

## Guatemala PanTheryx Study

This is a double blind, randomized, placebo-controlled trial to assess the impact of the nutritional product PTM202 on acute and long-term recovery from childhood diarrheal disease in Guatemalan Children. The study will have two arms. The first arm (Arm 1) will enroll children with more severe diarrheal disease and will include children requiring inpatient treatment, and the second (Arm 2) will enroll children with moderate disease not requiring inpatient management. Children with mild dehydration not requiring any rehydration or active medical intervention will not be included. All decisions related to need for hospitalization will be made by non-study attending physicians at the time of presentation to medical care without reference to study procedures. Subjects will be approached for enrolment after medical assessment at two sites in Guatemala (Guatemala City and Trifinio). Following consent and enrollment, subjects will be block-randomized and stratified by age (to control for age distribution) to receive the study product or placebo. The product/placebo will be administered once daily for 3 days.

Hospitalized (Arm 1) children will be followed daily while admitted. Following discharge parents will complete a diary of pertinent events for 4 weeks starting from day 3 of the study (at which point subjects will have been rehydrated), have telephone contact at 1 and 3 weeks and have two follow-up visits at 2 and 4 weeks following completion of the study product course. Thus the entire study period for hospitalized subjects will be 4 weeks plus 3 days.

Outpatient (Arm 2) children will be followed during any required clinic or emergency room treatment period, and have follow-up visits on days 2 and 3, telephone contact at 1 and 3 weeks and two follow-up visits at 2 and 4 weeks following completion of the study product course. Thus the study period for Arm 2 will be 4 weeks plus 3 days.

All study data will be collected initially in paper format, and then inputted and stored in a REDCap database. REDCap is a secure, web-based application for building and managing online surveys and databases, maintained at the Colorado Clinical and Translational Sciences Institute (CCTSI).