

APPROVED PROGRAMME BUDGET

2002 - 2003



UNDP/World Bank/WHO
Special Programme for Research and Training in Tropical Diseases
(TDR)



Approved Programme Budget for the Biennium 2002-2003

This Programme Budget was approved
on 25 and 26 June 2001 by
the Twenty-fourth Joint Coordinating Board



UNDP/World Bank/WHO
Special Programme for Research and Training in Tropical Diseases
(TDR)

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FOREWORD

The Programme Budget 2002-2003, as presented and approved by the Twenty-fourth Session of the Joint Coordinating Board, is the result of an intensive process which started almost two years ago with the formulation of the TDR Strategy 2000-2005. This Strategy has guided TDR towards being more responsive to the needs of control while maintaining its medium and long-term perspectives, as well as its basic values and operational capability driving force. The budget preparation process has been based on a careful analysis of needs and opportunities, and has included extensive consultations with control programmes at WHO. The result is a comprehensive and detailed product portfolio, which underlies the budget numbers presented in this document. The product portfolio is described in the TDR Product Portfolio Directory 2002-2003.

Geneva, June 2001

Carlos M. Morel, Director TDR

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1. INTRODUCTION

The Approved Programme Budget for the 2002-2003 Biennium (APB2002-03) is presented in a very different format from previous years. The new presentation aligns the TDR budget and detailed workplans with the new TDR Strategy and the WHO Programme Budget for the biennium.

The main features of the Strategy which have shaped the new format are:

- *Results orientation.* Rather than presenting the budget according to programme areas as previously, it is now presented according to Expected Results. This means that there are no a priori allocations of budget ceilings by organizational units. Resource requirements are presented according to outputs or 'products', that will be delivered within each 'expected result'* for which budget levels are indicated in the Strategy. This means that the principle of budgeting has changed from one based on inputs to one based on outputs. This will help focus the Programme, stimulate innovation, drive performance, and promote collaboration within TDR as well as with control programmes.
- *The foreseen significant increase in the overall budget level.* The budget presented in the APB2002-03 is roughly US\$35 million above the income level of the 1998-1999 biennium. Most, if not all, of this increase is expected to come from designated funding, which represents a major diversion from previous years. The Programme Budget is therefore presented indicating the source of funding, i.e. undesignated (UD), designated-funded (DF), and not-funded (NF). A significant budget increase was envisioned in the Strategy and is being made realistic by the increasing demand for new and improved tools and strategies resulting from the global initiatives, e.g. in controlling malaria, tuberculosis, and HIV/AIDS, the latter having an important interaction with TB.
- *The concept of 'floors' rather than 'ceilings'.* With the shift from an input- to an output-based budgeting principle, combined with the foreseen significant increase in designated funding, the previously used concept of budget ceilings has no meaning. The Approved Programme Budget 2002-2003 instead introduces the concept of floors. This implies that the Programme's undesignated funding will be allocated to ensure that the investment in products that are closest to the core values of the Programme, and for which it is difficult to raise funding, does not fall below a pre-determined level depending on the availability of undesignated funds. Those areas being particularly protected are upstream research, capacity strengthening, and the truly neglected diseases.
- *An analytical approach to priority-setting.* The basis for composing the product portfolio and budgeting is a systematic analysis of needs for research and TDR's comparative advantages in each of the Expected Results areas and diseases. TDR's strategic emphasis for each Expected Result and disease area has been identified, and this has guided the planning process. A summary of this analysis is presented in the APB2002-03.

- *The shift to a matrix approach for management.* TDR's budget is not only moving from an 'input' to an 'output' base, but is adding a disease dimension to the functional presentation of previous programme budgets. The budget summaries for 'operations' are therefore presented in a matrix format, i.e. 'expected results' versus 'disease'. Managerially, the matrix approach is represented by a Strategic Management Team (SMTeam) composed of functional coordinators (line managers) and disease research coordinators.
- *Emphasis on accountability.* The key elements of accountability are transparency, setting of output and performance measures, and reporting. The APB2002-03 provides, in a separate document,* all the products that the Programme currently foresees as being worked on during the biennium. For each Expected Result, the Strategy has 'indicators', which will be used to measure output and performance. As a natural part of any R&D organization's portfolio, unforeseen opportunities for new products may arise during implementation while other products may turn out to be non-viable. Thus the product portfolio will be dynamic by necessity.

The Joint Coordinating Board (JCB) approved the PB2002-03 with particular attention to the floors, allocation between budget elements, and the disease strategic emphases presented in Tables 1, 3, and Annex II. The Product Portfolio will be continuously monitored and updated, based on analysis of opportunities and needs, and using the established management mechanisms of the Programme, notably the SMTeam and the scientific steering committees. The Scientific and Technical Advisory Committee (STAC) will review progress at the product level and will make recommendations to the JCB.

* TDR's seven Expected Results are defined in the Strategy 2000-2005 as well as in the WHO Programme Budget 2002-2003, and are further elaborated upon in section 5 of the Programme Budget 2002-2003.

2. RESOURCE SCENARIO

The Strategy 2000-2005 sets out broad strategic budget frames at the expected results and disease levels, gradually increasing the budget level of the Programme from the previous US\$60 million to a US\$90-95 million level, with the steepest gradient found early in the strategic planning period. In the disease dimension, this budget increase is justified by including two new diseases, TB and dengue, in the Programme's disease portfolio. In the expected results dimension, the increase is justified by expanding into *Social, Economic, and Behavioural Research* under Expected Result A; *Diagnostics* under Expected Results B, C, and D; and *Implementation Research* under Expected Result D.

2.1 Resource mobilization

To achieve this increase in income, the Programme has to work on three fronts: increasing the contributions from current donors, expanding the donor base, and devising planning and funding mechanisms that are attractive to current and new donors. At the same time, it must sustain the high proportion of undesignated funding required to maintain scientific independence and rationality in priority-setting.

Extensive consultations have been held with TDR's donor group. These consultations confirmed continued strong support and commitment to maintaining or slightly increasing the current level of undesignated funding to the Programme. However, the consultations revealed the need for new approaches to raising funds for specific products or projects. The donors requested TDR to prepare a Resource Mobilization Strategy, presented to the JCB(24) in June 2001, to clarify how the additional resources would be raised and how the increased level of designated funding would be handled by the Programme.

2.2 Expected income

The Approved Programme Budget 2002-2003 assumes an undesignated income for the biennium of about US\$47.8 million, which includes a stipulated US\$5 million from designated funding as contributions towards TDR's analytical, technical information, and management products (Expected Results F and G respectively). With an overall value of the product portfolio of US\$95.2 million (Table 1), this leaves a net US\$47.4 million to be sought from designated sources. Out of this US\$47.4 million, about US\$28.8 million have already been secured or are in advanced stages of being secured, thus leaving a further US\$18.6 million to be raised in order to implement all the products in the portfolio.

* TDR Product Portfolio Directory 2002-2003.

3. SUMMARY BUDGETS

Table 1. Overall budget summary (expected results and sources of funding)

Expected result (by thousand US\$)	Undesignated (Floors)	Designated (Funded/pledged*)	Not funded	Total	%
A: New knowledge	8,859	0	3,000	11,859	12.5%
B: New & improved tools	6,995	18,050	7,533	32,578	34.2%
C: New & improved methods	3,392	4,688	1,569	9,648	10.1%
D: New & improved strategies & policies	1,812	2,088	5,466	9,367	9.8%
E: Partnerships & capacity strengthening	13,834	4,015	1,026	18,875	19.8%
F: Technical information	4,772	+	+	4,772	5.0%
G: Management	8,120	+	+	8,120	8.5%
Total	47,784	28,841	18,594	95,219	100.0%

*Agreement with contributor for funding of this has, at the time of printing, already been agreed or has reached an advanced stage.

+The US\$5 million contribution that will be received as designated funding for Expected Results F and G are listed as undesignated as they will be debited from the designated contribution when received.

The overall budget of US\$95.2 million is distributed as follows: about one-third to *new and improved tools*, one-fifth to *partnerships and capacity building* and one-tenth to each of *new knowledge*, *new and improved methods*, and *new and improved strategies and policies*. *Technical information* and *management* together receive about one-tenth as well. The floors, i.e. the 'undesignated' column in table 1, indicates that the highest floors are in *partnership and capacity building*, followed by *new and improved tools*, *new and improved methods*, and *new and improved strategies and policies*. It should be noted that, for *technical information* and *management*, the contributions from designated funding for these expected results are included as 'undesignated', as they will – once charged – lose their designated nature.

TDR's driving force, as identified in the TDR Strategy 2000-2005, is its operational capabilities, i.e. its ability to efficiently and effectively manage and guide R&D processes for developing solutions to public health problems caused by infectious diseases affecting poor and marginalized populations AND, during these processes to involve public and private sectors as well as researchers and developers from both developed and developing countries.

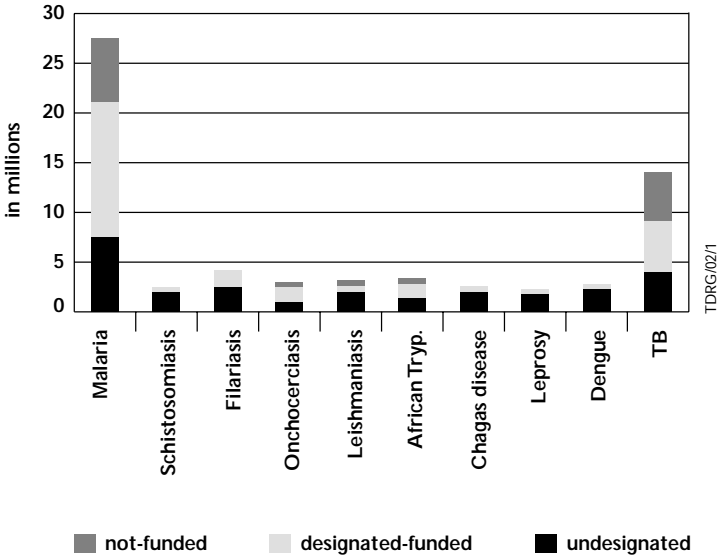
That is, TDR not only efficiently channels funds from its contributors to the researchers and developers that the Programme contracts, but also adds value by facilitating the establishment of global

R&D priorities while providing scientific and technical advice and guidance to these processes. This will encourage efficiency and relevance to the values, goals and objectives of the Programme. In budgetary terms, the inputs relate to personnel and operational support and the outputs relate to operations. The balance between the inputs and the outputs has historically been monitored closely by the JCB. The Strategy 2000-2005 and the Approved Programme Budget 2002-2003 foresees maintaining this balance.

3.1 Operations

'Operations' covers all contracts with external R&D organizations, communication, global research agenda setting, etc. All products consuming Operations Budget are directly linked to one or more of the TDR target diseases. As shown in Chart 1 (for details see Annex I.2), designated funding is foreseen to go mainly to the two 'big' diseases, i.e. malaria and tuberculosis. Onchocerciasis and African trypanosomiasis will also have a significant proportion of their budgets covered by designated contributions.

Chart 1: Operations budget (US\$) by disease and funding status*



* Reporting on expenditures by disease will be done as previously, based on information in TDR's project management system, i.e. not from the WHO financial system (AFI).

3.2 Personnel and operational support

The required professional and general service staff full-time-equivalents (FTE) for each of the products have been estimated. The product portfolio has been tuned to maintain the proportion of personnel to total budget as close as possible to the desired 20% threshold.

