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**DOCUMENT FOR STAG-TB 2007 ON WHO'S ROLE IN THE STOP TB  
PARTNERSHIP'S RESEARCH MOVEMENT TO ELIMINATE TB**

## **1. INTRODUCTION**

A process of consultation is under way to guide the development of the Stop TB Partnership's Research Movement. In line with its mandate to promote research, WHO is playing a lead role in the development of the Research Movement and therefore also in this process of consultation, under the overall auspices of the Stop TB Partnership. The Strategic and Technical Advisory Group (STAG) meeting provides an opportunity for STAG to review the role of WHO in the Research Movement. The outcome of STAG's discussions will help to inform the Stop TB Partnership Coordinating Board's decisions as to the Research Movement's strategic direction, goal and activities.

The purpose of this document is to provide the background to the development of the Stop TB Partnership's Research Movement in preparation for STAG to provide guidance on WHO's role.

## **2. STOP TB PARTNERSHIP'S RESEARCH MOVEMENT GOAL AND OBJECTIVES**

### **Stop TB Partnership's Research Movement Goal**

The goal is to stimulate, support and expand research to ensure the elimination of TB as a global public health problem by 2050.

### **Stop TB Partnership's Research Movement Objectives**

- i) To provide leadership and advocacy to mobilize increased resources to support a coherent and comprehensive global TB research agenda.
- ii) To provide a forum for funders and implementers of TB research to coordinate plans and actions with the result of ensuring that research needs are addressed, opportunities prioritized, and gaps filled.



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**Objective I: To provide leadership and advocacy to mobilize increased resources to support a coherent and comprehensive global TB research agenda.**

The recent assessment by the Treatment Action Group indicates that TB research globally remains severely under-funded,<sup>1</sup> 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),<sup>2</sup> 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".

In persuading key donors to increase TB research funding, the following steps will be helpful:

- a) Developing and articulating the arguments for increased funding for TB research and development;
- b) Assessing current funding levels and trends;
- c) Estimating the research funding gap and describing the expected benefits of increased investment in research;
- d) Coordinating plans for how Partners and the Partnership can advance these efforts to engage and persuade research funders to increase TB research funding and stimulate new approaches.

Collaboration between the Research Movement and the Inter-Governmental Working Group on Public Health, Innovation and Intellectual property (IGWG) provides an opportunity for the Research Movement to contribute to the development of innovative financing mechanisms for research and development.

**Objective II: To provide a forum for funders and implementers of TB research and development to coordinate plans and actions with the result of ensuring that research needs are addressed, opportunities prioritized, and gaps filled.**

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

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



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In seeking increased support for funding of a coherent and comprehensive TB research agenda, the Research Movement must indicate the new research opportunities that could be funded if new support were made available. The need for a comprehensive, global multi-partner TB research agenda has been articulated: "ultimately, a comprehensive research agenda for TB research and development is needed which is global; encompasses all major funders of TB research and development; incorporates basic science, epidemiology and transmission, and operational research as well as applied science targeting the discovery and development of new TB diagnostics, drugs and vaccines; links research funding with operational programs in high TB and TB/HIV burdened countries; explicitly states resource needs and gaps; and proposes strategies to meet these needs and fill these gaps" (Mark Harrington in letter of 27 April 2007 to Anthony Fauci, Director, United States National Institute of Allergy and Infectious Diseases). In developing such a comprehensive global TB research agenda, it will be necessary to identify ways of promoting coherence between the different parts of the research spectrum, e.g. between basic research and development of new tools (diagnostics, drugs and vaccines). The Stop TB Partnership has established the "Retooling Task Force" to promote coherence between development of new tools and their operational evaluation in the field.

### **3. RATIONALE FOR THE RESEARCH MOVEMENT**

Progress in global TB control is constrained by the lack of effective new tools, including effective, affordable and accessible 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 the 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 was mandated in 2006 by the Stop TB Partnership Coordinating Board and WHO's TB advisory body, STAG-TB, in view of the importance of research in speeding up progress towards achieving the Partnership's



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targets for 2015 and the goal of TB elimination by 2050. The increasing recognition of the importance of TB research is reflected by the inclusion of research as a key element of WHO's new Stop TB Strategy launched in 2006, and by the resolution at the World Health Assembly in May 2007, that included the request to the Director-General to enhance WHO's role in research. The Research Movement represents an opportunity for the Stop TB Partnership and WHO to engage the full range of TB researchers, TB program managers, and affected communities in a collaborative and concerted strategic effort to increase the scope, scale and speed of TB research across the continuum linking basic research, development of new tools, and operational research.

## 4. RESEARCH MOVEMENT SCOPE AND STAKEHOLDERS

### Scope

Research across a continuum is necessary to speed up progress in global TB control. Key areas of research on the continuum include the following:

- Basic research for discovery;
- Applied research focusing on the development of new tools to better detect, prevent and cure TB control, including new diagnostics, drugs and vaccines;
- Operational and program-centered research to optimize the use of current strategies and tools and to operationalise the introduction of new ones by linking their use with epidemiological, operational, behavioral, social, health systems, health economics and policy research.

### Stakeholders

Under the auspices of the Stop TB Partnership, the Research Movement will mobilize a broad alliance of stakeholders involved in TB research and development. These include those involved in basic research in academic and other research institutions, in applied research, in operational research, and among end-users of research, i.e. implementers of TB control interventions in the field, as well as those Stop TB partners already engaged as members of the Partnership's new tools and implementation Working Groups.

## 5. RESPECTIVE ROLES OF WHO AND STOP TB PARTNERSHIP

The development of the Research Movement is under the aegis of the Stop TB Partnership. WHO has played a lead role in establishing the Research Movement, since



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the goal and objectives of the Research Movement are fully consistent with WHO's global mandate to promote TB research. WHO's role in the Research Movement reflects four key developments:

- The incorporation of "promoting and enabling research" as one of the six elements in WHO's new Stop TB Strategy which will be crucial to reaching the international TB control targets for 2015;
- The contribution of the Stop TB Department to the process of developing WHO's new research strategy (coordinated by the Department of Research Policy and Cooperation) that highlights the need for WHO to have a coherent approach to research across the organization;
- The emphasis that the Director-General has put on research as one of the six priorities on WHO's agenda for the next five years;
- The endorsement by the World Health Assembly in May 2007 of the resolution "Tuberculosis control: progress and long-term planning", that includes the request to the Director-General to enhance WHO's role in TB research.

## 6. ACTIVITIES UNDERTAKEN TO DATE UNDER THE OVERALL SCOPE OF THE RESEARCH MOVEMENT

<b>Objective I: To provide leadership and advocacy to mobilize increased resources to support a coherent and comprehensive global TB research agenda.</b>	
<i>Assessment of TB research funding</i>	Treatment Action Group has made a preliminary assessment of current TB research and development funding (Treatment Action Group. <i>Tuberculosis research and development: a critical analysis</i> . New York, 2006).
	An assessment of trends in TB research funding was published on 6 March 2007 (Kaufmann S, Parida S. Changing funding patterns in tuberculosis. <i>Nature Medicine</i> ; 13 (3): 299-303).
<i>Raising awareness of the need to boost TB research</i>	Presentations and discussions at World TB Day events in, e.g. New York, Brussels, Berlin, Rome, and Paris helped to raise the profile of TB research in the TB community and the media.
	Development and launch by the Stop TB Partnership Secretariat in March 2007 of Research Movement webpage ( <a href="http://www.stoptb.org/researchmovement/">http://www.stoptb.org/researchmovement/</a> )
<i>Assessment of the expected benefits of</i>	The expected benefits of investment in new diagnostics, drugs and vaccines are set out in the long-term strategic



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<i>increased investment in research</i>	plans of the Partnership's new tools Working Groups (Global Plan to Stop TB, 2006-2015. WHO/HTM/STB/2006.35. Geneva, 2006).
<i>Providing information for advocacy</i>	The Research Movement is working closely with the Partnership's Working Group on Advocacy, Communications, and Social Mobilization (ACSM) to develop key messages and promote their dissemination.
<b>Objective II: To provide a forum for funders and implementers of TB research and development to coordinate plans and actions with the result of ensuring that research needs are addressed, opportunities prioritized, and gaps filled.</b>	
<i>Development of global TB research agendas</i>	<p>The Global Plan to Stop TB, 2006-15, includes the strategic plans of the new tools Working Groups.</p> <p>Recent reports addressing different parts of the overall global research agenda include:</p> <ul style="list-style-type: none"> <li>• WHO. TB/HIV research priorities in resource-limited settings. WHO/HTM/TB/2005.355;</li> <li>• Stop TB Working Group on DOTS-Plus for MDR-TB. A prioritized research agenda for DOTS-Plus for multidrug-resistant TB. Int J Tuberc and Lung Dis 2003; 7 (5): 410-414 (now being updated and including the response to XDR-TB);</li> <li>• WHO. A research agenda for childhood TB. WHO/HTM/TB/2007.381</li> <li>• 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.</li> </ul> <p>National TB research agendas, e.g. NIAID Research Agenda on MDR/XDR-TB; US government TB R&amp;D agenda under development by the TB Task Force (including CDC, NIH and USAID).</p>
<i>Engaging key research stakeholders</i>	Discussion of the Research Movement at STAG (June 2006) and at the meetings of the Stop TB Partnership Coordinating Board in Abuja (April 2006), Jakarta (November 2006) and Geneva (April 2007) to develop the strategic direction.





