

Ten Year Vision and Strategy

Endorsed by the Joint Coordinating Board, June 2007

*“Fostering an effective global
research effort on infectious diseases
of poverty in which disease endemic
countries play a pivotal role.”*



Special Programme for Research & Training
in Tropical Diseases (TDR) sponsored by
UNICEF / UNDP / World Bank / WHO

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This document was produced by the TDR secretariat based on the results of an External Review, direction from its Joint Coordinating Board, its Scientific and Technical Advisory Committee and consultation with its core governance constituents and external experts, including disease control, resource contributors, researchers from disease endemic countries and non-disease endemic countries, public private partnerships and the private sector, and consultation within WHO and with the WHO regional offices.

EXECUTIVE SUMMARY

Health research is increasingly seen as critical for poverty alleviation and for achieving the Millennium Development Goals. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) was created in 1975 to support the development of new tools to fight tropical diseases of poverty and to strengthen the research capacity of affected developing countries.

TDR has done this effectively and can be proud of its achievements. However, the research environment has changed significantly over the last decades in part due to TDR's efforts: (i) the epidemiology of infectious diseases is changing with some diseases moving to elimination and others emerging or re-emerging, (ii) there are many new initiatives and actors in the field providing new momentum but also leading to a more complex environment; (iii) disease endemic countries have enhanced research capability but are increasingly left behind in global research planning and priority setting; (iv) priority research needs are unequally covered and there remain several research areas that are neglected even though they are critical for the ultimate health impact of the global research effort. TDR is well placed to address the key challenges that result from these changes in the research environment and TDR is changing to meet those challenges.

Vision

TDR's new vision and strategy respond to the new research environment and to the need to make the collective global research effort more effective and responsive to research priorities in disease endemic countries. They also recognize the need for these countries to play a major role in research and priority setting to ensure relevance, sustainability and optimal health impact for the poor.

Hence TDR's renewed vision for the next 10 years is to foster:

*An effective global research effort on infectious diseases of poverty,
in which disease endemic countries play a pivotal role*

Strategy

In order to achieve the new vision, TDR will use a three-pronged strategy to: provide a collaborative framework and information service for research partners; empower scientists from disease endemic countries as research leaders; and support research on neglected priority needs. This strategy implies three major strategic functions that will underpin TDR's activities in the coming 10 years:

1. **Stewardship** for research on infectious diseases of poor populations: a major new role as facilitator and knowledge manager to support needs assessment, priority setting, progress analysis and advocacy, and to provide a neutral platform for partners to discuss and harmonize their activities.
2. **Empowerment** of researchers and public health professionals from disease endemic countries, moving beyond traditional research training to build leadership at individual, institutional and national levels so countries can better initiate and lead research activities, develop a stronger presence in international health research and effectively use research results to inform policy and practice.

3. **Research on neglected priority needs** that are not adequately addressed by other partners. This will focus on three research functions:
- a) Foster innovation for product discovery and development.
 - b) Foster research on development and evaluation of interventions in real life settings.
 - c) Foster research for access to interventions.

Other strategic considerations

- **Disease scope:** TDR currently focuses on 10 diseases¹. Operationally separating these from other neglected infectious diseases of poor populations is increasingly artificial. TDR will therefore cover infectious diseases of poverty more broadly, but will focus on a limited number of well defined activities within this broader disease scope.
- **Regional needs:** TDR will increase its responsiveness to regional needs by reinforcing regional influence on TDR policy and strategy, regional stewardship and empowerment, and support for regional research activities.
- **Strategic links with co-sponsoring agencies including WHO:** Stronger links with all co-sponsoring agencies will be developed. The links with WHO are crucial. WHO is giving higher priority to research and is developing a research strategy. TDR's stewardship and empowerment functions fit closely with WHO's stated goals for research. Properly positioned, TDR could become the infectious disease research arm of WHO and its other co-sponsoring agencies.

Operationalizing the strategy

Business lines

To effectively deliver on its strategy TDR will restructure its operations to a limited number of clearly delineated business lines. Each business line is inherently end-product oriented with a business plan that details deliverables, milestones, timelines, responsible persons and partnerships. Business lines will be established, assessed and terminated based on defined criteria of need, impact and progress. The business line approach will ensure more efficient and responsive management and administration, and will enable easier interaction with partners.

Monitoring and evaluation

Indicators will be developed that address progress, outcome and impact of strategic functions and business lines, managerial and administrative efficiency and the mainstreaming of key cross-cutting issues such as gender.

Financial resources

The strategy outlined requires a considerable increase of resources, with a possible doubling of TDR's current US\$ 50 million annual budget by 2012, in order to effectively implement the stewardship and empowerment functions and the research business lines. As this strategy is implemented, TDR will further explore options to expand its international role, as suggested by some stakeholders.

¹ TDR focused initially on eight diseases (African trypanosomiasis, Chagas disease, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, malaria and schistosomiasis) until 2000 when it expanded to take on dengue and tuberculosis. In recent years TDR has also taken on focused activities in sexually transmitted disease diagnostics and research to facilitate the scale up of antiretroviral treatment for HIV.

1. BACKGROUND

Poverty, human development and health research

Poverty creates conditions that favour the spread of infectious diseases and it prevents affected populations from obtaining adequate prevention and care. Conversely, infectious diseases predominantly affect poor populations and are a major cause of poverty. There has been increasing recognition that poor health is an obstacle to development and that the control of infectious diseases is a prerequisite for poverty alleviation and the achievement of the Millennium Development Goals (MDGs). All MDGs are related to infectious diseases, whether directly as for HIV/AIDS, malaria and other infectious diseases (MDG 6), child mortality (MDG 4) and maternal health (MDG 5), or indirectly as infectious diseases affect productivity and learning, stigmatize and burden women, and proliferate in urban slums and among poor populations who lack access to essential drugs.

The vicious cycle of infectious diseases and poverty is difficult to break. Research is urgently needed to develop more effective tools and strategies to fight the infectious diseases of the poor and help attain the MDGs. Research, especially through research capability and research leadership in developing countries, is increasingly seen as a critical component, not only for improvements in health, but also for economic and human development (Annex 1).

TDR - a Special Programme

The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) was created in 1975 to marshal the power of research and capacity building in the fight against infectious diseases of the poor, with the goal to improve the health of poor populations and to eliminate these diseases as obstacles to social and economic development. TDR has done this effectively and, largely due to tools and strategies developed through TDR partnered activities, five TDR diseases are now targeted for global or regional elimination as public health problems. A SWOT analysis concluded that TDR is built on a solid and proven foundation of scientific expertise and effective international networks, that it must address weaknesses such as over-administration, and that the Programme can play a major international role in realizing opportunities and addressing challenges that are resulting from changes in the research landscape (Annex 2).

Changed landscape and new strategic challenges

The research landscape of infectious diseases of poverty has evolved significantly over the last decades: (i) the epidemiology of infectious diseases is changing with some infectious diseases moving to elimination, and other diseases emerging or re-emerging, (ii) there are many new initiatives and actors in the field (again partly as a result of TDR incubation activities and support) providing new momentum but also leading to a more complex environment; (iii) disease endemic countries have enhanced research capability but are increasingly left behind in global research planning and priority setting; (iv) priority research needs are unequally covered and there remain several research areas that are neglected even though they are critical for the ultimate health impact of the global research effort (Annex 3).

This evolution has brought significant new opportunities but also new challenges that limit the effectiveness of the global research effort due to fragmentation of effort, limited involvement of disease endemic countries and neglect of critical research areas.

TDR is well placed to address these challenges but to do so effectively, TDR needs to adapt and evolve its vision, strategy and its way of operating. Through extensive review, consultation and discussion with many stakeholders, and guidance from TDR's governance and scientific advisory bodies, TDR has developed a new vision and strategy that address these key challenges and priority needs for infectious disease research while building on its scientific strengths, its values and its mandate as a special programme.

2. TDR VISION AND STRATEGY FOR THE NEXT 10 YEARS

TDR's renewed vision responds to the new opportunities and challenges for infectious diseases research and the urgency to make the collective global research effort more effective and aligned to the research needs of infectious disease control in disease endemic countries. It also recognizes the need for disease endemic countries to play a leading role in research and priority setting to guarantee relevance, sustainability and optimal health impact for the poor.

VISION

TDR's vision for the next 10 years is to foster:

**An effective global research effort on infectious diseases of poverty,
in which disease endemic countries play a pivotal role**

TDR is uniquely placed to make this vision a reality in collaboration with other partners in the global research effort, but it will involve a new way of working for TDR. Increasingly, TDR needs to be a facilitator that supports all partners in optimizing their collective research effort against infectious diseases of the poor and that assists disease endemic countries in playing a leading role in this effort. TDR can play such a stewardship role because of its close links with disease endemic countries, the scientific community and WHO. TDR is seen as a Programme that combines scientific competency, networking and experience, with a governance system that provides for equal participation of disease endemic countries at decision-making level.

TDR is also well placed to address neglected research on priority needs for disease control. A major strength of TDR over the last 30 years has been its impact-oriented research and capacity building that have yielded many tangible successes, have changed how disease control is managed, have reduced disease burden and have saved lives. The Programme has unique experience, expertise and research networks in the relevant research domains, and its breadth of scope in terms of disease and functional expertise facilitates integrated, multidisciplinary approaches to problems. Increasingly, TDR is integrating its research and capacity building activities to ensure that scientists from disease endemic countries take a leading role in the research that it funds and coordinates.

STRATEGY

In order to achieve the new vision, TDR will use a three-pronged strategy with the following objectives:

- To provide a collaborative framework and information service on global research needs and activities for partners at global, regional and national levels.
- To strengthen the scientific and management skills of researchers from disease endemic countries to empower them as leaders in research and to take a leading role in research priority setting and translation of research findings into health policy.
- To support research on priority needs for disease control that are not adequately addressed.

These objectives imply three major strategic functions for TDR:

1. **Stewardship** constitutes a major new role as facilitator and knowledge manager to: provide a neutral platform for partners to discuss and harmonize their research activities; provide up-to-date analysis and an online information service on global research needs, activities and progress; facilitate the identification of evidence-based research priorities through a process in which disease endemic countries play a leading role and that specifically addresses gender issues; advocate for research on infectious diseases of the poor; and help focus the global research effort on priority needs in disease endemic countries.
2. **Empowerment** of researchers and public health professionals from disease endemic countries, moving beyond traditional research training to build leadership at individual, institutional and national levels so disease endemic countries can better initiate and lead research activities, develop a stronger presence in international health research and effectively use research results to inform policy and practice.
3. **Research on neglected priorities** with focused support for innovative research on priority needs that are not adequately addressed by other partners, with a broad functional scope from discovery research to implementation research, but with a significant increase in support for implementation research. The stewardship and empowerment roles will permeate these research support activities and TDR will also facilitate entry of other partners into these neglected research areas.

STRATEGIC FUNCTIONS

Within the three strategic functions of stewardship, empowerment and research on neglected priorities, TDR will focus on the following activities:

STEWARDSHIP

TDR will provide a platform for partners to discuss and harmonize their research activities, and to review global progress in research on infectious diseases of the poor. TDR will facilitate the generation of consensus on global priority research needs for infectious diseases of the poor and help define the corresponding research agenda. This will be informed by a comprehensive analysis of research needs and opportunities, and involve the identification of evidence-based research priorities through a collective consensus-building process in which disease endemic countries will play a leading role. 'Hot topics' for research in terms of unmet need, new opportunities or controversial issues will be highlighted.

TDR will expand its knowledge management and knowledge sharing activities to support these collaborative processes. It will make evidence available to all partners, including as a service to resource contributors. TDR will provide an on-line knowledge platform with up-to-date information and links on infectious diseases research, and facilitate easy access by disease endemic country scientists to primary literature. TDR will also prepare a biennial report on global progress in research on infectious diseases of the poor, and possibly link its publication to a biennial stakeholder meeting.

Impact

- Global consensus on priority research needs
- Harmonization of global research efforts
- Equitable access to health research information
- Disease endemic country government support for health research

Specific attention will be paid to research prioritization processes and the translation of research into practice in disease endemic countries. TDR will support regional analysis of research needs and priorities, and the establishment of regional associations of tropical medicine and hygiene will be considered. Best practices for assisting countries to define an infectious disease research agenda with mechanisms for developing synergistic partnerships will be explored. Gender issues, both in terms of priorities and with respect to the prioritization process will be specifically addressed. TDR will partner with other organizations in these activities, with TDR focusing on the scientific dimension.

Through its stewardship function, TDR will become a global advocate for research on infectious diseases of the poor, and for specific research activities on priority research gaps. TDR will advocate with partners for greater and more sustained support for infectious diseases research in disease endemic countries, targeting both Ministries of Health and Ministries of Science and Technology and associated regional organizations. It will work with the regional offices of WHO as well as the World Bank, UNICEF and UNDP as the co-sponsoring organizations of TDR, to achieve this.

EMPOWERMENT

Training of individuals is important, but it is only a first step to sustainable capacity building. To achieve full sustainability such training should be undertaken strategically and within the context both of institutional needs and broader research goals (TDR manages training in a way that delivers a "return rate" to the original institution of over 90%). Full and appropriate utilization of research capabilities is the next step to ensure sustainability, both to gain appropriate experience, leadership and authority and to gain an ability to transition from trainee to trainer. Once again this is best managed through a strategic approach to research and institutional development. Within the broader human resources debate it is important to promote human resources for health research, work towards greater gender equity and recognize that health research is an important and integral part of the health system. Finally, it is through such collective development and the ability to initiate, manage and direct research from within institutions and countries, with self-generated resources, that true empowerment and ownership arise.

Impact

- Disease endemic country leadership in priority setting for health research
- Quality research led by disease endemic country scientists and institutions
- Disease endemic countries effectively negotiating research partnerships
- Effective use of research results in policy and implementation
- Sustainable regional research and knowledge networks

The empowerment concept described above will permeate all of the work that TDR undertakes, whether through its stewardship or research role. TDR will build on its successful research capacity strengthening activities and bring capacity building to a higher level with greater focus on advanced research training and course development, for example on best practices, research planning and management as well as technology transfer. TDR will launch new efforts in capacity building for health research leadership that respond to country needs and that include capacity strengthening in priority setting and in translation of research findings into policy and practice.

Where appropriate, TDR will support the development of networks that in a sustainable manner can strengthen critical research and knowledge management skills in

disease endemic countries, e.g. in research disciplines such as bioinformatics and social science, for best practice such as for medical editing and ethical review or for certain disease priorities such as the Multilateral Initiative for Malaria. By their nature, many of these networks will be regionally based. TDR will also advise countries on the inclusion of critical health research strengthening activities in applications to global health initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

TDR will continue to support the development of knowledge and research capacity in basic, applied and implementation research, but will expand this with training in focused, high need areas that also incorporate research management, negotiating and networking skills. Research training will be mainstreamed in priority research projects funded through the research function of TDR, and special efforts will be made to identify and support promising female scientists. Focused training will be provided in best practices. Institutional strengthening will aim at sustainability, increased regional training capacity and empowerment of the research arms of Ministries of Health. Special attention will be paid to researchers and public health professionals

for whom English is not the main language of communication. A non-degree fellowship programme will be expanded by supporting strategic hands-on training within priority research projects. The previous model of open demand-driven grants will be de-emphasized, but focused support for higher degree training will be maintained. Regional small grant schemes will continue to be promoted as part of the new overall strategic orientation. TDR will coordinate its empowerment and capacity building activities with other key players, e.g. COHRED, Wellcome Trust, European Commission and the Fogarty International Center of NIH.

RESEARCH ON NEGLECTED PRIORITIES

TDR's research on neglected priorities will be undertaken through focused and time-limited activities in the research functions below, for which TDR has a comparative advantage.

a. Foster innovation for product discovery and development, emphasizing disease endemic country engagement

While product development partnerships focus on the development of control tools, especially drugs, there remains a need for more effective "translation research" to feed "leads" into development pipelines; and greater engagement of scientists from disease endemic countries (DECs) in product R&D. TDR will work with and complement other research agencies and partnership activities by further developing networks between pharmaceutical companies, academia and institutions in disease endemic countries for the discovery of new leads for drugs and diagnostics. Promising leads will be transferred to other organizations as appropriate, or if important and not adequately taken up by others, then TDR might also pursue them.

Impact
– Promising leads identified and transferred to product development partnerships
– Effective north-south public-private innovation networks established
– Product R&D managed by disease endemic country institutions

Given the large investments being made through product development partnerships in malaria and TB and certain other diseases, TDR will move out of general product development for malaria and TB, and focus its product development support on neglected infectious diseases that other partners do not adequately address. It will however remain open to collaboration with organizations in all diseases where it can work with them to enhance DEC leadership within their projects and build sustainable research capacity that will last beyond their focused funding engagements e.g. in the area of clinical trial support.

There will be a new focus on strengthening innovation and product R&D in disease endemic countries. TDR will seek to establish and support projects and innovative initiatives within product R&D institutions in those countries, and assist with the development of proposals for funding. Due attention will be paid to the assessment and development of indigenous knowledge, e.g. related to herbal remedies, in taking this work forward. TDR will act as a broker between different stakeholders where appropriate.

Building on previous success, TDR will further partner and leverage global efforts on discovery and development of vector control tools through convening, brokering, and focused funding of research and support activities.

There will be collaborative activities to support vaccine research and development with the Initiative for Vaccine Research in WHO but research in the vaccines area is likely to remain limited in the short term.

b. Foster research on development and evaluation of interventions in real life settings

One of the most neglected research areas is the development, evaluation and improvement of new interventions and intervention strategies in real life settings, and within a public health context. This research is critical, and provides disease endemic countries with the evidence they need to make informed health policy decisions on which products to use, how to use them, when to use them and how to optimize their public health utility. This research, including large scale phase IV

Impact
– Evidence on real life safety and effectiveness of tools informing health policy
– Effective intervention tools and strategies for neglected diseases
– Cost-effective elimination and surveillance strategies
– Disease endemic country leadership in intervention research

safety and effectiveness evaluation, will become especially needed in the near future because of a growing pipeline of intervention tools from product development partnerships. TDR has a history of facilitating such policy oriented research (e.g. artemisinin combination therapy for malaria and point of care diagnostics for syphilis). Particularly as TDR reduces its emphasis on product development *per se* it is well placed to link, negotiate and bridge the product oriented research of the product development partnerships with the public sector policy oriented research required by countries.

TDR will expand its research activities and partnerships in this area, with greater focus on product evaluation, especially for diagnostics, drug combinations and novel therapeutic strategies, and evaluation in vulnerable populations, e.g. pregnant women, where others are reluctant to do research. Basic hypothesis driven clinical research will be supported where this can lead to enhanced case management.

Research on the effectiveness and appropriate use of new and existing products under conditions of real use will be central. It will include focused studies on the cost-benefit of interventions, and research to develop improved intervention strategies for increased effectiveness.

Epidemiological research will focus on the development of cost-effective and sustainable strategies for disease prevention, determine if and how diseases could be eliminated with available tools, and develop innovative strategies for infectious disease surveillance.

c. Foster implementation research for access to interventions.

Implementation research results in innovative strategies for the formidable task of getting effective interventions to the people who need them. Many products that have successfully completed the classical R&D process, have failed to achieve their full potential impact because of implementation problems that impeded access. It is increasingly recognized that research has a critical role to play in helping to solve major implementation problems. Experience has shown that it can make a major difference and help ensure that proven control products have their intended health impact. Examples include the development of community-directed treatment (ComDT) for onchocerciasis control, and of home-management for uncomplicated malaria. TDR will support implementation research for proven and available control products, and for promising new products that would have a significant impact on disease burden if access can be assured.

TDR's research will focus initially on community-based interventions and integrated delivery strategies, which are currently a priority need for disease control programmes and Ministries of Health, and address critical issues for scale-up. Implementation research will be undertaken in the context of national health systems and control programmes, and involve leveraging of support for related research activities in countries (e.g. through the Global Fund to Fight AIDS, TB and Malaria, and international and bilateral agencies).

Close partnership between researchers and control programmes is essential for successful strategy development and effective utilization of research findings in disease control, and TDR is well placed to facilitate this. Capacity building and empowerment are integral components of implementation research. Virtually all investigators are from disease endemic country institutions, and this facilitates decision making and the translation of research findings into policy within disease endemic countries. By working closely with disease control programmes a culture of research is generated within these programmes.

Impact
– Integrated, community-based strategies for large scale delivery of interventions
– Cost-effective strategies for scale-up of interventions
– Understanding determinants of effective implementation
– Research culture within control programmes

The social sciences will play a central role in intervention and implementation research, not only by providing key research methodologies, but also for undertaking related fundamental research on determinants of effective implementation of interventions, such as critical factors in compliance with interventions, the role of gender in access and health care delivery, and the cost-effectiveness of interventions.

OTHER STRATEGIC CONSIDERATIONS

DISEASE SCOPE

With respect to disease scope, TDR activities will not be restricted to the current core set of 10 TDR diseases but will involve a more flexible and differentiated approach for the different strategic functions. This will allow for a more appropriate response to the priority research needs in disease endemic countries²:

- Stewardship will address the full scope of infectious diseases that affect the most needy populations
- Intervention and implementation research will focus on the TDR core set of neglected diseases, but with flexibility to respond to specific research needs of other diseases affecting the neediest populations.
- Innovation for product development will be restricted to the most neglected diseases and critical areas which are not adequately covered by others.
- Empowerment will cover the spectrum of infectious diseases as above.

REGIONAL NEEDS

The epidemiology of infectious diseases, the level of health system development and the capacity for health research vary considerably between different (WHO) regions. TDR will enhance its responsiveness to differences in regional needs through three mechanisms:

- Regional influence on TDR policy and strategy
 - Participation in TDR's governing body, the Joint Coordinating Board (JCB), by JCB members selected by the WHO regional committees will be more strongly supported to represent the regional interests and provide annual feedback on TDR's activities to the regional committees.
 - TDR strategic linkages with WHO regional offices, and regional linkages with the Programme's co-sponsors and development agency contacts will be strengthened.
 - There will be a formal interface between TDR's Scientific and Technical Advisory Committee, which annually reviews the Programme and provides strategic advice, and the WHO regional advisory committees on health research. These committees consist of prominent scientists who can assist in assessing research needs and opportunities in the different regions.

² Summary of main decisions and recommendations made by the TDR Joint Coordinating Board at its twenty-ninth session in Accra, Ghana.

- Regional stewardship and empowerment.
 - Regional and national level institutions will be engaged to jointly assess regional research and capacity building needs and priorities, and to help develop solutions in collaboration with other organizations operating at the regional and country level.
 - New regional initiatives will be established, such as the development of regional associations of tropical medicine and hygiene, and support will be given to develop best practices and processes for prioritizing and harmonizing infectious disease research within resource constrained countries.
 - All TDR scientific committees will have regional representation from research and control communities, and will meet frequently in disease endemic countries.
- Regional research activities.
 - Certain research activities will be regionally based (e.g. the elimination of visceral leishmaniasis from the Indian sub-continent), and in such cases TDR will facilitate and work towards local review, management and administration of activities.
 - In line with current TDR trends, TDR-sponsored research will increasingly be undertaken and led by DEC scientists and institutions with accompanying increased national and regional engagement.

STRATEGIC LINKS WITH WHO AND OTHER CO-SPONSORING AGENCIES

TDR is co-sponsored by UNICEF, UNDP, the World Bank and WHO, and stronger links will be developed with all of them. Of these agencies the closest and most prominent link is with WHO. TDR is administered and implemented by WHO, which acts as its Executing Agency.

WHO

TDR enjoys significant benefit by being associated with WHO. WHO disease control expertise helps to define research priorities and translate research findings into policy. TDR staff have access to WHO regional and country offices and support structures, and through these structures to Ministries of Health. In turn, WHO benefits from TDR's research expertise and TDR-partnered accomplishments that have provided evidence for the development of intervention tools and strategies for several infectious disease control programmes. It is anticipated that TDR's operationalization of research through discrete business lines (see next section) will facilitate future interactions with WHO's disease control departments at both the global and regional level.

WHO is in the process of developing a research strategy that will facilitate better coordination of research activities within the Organization and TDR is playing a lead role in this discussion. WHO has recently placed more emphasis on research and in its Eleventh General Programme of Work (2006-2015) WHO highlights itself as an organization that seeks to "utilize the fruits of science and technology" and defines one of its six core functions as "shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge". This fits with TDR's new strategy and its emphasis on stewardship. It is envisaged that the activities associated with stewardship and empowerment will become increasingly fundamental to WHO's

role in research and that there should be little difficulty in effectively linking TDR activities to the future WHO strategy.

Other co-sponsoring agencies

There will be increased co-sponsor support for, and use of, TDR and a reinforcement of messages of common significance and value to TDR and the agencies. In particular there will be increased coordination and action on global advocacy for research on infectious diseases of poverty and for TDR as a Special Programme. This will be extended to further enhance support for fundraising where the reach of the World Bank to financial institutions and UNICEF's power of advocacy will be critically important. The co-sponsors will further elaborate their role in supporting TDR and make appropriate commitments.

TDR will improve its operational links with research and strategically related activities within the co-sponsor organizations, exploring more visible research, stewardship and research empowerment roles for this unique network of international agencies.

This will most notably manifest itself at regional level with direct and leveraged support for implementation and intervention research and appropriate research policy and capacity building. It is envisaged that such engagements will also benefit TDR activities by highlighting multisectoral issues, thus broadening the impact of research for health.

Properly positioned, TDR could become the infectious disease research arm of WHO and its other co-sponsoring agencies.

3. OPERATIONALIZING THE STRATEGY

BUSINESS LINES

To effectively deliver on its strategy, TDR will restructure its operations to a limited number of clearly delineated business lines. Business lines represent a discrete set of coherent activities that lie at the heart of the new strategy. Each business line is inherently end-product oriented with a business plan that details deliverables, milestones, timelines, responsible persons and partnerships. Business lines will be established based on defined criteria of need and expected impact, and measurable indicators for success.

Two of the business lines correspond to the strategic functions of Stewardship and Empowerment that are constant to the TDR strategy. Within the strategic function of Research on Neglected Priorities there will be several medium-term time-limited research business lines, each working to an objective that meets an unmet priority need for infectious disease control and that TDR is well placed to address. Research business lines may be introduced, modified or terminated as circumstances and needs dictate.

Three principles apply across all business lines. First, TDR cannot do everything on its own and partnering will be essential to success. Business lines will be expected to leverage additional efforts and synergies through partnered activity. Second, capacity building and capacity utilization of disease endemic country expertise will be essential and all business lines will be expected to leverage sustainable capacity from their activities. Third, the business line model accords flexibility. Not all business lines need to have a uniform scope; some can be functionally specific but cover a wide range of diseases, while others can be disease specific and cover a wide range of functions. A new business line may be initiated if a sufficient need exists, a high impact is feasible and funds are available.

TDR's business lines and their scope will be reviewed annually to ensure optimal use of resources. TDR's Scientific and Technical Advisory Committee will play a critical role in this review and in the selection of new business lines. The following criteria will be used to decide on entry of a new business line (all entry criteria to be met) or exit from an existing business line

Entry Criteria:	Exit criteria:
<ul style="list-style-type: none"> • Priority research need, demanded by countries, fitting within TDR strategy • Neglected research area not adequately covered and/or requiring DEC engagement • Expected high impact • Added value from TDR engagement • Potential for leveraging added benefit through partnering • Utilization and leverage of DEC research capacity and leadership • Adequate resources • Realistic business plan demonstrating the above and with risk/benefit assessment 	<ul style="list-style-type: none"> • Deliverables met and goal achieved • Conclusive evidence that objectives cannot be met nor goals achieved • Relevance significantly reduced due to external factors or risk / benefit change • Inadequate performance, business line superseded by others, or activity better taken over by others • Spin-off: new partners effectively and sufficiently engaged with adequate resources and strategy to keep research sustainable without full TDR support • Lack of adequate resources

(when one of the exit criteria is met). In case the available financial resources are not sufficient to fund all business lines that meet the entry criteria, the proposed business lines will be ranked using the entry criteria on disease endemic country need, research neglect, expected impact, added value, leverage and DEC leadership. This ranking will provide an objective basis for prioritization of potential business lines and for decision making on which business lines to start and which to delay or cancel.

INITIAL BUSINESS LINES

Based on the above entry criteria, the recommendations from recent scientific working groups and other stakeholder consultations on research needs and priorities, and an assessment of opportunities arising from TDR's current portfolio, a provisional set of research business lines has been drawn up as a potential starting point for the new strategy. The business lines are presented in Annex 4 to provide an idea of the scope of research activity envisaged.

In the medium and long term, decisions on the portfolio of business lines will be taken on the basis of the analysis of research needs and opportunities for infectious diseases of poverty that will be undertaken by the stewardship business line.

In order to sustain responsiveness to unmet priority needs and scientific opportunity, TDR will also create an Innovation Fund of US\$ 1-2 million per year. This will be an incubator for projects and ventures. It will fund innovative research or capacity strengthening of any type relevant to the TDR strategy that may lead to a sustainable initiative or activity of public health importance. Such an activity may ultimately take shape outside TDR or, if appropriate, can be included within, or develop into, a future business line.

Despite the increased disease scope of the strategy, it is not envisaged in the first instance that there will be a significant entry into new disease areas within research business lines. Initial extension of the disease scope is being explored primarily through the development of tools and integrated intervention strategies for helminths and in extending diagnostic activities to include some emergent infections. Further analysis and dialogue through the stewardship function, subject to governance review, will guide further entry into new disease research areas in the coming years.

Special mention needs to be made about cross-cutting activities such as social science research, basic hypothesis driven research and gender issues. Although social science research is not specifically highlighted in the title of any research business line, it is envisaged that the social sciences will significantly inform the analytical work undertaken by the stewardship function and will form a crucial, cross-cutting element of all other research areas, notably in intervention and implementation research. Basic hypothesis driven research will be supported as necessary by business lines if it can address their objectives. Indicators will be developed to ensure gender issues are strategically considered both in TDR supported research and in TDR's generic practices.

MANAGEMENT AND ADMINISTRATION

The business line model will facilitate a uniform management structure for activities in TDR. Each business line will have an advisory committee and a TDR manager, with associated staff, fully responsible for scientifically and technically operationalizing the business line's mandate. The committees will advise on business line strategy, and review activities and research projects both strategically and technically.

The introduction of the business line model as the principal mode of operation for TDR will provide an important opportunity to redesign and simplify TDR's administrative procedures. Delegation of authority for routine decision making to the business line manager, corresponding optimization and simplification of administrative procedures and the aggressive use of information technology to automate processes, integrate administrative information and support online scientific review will significantly accelerate the processing of research proposals and contracts. The business line model will also bring greater clarity for, and ease of interaction with, external partners.

This more business like approach will require the development of new skills within TDR. Managing a business line requires strong elements of strategy, planning, coordination, negotiation skills, management of small teams and a capacity to link and integrate the business line into TDR's overall strategic plan and the bigger international environment. This will be taken into account in developing TDR's future human resource strategy.

MONITORING AND EVALUATION

In order to monitor progress with the implementation of the strategy, a set of key indicators will be defined. There will be impact indicators that relate to the impact targets for the different strategic functions (see text boxes on pages 8-12). There will be progress and outcome indicators for the business lines that will be defined on the basis of an indicator framework already proposed by TDR's Scientific and Technical Advisory Committee. There will be indicators to measure the effectiveness and efficiency of TDR administration and management, to assess partners' perception of TDR's performance in its new role of facilitator, and to assess the effectiveness of gender mainstreaming within TDR operations. The selected indicators will need to reflect the core elements of the strategy, be meaningful to the Joint Coordinating Board, help TDR management optimize the Programme's performance and remain manageable without creating more time-consuming reporting procedures. A subset of indicators will be used as "dashboard indicators" that will allow a continuous and quick assessment of overall progress with the implementation of the strategy.

BUDGET

TDR currently has an annual budget of US\$ 50 million reflected as a biennial budget for 2006-2007 of US\$ 100 million.

Depending on the activity, business lines will require an initial budget of US\$ 2-5 million per year rising to US\$ 4-10 million per year when fully operational. If their budgets exceed this level they are probably reaching a level of operation that justifies a spin-off of some or all of their activities to another organization.

When the strategy is fully operational, maintaining a portfolio of activities that creates leadership in stewardship and empowerment and has 10 to 12 research business lines operating optimally, will require a considerable increase of resources with a possible doubling of the annual budget by 2012. This requires an aggressive growth rate, but is not unrealistic. This growth can be managed through the judicious and prioritized selection of an initial set of business lines that can grow in early years and which can be supplemented with and / or replaced by additional business lines thereafter.

As the strategy is implemented and develops, TDR will explore an option for further expanding its international role, as suggested by some stakeholders, primarily based on its impact in the areas of stewardship and empowerment impact.

RESOURCE MOBILIZATION

TDR's vision and strategy identifies a series of focused activities that will, if properly undertaken, have a major health impact. In moving forward as a facilitator of innovative and needed health research, as well as a fund provider, TDR will place emphasis on leveraging resources in cash and in kind for its partners' activities as well as its own activities. However, this section will restrict itself to the funds required to flow through TDR to allow the Programme to meet its vision and fully implement its strategy.

Funding will be sought at two major levels. The first level will be undesignated and will support the Programme in its entirety. The second level of funding will be at the level of the business line. We believe that the business line concept leads to straightforward communication about the value of the research activities involved and will facilitate fundraising.

Three major sources of funds are identified: governmental and international public sector; philanthropy / NGO sector, and private sector.

As a public sector based programme, with a strategy that is primarily directed at public sector goals, governmental and intergovernmental agency contributions remain at the core of TDR's resource base and we envisage maintaining a support level of 70% from this sector. In addition to current contributors in this category, we will seek to re-engage past contributors and recruit new contributors, including from disease endemic countries.

The significance and importance of the philanthropy / NGO sector, both as stakeholders in the broadest sense, as cooperating parties able to attend Joint Coordinating Board sessions and as

resource contributors and/or providers of technical and/or scientific support to the Special Programme, are greatly appreciated and recognized. They may frequently also be partners in research activities and may co-fund those activities with TDR. Recognizing that most contributions from this sector are likely to be designated contributions, attempts will be made to secure funds at the business line level and above. A target for 20% of funding from this sector will be set.

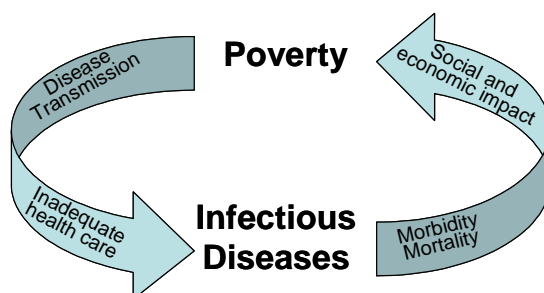
TDR continues to benefit from good interactions with industry and the private sector and will seek to enhance this through continued private sector funding, subject to WHO guidelines. We also see an opportunity to obtain funds from private individuals as well as from corporations. A target of 10% of funding will be set for this sector.

ANNEX 1. POVERTY, HUMAN DEVELOPMENT AND HEALTH RESEARCH

POVERTY AND HEALTH

Infectious diseases and poverty are closely interrelated³. Poverty creates social, economic and environmental conditions that favour the spread of infectious diseases while affected populations are too poor to obtain adequate prevention or care. Conversely, infectious diseases predominantly affect poor populations and are a major cause of poverty. They kill 10 million people every year and account for 32% of all deaths in low income countries and over 60% of deaths in Africa. Hundreds of millions suffer from the disabling consequences of infection, preventing them from leading a healthy and productive life, and 350 million Disability-Adjusted Life Years (DALYs) are lost annually because of infectious diseases. The socio-economic impact of infectious diseases is devastating. For example, the Indian sub-continent loses over US\$ 1 billion per year on a single neglected disease, lymphatic filariasis, and malaria reduces the annual economic growth rate of African countries by 1.3%.

Vicious cycle of infectious diseases and poverty



There has been increasing recognition that poor health is an obstacle to development and that the control of infectious diseases is a prerequisite for poverty alleviation and the achievement of the Millennium Development Goals (MDGs). All MDGs are related to infectious diseases, whether directly as for HIV/AIDS, malaria and other infectious diseases (MDG 6), child mortality (MDG 4) and maternal health (MDG 5), or indirectly as infectious diseases are an obstacle to food production (MDG1), negatively affect school attendance and learning capacity (MDG2), stigmatize and burden women (MDG3), proliferate in urban slums (MDG 7) and predominantly affect the poor who lack access to essential drugs (MDG 8). However, the vicious cycle of infectious diseases and poverty is difficult to break. The ecological, social and economic dimensions reinforce each other and complicate the control of infectious diseases. Tools and strategies capable of controlling and eliminating a disease in areas with a high level of development may have limited impact in poor areas where transmission is high and resources are constrained.

³ Commission on Macroeconomics and Health

THE IMPERATIVE FOR EFFECTIVE HEALTH RESEARCH

As the affected populations are poor, there continues to be little incentive for industry, by itself, to invest in the development of effective intervention tools like drugs or vaccines. Similarly, both national governments and international agencies have failed to provide adequate research investment, both to stimulate innovation for the development of new tools and to undertake the necessary research into how best to utilize and scale up existing interventions in the resource-constrained environments of the affected countries.

There have been some notable developments in recent years (outlined in Annex 3) but this fundamental market and public sector failure remain. Alternative research and funding mechanisms remain critical in order to develop the tools and strategies that are so urgently needed to effectively fight the infectious diseases of the poor and help attain the Millennium Development Goals by 2015. There is also a need to think beyond 2015 and prepare for the development of future tools and strategies that can sustain the achievements and ensure the elimination of infectious diseases of poverty in the long term.

Research, especially through research capability and research leadership in developing countries, is increasingly seen as a critical component, not only for improvements in health, but also for economic and human development. The World Bank has highlighted that countries with increased research capabilities are better equipped to make good policy decisions and good purchase of healthcare packages, and that targeted investment in research can deliver significant economic return through improvements in health⁴. The Commission for Africa⁵ declared "eliminating preventable diseases a top priority" and stressed that "donor governments should also fund research, led by Africa, to boost the continent's science, engineering and technology capacity". The Disease Control Priorities Project concluded that "development assistance for health would be more effectively used if a larger share were devoted to research and development"⁶. The need to invest in innovation driven research in developing countries was most recently highlighted by the Commission for Intellectual Property and Innovation in Health⁷, which also noted that TDR, "given its central position in the field and its strong networks and contacts, has the possibility of playing a more strategic role alongside its operational roles in research and training".

⁴ World Bank Policy Research Working Paper 3026

⁵ Our Common Interest. A Report of the Commission for Africa

⁶ Disease Control Priorities in Developing Countries, Second Edition

⁷ Public Health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights and Innovation in Public Health

ANNEX 2. TDR - A SPECIAL PROGRAMME

MISSION AND GOVERNANCE

In the 1970s there was a recognized need to marshal the power of research and capacity building in the fight against infectious diseases of the poor, and this led to the creation of TDR in WHO in 1975 with two main objectives:

- To **develop new and improved tools for tropical disease control.**
- To **strengthen the research capability of the disease endemic countries**

In 1978 TDR was established as a co-sponsored Special Programme to be governed through a Joint Coordinating Board (JCB). The Board consists of: (i) 12 disease endemic countries, selected through the six WHO regional committees and primarily represented through ministries of health; (ii) 12 resource contributor countries primarily represented by development agencies; (iii) 6 other cooperating parties⁸; and (iv) the four co-sponsoring agencies.

Additional countries which contribute to or support the Programme or are directly affected by the diseases dealt with by TDR, as well as intergovernmental and other non-profit making organizations which provide financial, technical and/or scientific support to TDR may attend the JCB sessions as observers, thereby keeping the operations of the JCB open and transparent.

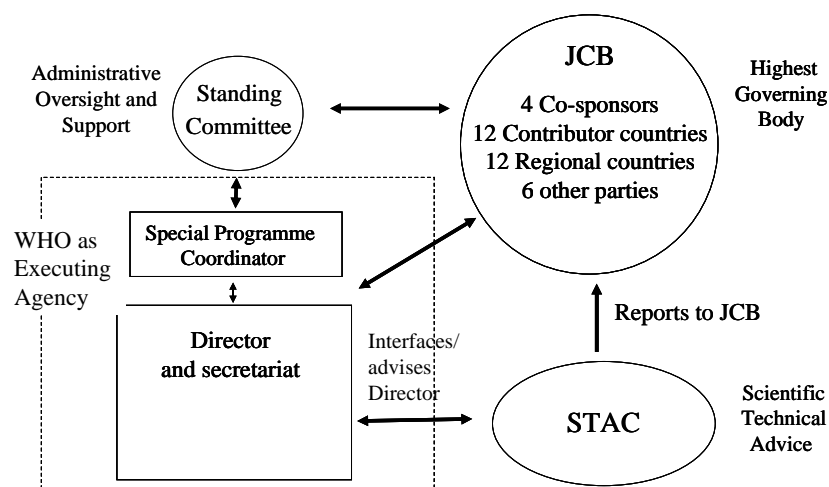
The JCB is supported by a Scientific and Technical Advisory Committee (STAC) comprised of globally recognized experts, for example heads of institutes or research councils, who are regularly advising their governments and other agencies on research and health issues. This committee undertakes an annual scientific review of the Programme and advises on strategy.

This model has provided TDR with convening power, legitimacy and access to global expertise and knowledge from multiple disciplines and sectors over the last 30 years.

⁸ Cooperating Parties are:

- those governments contributing to Special Programme Resources; those governments providing technical and/or scientific support to the Special Programme; and those governments whose countries are directly affected by the diseases dealt with by the Special Programme;
- those intergovernmental and other non-profit making organizations contributing to Special Programme Resources or providing technical and/or scientific support to the Special Programme.

TDR Governance Structure



A Standing Committee consisting of the four co-sponsoring agencies, namely UNICEF, UNDP, the World Bank and WHO reviews the overall management of the Programme. Recently the different arms of governance have been further linked by inviting both the chair and vice-chair of the JCB and the chair of STAC to attend the meetings of the Standing Committee on an ex officio basis to facilitate communication and dialogue among the various bodies of TDR. The possibility of inviting other members of the JCB to regularly attend these meetings on the same basis is now being assessed. Steps to further enhance the efficiency of the governance structure and to strengthen disease endemic country engagement and representation are under development.

ACHIEVEMENTS

TDR has developed long-standing relationships with its scientific partners in both developed countries and disease endemic countries, with governmental and multilateral sponsors, philanthropic organizations and various public-private partnerships. Through this far-reaching network, TDR has helped establish tropical disease R&D on the global health research agenda. It has supported more than ten thousand projects, trained thousands of developing-country scientists (including over 1,500 PhDs), and supported numerous partnerships and collaborative endeavours that have resulted in significant health impact.

TDR has played a pivotal role in initiating and catalysing the generation of key knowledge; the discovery and development of most of the drugs generated to treat tropical diseases over the last 30 years; and evidence for advances in health policy, strategy and practice in several important diseases, including malaria⁹. Largely due to tools and strategies developed through TDR partnered activities, five TDR diseases are now targeted for global or regional elimination as public health problems.

⁹ Morel, C.M. (2000) Reaching Maturity - 25 years of TDR. *Parasitology Today* 16, 522-528

TDR has facilitated the establishment of and supported initiatives, including public-private partnerships, that have changed the research landscape. These include: the Global Forum for Health Research, the Multilateral Initiative for Malaria, the Medicines for Malaria Venture, the Strategic Initiative for Developing Capacity in Ethical Review, the Drugs for Neglected Diseases initiative, the Forum for African Medical Editors and the Foundation for Innovative New Diagnostics.

STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

The fourth external review of the Programme¹⁰, discussions by the JCB and STAC, and further analysis by TDR staff have helped to define the strengths and weaknesses of the Programme, and the opportunities and threats that confront it.

Strengths		Weaknesses	
S	track record of research and capacity building achievements	a	administration and management weaknesses that may slow down and inhibit activities
S	scientific expertise and strong managerial support for research	a	attempting to take on too many issues with limited resources that may result in failures to deliver on commitments in a timely manner
S	focus on research capacity building	a	occasional disconnect between different activities occurring in different areas of TDR that can result in a lack of cohesion in overall strategy
S	promotion of best practices	a	difficulty in partnering with some of the new public private partnerships
S	convenor for analysis and priority setting	f	historical inability to significantly increase its resource levels
S	global network of investigators and partners in both developed and developing countries		
S	facilitator of partnerships, including public-private partnerships		
S	breadth and multi-disciplinary scope		
S	location in WHO and close links to disease control and Ministries of Health		
S	intergovernmental governance structure		
f	long standing support of resource contributors		
Opportunities		Threats	
f	enhanced resources from development agencies, disease endemic countries, philanthropic and private sectors	S	TDR becoming less relevant if it does not address the new needs for research stewardship and empowerment
S	enhanced capabilities of disease endemic country scientists and institutions	S	enhanced capability and funding of new initiatives, especially in product development, require TDR to adapt
S	a call from disease endemic countries to facilitate their engagement in innovation as well as technical partnership	S	reduced health impact of TDR research if TDR does not focus its research efforts
S	an increased recognition of the need for stewardship and facilitation of synergies across the many initiatives established nationally, regionally and globally	S	conflict with other actors if TDR funds research in areas where others are effectively operating
S	opportunities arising from new scientific developments	a	failure to change TDR operational practices could limit its ability to better partner and negotiate with a diverse range of organizations
S	neglect of critical research areas and capacity needs of endemic countries		

s: scientific/technical a: administrative/managerial f: financial

¹⁰ Fourth External Review of TDR. *Towards evolution and growth*. Geneva, TDR, 2006

It was concluded that: TDR is built on a solid and proven foundation of scientific expertise and effective international networks; its main weakness is that it is over-administered and under-managed; and the Programme is currently faced with significant new opportunities and threats relating to major recent changes in the research landscape.

The new strategy addresses the results of this SWOT analysis. It:

- builds on TDR's strengths in research management and capacity building, and significantly expands its unique convening and analytical role;
- provides a clear definition of TDR's role as a facilitator that supports all partners at global, regional and country level;
- introduces a system of business lines that will ensure greater focus of TDR's activities, enhance management through delegation of authority, simplify administration and strengthen fundraising; and
- addresses the current major challenges and priority needs for infectious disease research, while capitalizing on its mandate as a Special Programme.

ANNEX 3. CHANGED LANDSCAPE AND NEW STRATEGIC CHALLENGES

EPIDEMIOLOGICAL CHANGES

The epidemiology and control of infectious diseases of poverty have evolved significantly since TDR's inception, partly as a result of TDR research. Five of the original eight TDR diseases are now targeted for global (Chagas disease, leprosy, lymphatic filariasis and onchocerciasis) or regional (visceral leishmaniasis) elimination as public health problems, and the burden of disease for Chagas disease, leprosy and onchocerciasis has already significantly declined.

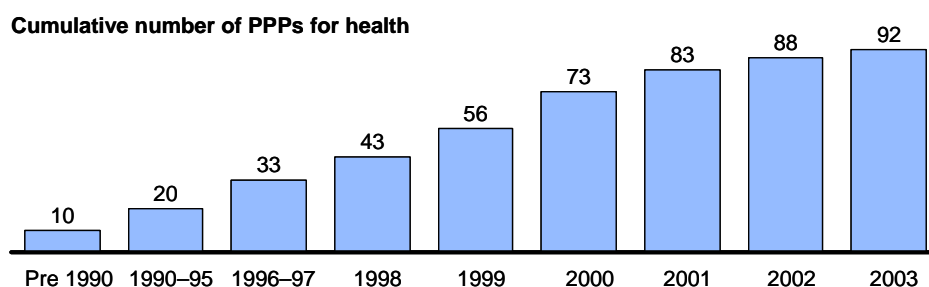
None of these diseases can be fully eradicated with the current tools and much research is still needed to achieve and sustain their elimination, but the research needs of these diseases have evolved significantly with cost-effective intervention tools and strategies now being available. Important new intervention tools and strategies (e.g. insecticide treated bednets, artemisinin combination therapies and home management of malaria) have also been developed for malaria but large scale implementation lags behind and the burden of malaria remains terribly high. The epidemiology of TB has radically changed and is increasingly driven by the HIV epidemic. The emergence of HIV/AIDS has dramatically altered the landscape, with average life expectancy as low as 40 years in several countries.

Other infectious diseases of the tropics, that were not originally included in TDR, e.g. certain helminthic infections, Buruli ulcer and several zoonoses, remain neglected. Their burden of disease, if known at all, persists and there are no adequate tools available for their control. Every 8 months a new human infectious disease emerges and 75% of these are zoonoses. However, for emerging infections that mainly affect the poor, there has been little research support for surveillance and capacity building in endemic countries. To enhance the impact of interventions, there is increasing interest in integrated intervention strategies against combinations of infectious diseases but the evidence on how to do that is lacking.

Separating the current 10 TDR diseases from other neglected infectious diseases of poor populations is increasingly artificial and there is a need for a more appropriate response to the priority research needs in disease endemic countries.

INCREASED ACTIVITY AND NEW ACTORS

The organizational environment for infectious diseases research has changed dramatically. There is one major new organization, the Bill & Melinda Gates Foundation, and many new public-private partnerships (PPPs - 34 in product development), single disease control initiatives, academic consortia and others.



Source: Initiative on Public Private Partnership for Health's "Partnership database"

This increase in the number of actors has been accompanied by a significant increase in resources for the development of new tools from various sources (Gates Foundation, industry, product development partnerships, funding agencies), and further increases in budgets are expected for product development through product development public-private partnerships. This increase in actors and resources is a very positive development for infectious diseases research, but it has also resulted in a fragmentation of efforts and resources. Multilateral and bilateral donors, philanthropies and governments would therefore welcome greater coordination in agenda setting, harmonization in research funding, and more reliable information on investments in infectious disease research¹¹. This would facilitate a better alignment of funding with priority research needs in disease endemic countries, and make donor actions more collectively effective in line with the Paris Declaration on Aid Effectiveness¹².

LIMITED ROLE OF DISEASE-ENDEMIC COUNTRIES

Despite the efforts of TDR and many other organizations, disease endemic countries are increasingly left behind in planning and priority setting for research on infectious diseases that are endemic in their countries. The technology gap is widening for many countries. They feel excluded from important debates and decisions, and are concerned that research is not properly targeting the public health problems that are of most significance to their populations. Disease endemic countries have expressed the need for more direct participation in research priority-setting and other consultations that shape decision-making, and for the establishment of mechanisms through which their voices can be heard and where their public health research needs are publicized and better understood⁹.

The research capacity in disease endemic countries 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 further capacity strengthening, especially at a more strategic level and in support of priority setting and research planning. Research capacity is still largely academic based, and disease endemic countries are still heavily reliant on north-south technology transfer. There is a great need to enhance capacity for innovation and product development in disease endemic countries, to build national capacities for policy and implementation research, and to enhance research capacity in control programmes and strengthen national commitment to health research.

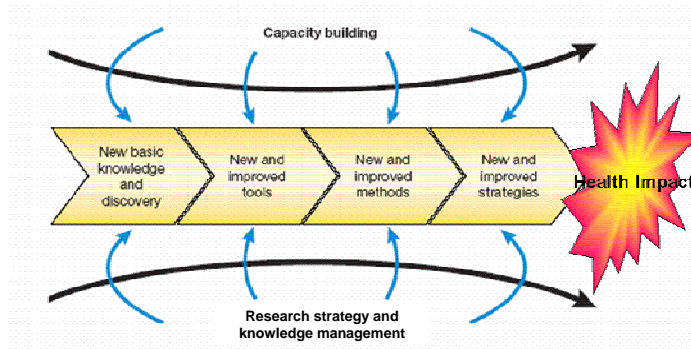
¹¹ Fourth External Review of TDR. *Towards evolution and growth*. Geneva, TDR, 2006

¹² High Level Forum on Aid Effectiveness, Paris, March 2005. *Paris Declaration on Aid Effectiveness*
<http://info.worldbank.org/etools/docs/library/238766/H&A%20Menu%20rev%202%20English.pdf>

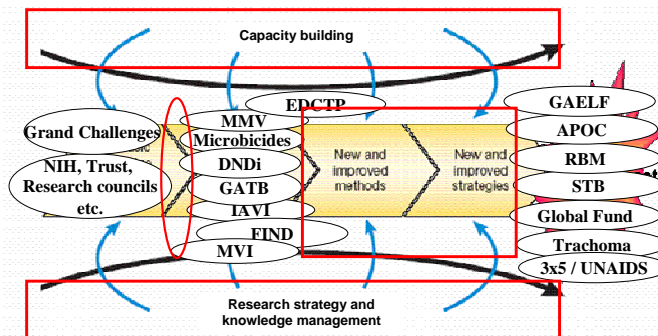
NEGLECTED RESEARCH AREAS

The global research effort on infectious diseases of the poor is diverse and fragmented. Some areas are well covered, e.g. drug development for malaria and TB, and there is little need for TDR to support research in these areas. But other areas are neglected even though they are critical for the overall impact of the global research effort. Among these neglected areas are interfaces between major research domains, e.g. translational research on the interface between basic research and product development, research on the effectiveness of interventions on the interface between product development and intervention policy, and implementation research on the final interface between research and large-scale disease control.

