

TDR

General Operations Guide

2004-2005

Reviewed and endorsed by Director, TDR

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

http: www.who.int/tdr/publications/publications/operations_guide.htm

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LIST OF ABBREVIATIONS

AMS	Activity Management System
APW	Agreement for Performance of Work
DEC	Disease Endemic Countries
DRC	Disease Research Coordinator
FC	Functional Coordinator
FTE	Full time equivalent
G-FTE	General Service Staff - Full time equivalent
GoG	General Operations Guide
G-Staff	General Service Staff
IDE	Intervention Development and Implementation Research
JCB	Joint Coordinating Board
PDT	Product Development Team
P-FTE	Professional Staff - Full time equivalent
PMS	Product Master Sheet
PPM	Programme Planning and Management
PRD	Product Research and Development
P-Staff	Professional Staff
R&D	Research and Development
RCS	Research Capability Strengthening
RCS-Plus	Research and development (R&D)-driven capability strengthening
SC	Steering Committees
SCRIHS	WHO Secretariat Committee on Research Involving Human Subjects
SMTeam	Strategic Management Team
SOP	Standard Operations Procedures
STAC	Scientific and Technical Advisory Committee
STR	Basic and Strategic Research
SWG	Scientific Working Group

TA	Travel Authorization
TDR	UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TIMS	TDR Information Management System
TSA	Technical Service Agreement
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WHO	World Health Organization

FOREWORD

The document at hand, the TDR General Operations Guide (GoG) is an attempt in a general way to describe how TDR operates under the Strategy 2000-2005. The document is not intended to replace or substitute specific Standard Operations Procedures (SOPs), manuals, etc., it is rather to provide a general overview and understanding of 'why' and 'how', thus linking strategy with tactics and operations.

The target audiences of the document are TDR staff, steering committee members, funding partners, and others who need to know about the general operation of the Programme.

The GoG reflects how TDR works as of September 2002. Because the way the programme will operate under the new strategy is significantly different from the past, the process of preparing the guide was deemed as important as the final product itself, and the working draft has therefore gone through a long internal process of dialogue, evolution, and refinement.

1. A predecessor, the 'Operational Planning Guide 2002-03', was first reviewed by the Line Managers in August 2001.
2. The penultimate draft of the above was reviewed by the SMTeam in September 2001.
3. The final Operational Planning Guide 2002-03 was distributed to all staff in September 2001.
4. Draft 1 of the General Operations Guide 2002-03 was first reviewed by SMTeam in November 2001.
5. Draft 2 was distributed to all staff for comments on 20 November 2001.
6. Draft 2 was presented to Standing Committee on 27 November 2001 to confirm direction and report on progress in operationalising the strategy.
7. Key elements of the guide were discussed during the P-Staff retreat in January 2002 to facilitate internalisation and further refinement.
8. The penultimate draft GoG was then distributed to all staff in March 2002 for comments.
9. The penultimate draft GoG went through a final review by the SMTeam in May 2002.
10. A small working group was established to finalize section 3.3 on steering committees and the final version of this section was circulated to all SMTeam members for final input in July 2002.
11. The content of section 7.4 on evaluation was reviewed and further developed in a special session of the SMTeam in July 2002, a final draft version will be reviewed electronically by the SMTeam members in November and December 2002 and included in Revision 2.
12. The final guide (Revision 1) was reviewed by Director, TDR, and printed and available for use in September 2002.
13. Two minor revisions, i.e., Rev.2 and Rev.3 were made in 2003.

14. Based on nearly two years of application, a further revision was made in June of 2004, involving the Linemanagers and the SMTeam. The main revisions were in respect the outlined authorities and responsibilities of sections 4.2 “The Product Portfolio Database” and an inclusion of section 7.4.1 “Strategic Output and Performance Indicators” with its associated Annex VII.
15. The resulting Guide (Revision 4) was reviewed by Director, TDR, and printed and available for use prior to JCB(27) in June of 2004
16. The General Operations Guide will regularly be updated and revised as part of the Programmes efforts for continuous improvement of efficiency of operation.

Erik Blas
Programme Manager, TDR
Geneva June,

1. INTRODUCTION

With the Strategy 2000 – 2005, the way in which TDR operates has changed significantly. The 2002 – 2003 biennium was the first biennium where this change was fully obvious and felt in all aspects of the Programme's operations. The Programme Budget 2002-2003, which was approved by JCB(24) embodied this change in that it was output, rather than input-based as was the case earlier; and in that a very large proportion of the income originated from designated contributions compared to the primarily undesignated nature of contributions before 1998-99. The 2002-2003 biennium was also the first biennium to report according to the strategic output and performance indicators, which were approved by JCB(26) in June of 2003.

Key operational features of the Strategy:

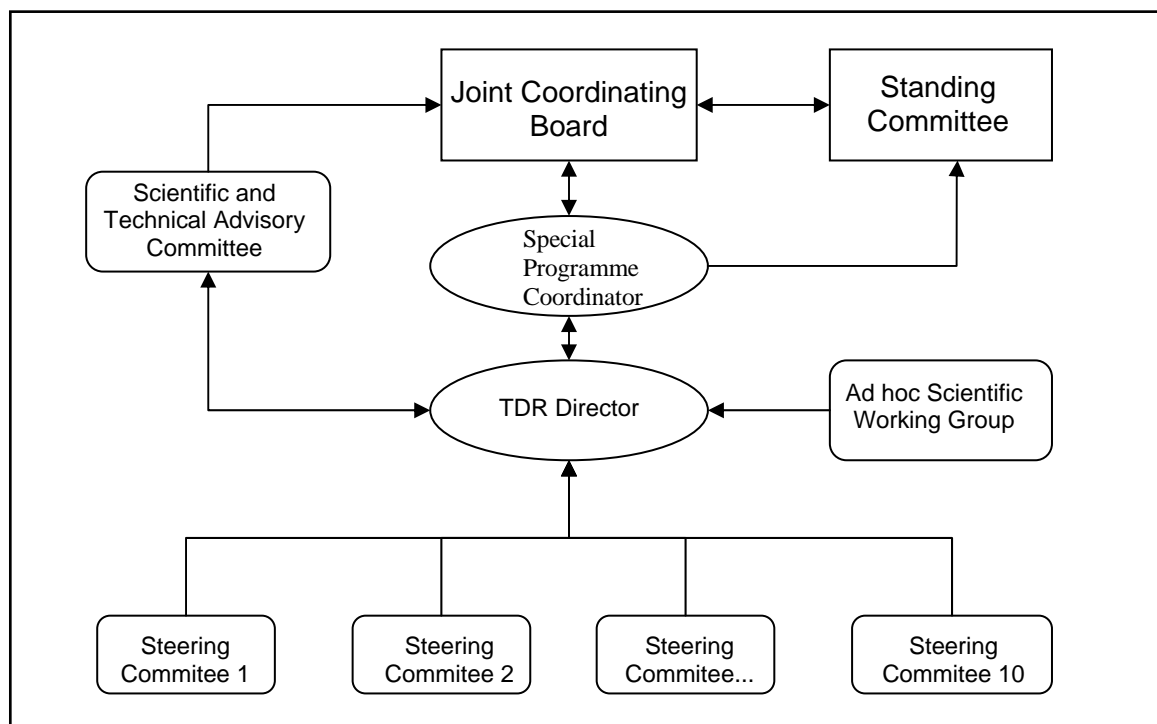
- The Strategy identifies the driving force of TDR to be its operational capabilities, i.e., the ability to receive and disburse funds, while applying efficient leadership, project and knowledge management to developing solutions to public health problems caused by TDR target diseases and affecting poor and marginalized populations.
- TDR has three levels of management, i.e., (1) Strategic Management Team (SMTeam), chaired by Director, TDR, and symbolised in the Strategy by a triangle, its sides consisting of the Functional Coordinators (FC), the Disease Research Coordinators (DRC) and the Programme Manager. The strategic management is concerned with managing the overall product portfolio of TDR. (2) Line Management consisting of functional coordinators, the overall disease research coordinator, the Programme Manager and the Director. The line management is concerned with the management of resources, including money, personnel and time. (3) product management concerned with the actual R&D processes.
- TDR's budget and plans are prepared and monitored in a matrix format with the seven Expected Results and ten Target Diseases being the two dimensions of the matrix.

2. TDR'S GOVERNANCE AND ADVISORY STRUCTURE

TDR is a special programme co-sponsored by UNICEF, UNDP, World Bank, and WHO. TDR's highest authority is the Joint Co-ordinating Board (JCB) which is composed of 12 governments representatives selected by the resource contributors, 12 government representatives selected by the WHO regional committees, three members designated by the JCB itself from among the remaining cooperating parties, and the four co-sponsoring agencies. The for co-sponsoring agencies constitute the Standing Committee, which carries oversight of TDR between the meeting of the JCB. JCB(25) decided that for future meetings of the Standing Committee both the chair and the vice chair of the JCB will participate. WHO is the executing agency and appoints the Special Programme Coordinator and the TDR Director.

The Director and the JCB are advised by the Scientific and Technical Advisory Committee (STAC) which is composed of 15 to 18 scientists selected by the executing agency and endorsed by the JCB. The STAC provides a continuous independent evaluation of the scientific and technical aspects of all activities of the Special Programme (for further details, please see TDR basic documents TDR/GEN/01.3)

Figure 1: Linkages between TDR's governing and advisory bodies



Director, TDR, is further advised by a number of Steering Committees covering the different aspects of the Programme's work (for a full list of Steering Committees, see Annex I). These Steering Committees review the specific work plans in, e.g., vaccines, implementation research, capacity building, etc., as well as R&D proposals for funding and make recommendations to the Director. The Steering Committees may also recommend establishment of Product Development Teams (PDT) to implement defined time-limited tasks and with distinct budgets, see section 3.3.

The Director may further decide to establish ad hoc Scientific Working Groups (SWG) to address specific scientific issues. Currently, two SWGs are foreseen per year to review the R&D needs and opportunities for the TDR target diseases, thus covering all ten target diseases in five years.

3. ORGANIZATION OF WORK

TDR's scientific work is organized in a matrix structure with Expected Results (Box 1) and Diseases as the two dimensions, as illustrated below in Figure 2.

Figure 2: TDR disease-function matrix

		Functional Coordinators					
		R&D Products				Knowledge Management Products	
		Expected Result A	Expected Result B	Expected Result C	Expected Result D	Expected Result E	Expected Result F
Disease Research Coordinators	African Trypanosomiasis						
	Chagas Disease						
	Dengue						
	Leishmaniasis						
	Leprosy						
	Lymphatic Filariasis						
	Malaria						
	Onchocerciasis						
	Schistosomiasis						
	Tuberculosis						
	Other diseases, e.g., STD, HIV/AIDS, etc.						

3.1 RESULTS-BASED PLANNING AND BUDGETING

As a consequence of shifting from input to results based planning and budgeting, resources are now allocated by Expected Results and Diseases. This means that no organizational unit or person *a priori* are allocated any resources. Through the prioritization process described in this section and section 4, a product portfolio for the entire Programme is established and the responsibility for implementation of the R&D products is then assigned to appropriate steering committees and individual product managers together with the resources. The results based planning and budgeting means that the use of resources (input) is justified by the result (output) it produces, rather than by right or custom. Results based budgeting also means that the *total cost* of producing a product should be taken into account, i.e., the 'true' cost should be established, including *direct costs*, such as research contracts, direct staff time, travel, etc. as well as the *indirect costs*, such as cost of steering committees, office rental, service charges, administration, etc.

Box 1. Expected Result¹	
A.	<i>New basic knowledge</i> about the biological, social, economic, health systems, and behavioural determinants, and other factors of importance for effective control of infectious diseases generated and accessible at national and international levels.
B.	<i>New and improved tools</i> for use in infectious disease prevention and control, e.g., drugs, vaccines, diagnostics, epidemiological tools, environmental tools, etc. developed.
C.	<i>New and improved intervention methods</i> for applying existing and new tools at the clinical and community levels developed and validated.
D.	<i>New and improved strategies and policies</i> for large-scale implementation of existing and new prevention and control methods developed, validated and guidance required for application in national control settings accessible.
E.	Partnerships established, and adequate support for research and product development capacity building in countries provided.
F.	Adequate technical information, research guidelines and instruments, and advice accessible to partners and clients in countries.
G.	<i>Resources</i> for research, product development, and capacity building efficiently <i>mobilized and managed</i> .

3.2 FUNCTIONS AND RESPONSIBILITIES

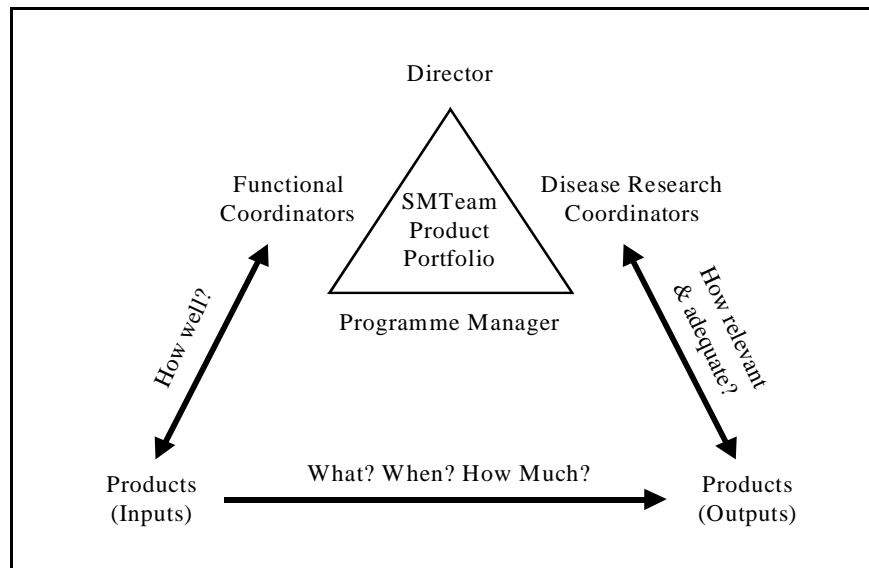
Following the adoption of the Strategy 2000-2005, functions and responsibilities have been redefined for several staff. As a consequence of the matrix structure of the budget and the results orientation, the Programme has developed a strategic and project-mode, or in TDR terminology² product-mode of operation. A schematic representation of the mode of operation is given in Figure 3.

