HPTN 084: Protocol Version 4.0, OLE2- DM Updates

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AGENDA

• New Visit Schedule – Step 6
• New CRF: Informed Consent – v4.0
• Step 6 Visits
  – How to create/populate visit
  – Data requirements
New Visit Schedule – OLE 2

<table>
<thead>
<tr>
<th>Visit Code</th>
<th>Description</th>
<th>Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>V116.0</td>
<td>Step 6-CAB LA</td>
<td>56</td>
</tr>
<tr>
<td>V117.0</td>
<td>Step 6-CAB LA</td>
<td>64</td>
</tr>
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<td>V118.0</td>
<td>Step 6-CAB LA</td>
<td>72</td>
</tr>
<tr>
<td>V119.0</td>
<td>Step 4c-CAB LA</td>
<td>80</td>
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<td>V120.0</td>
<td>Step 4c-CAB LA</td>
<td>88</td>
</tr>
<tr>
<td>V121.0</td>
<td>Step 4c-CAB LA</td>
<td>96</td>
</tr>
</tbody>
</table>

- Rave database has been migrated with OLE2 updates
- Data Communique #26 more details
New CRF: Informed Consent – Version 4.0

• New form has been added for all OLE 1 participants that have not terminated
• It is in the Product Choice-OLE folder
New CRF: Informed Consent – Version 4.0

- Form should be completed after protocol v4.0 IRB approval is obtained
- Form should be completed in Rave before the first Step 6 visit is entered
Step 6 Visits- ‘Add Event’

• When participant qualifies and is ready to start OLE2, generate the first Step 6 visit by using the ‘Add Event’ menu

• Similar process to Open Label Truvada visits (V2)
‘Add Event’ menu contains all Step 6 visits

*Did not apply programming or ‘form dynamics’ to DOV – OLE forms, giving sites direct access to Step 6 visit folders*

Stream-line data entry when changing tracks
Step 6 Visits- ‘Add Event’

- Add Event menu updated to remove the visits and CRFs that no longer apply:
  - Open Label Truvada visits
  - Interim Visit (non-OLE)
  - PREGNANCY (non-OLE)
  - Unblinding
  - Yearly Visit
Step 6- Transition and Retention

- For retention purposes, we expect to see a change of schedule on (V63-week 48) Date of Visit-OLE form
  - “Is ppt moving to new step or visit schedule?” is “Yes”
Step 6 - Transition and Retention

• “If yes, please indicate which step or visit schedule”
• Select “Step 6”
  – This datapoint will be reviewed and cleaned as it is important for accurate retention reporting
Delay in v4.0 Approval

• If a participant completes the last Step 4c visit (V63-week 48) consult the CMC
• On Date of Visit-OLE form at wk 48, mark “No” for “Is ppt moving to new step or visit schedule?”
• Add Interim Visit- OLE 63.1
• Once IRB approval is obtained indicate on Interim visit-OLE the change of schedule to Step 6
QUESTIONS???

For all data questions, please write the SCHARP CDM alias:

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