



HPTN

HIV Prevention
Trials Network

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

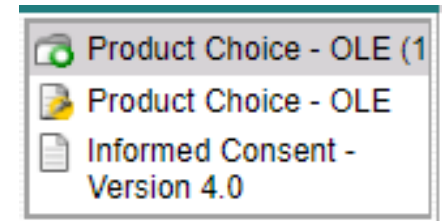
V116.0 - Step 6-CAB LA - Week 56
V117.0 - Step 6-CAB LA - Week 64
V118.0 - Step 6-CAB LA - Week 72
V119.0 - Step 4c-CAB LA - Week 80
V120.0 - Step 4c-CAB LA - Week 88
V121.0 - Step 4c-CAB LA - Week 96

- 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

 HPTN084  Test site 2  999508549  Product Choice - OLE (1)  Informed Consent - Version 4.0

Subject: 999508549
Page: Informed Consent - Version 4.0 - Product Choice - OLE (1)

Did the participant consent for Protocol Version 4.0? ☒ Yes ☐ No

If Yes, Date of Informed Consent ...

- 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



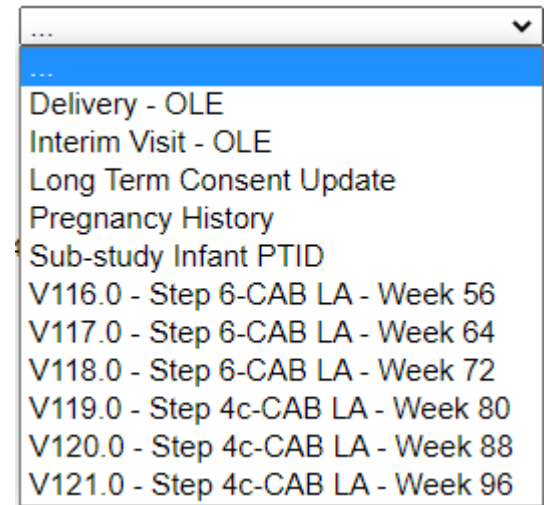
Step 6 Visits- 'Add Event'

- 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)



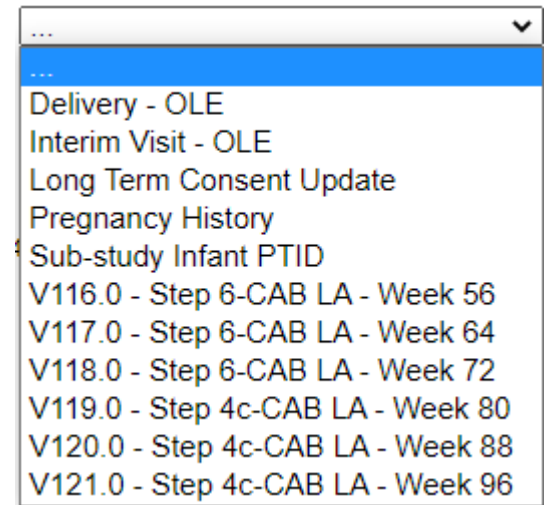
Step 6 Visits- 'Add Event'

- '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



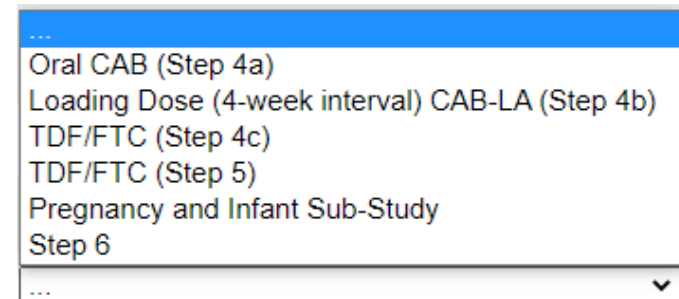
Step 6- Transition and Retention

- 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*



...

Oral CAB (Step 4a)
Loading Dose (4-week interval) CAB-LA (Step 4b)
TDF/FTC (Step 4c)
TDF/FTC (Step 5)
Pregnancy and Infant Sub-Study
Step 6

...



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:

`sc.084cdm@scharp.org`

