



Partnerships in TB Vaccine Research & Development

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Aeras' Mission & the PDP Model

- Develop new, more effective TB vaccines and ensure their affordability and availability to all who need them, with particular focus on developing countries, where the need is most urgent.
- Non-profit with “Industrial Model of Vaccine Development”
- Public Private Partnerships with industry, academia, governments and others



Need for a New TB Vaccine

- Developed in the early 1900s, the current TB vaccine, BCG, has been ineffective in curbing the global TB epidemic - 1.8 million TB-related deaths & 9.3 million new cases of TB annually
- TB is the number one killer of people living with HIV/AIDS
- Drug resistance and TB/HIV co-infection are key barriers in bringing the epidemic under control
- Nearly half a million died from TB/HIV in 2007; more than 80 countries have reported multidrug-resistant TB
- TB primarily affects adults of working age and exacts a vast economic toll in treatment costs and in lost productivity (approx. \$16 billion)
- The World Bank estimates the loss of 4% to 7% of GDP in some countries

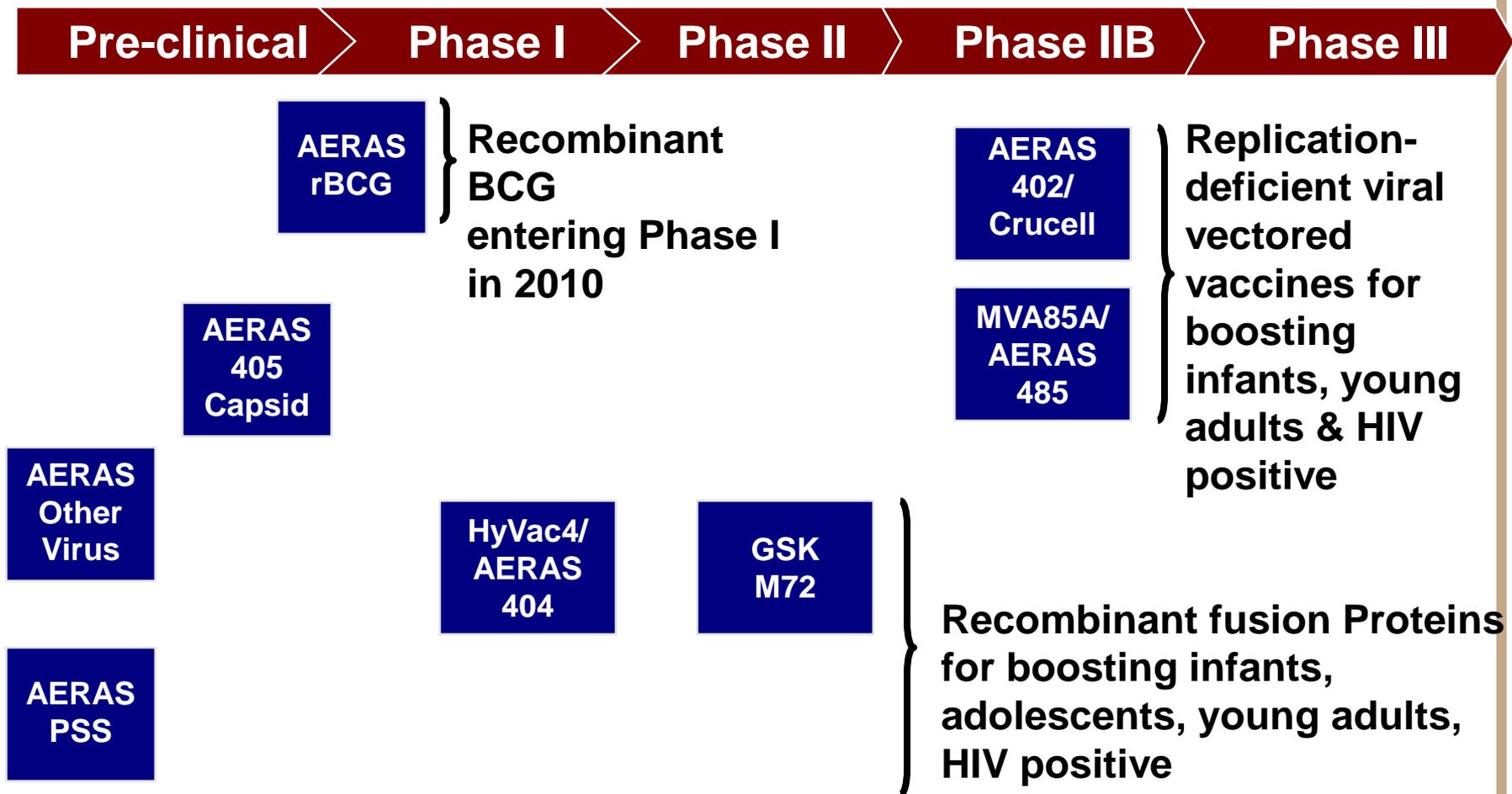
Human & Economic Toll of TB in South Africa