The shift from an input- to an output- based principle for budgeting, combined with half the income forecasted to originate from designated sources, has necessitated a revision in the way the Programme views its staffing resources. TDR's operational capabilities driving force is mainly vested in a group of staff who run the core functions, such as line management, steering committees, analytical work, communications, administration, etc. and the Programme needs to build and maintain scientific and managerial expertise in this group of staff. This group will therefore be employed on fixed-term contracts and financed from undesignated funds. To implement its product portfolio, TDR may, in addition to the group of staff with longer-term employment, need specific expertise, i.e. project staff depending on the nature and size of the funded product portfolio. The composition and size of this group of staff will vary over time. The project staff may be employed on short-term or fixed-term contracts and financed from undesignated or designated funds, depending on the tasks and availability of funds.

Table 2: Staff full-time-equivalents by expected result

Expected Result	Longer-term staff		Project staff		Total	
	Prof. (FTE)	Gen. Serv. (FTE)	Prof. (FTE)	Gen. Serv. (FTE)	Prof. (FTE)	Gen. Serv. (FTE)
A: New knowledge	4.0	4.0	1.2	0.7	5.2	4.7
B: New & improved tools	5.0	5.0	7.7	4.6	12.7	9.6
C: New & improved methods	1.5	1.5	1.9	1.5	3.4	3.0
D: New & improved strategies and policies	1.5	1.5	2.2	1.8	3.7	3.3
E: Partnership and capacity strengthening	4.0	5.0	3.3	1.7	7.3	6.7
F: Technical information	6.0	3.0	0.2	0.3	6.2	3.3
G: Management*	4.0	13.5	2.0	2.2	6.0	15.7
Total	26.0	33.5	18.5	12.6	44.5	46.1

*Including administrative support staff, i.e., 1 P and 5.5 G-staff in CDS/MSU and GMG

The operational support budget covers staff duty travel, short-term consultants, meetings of steering committees, governing bodies, supplies and equipment for TDR, as well as general administrative costs. Operational support is budgeted to keep the operations budget as close to 70% as possible.

Table 3: Overall budget by budget element

Budget elements	US\$	%
Operations	65,921	69.3%
Personnel services	21,750	22.8%
Operational support	7,547	7.9%
Total	95,218	100.0%

Details about the budget are given in Annexes I.1-4.

3.3 Comparison with the 2000-2001 biennium

Because of the different principles (output versus input) underlying the APB2002-2003 and the APB2000-2001, it is not possible to make a direct one-to-one comparison. Table 4 should therefore be viewed with this in mind.

Table 4: Comparison between APB2000-2001 and APB2002-2003**

Expected result	APB2002- 2003				APB2000 - 2001			
	Total	%	Personnel		Total	%	Personnel	
	US\$'000		P-FTE	G-FTE	US\$'000		P-FTE	G-FTE
A: New knowledge	11,859	12.5%	5.2	4.7	11,182	15.1%	5.5	4.5
B: New & improved tools	32,578	34.2%	12.7	9.6	20,938	28.3%	7	6.5
C: New & improved methods	9,648	10.1%	3.4	3.0	9,435	12.8%	3	3
D: New & improved strategies & policies	9,367	9.8%	3.7	3.3	2,321	3.1%	2.5	2
E: Partnerships & capacity strengthening	18,875	19.8%	7.3	6.7	21,353	28.9%	5	6
F: Technical information	4,772	5.0%	6.2	3.3	2,548	3.4%	3	1
G: Management	8,120	8.5%	6.0	15.7	6,136	8.3%	4	13.5
Total*	95,219	100.0%	44.5	46.3	73,913	100.0%	30	36.5

*All figures used are rounded therefore percentages may not total to 100%

The main areas of growth are *new and improved tools* and *new and improved strategies and policies*, with budget increases of US\$11.6 and US\$7.0 million respectively. For *technical information*, the budget increase is US\$2.2 million, reflecting the increased emphasis on analytical and agenda-setting functions of the Programme. *Management* is increasing by US\$2 million, reflecting the overall increase in the level of the Programme's activity and the increased costs of fundraising and reporting. For *partnership and capacity strengthening*, the budget remains the same but staffing is foreseen to increase, reflecting the more labour intensive nature of the new strategy for research capacity strengthening.

* Reporting on expenditures by disease will be done as previously, based on information in TDR's project management system, i.e. not from the WHO financial system (AFI).

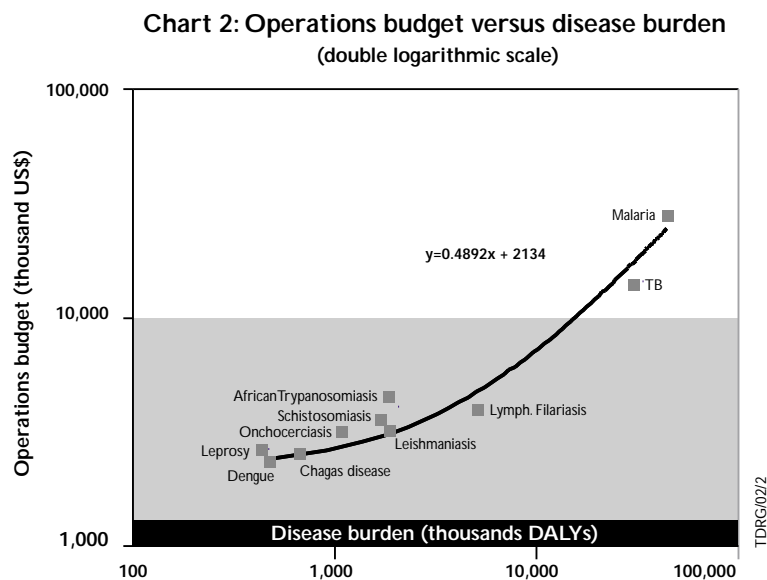
** The PB2000-2001 has been converted from a unit (programme area) base into an expected results base to enable comparison with the proposed PB2002-2003.

