### Study Design: UW 300 PIC

**Background:** Pilot, open-label, randomized, phase 3 trial evaluating impact of adding raltegravir to standard ART during early HIV

**Inclusion Criteria (n = 92)**
- Age ≥18
- Antiretroviral-naïve
- HIV RNA ≥500 copies/mL <14 days of study entry
- Early HIV infection*

**Treatment Arms**
- RAL 400 mg BID + 2 NRTIs + [NNRTI or PI QD]
- 2 NRTIs + [NNRTI or PI QD]

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*R Early HIV defined as current positive HIV EIA and western blot with either a negative HIV EIA in past 6 months or negative point-of-care test or nonreactive less sensitive HIV EIA in past month

**Raltegravir Group**
- Raltegravir plus 2 NRTIs plus [NNRTI or PI] (n = 5)

**Standard ART**
- 2 NRTIs plus [NNRTI or PI] (n = 5)

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Raltegravir plus Standard ART in Early HIV Infection
UW 330 PIC: Results

First Phase Plasma HIV RNA Decay

**Interpretation**: “Our results suggest homogeneity of responses in cell-associated RNA, HIV DNA, CD4(+) T-cells with replication-competent virus, and 2LTR circles with early HIV in both ART groups. The kinetics of 2LTR DNA did not reflect the kinetics of plasma HIV RNA decline following ART initiation.”
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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*