

## ABSTRACTS OF ORAL PRESENTATIONS

### OP 001

#### Quality of clinical trial registration at the Sri Lanka clinical trials registry: a 5-year analysis

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#### Introduction & Objectives:

Previous studies have highlighted the poor quality of clinical trial registration in international registries. We sought to evaluate the quality of trial registration in the Sri Lanka Clinical Trials Registry (SLCTR).

#### Methods:

We studied all trial records at SLCTR over a 5-year period (2012-2016). Records were evaluated for data quality, using pre-defined criteria, regarding the following: WHO minimum trial registration data set (WHO-TRDS), ethics review approval, and detailed analysis of contact information, interventions and outcomes.

#### Results:

A total of 144 trial records were studied. All records had meaningful entries for 12 out of the 20 items in WHO-TRDS, and over 95% of records had meaningful entries for 16 items, while the mean TRDS score was  $17.76 \pm 1.03$ . Details of ethics approval were provided in all records. Intervention specifics were recorded for 174 experimental or active comparator arms. Meaningful information was provided regarding intervention name, dose, duration, frequency and route in 173 (99.4%), 156 (89.7%), 123 (70.7%), 132 (75.9%) and 109 (62.6%) arms respectively. A total of 388 primary outcome measures were recorded. Of them, 79.1% (n=307) were considered to be of good quality (specific – 76%; safety monitoring – 3.1%). Recording of time frame was considered to be of good quality for 94.4% (n=366) of outcome (meaningful – 83.8%; irrelevant – 10.6%). All records provided either email address or telephone number of contact person; 98% (n= 141) had both.

#### Conclusion:

Quality of clinical trial registration at the SLCTR is better compared to other international registries in almost all the domains studied. Trial registration of good quality is feasible and sustainable in a resource-limited setting.