- South Africa is among the top 5 countries in the world with the highest number of TB cases
- More than one-third of the TB/HIV cases in Africa is in South Africa; drug resistant TB cases has more than tripled in South Africa in the past few years
- In 2008, over \$600 million were spent in TB control in South Africa



TB patient in South Africa
Photograph by David Rochkind

Aeras TB Vaccine Pipeline



Aeras Partnerships in Clinical Research



Why Develop Sites?

- Identify areas with high rates of TB
- Determine if site is suitable for large-scale trials
- Many endemic countries do not have adequate capacity to diagnose TB, collect and store blood specimens, or maintain Good Clinical Practice standards
- Need to train staff in study designs, ethical standards, informed consents, and other clinical research practices

India Site Before Site Development



India Site After Site Development



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Example of Capacity Building: South Africa

- **Partnerships with the South African Tuberculosis Vaccine Initiative (SATVI) & The Aurum Institute**
 - currently conducting clinical trials in infants and HIV+ adults
- **Site & Capacity development:**
 - State-of-the-art immunology laboratory
 - Highly skilled staff capable of maintaining the infrastructure and executing clinical research
 - Over 230 local staff trained in clinical trial research
 - Resource Center established in 2005
 - Quality Management System and electronic data capture mechanism
 - Most advanced site for large-scale TB vaccine trials in the world
- **Benefits: support community health & education; augment local skills and capacities; leverage infrastructure for other studies or health initiatives**



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Innovative Partnerships with Private Sector

- **Electronic Data Capture in Clinical Trials**

- **Challenges** - Internet connectivity not always available at trial sites; need to maximize data collection and prevention of data loss
- **Solution** – Aeras is utilizing innovative technologies such as, wireless low bandwidth mobile/cell phones and cell phone networks to capture cleaner data and transmit the data faster; data entry can be done anywhere
- **Partnerships** - Mobile phone companies can help support vaccine trials by donating data cards or airtime

- **TB Diagnosis in Epidemiology Studies**

- Becton, Dickinson and Company's Mycobacterial Detection Devices are being used in diagnosing TB at our field sites
- BD provides cost-savings through product discounts and donations of some reagents; Aeras trains local researchers on how to use new technology and equipments from BD



Innovative Partnerships with Private Sector

- **Other examples of possible partnerships with the private sector**
 - **Need for software to conduct statistical analysis of clinical trial data; cost-savings through subsidized license fees and additional licenses for multiple users**
 - **Need for vehicles to transport study participants and specimens**
 - **Need for computers, laptops, fax machines, printers, and other office supplies to set up offices for local staff**
 - **Need for diapers for infants participating in studies; snacks and meals for study participants**

Thank You!



*Please visit our website:
www.aeras.org*

*Feel free to contact me
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