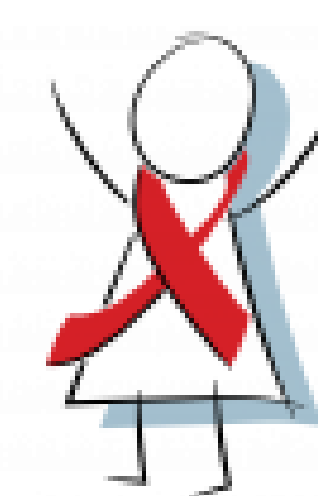




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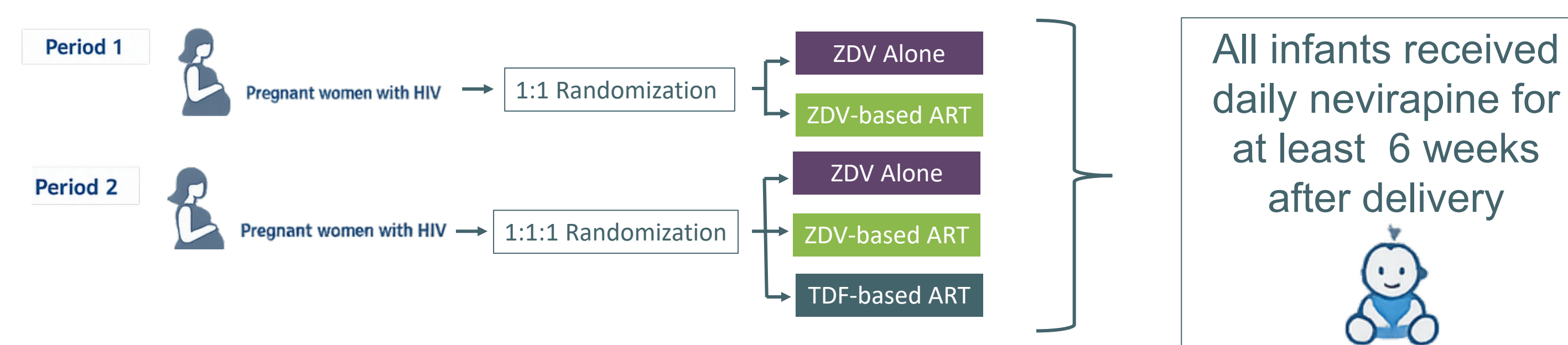
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BACKGROUND

- Children who are HIV-exposed experience multiple interrelated exposures that are associated with poorer early-life outcomes, including an increased risk of stunting.
- Among infants born to women with HIV randomized in PROMISE, we compared **infant growth** through **two years of age** by antepartum maternal ART exposure and prematurity status.

PROMISE STUDY

IMPAACT 1077BF/FF Antepartum component randomization:



PROMISE Countries: India, Malawi, South Africa, Tanzania, Uganda, Zambia, Zimbabwe

Among infants born to women with HIV:

- exposure to maternal antepartum ART was associated with *modestly lower* growth at **6 months**, but differences attenuated by two years of age
- prematurity was associated with *persistently lower* growth through **two years of age**

METHODS

Growth outcome measures:

- Length-for-age Z-scores (**LAZ**) based on WHO growth standards at **Weeks 26** (6 months) and **104** (2 years)
- Weight-for-age Z-scores (**WAZ**) based on WHO growth standards at **Weeks 26** (6 months) and **104** (2 years)

Comparison groups:

- Antepartum randomization arm: ZDV-based ART vs ZDV alone (Periods 1 & 2)/ TDF-based ART vs ZDV alone (Period 2)
- Gestational age at birth (by date of LMP): <37 (premature) vs ≥37 weeks

Statistical approach:

- Compared** growth outcome measures using two-sided Student's t-tests
- Point estimates for the difference of mean z-scores, 95% confidence intervals (CIs), and p-values are presented

RESULTS

- Among 3537 treatment-naïve women, 97% were enrolled in East and Southern African countries
- Of 3407 infants, 51% were male, 17% had a birth weight <2900 g, and 17% (n = 586) had a gestational age <37 weeks
- Across all arms, mean LAZ and WAZ were less than 0 and decreased from Week 26 to Week 104.

