

MTN-032 PTID

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Date of Form Completion

dd		MMM		yy	

MTN-032 Participant Status Form (PSF) Phase 1

Instructions: This form is to be completed for any MTN-020 participant who is considered for participation in MTN-032.

1.	Complete ASPIRE PTID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
								Yes	No
2.	Was the participant enrolled in MTN-032 Phase 1?							<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
3.	Date of enrollment in MTN-032 Phase 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		dd		MMM		yy			
4.	Date MTN-032 Phase 1 IDI conducted [record date or check N/A]:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	or	<input type="text"/>	
		dd		MMM		yy		N/A	
5.	Date MTN-032 Phase 1 FGD conducted [record date or check N/A]:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	or	<input type="text"/> →If n/a, go to 7	
		dd		MMM		yy		N/A	
6.	FGD Participant Pseudonym:	_____							
7.	What is the participant's drug detection level classification [mark one]?	<input type="checkbox"/> ₁ Low drug <input type="checkbox"/> ₂ Inconsistent drug <input type="checkbox"/> ₃ High drug							
8.	Record your assessment of the participant's physical/emotional reaction upon hearing her PK results. [Select all that apply]	<input type="checkbox"/> ₁ Anger <input type="checkbox"/> ₇ Distress/Unhappiness <input type="checkbox"/> ₂ Fear <input type="checkbox"/> ₈ Embarrassed/Uncomfortable <input type="checkbox"/> ₃ Sadness <input type="checkbox"/> ₉ Acceptance <input type="checkbox"/> ₄ Disbelief <input type="checkbox"/> ₁₀ Denial <input type="checkbox"/> ₅ Surprise <input type="checkbox"/> ₁₁ Neutral <input type="checkbox"/> ₆ Happiness <input type="checkbox"/> ₁₂ Other, specify: _____							
9.	Date of termination from MTN-032 Phase 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		dd		MMM		yy			
10.	Reason for termination from MTN-032 Phase 1 [mark one]:	<input type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Inappropriate enrollment <input type="checkbox"/> ₃ Other, specify: _____ →END FORM							
11.	Reason for non-enrollment in MTN-032 Phase 1 [mark one]:	<input type="checkbox"/> ₁ Participant did not give permission to be contacted <input type="checkbox"/> ₂ Participant was contacted, but refused participation, specify: _____ <input type="checkbox"/> ₃ Participant scheduled three times, did not show <input type="checkbox"/> ₄ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₅ Participant did not provide written informed consent <input type="checkbox"/> ₆ Other, specify: _____							

Comments:

Participant Status Form (PSF)

Purpose: This form is used to record participants' MTN-032 enrollment and termination status.

General Information/Instructions: This form will be completed for every participant considered for participation in MTN-032 (i.e. every participant whose ASPIRE file is checked for PTC regardless of whether they gave PTC).

Overall Instructions: Enter the PTID in the top left corner of this form, the date the form is completed in the top right corner, and initial and date in the bottom right corner. This form should be completed either on the date(s) that the IDI is completed for those enrolled into MTN-032, or on the date that the potential participant is determined to be ineligible for participation for all other participants. Any information recorded or modified on this form after the original date of completion should be initialed and dated, per GCP.

Item-specific Instructions:

Item	Instruction
1	Record the ASPIRE PTID for all participants considered for participation in MTN-032.
2	Record whether or not the participant was enrolled in MTN-032 Phase 1. If they were not enrolled for any reason, go to item 11 and check the option that best matches the reason for non-enrollment. For those participants not enrolled, assign the MTN-032 PTID of '9999.'
3	The date of enrollment is the date that the participant provided informed consent.
4	Enter the date that the IDI was conducted. If it was conducted on more than one day, enter the date that the interview was started and record a note in the comment box regarding the split visit, which includes the reason for splitting the visit.
5	Enter the date that the FGD was conducted. If it was conducted on more than one day, enter the date that the interview was started and record a note in the comment box regarding the split visit, which includes the reason for splitting the visit.
7	Mark this item based on the participant's drug detection level used for recruitment. This should match the level listed on the recruitment list. If a participant was recruited for an FGD and therefore does not have a drug detection level listed on the recruitment sheet, refer to that participant's visual tool and use the image for Month 3 blood plasma (as described in Operational Guidance #3). If the image is green then she is in the "high drug detection" group, if the image is white she is in the "low drug detection" group. If there is no blood plasma data for Month 3, use the next available blood plasma data to determine the drug detection level.
8	Record all the participant's reaction(s) to receiving their individual drug level results. If the reaction is not listed or the response/reaction does not fit clearly into one of the provided options (e.g. "guilty"), do not try to fit into one of the provided options, instead mark "Other, specify" and write in the reaction on the specify line.
9	Enter the termination date. This should be the day that the IDI is completed.
10	Enter the reason for termination from MTN-032 Phase 1. If there was more than one reason, mark the main reason. If the reason is not specified, mark "other" and describe the reason on the specify line. If you have reached this question, you are now finished with the form and should <u>not</u> complete Q11.
11	Record the reason for non-enrollment in MTN-032 Phase 1. If there was more than one reason, mark the main reason. If the reason is not specified, mark "other" and describe the reason on the specify line.