MTN-032
Study-Specific Training

22 March 2016

Assessment of ASPIRE and HOPE Adherence

Assessment of ASPIRE and HOPE Adherence (MTN-032): Protocol Overview

Sarita Naidoo & Jonathan Stadler

Protocol Training

22 March 2016

Outline

- Background and Rationale
- Study Objectives
- Study Design
- Study Sites
- Sampling Strategy
- Study Timeline

Overview Of Study Background

Similar to how VOICE-D assessed what factors influenced adherence and patterns of study product use in VOICE, MTN-032 will do the same for both ASPIRE (during Phase 1) and HOPE (during Phase 2).

Study Rationale

- To better understand what influences adherence to the dapivirine VR.
- MTN-032 will also look at a participant's perception of her own risk for HIV-infection, and if this had an influence on adherence.
- To better understand motivations for joining and continuing to participate in ASPIRE (during Phase 1) and HOPE (during Phase 2).
- Elicit perceptions about participant engagement and adherence promotion activities implemented in ASPIRE.

Study Objectives

Primary Objective

- To explore socio-contextual and trial specific issues, which affected participants' adherence to the dapivirine vaginal ring (VR)

Secondary Objectives

- To explore participants' HIV risk and perceptions of HIV risk, in general and specific to:
  - motivation to participate in ASPIRE and/or HOPE
  - product use (or lack of) in ASPIRE and/or HOPE

Study Objectives

- To explore factors influencing product initiation and patterns of use during ASPIRE and/or HOPE
- To explore participants' perceptions of various adherence support interventions and engagement activities implemented (or not implemented) during ASPIRE and/or HOPE
- To explore participants' understanding of the ASPIRE results and ring efficacy, and the impact of this understanding on:
  - participants' intention and/or ability to join HOPE and continue in follow-up
  - adherence to the dapivirine VR as part of an open label extension trial as compared to adherence in a Phase 3 safety and effectiveness trial

Study Objectives

Exploratory Objective

- To explore participants' preference regarding drug delivery modalities and attributes that might encourage end-user uptake

Study Design

- Qualitative Exploratory Study
- Phase 1 (~Q2 2016)
  - 7 sites
  - n=~224
  - 3 levels of adherence: low, inconsistent, high
  - Single IDI or FGD (grouped by age)
- Phase 2 (~Q2 2017)
  - n = ~84 Stage 1 participants
  - Single IDI
  - HOPE qualitative participants (ideally)

Study Sites

- Uganda
  Kampala (MU-JHU)
- Malawi
  Lilongwe
- Zimbabwe
  Chitungwiza (Spilhaus and Zengeza)
- South Africa
  Durban (Bothas Hill, eThekwini)
  Johannesburg (Wits RHI)

Sampling Strategy

- Based on objective measures of adherence in ASPIRE and HOPE

- Pre-determined strategy for group designation
  - Randomized to IDI or FGD
  - Based on age group and adherence level (IDI) or just age group (FGD)
  - Must meet other eligibility criteria and be willing to be contacted

Sampling Strategy – Phase 1

- IDI (n=16 per site):
  - Randomly select women within each age of 2 age groups, based on plasma cut off at month 3
  - Examine distribution of adherence data (pk and ring after Month 3, and refine if needed)

Age	PK plasma at Month 3		
		Low (<95pk/ml)	High (>95pk/ml)
	18 – 21 years old	5	3
	>21 years old	5	3

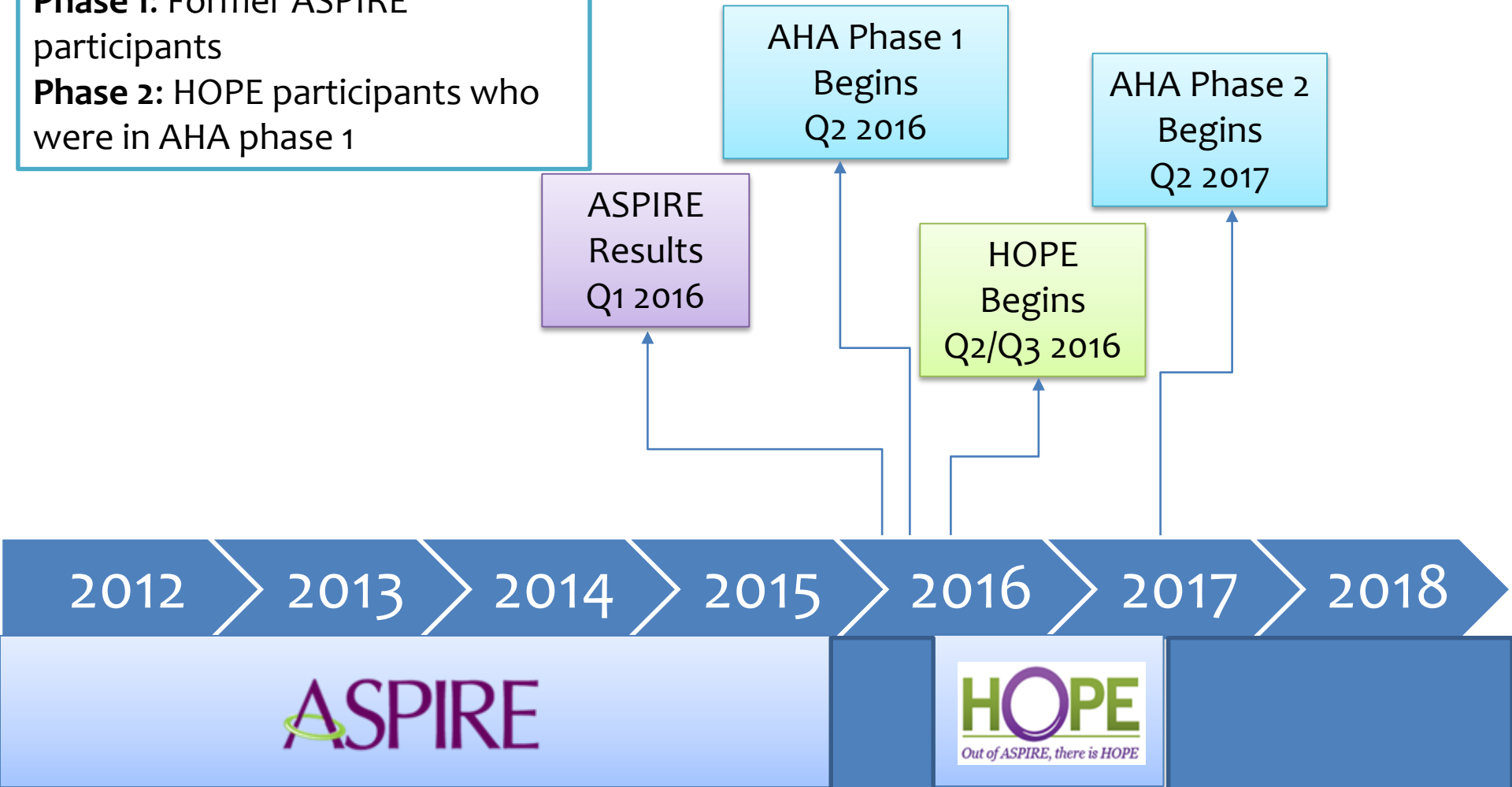
- FGD (2 groups, n=~8 per group, ~16 total)
  - Randomly select eligible women by age group to be invited for FGD

Study Timeline

MTN-032 (AHA)

Phase 1: Former ASPIRE participants

Phase 2: HOPE participants who were in AHA phase 1



ASPIRE

HOPE

Out of ASPIRE, there is HOPE

MTN-032
Eligibility Determination and Accrual (Phase 1)

Kat Calabrese

FHI 360

Durham, NC

USA

Inclusion Criteria (Phase 1)

1. Participated in the ASPIRE protocol, randomized to active product and informed of their randomization assignment.

2. Able and willing to provide written informed consent in one of the study languages.

3. Able and willing to complete the required study procedures.

Inclusion Criteria (Phase 1)

For participants who did not acquire an HIV infection while taking part in ASPIRE:

4. Evidence of study product dispensation at a minimum of three consecutive ASPIRE scheduled clinic visits.

5. Have a minimum of three ASPIRE PK data measurement points available.

For participants who acquired HIV infection while taking part in ASPIRE:

6. Evidence of study product dispensation in the month prior to the participant's acquisition of HIV infection.

7. Have a minimum of one ASPIRE PK data measurement available

Exclusion Criteria

1. Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

Recruitment Lists

SCHARP will pre-select former ASPIRE participants for recruitment/ screening for the MTN-032 study based on age group and adherence level, as well as inclusion criteria 4-7 (and part of inclusion criteria 1).

