



# Partnerships in TB Vaccine Research & Development

James E. Connolly  
President & CEO  
Aeras Global TB Vaccine Foundation

# 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

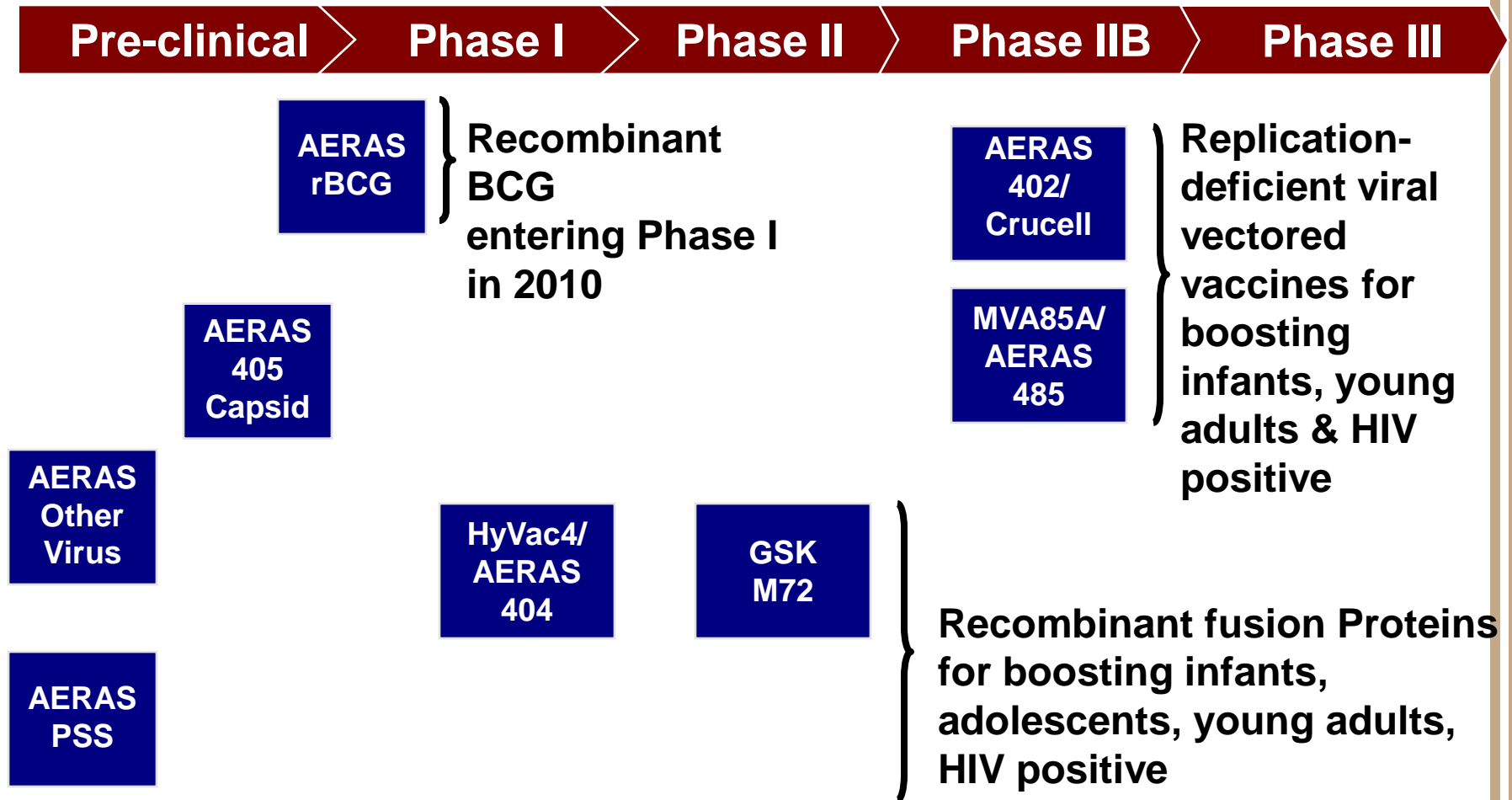
# Human & Economic Toll of TB in South Africa