3.2.1 STRATEGIC MANAGEMENT TEAM (SMTEAM)

The prime responsibility of the SMTeam is to manage the overall strategy of TDR's product portfolio, including matching the needs for new products for control and the opportunities of science, i.e., the push and the pull with the resources available. The SMTeam takes decisions on inclusion or exclusion of products from the portfolio and operates in a formal way. Participation is obligatory for the members. There are set agendas, analyses and proposals for decision must be distributed to the members one week in advance of the meeting where a topic is scheduled. Decision notes are prepared and communicated to all staff immediately following the meeting.

¹ For more details, please see Strategy 2000-2005 and Disease Strategic Emphasis Matrix. NB! The text for Expected Result D has been modified slightly as compared to the text in the strategy for purpose of clarity.

² TDR has adopted the term 'product' rather than 'project' for several reasons: (1) to avoid confusion with the individual projects funded for specific pieces of research and captured in TDRs Information Management System (TIMS), (2) to be intuitively close to the terminology used in the WHO Activities Management System (AMS). The notion or concept of what constitutes a product varies across the fields and disciplines of research that TDR is involved in. The decision to use 'product' for both the process and the output, therefore is a compromise.

Figure 3: Functioning of the Strategic Management Team (SMTeam)

3.2.2 FUNCTIONAL COORDINATORS

There are five functional coordinators, i.e., Basic and Strategic Research (STR), Product Research and Development (PRD), Intervention Development and Implementation Research (IDE), Research Capability Strengthening (RCS), and the Multilateral initiative for Malaria Research in Africa (MIM). The Functional Coordinators have formal line managerial responsibilities vis-à-vis the Steering Committee and Product Managers and the Products. Functional Coordinators are concerned with managing the inputs to the production processes, i.e., ‘how well’ the R&D processes are commencing, ensuring that activities are scientifically and ethically sound, that resources [in a broad sense] are applied in the most efficient and effective way, that timelines are kept, that the planned outputs are achieved, and that the human resource is continuously developed. Functional Coordinators are also collectively and individually responsible for mobilizing resources to increase the overall funding and to meet funding gaps in the portfolio.

3.2.3 DISEASE RESEARCH COORDINATORS

There are in principle ten Disease Research Coordinators (DRCs), i.e., one for each of the TDR target diseases. However, in practice some DRCs may cover more than one disease (See Annex I). Disease research coordination is a part-time staff-function, i.e., the DRCs do not exercise line management responsibilities. The DRCs are responsible for establishing the disease strategic frame work for TDR’s priority-setting, through continuous analysis of the disease, the medium and long-term control needs, and scientific opportunities. The DRCs also monitor the implementation of the research strategy for their disease, and discuss research outcomes with disease control. The DRCs are concerned with defining desired outputs and monitoring that the actual outputs are relevant and respond adequately to the needs. To undertake those tasks, they must stay in close contact with both the disease control and the scientific communities. The DRCs are supported in their work by the Disease Research Strategy Manager who is responsible for general coordination of TDR’s disease strategic planning activities and related interaction with disease control.

Figure 4: Disease Research Coordinators are hubs in wide networks of international disease expertise

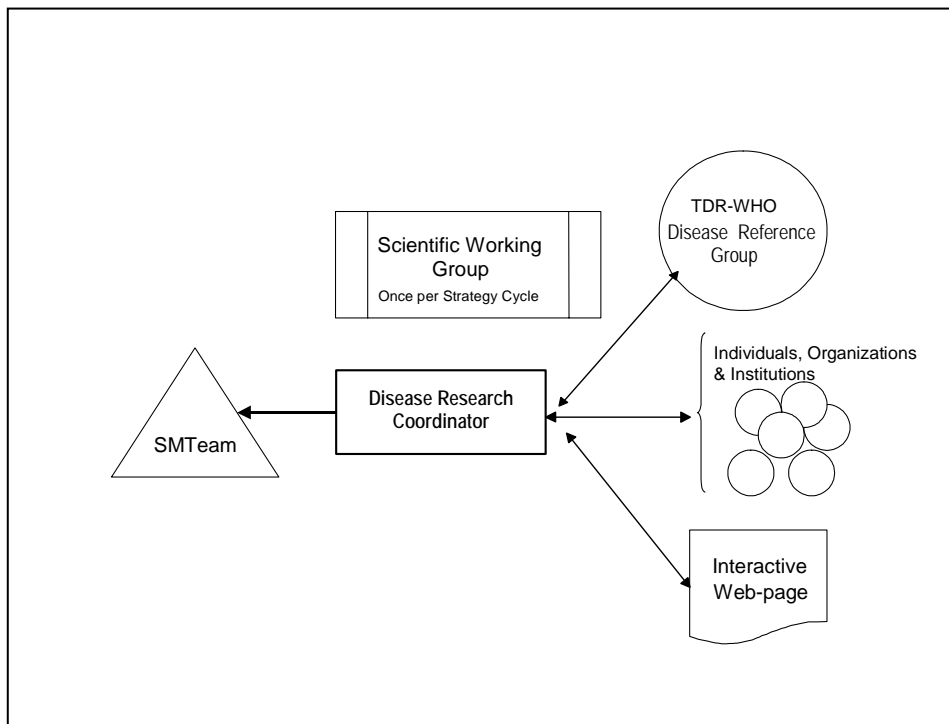


Figure 4 above depicts some of the major mechanisms that the DRCs have at hand to aid their analysis. Once in the strategic planning cycle (six years) each DRC organizes a major international review [Scientific Working Group], of the disease to set global priorities from which TDR, based on its comparative advantage, selects its strategic emphases for that particular disease. In between the Scientific Working Groups, the DRCs work closely with WHO colleagues in TDR-WHO Disease Reference Groups, which may have been particularly established for the purpose or form part of existing collaboration between research and control. In addition, the DRCs must maintain links with a broad range of individuals relevant to the disease through direct contact or through the interactive web page that the DRCs will maintain for each of the TDR target diseases.

3.2.4 PROGRAMME MANAGER

The Programme Manager co-manages with and supports the Programme Director in the strategic management of TDR. Key to implementing the strategy is the matrix structure, the mechanisms for priority setting and operation of the various organizational entities and bodies, such as SMTeam, Standing Committee, and the JCB. The Programme Manager is also responsible for day-to-day support of the disease research coordination function through the Disease Research Strategy Coordinator and for ensuring efficient implementation of the decisions by the SMTeam.

The Programme Manager, by delegation of Director, is responsible for the day-to-day management of the programme ensuring: adherence to established budgets and plans; smooth administration; and continuous development and improvement of processes, administrative and managerial tools and procedures. The Programme Manager is also responsible for coordinating TDR communications, advocacy, and fundraising as well as for the general staff management and development of the Programme.

3.2.5 PROGRAMME DIRECTOR

The Programme Director is the principal member of the SMTeam holding the authority of the Programme. The Director consults with the members of the SMTeam and the Line Managers as appropriate to take the final decision. The Programme Director's main concern is with the strategic management and direction of the Programme, including: partnership and network building; advocacy and resource mobilization; the relationship with the executing agency (WHO), the other co-sponsors (World Bank, UNDP, and UNICEF), as well as with other JCB members and financial contributors to TDR.

3.3 SCIENTIFIC REVIEW AND OVERSIGHT

As indicated in figure 1, the Director, TDR, is advised by a number of committees, including the Scientific and Technical Advisory Committee (STAC) and a series of steering committees. All these committees provide external scientific and technical input and review to the programme

3.3.1 STEERING COMMITTEES

The scientific backbone of TDR is peer review processes exercised through a number of Steering Committees (SC), covering TDR's major areas of work, see Annex I.

The Steering Committees are characterized by:

- Members are all external to and independent of TDR.
- They must declare their interests.
- The Director, TDR, appoints members.
- The lifetime of a SC is determined by overall TDR strategic and organizational concerns, i.e., not related to the life cycle of specific products.
- Steering Committees have the following general terms of reference:
- To develop scientific workplans based on the products of TDR's Product Portfolio, assigned to the Steering Committee.
- To review the relevance, scientific quality, budgets and disbursement plans for all research projects related to Products in its portfolio and make recommendations on funding to the Director, TDR.
- To technically and scientifically monitor progress of all its research activities.
- To annually evaluate progress of each Product and project and make recommendations for continuation, revision or termination.
- To prepare biennial progress reports for the Products in the portfolio.
- To identify and advise on new scientific opportunities.
- To develop specific work plans and budgets for the Products within its portfolio based on TDR's strategic emphasis matrix and in line with the values, goals, and objectives of the Programme.
- To identify scientists and institutions through open or invited calls for applications to carry out research and development projects for Products within its portfolio.

- To identify and develop opportunities for involvement of DEC scientists and develop relevant research training activities in coordination with other Steering Committees as appropriate.

Steering Committees may delegate management of specific products to Product Development Teams (PDT), see 3.3.2 below.

Each Steering Committee is managed by a Steering Committee Manager supported by a designated technical assistant. These staff support all the functions of the Steering Committee and have specific responsibility for:

- Process management, including preparations, documentation, and follow up to meetings of the Committee.
- Preparation of project documentation that is required for ethical clearance (SCRIHS-review) and follow up on SCRIHS recommendation.
- Project portfolio management in both scientific, financial, and administrative terms, including opening and closing of projects in TDR's Information Management System (TIMS), reporting on the milestones set for each product in the portfolio, meeting process benchmarks, etc. to ensure efficiency in operation
- Implementation of special initiatives as recommended by the Steering Committee.
- Facilitating *a posteriori* and value for money evaluations of products developed under the auspices of the committee.
- Ensuring coordination, collaboration, and sharing of information with relevant committees and staff within TDR.

3.3.2 PRODUCT DEVELOPMENT TEAMS

Some Products require intensive involvement of a range of external expertise for its development. For these Products, Product Development Teams (PDTs) may be established with the following general characteristics:

- PDTs are concerned with the development of specific products.
- PDTs are time-limited, i.e., the lifetime of a PDT is limited to the product development cycle of the specific product, i.e., not exceeding the 'success date'.
- PDTs have two types of members, i.e.,
 - three members, who are external to TDR and independent, i.e., they are not paid by TDR and neither they nor their host institution are financial beneficiaries of decisions taken/recommendations made by the PDT. Only these members take decisions that have financial implications. These members may or may not also be members of the overseeing Steering Committee and one of them will be the chairperson for the PDT.
 - A number of members who are directly involved with the implementation of the product, e.g., principal investigators of projects associated with and funded under the Product.
- PDT members are appointed by the Director, TDR

PDTs have the following general terms of reference:

- To prepare a detailed development work plan and budget for the Product in question which would efficiently use resources and would be in synchrony with the Product specifications in the Product

Portfolio Database. It would adhere to the General Operations Guide and be in line with the values, goals and objectives of TDR.

- To identify scientists and institutions through open or invited calls for applications to carry out research and development projects for the Product.
- To identify and develop opportunities for involvement of DEC scientists and develop relevant research training activities in coordination with other activities of TDR.
- To review the relevance, scientific quality, budgets and disbursement plans for all research projects related to the Product and make recommendations on funding to Director, TDR.
- To financially, technically and scientifically monitor progress of all its research activities.
- To annually evaluate progress of each individual project as well as for the Product as a whole and make recommendations for continuation, revision or termination.
- To prepare annual progress reports for the Products to the relevant Steering Committee(s).
- To identify and advise on new scientific opportunities.

Box 2

The R&D-driven capacity building initiatives (RCS Plus) are managed by an Initiative Team following the same general terms of reference of a PDT. The external members and TDR staff involved should represent both the RCS area and the corresponding R&D committee. The appointment will be made by the Director, TDR. RCS-Plus products are planned and budgeted simultaneously in Expected Result Area E, the capacity building component, as well in the corresponding R&D Expected Result Areas A to D.

Steering committees may decide to create *ad hoc* working groups to deal with a specific issue or to follow the development of a particular product. Such working groups may consist of members from the steering committee as well as external experts, including principal investigators, etc. Such working groups will differ from the more formal Product Development Teams in that they will not take decisions on funding of projects – but leave this to the parent steering committee.

Each PDT is managed by a Product Manager, who may be any TDR staff member, e.g., a Steering Committee Manager, a long-term staff covering several Products or functions, or a short-term staff recruited for development of one, two, or more specific Products. The responsibilities of a Product Manager include:

- Day-to-day management of the development process which includes: technical aspects, timelines [milestones], finances, communication with the PDT and relevant TDR staff, etc.
- Process management which includes: preparations, documentation, and follow up to meetings of the PDT.
- Timely reporting to the responsible Steering Committee *cum* Steering Committee Manager, any technical and financial issues of importance, whether routine or *ad hoc*.
- Obtaining external independent evaluations if necessary, e.g., in cases when a member of the PDT is a candidate for work to be commissioned by the PDT.