These ASPIRE PTIDs will be provided to sites as Recruitment Lists, and will also indicate whether the participant was pre-selected for an IDI or a FGD.

Recruitment Lists

SCHARP will pre-select based on the following inclusion criteria:

- Participated in the ASPIRE protocol, randomized to active product. *(Part of IC 1)*
- Evidence of study product dispensation at a minimum of three consecutive ASPIRE scheduled clinic visits. *(IC 4)*
- Have a minimum of three ASPIRE PK data measurement points available *(IC 5)*
- Evidence of study product dispensation in the month prior to the participant's acquisition of HIV infection. *(IC 6)*
- Have a minimum of one ASPIRE PK data measurement available *(IC 7)*

Eligibility Assessment Steps

- Review Permission to be Contacted (PTC)
- Contact only pre-selected participants who have given PTC, in sequential order of the Recruitment List
- Confirm eligibility requirements, as able *(IC 1)*
- Obtain informed consent *(IC 2 and 3 will be confirmed during the informed consent process)*
- Confirm any remaining eligibility requirements *(EC 1)*

Definition of Enrollment

Note that enrollment is defined as:

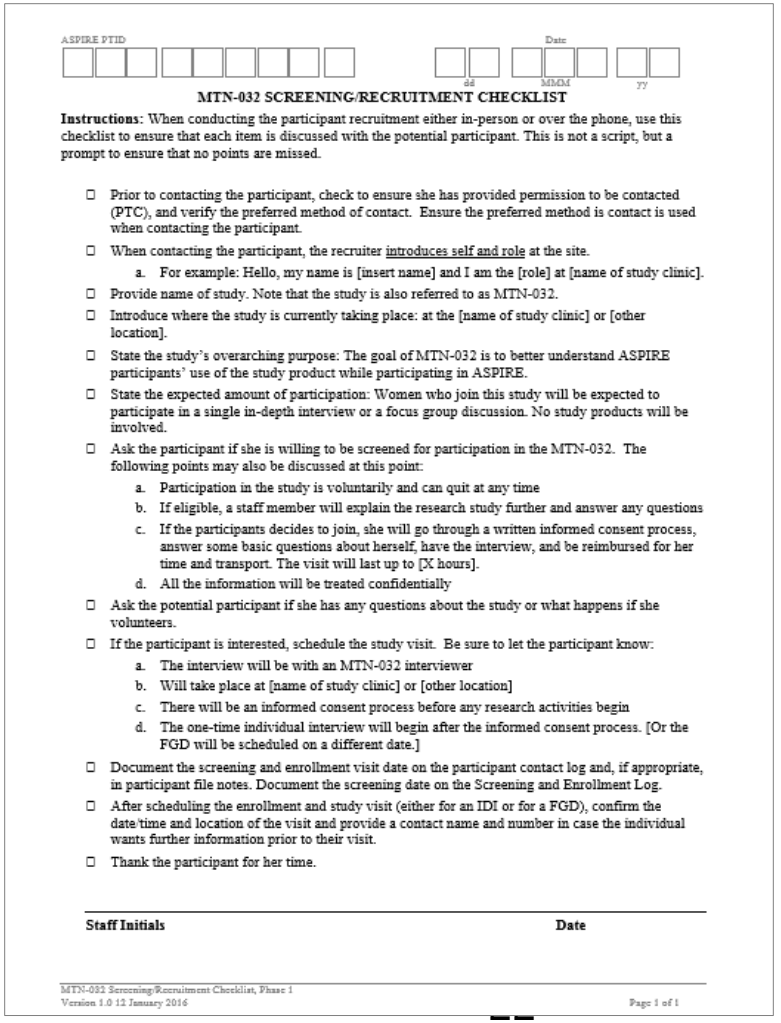
After a participant signs the informed consent and eligibility is confirmed

(Protocol Section 8.2)

Screening/ Recruitment Checklist

The sample Screening/ Recruitment Checklist provides talking-points for MTN-032 site staff to use when contacting the potential MTN-032 participants.

This is available on the MTN-032 website.



ASPIRE PTID ☐☐☐☐☐☐☐☐☐ Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

MTN-032 SCREENING/RECRUITMENT CHECKLIST

Instructions: When conducting the participant recruitment either in-person or over the phone, use this checklist to ensure that each item is discussed with the potential participant. This is not a script, but a prompt to ensure that no points are missed.

- ☐ Prior to contacting the participant, check to ensure she has provided permission to be contacted (PTC), and verify the preferred method of contact. Ensure the preferred method is contact is used when contacting the participant.
- ☐ When contacting the participant, the recruiter introduces self and role at the site.
  a. For example: Hello, my name is [insert name] and I am the [role] at [name of study clinic].
- ☐ Provide name of study. Note that the study is also referred to as MTN-032.
- ☐ Introduce where the study is currently taking place: at the [name of study clinic] or [other location].
- ☐ State the study's overarching purpose: The goal of MTN-032 is to better understand ASPIRE participants' use of the study product while participating in ASPIRE.
- ☐ State the expected amount of participation: Women who join this study will be expected to participate in a single in-depth interview or a focus group discussion. No study products will be involved.
- ☐ Ask the participant if she is willing to be screened for participation in the MTN-032. The following points may also be discussed at this point:
  a. Participation in the study is voluntarily and can quit at any time
  b. If eligible, a staff member will explain the research study further and answer any questions
  c. If the participants decides to join, she will go through a written informed consent process, answer some basic questions about herself, have the interview, and be reimbursed for her time and transport. The visit will last up to [X hours].
  d. All the information will be treated confidentially
- ☐ Ask the potential participant if she has any questions about the study or what happens if she volunteers.
- ☐ If the participant is interested, schedule the study visit. Be sure to let the participant know:
  a. The interview will be with an MTN-032 interviewer
  b. Will take place at [name of study clinic] or [other location]
  c. There will be an informed consent process before any research activities begin
  d. The one-time individual interview will begin after the informed consent process. [Or the FGD will be scheduled on a different date.]
- ☐ Document the screening and enrollment visit date on the participant contact log and, if appropriate, in participant file notes. Document the screening date on the Screening and Enrollment Log.
- ☐ After scheduling the enrollment and study visit (either for an IDI or for a FGD), confirm the date/time and location of the visit and provide a contact name and number in case the individual wants further information prior to their visit.
- ☐ Thank the participant for her time.

Staff Initials **Date**

Visit Scheduling

Visits will ideally be scheduled such that the informed consent can be administered on the same day as the interview.

For FGDs, a separate visit for the informed consent may need to be scheduled.

MTN-032
Informed Consent Process

Jonathan Stadler

Wits RHI

The Informed Consent Process

- Informed consent is a process by which an individual voluntarily expresses their willingness to participate in research, after having been informed of all aspects of the research that are relevant to her decision.
- It is not merely a form or a signature, but involves information exchange, comprehension, voluntariness, and documentation.

