BARDA International Influenza Vaccine Manufacturing Capacity Building Program

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Deputy Director
ASPR/BARDA/ID

6th Meeting with International Partners on Prospects for Influenza Vaccine Technology Transfer to Developing Country Vaccine Manufacturers
18-19 March 2013, Grand Hyatt Hotel, Dubai
Insufficient global vaccine manufacturing capacity to respond to an influenza pandemic
The mission of the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary of Preparedness and Response is to support development and availability of countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases through advanced product development, stockpile acquisition/building, manufacturing infrastructure building, and product innovation.

BARDA fulfills its mission by:

• Supporting advanced research and development of needed medical countermeasures;
• Working in collaboration with manufacturers, governmental and non-governmental agencies;
• Supporting technology innovation through strategic initiatives
BARDA International Program

Objectives

• Protect people by reducing the global risk of influenza

• Develop and sustain influenza vaccine manufacturing capabilities and capacity for pandemic readiness: promote international investment, diplomacy and partnerships

• Achieve sustainable influenza vaccine production capacity worldwide by leveraging BARDA’s unique resources
BARDA International Program
Timeline & Funding Activities FY2005 - 2013

FY2005: $1M
FY2006: $10M
FY2008: $14.4M
FY2009: $15M
FY2010: $10.9M
FY2011: $9.4M
FY2012: $1.5M
TOTAL: $62.2M

Geographical Distribution of Influenza Vaccine Production as of 2013

- **Licensed/Active Influenza Vaccine Producers**
  - Mexico Birmex
  - Brazil Instituto Butantan
  - South Africa Biovac
  - South Korea Green Cross
  - Vietnam IVAC VABIOTECH PATH
  - Indonesia Bio Farma
  - Egypt VASERA
  - India Serum Institute
  - Thailand GPO
  - Kazakhstan RIBSP
  - Serbia Torlak Institute
  - Romania Cantacuzino Institute

- **BARDA/WHO Cooperative Agreement Grantees**
  - Indonesia IVAC
  - Vietnam VABIOTECH PATH

- **BARDA/WHO Licensed Vaccine for Human Use as of 2013**

*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*
WHO Grants to Developing Countries = Huge ROI

$30M US -> 300M doses of pandemic vaccine capacity
Goal: Enhance Influenza Vaccine Manufacturing in Vietnam

Multi-faceted approach:
• Supporting the Institute of Vaccines and Medical Biologicals (IVAC) to produce good manufacturing practice (GMP)-quality clinical trial materials for influenza A/H1N1 and A/H5N1 influenza vaccine

• Collaborating with the Vietnam Ministry of Health to support the development and use of influenza vaccines in Vietnam

• Working with the Pasteur Institute in Ho Chi Minh City and IVAC to conduct a Phase 1 clinical trial of the GMP-quality A/H1N1 vaccine produced at IVAC

• Exploring options to secure mammalian cell line suitable for use in influenza vaccine manufacturing at VABIOTECH
BARDA/PATH Cooperative Agreement: Enhancing Influenza Vaccine Manufacturing Capacity in Vietnam
Major accomplishments in FY2012

- Licensed seasonal IIV vaccine in Brazil
- WHO prequalified pandemic H1N1 LAIV by SIIL
- Completed H1N1 vaccine clinical trial in Vietnam - PATH
- Established LAIV reference laboratory capability at US CDC
- Finalized bulk/fill finish agreement between Biovac and CSL
- Completed H5N2 LAIV Phase 1 clinical trial in Thailand - GPO
- Characterized adjuvants technology transferred from UNIL to Bio Farma
- Completed immunogenicity studies in mice for adjuvanted flu vaccine in Romania
- Supported & expanded intermediate and advanced biomanufacturing training program

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<th>Phase 1</th>
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BARDA International Program
Goals by 2016

- Advance clinical development of influenza vaccine by at least nine developing country vaccine manufacturers
- Licensure of influenza vaccine by at least seven developing country vaccine manufacturers
- Enhance technical skills and best practices through training in advanced manufacturing and in-country technical support
- Production capability for at least 500M doses of pandemic vaccine by the end of 2016

Global Partnerships = Make More Vaccine, Faster and Better
Significant Challenges

• Technical hurdles remain
• Limited resources
  – Financial, workforce
• Quality systems
  – Good Manufacturing Practices
  – Training and harmonization of NRAs
• Market development
  – Seasonal, target populations, regional supply
Utah State University
Biomanufacturing Training Program

USU Onsite training at VABIOTECH, Vietnam
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