**PTM Study --- a RCT for nutritional Intervention**

**in Bangladeshi Children**

**Background**

A randomized placebo-controlled trial in Bangladesh was conducted to determine the effect of PTM202 on environmental enteric dysfunction (EED). Healthy 6 to 9-month-old Bangladeshi infants were randomized to receive either 7g of PTM202 plus micronutrient sprinkles or micronutrient sprinkles alone, twice a day for 30 days via directly observed therapy. PTM202 is a nutritional supplement composed of a combination of bovine colostrum and egg protein. Both the cows and hens are specifically vaccinated to induce antibodies in colostrum and eggs which provide passive immunity against human enteric pathogens. PTM202 has been shown to decrease the duration of diarrhea in Guatemalan and Indonesian children.

**Three Datasets:**

1. PTM\_baseline: demographics and socioeconomic status

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| **Var Name** | **Description** |
| SID | Study Identification, Primary key field. |
| Trt | treatment group assignment (1=PTM202 , 2=Control) |
| Sex | Sex of Child (1 = Male & 2 = Female) |
| Aged | child age in days |
| MEMBER | number of members are in your household |
| CHILDREN | Number of living children |
| HH\_LIVE | years lived in current household |
| SLEEP | Number of people usually sleeping in household |
| FAMILY\_TP | Family type (1 = Nuclear & 2 = Joint) |
| OWNHH | Do you own the house you live in? (1=yes & 2=no) |
| INCOME | Total monthly Income (in taka). |
| EXPEN | Monthly Total expenditure (in taka) |
| HH\_CLASS | Household food availability: 1 = Deficit in whole year, 2 = Sometimes deficit, 3 = Neither deficit nor surplus, 4 = Surplus |
| Mom\_EDU | Mother education |
| Dad\_EDU | Father education |
| Septic\_toilet | 1 = Septic tank or toilet |
| treated\_water | Indicator for water treatment (1 = Yes) |
| toilet\_share | Toilet facility shared with other households (1 = Yes) |
| open\_drain | Open drain beside your house (1 = Yes) |

1. PTM\_Anthro\_long: longitudinal anthropometric data from screening to ~90 days after randomization

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| **Var** | **Description** |
| sid | Study Identification, Primary key field |
| vtime | visit time: 1=Screening/ Enrollment, 2=Start of intervention (Day 1), 3=End of the intervention (31-37 days), 4=Follow up (Day 60-67), 5=Final (Day 90-97) |
| agem | Age in Months |
| wtkg | Weight in Kilogram (KG) |
| htcm | Height in Centimeter (CM) |
| HAZ | Height for Age Zscore |
| WAZ | Weight for Age Zscore |
| WHZ | Weight for Height Zscore |

1. PTM\_lab: inflammatory biomarkers from fecal and blood samples

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| **Var** | **Description** |
| SID | Study Identification, Primary key field |
| SPECSEQ | Specimen sequence, 1= Enrollment; 2= 1 month after intervention |
| VST | visit time |
| MPO | Myeloperoxidase result ng/ml |
| Reg1b | Reg1B result µg/ml |
| sCD14 | sCD14 result ng/ml |
| CRP | CRP (mg/L) |

**Original study objective**: to evaluate the effectiveness of PTM202 in treating environmental enteric dysfunction (EED) and improving nutritional status.

However, the two arms are not significantly different in the outcome measures. Considering the heterogeneity in treatment effects and/or clinical factors, is there a subset of children who can benefit from the nutritional supplement? How to identify those children so that a targeted intervention can be developed?

**Current study objective**: to identify a subset of children who have benefited from the PTM nutritional intervention.