Discrepancies in the MERIT study between the original and enhanced Trofile assay were recently reclassified.

### Background

- **The proportion of patients with discordant original Trofile vs enhanced Trofile screening results was assessed.**
- **Overall, 106/721 (15%) of patients who had an R5 tropism result at screening with the original Trofile assay were retested with the enhanced assay.**
- **All analyses were prespecified by Pfizer in a statistical analysis plan.**
- **No clinical outcome information from the MERIT study was available to Monogram Biosciences.**

### Methods

- **The screening samples from MERIT patients enrolled on the basis of an R5 Trofile result were retested with the enhanced Trofile assay.**
- **The enhanced Trofile assay reclassified approximately 15% of patients as non-R5 HIV and identified a similar number of R5 virus at baseline or on study.**

### Results

- **Overall, 106/721 (15%) of patients who had an R5 tropism result at screening with the original Trofile assay were reclassified with the enhanced Trofile assay.**
- **Analysis of the enhanced Trofile assay identified 52% of patients who displayed DM virus on study in MERIT.**
- **The proportion of patients with discordant original Trofile vs enhanced Trofile screening results was similar between the MVC and EFV arms.**

### Discussion and Conclusions

- **This study demonstrates that the enhanced Trofile assay is a valuable tool for identifying patients with non-R5 HIV who may benefit from treatment with HIV-1 integrase inhibitors.**
- **Further studies are needed to evaluate the clinical outcomes of patients identified with non-R5 HIV.**

### References


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Table 2. Reanalysis with Enhanced Trofile at screening identified 52% of patients who displayed DM virus on study in MERIT

<table>
<thead>
<tr>
<th>N</th>
<th>D5</th>
<th>D6</th>
<th>DM on study</th>
<th>Enhanced DM</th>
<th>Total DM on study</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>6</td>
<td>19</td>
<td>70/261 (27.2%)</td>
<td>44/261 (16.9%)</td>
<td>114/261 (43.7%)</td>
</tr>
<tr>
<td>360</td>
<td>211</td>
<td>149</td>
<td>72.3%</td>
<td>69.3%</td>
<td>72.3%</td>
</tr>
</tbody>
</table>

Figure 4. Percentage of patients with HIV-1 RNA <400 copies/mL at Baseline Viral Load

- **Patients (%)**
- **Time (weeks)**

Figure 5. C4D cell count response at Week 48

- **Patients (%)**
- **Time (weeks)**

Table 5. Key adverse events causing discontinuation (all-cause)

<table>
<thead>
<tr>
<th>Reason for discontinuation</th>
<th>MVC</th>
<th>EFV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoma/Malignancy</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>6</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Other infecitious (excluding Tuberculosis)</td>
<td>21</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>Other non-infectious</td>
<td>34</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

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**Figure 1.** MERIT study design

- **Background**
- **Methods**
- **Results**
- **Discussion and Conclusions**
- **References**

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**Figure 2.** a) Percentage of patients with HIV-1 RNA <400 copies/mL by visit, and b) Percentage of patients with HIV-1 RNA <50 copies/mL by visit

- **Patients (%)**
- **Time (weeks)**

---

**Figure 3.** Percentage of patients with HIV-1 RNA <400 and <50 copies/mL at Week 48

- **Patients (%)**
- **Time (weeks)**

---

**Figure 4.** Percentage of patients with HIV-1 RNA <400 copies/mL by visit, and b) Percentage of patients with HIV-1 RNA <50 copies/mL by visit

- **Patients (%)**
- **Time (weeks)**