United States Department of Health & Human Services

ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

NIH NIAID

HHS H7N9 Vaccine Response

NVAC Meeting

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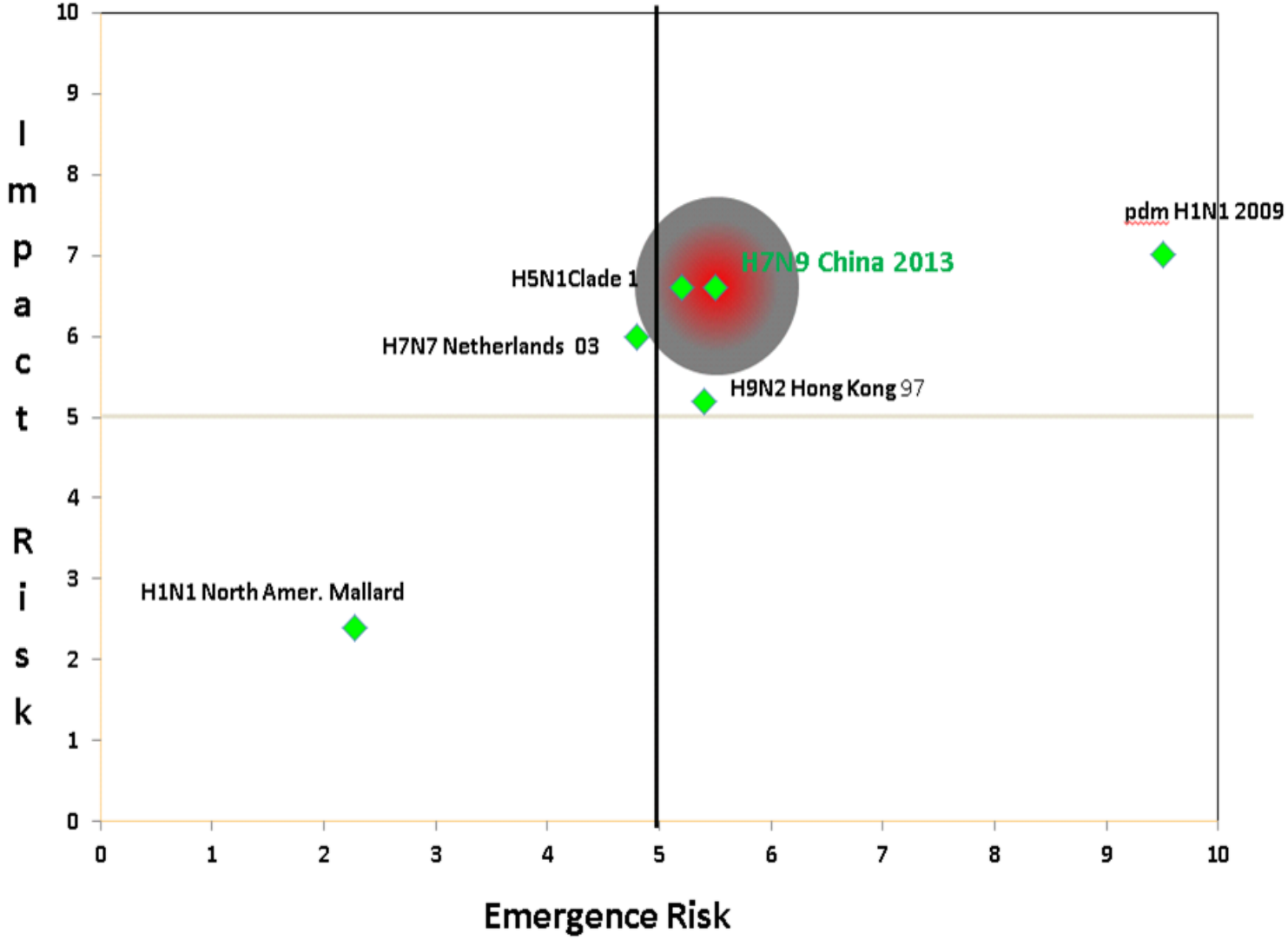
Influenza Risk Assessment Tool (IRAT): H7N9: Emergence vs. Impact Risks



Vaccine Decision Framework

Current Status: Clinical Lots and Trials

- No H2H transmission
- Plateau/ low increase in human cases
- Limited geographic distribution
- Significant morbidity & mortality
- Manufacturing process TBD
- Safety and Effectiveness TBD
- *Ex. H3N2*

Small Stockpile

- No H2H transmission
- Current conditions or increasing incidence
- Expanding Geographic Spread
- Significant morbidity & mortality
- Defined/tenable manufacturing process
- Safety and Efficacy identified from CT
- Capable of EUA status
- Emerging antiviral resistance
- *Ex. H5N1*

