Texas Children’s Hospital
Center for Vaccine Development

A Product Development Partnership
Research Interests - Neglected Tropical and Emerging Infectious Diseases

- **Protozoa**
  - Chagas Disease
  - Leishmaniasis
  - Human African Trypanosomiasis

- **Viruses**
  - Rabies
  - Dengue & Chikungunya

- **Bacteria**
  - Buruli Ulcer
  - Leprosy
  - Trachoma
  - Yaws

- **Helminth**
  - Cysticercosis
  - Guinea-worm
  - Echinococcosis
  - Foodborne trematodiases
  - Lymphatic Filariasis
  - Soil-transmitted helminthiases
  - River Blindness
Mission: Advancing knowledge from basic sciences to the application in clinical & community settings

SUSTAINABLE DEVELOPMENT GOALS

INNOVATION

T0
Basic and applied science research
Preclinical and animal studies
Defining mechanisms, targets and lead molecules

T1
Translation to humans
Proof of concept Phase 1 clinical trials
New methods of diagnosis, treatment and prevention

Implementing

T2
Translation to patients
Phase 2 clinical trials Phase 3 clinical trials
Controlled studies leading to effective care

T3
Translation to practice
Phase 4 clinical trials and clinical outcomes research
Delivery of recommended and timely care to the right patient

T4
Translation to community
Population level outcome research
True benefit to society

Translation of new data into the clinic and health decision making

Population Health
Vision: To Select, Develop and Test Vaccine Target Antigens from Bench to the Clinic

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<th>Research &amp; Development</th>
<th>Preclinical</th>
<th>Manufacture and Toxicology</th>
<th>Regulatory</th>
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- Antigen discovery and structure evaluation
- Feasibility of expression and scale-up process development
- Technology transfer for cGMP
- Analytical development and quality control
- Quality Assurance and Regulatory
- IND filings with US FDA and other NRAs
- Phase 1 clinical testing
- Modeling/cost-effectiveness studies

From Pathogen to Vaccine to Community
Product Development Partnership Model

- Total Quality Management System
- Portfolio Management System
- Functional Units
- Collaborators and Partners

Ensuring Regulatory Compliance and Quality
- Ensuring rigorous scientific and operational management
- Driving the decision making and mitigating risk

Bridging critical stages from basic discovery to clinical evaluation

Working in partnership and building capacity

Ad-Hoc Advisory Boards
Institutional Evaluation and Support
• Portfolio management of 9-10 different vaccine programs
• Based on recombinant protein vaccine technologies
• Management of in-house expertise and global partnerships
• Programs span from discovery to clinical trials
• The only academic health-based PDP
Provide the scientific underpinnings to shape policy
Package it for the policymakers

NEW CONCEPT

“Translational Public Policy”
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