

# **IMPAACT 2010**

## **Phase III Study of the Virologic Efficacy and Safety of Dolutegravir-Containing versus Efavirenz- Containing Antiretroviral Therapy Regimens in HIV-1-Infected Pregnant Women and Their Infants**

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Adherence Working Group Meeting, 30 May 2017



# VESTED

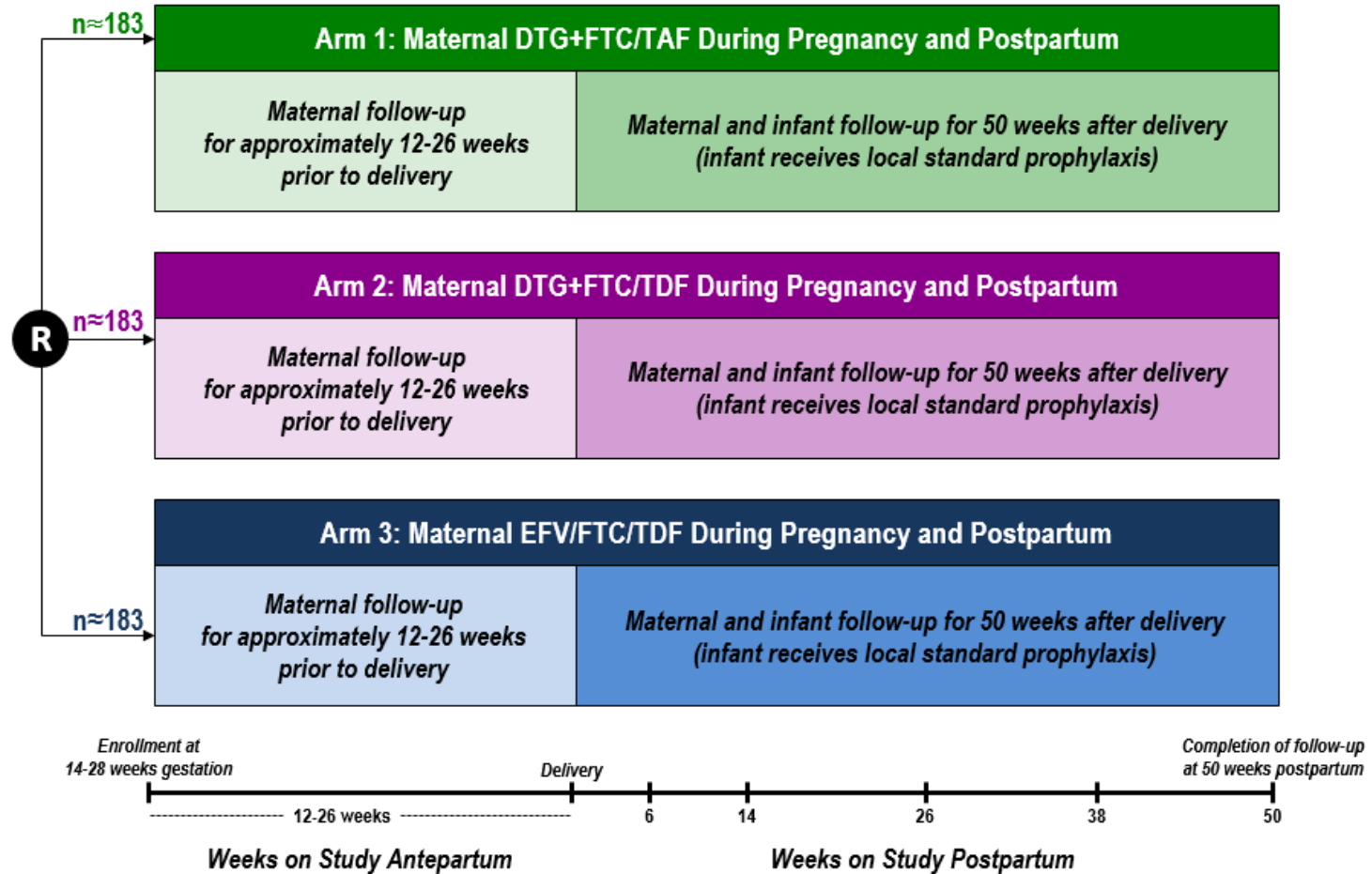
## Virologic Efficacy and Safety of ART Combinations with TAF/TDF, EFV, and DTG



# VESTED

- Purpose:** To compare the virologic efficacy and safety of three antiretroviral regimens for HIV-1-infected pregnant women and to compare the safety of these regimens for their infants
- Design:** Phase III, three-arm, randomized, open-label study
- Population:** HIV-1-infected pregnant women initiating antiretroviral therapy at 14-28 weeks gestation and their infants
- Sample Size:** 549 mother-infant pairs (approximately 183 per arm)

