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Planned actions to deliver on the aims of the Research Movement to Stop TB

1. Rationale for establishing the Research Movement

Progress in global TB control is constrained by the lack of effective new "tools" (diagnostics, drugs and vaccines). The diagnosis of most cases of pulmonary TB relies on 19th century technology, namely sputum microscopy (developed by Robert Koch in 1882) and radiography (based on X-rays discovered by Röntgen in 1895), the only TB vaccine (BCG) was first used in 1922, and the last new anti-TB drug to be widely introduced was rifampicin in the 1970s. The Stop TB Partnership and WHO are promoting the development of better technologies for preventing TB and improving the diagnosis and treatment of TB through its three Working Groups on new tools development. The Working Group on New TB Diagnostics, the Working Group on New TB Drugs, and the Working Group on New TB Vaccines has each developed its own ten-year strategic plan in contribution to the overall Global Plan to Stop TB, 2006-2015. There is scope for the three R&D Working Groups to work together on issues of common interest (e.g. stimulating basic research, regulatory processes, trial capacity, and re-tooling).

The development of the Research Movement to Stop TB was mandated in 2006 by the Stop TB Partnership Coordinating Board and WHO's TB advisory body (Strategic and Technical Advisory Group). The increasing recognition of the importance of TB research is reflected by the incorporation of the need to enable and promote research as a key element of WHO's new Stop TB Strategy launched in 2006. The Research Movement represents an opportunity for the Stop TB Partnership and the WHO to engage the full range of TB researchers in a collaborative and concerted strategic effort to increase the scope, scale and speed of TB research. Research across a wide spectrum is necessary to speed up progress in global TB control. Key areas of research include the following:

1. making the most of current approaches to TB control through epidemiological, programmatic, health systems, health economics and policy research;
2. developing new tools for TB control (diagnostics, drugs and vaccines);

3. improving our understanding of the basic science that underpins the development of new tools and that will enable the revolution in TB control technology needed to achieve the goal of TB elimination by 2050.

Successfully developing the Research Movement as a broad alliance of all those involved in TB research depends on engaging the full range of researchers. These include not only those already engaged as members of the Partnership's R&D Working Groups and implementation Working Groups, but also those involved in basic research in academic and other research institutions, and those involved in operational (programme) research.

2. Role of the Research Movement regarding global funding of TB research

The recent assessment by the Treatment Action Group indicates that TB research globally remains severely under-funded,¹ despite a significant boost in funding in the past few years for research and development for new tools. Besides the funding gaps related to the three main R&D areas defined in the Global Plan to Stop TB, 2006-2015 (new diagnostics, drugs and vaccines),² the "downstream" operational research for assessment of innovations within existing health systems and the "upstream" basic research that underpins new product development are under-funded. For each of the new tools (diagnostics, drugs and vaccines) the development pathway has a high attrition rate. The chances of a successful product emerging from the end of the development pipeline depend at least in part on the number of potential products entering the pipeline. Increased investment is necessary not only in product research and development but also in basic research to "keep the pipeline stocked".

One of the aims of the Research Movement is to help mobilise increased resources for TB research. In persuading key donors to increase TB research funding, the following steps will be helpful: a) an analysis of what influences the research funding environment; b) developing and articulating the arguments for increased funding for TB research, supported by an assessment of the current funding picture and trends in funding and of the expected benefits of increased investment in research; c) planning for how the Partnership can advance these arguments through the Research Movement to persuade research funders and the "funders of funders" to increase TB research funding.

3. Developments to date

3.1 Development of prioritised global TB research agendas

3.1.1 Global TB research agenda

Special Programme for Research and Training in Tropical Diseases (TDR). Report of the Scientific Working Group meeting on Tuberculosis, 3-6 October 2005, Geneva, Switzerland. TDR/SWG/06.

¹ Treatment Action Group. Tuberculosis research and development: a critical analysis. New York, 2006.

² Stop TB Partnership and WHO. Global Plan to Stop TB, 2006-2015. WHO/HTM/STB/2006.35. Geneva, 2006.

Within the context of this global TB research agenda, global programmatic research agendas have been developed in the areas of TB/HIV, MDR-TB and childhood TB.

3.1.2 TB/HIV

WHO. TB/HIV research priorities in resource-limited settings. WHO/HTM/TB/2005.355

3.1.3 MDR-TB

Stop TB Working Group on DOTS-Plus for MDR-TB. A prioritised research agenda for DOTS-Plus for multidrug-resistant tuberculosis. *Int J Tuberc and Lung Dis* 2003; 7 (5): 410-414

3.1.4 Childhood TB

WHO. A research agenda for childhood tuberculosis. WHO/HTM/TB/2007.381

3.2 *Assessment of TB research funding*

Treatment Action Group has made a preliminary assessment of current TB research and development funding.