Broader Stockpile
Potential Limited Vaccination

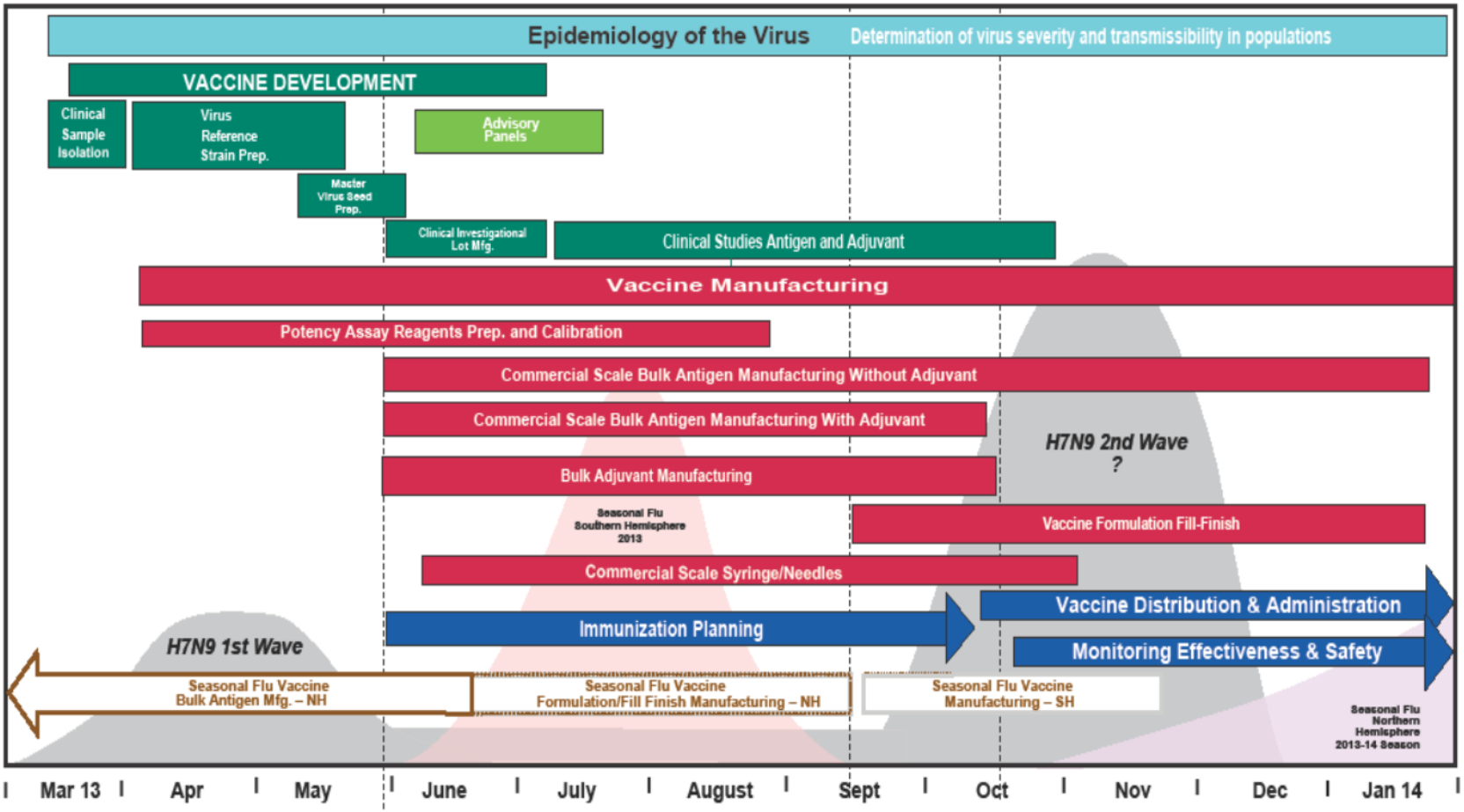
- No/early H2H transmission
- **Many case clusters, frequent health care workers infected**
- **Wide Regional or Multination Spread**
- Significant increase in genetic and phenotypic indicators of human adaptation
- Significant morbidity & mortality
- Manufacturing process established
- Safety and Effectiveness acceptable
- Vaccine approved or EUA allowed

Large Scale Vaccination Campaign

- **H2H Transmission**
- **High Population Attack Rates**
- High rates of hospitalization and CFR
- Genetic-phenotypic markers for sustained transmission
- Global spread
- Can manufacture for full population based on dosing data
- Costs are affordable
- Vaccine is safe, effective
- Vaccine is approved or EUA allowed