3.3.3 SCIENTIFIC AND TECHNICAL ADVISORY COMMITTEE

The Scientific and Technical Advisory Committee (STAC) is part of the overall governance structure of TDR and is defined in the Memorandum of Understanding of the Programme (see TDR Basic Documents TDR/GEN/01.3). The members of the STAC are nominated by Director, TDR and appointed by the JCB. STAC members are external to and independent of TDR. That is, they are not members of any TDR Steering Committee, nor are they recipients of grants from TDR.

The functions of STAC include:

- Providing *strategic advice* on scientific and technical issues related to the goals and objectives of the programme to Director, TDR and the JCB
- Overseeing, at a *strategic level* the entire product portfolio of TDR, including the strategic emphasis and priority-setting of the Programme and the work of the individual Steering Committees.
- Monitoring the technical achievements of the Programme, including using the strategic output and performance indicators and the pipeline indicators, as well as other means.

The responsible officer for the STAC is the Programme Director, supported by the Programme Manager and the Disease Research Strategy Manager.

4. THE TDR PLANNING PROCESS

4.1 STRATEGIC FRAME WORK FOR THE PRODUCT PORTFOLIO

TDR's product portfolio is developed and maintained within a strategic framework composed of two elements: the disease strategy and the research capacity strengthening strategy.

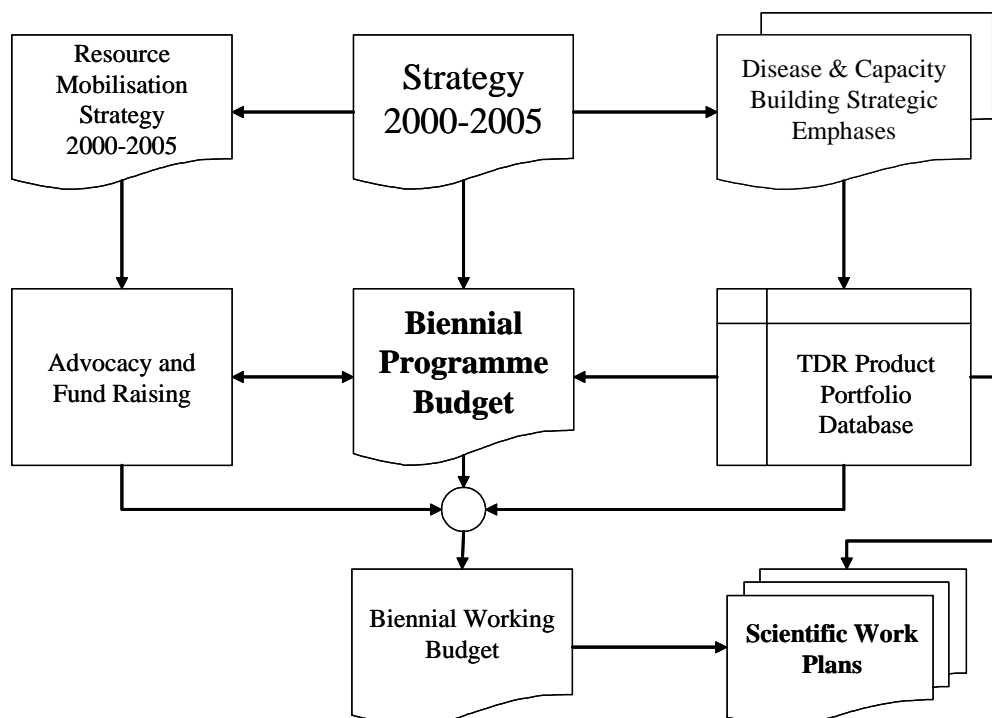
4.1.1 DISEASE STRATEGIC EMPHASES

Through the work of the DRCs, strategies are set for each of the target diseases with respect to the goals and objectives for each of the expected results as defined in the Strategy 2000-2005. The disease strategies are expressed in the Disease Strategic Emphases Matrix, which is attached to and approved by the JCB in the Programme Budget. The Matrix is updated annually, reviewed by the SMTeam and STAC, and forms the basis for inclusion and exclusion of products.

4.1.2 RESEARCH CAPACITY STRATEGIC EMPHASES

The strategic approach to attaining TDR's capacity building goal and objective is captured in two Research Capacity Strategic Emphases matrices, one for each of the major directions of the Programme's research capacity building efforts. These matrices are attached to the programme budget and approved by the JCB. They are further updated once per year, reviewed by the SMTeam and STAC.

Figure 5: Overview of TDR's work planning process



4.2 THE PRODUCT PORTFOLIO DATABASE

The Product Master Sheet (PMS) is the key planning instrument for the output-based approach to planning and budgeting and provides the core of the TDR product portfolio database. The idea of the PMS is to clearly up-front define and link all activities to the strategic emphases of the programme and to limit duplication of information and of work by 're-using' the same information for planning, monitoring, donor reporting, scientific communication, and by maintaining the information across biennia. For further details of the PMS, see Annex II.

TDR will continue to use the AMS as its main financial management tool and all staff are encouraged to take the basic training courses that will allow them to do simple financial queries using this tool.

Communication with the TDR product portfolio database will be established so that products and budget ceilings can be programmed into the AMS. The Product Portfolio Database will be the repository³ of information which needs to be carried across from one biennium to another.

- In a given biennium, products will not be actioned before both the PMS has been satisfactorily completed *and* resources are available, i.e., if either is missing, implementation cannot start.
- The Functional Coordinators are responsible for the process within their units, including appropriate information, delegation, instruction, and timely submission of a completed PMS.
- Content and relevant quality assurance will be done by FC and DRC, who will collectively sign-off the PMS.
- A PMS is not complete unless it is accepted by PPM and signed off by both FC and DRC.

4.2.1 NEW PRODUCTS

New products may be formulated and included in the product portfolio during the biennium. These new products must be within the frame of the either or both the disease or capacity building strategic emphases (see above). Prior to presentation, a full PMS for the product must be presented to and cleared by the Programme Manager (see Annex II).

Process

1. Any TDR staff member can propose a new product(s) to be added to the TDR portfolio but they need to be sponsored by one or more member(s) of the SMTeam (Product sponsor). Where appropriate the chair of the relevant Steering Committee is consulted.
2. PPM will review the proposed product with respect to the standard format and TDR guidelines (*Annex II*).
3. Final version of the proposed product is submitted for presentation to the SMTeam (10 days before the meeting) by PPM together with the financial implications.
4. The sponsoring SMTeam member(s) present at the SMTeam meeting.
5. SMTeam will review the product with respect to TDR strategy including disease strategic emphasis, etc.

If/when approved by the SMTeam PPM will update the product portfolio database

³ The AMS is a biennial tool and cannot carry forward any historical information, which will have to be 're-entered' each biennium. As most of TDR's products are multi-year, it has been necessary to establish the separate Product Portfolio Database.

Before a new product can be actioned, funding must be secured, pledged in writing and verified by the Programme Manager. In exceptional cases a Product may receive preliminary approval by Director TDR subject to it being fully funded and subsequent submission to the SMTeam.

4.2.2 MODIFICATION TO EXISTING PRODUCTS IN THE PORTFOLIO

Changes made to individual products in the portfolio are either for tactical [operational] or strategic purposes. Tactical changes are either dealt with in consultation between relevant Line Manager and Programme Manager, or by the Line Managers Meeting if it has implication for more than one organizational unit of TDR (see table 1).

Strategic changes are presented to and approved by the SMTeam.

Process

1. FC will contact PPM to suggest changes to portfolio at least two weeks prior to the Line Manager- or SMTeam meeting in which the change may eventually have to be presented for approval.
2. For modifications requiring approval by Linemanagers or SMTeam meetings, PPM will prepare a change report and depending on the nature of the change (see Table 1), the proposed change will be presented and approved by relevant body.
3. PPM will update the changes to portfolio and inform the Functional and Disease Research Coordinators as well as other relevant staff about the changes made.
4. PPM will adjust the AMS and TIMS as required.
5. PPM will update the web module.

4.2.3 TERMINATION/DISCONTINUATION OF PRODUCTS

Products may be terminated or discontinued at any time during the biennium, e.g., for any of the following reasons:

- Lack of scientific feasibility, e.g., a drug has proven toxic, or non-efficacious.
- The product is no longer relevant to control.
- Lack of funds.
- New opportunities and/or overriding priorities have emerged.

Process

1. Any TDR staff member can propose the termination of any product in the TDR portfolio but the proposal for termination needs to be sponsored by at least one member of the SMTeam who will present it to the meeting.
2. The SMTeam member submits a termination proposal to PPM stating the reasons for the request (10 days prior to the meeting).
3. PPM includes the proposal in the documentation for the SMTeam meeting.

Table 1: Authorities for making strategic and tactic changes to the Product Portfolio Database

Item (database fields) See annex II	Individual Functional Coordinator with Programme Manager	Line Managers Meeting	SMTeam Meeting
Index	x		
Short Title:	x		
Descriptive Title:			x
Product Manager:	x	(x) ⁴	
Expected Result		x	
Strategic indicator	x		
Responsible Functional Team		x	
Disease Proportion of budget			x
Funding Status	x		
Responsible Steering Committee:		x	
Control Need			x
R&D Product/ Process	x		
Operations budget	x		
Operations Support budget	x		
Approved FTE-P	x		
Approved FTE-G	x		
Impact on & Links with Capacity building		x	
Partners	x		
Success Criteria:			x
Success date			x
Milestones			
• Description	x		
• Achievement date	x		
• Percentage Achieved	x		
• Comments	x		
Critical Resource	x		
Brief Narrative:	x		
Year Product Started in TDR:	x		
Names Of TDR Staff Involved	x		
Name of Lead researchers involved	x		
Critical decisions taken	x		
Crises and how they were overcome	x		
The next phase? TDR Potential role			x
Cost in next phase			x
Risks and assumptions			x

⁴ If the change involves shift to staff under different supervision

4. SMTeam reviews and makes a decision.
5. PPM take the necessary action to terminate the product in collaboration with the relevant Functional Coordinator, including the resources and background information sections of the PMS (see annex II, sections 3 and 4)

Resources that are freed up by a termination will be re-deployed within the strategic emphasis (see Annex IV).

4.2.4 CLOSING OF SUCCESSFUL PRODUCTS

Once a product has been successfully completed, i.e., the success criteria have been met, a formal closing of the product should be undertaken. This will include review and update of the PMS, sections 3 and 4 with respect to costs and partners involved, whether the results were as expected, and lessons to be learned, etc. Appropriate documentation for the corresponding indicator will be assembled (see 7.4.1). The Product Manager will prepare a report to be submitted to the SMTeam by the relevant Functional Coordinator. The SMTeam or Programme Director may decide to undertake an *a posteriori* or a value for money evaluation of the product, see section 7.4.2.

4.3 PROGRAMME BUDGET

The Programme operates under biennial budgets. These budgets are prepared on the basis of an anticipated income and in response to the strategic emphases. The Programme Budget presents the resource frame for the biennium and is presented to the JCB at its session prior to commencement of the biennium. Key to the Programme Budget is the relative budget distribution between diseases, expected results areas, as well as between budget elements (operations, operational support, personnel). During the biennium, the Programme Budget may be revised as outlined in Annex IV.

4.4 WORKING BUDGET

The Working Budget is the financial tool used by programme management to steer the finances during the course of implementing the Programme Budget. The Working Budget sets ad hoc budget ceilings based on availability of funds. For Products financed from undesignated funds, the working budget ceiling is normally set as a flat percentage of the total Approved Programme Budget - this percentage is then adjusted as the biennium progresses and certainty increases about actual undesignated income. For Products to be funded from designated sources, ceilings are set according to actual availability of funds.

The Working Budget takes precedence over any other budget, including the Approved Programme Budget and the budgets associated with each Product in the Product Database. The Working Budget ceilings are set by the Programme Manager, in consultation with the Programme Director.

4.5 SCIENTIFIC WORK PLANS

Based on availability of the Working Budget, the Steering Committees will develop detailed workplans for the Committee's work and for each of the products in its portfolio. As the funding situation is rarely definite, this will often involve contingency planning. The Scientific Work Plans are the basis for the calls for proposals from researchers and are normally posted on TDR's web-site.

5. OPERATIONAL CAPABILITIES DRIVING FORCE AND OUTPUT- BASED BUDGETING

The relative distribution at the overall Programme level between the three budget elements: operations, personnel services, and operational support, and of 70-20-10 reflects TDR's operational capabilities driving force, i.e., the strive for efficiency in scientific and administrative management of research resources and assurance that, overall, the maximum possible goes to funding of research partners in countries. The distribution between these budget elements is one of the key indicators monitored by the JCB. The Standing Committee, STAC and JCB reconfirmed in 2001 that the Programme should comply with this split between the budget elements.

The introduction of results based planning and budgeting, as well as the increased proportion of the Programmes income which comes from designated resources, has necessitated introduction of some new cost concepts and principles. In results based planning and budgeting, it is important to get as close as possible to knowing the true cost of an output (product). The bulk of the true or *total cost* of a product is constituted by the *direct costs*, which are directly associated with the production process, i.e., research contracts and meetings (operations), duty travel and consultants (operational support), and time and cost of staff directly involved in the production process (personnel). However, the direct costs do not constitute all the costs associated with the production, there are also a number of *indirect costs*. Indirect costs cover functions which are necessary for the delivery of the product, but which are difficult to directly associate with each product. Examples of indirect costs are part of the functional coordinators' and their secretaries' salaries, as well as some of their operational support activities. Other examples of indirect costs are capacity costs at the Programme level, including TDR management and service costs, WHO administrative and legal costs, cost of overall scientific processes, such as disease review and Steering Committees, etc. Table 2 shows the products that are considered as indirect costs.

