



PANDEMIC INFLUENZA VACCINE STOCKPILE

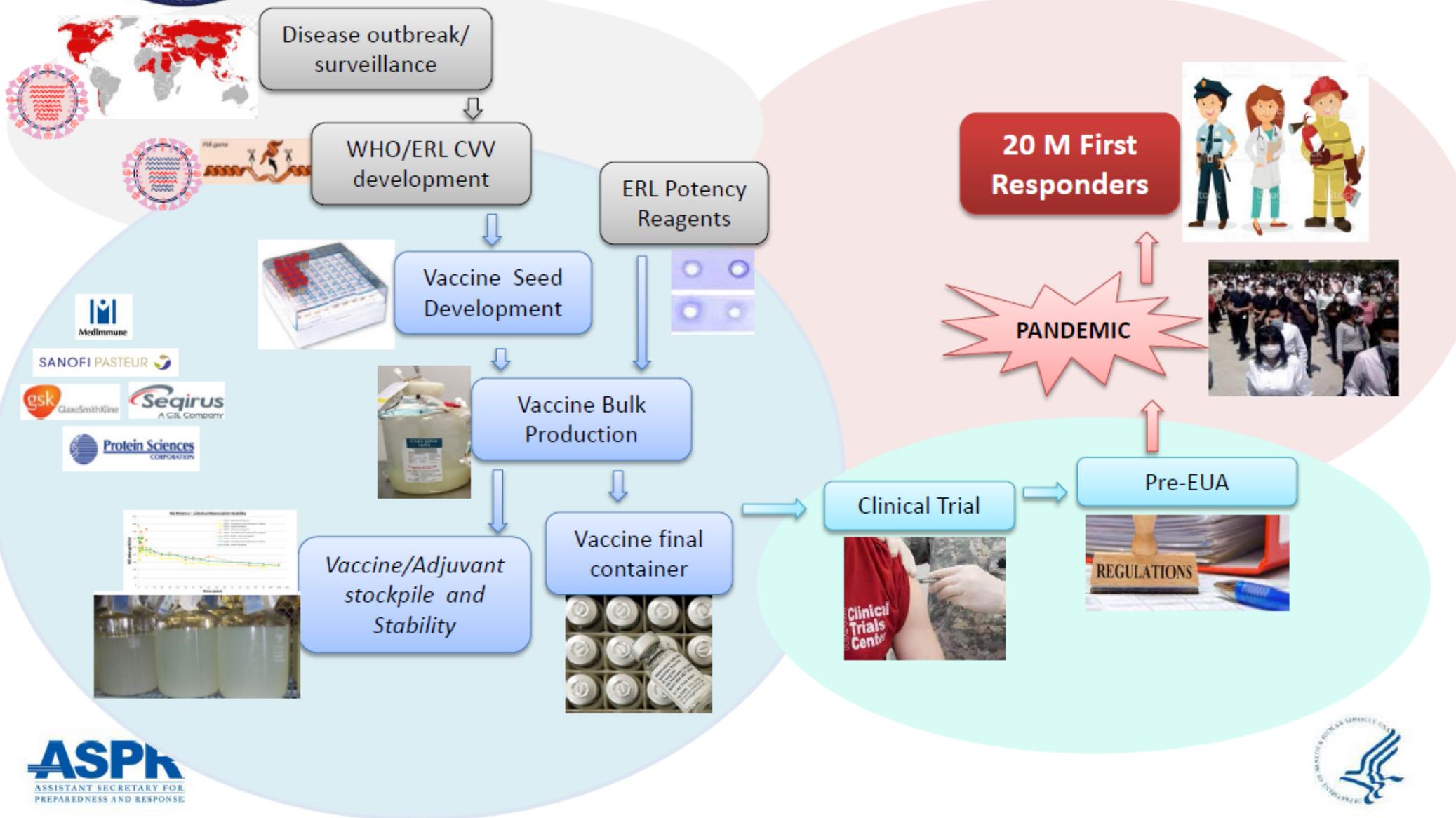
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BARDA Industry Day
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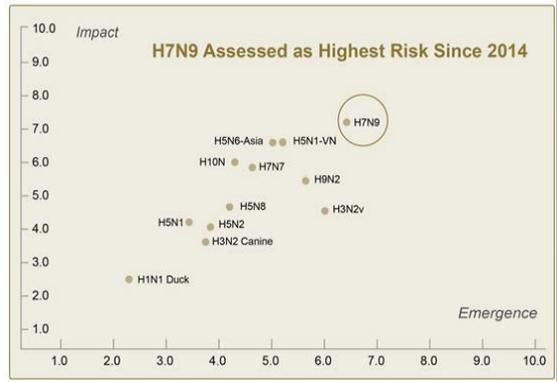


