

Tip Sheet

Safety and Immunogenicity Among Children Administered Quadrivalent Influenza Vaccine (QIV04 – Phase III)

The Disease

- Influenza is a highly contagious viral respiratory disease.
- The classic symptoms include rapid onset (12 hours or less) of fever, fatigue, malaise, muscle aches, headache, sore throat, and a non-productive cough.
- While influenza affects all age groups, very young children are at increased risk for complications and are more likely to be hospitalized with influenza than the general population.
- All children 6 months through 18 years of age are currently recommended to get a yearly vaccination against influenza (if <9 years of age, 2 doses one month apart, depending on the influenza vaccination history)
 - With a good match between vaccine and circulating strains, influenza vaccine has been shown to prevent illness in 70%–90% of healthy persons < 65 years of age
- Until 1976, the United States (US) influenza vaccines contained only two strains, but since 1978, the inclusion of three strains has been the norm (2 Influenza A strains and 1 influenza B strain).
- Over the past decade or so, 2 distinct types (lineages) of Influenza B have emerged. The annual vaccine has included the correct B strain, matching the B strain circulating in the community, only about half of the time.
- In Feb 2009, the Centers for Disease Control and Prevention (CDC) presented a model showing that increasing the number of strains in the vaccine from 3 (TIV) to 4 (QIV) may reduce influenza cases, hospitalizations and deaths.

The study vaccine (Quadrivalent Influenza Vaccine- 4 strains)

- The trivalent (3-strain, TIV) influenza vaccine, Fluzone[®], has been licensed in the US for decades. Numerous clinical trials have demonstrated Fluzone vaccine's safety, immunogenicity and effectiveness.
- In a clinical trial involving 190 adults who received the QIV version of the vaccine,
 - The safety profile was very similar to the 3 strain version of the vaccine.
 - The addition of a 4th strain did not adversely affect the antibody response to the other 3 strains.

The Study

- Children 6 months to < 9 years of age will be randomized to one of 3 groups
 - Group 1: Licensed 2010-2011 Fluzone vaccine (TIV) containing the primary B strain
 - Group 2: Investigational TIV containing an alternate B strain
 - Group 3: Investigational Quadrivalent Influenza Vaccine (QIV) containing both B strains
- Depending on the influenza vaccine history, each child will be given 1 or 2 doses of the study vaccine. If 2 doses are needed, they will be given one month apart.
- For children requiring 1 dose of study vaccine, there are 2 visits one month apart, with a blood draw at each visit (2 blood draws)
- For children requiring 2 doses of study vaccine, there are 3 visits over a 2 month period, with a blood draw at Visit 1 and 3 (2 blood draws)

Inclusion Criteria (additional inclusion criteria are listed in the protocol)

- Children 6 months to less than 9 years of age on the day of inclusion, and in reasonably good health.
- For children 6 months to < 24 months of age, born at full term of pregnancy (≥ 37 weeks) and with a birth weight ≥ 2.5 kg (5.5 lbs).

Exclusion Criteria (additional exclusion criteria are listed in the protocol)

- Receipt of any vaccine in the 4 weeks preceding the first study vaccination.
- Any vaccination scheduled between Visit 1 and Visit 2 (or Visit 1 and Visit 3 for those requiring two doses).
- Already received an influenza vaccination during the 2010-11 flu season.
- Major congenital defects, serious chronic illness, neurologic disorders or seizures
- Febrile illness (temperature > 100.4 degrees F) or moderate or severe acute illness/infection on the day of vaccination