

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

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

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruitment completed on 11-March-2017

Number assessed for eligibility: 2721

Number recruited and allocated/randomized: 2100

Number allocated/randomized to each intervention/arm (please edit as relevant)

Arm 1: Double blinded either TDV or placebo in a 2:1 ratio

Arm 2: Double blinded either TDV or placebo in a 2:1 ratio

Losses/exclusions after allocation/randomization:

Arm 1: Double blinded

Arm 2: Double blinded

Overall number of subject discontinue from the study in Sri Lanka - 24 subjects

3. Trial output

Summary of Interim/Final data (if available):

Not yet available

Abstract presentations of results at scientific meetings - Not yet available

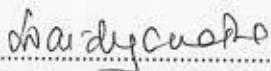
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Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
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Publications - Not yet available

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Dr Samantha Waidyanatha
Coordinating Principal Investigator

Date: 12/07/2018