



INSIGHT Influenza Studies: FLU 002 (Influenza Outpatient Study), FLU 003 (Influenza Hospitalization Study) and FLU 004 (Influenza Genomics)

### Message from FLU Co-chairs R. Davey, D. Dwyer, M. Losso, R. Lynfield

#### Colleagues:

As the current influenza season in the Northern Hemisphere progresses through the first half of February, it is interesting to note how it is manifesting both typical and atypical features of this annual scourge. Atypically, the season began rather early, but we should note that, as of the first week in February, at least 38 U.S. states were still reporting widespread geographic influenza activity, and the proportion of deaths attributable to influenza or pneumonia continues to be above the epidemic threshold. In the U.S., the disease appears to have peaked in the eastern half of the country but may still be rising in the western states, a pattern opposite to what is being seen in Europe. However, unlike the A(H1N1)pdm09 pandemic that first caused illness beginning in 2009, throughout the Northern Hemisphere the current seasonal subtypes are having the highest impact in the traditional at-risk subpopulations of the very young and the elderly. Over the past 8 weeks both outpatient visits and hospitalization rates for acute influenza infection, and complications thereof, in adults > 65 years of age have soared in many parts of the United States and Canada. The influenza-related pediatric death rate in the U.S. has also continued to rise and currently sits at 59 known cases. Fortunately, most of the A and B viral isolates identified to date have matched the subtypes incorporated in the 2012-2013 trivalent vaccine. The preliminary efficacy of that vaccine in the U.S. was recently estimated at 62%, roughly comparable to the efficacy of influenza vaccines in prior years. However, early disturbing reports elsewhere of possible antigenic drift in some isolates of H3N2 have started to appear.

Somewhat atypically, the disease burden throughout the Northern Hemisphere as a whole has been rather spotty, with parts of Europe having relatively mild seasons despite a robust season in the U.S. In some European countries this pattern has persisted despite regional vaccine uptake rates often reported to be less than those seen on the other side of the Atlantic. The distribution of viral isolates also remains somewhat discordant: whereas H3N2 (equaling approximately 95% of influenza A isolates found to date) clearly continues to dominate in the United States, in some European countries influenza A(H1N1)pdm09 has remained the predominant strain during the current season.

Although these regional differences are having a differential effect upon overall enrollment, we are gratified to see that site investigators in some of the hardest hit areas are making up for lost time by doing their best to enroll eligible patients aggressively into both the outpatient (FLU002) and inpatient (FLU003) trials.

Even as the enrollment numbers of new patients continue to rise, we would like to remind investigators in both Hemispheres of the opportunity to participate actively in planning the analysis of the prior data collected specifically on the original cohort of patients infected with the 2009 pandemic A strain. That database has recently been closed for review and is awaiting a formal analysis plan to which all investigators may now contribute ideas and suggestions. The best means by which investigators can share their thoughts and ideas would be to join the Influenza Interest Group through the INSIGHT website www.insight-trials.org> Interest Groups (tab on left margin of home page)> "Influenza". The Interest Group distribution list can then be used as an electronic forum through which to submit comments and suggestions to the membership for consideration

As always, we thank you for your dedication and participation in these important influenza studies.

### Top 5 Enrolling Sites Since Oct 1, 2012:

### **FLU 002\***

# 106-Practimed Medisch Centrum Tessenderlo,

# Tessenderlo, BE, J. Weckx

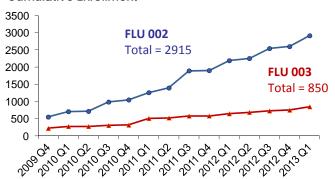
## 26-West Tallinn Central Hospital, Tallinn, Estonia, K. Zilmer

- 25-Washington DC VA Medical Center, Washington DC, USA, F. Gordin
- 22-Churchill Hospital, Oxford, UK, Brian J. Angus
- 21-Centre for Viral Diseases (KMA), Copenhagen, DK, J. Lundgren
  - \* Number of patients enrolled at all sites in this time period = 372

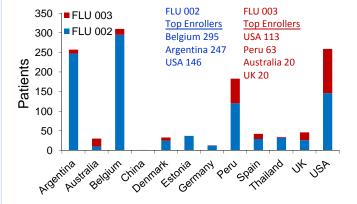
### FLU 003\*\*

- 20-Mayo Clinic, Rochester, MN, USA, Z. Temesgen
- **19**-Baystate Infectious Diseases Clinical Research, Springfield, MA, USA, D. Skiest
- 19-Montefiore Medical Center, Bronx, NY, USA, J. Shuter
- **12**-Centre Hospitalier Universitaire St. Pierre. Brussels, BE, N. Clumeck
- 12-Odense University Hospital, Odense, DK, C. Pedersen
- \*\*Number of patients enrolled at all sites in this time period = 121

### **Cumulative Enrollment**



### Enrollment by Country (01 FEB 2012 to present)



To track influenza activity in your area and worldwide: -Contact your local public health agencies

-INSIGHT website <u>www.insight-trials.org</u> > Influenza Links