IMPAACT P1092
RATIONALE AND OBJECTIVES

STUDY–SPECIFIC TRAINING
15 JUNE 2015
Severe malnutrition is one of the most common presentations of HIV infection in African children, with wasting recognized as a risk factor for mortality.

In severe malnutrition, metabolic and/or gut structural derangement may lead to inadequate ARV absorption and/or erratic drug levels.

The greater surface area to weight ratio in severely malnourished children could also place them at higher risk of ARV under-dosing.

There is a paucity of pharmacokinetic data in severely malnourished children, which this study aims to address in order to inform dosing guidelines for this vulnerable population.
PRIMARY OBJECTIVES

- To compare the PK exposure (plasma concentration over time) and clearance of ZDV, 3TC, and LPV/r under steady state conditions between severely malnourished children and normal to mildly malnourished children (Weeks 1, 12, 24)

- To evaluate the safety and tolerability of ZDV, 3TC, and LPV/r in severely malnourished children and normal to mildly malnourished children (through Week 24)
SECONDARY OBJECTIVES

- To compare the minimum concentration of LPV/r between severely malnourished children and normal to mildly malnourished children (Weeks 1, 4, 8, 12, 16, 24, 36, 48)

- To investigate the impact of malnutrition on LPV protein binding by comparing the free fraction of LPV in severely malnourished children and normal to mildly malnourished children (Weeks 1, 12, 24)
SECONDARY OBJECTIVES

- To compare viral loads between severely malnourished children and normal to mildly malnourished children (*baseline and Weeks 12, 24, 36, 48*).

- To compare CD4 cell percentages between severely malnourished children and normal to mildly malnourished children (*baseline and Weeks 12, 24, 36, 48*).

- To describe the recovery of lean body mass and linear growth in severely malnourished children (*Weeks 24, 48*).
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What are your questions about the study rationale and objectives?