An assessment of trends in TB research funding was published on 6 March 2007 (Kaufmann S, Parida S. Changing funding patterns in tuberculosis. *Nature Medicine*; 13 (3): 299-303).

3.3 *Raising awareness of the Research Movement*

3.3.1 Development and launch of Research Movement webpage

The Stop TB Partnership Secretariat developed and launched the Research Movement webpage (<http://www.stoptb.org/researchmovement/>) in March 2007.

3.3.2 Profile of Research Movement raised during World TB Day events 2007

Presentations and discussions at World TB Day events in, e.g. New York, Brussels, Berlin, and Rome, helped to raise the profile of the Research Movement in the TB community and the media.

3.4 *Engagement with key research partners*

The Partnership Secretariat and WHO are constructively engaged in discussions with a wide range of partners, including NGOs (e.g. Médecins Sans Frontières, Treatment Action Group), research funding institutions (e.g. including Medical Research Councils in the UK and South Africa), academic institutions, and other institutions (including the

Rockefeller Foundation) in order to build consensus on the aims of the Research Movement and the strategic approaches to achieve these aims.

The Partnership Secretariat and WHO have begun a constructive engagement with the European Commission Directorate-General for Research, including a visit of Hannu Laang (Scientific Officer, Poverty-related Diseases) to Geneva on 14 March 2007 to discuss opportunities for collaboration.

Discussions are under way with Tikki Pang (WHO Director, Research Policy and Cooperation) on the development of the new WHO research strategy, to which the WHO Stop TB Department is contributing, and the inter-relationship between the new WHO research strategy and the Stop TB Research Movement.

4. Planned activities

4.1 Mobilising increased global funding for TB research

Developing an approach to persuade key research funders to increase funding for TB research involves several steps: 1) assessing research needs, priorities and gaps; 2) understanding the research funding environment; 3) developing and articulating the arguments for increased funding for TB research (based on an assessment of the current funding picture and trends in funding, and of the expected benefits of increased investment in research; 4) planning how partners and the Partnership collectively can engage research funders with the aim of increasing TB research funding.

4.1.1 Assessing research needs, priorities and gaps

This should build on TDR's relative advantage in developing the global TB research agenda (Report of the Scientific Working Group meeting on Tuberculosis, 3-6 October 2005, Geneva, Switzerland. TDR/SWG/06).

4.1.2 A proposed analysis of the factors that influence the research funding environment.

The Stop TB Partnership secretariat will put out a tender for a consultant to analyse the factors that influence the research funding environment.

4.1.3 The development and articulation of the arguments for increased TB research funding, supported by an assessment of the current funding picture and trends in funding and of the expected benefits of increased investment in research.

4.1.3.1 Assessment of the current funding picture and trends in funding

The Stop TB Partnership secretariat will put out a tender for global tracking of TB research and development funding, building on the first survey done by Treatment Action Group.

An assessment will be made of global expenditure on operational research, using the WHO network of regional and country offices. Data on this expenditure will be collected through the annual monitoring and evaluation questionnaire that is sent to each country, with the collected data being published in the annual WHO Global TB Report.

4.1.3.2 Assessment of the expected benefits of increased investment in research

Assessment of the expected benefits of increased investment in research involves an appraisal of the expected outcomes of the different areas of research. The expected benefits of investment in new diagnostics, drugs and vaccines are set out in the long-term strategic plans of the Partnership's Research and Development Working Groups. There is a need to articulate the expected outcomes of basic research (in terms of improving the chances of successful development and application of new tools, including the new tools needed to revolutionise TB control and reach the 2050 goal of TB elimination) and of applied research (epidemiological, programmatic, health systems, health economics and policy research).

4.1.4 Development of plans for how research partners and the Partnership collectively can advance these arguments through the Stop TB Research Movement to persuade research funders and the "funders of funders" to increase TB research funding.

4.2 Building consensus on the Research Movement's strategic approach to achieving aims

The Partnership Secretariat and WHO will continue and widen their ongoing engagement with key research partners in order to build consensus on the aims of the Research Movement and the strategic approaches to achieve these aims. Opportunities are being explored for bringing key research representatives together, e.g. Bellagio meeting in collaboration with the Rockefeller Foundation; Research Movement forum at the IUATLD conference on lung health in Cape Town, 8-12 November 2007.