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**Partner Drug Dispensing Record**

VISIT MONTH:

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| Screening ID:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Screening Number* | Participant ID:   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Couple I/P Chk* | Visit Date:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |   *dd mm yy* |

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| **Partner Study Drug Dispensing Record** *Document bottle and tablet return and dispensing information below.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | **Bottle Return** | | | | *never accepted study PrEP* | | | | | | | | | | | | |  | | | | ***End of form*** | | | | | | | | | | | | |
|  |  | | | | *Enrolled* | | | | | | | | | | | | |  | | | | ***Go to item 2.*** | | | | | | | | | | | | |
| *i* | Number of bottles  returned: | | | |  | | | | *ii.* | | Number of pills returned: | | | | | | |  | | | | *iii.* | | | | Number of pills left at home: | | | | | | |  | |
| 2 | **Bottle Dispensing** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Number of bottles dispensed: | | | | | | | | | | | | | | | | |  | | | | | ***If > 0, go to item 3.*** | | | | | | | | | | | |
| 3 | Why were no bottles dispensed? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| i. | *Ongoing PSDI* | | |  | *ii.* | | | | | *Study Stop* | | | | |  | | | *iii.* | | | | | *PrEP Stop* | | | | | |  | ***Complete PSDI.*** | | | | |
| iv. | *Other* | | | | | | | | | | | | | |  | | |  | | | | | | | | | | | | | | | | |
|  | **MEMS cap number:** | | | |  | | | | | | | | | | | | | *participant did not bring MEMS cap* | | | | | | | | | | | | | | ***Go to item 5.*** | | |
| ***Items 4-8a are not completed at Enrollment. At Enrollment, end of form.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | Were MEMS data uploaded? | | | | | | | | | | | | *yes* | | | | | *no* | | | | | | ***If yes, Go to item 5.*** | | | | | | | | | | |
| a | Why not? | | i. | | | *lost /stolen* | | | | | |  | | *ii.* | | | *malfunctioning* | | | | | | | | | | | | | | | | |  |
| iii. | Others |  | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | Was a replacement cap dispensed today? | | | | | | | | | | | | | | | | | | | | ***Yes*** | | | | ***No*** | | | ***If no, go to item 6.*** | | | | | | |
| a | New cap number: | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| b | Reason dispensed: | | | | | | i. | *lost /stolen* | | | | |  | | | ***ii.*** | | | | *malfunctioning* | | | | | | | | | | | | | |  |
| iii. | Others: | | | | | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | Was a previously dispensed cap returned today? | | | | | | | | | | | | ***yes*** | | | | | | ***no*** | | | | | ***Go to item 7.*** | | | | | | | | | | |
| a | Returned cap number: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| ***Items 7-8a are interviewer-administered questions and should be read aloud directly as written.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***7*** | Since the last visit, how many times have you or someone else opened your special medication bottle without taking any tablets out of it? | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
| ***8*** | Since the last visit, how many times have you taken more than one tablet out of your special medication bottle at a time? | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | ***If 0, end of form.*** | | | |
| ***8a*** | Since the last visit, how many extra tablets in total have you taken out of your special medication bottle? Do not include the tablet taken out to be used that day. | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |

**Completed by:** *(initials/date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**Forms Instruction**

The **Partner Study Drug Dispensing Record (PDDR)** CRF documents bottle dispensing and return for the partner participant study drug and is completed at Enrollment and all follow-up visits.

**Item-specific Instructions:**

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| **Item 1** | The N/A (never accepted study PrEP) box is only for participants who have never been dispensed study drug at Enrollment or any follow-up visits. Do not use this box when the participant has previously been dispensed study PrEP and subsequently has a study drug interruption or a study stop visit.  At Enrollment, mark N/A (Enrollment). If the participant does not accept PrEP at Enrollment, mark “N/A  (Enrollment).” Enter “00” for item 2a, and mark item 2b “other” with an explanation that the participant did not accept PrEP.  Regardless of what container the participant uses to carry the pills to the visit (pill bottle, pill reminder box or envelope), all pills should count towards the total.  • If the participant returns pills only (no bottles): write “00” in item 1a and enter the number of pills returned in item 1b.  If bottles are forgotten at home, the participant should be asked about the number of pills remaining at home, regardless of where they are kept (e.g., envelope, pill reminder box, purse, pockets).  • Do not write “UNKNOWN” in item 1c. Ask the participant to estimate the number of pills at home if unsure of the exact amount.  Please remind the participant to try to take one tablet out of the bottle each day, rather than using a pill box or other reminder device so that the MEMS cap can record each opening as taking a pill. |
| **Item 2a** | If no bottles are dispensed at the visit, write “00.” |
| **Item 2b** | Mark “ongoing PSDI” if the participant has ongoing study drug interruption and a **PSDI** was previously completed. Complete a **PSDI** CRF if reason for no bottles being dispensed is a “PrEP Stop” or “Other Stop.” Refer to item 2 on the **PSDI** for categories that fall under “Other Stop.” |
| **Item 3** | Ask to see the participant’s special medication bottle and record the cap number from the side of the MEMS cap.  If the participant forgot his or her bottle, mark the box for “participant did not bring MEMS cap.” |
| **Item 4** | Upload the data using the MEMS reader. If the participant forgot to bring his or her MEMS bottle to the visit, mark “no” and ask him or her to bring it to the next study visit. If the participant returns on a separate day with the bottles, fill out this section on a new form and line through the rest of the questions.  ***Note:*** *The MEMS data must be uploaded at every follow-up visit.* |
| **Item 5** | Mark “yes” if the participant was given a new MEMS cap ***at this visit***. |
| **Item 6a** | If a participant was issued a new cap because the previous cap was lost or stolen and the participant has now recovered that cap, record the number of the previous cap that has been returned. |
| **Items 7 & 8** | These are interviewer-administered questions. Please read aloud directly as written |
| **Item 7** | We would like to know how many times the bottle has been opened for any reason without taking out any tablets (i.e., curiosity openings). If the participant has a hard time remembering, ask him or her to remember certain events (e.g., work schedules, trips, holidays) that may help trigger his or her memory. We want the best estimate possible. |
| **Item 8** | We would like to know how many times the participant has taken out more than one tablet at a time for any reason. If the participant has a hard time remembering, ask him or her to remember certain events (e.g., work schedules, trips, holidays) that may help trigger his or her memory. We want the best estimate possible. |
| **Item 8a** | If the participant has a hard time remembering, ask for his or her best guess. Be sure that the total number of tablets does not include the tablets that were taken on the day they were removed (e.g., if the participant removes 3 tablets on one day, 1 tablet on the next day and 2 tablets on the third day, the total number of extra tablets to be recorded is 3). |