The role of public-private partnerships in advancing vaccine technologies and improving vaccine effectiveness and delivery for developing countries

Ray Cummings
PATH

Follow this and additional works at: http://dc.engconfintl.org/vaccine_iv

Part of the Biomedical Engineering and Bioengineering Commons

Recommended Citation
http://dc.engconfintl.org/vaccine_iv/15

This Conference Proceeding is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Vaccine Technology IV by an authorized administrator of ECI Digital Archives. For more information, please contact franco@bepress.com.
The Role of Public-Private Partnerships in Advancing Vaccine Technologies and Improving Vaccine Effectiveness and Delivery for Developing Countries

Ray Cummings, MS, MBA
Senior Business Officer
Vaccine Technology Group
Vaccine Technology IV
Albufeira, Portugal
May 21, 2012

PATH
About PATH

PATH is an international nonprofit organization that seeks to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.

PATH has 1,100 employees in 34 offices in 23 countries.
Use of Funds by Area of Focus

PATH programs in vaccines, vaccine technologies, and immunization account for over one-third of PATH’s total annual budget: US$305 million for 2012.
Vaccines for Developing Countries

• To be broadly and effectively used in developing countries, vaccine products should be:
  - Affordable.
  - Optimized for the intended conditions of distribution, storage, and use.
  - Acceptable to recipients.
  - Easily and safely prepared and delivered.

• Vaccine product attributes needed for developing-country markets may be quite different from those for developed-country markets.
Key Drivers

- Vaccine technologies can help achieve product attributes needed in developing-country settings:
  - Adjuvants and vaccine delivery technologies can significantly reduce the dose and, therefore, the cost of vaccines.
  - Delivery technologies can improve safety and ease of use.
  - Formulation and processing technologies can improve vaccine thermostability, minimizing vaccine wastage and allowing use of vaccines with greater independence from the cold chain.

- Various government agencies and philanthropic foundations have recognized the important role vaccine technologies can play in creating vaccine products that meet developing-country needs.
Presentation Outline

- This presentation will provide an overview of:
  - Collaborative public-private partnerships created with funding from government agencies and foundations to advance vaccine technologies.
  - Examples of technical advancements achieved by public-private partnerships.
  - Common elements of projects.
  - Global access considerations.
Why Public-Private Partnerships?

• Public-private partnerships can bring together entities with expertise in specific technologies, biological testing, product development, global public health policy, and regulatory affairs to enhance the relevance and success of research and development.

• Combining existing, complementary areas of expertise can shorten timelines and reduce development risk.

• Partnerships are particularly important when traditional corporate economic considerations do not drive innovation and development for developing-country health needs.
# Vaccine Stabilization Projects

<table>
<thead>
<tr>
<th>Grantee/Contractor</th>
<th>Funder</th>
<th>Total Funding</th>
<th>Award Date</th>
<th>Project Partners</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hilleman Laboratories</td>
<td>Merck; Wellcome Trust</td>
<td>$130 million</td>
<td>Sept. 2009</td>
<td>Medicine in Need (MEND)</td>
<td>Develop affordable vaccines for low-income countries. Currently working to develop thermostable rotavirus vaccine.</td>
</tr>
<tr>
<td>MEND</td>
<td>Bill &amp; Melinda Gates Foundation (BMGF)</td>
<td>$3 million</td>
<td>Feb. 2010</td>
<td>Sanaria</td>
<td>Stabilize Sanaria’s PfSPZ malaria vaccine to simplify manufacturing, transportation, and storage.</td>
</tr>
</tbody>
</table>
| PATH                     | BMGF                                | $13.6 million | Sept. 2003 | Aktiv-Dry; Arecor; Aridis; Crucell; IIL; 
|                          |                                     |               |            | Niro; U. Col.; Wuhan; etc. (more than 30 collaborators) | Evaluate the technical and commercial feasibility of applying stabilization methods to vaccines used in developing country immunization programs. Heat and freeze stabilization with both EPI and new vaccines. Hep B, DTP, Hib, measles vaccines. |
| PATH                     | BARDA                               | $9.4 million  | July 2010  | Aridis; Arecor; U. Kansas; Tulane U.  | Test multiple technologies to increase shelf life of subunit and live-attenuated influenza vaccines to facilitate stockpiling and use. |
| Sabin Vaccine Institute  | BMGF                                | $13.8 million | Sept. 2006 | GWU; U. Kansas; Baylor; Butantan Inst. | Research and development of bivalent hookworm vaccine, including research on antigen stabilization. |
| Soligenix, Inc.          | NIAID                               | $9.4 million  | Nov. 2009  | U. Colorado; U. Kansas; Tulane U.; Battelle. | Consortium funded to develop thermostable technology to advance RiVax™ (ricin toxin vaccine) and other rapidly-acting vaccines. |
| Stabilitech              | DTRA                                | $4 million    | Aug. 2010  |                                       | Stabilization of biodefense adenovirus-vectored and adjuvanted vaccines. |
| TransForm Pharmaceuticals | BMGF                                | $8.8 million  | June 2005  |                                       | Design, build, and validate a high-throughput formulation platform, apply to improving stability of measles vaccine strains. |