Reminders (1)

- Written informed consent for all participants must be obtained before performing any MTN-032 data collection activities.
- All consent procedures should be conducted in the primary language of the participant.

Reminders (2)

- If the written informed consent form is requested in a language that is *different* from the language the procedure was conducted in, this discrepancy should be documented on the informed consent cover sheet or in the participant file notes.

Reminders (3)

- Per DAIDS policy, each step of the informed consent process must be documented, either using a cover sheet or an alternate method as described in the site Informed Consent SOP.

Comprehension Assessment

- Study staff are responsible for determining whether potential participants comprehend all information required to make an informed decision about study participation before proceeding to make a final enrollment decision.
- The MTN-032 Informed Consent Comprehension Checklist will be used as a tool to assist staff in assessing participant comprehension to ensure that participants understand all information required to make an informed decision.

IC Comprehension Checklist

MTN-032 Enrollment Informed Consent Comprehension Checklist

Name: **Date:**

	Open-Ended Question/Statement	Required Points of Comprehension	✓
1	Please tell me your understanding of the purpose of the study.	To better understand ASPIRE participant's use of study product	
		To better understand ASPIRE participant's sexual behavior	
2	How long will the study last?	There may be one interview and it will take about 3 hours [***sites can modify the length of time per site-specific ICF***]	
		There may be one focus group discussion that will take about 3 hours [***sites can modify the length of time per site-specific ICF***]	
3	What are participants being asked to do in this study?	Answer interview questions that will be written on a form	
		Answer interview questions that will be audio-recorded	
		May be chosen to take part in either a group discussion or an interview with clinic staff	
		Group discussion is with other former ASPIRE participants and clinic staff	
		Questions will include information about different ways women used study product during ASPIRE	
		Will receive ASPIRE results and own product use test results.	
4	What are the possible risks for participants in the study?	Questions may cause embarrassment	
		Others may find out about participation in the study	
		Loss of confidentiality	
5	What will happen if women decide not to join the study?	Free to make her own decision about joining the study	
		No change to her access to health care whether she joins the study or not	
6	How will information about participants in the study be protected?	Information about participants is confidential, private, and locked away	
		Only people working on the study have access to the information	
7	What are the possible benefits for participants in the study?	There are no direct benefits	
		Information provided may help researchers improve counseling materials	
8	What should participants do if they have questions or concerns about their health or about what is happening in the study?	*Must state how to contact study staff*	

Outcome

☐ Demonstrated comprehension of all required points, decided to enroll in study.

Optional Comment Codes

a. Answered correctly on first try

Group IC for FGD Participants

- For the FGD participants, the IC process can be initiated in a group setting.
  - The informed consent form and key aspects of the study can be reviewed with the FGD participants as a group.
  - Each FGD participant can then individually go to a private setting to ask questions, assess comprehension, consent to the study, or decline consent.

Site Discussion

- Please describe the informed consent process at your site
  - Where will the process will take place?
    - How will you ensure confidentiality?
  - Who at your site is responsible for obtaining IC?
  - How will the process be documented?

What are your questions about the informed consent process?

DATA COLLECTION TOOLS & PROCESSES

Ariana Katz, MPH

Women's Global Health Imperative

RTI International

San Francisco, CA, USA

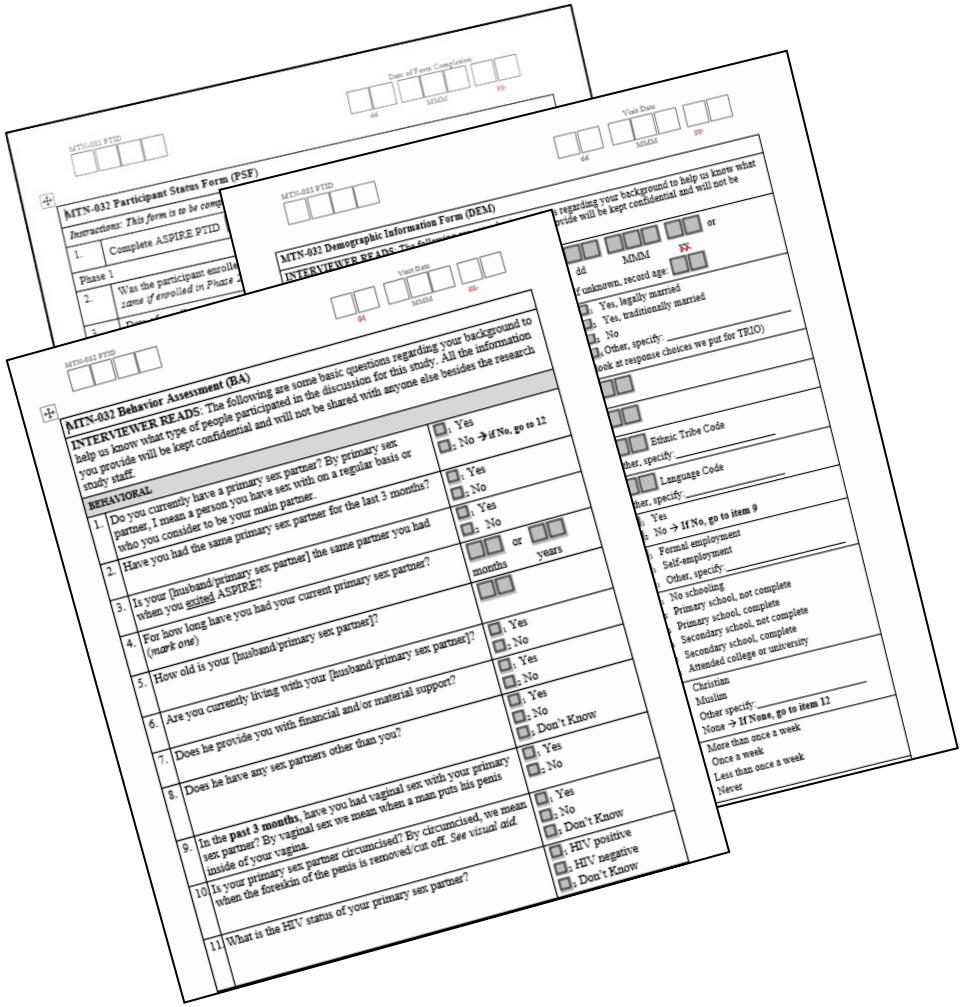
Overview Of Data Collection Tools

- CRFs
- Guides
- Visual tools

Data Collection Tools I: CRFs

CRFs:

- Behavior Assessment (BA)
- Demographic Information Form (DEM)
- Participant Status Form (PSF)
- Protocol Deviation Report (PD)
- Social Harms Report (SH)



DEMOGRAPHIC INFORMATION FORM

MTN-032 PTID ☐☐☐☐

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

MTN-032 Demographic Information Form (DEM)

INTERVIEWER READS: The following are some basic questions regarding your background to help us know what type of people participated in this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.		
1.	What is your date of birth?	☐☐ dd ☐☐☐ MMM ☐☐ yy or If unknown, record age: ☐☐
2.	How many children have you had who were alive at birth?	☐☐
3.	How many total children are you currently taking care of (i.e. children, grandchildren, etc.)?	☐☐
4.	What is your ethnic group or tribe? (*mark ethnic group/tribe code*)	☐☐ Ethnic Tribe Code Other, specify:_____
5.	What is the language most spoken at home? (*mark language code)*	☐☐ Language Code Other, specify:_____
6.	Do you currently earn an income of your own?	☐1 Yes ☐2 No → **If No, go to item 8**
7.	How do you earn your current income? (*mark all that apply*)	☐1 Formal employment ☐2 Self-employment ☐3 Other, specify:_____
8.	What is your highest level of education? (*mark one*)	☐1 No schooling ☐2 Primary school, not complete ☐3 Primary school, complete ☐4 Secondary school, not complete ☐5 Secondary school, complete ☐6 Attended college or university, not complete ☐7 Attended college or university, complete
9.	What is your religion? (*mark one*)	☐1 Christian ☐2 Muslim ☐3 Other specify:_____ ☐4 None → **If None, go to item 11**

