Risk Management:
Pre-pandemic Influenza Vaccines

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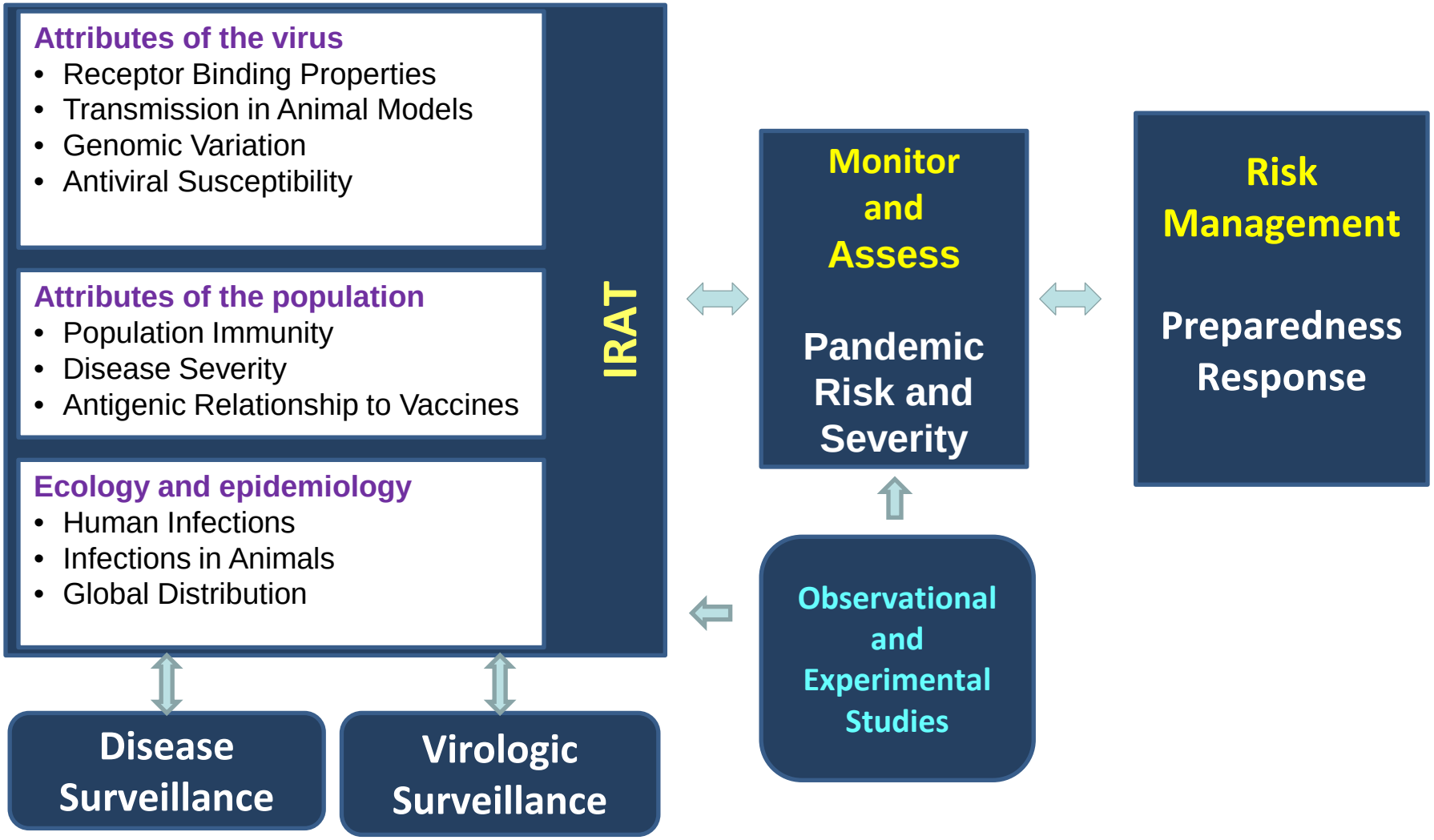
Influenza Risk Assessment & Management



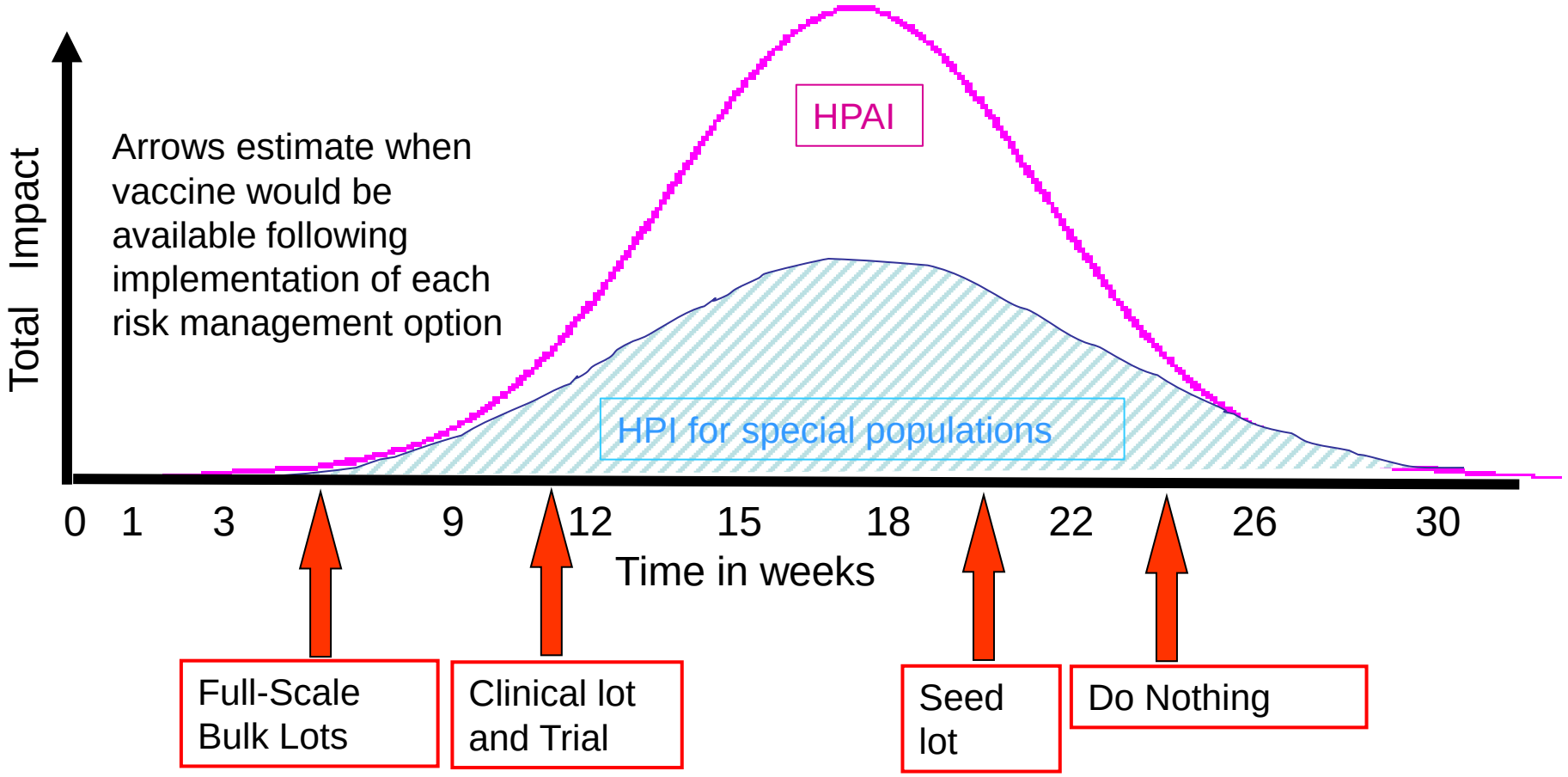
http://www.cdc.gov/flu/pandemic-resources/tools/risk-assessment.htm

Making Decisions about Pre-pandemic Influenza Vaccines

- HHS uses the Pandemic and Seasonal Influenza Risk Management Meeting (FRMM) to make decisions about influenza strains for inclusion in the pre-pandemic vaccine stockpile
  - Senior-level forum for decision-makers from stakeholder agencies to identify and address risk management issues related to the development, acquisition, deployment and utilization of medical and public health countermeasures for influenza
  - Decisions are evidence-based and use a metered approach to response, ranging from monitoring novel strain emergence to a full pandemic vaccine production response

Pre-Pandemic Influenza Vaccine Availability by Risk Management Option

Two pandemic scenarios represented here: HPAI = high pathogenicity avian influenza
HPI = high pathogenicity influenza



U.S. Pre-Pandemic Influenza Vaccine Stockpile: Risk Based, Metered Approach

- 2005 H5N1 outbreak in SE Asia
  - Established stockpile and met stockpile goals
  - Implemented innovative Mix and Match program
- 2009 H1N1 Pandemic
  - 186 M doses of H1N1 vaccine were filled by the manufacturers
  - 120 M doses of bulk adjuvants (AS03 & MF59) purchased as a contingency
- 2012 H3N2v outbreak in the US
  - Clinical lots were made and clinical trials conducted
- 2013 H7N9 outbreak in China
  - Clinical lots were made and clinical trials conducted
  - Stockpiled bulk antigen

U.S. Pre-Pandemic Influenza Vaccine Stockpile: A National Asset

Expands the scientific knowledge base 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
  - Contributes to research agenda for systems biology and development of more effective, next generation influenza vaccines