Program Overview





Making Decisions about Pre-pandemic Influenza Vaccines



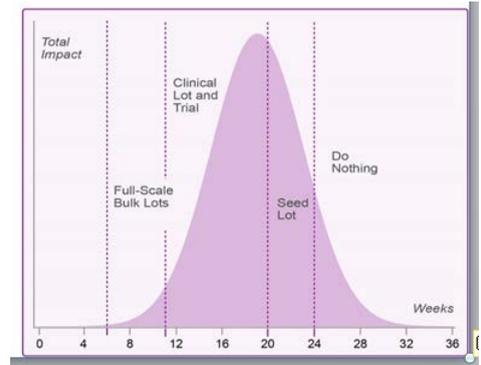
Interagency Decision-making body

Surveillance-Epi data

Decisions use a metered approach response

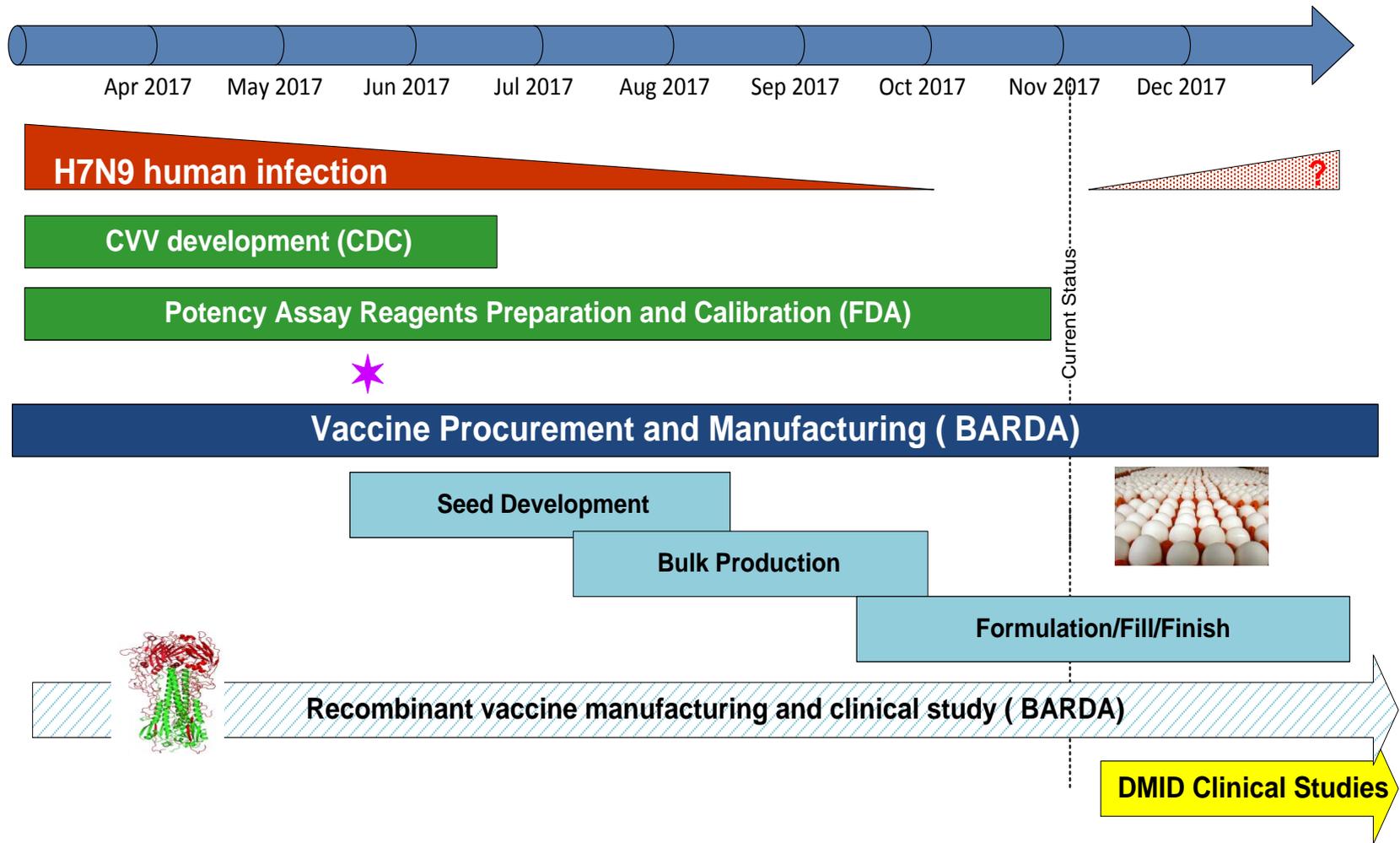


Implementation





H7N9 Risk Mitigation



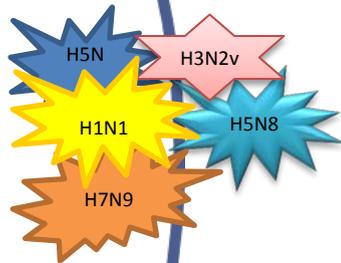


BARDA Pandemic Influenza Vaccine Stockpile Program – Unique Capability



Acquire and store pre-pandemic vaccines and adjuvants in bulk

- Achieved stockpile requirements for clades of H5N1 and H7N9
- Long term stable pre-pandemic vaccines
- Multiple vaccine platforms



Preparedness and Response

- Prepare and respond to pre-pandemic vaccine outbreaks
- Prepare pre-EUA packages for pre-pandemic vaccine use in pandemic situation



Pioneering clinical studies

- Immunological naïve population for pre-pandemic H5N1 clinical studies needs 2 doses of adjuvanted vaccine to induce immunological response
- BRITE study: Long term stored bulk antigen
- HPB study



Long Term Stored Bulk Antigen BRITE Study



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



Results:

- Data collection and analyses are on-going.
- No serious adverse event related to vaccination was observed.
- Preliminary immunogenicity results indicate that the vaccine remains safe and immunogenic.



Heterologous Prime-Boost clinical study supporting stockpile strategy and implementation