Table 2: Products regarded as indirect costs

Product Index	Short title
A-E.00.00	Review
F.13.03	Publication of guidelines, manuals and educational materials
F.13.04	Publication and dissemination of scientific and technical information
F.13.05	Scientific and technical Information - Disease coordination
F.13.06	Scientific Steering Committees
G.13.01	Advocacy and resource mobilization (including Programme Report)
G.13.02	<i>A posteriori</i> and value for money evaluations
G.13.03	Electronic/Web based protocol for enhancing grant processing
G.13.04	Fourth External Review
G.13.05	Joint Coordinating Board
G.13.06	STAC
G.13.07	Staff Development
G.13.08	Standing Committee
G.13.09	Administrative Support (TDR)
G.13.10	TDR General Management
G.13.11	TDR Information Technology Support
	Administrative and corporate support (WHO)
	Office rental

This approach means that the total budget for all products on average and regardless of their source of funding will consist of a direct cost element (88%) and an indirect cost element (12%). These concepts and principles are applied to all products, regardless of the origin of their source of funding, whether undesignated, designated, or mixed. For an example of costing a product, see Annex V.

5.1 DIRECT COSTS

Because the overall budget element distribution of 70-20-10 between Operations, Personnel, and Operational Support applies to the overall Programme level, and because the indirect costs mentioned above mainly are composed of Personnel and Operational Support Costs, translating the distribution to the individual product level [expected results A to E⁵] leads to the following guide for average Personnel and Operational Support costs:

- Personnel
 - 1 P-FTE⁶ or less per \$2,200,000 operations budget
 - 1 G-FTE⁷ or less per \$2,700,000 operations budget
- Operational Support
 - Must be less than 4% of the operations budget

It is the responsibility of the Functional Coordinator to ensure that the above guide is applied for the development of product budgets. This is so that overall conformity can be ensured for the combined products of the Steering Committees within their functional area, i.e., the cost ratios can vary between products of the same steering committee as long as the overall ratios for that steering committee complies with the above.

Individual staff who are negotiating with potential donors, need to take this into consideration. Exceptions to this policy will not be accepted unless PPM has been involved directly in the early stages of negotiation and authorized by Programme Director. See also Annex IV on procedures for budget revision as well as section 4 of this document.

5.1.1 OPERATIONS

Operations covers contracted services, participation in R&D workshops, training, etc.. Scientific/technical meetings that are part of the research development processes can be covered under Operations. However, there are different AMS codes for meetings and other research costs to enable monitoring of the relative distribution between the two. The operations will be captured in the TDR Information Management System (TIMS) and monitored in terms of 'disease' and 'geographical' distribution of expenditures, which must reflect the disease budget targets as well as the basic values of TDR [contractual instruments include Technical Services Agreements (TSA), Agreements for Performance of Work (APW), Exchange of letters, Travel Authorizations (TAs) for temporary advisors and participants, other than mentioned above].

The first level monitoring of the above is the Functional Coordinators' responsibility, while the day-to-day management of the budget for each Product is delegated to the responsible Product Manager.

⁵ For details of Expected Results, please see section 3.1 or the Strategy 2000-2005, page 16

⁶ ⁷ P-FTE and G-FTE are professional and general service staff full-time-equivalents respectively

5.1.2 PERSONNEL SERVICES

This includes all personnel costs related to:

- All individuals who work from the premises of TDR regardless of how they are recruited, i.e., which type of contract TDR has with them.
- All individuals who are contracted as fixed- or short-term staff, or as consultants (more than three months), regardless of from where they perform the contracted duties. Trainees are part of capacity building and could be financed from a capacity building product (Operations).

The overall FTE-ceiling for each product is given in the product portfolio. The P & G FTE's of all the [funded] products belonging to Steering Committees are added up and multiplied with the budget unit-cost to establish a personnel budget for each steering committee.

It is the responsibility of the respective Functional Coordinator to manage this 'pooled' personnel budget, ensuring that:

- ***the budget ceiling for personnel is not exceeded, while adhering to all commitments to short- and fixed-term staff, and***
- ***that all the [funded] products contributing to the pool are implemented.***

5.1.3 OPERATIONAL SUPPORT

The product specific operational support budgets are held by the product manager responsible for delivering each product. The planned costs are defined in the Product Master Sheet for each product to include

1. Duty travel of personnel as defined above.
2. Consultants employed for less than three months. [Note that consultants employed for over three month are considered personnel].
3. Supplies and equipment, e.g., books, etc.

It is the responsibility of the respective Functional Coordinator to oversee that operational support budget ceilings are adhered to for the totality of products within their areas of work, Products assigned to their steering committees. The day-to-day management of budget is delegated to the respective Product Managers.

5.2 INDIRECT COSTS

The indirect costs may, when expressed in dollars terms seem large, but relative to the total budget and in comparison with other similar operations, they are very modest. Programme management is continuously striving to keep these costs low, while ensuring the best possible service level.

The budgets and expenditures for these products are fully transparent to staff and can be found on the internal TDR shared drive. For the biennium 2004-2005 the location is *M:\Shared\Finance\TDR Finance Menu\2004-5 Workplans, Allotments & AMS Codes.xls*, where they are kept updated by the Planning and Monitoring Officer.

6. INCOME AND FUNDING OF PRODUCTS

TDR is 100% funded through voluntary contributions from co-sponsors, governments and others. TDR covers all of its expenses from these incomes.

6.1 UNDESIGNATED CONTRIBUTIONS

Undesignated contributions, which are the preferred mode of contributions, constitutes at the moment about half of all the income to the Programme. Undesignated contributions are given towards the overall work plan and budget which is presented to, and approved by, the JCB before the start of the biennium during which it will be implemented.

Contributors giving undesignated contributions believe that priorities should be set based on needs and scientific opportunities and not on funding opportunities. They are therefore concerned about designated funding distorting priority setting and that undesignated funds would become the provider of the infra structure, while designated funds would 'set the agenda'. The risk of this happening, of course, increases as the proportion of undesignated funding decreases.

Based on a forecast of undesignated funds for the following biennium, the Programme Budget approved by the JCB sets 'floors' to protect certain expected results and products (see Annex III). At the start of the biennium, management establishes a 'working' budget ceiling based on the forecasted availability of undesignated funding. This ceiling will be adjusted during the course of the biennium based on changes in the forecast. Undesignated funds which remain unspent at the end of a biennium will be pooled and reallocated to products in the following biennium according to needs and priorities, i.e., there is no 'carry-over' of undesignated funds at the individual product level.

6.2 DESIGNATED CONTRIBUTIONS

For various reasons, internal to the contributor or as a response to the international political agendas and drives to mobilize resources, e.g., for specific diseases, some contributors wish to designate their contributions for specific products.

All designated contributions must, in full or proportionally, contribute to all the budget elements of a product, including the direct as well as the indirect costs associated with managing the product. 12% of each contribution will be used to cover part of the indirect costs (see also table 2).

A revised policy for receiving designated funds was discussed by an electronic working group of the JCB and approved by the Standing Committee in November 2001. The text of the policy is found in Annex III.

Early in the process of specific negotiation on financing of a product, the total costs to TDR of that particular product must be established and agreed by PPM (for a sample see Annex V). Designated funds will be managed using contributor specific allotments⁷ and unspent balances may be carried-over from one biennium to another at product level, however, for mixed funded projects, please see 6.3 below.

⁷ Contributions of less than \$100,000 may not be given contributor specific allotments – but may be managed using pool-allotments

It is the responsibility of the Functional Coordinator that this is adhered to for each case within their functional area and that the contributor is made aware of TDR's policies and practices for handling designated funds.

6.3 MIXED FUNDING OF PRODUCTS

- It may happen that there will be products for which both undesignated funding and designated funding will be used. Examples of this would be when designated funds are received towards products, which were planned to be funded entirely by undesignated funds, and when the allocation of some undesignated funds to a specific product will have *significant* leverage power, etc.

The designated component of the funding will be managed as described in 6.2 above. However, the designated funds will always be spent first and only the unspent balance of the designated component will be carried over automatically. The undesignated component of the funds will be managed as described in 6.1 above

It is the responsibility of the Functional Coordinator that this is adhered to for each case within their functional area and that the contributor is made aware of TDR's policies and practices for handling designated funds.

7. MONITORING AND EVALUATION

7.1 MONITORING

7.1.1 MILESTONE AND BUDGET IMPLEMENTATION

The shift from an input to results based planning and management requires that regular monitoring at the programme level not only takes into account the inputs (money and staff) but equally [or even more so] focuses on the results. To this effect, well-formulated milestones become a critical instrument.

During the course of a year, the SMTeam will formally review progress three times. Each review will include:

- Achievement of milestones in relation to time elapsed
- Budget implementation in relation to expected results and disease

There will be three scheduled opportunities per year for updating the database with respect to Milestones. This frequent updating is also justified by the new approach to donor reporting (see Section 9).

The main purpose of the review is to take strategic decisions with respect to the compositions of the product portfolio, based on the progress and continued relevance and adequacy of the portfolio.

Process

1. One to two months before the SMTeam Meeting, PPM will request the Functional Coordinators to update the milestones report, using the web-based reporting tool.
2. FC will organize with the relevant Product/SC Managers the update of their respective products (achievements- % + comments).
3. Before submitting to PPM [*Ten days prior to the SMTeam meeting*], the Functional Coordinators will consult with Disease Research Coordinators.
4. PPM will then action the update of the portfolio database, which is available on the TDR intranet and web-site.
5. A milestone deviation report will be presented by the respective Functional Coordinators at the SMTeam meeting.

7.1.2 FEASIBILITY AND RELEVANCE

The Steering Committees will continuously monitor the scientific progress of the products within its specific portfolio and may recommend to the Director, TDR, to change the level of funding or discontinue a product based on scientific grounds.

Once per year the *Disease Strategic Emphasis Matrix* will be updated and the entire *TDR Product Portfolio* will be reviewed by the SMTeam in January for relevance, appropriateness, and adequacy vis-à-vis the strategic emphases. This may lead to some products being discontinued if they are deemed to no longer correspond to the strategic emphasis. The outcome of the review is presented to the STAC [in February] for comment and input.

7.2 PROCESS BENCHMARKING

The processing of individual research contracts and efficient project management are the nucleus of TDR's operational capabilities driving force. This process starts by posting of calls for applications and ends with technical and administrative closing of the project file. The process involves numerous steps and can stretch several years. In order to continuously monitor and improve the processing, a programme of internal process benchmarking will be launched.

7.3 FINANCIAL AUDIT

7.3.1 WHO OFFICE OF INTERNAL AUDIT

TDR's financial procedures and practices are subject to audit by WHO internal auditors, who do *ad hoc* audits following the schedules and procedures established for WHO as a whole.

7.3.2 EXTERNAL AUDIT

In addition to the above internal audit, TDR's finances are subject to separate independent external audit. The external auditor provides a report and statement to the JCB in the same years in which the financial report for the preceding biennium is presented.

7.4 EVALUATION

Establishing a framework for and carrying-out evaluation of TDR was foreseen in the Strategy 2000-2005. An evaluation framework can help the programme stay focused on producing relevant results, while at the same time give those who are investing in the programme a measure to ascertain delivery. For each of the seven expected results areas at least one performance indicator was listed in the Strategy. It is also foreseen to carry-out various *ad hoc* evaluations of specific activities. Finally, the evaluation framework also includes external programme reviews, at least once during the strategic planning cycle.

7.4.1 PERFORMANCE INDICATORS

Establishing and formalising reporting on quantifiable performance indicators provides transparency and accountability and is a critical step in redefining programme management from being input to becoming results oriented.

Work has been going on for some time, also in relation to general WHO efforts to put more emphasis on measuring the performance of the organization across its programmes and activities. For TDR considerable thinking has gone into defining indicators, which are valid and reliable measures reflecting the tenets of the Strategy 2000-2005, and describing how these indicators will be measured. In the course of this, some of the indicators listed in the strategy document have had to be revised as they proved impossible to measure or could only be measured with prohibitive difficulty and cost.

Indicators can fall into two major groups and a number of categories, each describing critical aspects of programme performance:

Indicator groups

- *Strategic performance indicators* are meant for providing an overall measure for the performance of the programme at the JCB and contributor [investor] level.
- *Pipeline performance indicators* are meant to provide a specific measure of the performance of TDR's pipeline across expected results and organizational units. The target users are the SMTeam and the STAC

Input: The funds, personnel, materials, etc. which are necessary to produce the intended output

Process: set of individual activities which together define the mode of operation

Output: immediate results that can be guaranteed as a result of TDR's activities

Outcome: broader result, which is outside the direct control of the Programme and therefore cannot be guaranteed

Impact: the positive or negative changes produced, direct or indirect, as the result of TDR's activities

7.4.1.1 Strategic performance indicators

The intent has been to strike a balance between having indicators that are as valid and reliable a measure as possible of the effect of TDR while at the same time being practical and extractable from the programme's various reporting systems. Further, as the Strategy does not only define the 'results' but also the way that these results are achieved, i.e., the values of the programme and its operational capabilities driving force, the aim has been to define the strategic performance indicators across the above categories. In the same vein and according to the strategy, TDR, due to its nature of operation, is rarely the sole contributor to the results. Therefore, it is necessary to define the role of TDR for several of the indicators.

'With the support of TDR': TDR has had a critical role in forwarding the R&D that led to the achievement. This role can be in form of providing considerable proportion of funding, providing or facilitating determining technical support, or through its convening power providing a lead role in bringing partners together.

