Update:
Working Group on New Vaccines

David Lewinsohn
Chair, Working Group on New Vaccines
United Nations General Assembly Will Convene Historic High-Level Meeting on TB with Heads of State

Stop TB Partners and Global Health leaders unite to support historic campaign towards a
The Stop TB Partnership

Global Partners' Forum

Global TB Drug Facility

Coordinating Board Partnership Secretariat

WHO Strategic & Technical Advisory Group

Global TB Drug Facility

DOTS expansion

TB/HIV

DOTS-Plus MDR-TB

New TB Vaccines

New TB Diagnostics

New TB Drugs

Advocacy Com. Soc. Mob.

Stop TB Partnership Secretariat hosted by WHO
About the Working Group on New Vaccines

The Working Group on New Vaccines supports the development of new TB vaccines by:

• Promoting collaboration and cooperation amongst multiple stakeholders
• Providing a forum to discuss challenges to TB vaccine R&D and identify solutions
• Helping to build consensus on key issues and questions related to TB vaccine R&D
• Serving as the mechanism of exchange and dialogue between the Stop TB Partnership and the research community
• Developing advocates for the development of TB vaccines
The New Tools Working Groups are the Stop TB Partnership’s only platform for engaging the TB research constituency, however

**Current funding levels are not sufficient to sustain the New Tools Working Groups**
Working Group Funding

Funding amount in USD provided by Stop TB Partnership to each working group

Thank You USAID!
Constituency Based Core Group

**Chair:** David Lewinsohn, Oregon Health and Science University (USA)

**Co-Chairs (Proposed):** Dara Erck (Aeras); Frank Verreck (TBVI)

**Field Sites:** Michele Tameris, South African Tuberculosis Vaccine Initiative (South Africa)

**Academic Institutions:** Vacancy

**Donors:** Willem Hanekom Bill & Melinda Gates Foundation (USA)

**Public Sector:** Katrin Eichelberg, NIAID/NIH (USA)

**Affected Communities:** Vacancy

**Private Sector/Industry:** Marie-Ange Demoitie, GSK Biologicals (Belgium)

**WHO:** Johan Vekemans, Initiative for Vaccine Research

**Aeras (standing member):** Sibusiso Hlatjwako (South Africa)

**TBVI (standing member):** Frank Verreck (The Netherlands)

**Secretariat:** Jennifer Woolley (USA)
Supporting the Partnership

- Increase Awareness of the Importance of New Tools (Vaccines)
  - Development of the Global Plan
  - Supporting the Partnership with advocacy materials and expertise
  - Presentations at the Partnership BOD meetings
    - NYC 2016
      - There is Nothing Latent about Latent TB
    - Berlin 2017
      - Vaccines
  - Supporting the Partnership in their meetings with ministers and other partners
- Kochon Prize 2017
The Cost of Inaction

- Guiding Principles
  - TB eradication not achievable without new tools
  - While tools not widely available in next 5 years, investments NOW are key
  - Harmonization with country settings
The Cost of Inaction (Complacency)

BY 2030, A FIVE-YEAR DELAY IN INVESTMENT FOR NEW TOOLS IS ESTIMATED TO RESULT IN:

1. **8.4 MILLION ADDITIONAL TB CASES**
2. **1.4 MILLION ADDITIONAL TB DEATHS**
3. **39.8 MILLION DALYs SUFFERED** (56.1 million without discounting)
4. **US$ 5.3 BILLION IN ADDITIONAL COSTS FOR TB TREATMENTS** (US$ 7.5 billion without discounting)
5. **US$ 181 BILLION IN LOST PRODUCTIVITY** (US$ 318 billion without discounting), valuing each DALY at per-capita GNI.

David Dowdy, Johns Hopkins University
Vaccines Working Group

• Members
  – Gavin Churchyard
  – Marie-Ange Demoite
  – Dara Erck
  – Mike Frick
  – Ann Ginsberg
  – Willem Hanekom
  – Frank Verreck
  – Jennifer Woolley

• Modeling
  – Angeline Nanni

• Review
  – Ellen Wilcox
  – Gerald Voss
  – Erna Balk
Document Development: A focus on Advocacy

• Goals
  – Tools or products leading to TB eradication
    • Adolescent vaccine

• Objectives & Milestones
  – Accomplishments that will enable the overarching goal
    • Short and long term
    • Measurable

• Resources
New Vaccines Strategic Framework 2016–2020

Vision: To develop new, more effective vaccines that will directly and safely prevent TB in all age groups and populations

Goals: Prevent TB disease and interrupt transmission through the development of new vaccines that would prevent infection, reactivation or reinfection; incorporate and consider access strategies throughout the TB vaccine development process; and strengthen community engagement in TB vaccine R&D.
Global Plan to End TB 2016-2020

**OBJECTIVE 1**
CONTINUE TO ADVANCE THE CLINICAL PIPELINE OF TB VACCINE CANDIDATES. This includes conducting clinical trials, exploring novel trial designs to identify promising vaccines, ensuring sufficient manufacturing and trial site capacity, and conducting epidemiological research at trial sites to optimize site selection and clinical trial design.