- 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



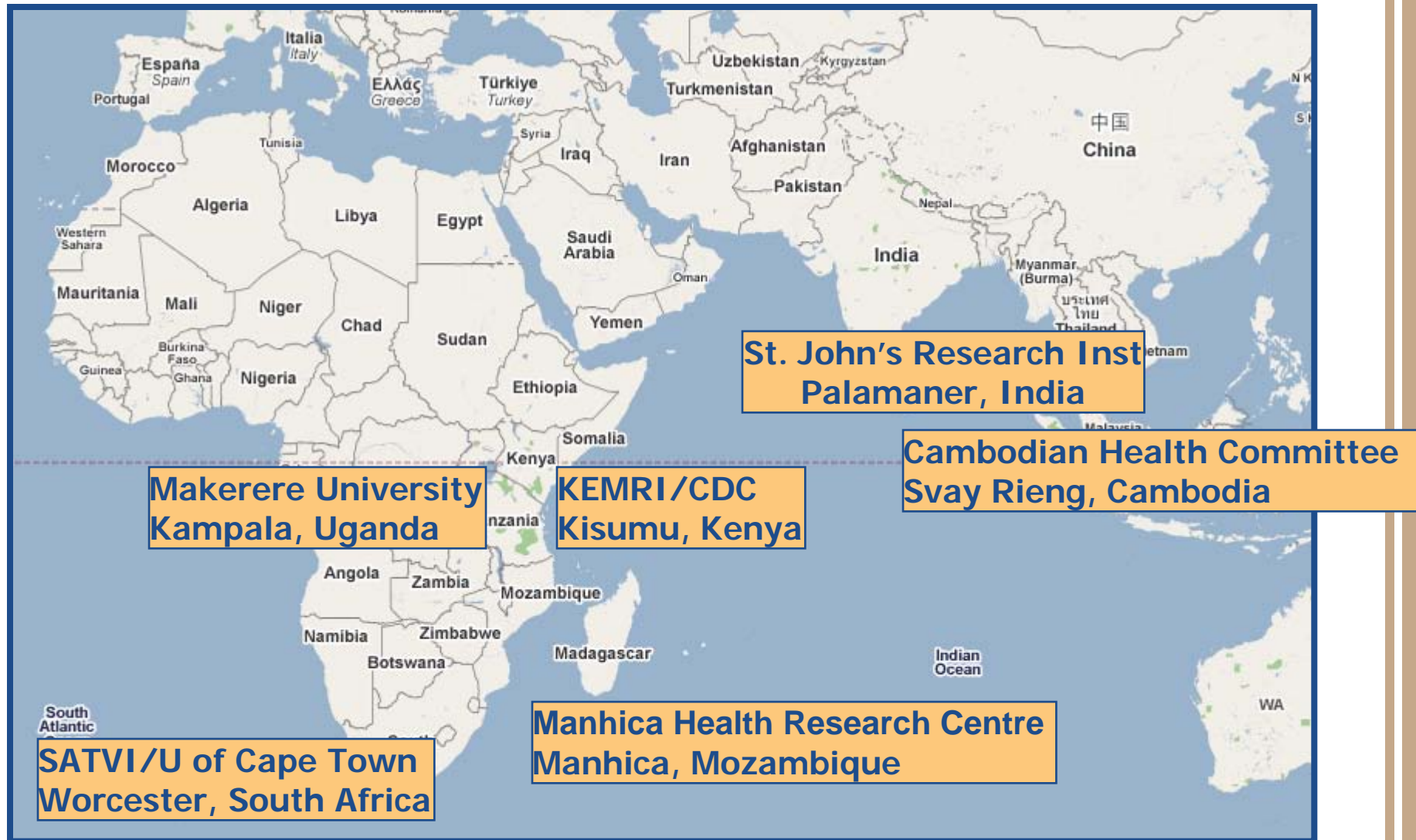
TB patient in South Africa  
Photograph by David Rochkind

# 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



# 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**



AERAS<sup>™</sup>

# 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](http://www.aeras.org)*

*Feel free to contact me  
with questions:  
[jconnolly@aeras.org](mailto:jconnolly@aeras.org)*

**AERAS**<sup>SM</sup>