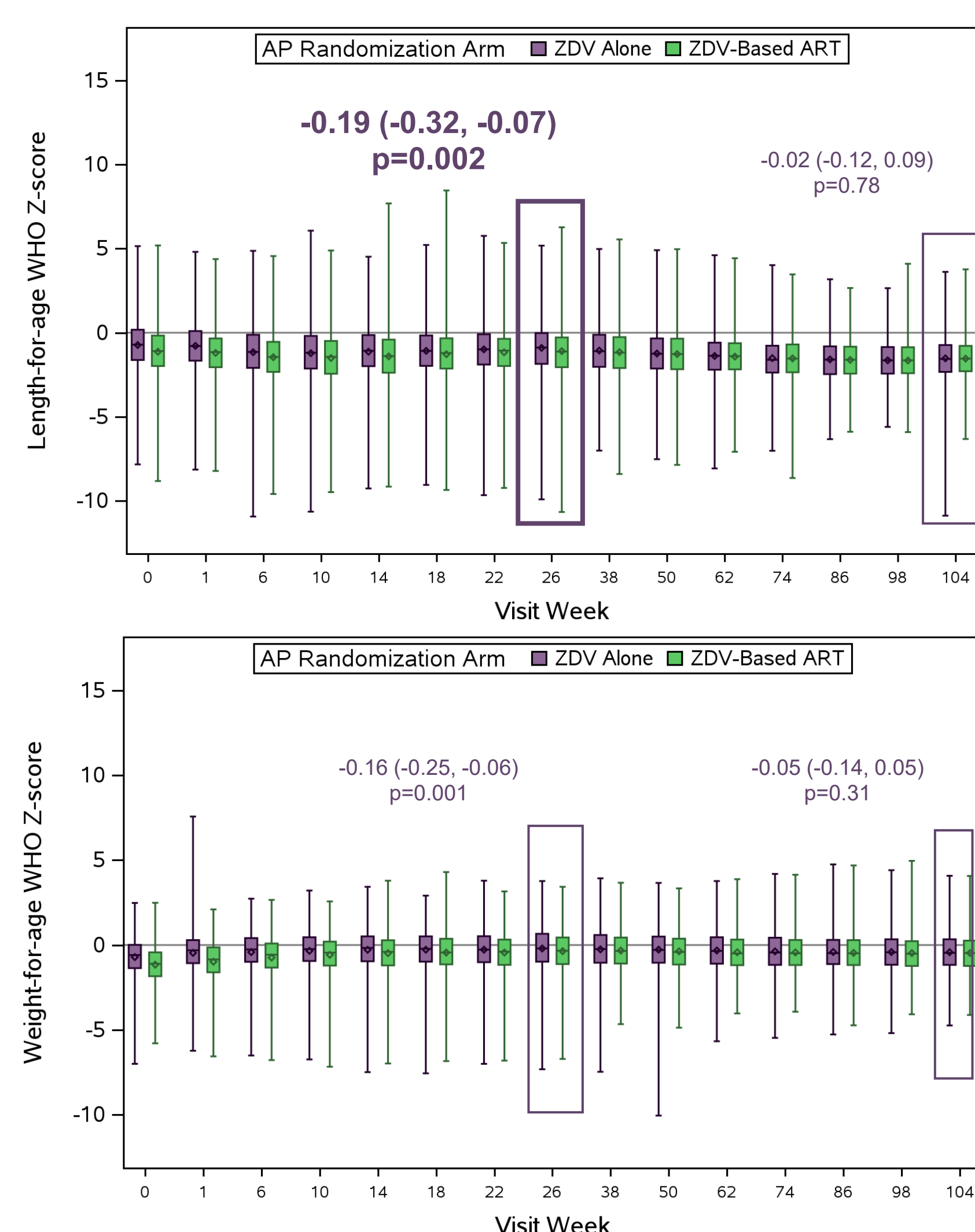


FIGURE 1. LAZ (top) and WAZ (bottom) for ZDV-based ART (green) vs ZDV Alone (purple) during Periods 1 & 2

- At Week 26, mean LAZ in the ZDV-based ART arm was 0.19 SDs lower than the ZDV alone arm (95% CI: -0.32, -0.07)
- This difference was negligible by Week 104 (-0.02; 95% CI: -0.12, 0.09; p=0.76)
- Findings were similar for WAZ