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	<p>Consultation and engagement with a wide range of partners, including the Working Groups, research funding institutions (e.g. including NIH, European Commission Directorate-General for Research, and the Medical Research Councils in the UK and South Africa), bilaterals (e.g. USAID, DFID), Foundations (e.g. Gates, Rockefeller), NGOs (e.g. Médecins Sans Frontières, Treatment Action Group), academic institutions, and TDR.</p>
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## 7. FUTURE PROPOSED ACTIVITIES UNDER THE OVERALL SCOPE OF THE RESEARCH MOVEMENT

<p><b>Objective I: To provide leadership and advocacy to mobilize increased resources to support a coherent and comprehensive global TB research agenda.</b></p>	
<p><i>Assessment of TB research funding and the funding gap</i></p>	<p>In 2008 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 TAG.</p> <p>Global expenditure on operational research will be assessed using the WHO M&amp;E system. Data on this expenditure will be collected through the annual M&amp;E questionnaire sent to each country, with the collected data being published in the annual WHO Global TB Report.</p>
<p><i>Raising awareness of the need to boost TB research</i></p>	<p>The Partnership Secretariat is identifying opportunities for raising the profile of TB research, e.g. at the 2008 Global Ministerial Forum on Research for Health (Bamako, 17-20 November 2008) and at scientific conferences and through the media.</p>
<p><i>Assessment of the expected benefits of increased investment in research</i></p>	<p>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 revolutionize TB control and reach the 2050 goal of TB elimination) and of applied/implementation research (epidemiological, programmatic, health systems, health economics and policy research).</p>
<p><i>Contributing to the development of innovative financing</i></p>	<p>Collaboration between the Research Movement and the Inter-Governmental Working Group on Public Health, Innovation and Intellectual property (IGWG) provides an</p>



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<i>mechanisms for research and development</i>	opportunity for the Research Movement to contribute to the development of innovative financing mechanisms for research and development.
<i>Coordinating plans for how Partners and the Partnership can persuade and engage funders</i>	Consultation among partners to coordinate plans and tactics for how individual Partners and the Partnership collectively can engage and persuade funders to increase TB research funding and stimulate new approaches.
<i>Providing information for advocacy</i>	The Research Movement will continue to work closely with the Partnership's Working Group on ACSM to provide information for advocacy.
<b>Objective II: To provide a forum for funders and implementers of TB research and development to coordinate plans and actions with the result of ensuring that research needs are addressed, opportunities prioritized, and gaps filled.</b>	
<i>Development of global TB research agendas</i>	It will be necessary to update the global TB research agendas that have been developed so far, and ultimately contribute to the development of a comprehensive global research agenda for TB research.
<i>Engaging key research stakeholders</i>	The Partnership Secretariat and WHO will continue and widen their ongoing engagement with key research stakeholders, including the Partnership's new tools Working Groups, to build consensus on how to achieve the Research Movement's goal and objectives. Opportunities are being explored to bring key research representatives together, e.g. Research Movement forum at the IUATLD conference on lung health in Cape Town, 8-12 November 2007; Bellagio meeting in collaboration with the Rockefeller Foundation.
	The Partnership Secretariat and WHO will explore with relevant partners a proposed meeting to bring together private and public sector researchers and identify common interests and establish a platform for coherence.
	Ongoing, at least two/ three HLM to research funders (NIH, Wellcome Trust, ECTD) in 2008 and initiatives (e.g. Global Health Forum for Research, Bamako meeting).





## 8. WHO'S ROLE IN RESEARCH MOVEMENT PROPOSED ACTIVITIES

Research Movement proposed activity	WHO role
<b>Objective I: To provide leadership and advocacy to mobilize increased resources to support a coherent and comprehensive global TB research agenda.</b>	
Assessment of TB research funding (for operational research)	Part of M&E system
Raising awareness of need to boost TB research	World Health Assembly resolution, WHO research strategy
Providing information for advocacy	Raising profile of need for research including research on XDR
Contributing to development of innovative financing mechanisms	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
Assessment of expected benefits of increased investment in research	Collaboration with Stop TB Partnership secretariat
Planning to engage and persuade key funders to increase research funding	Regular networking with research funders
<b>Objective II: To provide a forum for funders and implementers of TB research and development to coordinate plans and actions with the result of ensuring that research needs are addressed, opportunities prioritized and gaps filled.</b>	
Development of global TB research agendas	Contribution to development of research agendas of implementation WGs and subgroups, reflecting expressed needs of countries
Engaging key research stakeholders	In line with WHO mandate



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## 9. QUESTIONS TO STAG

- Does STAG agree with the overall approach emerging from the process of consultation?
- Does STAG agree that the specific activities proposed will serve to meet the Research Movement's objectives?
- Does STAG agree with WHO's role in the proposed activities?

## 10. NEXT STEPS

STAG chairperson to inform the Stop TB Partnership Coordinating Board of the outcome of discussions to contribute to the Board's decisions as to the Research Movement's strategic direction, goal and activities.