The Human Vaccines Project: Transforming Vaccine Development

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#P4C2014
The Human Vaccines Project

A bold new public-private partnership seeking to accelerate and transform global vaccine development by solving the principal scientific problem impeding the development of vaccines for many diseases:

How to generate specific and durable protective immune responses in humans.
Project Focus and Methods

**Focus**: Pre-competitive, transvaccinology space covering major infectious diseases and cancers, not on a single disease/product.

**Strategy**: Harness tech advances in bioinformatics, genomics and immune monitoring to:

- **Decipher the Human Immunome** creating a “parts list” of the human immune system for rational vaccine discovery.

- Conduct large numbers of *iterative, human clinical research studies* to systematically understand how to generate effective immune responses, and translate insights into vaccine design.

- **Create an enabling environment** to produce/test large numbers of immunogens in small exploratory clinical trials.
Project Goals

• Improve efficacy of selected licensed vaccines.
  – Emphasis on heterogeneous populations (infants, elderly and developing world populations).

• Expedite the development of new vaccines.
  – Chronic global killers such as AIDS, TB, malaria and selected cancers
  – Emerging epidemics needing rapid response (Ebola, Marburg, MERS).

• Redefine the requirements for licensure for future vaccines.
  – Identify and validate novel genetic and immune signatures correlating with vaccine safety and efficacy.
The Current Paradigm is Not Working

Vaccines which recently failed in efficacy trials:

- HIV
- TB
- Herpes Simplex
- Staph Aureus
- Melanoma
- Pancreatic Cancer

Cumulative Public and Private Development Costs: $Billions.

Projected number of deaths from major infectious diseases and cancers over next decade: 100 million.

We Can and Must do Better
Why Now?

• We have an unprecedented historical opportunity

• The biological sciences are going through a revolution driven by breakthrough technologies in genomics, computational biology and bioinformatics:
  • Systems biology, next generation sequencing, single cell mass spec, synthetic biology, nanotech, imaging tech, ‘omics…

• These technologies will allow us to systematically understand the human immune system and rationally design vaccines against some of our most intractable diseases.
Fundamental Principals

- Big Science Effort
- Precompetitive, transvaccinology space
- Nonprofit
- Honest broker able to partner across a wide range of global partners
- Research outcomes treated as a global good:
  - Significant data and material sharing
  - Flexible approach to IP that seeks to translate research breakthroughs into tangible global health outcomes
Business Model

- Independent nonprofit affiliated with a major research university
- Supported by smaller academic hubs with specific research expertise
- Center of a global consortium
- Parallel to and augmenting current disease specific efforts
- Significant engagement with industry
- Diversified funding base
Financing

Targeting Diversified Funding Base

- Foundations
- Startup Package Academic Center
- Industry
- Government (US and International)
- International Development Agencies
- Philanthropy
- State Economic Development Agencies
# Human Vaccines Project Steering Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Institution</th>
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<tr>
<td>Rafi Ahmed, PhD</td>
<td>Director, Emory Vaccine Center</td>
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<td>Carole A. Heilman, PhD</td>
<td>Federal Liaison, Division of Microbiology and Infectious Diseases, NIH</td>
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<td>Ripley Ballou, MD</td>
<td>Vice President, GlaxoSmithKline</td>
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<td>Marie-Paule Kieny, PhD</td>
<td>Assistant Director-General, World Health Organization</td>
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<td>Maharaj Kishan Bhan, MBBS, MD, DSc</td>
<td>Former Government Secretary India, Ministry of Science &amp; Technology</td>
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<td>Gary J. Nabel, MD, PhD</td>
<td>Chief Scientific Officer, Sanofi</td>
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<td>A.E. (Ted) Bianco, PhD</td>
<td>Director of Technology Transfer, The Wellcome Trust</td>
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<td>Stanley A. Plotkin, MD</td>
<td>Emeritus Professor of Pediatrics, University of Penn/Vaxconsult</td>
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<td>Mark M. Davis, PhD</td>
<td>Director, Institute for Immunity, Transplantation &amp; Infection, Stanford University School of Medicine</td>
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<td>Rino Rappuoli, PhD</td>
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<td>Ian Gust, AO, MD</td>
<td>Professional Fellow, The University of Melbourne</td>
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<td>Chris Wilson, MD</td>
<td>Director, Discovery &amp; Translational Sciences, Gates Foundation</td>
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Initial Workshops

La Jolla Scientific Workshop, February 2014
- 35 leading vaccine scientists endorsed the concept of a Project as: “meritorious, timely and potentially transformative”
- Laid down basis of scientific plan
- Estimated cost a minimum of $1 billion over a decade
- Outcomes published in Nature Immunology

New York Business Strategy Workshop, July 2014
- 20 management leaders from finance, law, industry, NGOs, and research institutes concluded the Project could: “transform disease prevention in the 21st century”
- Laid down basis of organizational structure, Outcomes in publication review

Stakeholder Workshop, 1Q 2015
- Stakeholder buy-in and launch
Next Steps

• Negotiation and selection of primary and secondary hubs (1Q15)
• Completion of full scientific and business plans (1Q15)
• Stakeholder meeting (1Q15)
• Expanded fundraising program (1Q15)
• Launch and establishment of permanent home (3Q15)
• Workshops (Cancer vaccines, Antigen Identification, Effective Immunity, Heterologous Populations). (2015)

• Engagement with global regulatory agencies (2Q15)
• Launch of Human Immunome Program (3Q15)
• Prep first human clinical research trials/pilot studies (3Q15)
• Establishment of Scientific Cores (3Q15)
• Completion of 5 yr. program plans (3Q15)
• Execution of global consortium agreement (2015)
• Expanded industrial partnerships (2015)
Conclusion

A successful Human Vaccines Project could make vaccine development faster, safer and more successful, while transforming global health by enabling the development of vaccines against some of our most difficult, pressing and intractable diseases.
How Partnering for Cures Participants Can Help

- Feedback
- Partnerships
- Funding
- Advocacy
- Spreading the Word