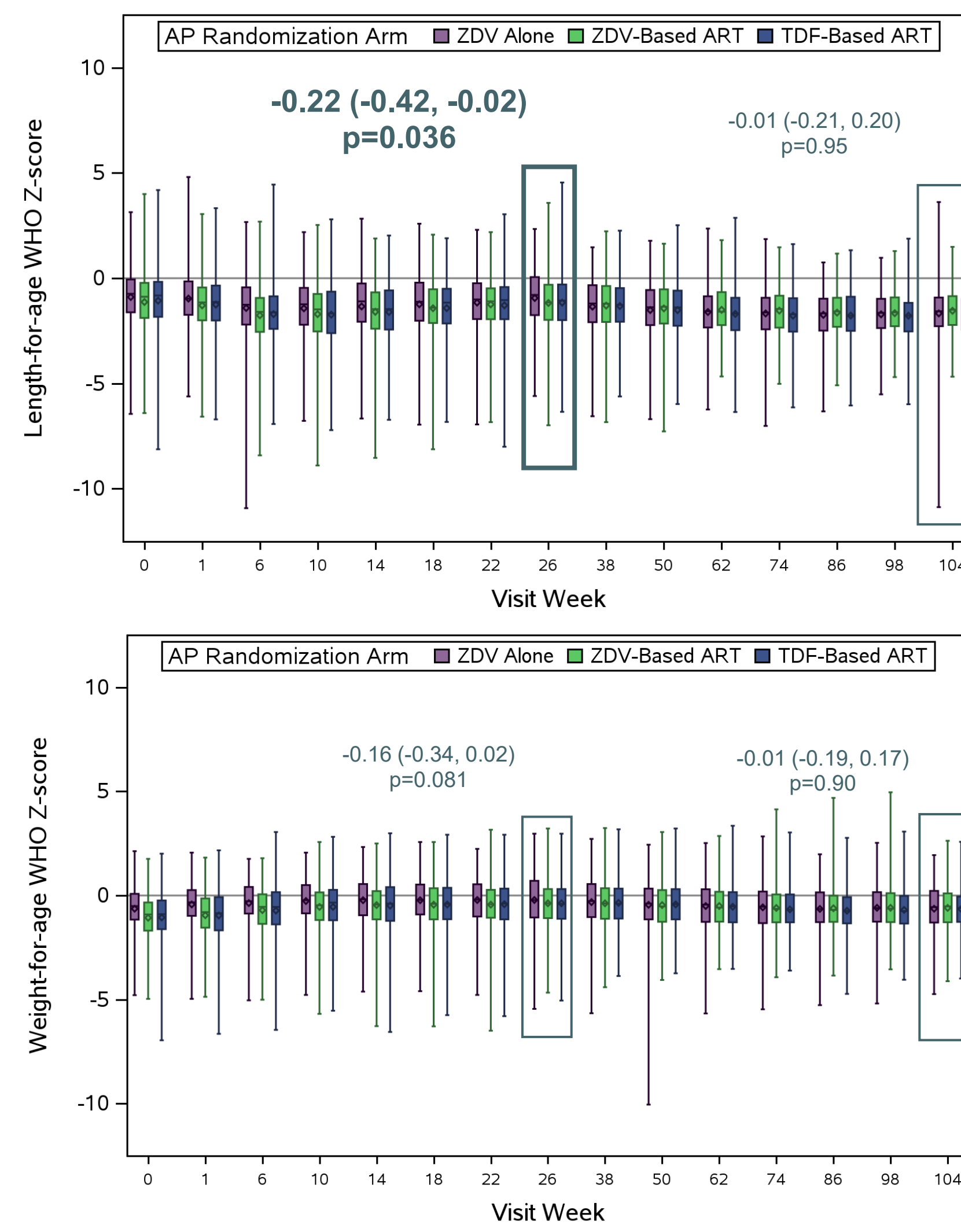


FIGURE 2. LAZ (top) and WAZ (bottom) for TDF-based ART (blue) vs ZDV Alone (purple) during Period 2

- At Week 26, mean LAZ in the TDF-based ART arm was 0.22 SDs lower than the ZDV alone arm (95% CI: -0.42, -0.02)
- This difference was negligible by Week 104 (-0.01; 95% CI: -0.21, 0.20; p=0.95)
- Findings were similar for WAZ

