



# Antepartum weight gain and adverse pregnancy outcomes in IMPAACT 2010

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# Antepartum weight gain and adverse pregnancy outcomes in IMPAACT 2010

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# Background and Rationale

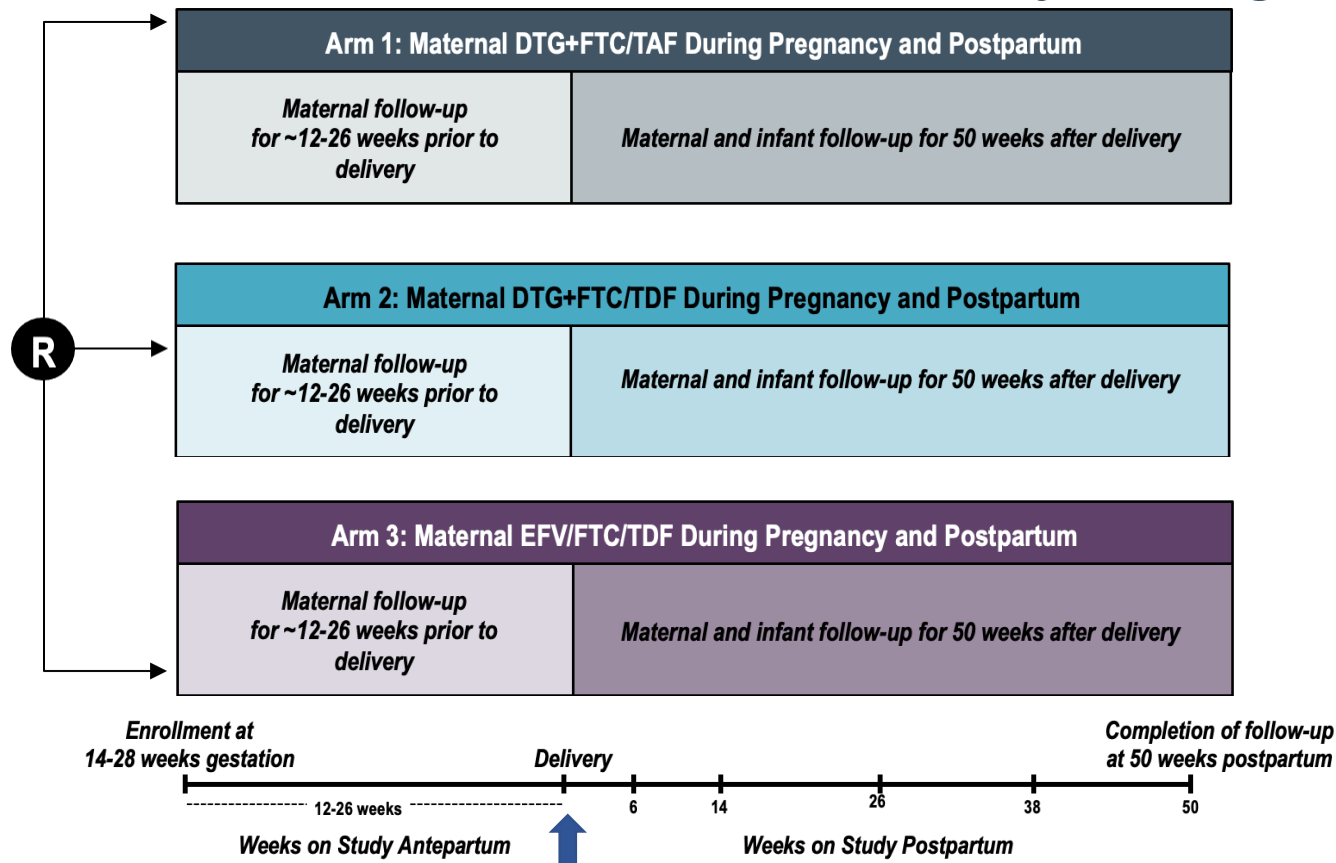
- ▶ ART containing dolutegravir (DTG) and/or tenofovir alafenamide fumarate (TAF) is associated greater weight gain in both non-pregnant and pregnant women<sup>1,2</sup>
- ▶ Efavirenz (EFV) and tenofovir disoproxil fumarate (TDF) have been associated with low weight gain in pregnancy<sup>2</sup>
- ▶ Both insufficient and excessive weight gain in pregnancy have been associated with adverse pregnancy outcomes<sup>3</sup>
- ▶ IMPAACT 2010: pregnant women with HIV-1 randomized to start treatment with DTG+FTC/TAF, DTG+FTC/TDF, or EFV/FTC/TDF
  - ▶ Significantly lower rate of adverse pregnancy outcomes in women in DTG+FTC/TAF arm than other two arms<sup>4</sup>

# Objectives and Methods

- ▶ Estimated by-arm differences in average antepartum weekly weight gain using generalized estimating equations
- ▶ Evaluated associations between weight gain and adverse pregnancy outcomes using Cox-proportional hazards regression\*:
  - ◆ Composite outcome of stillbirth ( $\geq 20$  wks GA), preterm delivery ( $< 37$  wks GA) and small for gestational age (SGA:  $< 10^{\text{th}}$  percentile)
  - ◆ Individual components of the composite outcome
  - ◆ Neonatal death
- ▶ Weight categories: low weight gain  $< 0.18$  kg/week and high weight gain  $> 0.59$  kg/week (Institute of Medicine Guidelines)

\*Weight included as a time-varying covariate; analyses adjusted for gestational age at baseline

# IMPAACT 2010 Study Design



**Key Eligibility Criteria**

- Pregnant women 14-28 weeks gestation

- ART-naïve



# Enrollment and Weight Data Availability

Screened = 810

Enrolled = 643 (79%)  
Jan 2018 – Feb 2019

Antepartum weight data  
available = 643 (100%)

Antepartum weight and pregnancy outcome data  
available = 632 (98.3%)

**Participants were enrolled at  
22 sites in 9 countries**

(Botswana, Brazil, India, South Africa,  
Tanzania, Thailand, Uganda, US,  
Zimbabwe)