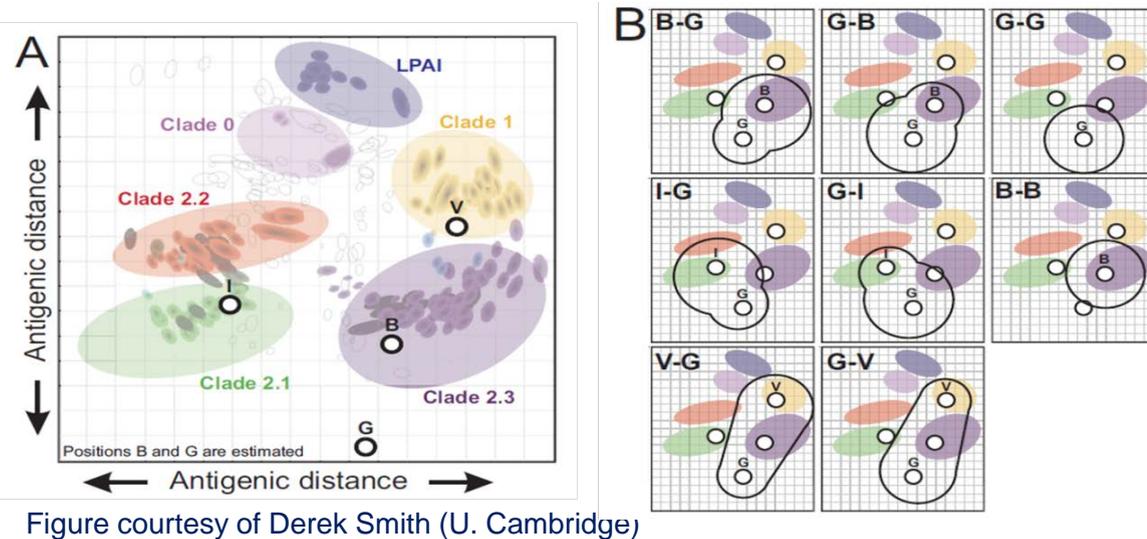
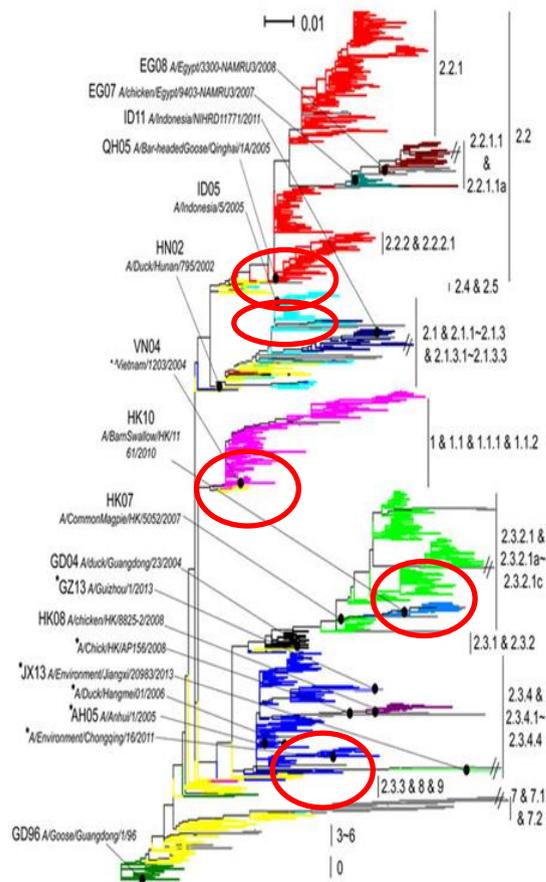
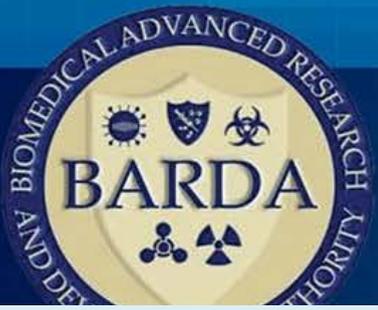


Figure courtesy of Derek Smith (U. Cambridge)