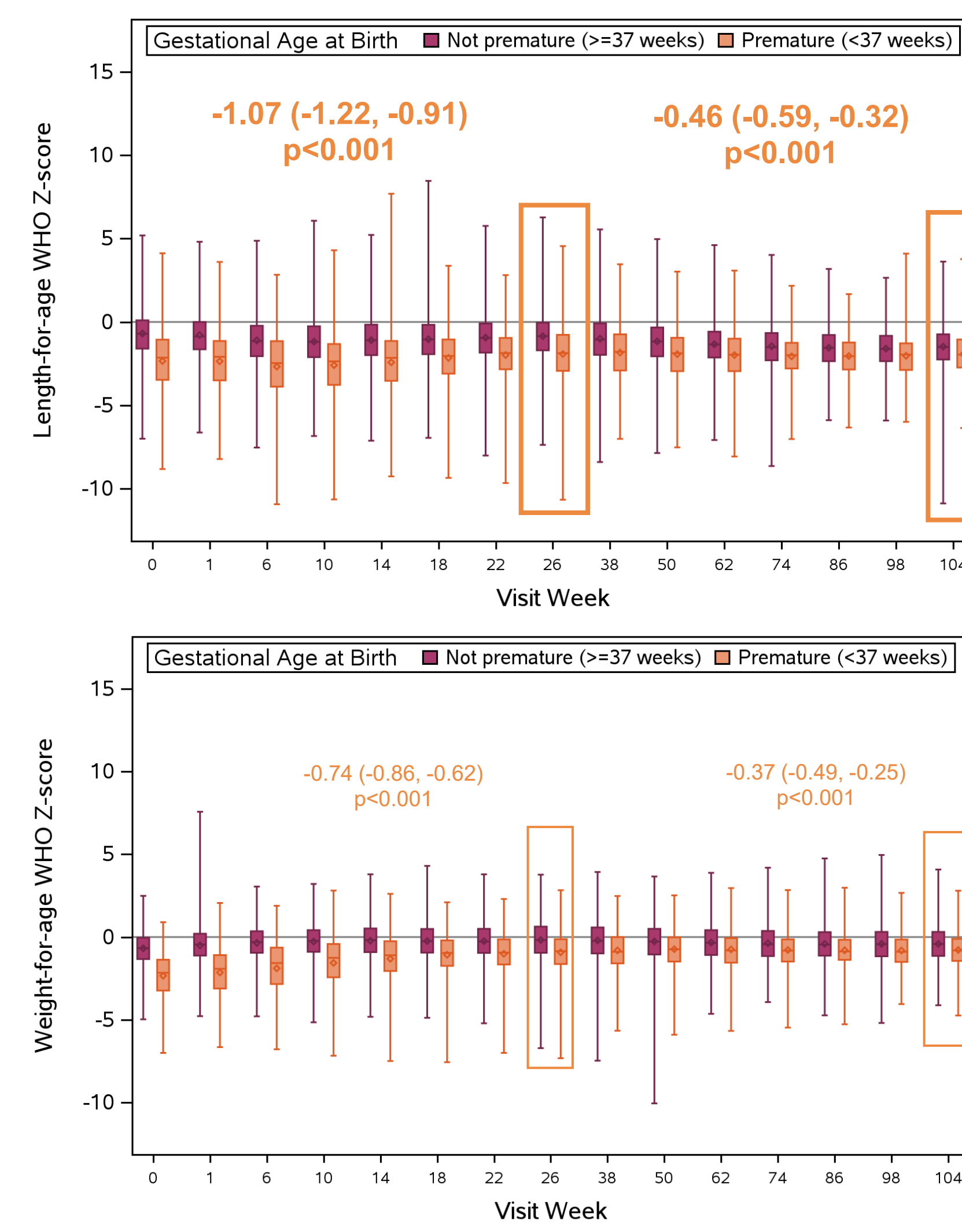


FIGURE 3. LAZ (top) and WAZ (bottom) for Premature (orange) vs Not Premature (maroon)

- At Week 26, mean LAZ for infants who were premature was 1.07 SDs lower than infants who were not premature (95% CI: -1.22, -0.91)
- The mean remained lower at Week 104 [-0.46 (-0.59, -0.32)].
- Similar patterns were observed for WAZ (both p<0.001).

CONCLUSIONS

Among infants born to women with HIV:

- Infant exposure to maternal antepartum ART was associated with *modestly lower* height- and weight-for-age z-scores at **6 months of age**, but differences attenuated by two years of age.
- Prematurity was associated with *persistently lower* height- and weight-for-age z-scores through **two years of age**, demonstrating suboptimal postnatal catch-up growth.

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