Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK Trial
### Study Design: STARTMRK Study

**Background:** Randomized, double-blind phase 3 study comparing the safety and efficacy of raltegravir with efavirenz, in combination with co-formulated 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

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**Raltegravir BID + TDF-FTC**  
(n = 281)

**Efavirenz + TDF-FTC**  
(n = 282)

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**StartMRK: Result**

**Week 48: Virologic Response (Primary Analysis, M=F)**

**Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC**

**STARTMRK: Result**

**Week 48 Virologic Response (Observed-Failure Method)**

```
<table>
<thead>
<tr>
<th>Baseline HIV RNA Level</th>
<th>Overall</th>
<th>≤100,000 copies/mL</th>
<th>&gt;100,000 copies/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir + TDF-FTC</td>
<td>241/263</td>
<td>111/120</td>
<td>130/143</td>
</tr>
<tr>
<td>Efavirenz + TDF-FTC</td>
<td>230/258</td>
<td>114/128</td>
<td>116/130</td>
</tr>
</tbody>
</table>
```

**HIV RNA <50 copies/mL (%)**

- Overall: Raltegravir + TDF-FTC 92%, Efavirenz + TDF-FTC 89%
- ≤100,000 copies/mL: Raltegravir + TDF-FTC 93%, Efavirenz + TDF-FTC 89%
- >100,000 copies/mL: Raltegravir + TDF-FTC 91%, Efavirenz + TDF-FTC 89%

Raltegravir versus Efavirenz in Combination Therapy
STARTMRK Trial: Results

Week 48 Virologic Response

Raltegravir + TDF-FTC vs. Efavirenz + TDF-FTC
STARTMRK: Result

Adverse Events through 48 Weeks

Raltegravir + TDF-FTC vs. Efavirenz + TDF-FTC

STARTMRK: Result

Week 48: Changes in Lipid Concentrations

## Raltegravir + TDF-FTC vs. Efavirenz + TDF-FTC

### STARTMRK: Common Adverse Events

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events in &gt;10% of Subjects in Either Arm</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 (IRIS)</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.”
Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

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