4. STRATEGIC EMPHASES

An important component of the Strategy 2000-2005 is to increase the Programme's analytical capacity and resource allocation for analytical work on TDR's disease and activity portfolio. The work in progress during the past year has provided strategic guidance for the preparation of the Programme Budget 2002-2003.

4.1 Disease strategic emphases

Chart 2 shows the relationship between burden of disease and proposed investment for each of the target diseases. The trend line shows that a linear relationship is a good approximation of the relationship between burden of disease and TDR investment in research for each disease.



As a first step in institutionalizing regular reviews of the research agenda for TDR target diseases, disease research coordinators have been appointed and each of the ten diseases have been subject to initial reviews. As a result of the analysis, the diseases have been grouped into three proposed categories:

Category 1: *African trypanosomiasis, dengue fever, and leishmaniasis*

- Diseases which are re-emerging or uncontrolled
- The research focus is on acquisition of new knowledge and design of new tools and systems.

Category 2: *Malaria, schistosomiasis and tuberculosis*

- Disease for which a control strategy is either not yet available or not yet proven effective for sustained reduction of the burden.
- Research covers the spectrum from acquisition of new knowledge to better strategies for implementation, but the emphasis is on development and testing of new tools and methods.

Category 3: *Lymphatic filariasis, leprosy, Chagas disease and onchocerciasis*

- Diseases with a control strategy of proven cost-effectiveness, declining disease burden and a target date for elimination.
- Research focus is on improvement and wider dissemination of existing policies, systems, and delivery strategies with attention to future risk assessment and avoidance.

A detailed analysis with the strategic implications for each of the Expected Results areas is presented in Annex II.

4.2 Research Capability Strengthening strategic emphasis

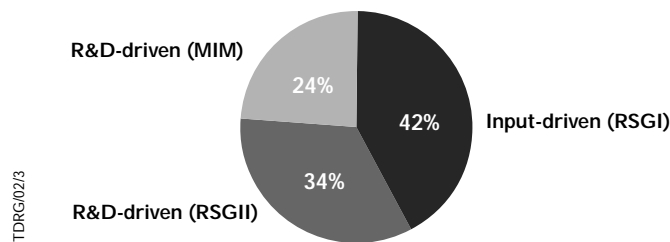
As a consequence of the Strategy, and after discussions in STAC, TDR's engagement in research capability strengthening is taking a two-pronged approach:

- Development of a comprehensive and equitable approach to research capacity strengthening in least developed countries (LDCs), with sustainability as the key consideration (input-driven or RSGI).*
- Facilitation of increased utilization of research, product development, and research training capacities in developing countries in support of TDR's R&D priorities, with optimization of previous investments as a key consideration (R&D driven or RSGII + MIM).**

The Strategy aims to allocate 40% of TDR's research capacity strengthening budget to the first approach and 60% to the second approach. A detailed analysis, with the strategic implications for each Expected Results area, has been carried out to guide the budget process for 2002-2003; it is presented in Annex III.

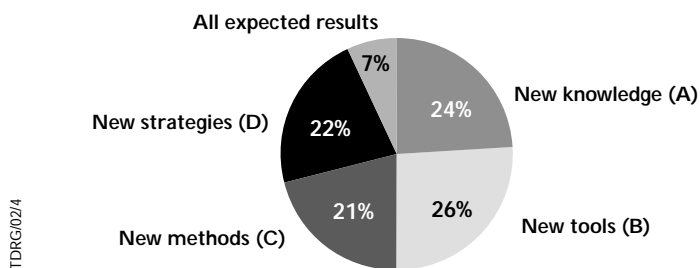
Chart 3 shows that the strategic shift from the traditional input-driven research capacity strengthening approach to an R&D-driven approach is achieved in the budget for 2002-2003, with 42% remaining for the traditional approach capacity building, reserved for least developed countries, and 58% being R&D-driven (RSGII and MIM) and available for all disease endemic countries including the least developed.

Chart 3: Operations by approach to capacity strengthening



The 34% budgeted for the R&D-driven (RSGII) approach is distributed across the expected results, with 20% to 26% for each of Expected Results A to D and 7% for products cutting across all expected results (Chart 4).

Chart 4: Distribution of R&D-driven capacity strengthening across expected results



5. EXPECTED RESULTS

The nature of TDR's field of work is such that the time frames of the products vary considerably, from less than two years to ten years or more for certain types of products. The uncertainty and risks involved also vary according to the nature of the specific product. Products from up-stream Expected Result areas (A and B) represent innovation in knowledge and are a prerequisite for the development and validation of novel interventions in tropical diseases. The rapid development in this area underscores a need for a TDR proactive role in assuring application and maximum benefit for meeting the challenges of neglected diseases. This also means that, at the upstream end of the portfolio, there will be small- and medium-sized investments in a diverse range of products, many of which may not turn out to be viable for subsequent investments.

The PB2002-03 operates with two categories of products:

- Products that have a high likelihood of successful completion within the biennium, i.e. they will contribute towards objectives and can be measured against the indicators defined for each Expected Results area. The product will either come into use in control/research or will move downstream through the R&D pipeline.
- Products with a time horizon beyond the biennium. They are either begun during the biennium or have a time frame extending over more than one biennium. They are also often associated with moderate to significant risk-taking by the Programme.

Both categories are followed closely by the programme management to maintain an appropriate balance between the medium- and long-term product horizons, and to sustain a steady flow of results. A brief description is given below of the main products foreseen to be completed within the biennium for each of the Expected Results.

Expected Result A: New basic knowledge

Brief description and strategic indicators

New basic knowledge about biological, social, economic, health systems, and behavioural determinants. Also any other factors of importance for effective control of infectious diseases generated and made accessible at national and international levels.

Strategic indicator

A1: Number of new, significant and relevant scientific advances (biomedical, social, economic, and public health sciences) in neglected tropical diseases.

Outputs will include: the publication of reviews and new findings relevant for better understanding of biomedical, social, economic and public health implications of neglected diseases; finalization and publication of studies on health sector reform and tropical disease; coordination of data availability from *Anopheles gambiae* genome sequencing in the public domain database, and proactive involvement of disease endemic country (DEC) scientists in post genome activities; understanding of parasite mechanisms in the invasion and role of disease severity in malaria; formation of a network on application of bioinformatics and applied genomics in tropical disease.

Expected Result B: New and improved tools

Brief description

New and improved tools for use in infectious disease prevention and control, e.g. the development of drugs, vaccines, diagnostics, epidemiological tools, environmental tools.

Strategic indicator

- B1: Number of new candidates (drugs, vaccines and diagnostics) ready to enter the development stage.
- B2: Number of new and/or improved tools (drugs, vaccines and diagnostics) resulting in regulatory approval for use in neglected tropical diseases.
- B3: Number of new and/or improved epidemiological tools developed for use in neglected tropical diseases.

A number of new products are expected to be completed during the biennium. These include: regulatory approaches for a rectal formulation of artesunate for the emergency treatment of malaria; low-cost oral formulation of a fixed combination of chlorproguanil and dapson for the treatment of uncomplicated malaria in Africa; the world's first oral treatment for visceral leishmaniasis, miltefosine, and an i.v. formulation of paromomycin to deal with antimony resistant disease. In addition, work on albendazole combinations for use in lymphatic filariasis should pave the way for a WHO Expert Report to recommend the use of such combinations, and simple, rapid and inexpensive diagnostics for active tuberculosis infection and drug-resistant disease should become available. Finally, an agreement is expected with major drug regulatory authorities over global guidelines for dossier preparation for new drugs active in tuberculosis. In addition, it is expected that three new candidate drugs will enter development: PX 6518 for the treatment of leishmaniasis, an antifungal azole for the treatment of chronic Chagas disease, and a synthetic endoperoxide for the treatment of malaria.

Expected Result C: New and improved intervention methods

Brief description

New and improved intervention methods for applying existing and new tools at the clinical and community levels, developed and validated.

Strategic indicator

C1: Number of new or improved intervention methods for the prevention, diagnosis, treatment, and rehabilitation of populations exposed to neglected tropical diseases, validated.

Products which will be completed include: field applicability of an existing diagnostic test for schistosomiasis; validation markers of antimalarial drug resistance; validation of new epidemiological tools for Chagas disease; efficacy and safety of Artesunate combination therapy (ACT); and the determination of efficacy and safety of rectal artesunate also for malaria.

Expected Result D: New and improved policies and control strategies

Brief description

New and improved policies for large-scale implementation of existing and new prevention and control strategies to be developed and validated, and the guidance required for their application in national control settings made accessible.

Strategic indicator

D1: Number of *currently used* control policies and strategies for neglected tropical diseases improved.

D2: Number of *new* control policies and strategies for targeted neglected tropical diseases formulated, tested and validated.

D3: Number of new and improved tools brought into the control of neglected tropical diseases.

Completed products will include: new elimination policy package for the control of Chagas disease; evaluation and improvement of tools for rapid mapping of lymphatic filariasis; rapid assessment method for level of *Loa loa* endemicity in a community; strategies for sustainable and affordable management of lymphoedema and associated adenolymphangitis (ADL); long-term impact of mass treatment with ivermectin on onchocerciasis transmission and feasibility of elimination; demonstration of large-scale impact on malaria through deployment of rectal artesunate.

Expected Result E: Partnerships and capacity building

Brief description

Partnerships established, and adequate support for research and product development capacity building in countries provided.

Strategic indicator

- E1: Number of partners in R&D work in countries.
- E2: Number of professionals trained.
- E3: Number of institutions strengthened.
- E4: Proportion of centres and experts from disease endemic countries (DECs) out of the total number engaged in TDR research and product development.
- E5: Proportion of research findings, new and improved tools and intervention methods produced by institutions in DECs.

Products include: Director's Partnership Fund operational; three Masters programmes in epidemiology and public health in operation in DECs; 20 LDC institutions developing control-related research, particularly in malaria, tuberculosis, African trypanosomiasis and dengue; conclusion of a consolidated report on first-line drug resistance estimates and laboratory correlates in six African countries based on standard clinical and laboratorial protocols; two to three DEC journals will have initiated a programme for continuous quality improvement; a multicountry study on mapping health research capabilities, resource flows and needs will be completed; presentation of the first collectively produced estimates on malaria related infant mortality rates; capacity established for social science studies on scaling up malaria interventions; capacity established in selected countries for health system, service and policy research in tuberculosis; and two to three DEC bioinformatics research and training centres in operation.

Expected Result F: Information, guidelines, instruments and advice

Brief description

Adequate technical information, research guidelines, instruments, and advice made accessible to partners and clients in countries.

Strategic indicator

F1: Number of R&D initiatives in neglected tropical diseases using the instruments developed.

F2: Number of requests for pages from TDR web-site from developing countries.

F3: Number of effective staff contacts with R&D partners working in neglected tropical diseases.

Tangible products include: global agenda setting for research and development needs in malaria, leishmaniasis, dengue, and tuberculosis; review of research needs for all TDR diseases; increased dissemination, through printed and electronic media, of information relevant to research and control of TDR diseases.

Expected Result G: Resource mobilization and programme management**Brief description**

Resources for research, product development, and capacity building efficiently mobilized and managed.

Strategic indicator

G1: Increase in overall funding level.

G2: Level of increase in contributions resulting from the participation of new groups of donors.

G3: Proportion of undesignated funding out of total funding received.

G4: Proportion of funds, out of total, allocated to Operations, Personnel, and Operational Support.

Products or improvements include: increased advocacy and proactive resource mobilization, further streamlining of administrative procedures (e.g. electronic processing of grant applications), preliminary activities related to the fourth external review, and evaluation of selected completed projects.

6. REVISION OF BUDGET AND PRODUCT PORTFOLIO

The product portfolio will need to be dynamic to allow adaptability to scientific and funding opportunities as they arise, with products either being completed, or shelved in case they turn out to be non-viable. The current list of products is available in the TDR Product Portfolio Directory, which will be updated quarterly and posted on the TDR web-site.

- Products identified for undesignated funding will be implemented pending the availability of undesignated funding or designated funding coming up against these products. The previous practice using annual working budget ceilings will be maintained for these products.
- Products identified for designated funding or listed as not funded will only be initiated when funding becomes available.

The Programme will manage the budget and the product portfolio using the SMTeam and the steering committees, and will consult and inform the Standing Committee, STAC and JCB as outlined in the proposed revised policy for budget revision.

ANNEXES

I: Detailed budget tables

- I.1: Total budget by expected result and source of funding.
- I.2: Operations budget by disease and source of funding.
- I.3: Management budget breakdown and comparison with the 2000-2001 biennium.
- I.4: Operational budget by disease and expected result.

II: Disease strategic emphasis

III: Research Capability Strengthening strategic emphases

- III.1: Research capability strengthening strategic emphasis for least developed countries (Input-driven).
- III.2: Research capability strengthening strategic emphasis for TDR's R&D agenda (R&D-driven).

UNDER SEPARATE COVER

TDR Product Portfolio Directory 2002-2003

- Product descriptions
 - Title of the product
 - Description of R&D activity
 - Control need
 - Success criteria and date
 - Funding status

- Product portfolio summary with key numbers

ANNEX I: DETAILED BUDGET BREAKDOWN

I.1: Total budget by expected results and source of funding

	Undesignated (Floors)	Designated** (Fund./pledg.)	Not Funded	Total	%***
A: New knowledge*	8,858,829	0	3,000,250	11,859,079	12.5%
Operations	6,484,329	0	2,500,000	8,984,329	
Personnel Services	2,050,500	0	414,250	2,464,750	
Operational Support	324,000	0	86,000	410,000	
B: New tools*	6,995,250	18,050,100	7,532,650	32,578,000	34.2%
Operations	4,776,600	14,653,350	6,380,000	25,809,950	
Personnel Services	1,793,650	2,716,750	920,650	5,431,050	
Operational Support	425,000	680,000	232,000	1,337,000	
C: New methods*	3,392,000	4,687,500	1,568,750	9,648,250	10.1%
Operations	2,585,000	4,040,000	1,260,000	7,885,000	
Personnel Services	682,000	572,500	263,750	1,518,250	
Operational Support	125,000	75,000	45,000	245,000	
D: New strategies and policies*	1,812,000	2,088,150	5,466,350	9,366,500	9.8%
Operations	1,350,000	1,720,000	4,330,000	7,400,000	
Personnel Services	412,000	298,150	958,350	1,668,500	
Operational Support	50,000	70,000	178,000	298,000	
E: Partnership and capacity*	13,834,070	4,014,500	1,026,000	18,874,570	19.8%
Operations	10,970,920	2,931,000	900,000	14,801,920	
Personnel Services	2,353,150	934,500	106,000	3,393,650	
Operational Support	510,000	149,000	20,000	679,000	
F: Technical information**	4,772,125	0	0	4,772,125	5.0%
Operations	1,040,000	0	0	1,040,000	
Personnel Services	2,574,125	0	0	2,574,125	
Operational Support	1,158,000	0	0	1,158,000	
G: Management**	8,119,875	0	0	8,119,875	8.5%
Operations	0	0	0	0	
Personnel Services	4,699,875	0	0	4,699,875	
Operational Support	3,420,000	0	0	3,420,000	
Total	47,784,149	28,840,250	18,594,000	95,218,399	100.0%

* For expected results A to E, the undesignated column indicates the minimum budget which will be allocated to each expected result using undesignated contributions, depending on the availability of such funds.

** Every designated contribution/project will contribute approximately 10% to the technical information and management expected result. These will be treated as undesignated contributions and are captured in the undesignated column.

*** All figures used are rounded therefore percentages may not total to 100%

I.2: Operations budget by disease and source of funding (US\$)

	Undesignated	Designated	Not funded (Funded1)	Total	%
Malaria	7,277,326	13,208,600	7,074,000	27,559,926	41.8%
Schistosomiasis	2,106,900	43,600	825,000	2,975,500	4.5%
Filariasis	2,747,975	243,600	775,000	3,766,575	5.7%
Onchocerciasis	1,206,045	1,613,660	303,000	3,122,705	4.7%
Leishmaniasis	2,237,020	543,600	527,000	3,307,620	5.0%
African Trypanosomiasis	1,417,520	1,916,890	563,000	3,897,410	5.9%
Chagas disease	2,299,900	243,600	0	2,543,500	3.9%
Leprosy	1,900,545	43,600	430,000	2,374,145	3.6%
Dengue	2,302,200	43,600	213,000	2,558,800	3.9%
Tuberculosis	3,711,418	5,443,600	4,660,000	13,815,018	21.0%
Total	27,206,849	23,344,350	15,370,000	65,921,199	100.0%

1) Every designated contribution/project will contribute approximately 10% to the technical information and management expected result. These contributions are captured in the undesignated column.

2) Reporting on expenditures by disease will be done as previously, based on information in TDR's project management system, i.e. not from the WHO financial system (AFI).

