TDR SUMMARY REPORT 2004-05
WITH AN OVERVIEW OF SOME KEY ACTIVITIES FOR 2006-07
LETTER FROM THE DIRECTOR

I am pleased to provide this report that identifies some selected achievements from TDR’s 2004-05 research activities, and ongoing activities that we believe will lead to notable achievements for the coming two years, 2006-07.

You will see within these topics a wide range of diseases. The main aspect linking these diseases is their association with poverty. Appropriately directed research can help break the cycle of poverty and disease that cripples many communities.

It is important to maintain focus on the immediate deliverables and outputs of our research activities, but ultimately, our goal is to have an impact – on human health and well being, and on the capacity of developing countries to drive and implement the innovations. So it is with great honour that in the first section of this report we outline four major examples of impact that resulted this year from many years of attention and commitment by the people and organizations whom we support and with whom we work.

Rob Ridley, Director, TDR
**TDR research leading to high impact**

**Plans for visceral leishmaniasis elimination**
Visceral leishmaniasis, also known as kala azar, is fatal within two years if untreated. One of the worst affected areas in the world, with 70% of all reported deaths, is in Bangladesh, India and Nepal. Based on new tools developed with support from TDR, these countries have now developed plans to eliminate this disease and at the 2005 World Health Assembly, their ministers of health signed a memorandum of understanding to eliminate visceral leishmaniasis on the Indian sub-continent by 2015.

**Stopping congenital syphilis**
Every year, at least half a million infants are born with congenital syphilis. Yet with the development of reliable and simple tests, the disease could easily be screened and treated at little cost by giving infected women a single dose of penicillin early in pregnancy. TDR has evaluated existing marketed diagnostic tests for syphilis and nine tests were put on the WHO procurement list. This led to a reduction in cost and to the development of national plans for the elimination of congenital syphilis in several countries.

**Confirming treatment safety for river blindness**
The TDR rapid assessment tool to detect communities that are highly infected with Loa loa has led to an improvement in onchocerciasis control, a disease that causes blindness and severe skin lesions. This test identifies populations where it is safe to use ivermectin, the drug that is central to controlling the disease. Distribution of the drug is now being re-established in many areas where it had previously been stopped.

**Ethical guidelines for clinical research**
The TDR supported Strategic Initiative to Develop Capacity for Ethical Review (SIDCER), begun in 1999, has led to new legislation in several south-east Asian and eastern European countries to improve and strengthen human subject protection during research. It has also led to the creation of national ethical review committees in several countries where these did not previously exist.
TDR supports research that can reduce poverty and ill health in developing countries. We do that by investing in the generation of new knowledge, through development of new tools and strategies, and through supporting people and institutions in developing countries. Below are a few highlights of achievements for 2004-05.

**NEW KNOWLEDGE**

**Genetic research on malaria mosquitoes**
Malaria is transmitted by mosquitoes, but a major research goal is to change that by genetically manipulating mosquitoes so that they cannot transmit the malaria parasite. There remain many ethical, legal and social issues to address with this approach. However, technically this long term research activity is progressing well and some studies now focus on how such mosquitoes might spread in the wild. Recent studies supported by TDR have demonstrated the fitness consequences of population cross-hybridization and the spread rate of the introduced genes in *Anopheles gambiae* under semi-field conditions. This information is of fundamental importance in predicting how well genetically modified mosquitoes might be integrated in the wild.

**Vaccine discovery for schistosomiasis (bilharzia)**
No vaccine has ever been developed for a human helminthic disease, such as schistosomiasis. TDR supported research has identified a promising antigen, SM14, that was patented in seven countries for use in developing a vaccine for intestinal schistosomiasis.

**Drug discovery for onchocerciasis (river blindness)**
Although there are now several public-private partnerships active in drug development for tropical diseases, there remains an important gap in the area of early drug discovery. TDR is taking a lead in this area through effective partnerships with the pharmaceutical industry. Recent successes in drug discovery include the identification of a compound that is a promising development candidate for a macrofilaricide, a drug that kills the adult worms. This is a top priority for onchocerciasis control.

**NEW AND IMPROVED TOOLS**

**Malaria drug can be used in very young children**
Young children and pregnant women are most at risk in malaria. However, the safety of using the new artemisinin-based antimalarial drug combination Coartem was not yet established in the youngest children with a weight below 15 kg. TDR studies carried out with Novartis, the drug manufacturer, have now provided the evidence that it is safe to give small children Coartem, currently the most widely used antimalarial drug combination. The label of use has been changed from a limit of 15 kilograms of weight down to 5 kilograms.

**Safety of drug co-administration for several neglected tropical diseases**
The control strategy for onchocerciasis (river blindness), lymphatic filariasis (elephantiasis), schistosomiasis (bilharzia) and intestinal helminths is based on mass treatment of the population at risk with low cost (or free) drugs. As the control programmes for these diseases use similar intervention strategies, often in the same populations, there is an increasing interest to integrate the mass treatment activities for the different diseases. However, it was not known whether the drugs used – ivermectin, albendazole and praziquantel – could be safely administered at the same time. TDR research has now established the safety of co-administering these drugs and has removed a major obstacle to integration.

**Diagnostics for tuberculosis**
Tuberculosis kills millions of people every year and there is an urgent need to improve case detection and treatment. Reliable diagnostics are essential and TDR has evaluated 19 serological diagnostic tests that are currently available on the market. The study showed that all of these tests had poor specificity or poor sensitivity and that none of them could be recommended for use in tuberculosis diagnosis. A negative finding, but very important for tuberculosis control.

**Diagnostics for visceral leishmaniasis**
Following the development of miltefosine as the first oral drug for visceral leishmaniasis, there is an increasing demand for improved diagnostics for this disease. The current diagnostic tests are very invasive and involve spleen or bone marrow.
aspirations. TDR has supported studies to compare simple rapid diagnostic tests and one of them, the rK39 dipstick test, was recommended for use in the visceral leishmaniasis elimination initiative in the Indian subcontinent. A positive finding in this case, and a very timely one.

NEW AND IMPROVED STRATEGIES

Cost effectiveness of artemisinin combination therapy in malaria control
Clinical trials have shown that artemisinin combination treatment (ACT) is much more effective than monotherapy. But ACTs are also much more expensive. A large scale study in South Africa has now shown that the increased efficacy of the drugs means it is still much more cost-effective to use ACTs. The introduction of ACTs dramatically reduced malaria cases and deaths, and the cost of each life saved was one-eighth that of conventional drugs.

Dengue vector control
Mosquitoes that transmit dengue breed in water containers near homes. Past strategies have focused on controlling this breeding by spraying all possible breeding sites but this has been costly. A nine-country study has shown that a simple survey method can rapidly identify the most productive types of water containers that are responsible for most of the mosquito breeding. The use of this method will allow for more cost-effective mosquito control by targeting the most productive water containers. The method is also useful as a survey tool to predict the risk of epidemics.

Lymphatic filariasis elimination
Previous TDR studies have demonstrated the effectiveness of mass treatment with a single dose of DEC or ivermectin, and a global programme for the elimination of lymphatic filariasis (LF) was launched in 2000. A main objective of the programme is to interrupt LF transmission using mass drug administration (MDA) but it was not known how many years of MDA would be required to achieve this. Longitudinal studies in India and Africa have confirmed the effectiveness of MDA but indicate that in most places, more than the currently suggested 4 - 6 years of MDA will be required to eliminate LF transmission. Eliminating transmission of the disease may prove to be more complex and difficult than first thought.

PARTNERSHIPS AND CAPACITY BUILDING

R&D partners and trainees
Over 1,000 scientists were funded by TDR in 2004-2005, and 77% of those were from developing countries that are affected by tropical diseases. TDR continues to support research training of scientists from developing countries and 15 trainees obtained an MSc and 45 trainees a PhD degree during the past two year period.

Institutional strengthening
One of the success stories of TDR’s institutional strengthening efforts is the Institute of Endemic Diseases (IEND) of the University of Khartoum, Sudan. Following five years of TDR support, the IEND now has state-of-the-art laboratory facilities and field sites, 22 scientists (15 with PhDs) and 11 technicians. IEND has become a mature research institution that has won competitive grants from TDR in the areas of pathogenesis and vaccines, and is obtaining competitive grants from other funding agencies. In recent years IEND scientists have made more than 50 contributions in peer-reviewed journals and are short-listed for a competitive 2.7 million Euro grant to study TB in eastern Sudan.

Forum for African Medical Editors (FAME)
A lot of useful research in developing countries is under-reported, in part because of a lack of quality and international accessibility of local scientific journals. Following meetings convened by TDR on this topic, FAME was established to find ways of sustaining medical research publishing in Africa and raising the quality, visibility and impact of African medical journals at national and international levels. It strives to promote best publishing practices and peer review methodology. Workshops for editors, authors and reviewers have been conducted and guidelines produced. The impact of the initiative will be monitored by an increased international abstracting of articles from the journals involved, such as through Medline.
TDR is active across a large number of research areas and diseases. Below are a few examples of the output anticipated in 2006-07.

**NEW KNOWLEDGE**

**Innovative approaches to insect vector control – tsetse fly genome**

African trypanosomiasis is a neglected disease that affects some of the poorest people in the world. It is transmitted by the tsetse fly (*Glossina*). TDR has facilitated the creation of an International *Glossina* Genomics Initiative which has leveraged funding for the sequencing of the *Glossina* genome. It is expected that the genome will be available by 2007 and that this will provide opportunities to develop radically new approaches to sleeping sickness prevention.

**Drug discovery – new leads to be identified**

New drugs are badly needed for neglected diseases. One of the most challenging aspects is the early innovation stage of discovering a new lead series of molecules. TDR is focusing on this by building partnerships and networks between academic labs that have the drug targets, and pharmaceutical companies that have libraries of compounds for high throughput screening. The activity includes a specific focus on helminth diseases such as schistosomiasis, onchocerciasis and lymphatic filariasis. One or two new lead series are anticipated by the end of 2007.

**NEW AND IMPROVED TOOLS**

**Discovery and product development in disease endemic countries**

For sustainable solutions to neglected diseases, scientists and institutions from affected countries need to play a greater role in innovation leading to product development. TDR supports initiatives to make this happen. A good example that could soon yield a valuable product is the development of a new diagnostic for visceral leishmaniasis by a company in India, based on a discovery by an Indian investigator. Now in clinical studies, data will be available in 2007 to enable a decision on its applicability in disease control.

**Diagnostics evaluation for public health**

Many of the diagnostic tests that are marketed and available in primary health care settings in developing countries are sold and used with little or no evidence of their effectiveness. This is because, unlike drugs, diagnostics are not subject to strict regulatory approval standards. During 2006 and 2007, TDR will evaluate rapid diagnostic tests for malaria, tuberculosis, dengue, schistosomiasis and sexually transmitted diseases in their intended settings of use, and make this data available to policy makers so that decisions can be made based on sound evidence.

**Treatment of helminth infections**

Praziquantel is the principal drug for schistosomiasis treatment. It is very effective against all forms of human schistosomiasis, but there have been increasing reports of reduced parasite susceptibility to this drug. So TDR is studying the efficacy and safety of alternative treatment regimens using higher doses of praziquantel and is evaluating a drug combination of praziquantel and oxamnique. The results will be available by 2007.

Ivermectin, the drug donated by Merck for onchocerciasis treatment, has brought the disease under control in many affected areas. The main limitation is that it only kills microfilariae, so a drug that kills the adult worms remains a top priority for onchocerciasis elimination. Results of a phase 2 study with a new drug moxidectin will be available at the end of 2007.

**Malaria drug development and treatment during pregnancy**

A top priority for malaria research is the development of new antimalarial drug combinations. A partnership between TDR, Medicines for Malaria Ventures and GlaxoSmithKline Inc., will complete phase 3 studies for the development of chlorproguanil/dapsone/artsunate (CDA) and, if all goes well, submit the regulatory dossier before the end of 2007.

Pregnant women are usually excluded from regulatory-type clinical trials but together with young children, they are most at risk of malaria. Information on the efficacy and safety of antimalarial drugs in pregnancy is desperately needed to guide treatment of pregnant women. TDR is supporting these studies, and results are expected in 2007 for chlorproguanil/dapsone (Lapdap) and Coartem.

**Treatment of TB/HIV co-infected patients**

Most tuberculosis patients in Africa are co-infected with HIV, and their management requires antiretroviral treatment of HIV as well as treatment
with TB drugs. TDR is supporting studies with several national tuberculosis control programmes in Africa on how best to utilize and combine first line treatments of anti-retroviral drugs and anti-tuberculosis drugs. Results of pharmacokinetic data will be available by the end of 2007 assessing issues of drug-drug interaction within a sub-Saharan African setting to establish if there are any safety concerns that need to be taken into account in later studies.

NEW AND IMPROVED STRATEGIES

VL elimination in Indian sub-continent
Bangladesh, India and Nepal have launched a joint initiative to eliminate visceral leishmaniasis from the Indian subcontinent by 2015. TDR is supporting research to determine the most cost-effective implementation strategies for case detection and management, and the optimal combination of these strategies with integrated vector management. Improved drug use, particularly in combinations to enhance effectiveness and prevent resistance, will also be assessed. The first results will be available in 2007.

Malaria home management using ACTs
Many malaria deaths in young children are due to failure to reach a health facility in time and start treatment within 24 hours after the onset of fever. A strategy for home management of malaria was developed by TDR and adopted by Roll Back Malaria. Following the change in malaria treatment policy from monotherapy to the new artemisinin combination therapy (ACT), TDR has launched a multi-country study on the feasibility, accessibility and safety of using ACTs in home management. The results will be available by mid-2007.

Integrated community-based intervention strategies
In many countries, especially in Africa, health systems cannot deliver interventions to all the people who need them. TDR studies have shown that community-based delivery strategies can greatly increase access, especially when communities are empowered to manage the process themselves. A multi-country study is determining to what extent this strategy, which has been so effective for ivermectin distribution in onchocerciasis control, can be used for integrated delivery of other community-based interventions against various helminth infections, malaria and tuberculosis. Preliminary results will be available by the end 2006, with final results by the end of 2007.

PARTNERSHIPS AND CAPACITY BUILDING

Capacity for project planning
Planning and managing a research project can be very complex. TDR has developed a course for project management in research. More than 100 African scientists have already been trained to better organize and manage their projects and strengthen their competitiveness in applying for research grants. A train-the-trainer programme and network is being developed and training material will be published on the TDR website in 2006. The course will be disseminated and expanded in the coming years.

KNOWLEDGE MANAGEMENT FOR TROPICAL DISEASES RESEARCH

Knowledge platform
Recent surveys have shown that scientists from endemic countries have great difficulty in accessing up-to-date scientific information and that this is a major obstacle to their effective participation in the global research effort. TDR is developing an on-line global knowledge platform for tropical diseases research that will include up-to-date information on research needs; activities and achievements; highlights of recent scientific publications; simplified access to published articles; news on tropical diseases research and control; review articles on critical issues; discussion forums and various resources including multimedia. The knowledge platform will be launched during the first half of 2007.
TDR brings people and organizations together. In the past two years, we have worked with hundreds of researchers and institutions across the world.

COUNTRIES OF RESEARCH PARTNERS


MAIN PHARMACEUTICAL PARTNERS 2004-05

Bayer (Germany)  Chemical Diversity Labs (USA)  Chemtura (US)  GlaxoSmithKline (UK)  Knoll Pharmaceutical Company (USA)  Lionex Diagnostics and Therapeutics (Germany)  Lupin (India)  Meiji (Japan)  Merck & Co (USA)  Novartis Pharma AG (Switzerland)  Paratek (USA)  Pfizer (USA)  Pharmacopeia (USA)  Princeton BioMolecular Research (USA)  Rapid Sensor Systems Ltd (UK)  RCC (Switzerland)  RP Scherer (USA)  Sanofi-Aventis (France)  Scanpharm (Denmark)  Serono (Switzerland)  TopoTarget (UK)  Wyeth (USA)  Zentaris GmbH (Germany)
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Total: 64,981,549
THE JOINT COORDINATING BOARD
JCB, 2006

TDR’s top governing body is the JCB. Its principal role is to coordinate the interests and responsibilities of all parties cooperating in TDR. It meets annually to review activities, evaluate progress and determine the budget.

JCB chair:
Dr Bijan Sadrizadeh
Iran (Islamic Republic of)

JCB vice chair:
Dr Jacques Laruelle
Belgium

4 co-sponsors
UNICEF
UNDP
World Bank
WHO

3 cooperating parties selected by the JCB
Iran (Islamic Republic of)
Sweden
United States of America

12 governments selected by TDR resource contributors
Belgium
Canada
Denmark
Germany
India
Japan
Luxembourg
Mexico
Netherlands
Norway
Switzerland
United Kingdom

12 governments selected by WHO regional committees
Cape Verde (AFR)
Central African Republic (AFR)
Cuba (AMR)
Panama (AMR)
Bahrain (EMR)
Djibouti (EMR)
Georgia (EUR)
Greece (EUR)
Bangladesh (SEAR)
Myanmar (SEAR)
Mongolia (WPR)
Philippines (WPR)
THE STANDING COMMITTEE

The Standing Committee oversees the management and financing of TDR and comprises the four co-sponsors – UNICEF, UNDP, the World Bank and WHO. It meets three times a year in March, June and October. The JCB chair and vice chair and the chair of STAC attend as ex officio participants.

THE SCIENTIFIC AND TECHNICAL ADVISORY COMMITTEE, STAC 2006

The STAC's function is to oversee TDR’s scientific activities, independently evaluating and recommending priorities. It consists of 15-18 scientists, selected on the basis of scientific or technical competence, and reports to the Joint Coordinating Board.

Professor Peter Martins Ndumbe (chair), Cameroon

Professor Hannah Akuffo, Sweden/Ghana
Professor Pascale Adukwei Allotey, Australia/Ghana
Professor Alan Fairlamb, United Kingdom
Professor Bernhard Fleischer, Germany
Professor Nirmal Ganguly, India
Professor Nouzha Guessous-Idrissi, Morocco
Professor Maria Guzman, Cuba
Professor Jie Chen, China
Dr Andrew Y Kitua, Tanzania
Dr Mary Ann D Lansang, Philippines
Professor Anthony David Mbewu, South Africa
Dr Niels Ørnbjerg, Denmark
Professor Michael R. Reich, USA
Dr Gill Samuels, United Kingdom
Professor Marcel Tanner, Switzerland
Professor Dyann F Wirth, USA

SCIENTIFIC STEERING COMMITTEES

TDR operates with a number of steering committees that provide technical advice and recommendation for funding. They meet on a regular basis to define priorities and review proposals.
TDR research led to 445 articles in peer-reviewed scientific journals in 2004-05, with almost 60% of them produced by scientists from disease endemic countries.

In addition, TDR produces scientific and technical reports, guidelines, and manuals. Below is a selected list, but all TDR publications and scientific articles are on the CD of this publication and on our website at www.who.int/tdr.

**BUILDING RESEARCH CAPACITY**

Effective project planning and evaluation in biomedical research
Training manual and step-by-step guide

FAME editorial guidelines
Published on behalf of FAME (Forum for African Medical Editors)

Handbook: Non-clinical safety testing

Operational guidance: information needed to support clinical trials of herbal products

Operational guidelines for the establishment and functioning of data and safety monitoring boards
SCIENTIFIC TECHNICAL REPORTS

African trypanosomiasis control: strategic review of traps and targets for tsetse flies and African Trypanosomiasis

Community participation and tropical disease control in resource-poor settings
Social, Economic and Behavioural Research. Special Topics No. 2

Dengue diagnostics: proceedings of an international workshop

Dengue fever: planning social mobilization and communication for prevention and control
A step-by-step guide prepared in collaboration with WHO’s Mediterranean Center for Vulnerability Reduction in Tunis, Tunisia

Filariasis: RNA interference as a means of identifying drug targets for filariasis
A WHO/TDR scientific working group. This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

Gender agenda in the control of tropical diseases: a review of current evidence

Globalization and infectious diseases: a review of the linkages
Social, Economic and Behavioural Research. Special Topics No. 3

Health policy and systems research in China
By Q Meng, G Shi, H Yang, M Gonzalez-Block, E Blas

