

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2016/019

Scientific title of trial: Phase III, Double-Blind, Randomized, Placebo-Controlled Trial to Investigate the Efficacy, Safety and Immunogenicity of a Tetravalent Dengue Vaccine (TDV) Administered Subcutaneously in Healthy Children Aged 4 – 16 Years Old

Date of commencement (enrolment of first participant): 10 Aug 2016 (first subject was screened to the study from site 3409, Negombo District General Hospital)

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Date of commencement: 10 Aug 2016 (first subject was screened to the study from site 3409, Negombo District General Hospital)

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruiting

Number assessed for eligibility: 1460

Number recruited and randomized: 664

Number allocated to each intervention/arm: Double blinded

Losses/exclusions after randomization: 00

3. Trial output

Summary of Interim/Final data (if available): NA

Presentations of results at scientific meetings: NA

Publications: NA

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Date: