

# Lilly's Commitment to TB



*Initiated in 2007*

## ***Lilly Not-For-Profit Partnership for TB Early Phase Drug Discovery***

Facilitate the discovery and development of clinical candidates for TB by bringing together leading academic investigators and drug discovery capabilities and expertise.

*Initiated in 2003*

## ***Lilly MDR-TB Partnership***

Focuses on expanded access for treatment of MDR-TB by technology transfer, concessionary pricing and working with the WHO. Improve training to maximize the effectiveness of existing drugs.

**Exploratory**

**Candidate**

**Clinical Development**

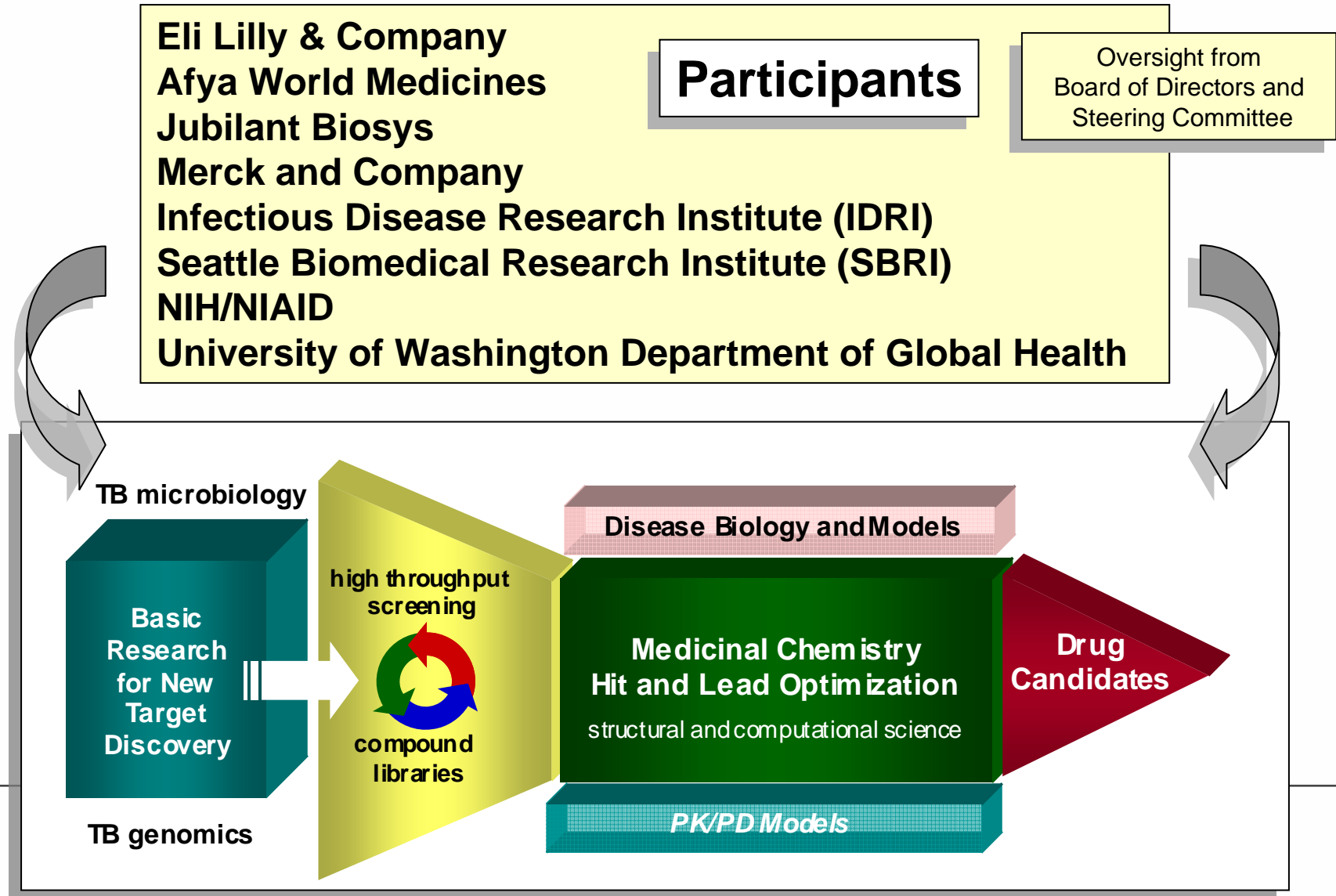
**Patients**

***Synergy with the Global Alliance for TB Drug Development***

# Lilly Not-For-Profit Partnership for TB Early Phase Drug Discovery

- Partnership announced by Eli Lilly & Co. in June of 2007.
  - Partnership will be based in Seattle, Washington and is centered on a close collaboration with the NIH and NIAID.
  - The Partnership brings medicinal chemistry and associated technologies into the network of academic and government sponsored researchers focusing on TB.
  - A primary goal of The Partnership is to actively integrate the key scientific disciplines necessary for the sustained discovery of new medicines for the treatment of TB.
  - The Partnership will work to enhance the early stage pipeline of the TB Alliance which focuses on accelerating the discovery and development of new TB drugs, as well as providing accessibility and affordability to patients in need.
  - Any profits from research will be returned to the 501(c) (3) organization.
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# Partnership Brings Together Key Scientific Leadership and Capabilities



# Lilly's Contribution to the Partnership

## ➤ **\$15MM to establish the Partnership**

- \$9MM USD in kind including fully equipped high throughput screening and medicinal chemistry laboratories, research tools, databases, and scientific and technical expertise.
- \$6MM USD in cash over 5 years to seed research activities.

