

**Report on the Stop TB Working Group on Diagnostics Meeting
Palais des Congrès, Paris, France
29 October, 2004**

Objectives

1. To review the history of the Stop TB Working Group (WG) on Diagnostics - progress, setbacks, new developments
2. To provide participants with an overview of FIND/TDR¹ strategic agenda and workplan for the development of new TB diagnostic tests, highlighting areas for collaboration and overlap with WG member interests.
3. To identify knowledge, communication and resource gaps that can be addressed in the framework of the WG and its Members
4. To discuss mechanisms/strategies to achieve improved and sustainable

¹ Foundation for Innovative New Diagnostics is the lead agency of the STOP TB Working Group on Diagnostics UNICEF/UNDP/World Bank/WHO/Special Programme for Research and Training in Tropical Diseases (TDR)

communication between various stakeholders² in diagnostic development and across R&D WGs (Diagnostics, Drugs, Vaccines).

5. To discuss the role of WG members in advocating for new TB diagnostics and to define the priority messages
6. To reconstitute a core Diagnostics WG and expand membership to other interested public and private sector groups.

Presentations-Discussions	Highlights	Actions to be taken	Actors
1. Welcome and introduction	The importance of revitalizing the commitment of the WG in order to reach the goals of the Stop TB partnership was stressed. In addition, the creation of FIND was mentioned as a means to accelerate the introduction of new diagnostic technologies in the public sector of developing countries.	Ensure that annual WG meeting are conducted and that WG participants are updated on a regular basis.	TDR FIND
2. Overview of the Stop TB partnership and the significance of the WG	It is important that the research and development WGs (Diagnostics, Drugs, Vaccines) collaborate with the other Stop TB WGs and that they play an active role in the Stop TB partnership since it has direct links with countries, lead organizations and financial donors. For demonstration and evaluation projects and eventual scale-up of new diagnostic tools, collaboration with other WGs would be essential.	Continue to play an active role within the Stop TB partnership and collaborate closely with other WGs.	WG Participants
3. The DOTS expansion WG	One of the main constraints of the DOTS expansion WG is the weak laboratory capacity in countries. Today developing		

² academics, commercial, end-users

	countries are not using the newer diagnostic tools available but rely on sputum smear microscopy. Again the importance of collaboration between the WGs was stressed.		
4. Becoming a better advocate	In order to explain diagnostics issues to members of the other WGs, policy makers, donors etc. the message must be made simple. Diagnostics must be put in a context and should not be made complicated. The TB control areas with most attention today are MDR-TB and TB/HIV. Diagnostics for these areas could serve as an entry point for explaining the overall impact of better treatment success and increased case detection.	A resource mobilisation plan should be developed. The Stop TB advocacy and communication WG could assist with communicating the message of diagnostics.	TDR FIND STOP TB WG Advocacy
5. The global plan to Stop TB	<p>The 2015 Millennium Development Goals (MDGs) are to halve the TB prevalence and deaths. To achieve these goals, the second global plan to Stop TB will be developed. The Stop TB partnership is coordinating the work and it is based on the contributions from the seven Stop TB partnership WGs.</p> <ul style="list-style-type: none"> • Each WG should to develop its workplan in contribution to the Global Plan. • The secretariat of each WG should facilitate the contribution of the WG. <p>Possible scenarios on how regions and the world can reach the MDGs should be developed. The WGs should develop long-term workplans based on the scenarios containing milestones, timelines and budget.</p>	The secretariat of the WG to coordinate the development of the diagnostics WGs contribution to the second Global Plan to Stop TB.	STB Secretariat All WG Participants; TDR - focal point