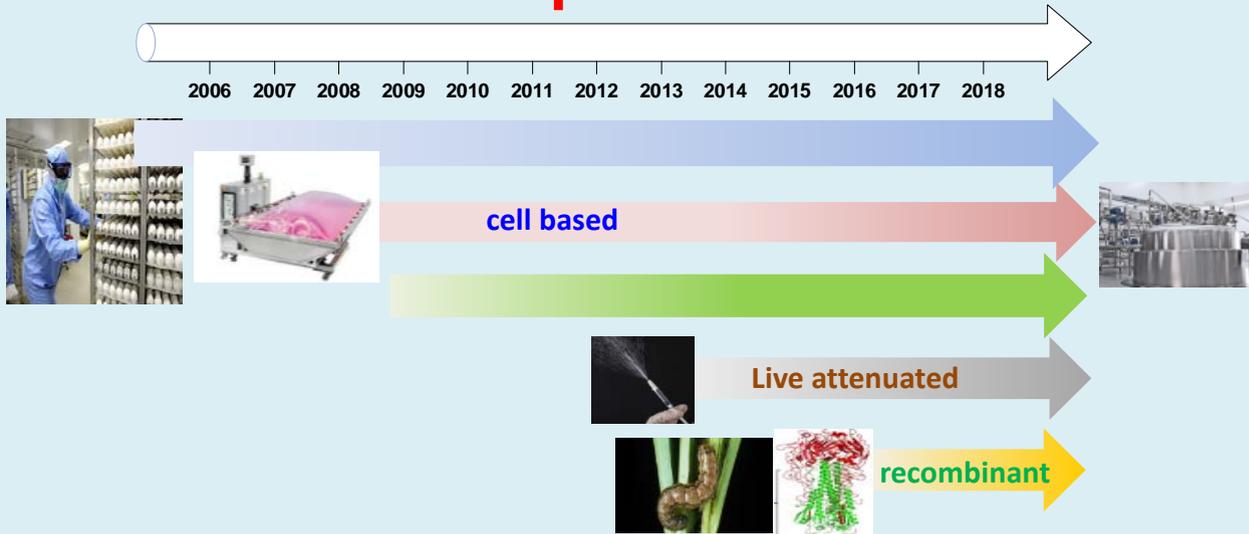
Vaccination strategy for induction of cross-protective immunity using stockpiled influenza H5 vaccines