Leishmaniasis: scientific working group meeting report. 2-4 February 2004

Leprosy: scientific working group meeting report. 26-28 November 2004

Malaria: scaling up home-based management, from research to implementation

Sexually transmitted infections: mapping the landscape of diagnostics

Tropical disease research: progress 2003-2004 Seventeenth programme report of TDR
<table>
<thead>
<tr>
<th><strong>Expected Result A: New Knowledge</strong></th>
<th>Achieved by biennium</th>
<th>Total strategy period 2000-2005</th>
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<td><strong>A2</strong> Number of patents resulting from TDR funded research and development</td>
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<td><strong>A3</strong> Number of outstanding advances in scientific knowledge</td>
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<td><strong>B1</strong> Number of new and improved tools receiving regulatory approval and/or label extensions or for diagnostics, recommended for use</td>
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<td>8 6</td>
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<td><strong>B2</strong> Number of new and improved epidemiological and environmental tools recommended for use in controlling neglected diseases</td>
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<td><strong>C1</strong> Number of new and improved intervention methods validated for prevention, diagnosis, treatment of infectious disease</td>
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<td><strong>D2</strong> Number of new and improved strategies for enhanced access to interventions developed, validated and recommended for use</td>
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<td><strong>E2.2</strong> Number of PhD/dotalcary degrees completed</td>
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<tr>
<td><strong>E2.3</strong> Number of persons trained in short courses</td>
<td>n.a 657 502</td>
<td>250* 1159**</td>
</tr>
<tr>
<td><strong>E3</strong> Number of research institutions in low income disease endemic countries strengthened</td>
<td>n.a 4 5</td>
<td>13 9**</td>
</tr>
<tr>
<td><strong>E4</strong> Proportion of partners who are from disease endemic countries out of the total number of partners engaged</td>
<td>60% 72% 79%</td>
<td>50% 70%</td>
</tr>
<tr>
<td><strong>E5</strong> Proportion of total new and significant scientific advances produced by scientists from disease endemic countries</td>
<td>37% 49% 57%</td>
<td>15% 48%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Expected Result F: Technical Information, Guidelines, Instruments and Advice</strong></th>
<th>Achieved by biennium</th>
<th>Total strategy period 2000-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F1</strong> Number of research instruments and guidelines for infectious diseases developed and published</td>
<td>7 13 18</td>
<td>n.d. 38</td>
</tr>
<tr>
<td><strong>F2</strong> Number of global research priority-setting reports for neglected infectious diseases published</td>
<td>0 2 2</td>
<td>n.d. 4</td>
</tr>
<tr>
<td><strong>F3</strong> Mean monthly number of page views to the TDR web site</td>
<td>51,808 133,968 296,061</td>
<td>n.d. 160,612</td>
</tr>
<tr>
<td><strong>F4</strong> Number of unsolicited requests for research guidelines and instruments</td>
<td>n.a 3,912 6,046</td>
<td>n.d. 9,958</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Expected Result G: Resource Management</strong></th>
<th>Achieved by biennium</th>
<th>Total strategy period 2000-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>G1</strong> Resources for research, product development, and capacity building priorities mobilized</td>
<td>US$ 56.0 million</td>
<td>US$ 71.3 million US$ 67.2 million 60% increase 24% increase</td>
</tr>
</tbody>
</table>

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* Target for immunology training only
** Reported total for 2002 to 2005 only
n.d. Target not defined in strategy document for 2000-2005
TDR MISSION

• To improve existing approaches and develop new ones for preventing, diagnosing, treating, and controlling tropical diseases.

• To strengthen the research capability of countries where tropical diseases occur so that they can lead the development of new and improved approaches.

For more information on TDR, visit our website at www.who.int/tdr

The CD below has complete details on all the strategic performance indicators listed to the left.
TDR

TDR is a programme that funds and promotes international scientific collaboration. For almost 30 years, TDR has been targeting a wide range of diseases that primarily affect the poor. The programme sets priorities in health research, identifies needs and opportunities, and acts on these through basic research, discovery research, product development, implementation research and research capacity building in disease endemic countries.

www.who.int/tdr