Synopsis:
This study is a prospective, open label, multicenter, pharmacokinetic/pharmacodynamic safety evaluation of intravenous oseltamivir therapy in three cohorts:
- Cohort 1: Infants 91 to < 365 days
- Cohort 2: Infants 31 to 90 days of age
- Cohort 3: Infants 0 to 30 days of age

Number of subjects: Up to 36 male and female infants will be enrolled according to their age in one of three cohorts: Cohorts I and II will enroll 10-13 patients, and Cohort III will enroll 5-10 patients. Enrollment into cohorts will be in parallel.

Target population: Infants 0 to < 365 days. Subjects will have a diagnosis of influenza by virology testing or clinical diagnosis based on symptoms suggestive of influenza.

Length of study: Up to approximately 4 weeks (from screening through to study completion), for each enrolled subject as follows:
- Screening: Up to 4 days (96 hours)
- Dosing: Day 1 to Day 5/6, or Day 1 to Day 10/11 (maximum of 10 or 20 doses, respectively, in total)
- Follow-up: approximately 30 days after first dose of study medicine received

It is anticipated that it will take at least 2 influenza seasons to enroll the minimum number of subjects per cohort.

Objectives:
- To define the pharmacokinetics of oseltamivir and oseltamivir carboxylate and evaluate the safety profile following intravenous (IV) administration of oseltamivir phosphate in infants less than one year of age with influenza.
- To evaluate the viral load and viral shedding
- To evaluate all isolates for phenotypic and, where necessary, genotypic resistance