- Interviewer-administered prior to IDI/FGD
- 19 questions:
  - Collect new information
  - Record updates/changes since ASPIRE data was last captured

BEHAVIOUR ASSESSMENT

MTN-032 PTID ☐☐☐☐

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

MTN-032 Behavior Assessment (BA)

INTERVIEWER READS: The following are some basic questions regarding your background to help us know what type of people participated in this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.		
BEHAVIORAL		
1.	Do you currently have a primary sex partner? By primary sex partner, I mean a person you have sex with on a regular basis or who you consider to be your main partner.	☐1 Yes ☐2 No → **if No, go to 14**
2.	Are you currently married? (*choose one*)	☐1 Yes, legally married ☐2 Yes, traditionally married ☐3 No ☐4 Other, specify: _____
3.	Have you had the same [husband/primary sex partner] for the **last 3 months**?	☐1 Yes ☐2 No
4.	Is your [husband/primary sex partner] the same partner you had when you exited ASPIRE?	☐1 Yes ☐2 No ☐3 Can't remember
5.	For how long have you been with your current [husband/primary sex partner]? (*mark one*)	☐☐ or ☐☐ months years
6.	How old is your [husband/primary sex partner]?	☐☐
7.	Are you currently living with your [husband/primary sex partner]?	☐1 Yes ☐2 No
8.	Does your [husband/primary sex partner] provide you with financial and/or material support?	☐1 Yes ☐2 No
9.	Does he have any sex partners other than you?	☐1 Yes ☐2 No ☐3 Don't Know

- Interviewer-administered prior to IDI/FGD
- 34 questions:
  - Used to inform different aspects of data collected during the IDIs and FGDs

PARTICIPANT STATUS FORM

MTN-032 PTID ☐☐☐☐

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

Captures:

- MTN-032 PTID
- ASPIRE PTID
- Phase 1 status
- Drug detection level and response to individual adherence results
- Enrollment, interview and termination dates
- Reason for termination
- Reason for non-enrollment

SOCIAL HARMS REPORT

MTN-032 PTID ☐☐☐☐ SH# ☐ Date Form Completed ☐☐ dd ☐☐☐ MMM ☐☐ yy

Social Harms Report (SH)

Instructions: This form is to be completed for any MTN-032 participant who reports a social harm. Interviewer completes form based on report from the participant.

1.	Describe the social harm event: _____ _____ _____ ☐1 Participant declined to describe	
2.	Date of social harm onset	☐☐ dd ☐☐☐ MMM ☐☐ yy
3.	What type of social harm is this event? *(mark all that apply)*	☐1 Physical ☐2 Emotional ☐3 Financial ☐4 Other, specify: _____
4.	Did this event include unwanted disclosure of study participation? *(choose one)*	☐1 Yes, specify to who: _____ ☐2 No ☐3 Unknown/information not provided ☐4 Other, specify:_____
5.	What impact did this situation have on the participant's quality of life? *(choose one)*	☐1 No disturbance ☐2 A minimal disturbance that had no significant impact. ☐3 A moderately upsetting disturbance, but did not have a significant impact. ☐4 A major disturbance that had a significant impact. ☐5 Other (specify)_____ ☐6 Unknown/Declined to provide information
6.	Other participant comments or remarks:	_____ _____ _____ ☐1 None
7.	Based on your discussion with the participant, do you think this situation is resolved?	☐1 Yes ☐2 No ☐3 Other, specify:_____
8.	What action, recommendation or suggestion was provided to participant to help resolve this situation?	_____ _____ _____
9.	Referrals made *(mark all that apply)*: ☐1 Counselor on site ☐2 Other, specify: _____ ☐3 No referrals needed	

Captures:

- Details of any social harms event (date and type)
- Impact of social harm
- Actions taken/needed
- Referrals made

PROTOCOL DEVIATION

MTN-032 PTID ☐☐☐☐ PD# ☐ Date Form Completed ☐☐ dd ☐☐☐ MMM ☐☐ yy

Protocol Deviation Report (PD)

	Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.	
1.	Site Awareness date	☐☐ dd ☐☐☐ MMM ☐☐ yy
2.	Deviation date	☐☐ dd ☐☐☐ MMM ☐☐ yy
3.	Has or will this deviation be reported to local IRB/EC?	☐1 Yes ☐2 No
4.	Has or will this deviation be reported to DAIDS as a critical event?	☐1 Yes ☐2 No
5.	Type of deviation *(See back of form for code listing)*	☐☐ deviation code
6.	Description of deviation:	_____ _____ _____ _____ _____
7.	Plans and/or action taken to address the deviation	_____ _____ _____ _____ _____
8.	Plans and/or action taken to prevent future occurrences of the deviation	_____ _____ _____ _____ _____

Captures:

- Details of any protocol deviation event (date, type and reporting)
- Actions taken/needed
- Plans/actions to prevent future occurences

Data Collection Tools II: Guides

IDI Guide

A. Experience in ASPIRE – What was the participant's experience in ASPIRE/using the ring?

We would like to start by talking about the study in general.

1. Tell me about your experiences in ASPIRE. *[Possible tools: timeline tool]*

Possible probing topics:

- What did you like most about being in the ASPIRE study?
- What did you like least about being in the ASPIRE study?
- How did these attitudes change from the beginning to the end of the study?
- [*If attitudes changed*] what brought about the change? (Type and sources of influences: e.g. study staff, other participants, family/friends, partners, community rumors, study activities, life events)
- What stories did you hear from other participants about the study?

B. Perceptions of health and HIV Risk – What are the participant's perceptions about her health and specifically her risk of HIV?

2. How worried are you about your health?

Possible probing topics:

- What are you worried about?
- How was this changed since ASPIRE ended (different types of worries? Increased or decreased?)

Now let's talk about your thoughts about HIV risk. *[Seroconverters skip to section C.]*

3. How worried are you about getting HIV?

Possible probing topics:

- How worried were you about getting HIV after you joined ASPIRE?
- How has this changed since ASPIRE ended?
- What is influencing your level of worry (multiple partners, condom use, seropositive partner, drug/alcohol use, receiving money/goods for sex, HIV testing, etc.)? [*specify if they increase or decrease worry]*
- How did your level of worry while in ASPIRE affect your ring use?
- How did ring use change your level of worry while in ASPIRE?
- How are worries about getting HIV affecting how and/or with whom you have sex?

FGD Guide

A. Community – Are local communities supportive of HIV prevention?

I would like to start by asking you all about your community…

1. In what ways do people in your community talk about HIV?

Possible probing topics:

- Attitudes towards people/women/men/children living with HIV: stigma, gossip and rumor
- Attitudes towards HIV prevention, including the use of condoms
- Attitudes towards HIV testing in general, including women who get tested (either in trials, in clinics, or mandatory testing when pregnant)

2. How did people in your community talk about ASPIRE?

Possible probing topics:

- Knowledge of study and the ring
- Positive and negative attitudes/comments/rumors about study or ring
- Positive and negative attitudes/comments/rumors about ASPIRE participants
- Effects of attitudes/comments/rumors on participants
- How did participants respond to others who spoke positively/negatively about the study and/or the ring?
- Positive and negative attitudes/comments/rumors about researchers from overseas?