Stop vaccine development

U.S. 2013-H7N9 Vaccine Strategy



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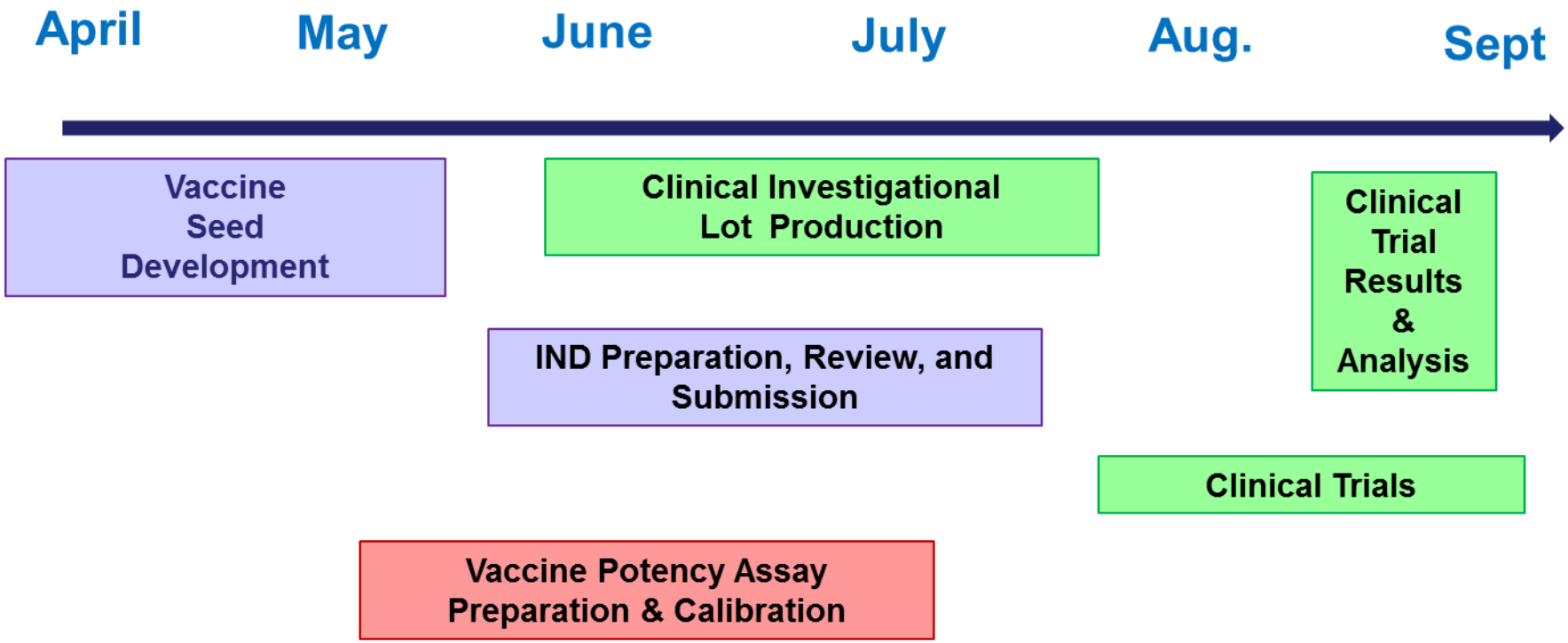
H7N9 Vaccine Development Timelines



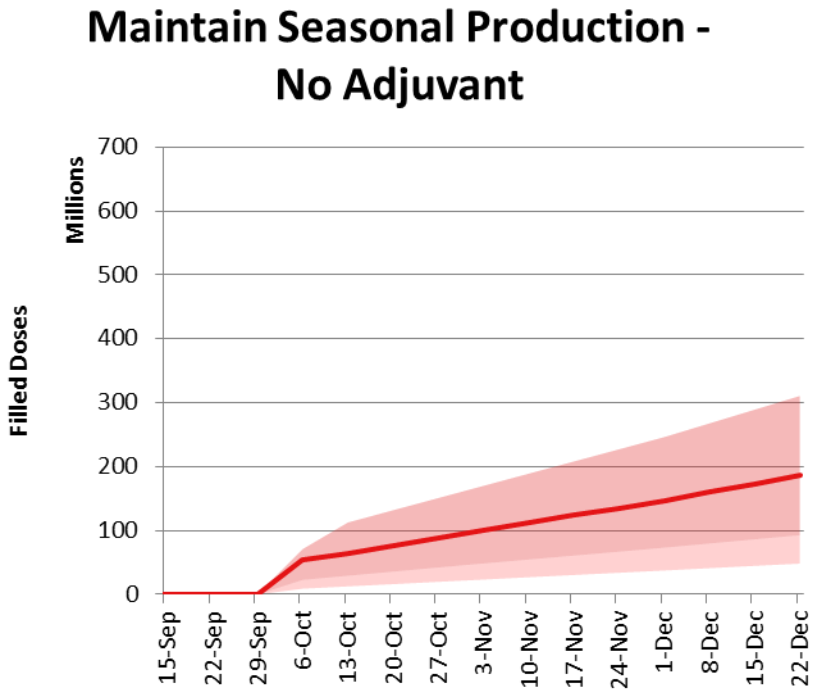
Pre-Pandemic H7N9 Vaccine Stockpile Factors