The table below shows the distribution of the 20 strategic performance indicators that have been chosen by expected result and indicator category. As it can be seen, most indicators are in the output and outcome categories. For detailed definition of each indicator, please see ANNEX VII

Expected Result	Indicator category				
	Input	Process	Output	Outcome	Impact
A New Knowledge			A1	A2	A3
B New and Improved Tools			B1	B2; B3	
C New and Improved Methods			C1		
D New and Improved Policies and Strategies				D1	
E Partnership and Capacity Strengthening		E1	E2	E3; E4	E5
F Technical Information			F1	F2; F3	F4
G Management	G1	G2	G3		
Total (= 20)	1	2	6	8	3

Interim evaluation reports will be made each year and presented to the STAC for endorsement as part of its role in monitoring progress and achievements of the Programme. STAC will, in turn report to JCB. Each biennium, a comprehensive update of the indicators will be prepared for the STAC and reported in the biennial programme report.

7.4.1.2 Pipeline performance indicators

The pipeline indicators are all process indicators, measuring performance of the R&D pipeline in terms of transition from one phase of research and development to the next. Four, P1 to P4 pipeline indicators will be used to measure the performance of the pipeline (see ANNEX VIII). Interim evaluation reports will be prepared twice per year for review by the SMTeam. Once per year, the evaluation report will be reviewed by the STAC for feed back and advice to the Programme Director. The indicators, P1 to P4 listed in the annex should, at this point be viewed as work in progress as further refinement is taking place through internal discussions and consultations with STAC

7.4.2 A POSTERIORI AND VALUE FOR MONEY EVALUATIONS

A posteriori and value for money evaluations are done when a product has come to an end, i.e., the success criteria has been met or it has been decided to terminate the product. The *a-posteriori* evaluations will address issues of impact on science, research capacity, and/or disease control; value of money (outcome versus costs borne by TDR and partners); as well as the production process. By nature these evaluations will take place on an *ad hoc* basis and may be done internally or by contracting outside expertise depending on the specific requirements in each case. About two such evaluations are foreseen per biennium and may be initiated by the programme management or by STAC.

7.4.3 EXTERNAL PROGRAMME REVIEW

External programme reviews are major programme-wide undertakings commissioned by the JCB, which also establishes the terms of reference for the review. External programme reviews take place every five to seven years. It is foreseen that the next external programme review will take place towards the end of the current strategic period, i.e., in 2004.

8. BUDGET REVISION

The procedures for budget revision were discussed in an electronic working group of the JCB and subsequently approved by the Standing Committee in November 2001. The new procedure is found in Annex IV of this guide.

9. REPORTING TO CONTRIBUTORS

The primary route of reporting to the donors will continue to be through the various reports presented to the JCB, including the financial report, Director's report, and the Programme report. Other reporting to designated donors will be kept at a minimum, standardized, and automated as much as possible in order to limit the demand on staff time, while at the same time providing each contributor with a satisfactory quality report.

The Product portfolio database will form the primary basis for all reporting to contributors. A sample standard report format is found as Annex VI. In fact, there are only two pieces of information that will be done specifically for the event of the reporting. These are: (1) the 'comments' to be provided by the Product Manager and cleared by the Steering Committee Manager, or Functional Coordinator and (2) the financial information to be provided by PPM.

Key to this automated reporting is the Milestones. Only if these are appropriately defined and regularly updated, will the donor find this reporting acceptable.

The reporting is orchestrated by the Advocacy and Fundraising Officer in PPM. It is the responsibility of the Functional Coordinators that contributors of designated funds to products within their respective areas are made aware of TDR's reporting policy.

ANNEX I: TDR ORGANIZATIONAL UNITS

Basic and Strategic Research (STR)

STR [Functional] Coordinator: Ayo Oduola, email: oduolaa@who.int

Steering committees:

1. Pathogenesis and Applied Genomics (PAG)
Manager: Ayo Oduola, email: oduolaa@who.int
2. Molecular Entomology (BCV)
Manager: Yeya Touré, email: tourey@who.int
3. Social, Economical and Behavioural Research (SEB)
Manager: Johannes Sommerfeld, email: sommerfeldj@who.int

Product Research and Development (PRD)

PRD [Functional] Coordinator: Janis Lazdins a.i.; email: lazdinsj@who.int

Steering Committees

4. Vaccines Discovery Research (VDR)
Manager: Ali Mohammadi (acting), email: mohammadia@who.int
5. Drug Discovery Research (DDR)⁸
Manager: Mary Bendig (acting), email: bendigm@who.int
6. Diagnostics and Development Research (DRD)
Manager: Rosanna Peeling, email: peelingr@who.int
7. Chemotherapy Portfolio Review (CPR)
Manager: Annette Kuesel, email: kuesela@who.int

Intervention Development and Implementation Research (IDE)

IDE [Functional] Coordinator: Hans Remme, email: remmej@who.int

Steering Committees

8. Proof of Principle (PoP)
Manager: Melba Gomes, email: gomesm@who.int
9. Implementation Research (IR)
Manager: Axel Kroeger, email: kroegera@who.int

Research Capability Strengthening (RCS)

RCS [Functional] Coordinator: Fabio Zicker, email: zickerf@who.int

⁸ At the moment the DDR steering committee functions as a Product Development Team under the CPR committee. However, its Products are, in the Product Portfolio Database still referred to under indices, e.g., B.05.-

Steering Committees

10. and 11. Research Strengthening Group (RSG I and RSG II one committee)
Manager: Fabio Zicker, email: zickerf@who.int

Multilateral Initiative on Malaria in Africa (MIM)

12. MIM [Functional] Coordinator: Jane Kengeya-Kayondo, email: kengeyakayondo@who.int

Multilateral Initiative on Malaria Research in Africa (MIM)

13. Manager: Olumide Ogundahunsi, email: ogundahunsio@who.int

Programme Planning and Management (PPM)

14. Programme Planning and Management (PPM)
Programme Manager: Erik Blas, email: blase@who.int
15. Disease Research Coordination
Disease Research Strategy Manager: Janis Lazdins, email: lazdinsj@who.int

Director's Office

16. Director (DIR)
Director: Robert Ridley, a.i., email: ridleyr@who.int

Disease Research Coordinators

African Trypanosomiasis	Deborah Kioy (Acting)	kioyd@who.int
Chagas Disease	Janis Lazdins	lazdinsj@who.int
Dengue	Axel Kroeger	kroegera@who.int
Leishmaniasis	Philippe Desjeux	desjeuxp@who.int
Leprosy	Howard Engers	engersh@who.int
Lymphatic Filariasis	Hans Remme	remmej@who.int
Malaria	Yeya Touré	tourey@who.int
Onchocerciasis	Janis Lazdins	lazdinsj@who.int
Schistosomiasis	Lester Chitsulo	chitsulol@who.int
Tuberculosis	Philip Onyebujoh	onyebujohp@who.int
Other ⁹	Janis Lazdins	lazdinsj@who.int

⁹ Janis Lazdins, who is the Disease Research Strategic Manager, will be responsible for new diseases coming into the portfolio, until the disease has formally been incorporated into the portfolio or until another solution has been found.

ANNEX II: PRODUCT MASTER SHEET

The Product Master Sheet (PMS) is a database record of all the relevant management information for each Product/activity in which TDR is involved.

SECTION 1: PRODUCT IDENTIFIERS

The Product identifier section consists of the following:

- Index: The index number consists of three parts (1) indication of the Expected Result [A to G]; the Steering Committee [1 to 14], see Annex I, and (3) a serial number.
- Short title
- Descriptive title
- Expected result
- Strategic indicator
- Funding status
- Product Manager
- Responsible Steering Committee
- Responsible Functional Team
- Disease proportion
- Funding status
- AMS code, each product will have three AMS codes, two for Operations and one for Operational Support. The AMS codes will only be valid for the biennium in which they are issued.

SECTION 2: PRODUCT JUSTIFICATION AND MONITORING

The Product identification and monitoring section consists of:

(Those items marked with '*' will be available in the product directory accessible on the web)

* Control need/Scientific opportunity¹⁰

Addresses the basic questions: **WHY** is TDR involved in this activity? To which need is the Product a response? The Strategy states that TDR is about producing *solutions to public health problems* and defines the end-users as:

¹⁰ TDR is not doing purely basic research without a purpose, there must always be an idea of resolving a control problem. However, TDR is not exclusively responding to needs or requests defined by control. It is a balance between push and pull.

“TDR end-users are the poor and marginalized populations in developing endemic countries who do not have access to appropriate and cost-effective means to prevent and treat their neglected infectious diseases”

and it specifically says:

“The resulting solutions to public health problems will emerge from knowledge generated by research and increased research capacity, and from developing, testing, and validating tool, intervention methods, and implementation strategies. The products will range from environmental, through population and systems based interventions, to those aimed at diagnosing and treating diseases in the individual”

* R & D Product/Process

Describes **WHAT** TDR will be doing, i.e., briefly describing the process and the role that TDR will have in this process. The Strategy says:

“TDR acts as a catalyst. It facilitates the R&D agenda through setting priorities, funding projects, and providing services in the form of technical guidance, capacity building, and brokerage for bringing together partners who have the comparative advantages required to make end-products become realities.”

Impact on and links to partnership and capacity building:

Defines **WHO** and **HOW**. TDR is characterised, not only by the direct outputs it produces but also by the way and with whom it works. The Strategy states:

“TDR has unique operational capabilities which allow it to bring together the world’s leading researchers and product developers, from both public and private sectors and both developing and developed countries, to address the public health problems related to neglected infectious diseases.”

Two of TDR’s basic values defined in the Strategy are relevant in this respect:

“Knowledge is a crucial element in health improvement, and attainment of self-reliance in research and development in disease endemic countries is key to sustainability.”

“Closing the global gap in research and product development, between the rich and the poor and marginalized populations suffering from neglected infectious diseases, requires collaboration and partnership between public and private sectors and involvement of research, planning and implementing agencies at international, national, and local levels, as well as the targeted populations.”

In particular for the RCS Plus products, the links between the R&D and the capacity building components must be made clear by cross-referencing to the Product Indices.

* Success Criteria

Describes the particular and immediate **OUTPUT** of the product, i.e., what is expected to have been produced when the product’s R&D-cycle has successfully been completed. It is important to distinguish the output of TDR’s activities from what could be the possible outcome or impact of applying that output in, e.g., a control situation.

* Success Criteria will be met

Defines the **DATE** when TDR is expected to deliver the output. The date is defined by month and year.

* Milestones

Milestones are major achievements in the product's R&D-cycle towards meeting the success criteria – delivering the final output. A milestone involves a discrete, clear, and measurable state that a product will reach and the time at which this is expected to have happened. Milestones are not process, rather they are **intermediate accomplishments with a date mark**. A meeting is therefore not a milestone however, the outcome of the meeting could be, e.g., 'consensus on the priorities for...', 'protocols for multilevel globalization research', etc.

Each product R&D cycle will normally have two to three significant milestones between the launching of the product development and the date when the success criteria will be met. A milestone, i.e., an achievement plus a predefined time, represents a point in the R&D cycle when a substantial review can take place by the SMTeam.

Examples of possible action if a milestone is not reached at the stipulated time:

- Revision of the timelines.
- Reassignment of responsibility to a more appropriate product manager.
- Review of the resource allocation.
- Termination of the product R&D process.

A minimum of two and a maximum of three milestones must be defined for **each product's total R&D cycle**.

SECTION 3: RESOURCES

The resource section of the PMS will capture all relevant resources for each product, whether they are coming through TDR or not

(items marked "***" will define the planned costs for the product in AMS)

**** Operations**

- Research contracts
- Other research costs.

**** Operational support****** P-Full Time Equivalents (P-FTE), by name****** G-Full time Equivalents (G-FTE), by name**

Indirect costs

Designated biennial resources from partners (coming through TDR)

Name of partners and amounts, direct {A-E} and indirect {F-G}

Biennial Resources from partners (not coming through TDR)

The donors requested at both the Paris Donor's meeting in 2001 and JCB(24), to have some indication of the TDR leverage power, i.e., how much partners are contributing outside of the TDR Trust Fund, e.g., through direct funding to country projects, etc..

Product R&D -cycle resources

- TDR and partners previous biennia
- TDR and Partners current biennium
- During the remaining R&D cycle by TDR and partners (subsequent biennia)

Critical resource

A brief narrative analysis of what are the most critical resources determining the progression of the product R&D.

SECTION 4: BACKGROUND INFORMATION

The background section captures other information relevant to the product.

History

A narrative description of the history of the product in TDR.

- Year started in TDR and how the decision to become involved emerged
- Names of TDR staff who have been involved
- Lead researchers who have been involved
- Critical decisions that were taken
- Crises and how these were overcome

Future

A narrative description of the product's future in TDR.

- Next steps in taking the product [output] into actual large-scale use and TDR's potential role
- Estimation of future costs involved
- Risks and assumptions

ANNEX III. POLICY FOR RECEIVING DESIGNATED FUNDING

(Replacing TDR/JCB(9)/86.7 Rev.1)

TDR is anticipated to shift from a predominantly undesignated funding base to one including a significant proportion of income being designated.

1. Designated contributions can be received [in order of preference] against any disease, expected results area, group of products, or individual products listed in the TDR Product Portfolio Directory, whether these are listed with funding status ‘undesignated’ or ‘not-funded’
2. Designations on part of the contributor cannot be made conditional of TDR providing additional funds from undesignated contributions. However, a contributor can make designation for full or part financing of product listed in the undesignated category.
3. The scientific independence of the STAC and the Steering Committees should not be compromised.
4. Designations must contribute in full or proportionately to all cost elements of the disease, expected results area, group of products, or products for which it is meant, i.e. operations, personnel and operational support.
5. All designations must at an appropriate level, to be determined in each case by programme management, contribute towards the indirect core costs represented in the general programme activities of expected results area ‘F’ and ‘G’¹¹.
6. Designations must be deposited in the TDR trust fund and interest earned will contribute towards the indirect core costs as mentioned under item 5.
7. Separate financial and progress reporting on each designation should be limited to a minimum and should follow established WHO/TDR practices.
8. Specific acknowledgement/recognition of funding source should be kept to a minimum and will not be acceptable below the level of ‘Products’, i.e., not in relation to specific projects or activities within a ‘product’.