# VESTED Study Design



# Primary Objectives

*To determine the following among HIV-1-infected pregnant women and their infants:*

- Whether treatment initiated during pregnancy with a DTG-containing regimen is superior to EFV/FTC/TDF with regard to virologic efficacy (HIV-1 RNA <200 copies/mL) at delivery
- Whether rates of the following safety outcomes differ for any pairwise regimen comparison
  - Adverse pregnancy outcomes (spontaneous abortion, fetal death, preterm delivery, or small for gestational age)
  - Maternal grade 3 or higher adverse events through 50 weeks postpartum
  - Infant grade 3 or higher adverse events through 50 weeks postpartum

# Adherence Support

- Adherence counseling throughout the study period
  - Consistent with local standards of care and site SOPs
  - Client-centered, tailored as needed to the information, skills building, supportive of needs of each mother
  - Two-tiered: routine counseling, with additional client-centered counseling in instances of adherence challenges, virologic failure (to help identify and overcome barriers, and identify and support facilitators of adherence)
  - Results of HIV-1 viral load may be used to guide feedback to mothers and associated adherence counseling

# Adherence-Related Scientific Objective

The exploratory objective:

Assess adherence to maternal ART regimens in the antenatal and postnatal periods and describe barriers and facilitators of adherence during these periods

# Adherence-Related Assessments

- Virologic suppression
  - HIV-1 RNA at entry, 4, 8, 12 and every 12 weeks thereafter until delivery
  - HIV-1 RNA at delivery and at 14, 26, 38, 50 weeks postpartum
- Self report, with routine adherence questionnaire at every study visit
  - 3-item measure (Wilson et al, AIDS and Behavior 2014 and 2016) plus visual analogue scale
  - Administered by individual who does not prescribe study ARVs; results not used in adherence support
- Assessment of barriers and facilitators (weeks 8 on study and 38 postpartum)
  - Also administered by individual who does not prescribe study ARVs
- Questionnaire regarding participant experience of adherence support provided (or not) at their study clinic (final/week 50 visit, questions not yet finalized)
- Hair ARV levels
  - One time, at delivery (mother)/ birth (infant)



# Routine Adherence Assessment

2010\_V1.0.0 Matrices: Print Matrix

Folder: PRINT

Form: QLW10001: IMPAACT 2010 Routine Adherence Assessment

1 - Was this questionnaire completed? Yes   
No

If No, specify reason not done [200]: \_\_\_\_\_

I am going to ask you some questions about taking your ARVs. We are collecting this information from all women in the study so we can get an idea of how everyone is doing with trying to take ARVs each day, which we know can be really challenging. I am happy to speak with you about any of these questions and answers after we complete the questions. I also want to be clear that the information you give me is private. Your answers will be combined with other women's answers, but will not otherwise be shared. My job is to ask these questions and collect your answers. Are you ready to begin? {confirm and then proceed}

2. - In the last 30 days, on how many days did you miss at least one dose of any of your ARVs? [nm] \_\_\_\_\_

3. - In the last 30 days, how good a job did you do at taking your ARVs in the way you were supposed to? Very poor   
Poor   
Fair   
Good   
Very good   
Excellent

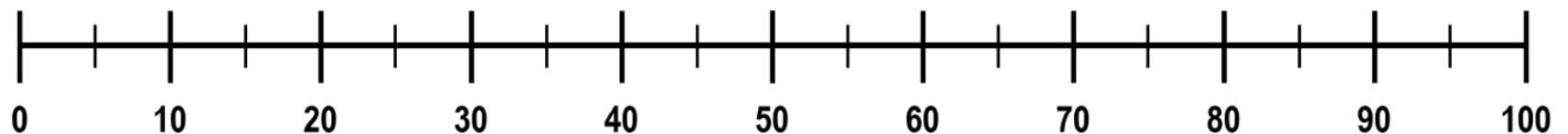
4. - In the last 30 days, how often did you take your ARVs in the way you were supposed to? Never   
Rarely   
Sometimes   
Usually   
Almost always   
Always

5. - Point to the place on the line showing how much of your ARVs you have taken in the last 30 days. Fixed Unit: % \_\_\_\_\_

# Routine Adherence Assessment

## VISUAL ANALOGUE SCALE

Point to the place on the line showing how much of your ARVs you have taken in the last 30 days.



1. - Was this questionnaire completed?

Yes No 

If No, specify reason not done [200]:

Antepartum Week 8 Instructions

These questions are about experiences women have with trying to take their ARVs each day. Different things make taking ARVs every day difficult, while other things make it feel easier to do. First, I will go over a list of challenges women have reported to taking ARVs. Please tell me YES if what I say describes a challenge you have had with taking ARVs every day. Tell me NO if what I say has not been a challenge or has not created difficulty for you. I will not ask you about taking or missing doses during these challenges. The question is just whether or not you experienced the challenge at all since you entered the study, which was about 2 months ago. May we begin this section?

