware and human capacity.

TABLE 4. INTERACTIONS BETWEEN EMPOWERMENT FUNCTION AND RESEARCH ACTIVITIES

Interface with TDR business lines	Shared/ complementary objectives	Related specific activities	Mechanisms for coherence and coordination
BL1	Networking	South-South initiative Social science for product R&D course	Communication Working through local networks
BL3	CDF programme	Administering grants	Procedures
BL6,8,9,10,IVR	Clinical coordination	Monitoring studies, training investigators Audits of studies	Through standard operating procedures
BL6,7,8,9,10,11, PAD, director's office, South-East Asia Regional Office, IVR	Leadership development	LDF programme	Communication and procedures
BL3,5,6,7,8,9,10	Priority-setting for building capacity	--	Communication

5. Critical issues and suggested solutions

- **Active engagement of DEC institutions.** Developing countries' increased participation in health research is essential for sustainability in addressing global health issues. TDR's strategy is to build a critical mass of stable and active research institutions with adequate human resources working in research environments conducive to addressing country-specific research agendas.
- **Fostering the transfer of ownership and institutionalization of research training programme to DECs.** This is an important element in ensuring the sustainability of DECs' capacity in health research. Monitoring and evaluation of training courses at each TDR-supported training centre remain key challenges that will need to be addressed. In this context, the reorientation of the Empowerment Function's role from funder to facilitator is vital. This new role must be communicated effectively to researchers and institutions.
- **Supporting, mentoring, monitoring and evaluating each researcher and research project.** In order for DECs to develop a sustainable research culture there must be simultaneous development of human and institutional resources with the generation of new research knowledge and evidence for policy. This is an ongoing challenge that requires the Empowerment Function to become involved with every researcher and research institution it supports, as well as linking with specific thematic or disease-related areas of R&D endeavour.
- **Commitment to adopt quality management within TDR and affiliated research and training centres is vital.** The quality management curriculum still needs to be fully developed and training made available to TDR staff and all research and training institutions.
- **Cross-cutting Empowerment Function activities.** It is important to continue building activities across all of TDR. This requires the Empowerment Function to work closely with TDR business lines to both support their activities and engage their active support.

6. Annexes

6.1. Publications resulting from Empowerment Function or related activities

6.1.1 Publications by TDR staff

Karbwang J, Crawley P, Idänpään-Heikkilä JE, Koski G. The global imperative for human subjects protection: WHO's responsible? *The Monitor* 2008;22:73-78.

6.1.2. Publications by MIM/TDR grantees 2007-2008 (grantees in bold)

- Moatcho JC, Hargreaves K, **Koekemoer LL**, Brooke BD, Shüne V Oliver¹, Richard H Hunt, and Maureen Coetzee. Indoor collections of the *Anopheles funestus* group (Diptera: Culicidae) in sprayed houses in northern KwaZulu-Natal, South Africa. *Malaria Journal* 2007;6:30 10.1186/1475-2875-6-30. PMID:17359529 doi:10.1186/1475-2875-6-30
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6.1.3. Publications by research-strengthening grantees

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13. Zhang HJ, Zhu R, Wu CG. **Guo JG**. Impact of people's social behavior on schistosomiasis transmission in the Three Gorges Reservoir area. [Chinese.]. *Zhonghua Yu Fang Yi Xue Za Zhi* 2007; 41(Suppl):138-142. PMID:17767880
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6.2. Scientific Advisory Committee (SAC) membership

Name	Expertise	Institution	Country
Prof. Chitr Sitthi-Amorn, Chair SAC	Epidemiologist, hospital director	Chulalongkorn University	Thailand
Prof. Marita Reyes, Vice chair SAC	Biomedical scientist, former University of the Philippines College of Medicine chancellor	University of the Philippines	Philippines
Dr Beat Widler	Biomedical scientist, head of quality assurance	Hoffman-La Roche Ltd	Switzerland
Dr Angela Bowen	Endocrinologist, President of WIRB	Western Institutional Review Board	USA
Dr Greg Koski	Anaesthesiologist, former director of Office for Human Research Protections, USA	Harvard University	USA
Dr Ana Rabello, Chair RSG	Biomedical scientist (leishmania, TB and schistosome)	Fundação Oswaldo Cruz (Fiocruz)	Brazil
Dr Kenji Hirayama, Chair TSC	Clinical immunologist, dean of Institute of Tropical Medicine, Nagasaki University	Nagasaki University	Japan
Dr Barbara Sina, Chair NEC	Malariologist and manager for Networks and Training	Fogarty International Center	USA
Dr Abraham Aseffa, Chair QMAC	Clinical immunologist and deputy director of AHRI	AHRI	Ethiopia
Dr Mwenesi Halima, Chair MIM	Social scientist and director, Public Policy Initiatives	Academy for Educational Development (AED), Washington, DC, USA	Kenya

6.3. Responses to specific JCB/Scientific and Technical Advisory Committee (STAC) requests

JCB recommendations and Empowerment Function responses

Milestones for the Empowerment Function should be established at regular intervals over the coming 10 years. The milestones for monitoring the activities are presented in **Table 3**; however, the plan is up for a six-year period, i.e. until 2013.

Indicators should be established for DEC's playing a pivotal role. The issue has been discussed extensively in the Empowerment Function's SAC 2 – see the indicators in **Table 1** and attached report on indicators for the four-step leadership development ladder.

A strategy for providing support to smaller countries should be developed. This was under way in 2008.

Greater linkages should be promoted between researchers, policy-makers and other stakeholders. The Empowerment Function's research and training function implemented an operational process that would ensure greater linkages between researchers and policy-makers and address equity and gender issues.

TDR's work in particular countries should have greater visibility in the regional and country offices of its co-sponsors. The Empowerment Function initiated collaboration with research institutions (in Guinea, Bhutan and Nepal) to strengthen health research capacity. This involves research teams, research institutions, ministries of public health, WHO country offices and WHO regional offices.

There should be greater collaboration between the Empowerment Function and TDR BLs. This is addressed through the development of shared/complementary objectives (**Table 4**).

STAC recommendations

- Survey other actors in research capacity strengthening, and articulate when and how TDR will engage with such actors.
- Foster a research culture = priority setting at all levels (training, research, etc.).
- Training should be multidisciplinary.
- Different networks should be clarified.
- The target of empowerment should include institutions, not only individuals.
- Gender and equity issues need to be addressed.

All of these recommendations have been incorporated into the operating processes of networking, research and training to ensure a multidisciplinary approach and to address gender and equity issues. Different networks have been clarified in the progress report submitted to the JCB in 2008. Terms of reference for each network are being developed and will be posted on the TDR web site. Training or research grants have been redesigned to include individuals, research teams and institutional development.



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The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration established in 1975. Its focus is research into neglected diseases of the poor, with the goal of improving existing approaches and developing new ways to prevent, diagnose, treat and control these diseases. TDR is sponsored by the following organizations:

