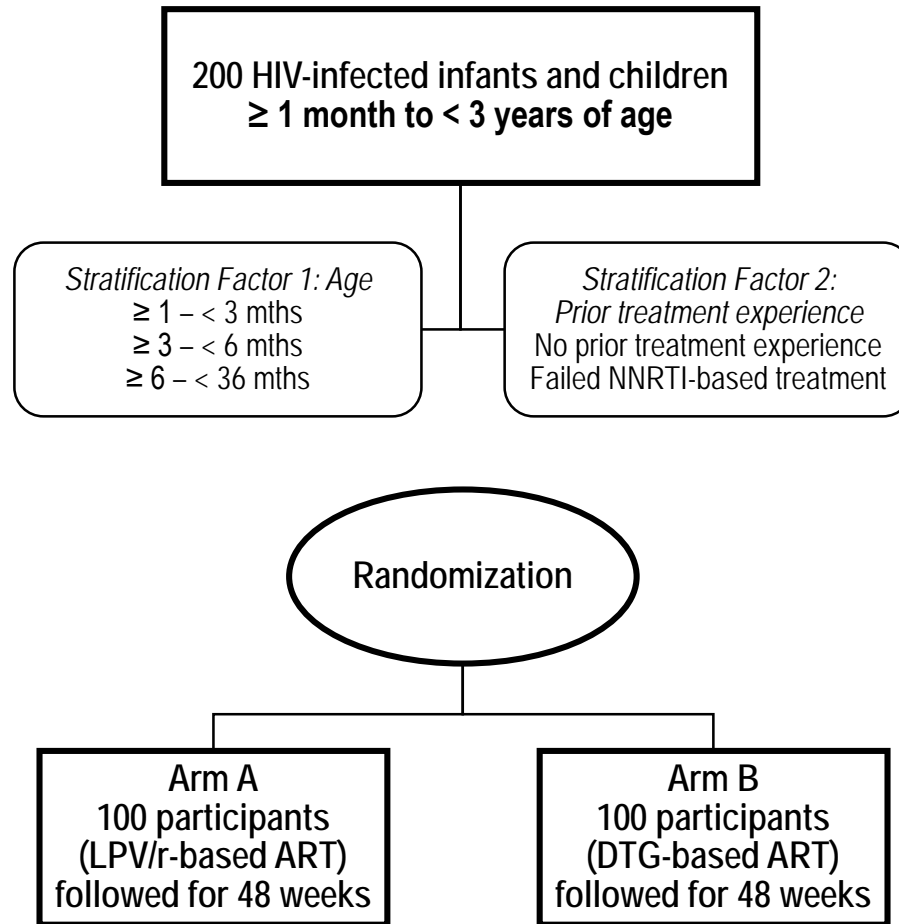


IMPAACT 2006

**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



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**