June 23rd, 2015

Antibiotic Prophylaxis versus Placebo in Infants diagnosed with Hydronephrosis Antenatally (ALPHA). A prospective, randomized controlled trial.

**DSMB Meeting #6 Report**

The sixth Data Safety Monitoring Board (DSMB) for the ALPHA trial included participating members Dr. Steven Arora, Dr. Peter Fitzgerald and Mandy Rickard. Ms. Jennifer DCruz has reviewed the screening and recruitment of the ALPHA Trial thus far.

The trial opened on August 1, 2010 and at the time this meeting was convened 83 patients had been recruited from McMaster. All adverse and serious adverse events were reviewed for the 26 active subjects since the last meeting of this committee: from the period of May 12th 2014 to June 18th 2015.

There were a total of 51 events reviewed at this meeting, 51 of which were considered non-serious and 0 as serious adverse events. The events were categorized by their degree of severity: 10 were moderate, 39 were mild, and 2 had no signs or symptoms. Events were reviewed for relatedness to the study drug: 42 were considered unlikely related to the study drug and 9 were possibly related. None of the events reviewed were categorized as probably or definitely related to the study drug.

There were no concerns of the safety of patients enrolled in the ALPHA Trial. The committee members unanimously agreed that this trial should remain open and continue to enroll patients.

Respectfully submitted,

[Signature]

Dr. Steven Arora  
DSMB Chair for the ALPHA Trial