I.3 Management, comparison with 2000-2001 biennium (US\$ excluding salaries)

	2002-03	2000-01
Governing bodies		
Scientific and Technical Advisory Committee	190,000	160,000
Standing Committee	60,000	60,000
Joint Coordinating Board	148,000	148,000
Fourth external review	40,000	0
A posteriori and value for money evaluations	100,000	60,000
General management	179,000	205,000
Staff development	120,000	40,000
Advocacy and resource mobilization	500,000	60,000
Information technology	-	410,000
TDR information technology support	398,000	-
Electronic/web based protocol for grant processing	150,000	-
Administrative support	1,535,000	-
Common services	-	290,000
Premises rent	-	900,000
Postage, telephone, etc.	-	260,000
Total	3,420,000	2,593,000

I.4 Operations budget by disease and expected result (All sources US\$)*

	New knowledge	New and Improved tools	New and Improved Methods	New and Improved Strategies & Policies	Partnership & Capacity Strengthening	Technical Information	Management	Total
Malaria	3,780,626	8,790,000	5,140,000	3,806,000	5,863,300	180,000	0	27,559,926
Schistosomiasis	331,000	580,000	525,000	500,000	979,500	60,000	0	2,975,500
Filariasis	704,000	576,000	80,000	1,171,875	1,174,700	60,000	0	3,766,575
Onchocerciasis	339,400	1,500,000	0	708,125	515,180	60,000	0	3,122,705
Leishmaniasis	529,000	1,568,100	0	164,000	886,520	160,000	0	3,307,620
African trypanosomiasis	283,200	2,255,850	300,000	0	998,360	60,000	0	3,897,410
Chagas disease	148,000	1,100,000	400,000	400,000	435,500	60,000	0	2,543,500
Leprosy	658,525	200,000	260,000	250,000	945,620	60,000	0	2,374,145
Dengue	732,000	540,000	180,000	0	946,800	160,000	0	2,558,800
Tuberculosis	1,478,578	8,700,000	1,000,000	400,000	2,056,440	180,000	0	13,815,018
Total	8,984,329	25,809,950	7,885,000	7,400,000	14,801,920	1,040,000	0	65,921,199

* Reporting on expenditures by disease will be done as previously, based on information in TDR's project management system, i.e. not from the WHO financial system (AFI).

ANNEX II: DISEASE STRATEGIC EMPHASES

A: New Basic Knowledge	B: New and Improved Tools Intervention Methods	C: New and Improved Strategies and Policies	D: New and Improved Strategies and Policies
<p>African trypanosomiasis</p> <ul style="list-style-type: none"> Applied genomics to identify drug targets Bioinformatics to look for applications and evaluation of genome Pathogenesis and parasite/host interactions Social and behavioural risk factors for epidemics, especially among refugees Biotechnology transfer <p>Dengue</p> <ul style="list-style-type: none"> Molecular tools for Aedes transformation; vectorial resistance to dengue; Aedes population genetics Host-pathogen interactions in dengue Dynamics of virus transmission, and population genetics (including modelling) Social, economic and biological factors related to a) promotion of community-based interventions and b) release of transformed Aedes vectors 	<ul style="list-style-type: none"> New drug development – priority: oral efornithine and evaluation of meglazol and diminazine aceturate New drug discovery Development of field methods for detecting melarsoprol resistance 	<ul style="list-style-type: none"> New treatment regimens for seropositive/parasite negative cases 	
<p>Category 1</p> <p>Leishmaniasis</p> <ul style="list-style-type: none"> Development of methods to measure drug resistance Identification of targets for drugs, vaccines and diagnostics Pathogenesis and host interactions Impact of inequity of access to services and health sector reform Impact of globalization Impact of population displacement 	<ul style="list-style-type: none"> Vaccine R&D, including application of guidelines for trials currently under development 	<ul style="list-style-type: none"> Development of approaches/procedures for community control of breeding sites 	<ul style="list-style-type: none"> Development of strategies for use of insecticide treated materials (ITNs)

Category 2	<p>Malaria</p> <ul style="list-style-type: none"> Anopheles genome sequencing and mosquito population control Functional genomics of malaria parasite Impact of health sector reform Development of methods for assessing resistance 	<ul style="list-style-type: none"> Discovery of new drugs and combinations Development of a vaccine(s) 	<ul style="list-style-type: none"> Development of methods to increase access of children to treatment cases Development of field methods for different drug combination 	<ul style="list-style-type: none"> Development of strategies for ITN use Scaling up of effective home management strategies
	<p>Schistosomiasis</p> <ul style="list-style-type: none"> Genetic research for drugs, vaccines and diagnostics target identification Pathogenesis research Social and economic impact 	<ul style="list-style-type: none"> New drug discovery Evaluation of efficacy of new drug development opportunities from the animal health field Vaccine R & D 	<ul style="list-style-type: none"> Field evaluation of diagnostics Optimization of praziquantel Impact of artemisinins used against malaria Standardization of ultrasound vs S. japonicum 	<ul style="list-style-type: none"> Development of strategies for sustainable control, including improved communication strategies
	<p>Tuberculosis</p> <ul style="list-style-type: none"> Identification of targets for new tools development Impact of health sector reform, globalization and inequality of access 	<ul style="list-style-type: none"> Diagnostic test development: detection of disease, rifampicin resistance, latent infection New drug discovery and development 	<ul style="list-style-type: none"> Establishment of role of 4 fixed drug combinations (4FDCs) and evidence base for registration Development of evidence base for effectiveness of TB preventive therapy in high HIV prevalence areas 	<ul style="list-style-type: none"> Analysis of approaches to use of antiretrovirals in high HIV prevalence for prevention of primary and secondary TB
	<p>Lymphatic filariasis</p> <ul style="list-style-type: none"> Genomic identification of new leads for drugs Progression/reversibility of disease manifestation and burden assessment 	<ul style="list-style-type: none"> New macrofilaricidal drugs or drugs to permanently inhibit microfilariae production Efficacy and safety of albendazole combinations 	<ul style="list-style-type: none"> Field evaluation of diagnostics for Brugia malayi 	<ul style="list-style-type: none"> Improved elimination strategies Improved drug delivery strategies Sustainable strategies for management of lymphoedema
	<p>Leprosy</p> <ul style="list-style-type: none"> Genome utilization for target identification to detect infection Pathogenesis of nerve reactions 	<ul style="list-style-type: none"> Rifampicin susceptibility test development 	<ul style="list-style-type: none"> Development of shorter treatment regimens 	<ul style="list-style-type: none"> Health systems and services research aimed at integration of multidrug therapy (MDT) into general health services
	<p>Chagas disease</p> <ul style="list-style-type: none"> Applied genomics for drug discovery 	<ul style="list-style-type: none"> New drug discovery Drug development for chronic disease 	<ul style="list-style-type: none"> Development of methods for control of non-domiciliated vectors in Andean countries and Central America 	<ul style="list-style-type: none"> Improved strategy for control of non-domiciliated triatomines
Category 3	<p>Onchocerciasis</p> <ul style="list-style-type: none"> Understanding ivermectin resistance mechanisms Identification of targets and leads for new drugs 	<ul style="list-style-type: none"> New macrofilaricidal drugs or drugs to permanently inhibit microfilariae production Diagnostics for surveillance Ivermectin resistance test 		<ul style="list-style-type: none"> Strategies for sustainable drug delivery post Onchocerciasis Control (OCP) / African Programme for Onchocerciasis Control (APOC) Feasibility of onchocerciasis elimination Rapid mapping of Loa loa

ANNEX III.1: RESEARCH CAPABILITY STRENGTHENING STRATEGIC EMPHASES FOR LCD (INPUT-DRIVEN)

A. New basic knowledge	B. New and improved tools	C. New and improved Intervention methods	D. New & improved policies
Overall capacity requirement for infectious disease research in least developed countries			
<p>The generation of new basic knowledge requires strong institutions, scientific autonomy, adequate infrastructure, sustained funding and trained human resources. Research leadership, access to information technology (IT), state-of-the-art-laboratory technologies expertise, including genomics, critical social science, and research collaboration.</p>	<p>Discovery/development of new and improved tools covers a wide range of research capabilities, from good research practices across laboratory-based disciplines, facilities for pre-clinical studies, experimental animal models, and clinical research including clinical trials in DEC with good clinical practices and strengthened ethical review processes.</p>	<p>Development of intervention area requires competence in quantitative and qualitative research methods, including social-economic-behavioural research. Proof-of-principle studies will require expertise in controlled community-based intervention studies and close collaboration with control programmes.</p>	<p>The introduction of research results into policy and practices requires expertise in large-scale intervention, cost-effectiveness analysis, health systems, services and implementation research capabilities. Social science research is critical to sustained implementation of new public health policies. Implementation of new policies requires leadership and good interaction between R&D and control.</p>
TDR Strategic emphases for developing research capacity in least developed countries			
<p>Long-term goal</p> <ul style="list-style-type: none"> • Political support, individual training, infrastructure development. • Development plans for critical mass built on pre-existent programmes. • Collaboration with bilateral agencies. 	<p>Medium-term goal</p> <ul style="list-style-type: none"> • Progressive involvement of DEC in discovery, (pre-)clinical development & manufacturing. • Individual training in basic and applied disciplines, promotion of technology transfer. • Research leadership, ethical review process and managerial capacity. 	<p>Short-medium term goal</p> <ul style="list-style-type: none"> • Focused training on qualitative and quantitative methods and control related disciplines. • Improved control/research interaction and research priority definition. • Development of DEC training capability and inter-institution collaboration. 	<p>Short-term goal</p> <ul style="list-style-type: none"> • Involvement of high burden countries in implementation research and health systems and policy research. • Development of research culture within public health sector.

ANNEX III.2: RESEARCH CAPABILITY STRENGTHENING STRATEGIC EMPHASES FOR TDR's R&D AGENDA (INPUT-DRIVEN)

A. New basic knowledge	B. New and improved tools	C. New and improved intervention methods	D. New & improved policies
<p>Opportunities and advantages in disease endemic countries for R & D infectious diseases</p>			
<p>Technology transfer through N-S and S-S partnership projects. Application of high-tech procedures in clinical research due to disease proximity. Under-exploited intellectual resources. Capacity to develop equitable bioinformatics expertise. Pro-active identification and promotion of research leadership.</p>	<p>S-S networking/multicentric trials to standardize methods and quality data to allow results to be compared directly. Development of reference collaborator centres in DECs. Research and training capacity utilization. Capability to fully engage in late stage of product R&D. Under-exploited laboratory and development skills capacity.</p>	<p>Self-reliance in identifying research needs and evaluating new or improved tools and intervention strategies. Expertise in field studies and scaling up of interventions. Equal partnership/ownership. Interaction with control programmes. Research & training capacity utilization. Potential close interaction between research and control.</p>	<p>Increased involvement of DEC scientists and control personnel/institutions in the evaluation and introduction of research results into policy. Need strong collaboration between research/control. The proximity to diseases and their socio-political context facilitates the development of new strategies and policies.</p>
<p>TDR strategic emphases for R&D driven capacity projects in disease endemic countries</p>			
<ul style="list-style-type: none"> • Within-project training in socioeconomic and behavioural research, molecular biology, entomology, genomics on drugs and vaccines. • Molecular tools in pathogenesis of vector-parasite and host-parasite interactions. • Development of genomics and bioinformatics. 	<ul style="list-style-type: none"> • Technology transfer for development and manufacturing • Partnerships in chemistry/pharmacy & expression formulation (biologicals). • Pre-clinical/clinical studies. • Project-based good practices (GCP, GLP, GMP, ethics). • Engagement in drug, vaccine and diagnostics development. • Training in intellectual property rights(IPR). 	<ul style="list-style-type: none"> • Priority-setting mechanisms, country research agenda. • Involvement in clinical and field evaluation of new drugs, vaccines, diagnostics and intervention methods. • Optimization of new drug regimens. • Team building and focused training of 2nd/3rd generation of scientists. 	<ul style="list-style-type: none"> • Within-project strengthening of public health and social science for developing strategies and policies for large-scale application of available tools. • Capacity to develop innovative integrated intervention approaches. • Implementation research. • Mentorship programme. • Promotion of networks.



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