



# PANDEMIC INFLUENZA VACCINE STOCKPILE

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*Resilient People. Healthy Communities. A Nation Prepared.*

# Pandemic Influenza MCM

## Strategic Goals

- *(2005) Establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza viruses that pose a pandemic threat*
- Monitor emergence of pre-pandemic influenza strains and assess pandemic threat through CDC surveillance and IRAT (Influenza Risk Assessment Tool)
- Address gaps created by emerging novel virus groups and subtypes
- Maintain stockpiles of influenza pre- pandemic vaccines (H5N1, H5N8, H7N9) and adjuvants (ASO3 and MF59) monitoring the stability of products in long term storage



# Acquisition of MCM for Pandemic Influenza Preparedness and Response – Strategies

- Work with manufacturers of US-licensed seasonal influenza vaccines (inactivated, LAIV, recombinant, cell-based) and adjuvants
- Manufacturing of pre-pandemic vaccines using processes, facilities, systems and trained personnel for US-licensed influenza vaccines
- Contractual mechanism: RFP



# Pandemic Vaccine Stockpile

## Preparedness

- Program established in 2004
  - National stockpile comprised primarily of H5N1 and H7N9 bulk antigen and oil-in-water adjuvants
  - 2009 - Achieved the goal of 20M doses of H5N1 vaccine for the critical work force
- 2012 H3N2v outbreak in the US: Investigational lots were manufactured and clinical trials conducted
- 2013 H7N9 outbreak in China : Investigational lots were manufactured and clinical trials conducted; Stockpiled bulk antigen
- 2015 H5N8 poultry outbreak in the US : Clinical lots manufactured and clinical trial in progress



# Pandemic Vaccine Stockpile

## Response

- 2009-H1N1 pandemic
  - 186 million doses of H1N1 vaccine were filled by the manufacturers (149 provided to CDC for distribution to public, 16 million doses donated internationally, 2.7 million doses supplied to the US military)
  - 120 Million doses of bulk adjuvants (ASO3 and MF59) were also purchased as a contingency.



# Long Term Stored Bulk Antigen: BRITE Study

- 1<sup>st</sup> BARDA sponsored clinical study: A randomized, double-blinded, Phase 2 clinical trial is on-going to assess safety and immunogenicity of long-term stored A/Vietnam/2004 (H5N1) vaccine (Sanofi Pasteur) administered with and without MF59 adjuvant (Novartis)
- Results:
  - Data collection and analysis are on-going
  - Preliminary data: vaccine/adjuvant was well-tolerated with no safety concerns



# Heterologous Prime-Boost clinical study: supporting stockpile strategy and implementation

- Assess cross-protective immune responses induced by adjuvanted influenza H5 vaccines
- Heterologous prime-boost vaccination is superior to homologous prime-boost for induction of cross-protective immunity to H5 viruses from clades other than those used for prime and boost
- Identify best vaccination strategy for induction of cross-protective immunity using stockpiled influenza H5 vaccines
- Inform potential deployment strategies of influenza H5 stockpiled vaccine during a pandemic response



# Mix & Match Program: H1N1, H5N1, H7N9, H5N8

- Mix and Match Studies support safety and immunogenicity of MF59 and AS03 with stockpiled antigens from multiple manufacturers.
- Collaboration with NIH-NIAID
  - Vaccines: H1N1, H5N1, H7N9, H5N8
  - Adjuvants: AS03 and MF59
  - More than 12 studies with inactivated H5N1, H7N9, H3N2 and H5N8 vaccines conducted by NIH-DMID



# Pre-Pandemic Influenza Vaccine Stockpile: A National Asset

The Stockpile has increased our understanding of diverse influenza viruses and antigens

- Physical properties
  - Production experience for a variety of influenza viruses
  - Antigen / adjuvant stability
  - Storage conditions
- Immunological properties
  - Mix and Match antigen / adjuvant combinations
  - Heterologous prime / boost strategies



THANK YOU!