¹¹ The Expected Results are defined in the Strategy 2000-2005. “F” is Technical Information, Research Guidelines and Instruments, and “G” is ‘Management’

ANNEX IV. PROCEDURES FOR BUDGET REVISION

(Replacing TDR/JCB(10)/87.9)

TDR prepares biennial programme budgets based on the principle of outputs (expected results and products) rather than inputs (predefined resource envelopes or budget ceilings), which was previously the case. Control needs and research opportunities for each of the target diseases, as well as research capacity strengthening needs are established, prioritized, and organized by Expected Results¹² in Strategic Emphases Matrices which form integral parts of the Programme Budget presented to and approved by the JCB. These strategic emphases are then translated into operational ‘products’ which, together, form the actual work plan of the Programme.

The Programme Budget sets floors, i.e., a minimum budget for each Expected Result comprising groups of products that are expected to be financed using forecasted undesignated funding. Director, TDR, may wish to revise the budget during the course of implementation based on availability of funds, needs, as well as research and development opportunities. The following procedures shall apply to such revisions:

1. **Adjustment of Expected Results floors, which are set in the Approved Programme Budget as TDR’s minimum budget for each Expected Result, pending availability of undesignated and other funding.**
 - 1.1 During the course of implementation, the Director may adjust the floors upwards or downwards for the expected results areas, depending on the availability of undesignated funding, while maintaining the relative distribution of floor levels between expected results. The Standing Committee shall be informed of such adjustments as well as the basis on which the adjustments were made. The Director shall report at the first Standing Committee meeting following the adjustment.
 - 1.2 During the course of implementation, the Director may wish to shift undesignated funding from one expected results area to another, i.e. *shift the relative distribution of the floors* between expected results. Revisions *in excess of 10%* of the floor approved by the JCB for any expected result, shall require the *concurrence* of the STAC and JCB Chairs and the Standing Committee.
2. **Termination of products and inclusion of new products, which are within the strategic emphases defined in the Approved Programme Budget**
 - 2.1 The Director may decide during the course of implementation to terminate products already in the portfolio, which are found not to be viable. Budget freed up from such termination shall be shifted to another product within the defined strategic emphases. In case of designated funding, agreement for the new deployment of resources shall be sought from the contributor, when required by the terms of designation. The Standing Committee shall be informed of the decision made by the Director as well as the justification for the same at its first meeting following the decision.

¹² The seven Expected Results, i.e., New Knowledge, New and Improved Tools, New and Improved Methods, New and Improved Strategies and Policies, Partnership and Capacity Building, Technical Information, Research Guidelines and Instruments, and Management are defined in the Strategy 2000-2005

- 2.2 The Director may decide, based on control needs and scientific and funding opportunities, to include *new products* during the course of implementation, which are *within the defined strategic emphases*. The Standing Committee shall be *informed* of the decision made by the Director as well as the justification for the same at its first meeting following the decision.
- 3. Inclusion of new products, which are not within the strategic emphases defined in the Approved Programme Budget**
- 3.1 The Director may wish, during the course of implementation and based on control needs and scientific and funding opportunities to include new products, which are *not within the strategic emphases*. Inclusion of such products shall only be done *with concurrence* of the STAC and JCB Chairs and the Standing Committee
- 4. All budget revisions made under the procedures described above shall be reported to the STAC and the JCB at their next sessions.**

ANNEX V: SAMPLE PRODUCT COSTING

BUDGET FOR PRODUCT XYZ								
2004-2005 biennium				2006-2007 biennium			Total R&D	
Unit cost	Units	Sub-totals	Totals	Units	Sub-totals	Totals	cycle	
Operation								
Item 1		250,000			100,000			
Item 2		100,000			50,000			
Item3		35,000			0			
Total Operations			385,000			150,000	535,000	
Personnel								
P-staff (FTE)	303,000	0.2	60,600		0.1	30,300		
G-Staff (FTE)	185,000	0.15	27,750		0.05	9,250		
Total Personnel			88,350			39,550	127,900	
Operational support								
TDR duty travel			15,000			5,000		
Total Operational Support			15,000			5,000	20,000	
Total Direct Costs (88% of total cost)			488,350			194,550	682,900	
Indirect Costs (12% of total cost)			66,593			26,30	93,123	
Total Cost (100%)			554,943			221,080	776,023	
Financing								
Source 1			300,000			200,000	500,000	
Source 2			117,758			21,080	138,838	
Source 3			137,185			0	137,185	
							0	
Financing gap			0			0	0	

ANNEX VI: SAMPLE CONTRIBUTOR REPORT

Product Implementation Report.

Date:

Report to contributor:

Initials:

<Index>	Product: <Descriptive title>	
Expected Result Area:		
Responsible Officer:	Steering Committee:	
Control need:	R&D Product/Process	
Success Criteria:		
Success Criteria will be met: <Date>		
Progress: MILESTONES	Target date	% Achieved
Milestone 1		
Milestone 2		
Milestone 3		
Comments:		

All the information in this table comes directly from the database (which is updated at least three times per year)

BUDGET IMPLEMENTATION REPORT FOR PRODUCT XYZ		
	Budget	Biennium to date
Operation	\$	\$
Personnel¹	\$	\$
Operational support	\$	\$
Total Direct Costs	\$	\$
Total Indirect Costs	\$	\$
Total Cost	\$	\$
Financing		
Source 1	\$	\$
Source 2	\$	\$
Source 3		
Balance	\$	\$

ANNEX VII: STRATEGIC PERFORMANCE INDICATORS

EXPECTED RESULT A: NEW KNOWLEDGE

Strategic performance indicator A1: [OUTPUT]

Number of new and significant scientific advances.

Definition

Scientific advances: Additions to the international pool of research-based knowledge that can potentially advance thinking and research towards solutions to public health problems caused by neglected infectious diseases.

New and significant: Judged by bodies external to TDR to represent important additions to the body of knowledge in the field.

Verification of Achievement

What will be measured:

Number of publications indexed by Medline or Web of Science originating from TDR supported research [all expected results] made accessible within the biennium in international peer reviewed electronic or printed publications.

How will it be measured:

Through review of the TIMS data-base, which, based on the final technical reports from investigators, capture publications, combined with identification in PubMed and Web of Science of articles acknowledging TDR funding, or otherwise identified as, or known to have emerged from, TDR supported research.

Who will measure [verify]:

PPM will do a first search which will be distributed to the Steering Committee Managers, who, based on his or her knowledge of their research portfolio, will do a further search. A resulting report will be consolidated by PPM and presented to the STAC for endorsement.

Quantification

Baseline:

1996-1997: 247

1998-1999: 294

Achievements & Targets (Duration of Strategy):

2000-2001: 458

2002-2003: 500

2004-2005: **300** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 1,258 (target)

EXPECTED RESULT A: NEW KNOWLEDGE

Strategic performance indicator A2: [OUTCOME]

Number of patents resulting from TDR funded research and development

Definition

Patent: A document issued by a legal authority granting an inventor sole rights to an invention.

Verification of Achievement

What will be measured:

Number of patents awarded within the biennium resulting from TDR supported R&D.

How will it be measured:

Through review of TDR progress and final report forms submitted by researchers¹³. Through direct follow up with researchers who have been, or are, supported for research that potentially could have resulted in granting of patent(s).

Who will measure [verify]:

PPM will do a first search, based on data in TIMS, which will be distributed to the Steering Committee Managers. These will, based on their knowledge of their respective research portfolios, conduct the above review and will seek to verify through patent registers. A resulting report will be consolidated by PPM and presented to the STAC for endorsement.

¹³ Awards of patents is among the requested information on TDR progress and final report forms

Quantification

Baseline:

1996-1997: 5

1998-1999: 3

Achievements & Targets (Duration of Strategy):

2000-2001: 4

2002-2003: 4

2004-2005: **5** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 13 (target)

EXPECTED RESULT A: NEW KNOWLEDGE

Strategic performance indicator A3: [IMPACT]

Number of outstanding advances in scientific knowledge

Definition

Outstanding advances: single, or group of related, contributions to scientific knowledge that are judged to have a significant direct or indirect impact on how science is conducted or on thinking about control of neglected infectious diseases.

Verification of Achievement

What will be measured:

Number of single, or groups of, research projects that have been completed [or published] with TDR support within the biennium, representing advances in knowledge that stand out in an international context.

How will it be measured:

Steering committees will annually review the results emerging from TDR's portfolio within its areas of oversight and will, based on its international expertise in the field, identify and propose advances in knowledge which it judges to stand out internationally.

Who will measure [verify]:

The Steering Committee manager will, through the appropriate functional coordinator, present the proposal to the STAC for validation.

Quantification

Baseline:

1996-1997: 5

1998-1999: 6

Achievements & Targets (Duration of Strategy):

2000-2001: 7

2002-2003: 12

2004-2005: **5** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 24 (target)

EXPECTED RESULT B:

NEW AND IMPROVED TOOLS

Strategic performance indicator B1: [OUTCOME]

Number of new and improved tools, such as drugs, vaccines, receiving regulatory approval and / or label extensions or, in the case of diagnostics, being recommended for use in controlling neglected tropical diseases.

Definition

Regulatory approval: approval by an appropriate legally authorized agency of the *drug* or *vaccine* for use in humans for the control of infectious diseases.

Label extension: approval by an appropriate legally authorized agency of the extended use of the *drug* or *vaccine* for use in humans for the control of infectious disease.

Recommended: recommended for use by an appropriate authority, e.g., ministry of health, WHO, or global disease control programme of the diagnostic for use in humans for control of infectious disease assuming that 'regulatory approval' is not required for diagnostics.

Tool: drug, vaccine, diagnostic

Drug: a natural or synthetic compound, or combination of compounds, developed as a medicine for the treatment of a disease.

Vaccine: material (e.g. antigen, DNA sequence) that elicits an immune response that prevents, limits or treats a disease.

Diagnostic: A tool which predicts the biological status of an individual or population in terms of infection, disease, or immunity.

New: The particular drug, vaccine or diagnostic has never been approved or recommended for use in humans before or for the disease in question.

Improved: an existing drug, vaccine or diagnostic that has been approved or recommended before, but which required a new approval/recommendation for new indications, combination, dosage, etc.

Verification of Achievement

What will be measured:

Number of drugs and vaccines within a biennium receiving first regulatory approval or label extension by an authorized agency for use in control of human disease. Normally, subsequent approvals by other agencies of the same drug or vaccine for the same indications will not count, unless this has required a specific, focused TDR input.

Number of diagnostics within a biennium receiving first recommendation by an appropriate authority for use in the control of human disease. Normally, subsequent recommendations by other agencies of the same diagnostic and same use will not count, unless this has required a specific, focused TDR input.

How will it be measured:

Review of product documentation, e.g., letter of registration, formal statements of recommendation, documentation from health agencies, etc.

Who will measure [verify]:

The Appropriate Manager will prepare a validation report to be submitted through the appropriate functional coordinator and then through SMTeam / Director to STAC for endorsement.

Quantification

Baseline:

1996-1997: 0

1998-1999: 1

Achievements & Targets (Duration of Strategy):

2000-2001: 0

2002-2003: 3

2004-2005: **5** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **8** (target)

EXPECTED RESULT B:

NEW AND IMPROVED TOOLS

Strategic performance indicator B2: [OUTCOME]

Number of new and improved epidemiological and environmental tools being recommended for use in controlling neglected tropical diseases

Definition

Recommended: recommended for use by an appropriate authority, e.g., ministry of health, WHO, or global disease control programme for control of infectious disease.

Tool: epidemiological or environmental

Epidemiological: an aide that improves the identification of population at risk and/or quantifies the degree of risk to which a population is exposed.

Environmental: a non-invasive means aimed at preventing transmission of disease or controlling the relevant vectors.

New: The particular epidemiological or environmental tools have never been recommended for the disease in question.

Improved: existing epidemiological or environmental tools that have been recommended for use before, but which have been developed to have an increased efficacy so that the use of the previously recommended tool [or version] is no longer recommended.

Verification of Achievement

What will be measured:

Number of epidemiological or environmental tools within a biennium receiving first recommendation by an appropriate authority for use in control of disease, i.e., subsequent approvals by other agencies of the same tool for a similar purpose will not count.

How will it be measured:

Review of product documentation, e.g., letter of registration, formal statements of recommendation, documentation from health agencies, etc.

Who will measure [verify]:

The Steering Committee Manager who will prepare a validation report to be submitted, through the appropriate functional coordinator to STAC for validation.

Quantification

Baseline:

1996-1997: 3

1998-1999: 1

Achievements & Targets (Duration of Strategy):

2000-2001: 1

2002-2003: 0

2004-2005: **2** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 3 (target)

EXPECTED RESULT C:

NEW & IMPROVED INTERVENTION METHODS

Strategic performance indicator C1: [OUTPUT]

Number of new and improved intervention methods validated for the prevention, diagnosis, treatment, or rehabilitation of populations exposed to or affected by infectious disease.

Definition

Intervention method: A systematic procedure or technique for public health intervention guided by a set of written instructions on use that cover general settings and/or conditions.

