

***WELCOME TO THE WORKSHOP:***  
**Immune Correlates of Protection Against  
Influenza A in Support  
of Pandemic Vaccine Development**

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# CBER Perspective on Big Picture

- What is needed:
  - better assays and correlates...meaning....
  - assays that can be easily performed in a variety of settings with results reproducible and comparable across studies and sites
  - and, the results of which, are predictive of/and can, ideally, serve as surrogates for clinical outcomes: *not just infection but protection against illness, hospitalization, death*
    - *may be more meaningful/achievable*
    - need the same for non-HA vaccines

# MAJOR ISSUES AND OPPORTUNITIES

- Performance: reproducibility, speed, cost
- Clinical prediction
  - Include prediction of heterologous effects
  - Include markers/levels for effective priming
- Don't forget antigen choice, quality, conformation and availability issues
- What's left out by anti-HA - is it important?
  - Other antigens, mucosal immunity, CMI
  - HA vs. other proteins, live vaccines
  - Other administration routes

# ISSUES AND OPPORTUNITIES: (continued)

- *Correlates and assays not only needed for H5 but also for other pandemic and seasonal vaccines*
- *Support and tie to needed basic & animal studies and models*
  - *Ideally animal model tied to clinical surrogate*
- *Underlying findings and science will also be critical to achieving better and more meaningful potency assays*

# Moving Forward

- Assay development and immune correlates must be moved to the front burner as a high priority – *you are helping do this in these 2 days*
- Practical:
  - Support lab quality/standards efforts and preparedness with current assay technologies
  - Sample banks/sharing?
  - Design clinical studies to evaluate assay issues, new assays, clear outcomes and correlates, and to store diverse samples for future uses
  - *Challenge: speakers and panelists try to identify practical opportunities and next steps*

# Thanks!

- We appreciate your interest and participation
- Thanks to HHS, WHO, NIAID and to colleagues at FDA/CBER for the support
- *We will work with and as partners to facilitate additional work moving forward*