Preparing a HPTN 084 manuscript concept

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HPTN 084 Version 4.0 Face to Face
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Step 1: Idea Generation

• Have an idea?

• Review Previous 084 publications, abstract and planned publications to verify that it hasn’t already been proposed.
  • If proposed- Reach out to the Team to ask to participate
  • If not yet proposed- Develop a new concept
Step 2: Access the “Manuscript Concept Proposal Form” on HPTN website

https://www.hptn.org/research/studies/hptn084#views-field-field-public-files
Step 3:

- Follow Template as instructed
- Should be Brief (1-3 pages)
Tips for the concept

• Think of the data you collected and entered in eCRFs
  • Data must be in the database to be evaluable
  • Consider how it was collected to determine how variables will be considered for your analysis
    • Continuous
    • Dichotomous

• Think of the timeline/implications for your research question
Timeline of HPTN 084

- **Blinded Phase**
  - 2017-Nov 5 2020

- **Unblinded Phase**
  - Nov 6 2020- Jan 2022

- **Open Label Extension 1:**
  - Jan 2022 to present

- **Open Label Extension 2:**
  - Jan 2023- July 2024

- **Transition Participants to Local Programs**
# Comparison of Phases

<table>
<thead>
<tr>
<th></th>
<th>Blinded</th>
<th>Unblinded</th>
<th>Open Label Extension 1</th>
<th>Open Label Extension 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
<td>Women at Substantial Risk</td>
<td>Same</td>
<td>HPTN 084 + HPTN 084-1 participants</td>
<td>Those who received CAB in OLE 1</td>
</tr>
<tr>
<td><strong>HIV Testing</strong></td>
<td>Rapid Antibody (1 or 2) plus Ab/Ag</td>
<td>Rapid Antibody (1 or 2) plus Ab/Ag</td>
<td>Routine VL added to algorithm</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Family Planning Requirement</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Pregnancy</strong></td>
<td>Stopped CAB, Used TDF/FTC</td>
<td>Stopped CAB, Used TDF/FTC</td>
<td>Pregnancy Study for CAB dosing</td>
<td>Pregnancy Study for CAB dosing</td>
</tr>
<tr>
<td><strong>Oral Lead in</strong></td>
<td>Oral Lead in required</td>
<td>Not applicable</td>
<td>Not required</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Next Steps

• Review Tables with Statisticians
• Discuss results and if other tables/data are needed
• Once satisfied with Data, write manuscript!