Research pipeline covered by TDR in 2000-2005



Activity of other research and control organizations and major gaps (in red) informing the basis of new TDR strategy



Research on each of these interfaces is absolutely critical: translational research to feed the product development pipeline, intervention effectiveness research to inform policy of use, and implementation research to help ensure that interventions reach the poor. The need for implementation research is especially great given the problems that health systems and disease control programmes have in achieving adequate coverage with available health interventions. Without significant research activities in these interfaces, the overall global research effort will fail to deliver the intended public health impact.

ANNEX 4. POTENTIAL BUSINESS LINES

Two business lines (BL) will be established within the strategic functions of stewardship and empowerment and these will remain constant throughout the strategy period. They will closely interface with each other and with the research business lines

BL 1) *Stewardship*. See main document pages 7 and 8 for detailed description.

BL 2) *Empowerment*. See main document pages 7 and 9 for detailed description.

Research business lines are less fixed and will be time limited based on entry / exit criteria. The following provisional list of research business lines is indicative of the types of work business lines would undertake and representative of business lines that could be initiated rapidly. Most business lines would span multiple research functions but in order to provide some categorization, the business lines are placed under the research function that would occupy the dominant direction and end product of the business line. The number of business lines that could be implemented at any one time is dependent on resources.

Foster innovation for product discovery and development, emphasizing disease endemic country engagement

BL 3) *Lead discovery for drugs*

There is a continuing and compelling need for new and better drugs and diagnostics for infectious diseases of poverty. The product development partnerships require quality leads to feed their development pipelines. This business line provides a coordinated mechanism to work with partners to fill this gap and support the translation of available scientific knowledge (for example genomics) into product leads. It will achieve this by facilitating and supporting the discovery of new drug and diagnostic leads for infectious diseases through networks and partnerships between pharmaceutical companies, academia and disease endemic country institutes.

BL 4) *Innovation for product development in disease endemic countries*

There is a significantly increased need and capability for disease endemic countries to participate in product development activities and generate the tools that address infectious diseases of poverty instead of relying wholly on technology transfer. This line seeks to facilitate and support such developments through establishing networks and partnerships. It will also seek to identify and fund innovative product development activities, led by institutions in disease endemic countries, based on a public-private partnership model.

BL 5) *Innovative vector control interventions*

Vector-borne infectious diseases are emerging or resurging because of changes in public health policy, insecticide and drug resistance, shift in emphasis from prevention to emergency response, demographic and societal changes, and genetic changes in pathogens. Thus there is a significant need for innovative vector control strategies for prevention of these neglected diseases in disease endemic countries. This line will focus upon facilitating networks to support vector genomic initiatives. It will seek to convene and ensure disease endemic country participation in initiatives

already under way through international funding. It will provide a link to ensure appropriate disease endemic country participation and decisions on whether and how to evaluate and test deployment of new tools that may have difficult ethical, legal and social issues associated with them e.g. the eventual deployment and use of genetically modified vectors for malaria and dengue, and the deployment of new insecticides and alternative approaches to vector control.

Foster research on development and evaluation of interventions in real life settings

BL 6) Drug development and evaluation for helminths and other neglected tropical diseases

The priority need for onchocerciasis and lymphatic filariasis control is the availability of a drug which will kill or permanently sterilize the adult worm that will allow interruption of transmission and elimination of onchocerciasis or lymphatic filariasis infection. Schistosomiasis depends on a single drug (praziquantel) and it is stage specific. Additional drugs that will kill both the adult and the immature forms are urgently needed. This BL aims to manage and provide support for drug candidate development, registration and field-use evaluation of drugs for onchocerciasis, lymphatic filariasis and other helminth infections including schistosomiasis, through a network of collaborators in developing and developed countries.

BL 7) Accessible quality assured diagnostics

Although many high-quality, sophisticated diagnostic tests for infectious diseases are available in the developed world, they are neither affordable nor accessible to patients in developing countries due to the lack of appropriate facilities and resources. This line will build upon TDR expertise in: upstream use-inspired diagnostic research; managing diagnostic evaluations; and standard setting for testing and application of diagnostics in developing country settings. It will take advantage of TDR's strong relationships with WHO's disease control programmes and its global network of collaborating centres and regional offices. It will focus on both point-of-care diagnostic tests for case management and tests to support disease surveillance e.g. for emerging and re-emerging infections.

BL 8) Evidence for treatment policy of HIV and TB co-infection

Evidence on strategies to optimize the clinical management of patients infected with TB and TB/HIV is limited. There is a clear research need to develop evidence for optimal management and care of TB and HIV-infected TB cases within the context of available health care infrastructure in resource-limited settings. This business line aims to produce evidence for safe and efficacious treatment and case management of TB and TB/HIV co-infected patients. The focus of activity of this business line's research activities will be at the national control programme primary care level.

BL 9) Evidence for antimalarial policy and access

Several highly effective antimalarials are available for the treatment of uncomplicated and severe malaria, and more are being developed. Increased funds are becoming available for endemic countries to procure and widely deploy such antimalarials. However, reliable information on how these drugs perform in the conditions of use at different levels of the health system (including at community level and in home management), with or without diagnostics, and often in the presence of other febrile illnesses such as pneumonia, is scarce yet essential to inform policy

makers, care providers, donors and drug developers. This line will develop a framework to conduct, review and disseminate results from real-life evaluation of antimalarials. It will also support implementation research on how to optimize access to treatment in resource poor settings and to inform the scale up of malaria control.

Foster research for access to interventions

BL 10) Visceral leishmaniasis (VL) elimination

For the first time ever it is possible to realistically plan elimination of VL in the Indian subcontinent. VL elimination in this sub-continent and elsewhere will require an integrated research strategy. This BL will work with national programmes to assist scale-up to evaluate and implement improved intervention tools (including drug combinations and diagnostics). It will provide evidence on the optimal combination of interventions, and develop an effective strategy for VL elimination in the Indian subcontinent and elsewhere.

BL 11) Integrated community-based interventions

This business line will develop and test innovative ways of getting new and existing interventions to populations who have poor geographical and/or economic access to health services. Of special interest are community-based interventions that empower communities and complement the often sub-optimally working health services at the grass roots level. The business line will provide evidence-based understanding of what combination of tasks can be managed efficiently by community care providers, how different community-based interventions can be effectively integrated, and how community empowerment can be sustained. The main and global end product from these activities will be evidence-based, innovative approaches for integrated delivery of interventions for the major neglected tropical diseases and other diseases.

**Special Programme for Research & Training
in Tropical Diseases (TDR) sponsored by**
UNICEF / UNDP / World Bank / WHO



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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:

