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**The Stop TB Partnership Working Group on New Drugs  
Proposed Summary Biennial Work Plan 2008-2009  
Submitted to The Stop TB Partnership Coordinating Board, October 12, 2007**

**Summary:** The Stop TB Partnership Working Group on New Drugs (WGND) is a forum to facilitate global collaborations for the development of new TB drugs. The goal of the WGND is to meet the targets of the Global Plan to Stop TB 2006-2015, as described in the WGND Strategic Plan. The following document outlines the four areas of work the WGND proposes to prioritize during 2008 and 2009. A list of proposed activities and is given for each area of work. The total estimated budget is provided at the close of the document. Estimated budgets for each activity and proposed contributions from the Partnership and the TB Alliance (the lead agency of the WGND) are provided as an appendix.

**Priority Area 1: Support Global R&D for New TB Drugs**

Objective A

Promote coordination among researchers to support the advancement of the global TB drug pipeline.

Activities

- Organize and co-sponsor annual symposia on recent advances in TB drug development. Symposia will be held in conjunction with the IUATLD World Conference on Lung Health, and feature WGND member activities;
- Gather and disseminate data on TB R&D projects and resource needs through the WGND activity mapping project. The project comprises comprehensive mapping of the global TB drug portfolio via a web-based survey. Results will be updated annually, made available to WGND members and e-published on the WGND website.

Objective B

Support development of appropriate trial site capacity for the clinical evaluation of new TB drug candidates.

Activities

- Perform assessment of funding needs for clinical trial site capacity building.

Objective C

Promote research resulting in development of biomarkers, surrogate endpoints and animal models.

Activities

- Contract and publish a review on the state of the art of biomarkers;
- Organize or co-sponsor a symposium on biomarkers, surrogate endpoints and animal models.

Objective D

Identify strategies to evaluate new TB drugs for the treatment of MDR- and XDR-TB

#### Activities

- Sponsor and help to organize meetings of the WGND MDR/XDR Task Force;
- Sponsor publication of documents produced by the WGND MDR/XDR Task Force;
- Develop a research agenda for improving outcomes of treatment of MDR and XDR-TB;
- Identify the most efficient path to new drug regimens for MDR and XDR-TB;
- Integrate animal and preclinical research with clinical trials design;
- Stimulate funding for clinical trials of MDR- and XDR-TB treatment by providing a defined pathway for the future;
- Define compatibility between antiretrovirals and drugs for MDR treatment.

#### **Priority Area 2:**

**Promote development of harmonized regulatory guidelines for TB drug development, including drugs for treatment of MDR TB**

#### Activities

- Organize and co-sponsor annual Open Fora on key regulatory issues, with regulatory authorities, industry and WGND members present.

#### **Priority Area 3:**

**Promote dialogue between researchers and affected community representatives (ACRs) and ensure ACR participation in WGND projects**

#### Activities

- Sponsor travel of ACRs to WGND annual meetings, symposia on TB drug development and Open For a;
- Provide support and training to ACRs to facilitate their participation in meetings and WGND activities, including selection of additional ACRs;
- Solicit feedback from ACRs on WGND documents and projects.

#### **Priority Area 4:**

**Maintain communication and collaboration among WGND members, between Working Groups and between the WGND and the Retooling Task Force, the Partnership and the public.**

#### Activities

- Develop and publish an updated Strategic Plan;
- Provide annual reports detailing progress toward Global Plan milestones and indicators as outlined in the Strategic Plan;
- Produce regular WGND publications including a brochure, advocacy material and a quarterly newsletter. Maintain the WGND website;
- Retain the services of a full-time Secretariat;
- Convene an annual WGND meeting;
- Provide representation at key Partnership meetings and events;
- Convene a core group to oversee implementation of the Strategic Plan and assist in development of bi-annual Work Plans;
- Form additional subcommittees to put aspects of the Work Plan into action;
- Develop annual funding proposals and funding reports;
- Support the activities of the Retooling Task Force, for example the development of a target product profile for TB drug candidates.

