NextGen Strategy Trial: A Phase II, Randomized Study Assessing Lopinavir/Ritonavir- and Dolutegravir-Based ARV Treatment in Infants and Children ≥ 1 Month to < 3 Years of Age
OVERVIEW OF 2006 STUDY DESIGN

200 HIV-infected infants and children
≥ 1 month to < 3 years of age

Stratification Factor 1: Age
≥ 1 – < 3 mths
≥ 3 – < 6 mths
≥ 6 – < 36 mths

Stratification Factor 2:
Prior treatment experience
No prior treatment experience
Failed NNRTI-based treatment

Randomization

Arm A
100 participants
(LPV/r-based ART)
followed for 48 weeks

Arm B
100 participants
(DTG-based ART)
followed for 48 weeks

Note: No limits on the number of participants in each stratum. Will aim to enroll a minimum of 12 participants less < 6 months of age in each treatment arm equally divided between 1-3 months and 3-6 months of age.
Additional Elements

• Recent approval by IMPAACT/DAIDS:
  – Pilot cohort of 30 TB/HIV co-infected children
  – Repository plasma samples for future inflammatory marker studies (Agwu, Complications)
  – Parallel Neurodevelopment Assessment Study (Boivin; needs to be submitted for review)

• Awaiting P1093 pk dose for dispersible tabs
  – Expected by end of 2016
  – Potential for 2006 V1.0 by early 2017