

## Progress Report: Sri Lanka Clinical Trials Registry

---

SLCTR registration number: SLCTR/2015/004

Scientific title of trial: A Phase 3 Randomized Double-blind Study Comparing TR-701 FA and Linezolid in Ventilated Gram-positive Nosocomial Pneumonia

Date of commencement (enrolment of first participant): In Sri Lanka sites initiated in May 2015. Globally first patient was randomized on 19 Jun 2014.

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

---

### 1. Baseline data

Date of commencement:

- Sites Initiated in May 2015

Any changes to the trial design/ methodology/ protocol after commencement:

- Yes. Was notified via protocol amendment sheet dated 30 Sep 2015.

Any changes to trial outcomes after commencement:

- No

### 2. Current status

Recruitment status:

- recruiting

Number recruited and randomized:

- Globally 344: Sri Lanka - 01 (randomized/ no drug given)

Number allocated to each intervention/arm:

- To be confirmed at the end of trial, since it is double-blinded

Losses/exclusions after randomization:

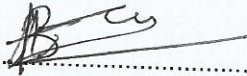
- 77 excluded after randomization: 10 randomized/ no drug given and 67 discontinued (USA 07, Russia 18, Ukraine 13, Georgia 16, Guatemala 03)
- Sri Lanka 01 (Consent withdrawal = randomized/ no drug given)

### 3. Trial output

Summary of Interim/Final data (if available): No final data available at this time

Presentations of results at scientific meetings: There have been no presentations on the study at any scientific meetings.

Publications: There have been no publications on this study.



.....  
Name and signature of Responsible Registrant  
Coordinating Principal Investigator  
Dr Asantha de Silva  
MBBS, MD (Anesthesiology), FRCA (Lond)  
Coordinating Principal Investigator

24.10.16  
.....  
Date: