TB Immune Correlates of Protection (continued)

A/Prof Elisa Nemes
Samples

D0, D70, M6 (2 vials!)
D0, D37, M6 (6 vials)

D0, D7 (BCG) or D3 (Pl), M6
D0, D37, M6

D0, D7 (BCG) or D3 (Pl), M6
D0, D37, M6
What do we do in the meantime???

- Prepare for success!
- Develop the models
- Collect the samples
**IMPAACT 2035/ HVTN 604**

**Safety and immunogenicity RCT in 10–14-year-olds**

![Diagram showing the flow of participants between the groups]

<table>
<thead>
<tr>
<th></th>
<th>With HIV</th>
<th>Without HIV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IGRA−</strong></td>
<td>40</td>
<td>40</td>
<td>160</td>
</tr>
<tr>
<td><strong>IGRA+</strong></td>
<td>40</td>
<td>40</td>
<td>160</td>
</tr>
</tbody>
</table>

**Sample Size N=480**

<table>
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<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>4</th>
<th>10</th>
<th>24</th>
<th>48</th>
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<tbody>
<tr>
<td><strong>Weeks</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>PBMC &amp; Plasma</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td><strong>WB RNA</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>WB fixed cells</strong></td>
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<td>X</td>
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<td>X</td>
</tr>
<tr>
<td><strong>Serum</strong></td>
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<td>X</td>
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<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
**BAL sampling in BCG REVAX**

![Diagram of BAL sampling in BCG REVAX](image)

- **QFT IFN (IU/mL)**
  - Sustained QFT conversion
  - Transient QFT conversion (reversion)
  - QFT IFN cutoff

- **BCG Placebo**
  - 6, 12, 18, 24, 30, 36, 42 or 48 months post vaccination

- **Recent QFT converters**
  - n=60

- **QFT non-converters**
  - n=40

- **QFT non-converters**
  - n=60

* Recruited within 4 weeks of INITIAL QFT conversion
* Recruited at ANY visit, once >18 years old