Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK Trial
**Background:** Randomized, double-blind, phase 3 study comparing the safety and efficacy of raltegravir versus efavirenz, each in combination with tenofovir DF and emtricitabine

**Inclusion Criteria (n = 569)**
- Antiretroviral-naïve patients
- Age ≥18 years
- HIV RNA ≥5000 copies/mL
- No resistance to EFV, TDF, or FTC

**Treatment Arms**
- Raltegravir + TDF-FTC
- Efavirenz + TDF-FTC

**Treatment Arms:***
- Raltegravir BID + TDF-FTC (n = 281)
- Efavirenz + TDF-FTC (n = 282)

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK: Results

Week 48: Virologic Response (Primary Analysis, Missing=Failure)

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Results

Week 48 Virologic Response (Observed-Failure Method)

STARTMRK: Results

Week 48 Virologic Response

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK: Results

Adverse Events through 48 Weeks

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK: Results

Week 48: Changes in Lipid Concentrations from Baseline

## Treatment Emergent Adverse Events in >10% of Subjects in Either Arm

<table>
<thead>
<tr>
<th></th>
<th>RAL + TDF-FTC (n = 281)</th>
<th>EFV + TDF-FTC (n= 282)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>6%</td>
<td>34%</td>
</tr>
<tr>
<td>Headache</td>
<td>9%</td>
<td>14%</td>
</tr>
<tr>
<td>Abnormal dreams</td>
<td>7%</td>
<td>13%</td>
</tr>
<tr>
<td>Immune Reconstitution Inflammatory Syndrome</td>
<td>6%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Interpretation: “Raltegravir-based combination treatment had rapid and potent antiretroviral activity, which was non-inferior to that of efavirenz at week 48. Raltegravir is a well tolerated alternative to efavirenz as part of a combination regimen against HIV-1 in treatment-naive patients.”
The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.