

# Translational Research on Neglected Tropical Diseases

November 24-25, 2008

Questions and Issues

# Managing the Pipeline

- At Brazil's major research institutes and federal universities there is significant activity in the area of antigen discovery and the establishment of a robust pipeline of antigens
- At the same time, in Brazil there is very limited capacity for scale-up process development and manufacture
- This situation creates a "Funnel" effect
- How is the "Funnel" managed?
- What is the best way to ensure that only the best antigens and technologies move into development, manufacture, and clinical testing

# Prioritizing the Investment

- In order to ensure that more technologies translate and enter a clinical pipeline, where should investment be maximized in order to open up the funnel?
  - Scale-up process development?
  - Technology transfer?
  - cGMP pilot manufacture?
  - First-in-humans clinical testing?
- How should the investment be made?
  - Centralized core facilities?

# The Special Case of Scale-up Process Development

- This was identified as a key component of the “valley of death”
  - How should this be expanded?
  - How many PD facilities are required?
  - Separate facilities for recombinant proteins vs. live viral vaccines?

# National Training Needs

- Is there a need for Brazilian training programs in scale-up process development?
- Training programs for cGMP?
- Training programs for Phase 1 first-in-human clinical trials?

# National, Regional, Global Access

- National access
  - BioManguinhos and Butantan require government guarantees that they will purchase neglected disease vaccines
  - What are the mechanisms to ensure that Brazil MOH will support delivery and distribution of neglected disease vaccines
- Regional LAC access
  - What international policies are needed to ensure vaccines for helminths, leishmaniasis, etc will be delivered for all of LAC's poor?
- Global Access
  - What should be the best approach to licensure?
  - Registration in Brazil followed by WHO prequalification?
  - Role of DCVMN

# Engaging ANVISA and CONEP

- Timelines are slow
- How to best engage these bodies to promote more rapid turnaround?

# Veterinary Vaccines

- Role in human health
  - Food production
  - Zoonotic transmission
- Lower costs for veterinary vaccines?
- Focus on Brazil zoonoses?
  - Leishmaniasis
  - Chagas disease
  - Leptospirosis
  - Cysticercosis
  - Fascioliasis

# Partnerships

- Should the product development partnership model be expanded for Brazil?
- Sabin model?
  - FIOCRUZ
  - Butantan
- National Institute – CDTS?
  - FIOCRUZ-Genzyme
  - FIOCRUZ-DNDi

# Intellectual Property

- What should be the IP policies for NTD vaccines?
- Where should patents be filed outside of Brazil?
  - Innovative developing countries?
- Do patents help or hurt innovation?
  - Leptospirosis

# Breakdown in Brazil's R&D and Health Neglected disease investment

- Breakdown
- Ways to increase
- Selective increases