B. Experience in ASPIRE – What were the participants' experiences of being in ASPIRE/using the ring?

Now let's talk about your experiences in ASPIRE…

3. What are your feelings about having been in the ASPIRE study?

Possible probing topics:

- Likes/dislikes about being in ASPIRE
- Thoughts on study procedures, visits, staff, reimbursement
- Changes from the beginning to the end of the study
- How was ASPIRE different than other studies you have taken part in?
- How do you think taking part was different for older vs. younger women (e.g. women 21 and under)?

4. What is your opinion of the ring?

Possible probing topics:

- Likes/dislikes about the ring?
- Change from the beginning to the end of the study
- Product characteristics (size, shape, color)
- How product is used (dosing regimen, feelings of wearing ring, inserting/removing ring)

C. Drug detection level results & Reasons for Adherence/non-Adherence – What were the factors that influenced participants' adherence/non-adherence?

The blood samples and returned rings showed that some participants did not use their rings or have drug in their blood all or most of the time. We would like to find out from you, since you participated in the trial, why this may have been… *[Available tools: Adherence trajectory tool, SAMPLE drug level results visual tool]*

IN-DEPTH INTERVIEW GUIDE

A. Experience in ASPIRE – What was the participant's experience in ASPIRE/using the ring?

We would like to start by talking about the study in general.

1. Tell me about your experiences in ASPIRE. *[Possible tools: timeline tool]*

Possible probing topics:

- What did you like most about being in the ASPIRE study?
- What did you like least about being in the ASPIRE study?
- How did these attitudes change from the beginning to the end of the study?
- [*If attitudes changed*] what brought about the change? (Type and sources of influences: e.g. study staff, other participants, family/friends, partners, community rumors, study activities, life events)
- What stories did you hear from other participants about the study?

B. Perceptions of health and HIV Risk – What are the participant's perceptions about her health and specifically her risk of HIV?

2. How worried are you about your health?

Possible probing topics:

- What are you worried about?
- How was this changed since ASPIRE ended (different types of worries? Increased or decreased?)

Now let's talk about your thoughts about HIV risk. *[Seroconverters skip to section C.]*

3. How worried are you about getting HIV?

Possible probing topics:

- How worried were you about getting HIV after you joined ASPIRE?
- How has this changed since ASPIRE ended?
- What is influencing your level of worry (multiple partners, condom use, seropositive partner, drug/alcohol use, receiving money/goods for sex, HIV testing, etc.)? [*specify if they increase or decrease worry]*
- How did your level of worry while in ASPIRE affect your ring use?
- How did ring use change your level of worry while in ASPIRE?
- How are worries about getting HIV affecting how and/or with whom you have sex?

Interview will follow guide:

- Primary research topics appear in gray.
- Two levels of questions:
  - Primary interview questions: appear in bold text.
  - Probing topics: indicated with a bullet.
- *Instructions/suggestions to interviewer are in italics and [brackets].*

FOCUS GROUP DISCUSSION GUIDE

A. Community – Are local communities supportive of HIV prevention?

I would like to start by asking you all about your community…

1. In what ways do people in your community talk about HIV?

Possible probing topics:

- Attitudes towards people/women/men/children living with HIV: stigma, gossip and rumor
- Attitudes towards HIV prevention, including the use of condoms
- Attitudes towards HIV testing in general, including women who get tested (either in trials, in clinics, or mandatory testing when pregnant)

2. How did people in your community talk about ASPIRE?

Possible probing topics:

- Knowledge of study and the ring
- Positive and negative attitudes/comments/rumors about study or ring
- Positive and negative attitudes/comments/rumors about ASPIRE participants
- Effects of attitudes/comments/rumors on participants
- How did participants respond to others who spoke positively/negatively about the study and/or the ring?
- Positive and negative attitudes/comments/rumors about researchers from overseas?

B. Experience in ASPIRE – What were the participants' experiences of being in ASPIRE/using the ring?

Now let's talk about your experiences in ASPIRE…

3. What are your feelings about having been in the ASPIRE study?

Possible probing topics:

- Likes/dislikes about being in ASPIRE
- Thoughts on study procedures, visits, staff, reimbursement
- Changes from the beginning to the end of the study
- How was ASPIRE different than other studies you have taken part in?
- How do you think taking part was different for older vs. younger women (e.g. women 21 and under)?

4. What is your opinion of the ring?

Possible probing topics:

- Likes/dislikes about the ring?
- Change from the beginning to the end of the study
- Product characteristics (size, shape, color)
- How product is used (dosing regimen, feelings of wearing ring, inserting/removing ring)

C. Drug detection level results & Reasons for Adherence/non-Adherence – What were the factors that influenced participants' adherence/non-adherence?

The blood samples and returned rings showed that some participants did not use their rings or have drug in their blood all or most of the time. We would like to find out from you, since you participated in the trial, why this may have been… *[Available tools: Adherence trajectory tool, SAMPLE drug level results visual tool]*

Discussion will follow guide:

- Primary research topics appear in gray.
- Two levels of questions:
  - Primary discussion questions: appear in bold text.
  - Probing topics: indicated with a bullet.
- *Instructions/suggestions to interviewer are in italics and [brackets].*

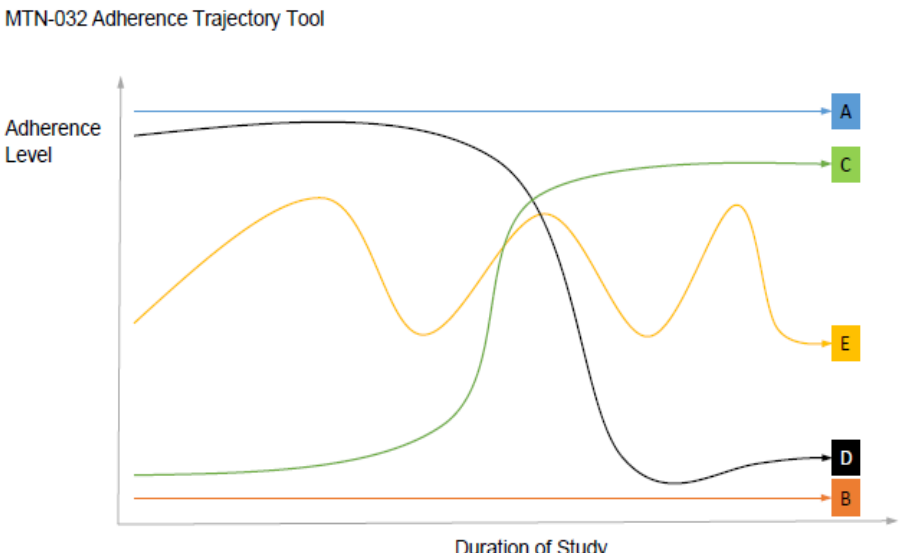
Before starting the FGD, the facilitator must remind the group of:

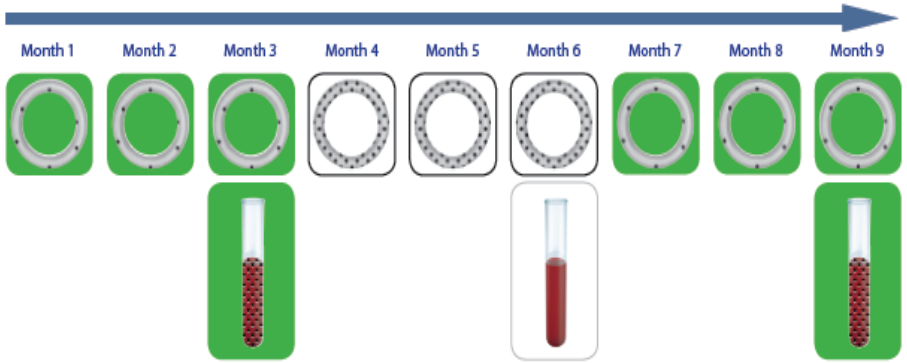
- The purpose of the FGD
- Ground rules for FGD (per study SSP), including importance of confidentially and use of pseudonyms

Data Collection Tools III: Visual tools

Tools:

- Adherence trajectory tool
  - IDI: Used to stimulate discussion of participant's perception of her adherence pattern during ASPIRE
  - FGD: Used to discuss patterns of use in ASPIRE generally
- Individual Drug Level Results Visual Tool (in progress)
  - Used to discuss individual-level results
  - For FGD – used before discussion; for IDI presented during interview





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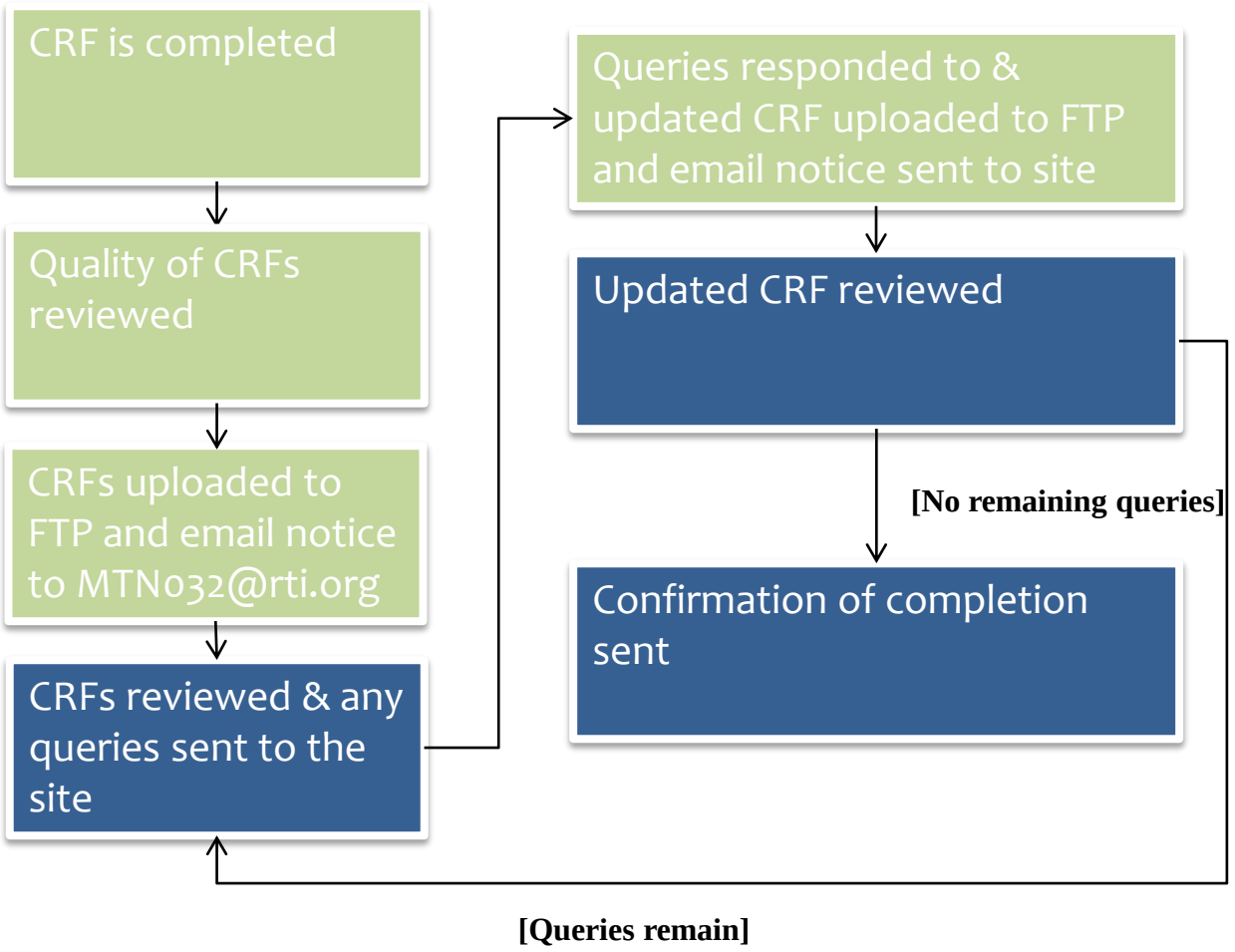
Data Management

Overview

- Management of:
  - CRFs
  - Audio files
  - Debriefing reports
  - Transcripts

CRF Management



Site Staff | RTI/DCC

CRF Queries

Demographic Form (DEM) Queries

Query #	MTN-032 PTID	Question #	Issue	Action Taken	Site Staff Initials	Action Date	Date Issue Resolved	RTI Staff Initials

Completion Responsibility Legend:

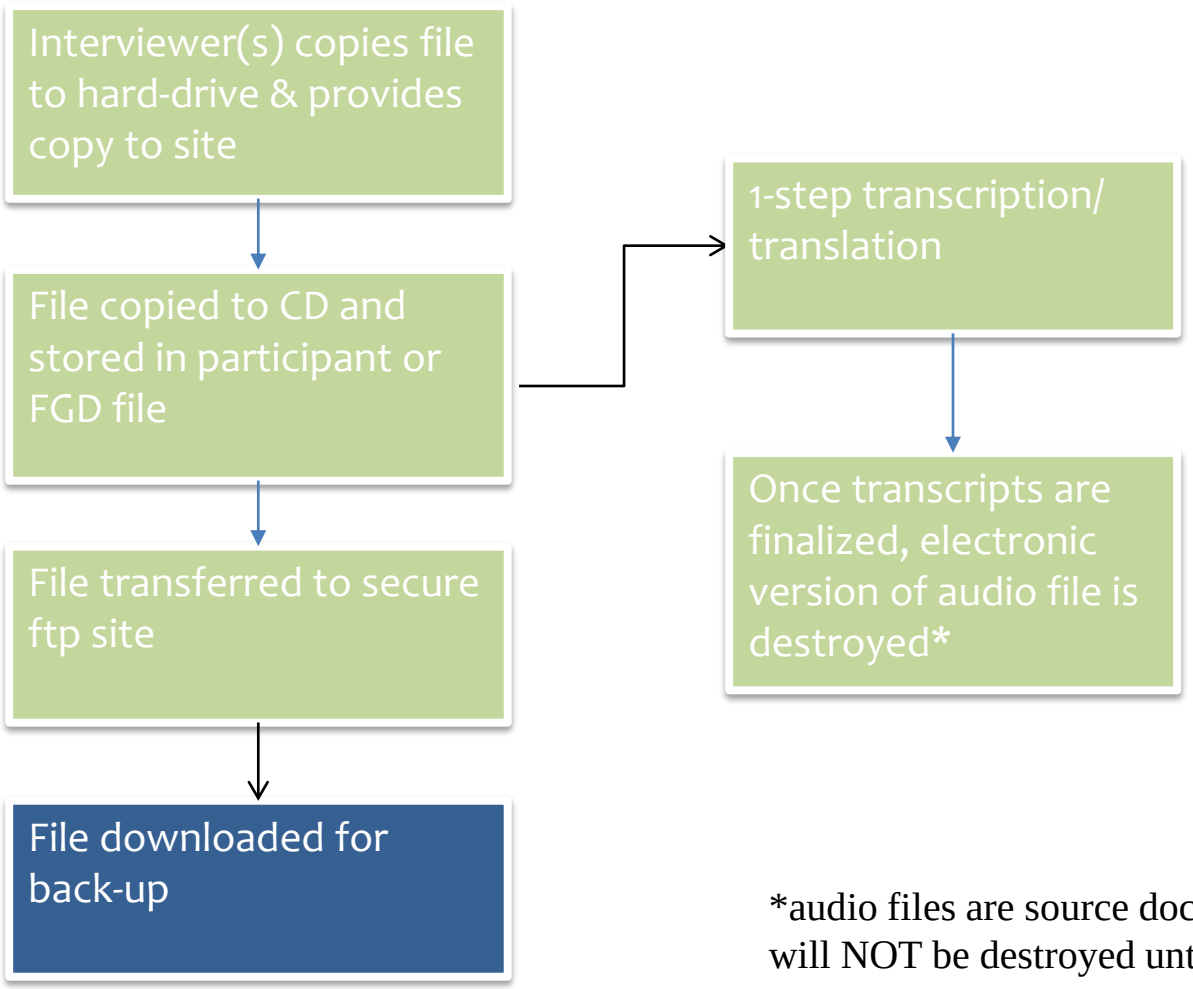
Column completed by RTI

Column completed by Site

CRF Timeline

Task	Timeline
Completed CRFs reviewed locally and uploaded via FTP; notify of the upload RTI via MTN032@rti.org email	**Initial timeline:** Within three working days of completion **Timeline upon reaching high quality status:** Once per week
CRFs reviewed by RTI and queries sent to site	Within ***three working days*** of initial receipt
Queries responded to and updated CRFs re-uploaded to RTI via FTP and email notification to MTN032@rti.org.	Within ***three working days*** of receipt of queries

Audio File (AF) Management



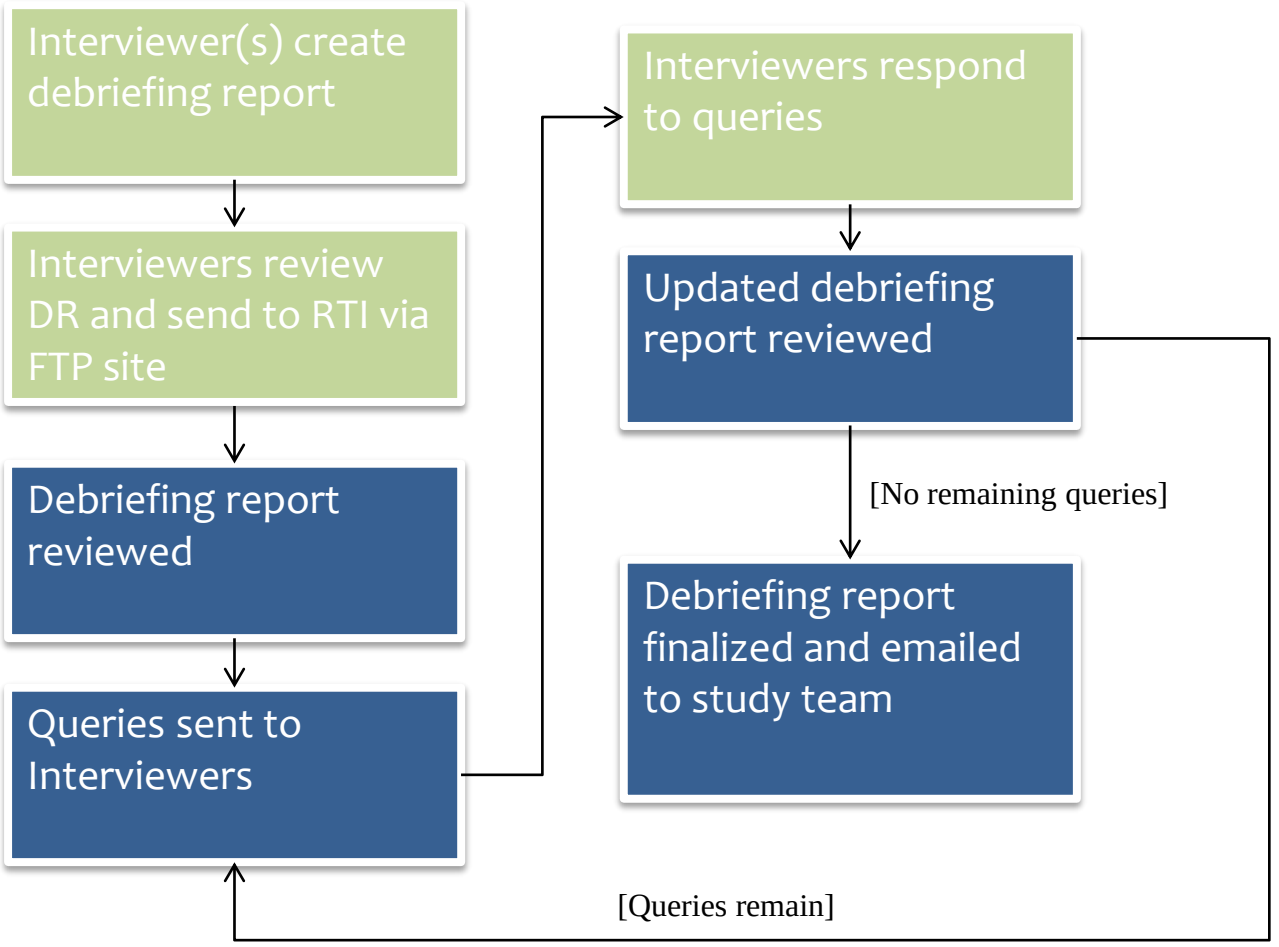
*audio files are source documentation and will NOT be destroyed until directed by DAIDS

Site Staff RTI

Audio File Timeline

Task	Timeline
Audio file checked, saved to hard-drive, copied for the site	***Same day*** as IDI completion
Audio file copied onto CD and stored	***Same day*** as IDI completion
Site staff upload audio file to ftp site	***Within one week in weekly batches*** by Friday

