**Safety of Flubio (Influenza HA) Vaccine in 6 month – 11 year Indonesian Children**

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**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. Antibody titers were measured at visit V1 (Day 0), V2 (V1 + 28 days/+7days) and at visit V3 (V2+28 days/+7 days) by Haemaglutination Inhibition test. Safety was assessed immediately until 28 days after each dose.

**Results.** A total of 404 subjects completed the study. All subjects (100%) were protected against Influenza A/California/7/2009 (H1N1), A/Texas/50/2012 (H3N2), and B/Massachusets/2/2012. 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. Most of the reactions 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, infant, children.