



BARDA INDUSTRY DAY

Pandemic Influenza Vaccine Stockpile

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Adjuvant Branch**

October 29, 2018

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



Pre-Pandemic Vaccines for Pandemic Preparedness

Procure Pre-pandemic Vaccines and Adjuvants



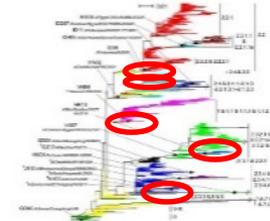
Monitor Stability of Vaccines & Adjuvants Tests & clinical trials



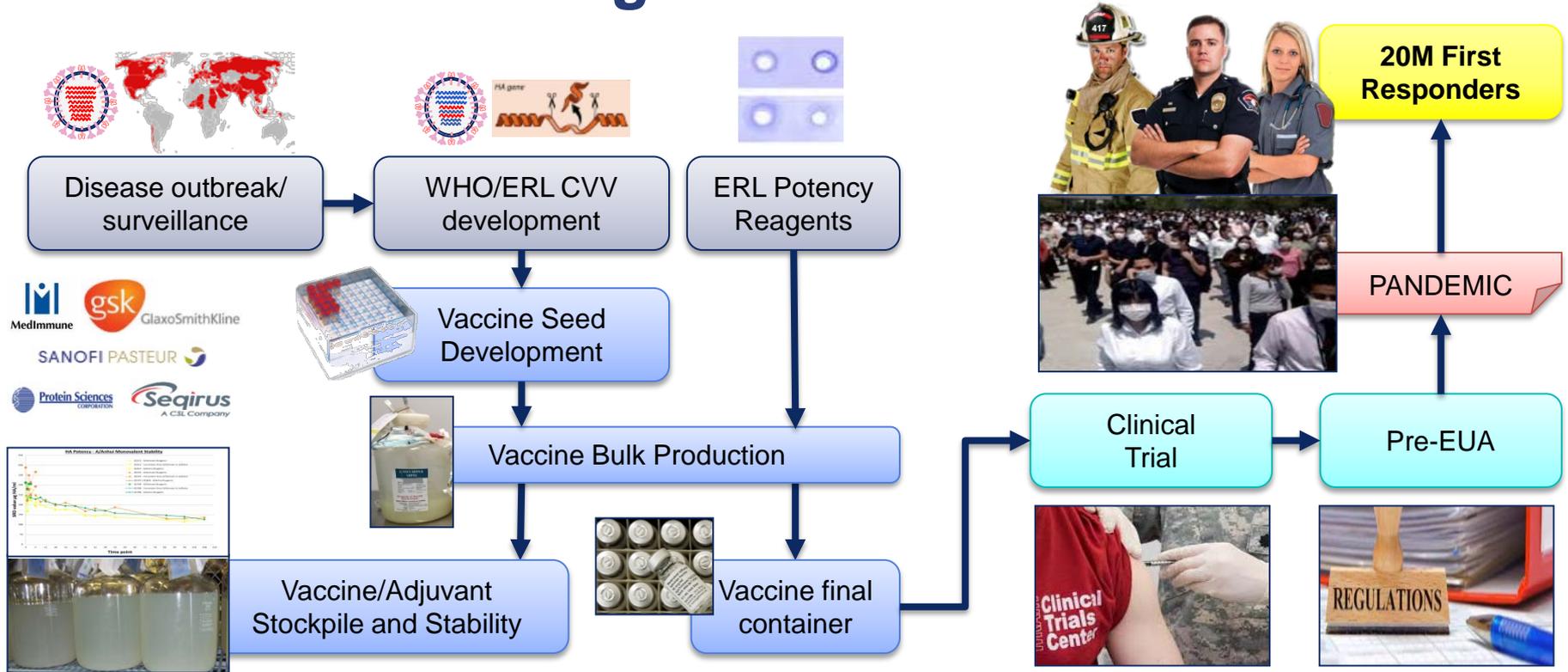
Flexible & Optimized Stockpile: Antigen + Adjuvant Studies



Broader Protection: Induction of cross-protective immunity



Program Overview



Making Decisions about Pre-Pandemic Influenza Vaccines

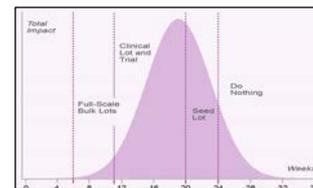
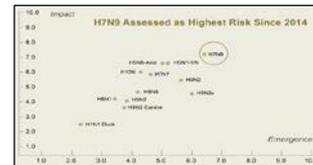


Interagency Decision –
making body

Surveillance – Epi data

Decision using a metered
approach response

Implementation



ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE



Saving Lives. Protecting Americans.

Procure and Test Pre-Pandemic Vaccines

HxNc Human Infection

CVV Development (CDC)

Potency Assay Reagents Preparation & Calibration (FDA)

Vaccine Procurement and Manufacturing (BARDA)

Vaccine Seed Development

Bulk Production

Formulation/Fill/Finish

Clinical Studies

BARDA

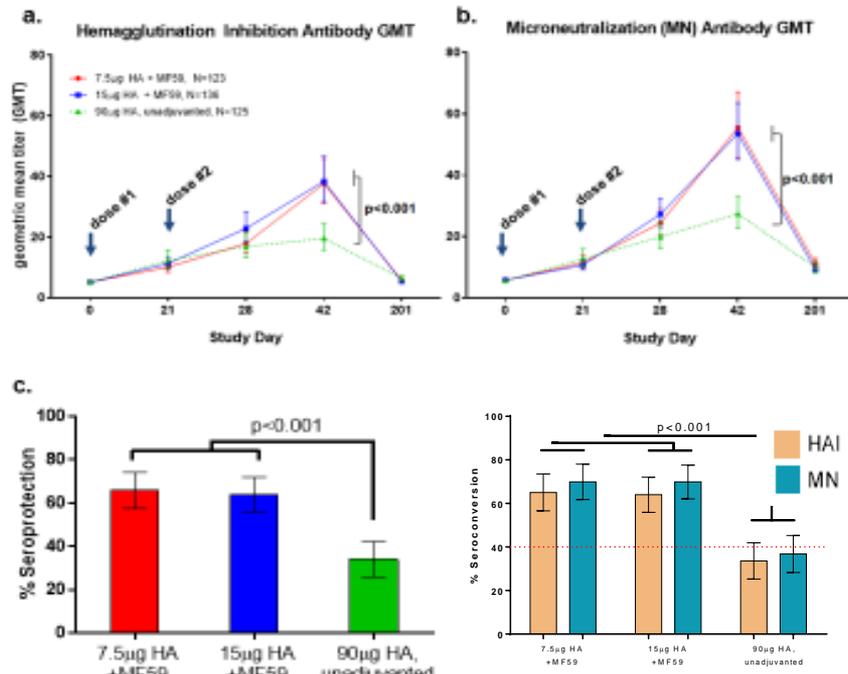
NIH

Companies



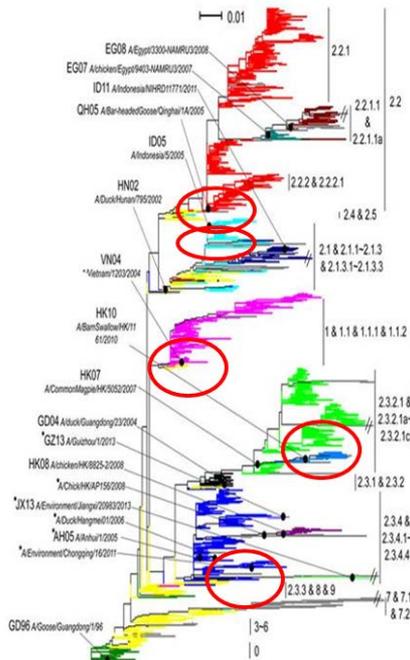
Monitor Stability

1st BARDA sponsored clinical study: A randomized, double-blinded, Phase 2 clinical trial to assess safety and immunogenicity of long-term stored A/Vietnam/1203/2004 (H5N1) vaccine administered with and without adjuvant

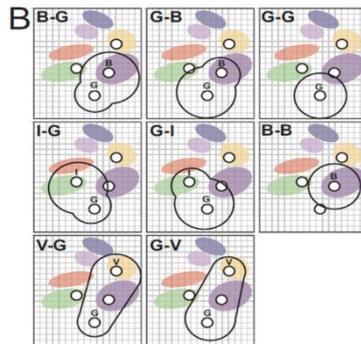
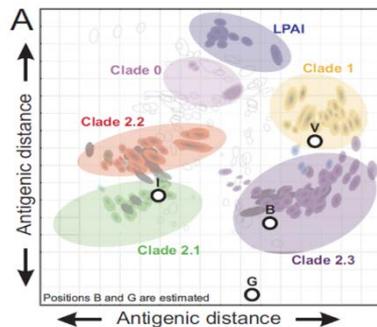


Submitted for publication

Broader Protection: Induction of Cross-protective Immunity

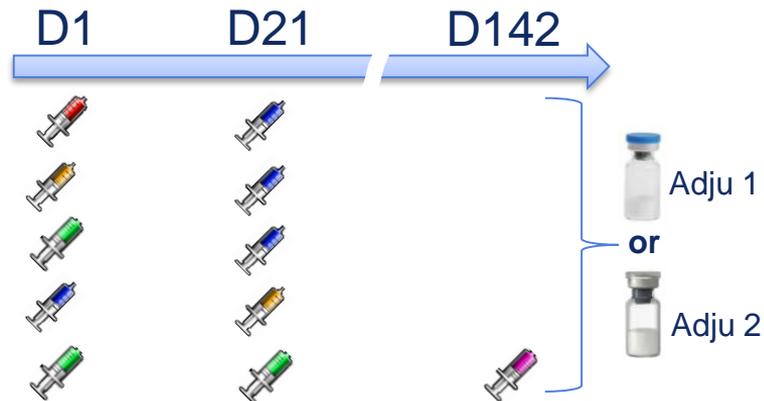


Peng et al, 2017. Scientific Reports



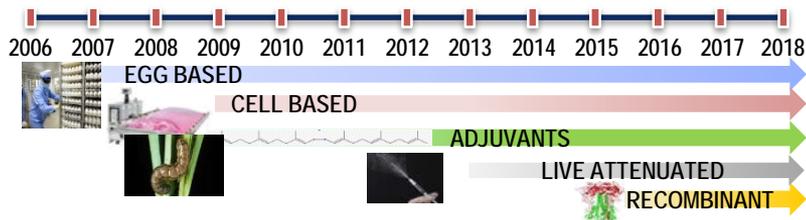
urtesy
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Vaccination strategy for induction of cross-protective immunity using stockpiled influenza vaccines



Flexible and Optimized Stockpile

MULTIPLE VACCINES



MIX AND MATCH STUDIES

Vaccine A-B-C



A+X

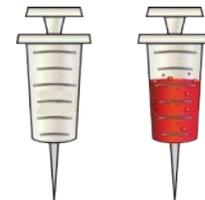
C+Y

B+Y

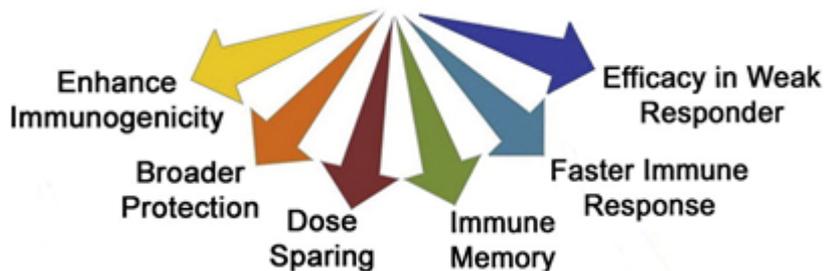
A+Y

C+X

Adjuvant X-Y



ANTIGEN-ADJUVANT SPARING



...more than a Stockpile

- Vaccine properties: Production, Yield, Stability, Storage conditions.
- Performance/Immunogenicity: Mix & Match vaccine/adjuvant combination; safety and immunogenicity of LT stockpiled vaccines; heterologous prime boost studies
- A national asset!

How to contact BARDA



Medical
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

Portal to BARDA: **Register to request a TechWatch meeting!**



www.fbo.gov/
("FedBizOpps")

Official announcements and info for all government contract solicitations



<https://www.phe.gov/about/BARDA/Pages/default.aspx>

Program description, information, news, announcements



www.drive.hhs.gov

DRIVE questions

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