**Safety of Flubio® (Bio Farma Influenza HA Vaccine) in 6 months – 11 years Indonesian Children**

Soedjatmiko\*, Medise BE\*, Hadinegoro SR\*, Gunardi H\*, Sekartini R\*, Satari HI\*,

Bachtiar NS\*\*, Sari RM\*\*, Puspita M\*\*, Fahmi J\*\*

\*Child Health Department, Faculty of Medicine, University of Indonesia, Jakarta.

\*\*PT Bio Farma, Bandung, Indonesia.

**ABSTRACT**

**Objectives.** To assess the safety of Influenza HA (Flubio®) vaccine 28 days after two doses immunization in infants and children (6 months - 8 years old) and one dose immunization in children 9-11 years of age.

**Methods**. This study was a phase II clinical trial, open labeled bridging study. The subjects included in this study were healthy infants/children age 6 months - 11 years. Subjects were vaccinated with 1 dose or 2 doses of Influenza HA vaccine which contained A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2), and B/Massachusets/2/2012. Safety was assessed immediately until 28 days after each dose. Parents were trained to record the reactions and symptoms after immunization. The study officer confirmed the reactions and symptoms occurred at day 3 after each injection .

**Results.** A total of 404 subjects completed the study. There were 11.1% subjects with local reaction and 1.7% with systemic event within 30 minutes after immunizations. There were 23% subjects with local reaction and 10.4 % with systemic event within 31 min - 72 hours after immunization. The most frequent local reaction was pain and the most frequent systemic event was muscle pain. Most of the reactions and events were mild. No serious adverse event related to the vaccine was reported.

**Conclusion**. Flubio® (Bio Farma Influenza HA Trivalent) vaccine was proven safe for children aged 6 months up to 11 years. No serious adverse event related to the vaccine.

**Keywords**: Influenza vaccine, safety, adverse event, infant, children.