**Total Estimated Budget for 2008 and 2009: \$398,500**

## Appendix

### The Stop TB Partnership Working Group on New Drugs Proposed Summary Biennial Work Plan 2008-2009 Estimated Budgets by Activity and Proposed Sources of Funding

<b>WGND Proposed Budget 2008</b>					
<b>Priority Area</b>	<b>Activity</b>	<b>Detailed Explanation</b>	<b>Partnership Contribution</b>	<b>TB Alliance Contribution</b>	<b>TOTAL</b>
1A	Symposium at IUATLD	Speaker travel and expenses, venue hire, AV, IUATLD admin fee	\$5,000.00	\$20,000.00	\$25,000.00
1A	WGND Activity mapping project	E-publication of survey results	\$1,500.00	\$0.00	\$1,500.00
1B	Assessment of funding for clinical trial sites	Study to be contracted	\$5,000.00	\$0.00	\$5,000.00
1D	XDR Taskforce	Taskforce meetings and teleconferences; publication of taskforce documents	\$30,000.00	\$0.00	\$30,000.00
2	Open Forum Contribution	venue hire, speaker travel, refreshments, AV	\$0.00	\$10,000.00	\$10,000.00
3	Affected Community Representatives	Travel to Annual meeting, symposium and open forum; training	\$17,500.00	\$0.00	\$17,500.00
4	Strategic Plan Update	Teleconferences of core writing group; printing costs	\$7,000.00	\$0.00	\$7,000.00
4	WGND Publications	Brochure printing	\$4,000.00	\$0.00	\$4,000.00
4	Working Group Support-staff	Full-time secretariat	\$20,000.00	\$52,000.00	\$72,000.00
4	Working Group Annual Meeting	venue hire, speaker travel, refreshments, AV, supplies, shipping	\$3,000.00	\$7,000.00	\$10,000.00
4	Travel to Partnership Meetings	Co-chairs' travel to CB mtgs; Secretariat travel to Annual meeting	\$5,000.00	\$10,000.00	\$15,000.00
4	Convene a core group	Four planning teleconferences	\$2,000.00	\$0.00	\$2,000.00
	<b>TOTAL</b>		<b>\$100,000.00</b>	<b>\$99,000.00</b>	<b>\$199,000.00</b>

### WGND Proposed Budget 2009

<u>Priority Area</u>	<u>Activity</u>	<u>Detailed Explanation</u>	<u>Partnership Contribution</u>	<u>TB Alliance Contribution</u>	<u>TOTAL</u>
1A	Symposium at IUATLD	Speaker travel and expenses, venue hire, AV, IUATLD admin fee	\$5,000.00	\$20,000.00	\$25,000.00
1C	Symposium on Biomarkers	venue hire, speaker travel, refreshments, AV, supplies, shipping	\$20,000.00	\$0.00	\$20,000.00
1D	XDR Taskforce	Taskforce meetings and teleconferences; publication of taskforce documents	\$30,000.00	\$0.00	\$30,000.00
2	Open Forum Contribution	venue hire, speaker travel, refreshments, AV	\$0.00	\$10,000.00	\$10,000.00
3	Affected Community Representatives	Travel to Annual meeting, symposium and open forum; training	\$17,500.00	\$0.00	\$17,500.00
4	Working Group Support-staff	Full-time secretariat	\$20,000.00	\$52,000.00	\$72,000.00
4	Working Group Annual Meeting	venue hire, speaker travel, community rep travel, refreshments, AV, supplies, shipping	\$2,500.00	\$7,500.00	\$10,000.00
4	Travel to Partnership Meetings	Co-chairs' travel to CB mtgs; Secretariat travel to Annual meeting	\$5,000.00	\$10,000.00	\$15,000.00
	<b>TOTAL</b>		<b>\$100,000.00</b>	<b>\$99,500.00</b>	<b>\$199,500.00</b>

**Total Estimated Budget for 2008 and 2009: \$398,500**