**OBJECTIVE 4**
IMPROVE ANIMAL MODELS. Refined animal models that better mimic human disease and/ or reflect natural TB transmission, and allow for the preclinical readout of vaccines that are possibly capable of preventing sustained infection, will be essential to the development of new and improved vaccines.

**OBJECTIVE 2**
ENHANCE KNOWLEDGE THROUGH EXPERIMENTAL MEDICINE. Several small, early-phase human studies of TB vaccine concepts should address specific scientific hypotheses and provide data to inform future vaccine development.

**OBJECTIVE 5**
IMPROVE PRECLINICAL AND CLINICAL READOUTS, STANDARDIZING REAGENTS AND HARMONIZING ASSAYS. This should include the use of advanced imaging in conjunction with immunological and transcriptional profiling in order to better define correlates of protective immunity.

**OBJECTIVE 3**
INCREASE EMPHASIS ON EARLY-STAGE AND DISCOVERY RESEARCH. Increased investment and focus on early-stage research, including the development of novel vaccination targets, will be essential to diversifying the TB vaccine portfolio, enhancing the knowledge and understanding of the pathogen, and identifying breakthroughs that will advance the field and accelerate the TB vaccine R&D process.

**OBJECTIVE 6**
LAY THE GROUNDWORK FOR ADOLESCENT AND ADULT VACCINATION CAMPAIGNS. This involves conducting strategic access and implementation research, including studies of cost-of-goods, TB cost-effectiveness, country vaccine readiness, and vaccine landscape.
## Milestones

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<tr>
<th>Enhance knowledge through experimental medicine</th>
<th>Develop and test a human challenge model to speed TB vaccine R&amp;D</th>
<th>Support consortium to advance human challenge model through development and preclinical phase, and initiate clinical phase</th>
<th>20</th>
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<tbody>
<tr>
<td>Complete human studies in parallel with NHP challenge in order to learn about protective immune responses</td>
<td>Conduct NHP challenge studies to determine correlates of protective immunity</td>
<td>100</td>
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<tr>
<td>Test key hypotheses about protective immune responses</td>
<td>Conduct multiple experimental medicine studies to test different hypotheses</td>
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<td><strong>Total Objective 2 – Experimental medicine</strong></td>
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<td><strong>220</strong></td>
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The only conference that brings together stakeholders from across the spectrum of TB vaccine R&D to
- Review progress and share the latest research and data
- Identify and promote innovative and transformative approaches to TB vaccine R&D
- Encourage partnerships and collaboration to accelerate TB vaccine R&D
- Increase global recognition of the critical role vaccines will play in global efforts to end TB

Convened by the Working Group on New Vaccines since 2010
- 2nd Global Forum – Tallinn, Estonia  September 2010
- 3rd Global Forum – Cape Town, South Africa  March 2013
- 4th Global Forum – Shanghai, China  April 2015

5th Global Forum planned for 20-23 February 2018 in New Delhi, India. Details to be announced shortly.
• Initiatives 2017

Advocacy
Goal

• Create advocates who can enable the R&D efforts needed for the successful discovery and implementation of TB Vaccines

Approach

• Recruit advocates for the coordinating board
• Use the Global Forum as an opportunity to enhance advocacy
  • Advocate training
  • Researcher training
Goal

• Create materials useful for promoting vaccine advocacy

Approach

• Participation in the “State of Vaccines” initiative
• Creation of materials for the partnership
• Development of WG website
• Track Progress on the GP (TAG)
Knowledge

Goal

• Provide a forum to discuss challenges to TB vaccine R&D and identify solutions

Approach

• The Global Forum
• Participation in “Out of the Box’ meetings
  • Aeras / NIH Meetings
  • TBVI Symposium
Partnership

Goal

• Improve the effectiveness of the WG in promoting partnership

Approach

• Broaden the WG membership
• Create a WG website
  • Broaden our members
  • Allow for the presentation of current vaccine candidates
  • Provide a forum for discussion
An Expanded Vision

Discussion

• How best to expand the WG membership?
• Where can it be most effective?
Thank you
Focus for 2017

Research
• Work with partners to develop a “state of the field” report
• Identify opportunities to support or convene meetings to discuss new approaches to TB vaccine R&D

Advocacy
• Expand the network of advocates for R&D
• Strengthen their knowledge and build their capacity to more effectively advocate for TB vaccine R&D
• Identify advocacy/affected community representative(s) to serve on Core Group
• Support initiatives that will raise the visibility, profile, and support for TB vaccine R&D (e.g., 2017 Global Ministerial Conference on TB, 2018 UN High Level Meeting on TB
• Develop advocacy and communication tools
• Consider opportunities to engage researchers as advocates

Operations
• Review and revise the Terms of Reference and operation procedures
• Develop and promote opportunities for broader engagement in the WGNV