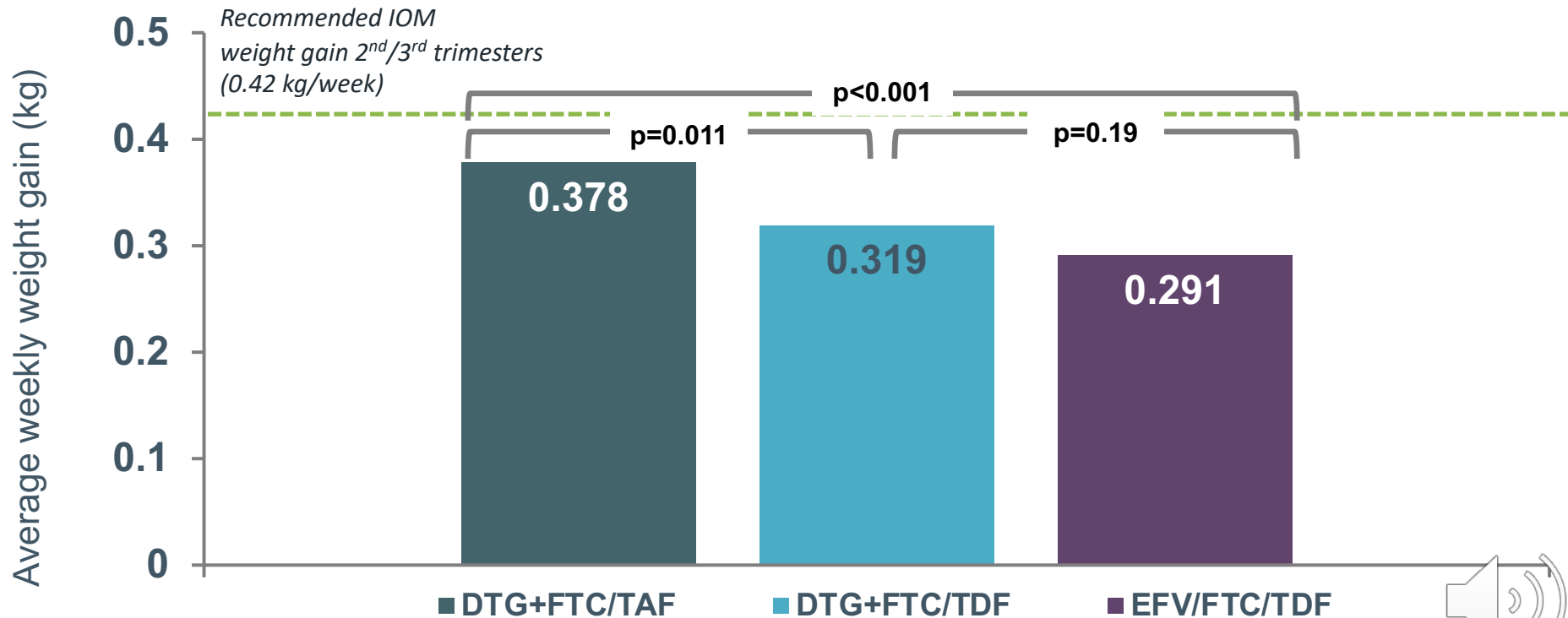
# Maternal Baseline Characteristics

	DTG+FTC/TAF (N = 217)	DTG+FTC/TDF (N = 215)	EFV/FTC/TDF (N = 211)	Total (N = 643)
<b>Age (median years)</b>	26.8	26.0	26.6	26.6
<b>Enrolled in Africa</b>	187 (86%)	189 (88%)	188 (89%)	564 (88%)
<b>Gestational age (median weeks)</b>	22.1	21.3	22.1	21.9
<b>CD4 count (median cells/mm<sup>3</sup>)</b>	467	481	439	466
<b>HIV-1 RNA (median copies/mL)</b>	781	715	1357	903
<b>Enrollment weight, mean kg (SD)</b>	67.7 (15.1)	66.3 (16.8)	64.5 (13.3)	66.2 (15.2)

*Median duration of antepartum follow-up: 17.4 weeks*

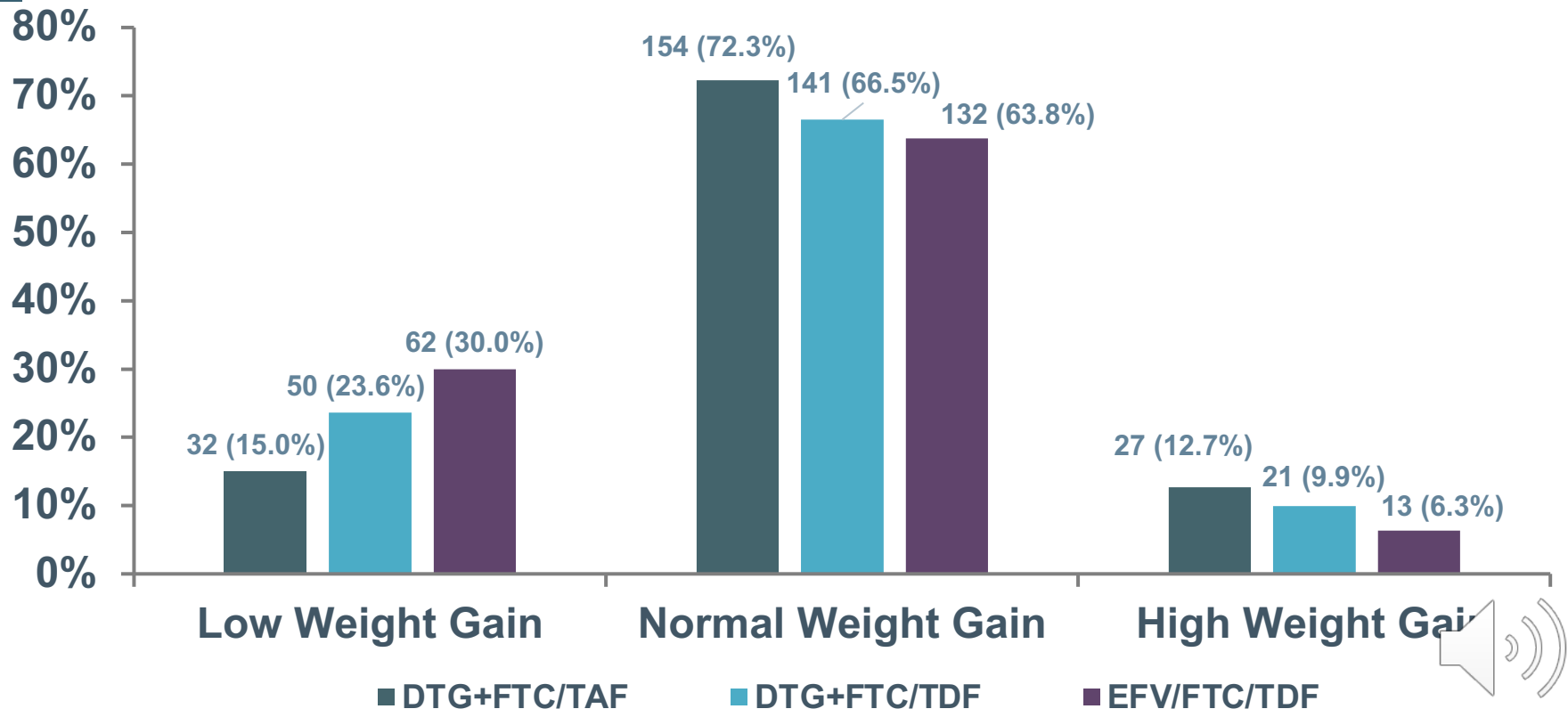


# Results: Average Weekly Maternal Weight Gain by Arm

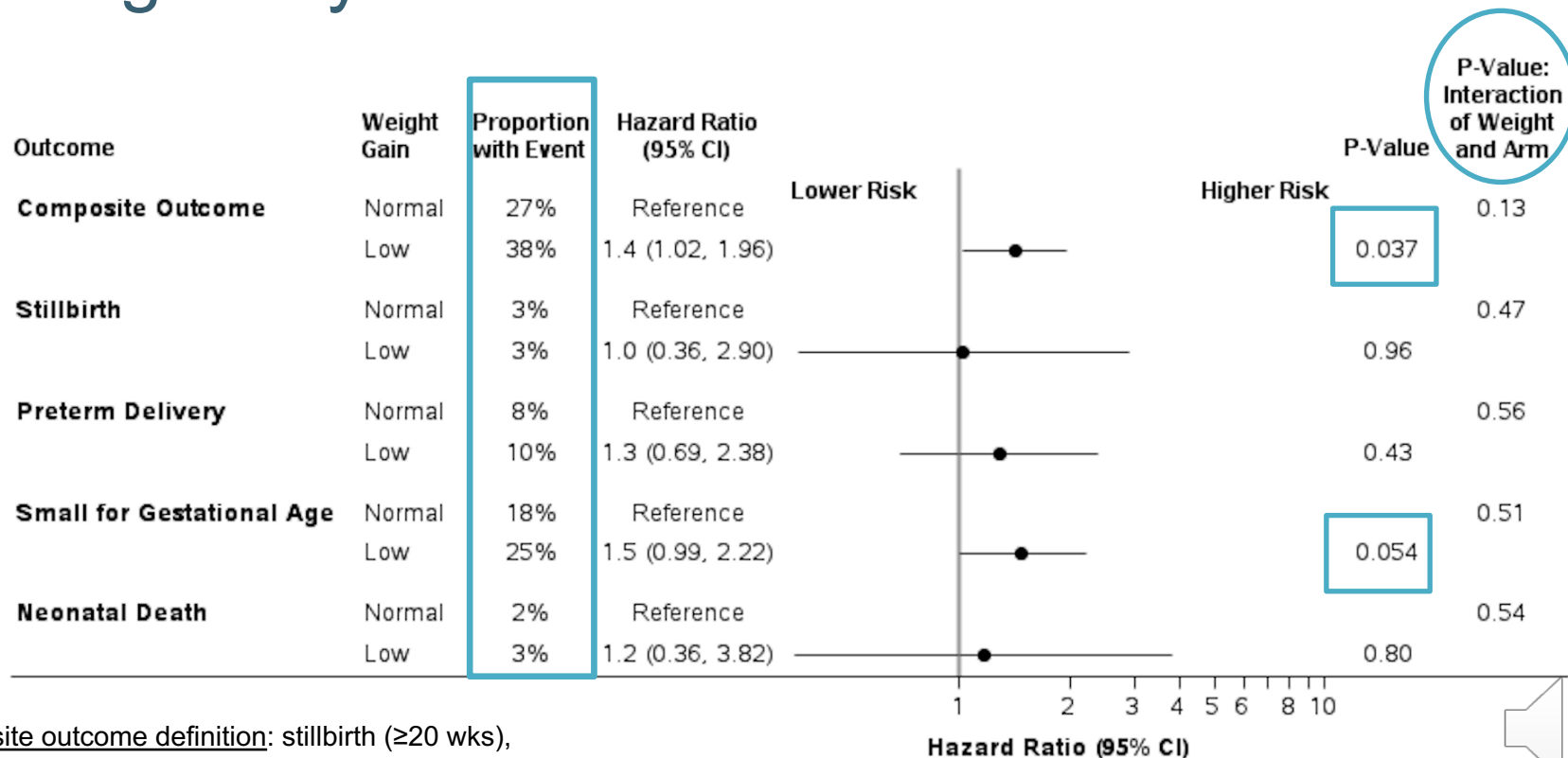




# Low, Normal, and High Antepartum Weight Gain by Arm



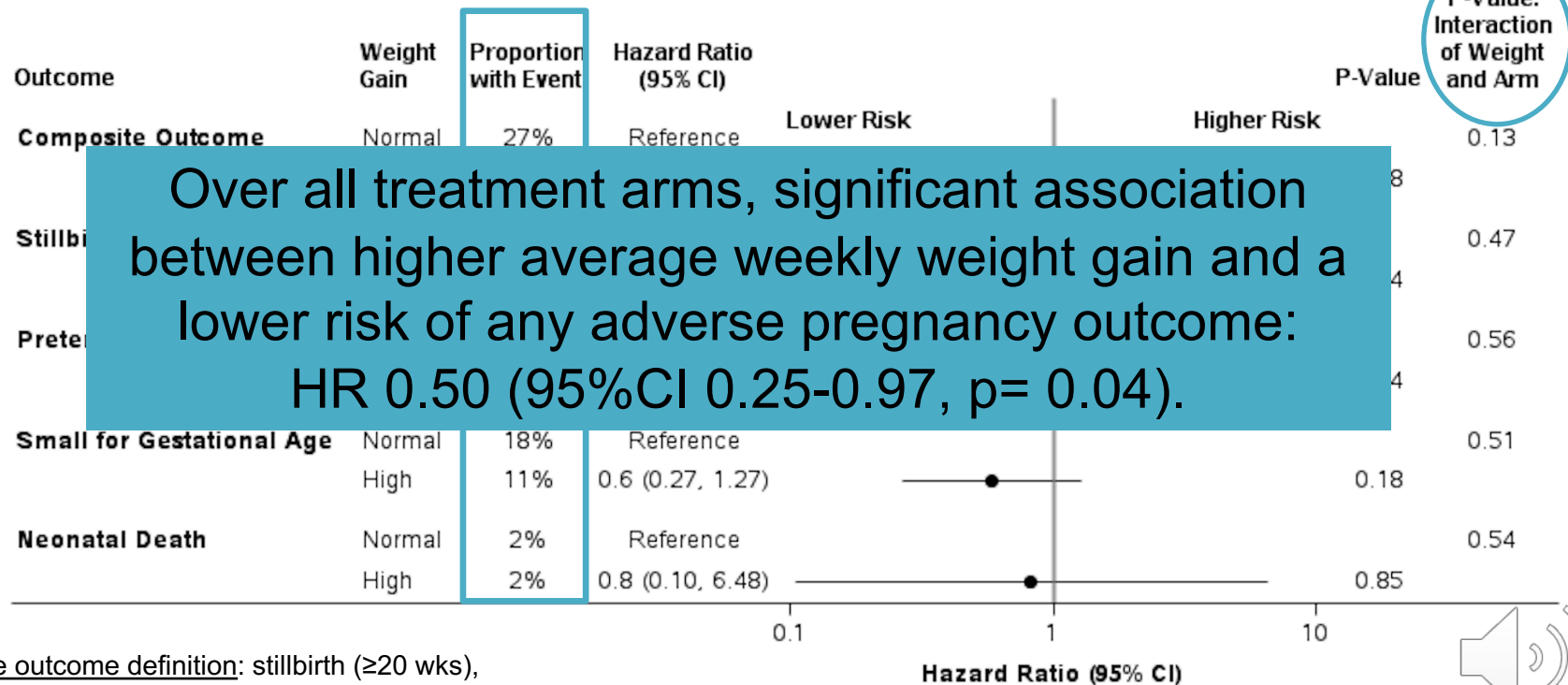