Validated: provision, through scientific research, of 'proof of principle' that the intervention method is effective in a public health setting, i.e., that the method is superior to methods used previously.

New: the method has not existed before.

Improved: an existing intervention method that has been recommended for use before, but that has been further developed to have a significantly increased cost-effectiveness with the result that the use of the 'old version method' should no longer be recommended.

Verification of Achievement

What will be measured:

Number of new or improved intervention methods resulting from TDR funded research, which has completed validation within the biennium.

How will it be measured:

Review of evidence from validation documentation by Steering Committee.

Who will measure [verify]:

Steering Committee Manager will prepare an evaluation report through the appropriate functional coordinator to STAC for validation.

Quantification

Baseline:

1996-1997: 6

1998-1999: 2

Achievements & Targets (Duration of Strategy):

2000-2001: 4

2002-2003: 0

2004-2005: **5** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 9 (target)

EXPECTED RESULT D:

NEW AND IMPROVED POLICIES AND STRATEGIES

Strategic performance indicator D1: [OUTPUT]

Number of new and improved public health policies and strategies for which the effectiveness has been determined, and evidence on effectiveness made available to decision makers.

Definition

Policy: A comprehensive public health guidance and/or regulation covering the health sector and possibly beyond, e.g. addressing issues in the private and the non-health sectors.

Strategy: A comprehensive plan of intervention that is designed to achieve a defined public health goal or impact, and that is appropriate for use in several disease endemic countries.

Public health: the science and art of preventing disease, prolonging life and promoting health of populations through organized efforts in society.

Effectiveness: measure of the extent to which a policy or strategy, when employed in the field under routine circumstances, does what it is intended to do.

New: the policy/strategy has not existed before.

Improved: an existing policy/strategy that has been recommended for use before is developed further to have a significantly increased cost-effectiveness with the result that the use of the 'old version policy/strategy' should no longer be recommended.

Verification of Achievement

What will be measured:

Number of new and improved public health policies and strategies for which the effectiveness has been determined within the biennium in TDR supported research and evidence made available to public health decision makers.

How will it be measured:

The Steering Committee will review evidence from validation documentation and evidence of recommendation by appropriate authorities.

Who will measure [verify]:

The Steering Committee Manager will prepare an evaluation report to be submitted, through the appropriate functional coordinator to STAC for validation.

Quantification

Baseline:

1996-1997: 2

1998-1999: 0

Achievements & Targets (Duration of Strategy):

2000-2001: 3

2002-2003: 2

2004-2005: **2** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 7 (target)

EXPECTED RESULT D:

NEW AND IMPROVED POLICIES AND STRATEGIES

Strategic performance indicator D2: [OUTCOME]

Number of new and improved policies and strategies for enhanced access to proven public health interventions developed, validated and recommended for use.

Definition of the indicator

Policy: A comprehensive public health guidance and/or regulation covering the health sector and possibly beyond, e.g., addressing issues in the private and the non-health sectors.

Strategy: A comprehensive plan of intervention that is designed to achieve a defined public health goal or impact, and that is appropriate for use in several disease endemic countries.

Access: The facility with which disease-affected populations can obtain relevant components of specific public health interventions. Access reflects both supply of and demand for the intervention.

Enhanced: increase in proportion of the population in a given area that accesses an intervention, to a level compatible with the target of a public health strategy and/or with effective expansion to scale, while ensuring similar levels of access.

Public health: the science and art of preventing disease, prolonging life and promoting health of populations through organized efforts in society.

Intervention: An activity or set of activities aimed at modifying a process, course of action or sequence of events, in order to change one or several of their characteristics such as performance or expected outcome.

Proven: the intervention has been demonstrated to be effective, and the evidence is available in the scientific literature.

Developed: applying scientific approaches to work out, in collaboration with public health experts and authorities, new or better policies and strategies for access to public health interventions.

Validated: provision, through scientific research, of evidence that the policy/strategy works in real-life public health settings (health care system environment) and that it is superior, i.e., more cost-effective than the one(s) previously used.

Recommended: recommended for use by an appropriate authority, e.g., ministry of health, WHO, or global disease control programme for public health efforts to control of infectious disease.

New: the policy/strategy has not existed before.

Improved: an existing policy/strategy that has been recommended for use before it is developed further to have a significantly increased cost-effectiveness with the result that the use of the 'old version policy/strategy' should no longer be recommended.

Verification of Achievement

What will be measured:

Number of new and improved control policies and strategies completed within the biennium resulting from TDR supported research, validated *and* recommended for use in public health.

How will it be measured:

The Steering Committee will review evidence from validation documentation and evidence of recommendation by appropriate authorities.

Who will measure [verify]:

The Steering Committee Manager will prepare an evaluation report to be submitted, through the appropriate functional coordinator to STAC for validation.

Quantification

Baseline:

1996-1997: 3

1998-1999: 2

Achievements & Targets (Duration of Strategy):

2000-2001: 3

2002-2003: 2

2004-2005: **3** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 8 (target)

EXPECTED RESULT E:

PARTNERSHIPS AND CAPACITY BUILDING

Strategic performance indicator E1: [PROCESS]

E.1: Number of R&D partners engaged.

Definition

R&D Partners: Investigators and temporary advisors who are involved with TDR in research related activities, other than those receiving training. Partners may or may not receive funds from or provide funds to TDR.

Engaged: the involvement is confirmed through a formal agreement.

Verification of Achievement

What will be measured:

Number of different partners engaged during the biennium by issuance of a new or a renewal contract [or agreement].

How will it be measured:

Identification and review of new TSAs, APWs, and TAs (excluding participants)¹⁴ in TIMS.

Identification and review of new MOUs¹⁵.

Who will measure [verify]:

PPM will review the TIMS database and other relevant records and will, after consultation with the Functional Coordinators prepare an evaluation report to be submitted to the STAC for endorsement.

¹⁴ This will require splitting the TA category in TIMS into (1) TAA= Temporary Advisors, (2) TAP= Participants

¹⁵ this will require central registration of all MOUs in PPM

Quantification

Baseline:

1996-1997: 629

1998-1999: 611

Achievements & Targets (Duration of Strategy):

2000-2001: 609

2002-2003: 898

2004-2005: **700** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 2,207 (target)

EXPECTED RESULT E:

PARTNERSHIPS AND CAPACITY BUILDING

Strategic performance indicator E2: [OUTPUT]

Number of persons trained

E 2.1: Number of MSc degree completed

E 2.2: Number of PhD/Doctoral degree completed

E 2.3: Number of persons trained in short courses

Definition

MSc: Master of Science in a TDR research related subject.

PhD: Doctoral degree in a TDR research relate subject.

Completed: awarded the degree (MSc or Doctoral degree) from a recognized university, school, institute, etc.

Short courses: courses of varied length and which are not aimed at providing a formal academic degree.

Verification of Achievement

What will be measured:

E 2.1 and E2.2: number of degree certificates (MSc or Doctoral degree) awarded within the biennium to TDR supported students.

E 2.3: Number of TAs issued for participants (i.e., other than temporary advisors) plus number of participants covered by APWs with organizers.

How will it be measured:

E2.1 and E2.2: Review of register for TDR funded students with verification of award from relevant institution.

E2.3: Review of TIMS and TMAS databases as well as records of TDR functional units.

Who will measure [verify]:

E2.1 and E2.2: Manager Training (RCS), who will prepare an evaluation report to be submitted though the functional coordinator RCS to STAC for endorsement.

E2.3: PPM will review the TIMS/TMAS databases and the Manager, Training will include in the above evaluation report.

Quantification

Strategic indicator E2.1	Strategic indicator E2.2	Strategic indicator E2.3
<u>Baseline:</u> 1996-1997: N.a 1998-1999: N.a	<u>Baseline:</u> 1996-1997: N.a 1998-1999: N.a	<u>Baseline:</u> 1996-1997: N.a 1998-1999: N.a
<u>Achievements & Targets (Duration of Strategy):</u> 2000-2001: 19 2002-2003: 10 2004-2005: 10* 2000-2005 (Total): 39**	<u>Achievements & Targets (Duration of Strategy):</u> 2000-2001: 27 2002-2003: 49 2004-2005: 49* 2000-2005 (Total): 125**	<u>Achievements & Targets (Duration of Strategy):</u> 2000-2001: N.a 2002-2003: 657 2004-2005: 800* 2000-2005 (Total): n.a

* target as proposed in the Approved Programme Budget 2004-2005

** target

EXPECTED RESULT E:

PARTNERSHIPS AND CAPACITY BUILDING

Strategic performance indicator E3: [OUTCOME]

Number of research institutions in low income disease endemic countries strengthened.

Definition

Research institution: An organizational entity, which fulfils the following eligibility criteria¹⁶:

- Low income, disease endemic country
- Clear mandate for research in TDR target diseases
- Institutional government support
- Institutional leadership present
- History of institutional stability
- Integrated/linked to government public health mainstream programmes
- Minimum core staff already available
- Potential for national/regional training support
- Potential for expansion and partnerships
- Institutional national/regional credibility

Low income countries: Classified by the World Bank in 1997 as countries whose GNP per capita was \$765 or less in 1995.

Disease Endemic Countries: Countries where one or more TDR disease is usually present at relatively high prevalence and incidence rates, in comparison with other countries.

Strengthened: Successful completion of institution-strengthening projects¹⁷, i.e., attainment of 'Success Criteria' by an institution for capacity building:

- Research leadership developed in the supported institution
- Institution increasingly able to generate resources through competitive processes
- Mature institution, able to re-create research capacity, through attracting and developing new researchers and managers
- Production of research results of national and international significance and based on partnerships and networks
- Adherence to ethical principles and internationally accepted scientific standards

Verification of Achievement

What will be measured:

Number of institutions that have successfully completed their research strengthening project within the biennium.

How will it be measured:

Through preparation of standardized evaluation reports of attainment of success criteria for each individual institution strengthened.

¹⁶ RCS strategy page 8 (TDR/RCS/Strat/02.1). However, the first bullet in the eligibility criteria has been modified for this indicator in order to make the criteria more reliable

¹⁷ Note that these projects are few, fairly large in resource terms and with timeframes of five to ten years

Who will measure [verify]:

The above report will be prepared jointly by the institution and RCS staff, reviewed by the Research Strengthening Group (RSG) and submitted by the functional coordinator RCS to the STAC for validation.

Quantification

Baseline:

1996-1997: N.a

1998-1999: N.a

Achievements & Targets (Duration of Strategy):

2000-2001: N.a

2002-2003: 4

2004-2005: **6** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): n.a

EXPECTED RESULT E:

PARTNERSHIPS AND CAPACITY BUILDING

Strategic performance indicator E4: [OUTCOME]

Proportion of partners who are from Disease Endemic Countries out of the total number of partners engaged.

Definition

R&D Partners: Investigators and temporary advisors who are involved with TDR in research related activities other than those receiving training. Partners may or may not receive funds from TDR or provide funds to TDR.

Engaged: the involvement is confirmed through a formal agreement/contract.

Disease Endemic Countries: Countries where one or more TDR diseases are usually present at relatively high prevalence and incidence rates, in comparison with other countries.

Verification of Achievement

What will be measured:

Number of partners engaged from DEC during the biennium by issuance of a new or renewal contract [agreement] over total number of partners engaged (see indicator E1).

How will it be measured:

Identification and review of new TSAs, APWs, and TAs (excluding participants)¹⁸ in TIMS.

Identification and review of new MOUs¹⁹.

Who will measure [verify]:

PPM will review the database created for indicator E1 and will, after consultation with Functional Coordinators, issue an evaluation report to be submitted to the STAC for endorsement.

¹⁸ This will require splitting the TA category in TIMS into (1) TAA= Temporary Advisors, (2) TAP= Participants

¹⁹ this will require central registration of all MOUs in PPM

Quantification

Baseline:

1996-1997: 58.2%

1998-1999: 60.7%

Achievements & Targets (Duration of Strategy):

2000-2001: 59.9%

2002-2003: 72.3%

2004-2005: **65%** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **65%** (target)

EXPECTED RESULT E:

PARTNERSHIPS AND CAPACITY BUILDING

Strategic performance indicator E5: [IMPACT]

Proportion out of total new and significant scientific advances produced by scientists from disease endemic countries.

Definition

Scientific advances: Additions to the international pool of research-based knowledge that can potentially advance thinking and research towards solutions to public health problems caused by neglected infectious diseases.

New and significant: Judged by bodies external to TDR to represent important additions to the knowledge base in the field.

Disease endemic countries: Countries where one or more TDR disease is usually present at relatively high prevalence and incidence rates, in comparison with other countries.

Verification of Achievement

What will be measured:

Number out of the total publications originating from TDR supported research [all expected results] made accessible within the biennium in international peer reviewed electronic or printed publications with the first author's postal address in a DEC.

How will it be measured:

Review of the database created for *Strategic Indicator A1* to identify and count those first authors whose postal address is in a DEC.

Who will measure [verify]:

PPM will undertake the review and will prepare an evaluation report which will, after consultation with the Functional Coordinators, be submitted to the STAC for endorsement.

Quantification

Baseline:

1996-1997: 32.8%

1998-1999: 41.8%

Achievements & Targets (Duration of Strategy):

2000-2001: 36.7%

2002-2003: 49.0%

2004-2005: **45%** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **45%** (target)

EXPECTED RESULT F:**TECHNICAL INFORMATION, GUIDELINES, INSTRUMENTS AND ADVICE****Strategic performance indicator F1: [OUTPUT]**

Number of research instruments and guidelines for infectious diseases developed and published

Definition

Instrument: a tool or a means to facilitate or enable conduct of research.