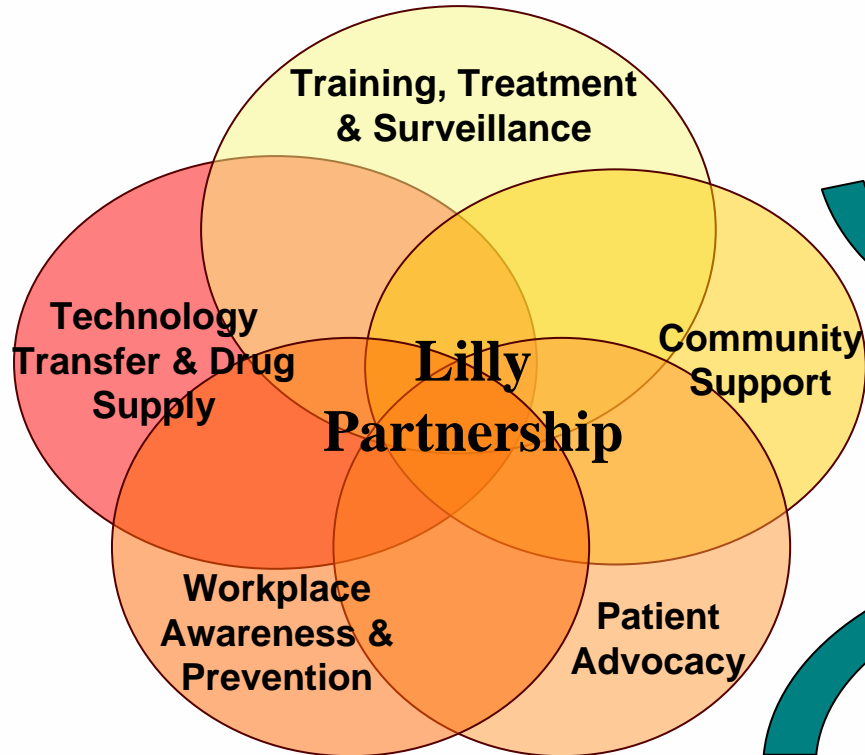
## ➤ **Access to ~500,000 Lilly compounds for screening against prioritized TB targets as well as the Lilly library of virtual compounds.**

## ➤ **Access to non-proprietary computational tools to aid in data analysis and modeling.**

## ➤ **Lilly Chemistry Steering Committee composed of six experienced drug discovery scientists representing the disciplines of medicinal chemistry, computational science and quantitative biology. This group will provide formal reviews and informal counsel to the Partnership.**

## ➤ **Discovery leadership participation on Partnership Steering Committee and Board of Directors.**

# The Lilly MDR-TB Partnership



***Reaching patients throughout the world***

- Brigham and Women's Hospital/PIH/Harvard
- Centers for Disease Control
- International Council of Nurses
- International Hospital Federation

- International Federation of the Red Cross & Red Crescent Societies
- Manufacturing plants:  
Hisun (China), Shasun (India),  
SIA (Russia), Aspen (South Africa)

- Purdue University (USA)
- World Economic Forum
- World Health Organization
- World Medical Association

# Characteristics of the Lilly Philanthropic MDR-TB Partnership

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- **Transfer of Technology to those countries with the highest disease burden (no strings attached); Russia, India, China, South Africa**
  - **Drug Supply at concessionary prices**
  - **Training tools for health care professionals/training of trainers**
  - **Involving communities and businesses in improving MDR-TB prevention and treatment adherence**
  - **Assistance to governments to design sound MDR-TB (DOTS-Plus) strategies**
  - **Strengthen surveillance systems to understand and handle drug resistance**
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# The Lilly MDR-TB Partnership

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## Technology Transfer

### Our Goal

- Share all Lilly's specific and general manufacturing knowledge.  
e.g. precise process controls (e.g. temperature); fermentation raw materials; transportation conditions; laboratory testing procedures; aseptic operational procedures
- Create self-sustaining centers of manufacturing excellence capable of providing additional products and employment.
  - these products provide examples of fermentation, chromatographic purification, synthetic chemistry, oral and injectable dosage forms
  - seek out additional products - unrelated to MDR TB - to provide additional revenue
- Support reliable producers to ensure an expanded multi-source availability of the two drugs.
  - provide capital grants for equipment and facility upgrades; provide additional specific high quality training through Purdue partnership
- Negotiate with manufacturing partners a "controlled price" for WHO sponsored purchasers to assure supplies of affordable drugs and sustainability of the business.

# The Lilly MDR-TB Partnership

## Technology Transfer

- Offers manufacturing firms in MDR-TB “hot spots” technology to produce *capreomycin* and *cycloserine* and provides training in GMPs and Good Business Practices.
- Provide a 10 full-time Lilly staff over 4 years on-site for technical assistance/training - insuring high standards and regulatory compliance.
- Facilities in China and South Africa will receive technology to produce *capreomycin*.
- Facilities in India and South Africa will receive technology to produce *cycloserine*.
- Lilly is pursuing opportunities to convert facilities in Russia for production of *capreomycin* and *cycloserine*.





# Lessons Learned

- **It is not just about products. It is making medicines matter. Medicines matter only when they reach the patient.**
  - **Magnitude of challenge of MDR-TB is so great no single player has the resources and incentives to manage the entire process whether it involves making existing drugs matter or developing new drugs.**
  - **Public/private partnerships make the impossible possible.**
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