





Immune Correlates of Protection Against Influenza A Viruses in Support of Pandemic Vaccine Development

December 10 - 11, 2007, Bethesda, MD, USA

Introduction and Welcome

- Organizing Committee
- Announcements
- Introductory Remarks from FDA/CBER, NIH/NIAID and WHO
 - Jesse L. Goodman, MD, MPH
 - Director, Center for Biologics Evaluation & Research/FDA
 - Anthony S. Fauci, MD
 - Director, National Institute of Allergy & Infectious Diseases/NIH
 - David Wood, PhD
 - Coordinator, Quality Safety & Standards/WHO

Organizing Committee

- Maryna Eichelberger, PhD
 - Principal Investigator, US Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review/Division of Viral Products
- Hana Golding, PhD
 - Chief, Lab of Retrovirus Research, US Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review/Division of Viral Products
- Maureen Hess, MPH, RD
 - Science Policy Analyst, US Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review
- Jerry Weir, PhD
 - Director, Division of Viral Products, US Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review
- Catherine J. Luke PhD
 - Staff Scientist (Core), National Institutes of Health, National Institute of Allergy and Infectious Diseases/ Laboratory of Infectious Diseases
- Kanta Subbarao, MD, MPH
 - Senior Investigator, National Institutes of Health, National Institute of Allergy and Infectious Diseases/Laboratory of Infectious Diseases
- Martin Friede, PhD
 - Scientific Officer, World Health Organization
- David Wood, PhD
 - Coordinator, Quality Safety and Standards/IVB, World Health Organization

Announcements

- All Use the microphones at all times
 - Workshop is being webcast
- Speakers Load slides before your session
- All Submit ideas for panel discussion at the end of Day 2

Goals of the Workshop

 Identify the gaps in our knowledge and abilities in addressing the unique challenges encountered in the development and evaluation of vaccines intended to protect against pandemic influenza

 Facilitate implementation of a global research agenda to improve efficacy assessment of pandemic influenza vaccines

Agenda

- Four Sessions
 - current knowledge regarding correlates of protection against seasonal influenza
 - immune responses to avian influenza infections and vaccines for novel influenza viruses in humans
 - assays to evaluate vaccine immunogenicity
 - evaluation of avian influenza vaccine efficacy
- Panel Discussion at the end of day 2
 - Submit comments/questions/issues for discussion to one of the organizing committee members of chairpersons of one of the 4 sessions

Welcome