Postpartum Week 38 Instructions

These questions are about experiences women have with trying to take their ARVs each day. Different things make taking ARVs every day difficult, while other things make it feel easier to do. First, I will go over a list of challenges women have reported to taking ARVs. Please tell me YES if what I say describes a challenge you have had with taking ARVs every day. Tell me NO if what I say has not been a challenge or has not created difficulty for you. I will not ask you about taking or missing doses during these challenges. The question is just whether or not you experienced the challenge at all since you were pregnant, which was about 9 months ago. May we begin this section? "Since you were pregnant" refers to the period since delivery or other pregnancy outcome.

2. - BARRIERS: Mark a check box if 'Yes', or leave blank if 'No' (or if the mother declined to answer)

- |   |                          |
|---|--------------------------|
| a. - I did not understand how to take my ARVs   | <input type="checkbox"/> |
| b. - I forget to take my ARVs   | <input type="checkbox"/> |
| c. - I ran out of ARVs  | <input type="checkbox"/> |
| d. - I could not get to clinic because of transportation problems   | <input type="checkbox"/> |
| e. - I was traveling away from home and did not take my ARVs with me or ran out of ARVs while I was away              | <input type="checkbox"/> |
| f. - I could not get to the clinic for refills due to work schedule   | <input type="checkbox"/> |
| g. - I could not get back to my ARVs until past my dosing time, and did not take that dose of ARVs                    | <input type="checkbox"/> |
| h. - I had to share my ARVs with other people   | <input type="checkbox"/> |
| i. - My ARVs were lost, damaged, or stolen  | <input type="checkbox"/> |
| j. - I was around people who know my HIV status but don't know I am taking ARVs (I was trying to hide taking my ARVs) | <input type="checkbox"/> |
| k. - I was around people who don't know my HIV status (I was trying to hide taking my ARVs)                           | <input type="checkbox"/> |
| l. - I was around people who don't support taking ARVs  | <input type="checkbox"/> |
| m. - I had side effects from the ARVs that made me feel sick  | <input type="checkbox"/> |
| n. - I was worried about having side effects from the ARVs  | <input type="checkbox"/> |
| o. - I was worried about the ARVs being safe for my baby  | <input type="checkbox"/> |
| p. - I was worried about mixing the ARVs with other drugs or alcohol  | <input type="checkbox"/> |

1. - Was this questionnaire completed?

Yes

No

If No, specify reason not done [200]: \_\_\_\_\_

Antepartum Week 8 Instructions

Now I would like to ask you about things that may have made it easier for you to take your ARVs each day since you entered the study, which was about 2 months ago. Please think specifically about things that helped you or made you feel very confident about taking your ARVs. You may not have felt this way all the time, but if you felt this way at all in the last 2 months, please let me know. For each item I read to you, please tell me YES if what I say is something that was or is helpful to you; tell me NO if what I say has not been helpful to you. May we begin this section?

Postpartum Week 38 Instructions

Now I would like to ask you about things that may have made it easier for you to take your ARVs each day since you were pregnant, which was about 9 months ago. Please think specifically about things that helped you or made you feel very confident about taking your ARVs. You may not have felt this way all the time, but if you felt this way at all in the last 9 months, please let me know. For each item I read to you, please tell me YES if what I say is something that was or is helpful to you; tell me NO if what I say has not been helpful to you. May we begin this section? "Since you were pregnant" refers to the period since delivery or other pregnancy outcome.

2. - FACILITATORS: Mark a check box if 'Yes', or leave blank if 'No' (or if the mother declined to answer)

- a. - I thought about taking ARVs to stay healthy
- b. - I thought about taking ARVs to protect the health of my baby
- c. - I am used to taking my ARVs - it is habit
- d. - I was scared of what would happen if I didn't take my medications
- e. - I kept ARVs available/with me when I would need them
- f. - I took ARVs at the same time as something else I do every day
- g. - I had support from people close to me
- h. - I used a reminder (for example, phone alarm or person who reminded me)
- i. - I kept ARVs out where I could see them
- j. - I believed in the positive effects of the ARVs
- k. - I focused on what I wanted to do for myself - not what others thought I should do
- l. - I got helpful advice or support from study staff
- m. - I got helpful advice or support from other study participants
- n. - I wanted to avoid study staff getting mad or disappointed in me if I missed ARV doses
- o. - I wanted to see (or continue to see) my suppressed viral load result
- p. - I figured out a way to take my ARV medications in private
- q. - I feel uncomfortable when I miss taking an ARV dose
- r. - Identify any other factors that made it easier [200]: \_\_\_\_\_

3. - Of all the choices above, what is the MAIN reason that made it easier for you to take your ARV medication(s) every day?

I thought about taking ARVs to stay healthy



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