Guideline: a set of written procedures to be followed in specific research or as part of the course of research.

Published: printed with an ISBN or ISSN number²⁰, searchable from public, e.g., library databases, and available for sale or distribution to scientists.

Verification of Achievement**What will be measured:**

Number of instruments and guidelines published under TDR name and logo.

How will it be measured:

Counting number of instruments and guidelines published.

Who will measure [verify]:

PPM will prepare, in consultation with the Functional Coordinators, an evaluation report for submission to the STAC for endorsement.

²⁰ Up to the end of 2002 ISBN and ISSN were not used by TDR - only TDR numbers, which will consequently be used as inclusion criteria for pre-2003 instruments and guidelines

Quantification

Baseline:

1996-1997: 4 [data from 1996 missing]

1998-1999: 6

Achievements & Targets (Duration of Strategy):

2000-2001: 7

2002-2003: 13

2004-2005: **8** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): 28 (target)

EXPECTED RESULT F:**TECHNICAL INFORMATION, GUIDELINES, INSTRUMENTS AND ADVICE****Strategic performance indicator F2: [OUTCOME]**

Number of global research priority-setting reports for neglected infectious diseases published.

Definition

Priority-setting report: a report resulting from an international consultation of experts representing research as well as health systems and disease control programmes, reviewing and ranking the public health need for R&D.

Published: printed with an ISBN or ISSN²¹ number, searchable from public, e.g., library databases, and available for sale or distribution to scientists and others.

Verification of Achievement**What will be measured:**

Number of priority-setting reports published under TDR name and logo.

How will it be measured:

Counting number of priority-setting reports published.

Who will measure [verify]:

PPM will prepare an evaluation report for submission to the STAC for endorsement.

²¹ Up to the end of 2002 ISBN and ISSN were not used by TDR - only TDR numbers, which will consequently be used as inclusion criteria for pre-2003 instruments and guidelines

Quantification

Baseline:

1996-1997: 0

1998-1999: 0

Achievements & Targets (Duration of Strategy):

2000-2001: 0

2002-2003: 2

2004-2005: **4** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **6** (target)

EXPECTED RESULT F:

TECHNICAL INFORMATION, GUIDELINES, INSTRUMENTS AND ADVICE

Strategic performance indicator F3: [OUTCOME]

Mean monthly number of page views to the TDR web site.

Definitions

Page: Any HTML document, dynamic page, or form on the www.who.int domain. This does not include graphic images (.gif .jpg etc.), audio clips, video files, or dynamically generated pages hosted on domains other than www.who.int (e.g. the TDR image library).

Page View (Impressions): A hit to any file classified as a page.

Verification of Achievement

What will be measured:

Any request for TDR web pages (including TDR application forms) made to the WHO production server, regardless of whether it was successful or not. The number will exclude hits to the site generated by search engine robots, but include requests from cache proxy servers, which represent an unknown number of individuals' requests. The measure is an indication of change in level interest and should thus be viewed relative to time, rather than as an absolute measure. A mean monthly page view will be calculated by adding the pages viewed for the months where data are available divided by the number of months.

How will it be measured:

Real time statistics are generated using Web Trends software, and are at any time on <http://webtrends.who.int/>.

Who will measure [verify]:

PPM will prepare an evaluation report to be submitted to the STAC for endorsement.

Quantification

Baseline:

1996-1997: N.a

1998-1999: 30,705

Achievements & Targets (Duration of Strategy):

2000-2001: 51,808

2002-2003: 133,968

2004-2005: **200,000** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005: **150,000** (target)

EXPECTED RESULT F:**TECHNICAL INFORMATION, GUIDELINES, INSTRUMENTS AND ADVICE****Strategic performance indicator F4: [IMPACT]**

Number of unsolicited requests for research guidelines and instruments.

Definitions

Unsolicited request: requests for copies generated from outside of TDR, e.g., use in TDR conducted workshops, general mailings, etc. will not be counted.

Research guidelines: written/published procedures and principles for conducting research.

Research instrument: individual tools and devices for conducting research, e.g., computer software, questionnaires, etc. other than what is included in the above guidelines.

Verification of Achievement**What will be measured:**

The number of unsolicited requests for TDR developed and/or funded research guidelines and instruments received in TDR or by collaborating partners whether for hard, electronic copies or downloads from the TDR web-site.

How will it be measured:

Statistics on requests for paper and CD copies of the guidelines and instruments will be kept by the TDR communication group.

Real time statistics are generated using Web Trends software, and are at any time on <http://webtrends.who.int/>. for the downloads of PDF files of guidelines and instruments.

Who will measure [verify]:

PPM will prepare an evaluation report to be submitted to the STAC for endorsement.

Quantification

Baseline:

1996-1997: N.a

1998-1999: N.a

Achievements & Targets (Duration of Strategy):

2000-2001: N.a

2002-2003:

- 65,825 downloads from web-site

2004-2005: **2,000** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005: n.a

EXPECTED RESULT G:

RESOURCE MANAGEMENT

Strategic performance indicator G1: [INPUT]

Resources for research, product development, and capacity building priorities mobilized.

Definitions

Priorities: are products defined in consonance with TDR's disease and capacity building strategic emphasis matrices and part of TDR's product portfolio.

Mobilised: raised from contributors and paid into TDR's trust fund.

Verification of Achievement

What will be measured:

The total income received in the trust fund for TDR products.

How will it be measured:

From income statements

Who will measure [verify]:

PPM will prepare biennial and interim annual financial reports verified by WHO accounts.

Quantification

Baseline:

1996-1997: \$54.4 million

1998-1999: \$50.6 million

Achievements & Targets (Duration of Strategy):

2000-2001: \$56.0 million

2002-2003: \$71.3 million

2004-2005: **\$100 million** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **\$227.3 million** (target)

EXPECTED RESULT G:

RESOURCE MANAGEMENT

Strategic performance indicator G2: [PROCESS]

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

Definitions

Efficiently managed: optimizing the proportion of total resources disbursed to partners for R&D for capacity building, i.e., adhering to a budget element distribution of 70% for operations, 20% for personnel, and 10% for operational support²².

Verification of Achievement

What will be measured:

The relative distribution between the three budget elements of the total obligations for the biennium.

How will it be measured:

From WHO financial system (AFI).

Who will measure [verify]:

PPM will prepare biennial and interim annual financial reports, verified by WHO Accounts.

²² for definition of these budget elements, please see TDR General Operations Guide section 5

Quantification

Baseline:

1996-1997: 67-23-10

1998-1999: 70-21-9

Achievements & Targets (Duration of Strategy):

2000-2001: 67-22-11

2002-2003: 59-28-13

2004-2005: **68-21-11** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **68-21-11** (target)

EXPECTED RESULT G:**RESOURCE MANAGEMENT****Strategic performance indicator G3: [OUTPUT]**

Resources for research, product development, and capacity building efficiently disbursed.

Definitions

Efficiently disbursed: optimizing the turn-over speed of available financial resources.

Verification of Achievement**What will be measured:**

The average number of times the unobligated balance at hand is turned-over per annum. The maximum feasible speed is expected to be 6 times per year, corresponding to an average of two months from contributions from being received until they are obligated. The indicator will thus provide a gross picture of the TDR trust fund.

How will it be measured:

Every six months, i.e., four times in a biennium, the following will be measured and calculated:

1. FINANCIAL RESOURCE TURN-OVER SPEED = $\{2 \times (\text{UNOBLIGATED BALANCE AT START} + \text{INCOME RECEIVED} - \text{UNOBLIGATED BALANCE AT END}) / \text{UNOBLIGATED BALANCE AT END}\}$
2. AVERAGE FINANCIAL RESOURCE TURN-OVER SPEED = ROLLING AVERAGE OF THE FOUR MEASURES OF THE BIENNIUM

Data will be obtained from WHO financial system (AFI)

Who will measure [verify]:

PPM will prepare biennial and interim annual financial reports verified by WHO Accounts .

Quantification

Baseline²³:

1996-1997: 14

1998-1999: 3.8

Achievements & Targets (Duration of Strategy):

2000-2001: 3.8

2002-2003: 2.3

2004-2005: **6** (target as proposed in the Approved Programme Budget 2004-2005)

2000-2005 (Total): **6** (target)

²³ Due to non-availability of detailed data for 1996 to 1999, the turn-over speed has been calculated using a different formula, i.e., $\{ \frac{1}{2} \times (\text{CARRY-OVER AT START} + \text{INCOME} - \text{CARRY-OVER AT END}) / \text{CARRY-OVER AT END} \}$. The large difference between the two biennia is due to special circumstances and using one measuring point per biennium only.

ANNEX VIII: PIPELINE PERFORMANCE INDICATORS

PIPELINE INDICATORS

Pipeline performance indicator P1: [PROCESS]

Number of targets identified, validated and progressed to adaptation for discovery

Definition

Target: biomolecules, particular proteins, which are instrumental in a disease process or pathway.

Discovery: a process that optimizes and identifies a candidate product for entry into development.

Defined Discovery phases : activities that define whether or not products can progress through decision points along the discovery pathway. These decision points are defined by the following:

Discovery phases:

- a) Target identification and validation
- b) Target adaptation for discovery (establishment of *in vivo* and *in vitro* screening and optimization)
- c) Identification of a 'lead' (compound, immunogen) worth optimizing as a development candidate;
- d) identification of a development candidate for entry into phase 0 (pre-clinical development).

Verification of Achievement

What will be measured:

Number of targets originating from TDR supported research progressed from target identification and validation to adaptation for discovery.

How will it be measured:

The respective steering committee/PDT will review documentation for each particular discovery activity.

Who will measure [verify]:

The responsible Steering Committee Manager/Product Manager will prepare a report, based on the above, to be submitted through the appropriate functional coordinator and then to SMTeam / Director before going to STAC.

Quantification

Achievements & Targets (Duration of Strategy): *(In preparation)*

2002-2003:

2004-2005:

2000-2005 (Total):

PIPELINE INDICATORS

Pipeline performance indicator P2: [PROCESS]

Number of Products progressed to subsequent defined phases of discovery

Definition

Product: Molecule with potential for drug, vaccine or diagnostic development.

Discovery: a process that optimizes and identifies a candidate product for entry into development.

Defined Discovery phases : activities that define whether or not products can progress through decision points along the discovery pathway. These decision points are defined by the following:

Discovery phases:

- e) Target identification and validation
- f) Target adaptation for discovery (establishment of *in vivo* and *in vitro* screening and optimization)
- g) Identification of a 'lead' (compound, immunogen) worth optimizing as a development candidate;
- h) identification of a development candidate for entry into phase 0 (pre-clinical development).

Verification of Achievement

What will be measured:

Number of TDR supported products progressed from one phase to the next phase of discovery, i.e.:

1. From (b) adaptation for discovery to (c) identification of 'lead'
2. From (c) identification of 'lead' to (d) 'identification of development candidate'

How will it be measured:

The respective steering committee/PDT will review documentation for each particular discovery activity.

Who will measure [verify]:

The responsible Steering Committee Manager/Product Manager will prepare a report, based on the above, to be submitted through the appropriate functional coordinator and then to SMTeam / Director before going to STAC.

Quantification

Achievements & Targets (Duration of Strategy): *(In preparation)*

2002-2003:

2004-2005:

2000-2005 (Total):

PIPELINE INDICATORS

Pipeline performance indicator P3: [PROCESS]

Number of Products progressed to subsequent defined phases of development.

Definition

Product: drug, vaccine or diagnostic.

Development: a process that takes a candidate product to a point where it can be manufactured, produced and sold, either as a new entity or for a new indication.

Defined phases : activities that define whether or not products can progress through decision points along the discovery and development pathway, as described in the Product Development Plan. These decision points are defined by the following:

Development phases:

Phase 0: pre-clinical development

Phase 1: entry into man;

Phase 2: clinical proof of principle;

Phase 3: pivotal studies for regulatory approval

Verification of Achievement

What will be measured:

Number of TDR supported products progressed from one phase to the next phase of development, i.e.,

- I. Transition from Phase 0 to phase 1
- II. Transition from Phase 1 to Phase 2
- III. Transition from Phase 2 to Phase 3

How will it be measured:

The respective steering committee /PDT will review documentation for each particular development activity.

Who will measure [verify]:

The responsible Steering Committee Manager/Product Manager will prepare a report, based on the above, to be submitted through the appropriate functional coordinator and then to SMTeam / Director before going to STAC.

Quantification

Achievements & Targets (Duration of Strategy): *(In preparation)*

2002-2003:

2004-2005:

2000-2005 (Total):

PIPELINE INDICATORS

Pipeline performance indicator P4: [PROCESS]

Number of Products that have progressed from registration [recommendation for use] to assessment of effectiveness and development for application in public health.

Definition

Product: drug, vaccine or diagnostic.

Development for application in public health: development of a systematic procedure or technique for public health intervention guided by a set of written instructions on use that cover general settings and/or conditions.

Assessment of effectiveness in public health: provision, through scientific research, of 'proof of principle' that the product, in a public health setting, is superior to products used previously or covers a need for which there is no previous comparator.

Verification of Achievement

What will be measured:

Number of products resulting from TDR funded research, which have moved from registration [or recommendation for use in the case of diagnostics] to assessment of usefulness and development for application in public health within the biennium.

How will it be measured:

The respective steering committee or product development team will review documentation for each particular development activity.

Who will measure [verify]:

The responsible Steering Committee Manager/Product Manager will prepare a report, based on the above, to be submitted through the appropriate functional coordinator and then to SMTeam / Director before going to STAC.

Quantification

Achievements & Targets (Duration of Strategy): *(In preparation)*

2002-2003:

2004-2005:

2000-2005 (Total):