# Low Antepartum Weight Gain and Adverse Pregnancy Outcomes



Composite outcome definition: stillbirth ( $\geq 20$  wks), preterm delivery ( $< 37$  wks), and small for gestational age ( $< 10^{\text{th}}$  percentile)

Adjusted for gestational age stratum at baseline

# High Antepartum Weight Gain and Adverse Pregnancy Outcomes

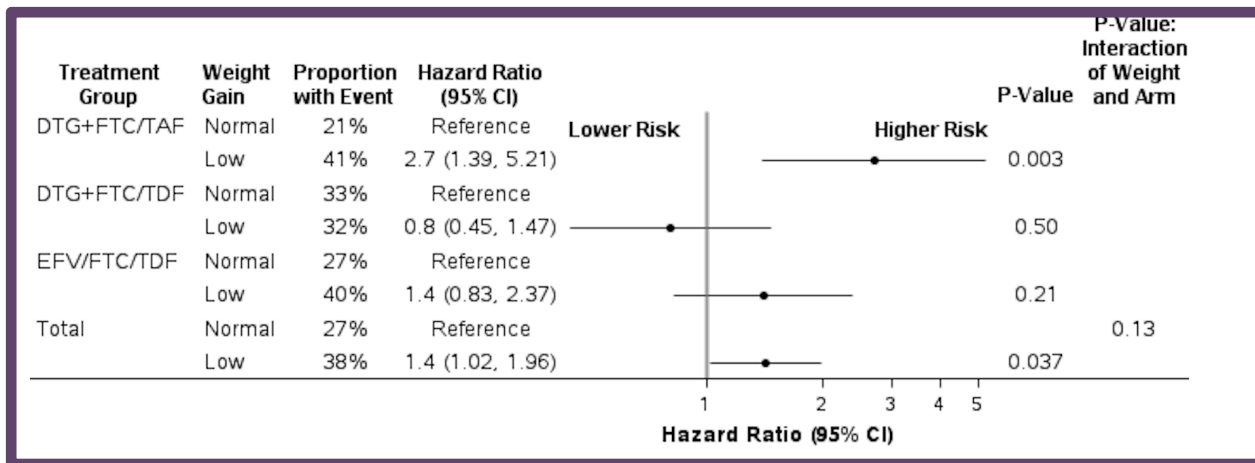


Composite outcome definition: stillbirth ( $\geq 20$  wks), preterm delivery ( $< 37$  wks), and small for gestational age ( $< 10^{\text{th}}$  percentile)

Adjusted for gestational age stratum at baseline

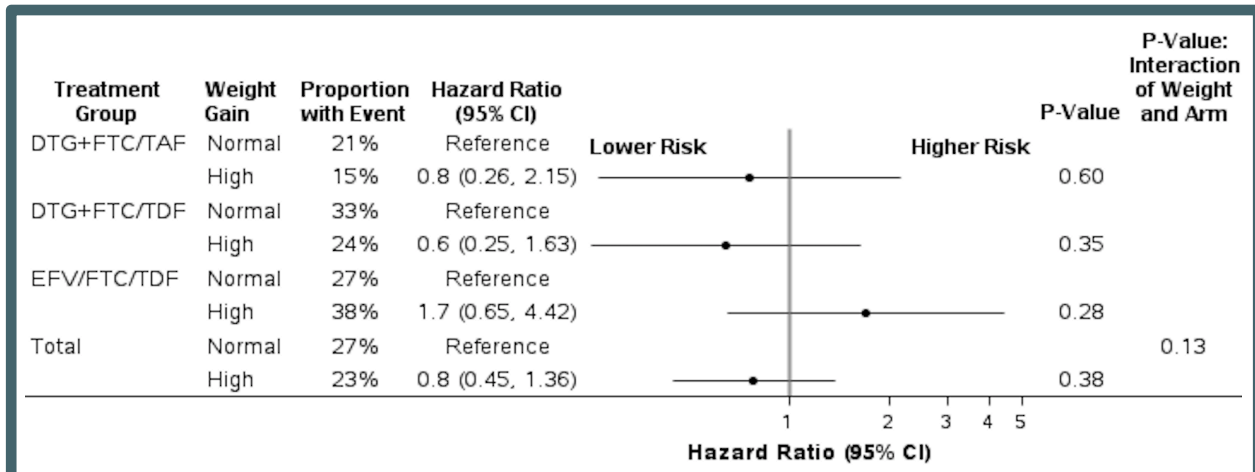
# Weight Gain and Composite Adverse Pregnancy Outcome\* by Arm

## Low vs Normal Weight Gain



Adjusted for gestational age stratum at baseline

## High vs Normal Weight Gain



\*Composite outcome definition:  
stillbirth ( $\geq 20$  wks), preterm delivery ( $< 37$  wks), and small for gestational age ( $< 10^{\text{th}}$  percentile)



# Future Analyses and Limitations

- ▶ Further planned analyses
  - ▶ Weight gain and severe outcomes (very preterm <32 weeks; very small for gestational age (<3<sup>rd</sup> percentile), stillbirth, and neonatal death)
  - ▶ Weight gain and macrosomia
  - ▶ Weight gain and C-section
  - ▶ Detailed analysis of postpartum weight through 50 weeks
- ▶ Limitations: lack of pre-pregnancy weight/BMI; predominantly an African population, all women initiated ART in pregnancy

# Conclusions

- ▶ Low weight gain during pregnancy was most common in women starting EFV/FTC/TDF and least common with DTG+FTC/TAF
- ▶ Low but not high weight gain associated with adverse pregnancy outcomes
- ▶ Weight gain on DTG+FTC/TAF approached average weight gain recommended in the 2<sup>nd</sup>/3<sup>rd</sup> trimester based on IOM standards
- ▶ The lower rate of adverse pregnancy outcomes observed in the DTG+FTC/TAF arm could be related to higher antepartum weight gain

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