

**Department of Health and Human Services  
National Institutes of Health/NIAID  
Bethesda, MD**

**Development of a Clinical Trial Plan for Pandemic Influenza Vaccines**

**Monday, September 22**

8:30 a.m. - 8:45 a.m.            **WELCOME/INTRODUCTION**  
Linda Lambert

**Morning Session**

Moderator:                      Arnold Monto

8:45 a.m. - 9:15 a.m.            **VACCINE EXPERIENCES/LESSONS FROM THE PAST**  
Robert Couch

9:15 a.m. - 9:45 a.m.            **RECENT VACCINE EXPERIENCE WITH NOVEL ANTIGENS**  
Karl Nicholson

9:45 a.m. - 10:15 a.m.          **POTENTIAL PANDEMIC VIRUSES: PRIORITY FOR VACCINE  
EVALUATIONS**  
Robert Webster  
Introductory remarks by Klaus Stöhr

10:15 a.m. - 10:45 a.m.          **BREAK**

10:45 a.m. - 11:15 a.m.          **MANUFACTURING RISK ASSESSMENT UPDATE and EUROPEAN  
REGULATORY UPDATE**  
John Wood  
Introductory remarks by Klaus Stöhr

11:15 a.m. – 11:45 a.m.          **REGULATORY ISSUES**  
Karen Midthun

NOON – 1:00 p.m.                **LUNCH**

# Development of a Clinical Trial Plan for Pandemic Influenza Vaccines Workshop Agenda

## Monday, September 22

### Afternoon Session

### **WORKSHOP DISCUSSIONS: Establishing Needs and Variables for Clinical Evaluation**

#### **I. PRECLINICAL TOOLS AND ISSUES**

1:00 p.m.

#### **OVERVIEW OF THE ISSUES AND OPTIONS FOR DISCUSSION**

Nancy Cox

#### **Moderators:**

Roland Levandowski

Linda Lambert

#### **POINTS FOR DISCUSSION**

AVAILABILITY OF PANDEMIC REFERENCE STRAINS

SUBSTRATES FOR PRODUCTION

AVAILABILITY OF REAGENTS

SAFETY CONSIDERATIONS

OTHER REGULATORY ISSUES

#### **BREAK**

#### **II. CLINICAL TRIALS: Interpandemic and Pandemic**

#### **OVERVIEW OF THE ISSUES AND OPTIONS FOR DISCUSSION**

John Treanor

#### **Moderators:**

Karl Nicholson

John Treanor

#### **POINTS FOR DISCUSSION**

VIRUSES/VACCINES TO BE EVALUATED

VACCINE PREPARATIONS TO BE EVALUATED

DOSE RANGE AND SCHEDULE

AGES FOR EVALUATION

IMMUNOLOGICAL ASSESSMENTS

ADJUVANTS

**Development of a Clinical Trial Plan for Pandemic Influenza Vaccines  
Workshop Agenda**

**Tuesday, September 23**

8:30 a.m. – Noon

**DRAFT PLAN FOR CLINICAL TRIALS**

**Presentation and discussions of key points raised from Monday**

Linda Lambert

Robert Couch