<p>6. FIND/TDR strategic approach and workplan</p>	<p>The Diagnostics WG has been working without a coordinated strategy for tool-directed research, coordination of field site strengthening, diagnostic trial registration and standardization and a consensus on phase IV research priorities. FIND is working between discovery/research and distribution to drive the development of new diagnostic tools. In order to achieve this, FIND/TDR is creating an enabling infrastructure for development, evaluation and demonstration of new tools. The top three priorities for tool development are all within the area of improving case detection of active TB. The key issue in health clinics is to develop a test which is more sensitive than AFB smear. In more central units of the health system the key issue is to find a test that is faster than culture. FIND has agreements with two companies developing the TK media and a phage replication assay for detection or drug susceptibility testing.</p>		<p>FIND/TDR and partners</p>
<p>7. Laboratory strengthening</p>	<p>The laboratory strengthening subgroup is working to improve laboratory work on all levels of the TB laboratory network in developing countries. Laboratories in a number of countries have been assessed. Common for all assessed countries were that smear microscopy, culture and DST were deficient in availability, capacity and reliability in all countries. The subgroup is participating in the development of a global strategy to improve the capacity of TB diagnostic services. The subgroup is planning to organize a consortium meeting for improving smear microscopy.</p>	<p>Planned activities</p> <ul style="list-style-type: none"> • Continue lab assessment in ISAC region and TB high burden countries • Organize consortium meeting for improving smear microscopy • Organize two training sessions for the lab management training for managers of national reference labs • Finalize development of Standard Operating Procedures (SOP) guidelines 	<p>DOTS Expansion - Lab Subgroup</p>

		<ul style="list-style-type: none"> • Finalize development of standardized training curricula for AFB smear microscopy and quality assurance • Development of standardized training curricula for culture, DST and lab management 	
8. The Working Group and planning future activities	<p>The organizational structure of the WG is suggested to be as follows:</p> <ul style="list-style-type: none"> • A chair (G. Roscigno) and secretariat (J. Cunningham) • A core team with focal points for the different areas (industry, national reference laboratories, public research institutes, academia and donors). • Four proposed subgroups: <ul style="list-style-type: none"> ○ Discovery research ○ Diagnostics trials ○ Market-entry ○ Advocacy (may not be a subgroup but needs focal points for the larger WG) <p>The progress of the WG should be monitored through quarterly reports and an annual report.</p>	<ul style="list-style-type: none"> • Planned activities for the WG are: <ul style="list-style-type: none"> ○ Annual meetings of the WG meeting and the core group ○ Contribution to the Global Plan to Stop TB II ○ Compile and publish inventory of WG members, TB diagnostic activities and clinical trial sites ○ Develop a website containing: inventories, strategic agenda, meeting information and reports, guidelines, <i>in vitro</i> diagnostics regulatory policies, discussion forums, possibilities to inform on results on research into new diagnostic tools. ○ Develop and publish advocacy materials 	
9. Identifying gaps and	Suggested Activities, initiatives	Comments	

setting WG priorities			
	A website should be created for publishing negative results, that are not published in peer reviewed papers, on new technologies, ideas and evaluations could be published.		
	Nanotechnologists should be encouraged to join the TB efforts.		
	Guidelines for when frozen specimens could be used should be created.		
	Holdings of specimens that a laboratory is willing to share should be registered on a website.		
	The focus of the WG should be on finding a replacement test, not an add-on test to existing tests.		
	Focus should be put on finding ways to preserve specimens for transportation to specialized test centres.		
	The WG should either find low-tech solutions or augment the capacity of developing countries in order for them to be able to use technologically more advanced methods.		
	The WG should work for common ethical rules in EU.		
	The WG should have an independent group of experts setting up draft guidelines for the use of new tools and lobby governments around the world to implement the guidelines.		
	The WG should go through an independent body to streamline grant funding for initiatives like this.		
	Capacity to perform demonstration projects should be developed in developing countries. The industry should have access to the sites to perform projects by paying for the service.		
	More evaluation sites are needed.		
	Laboratories that have the capacity to perform clinical trials should be able to announce that on the website.		
	One objective of the projects run by the WG should be to foster the trial sites in research.		
	If a number of commercial and non-commercial actors can collaborate a critical mass will be reached so that a good laboratory infrastructure can be set up on trial sites.		
	More effort should be put into finding funding for using existing but expensive test until new cheap tests have been developed.		
	The WG should go to European & Developing Countries Clinical Trials Partnership (EDCTP) and push for diagnostics. Diagnostics should not be put as a subgroup to drugs.		

	<p>Focal points should be appointed for the different areas of the WG.</p>	<p>Focal point Volunteers are:</p> <ul style="list-style-type: none">○ National Reference Laboratories – Fadéla Boulahbal○ Industry – Peter Wrighton-Smith, David Laconi, BD, Biotec, Salubris,○ Public Research Inst – Tom Shinnick, Stefan,○ Academia – Peter Godfrey-Faussett and Ruth McNerney, LSHTM	
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