Note: list not comprehensive.
Vaccine Stabilization Advancements

• **Protection from freeze damage:** Formulation approaches developed that protect alum-adjuvanted vaccines from damage due to accidental freezing.\(^1\) *PATH, U. Colorado; BMGF funding.*

• **Stabilization of recombinant hookworm vaccine:** Na-GST-1 antigen is stable up to 6 months at 25°C (control: 3 months at 2°–8°C).\(^2\) *Sabin Inst., GWU, U. Kansas, Baylor U.; BMGF funding.*

• **Stabilization of influenza vaccines:**
  - Spray-dried and freeze-dried subunit influenza vaccine formulations have > 4 months stability at 37°C (control: 1 week at 37°C).\(^3\) *PATH; BARDA funding.*
  - Foam-dried live attenuated vaccine formulation have > 4 months stability at 37°C (control: 1 week at 37°C).\(^4\) *PATH, Aridis; BARDA funding.*


\(^3\)\(^4\)PATH and Aridis Pharmaceuticals, unpublished data, 2012.
### Vaccine Adjuvant Projects

<table>
<thead>
<tr>
<th>Grantee/Contractor</th>
<th>Funder</th>
<th>Total Funding</th>
<th>Award Date</th>
<th>Project Partners</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emory University</td>
<td>BMGF</td>
<td>$4.5 million</td>
<td>July 2006</td>
<td>Fred Hutchinson Cancer Res. Ctr.</td>
<td>Explore molecular pathways by which adjuvants enhance cellular immune responses, comparing existing and novel adjuvants.</td>
</tr>
<tr>
<td>Fred Hutchinson Cancer Research Center</td>
<td>BMGF</td>
<td>$30.1 million</td>
<td>August 2006</td>
<td>U. Wash.; ISB; Emory U.; OHSU.; NYU</td>
<td>Research consortium funded to develop vaccine adjuvants that boost cellular immunity to HIV vaccines.</td>
</tr>
<tr>
<td>Infectious Disease Research Institute (IDRI)</td>
<td>BMGF</td>
<td>$30 million</td>
<td>October 2007</td>
<td>WHO; PATH; Walter Reed</td>
<td>Develop adjuvants suitable for use with malaria vaccine candidates.</td>
</tr>
<tr>
<td>IDRI</td>
<td>BARDA</td>
<td>$8.5 million</td>
<td>July 2010</td>
<td></td>
<td>Develop and evaluate adjuvant formulations to enhance influenza vaccine immunogenicity.</td>
</tr>
<tr>
<td>U. of Lausanne</td>
<td>EC</td>
<td>$0.7 million</td>
<td>Jan. 2010</td>
<td></td>
<td>Vaccine Formulation Laboratory funded to facilitate access to adjuvant systems and associated know-how for the public sector.</td>
</tr>
<tr>
<td>U. of Lausanne</td>
<td>BARDA</td>
<td>$3.1 million</td>
<td>Sept. 2010; 2011</td>
<td></td>
<td>Develop adjuvants and other technologies for influenza vaccines that can be transferred without the restriction of intellectual property rights.</td>
</tr>
<tr>
<td>PATH</td>
<td>BMGF</td>
<td>$7.0 million</td>
<td>Nov. 2011</td>
<td>Parallel Solutions, Inc.; U. Lausanne</td>
<td>Facilitate global access to new adjuvants and formulation technologies. Initial focus: evaluating novel adjuvants for potential use in developing an affordable inactivated polio vaccine.</td>
</tr>
</tbody>
</table>
Vaccine Adjuvant Advancements

- **Malaria vaccine development**: Preclinical studies showed potent immune responses to CelTOS – GLA-SE in small animals, resulting in a protective immune response during the infectious mosquito-stage of malaria parasites. USAID funding development of a malaria vaccine.\(^1\) *IDRI, Walter Reed; funding from BMGF and USAID.*

- **Virus-mimicking nanoparticles can stimulate long lasting immunity**: Immunization of mice with synthetic nanoparticles containing antigens plus ligands that signal through TLR4 and TLR7 induced synergistic increases in antigen-specific, neutralizing antibodies.\(^2\) *Emory U., Mt. Sinai, Duke U., Georgia Tech, U. Georgia; funding from BMGF and NIH.*