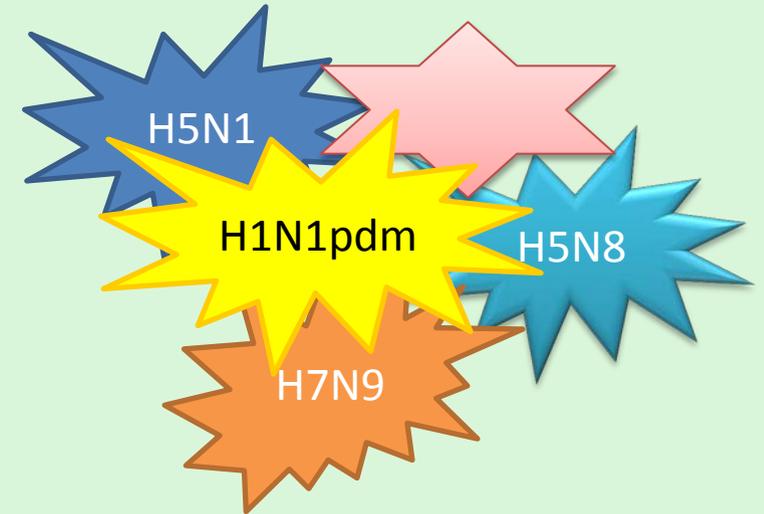


Stockpile Strategy

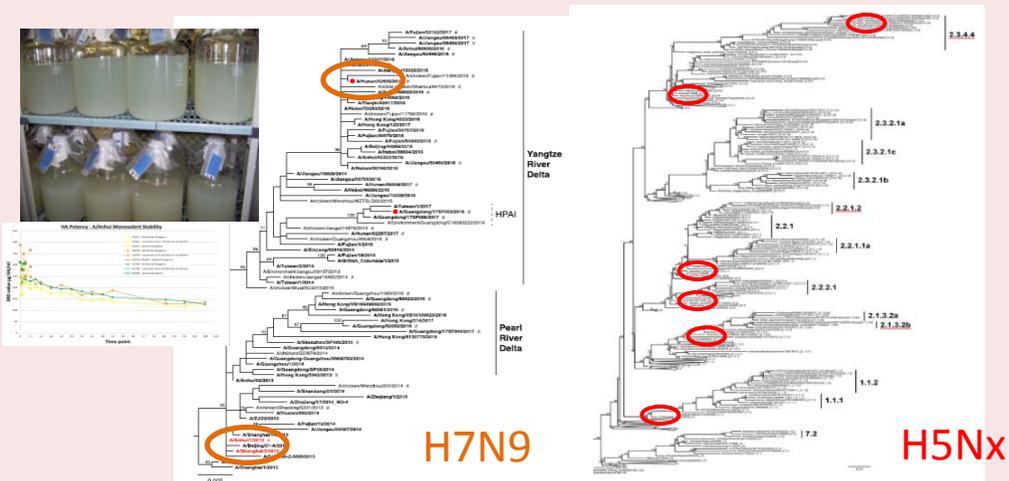
Multiple Vaccines



Outbreak Response



Vaccine, Adjuvant Stockpile/Stability



Mix and Match Studies