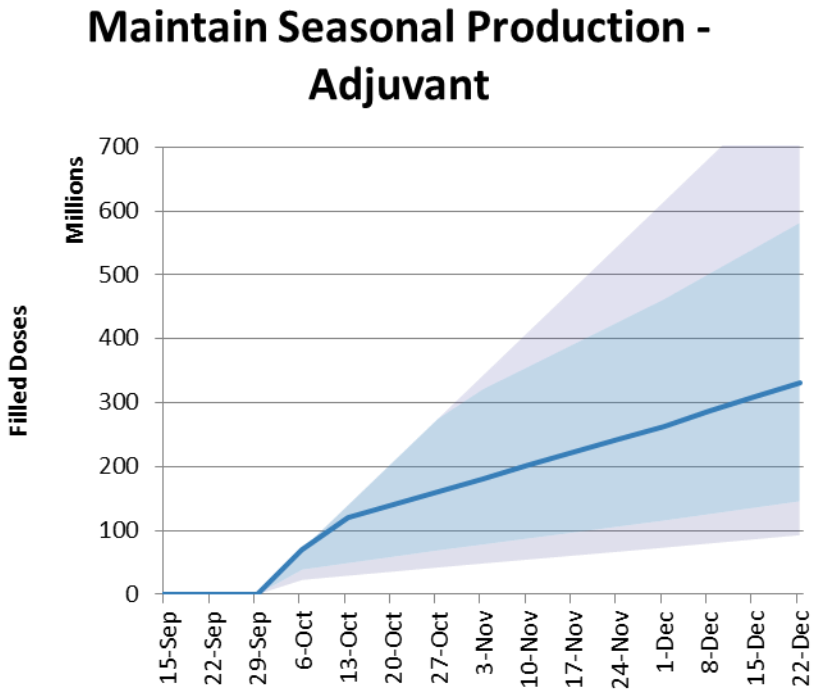
- Intended Use
  - Entire Population
  - Portion of Population
    - Public safety workers and/or other essential workers
    - Persons at high risk of adverse outcomes
    - Children
  - Priming vaccine immunization
- Vaccine Types
  - Live, attenuated
  - Inactivated Split Virion or Subunit
    - Egg-based
    - Cell-based
  - Recombinant
  - H5N1 stockpile (inactivated only) vs. H7N9 stockpile (pending clinical results)
  - Production capacities

Pre-Pandemic H7N9 Vaccine Stockpile Factors

- Timing
  - Optimization of vaccine production yields
  - Uninterrupted seasonal vaccine production campaign
  - Window of opportunity balanced with urgency
  - Budgetary considerations
  - Access to manufacturing lines and staff
  - Knowledge or lack thereof of dose requirements
- Cost
  - Unit cost per vaccine lot in contracts
  - Other factors
    - Number of vaccine lots ordered (volume discounts)
    - Production yield (Total amount of vaccine antigen per lot)
    - Dose requirement (Number of doses per vaccine lot)
  - Possible opportunity and carrying costs
  - Availability of funds

H7N9 Vaccine Production Campaigns: (-/+) Adjuvant





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H7N9 Vaccine Summary

- Risk assessment for H7N9 is similar to H5N1
  - Decision for H5N1: develop vaccine and stockpile bulk antigen
- HHS has already taken multiple steps in the vaccine development process: 1) vaccine seed strain development, 2) clinical lot manufacturing, 3) potency assay reagent preparation, and 4) clinical trial protocols in preparation
  - Clinical trials expected to start in August 2013
- Vaccine stockpiling decision under deliberation
- Decision to conduct a large scale vaccine manufacturing campaign depends on risk of emergence of sustained human-to-human transmission

Vaccine Lessons Learned

- 2009 H1N1
  - Need for new vaccine technology (Cell- & recombinant- based now FDA approved and available)
  - Need to shorten vax mfg. process from beginning to end.:
    - Expedited sterility/potency testing are used when possible
    - Optimization of Vaccine seeds employed
- 2013 H7N9
  - Streamline vaccine seed strain qualifying process & provide guidance to manufacturers
  - Better coordination of HHS & USDA on biocontainment permitting
  - Recombinant-based vaccines moving faster than other technologies in development