---


# Vaccine Delivery Technology Projects

<table>
<thead>
<tr>
<th>Grantee/Contractor</th>
<th>Funder</th>
<th>Total Funding</th>
<th>Award Date</th>
<th>Project Partners</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aktiv-Dry</td>
<td>NIH</td>
<td>$19.5 million</td>
<td>Dec. 2005</td>
<td>U. Colorado; CDC; Serum Inst. of India; Johns Hopkins; BD Technologies; etc.</td>
<td>Development of inhalable aerosol <strong>measles</strong> vaccine.</td>
</tr>
<tr>
<td>Emory University and Georgia Tech</td>
<td>NIH</td>
<td>$11.5 million</td>
<td>Oct. 2007</td>
<td>Cardiff U.</td>
<td>Development of microneedle technology for delivery of <strong>influenza</strong> vaccines.</td>
</tr>
<tr>
<td>Georgia Tech</td>
<td>NIH</td>
<td>$10 million</td>
<td>Nov. 2010</td>
<td>Emory U.; PATH</td>
<td>Advance microneedle technology for self-administration of <strong>influenza</strong> vaccines through Phase I clinical testing.</td>
</tr>
<tr>
<td>Inovio</td>
<td>US Dept. of Defense</td>
<td></td>
<td>April 2012</td>
<td></td>
<td>Advance development of a low-cost, non-invasive surface electroporation delivery device and test its utility in combination with synthetic DNA vaccines, including <strong>pandemic influenza</strong>.</td>
</tr>
<tr>
<td>Inviragen</td>
<td>NIAID</td>
<td>$15.5 million</td>
<td>Oct. 2010</td>
<td>Pharmajet</td>
<td>Development of a needle-free <strong>Dengue</strong> vaccine.</td>
</tr>
<tr>
<td>PATH</td>
<td>BMGF</td>
<td>$9.9 million</td>
<td>Oct. 2007</td>
<td>Pharmajet; Bioject; Serum Institute; Bio-Manguinhos; SATVI; CDC; WHO; GPEI; PAHP; Indian Immunologicals</td>
<td>To advance the field of disposable-syringe jet injectors for mass immunizations.</td>
</tr>
</tbody>
</table>

*Note: list not comprehensive.*
Vaccine Delivery Technology Advancements

- **Needle-free, intradermal delivery of poliovirus vaccine**: Fractional doses (20% of full dose) of inactivated polio vaccine given intradermally with a needle-free jet injector gave similar levels of seroconversion in infants as full doses given intramuscularly.\(^1\) *Oman Ministry of Health, WHO, CDC, Bioject; funding from BMGF (via PATH) & WHO.*

- **Microneedle delivery of influenza vaccine**: Microneedle delivery of H1N1 virus gave similar IgG titers and protection against lethal virus challenge in an animal model compared to subcutaneous injection. Protective immunity was longer lived with microneedle than subcutaneous administration.\(^2\) *Emory U., Georgia Tech., funding from NIAID.*


Common Features of Projects

• Vaccine targets are typically diseases of global impact: HIV, malaria, influenza, tuberculosis, polio, dengue, measles.

• Many projects involve robust partnerships among nonprofit organizations, private-sector technology and vaccine companies, and universities. Private sector, commercial partners may be involved from project inception, or may join later.

• Funding often supports work to a proof-of-concept stage. Additional funding is needed for full product development.

• Funding (especially from foundations) comes with certain requirements relating to global access to data and any resulting products.
Global Access to Data

• Publication of findings and access to project data promote:
  - **Innovation**—encouraging diversity of analysis and opinion and facilitating synthesis of results from individual projects into a larger whole.
  - **Collaboration**—between teams and institutions.
  - **Efficiency**—preventing unnecessary duplication of effort.
  - **Accountability**—by encouraging independent verification and analysis.
  - **Capacity strengthening**—facilitating education of new researchers and evaluators. ¹

Global Access to Products

• Funding provided directly by funders or via primary grantees may be used to develop products by private-sector collaborators. Agreements should consider:

  ➢ **Availability**—is the program sufficiently rigorous, funded, and prioritized to provide a reasonable opportunity for success? Is the private-sector company’s need for commercial benefit recognized in a way that will ensure a sustainable commitment?

  ➢ **Accessibility**—will sufficient quantities of the resulting product be available to meet public-sector demand in developing countries?

  ➢ **Affordability**—has pricing been agreed upon that can result in widespread adoption in public-sector programs of developing countries?¹

¹PATH’s Guiding Principles for Private-Sector Collaborations. PATH. Available at: www.path.org.
Conclusions

• Over the past 10 years, public-private partnerships funded by government agencies and foundations have significantly advanced vaccine technologies that can address specific developing-country needs.

• Additional support by industry, funders, and regulatory agencies will be needed to ensure the incorporation of new technologies into vaccine products that meet developing-country needs.

• Vaccine formulation, delivery, and packaging technologies need to be incorporated early in the product development process.

• Global access requirements of private-sector partners are an appropriate *quid pro quo* for the funding provided and are typically structured to allow a sustainable business model, often with upside in developed-country markets.
Acknowledgments

- PATH
  - Debra Kristensen, MBA
  - Dexiang Chen, PhD
  - Alex Flood, PhD
  - Darin Zehrung, MBA
  - Amy Wales, MPhil
  - Patricia Logan
- Biomedical Advanced Research and Development Authority
- Bill & Melinda Gates Foundation