Debriefing Report (DR) Management

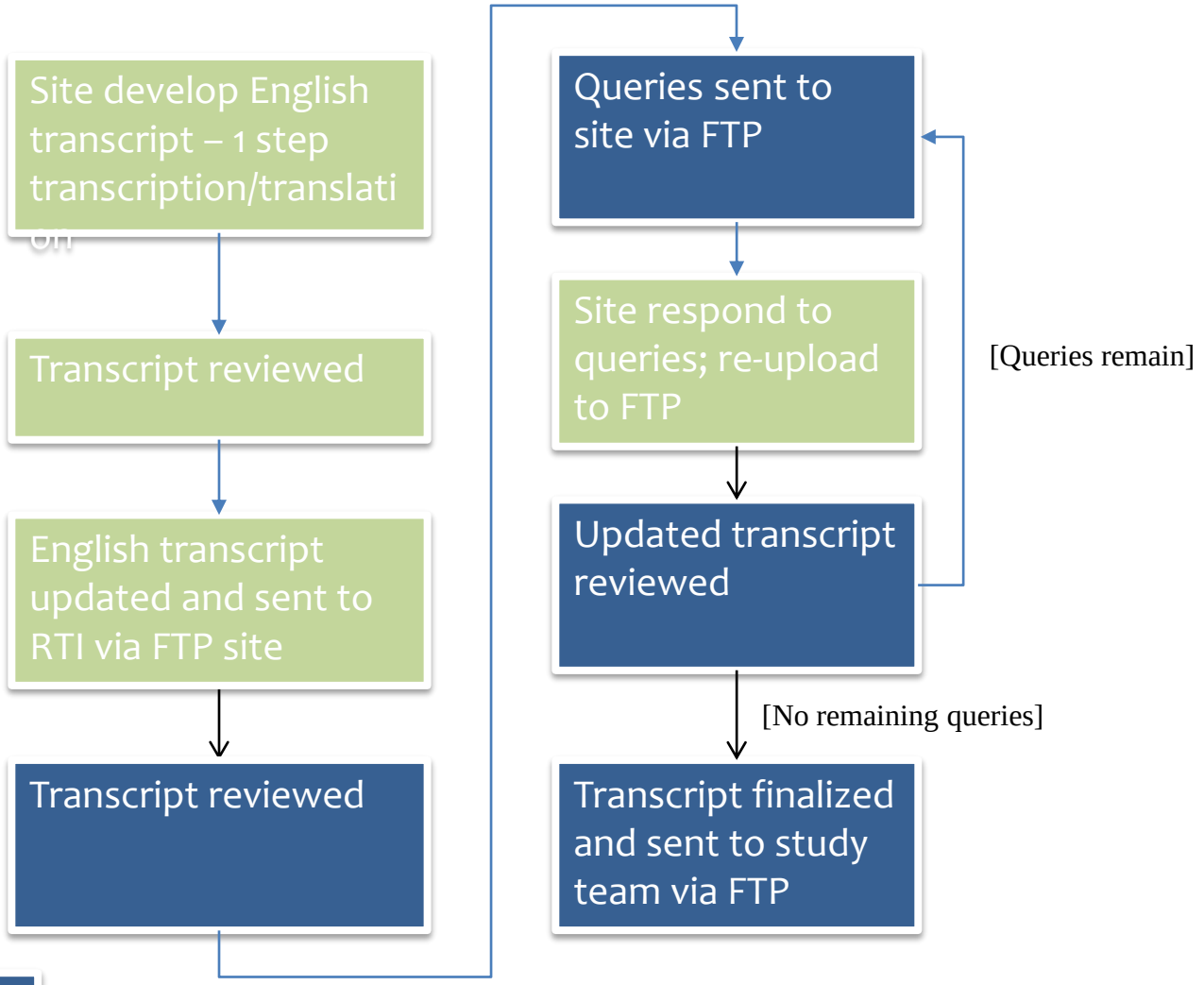


Site Staff | RTI

Debriefing Report Timeline

Task	Timeline
Initial Debriefing Report completed	***Same day*** as interview completion
DR reviewed by Interviewers/Note-takers and emailed to RTI	Within ***one week*** of IDI completion
RTI reviews DR and sends queries to Interviewers/Note-takers	Within ***one week*** of initial receipt
Interviewers/Note-takers respond to RTI queries	Within ***one week*** of query receipt

Transcript Management



Site Staff | RTI

Transcript Timeline

Task	Timeline
Initial English language transcript developed and sent to RTI (inclusive of site-level review) via FTP	Within ***one month*** of the IDI completion
RTI reviews transcript and sends queries to Interviewers	Within ***two weeks*** of initial transcript receipt
Interviewers respond to RTI queries	Within ***two weeks*** of query receipt

Data Transfer Timeline Recap

Timeline	Activity
3 working days • Send list of what was uploaded to FTP to MTN032@rti.org	• First 5 CRFs
Weekly batches on Friday • Send list of what was included in weekly FTP batch to MTN032@rti.org*	• CRFs (After first 5 with 0-1 queries) • AFs • DRs
Within one month	• Transcripts**

*If interview completed Thursday or Friday but documents not yet ready, can send the following week

**Once transcripts are finished with transcription/translation, they can be included in weekly batch upload to FTP site

Data Query Timeline Recap

Timeline	Activity
Within 3 working days	• CRFs
Within one week	• DR
Within two weeks	• Transcripts

File Naming Conventions

- Initial format:
  - IDI_1001_Audio File_22MAR16
- Query format:
  - IDI_1001_Debriefing Report_22MAR16_CN_AK
- Final format:
  - IDI_1001_Transcript_22MAR16_FINAL

Transcript Formatting Tips

- **Use consistent font across transcripts -- Times New Roman or similar, 11 or 12 point font and 1.15 spacing.**
- Header Includes: Interview Type, Participant ID, Drug Detection Level, Interview Date, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Transcriber/Translator Name, Interview Language
- After header, label next section "**Interview Text**," insert a hard return and begin transcribing the content of the audio file verbatim (in English).
- Use "I:" before Interviewer remarks and "R:" before respondent remarks.
- *Italicize all respondent remarks*

Transcript Formatting Tips

- Auto-number the transcript **by paragraph** so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets] not parentheses
- Long pauses can be represented by use of an ellipsis "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described in section 7-7 SSP
- Be consistent with all formatting!

VISIT PROCEDURES (Phase 1)

Sarita Naidoo

Protocol Training

22 March 2016

Visit Checklists

Visit checklists outline a step-by-step guide to visit procedures:

Phase 1 IDI Visit Checklist Page 1 of 2

MTN-032 PTID:	Visit Date:
Initials	**Procedures**
	Preparation
	Audio-recorder checked (power supply, extra batteries, etc.)
	Supplies gathered: pen and stationery for note-taking, consent form, discussion guide, refreshments (if applicable), reimbursement
	Verification of participant status (PK results, HIV status, and adherence group)
	Participant Arrival, IC & Data Collection
	Greet participant and offer refreshments
	Confirm participant identity
	Explain, conduct, and document informed consent process per site SOPs: ❑ Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. [*Inclusion criteria 2, and 3*] ❑ NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.
	Confirm eligibility criteria: ❑ ASPIRE PTID included on Recruitment List from SCHARP [*Inclusion criteria 4-7*] ❑ Participant informed of her randomization assignment in ASPIRE [*Inclusion criteria 1*] ❑ ELIGIBLE ⇒ CONTINUE. ❑ Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives [*Exclusion criteria 1*] ❑ NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.
	Administer Demographic Information Form (DEM)
	Review IDI ground rules: • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off
	Conduct sections A-B of the Phase 1 IDI Topic Guide
	Complete PK Response section of PSF or note response to PK discussion in interview notes and record on PSF immediately following IDI.
	Conduct section C of the Phase 1 IDI Topic Guide, including presenting the participant with her individual PK results.

Phase 1 FGD Individual Participant Visit Checklist
Page 1 of 1

MTN-032 PTID:	FGD No.:	Visit Date:
Initials	**Procedures**	
	Participant Arrival, IC & Data Collection	
	❑ Confirm participant identity	
	Explain, conduct, and document informed consent process per site SOPs: ❑ Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. [*Inclusion criteria 2, and 3*] ❑ NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.	
	Confirm eligibility criteria: ❑ ASPIRE PTID included on Recruitment List from SCHARP [*Inclusion criteria 4-7*] ❑ Participant informed of her randomization assignment in ASPIRE [*Inclusion criteria 1*] ❑ ELIGIBLE ⇒ CONTINUE. ❑ Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives [*Exclusion criteria 1*] ❑ NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.	
	❑ Administer Demographic Information Form (DEM) ❑ Present the participant with her individual PK levels from ASPIRE	
	❑ Alert the participant that she will now be joining the FGD with participants who have drug levels similar to hers.	
	Post FGD (Immediately following FGD)	
	❑ Complete PSF	
Comments: *Initial and date all comments.*		

Phase 1 FGD Group Visit Checklist Page 1 of 1

FGD No.:	Visit Date:
Initials	**Procedures**
	Preparation
	Audio-recorder checked (power supply, extra batteries, etc.)
	Supplies gathered: pen and stationery for note-taking, consent forms, PSFs, discussion guide, refreshments (if applicable), reimbursements
	Verification of participant status (PK results and study product group)
	Participant Arrival, IC & Data Collection
	Greet participants and offer refreshments
	Complete procedures with all individual FGD participants as outlined on the FGD Individual Participant Visit Checklist.
	Review FGD ground rules: • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off
	Conduct Phase 1 FGD Topic Guide
	Thank and reimburse the participants
	Post FGD (Immediately following FGD)
	Check audio recording to verify that the session was properly recorded.
	Expand notes and complete debriefing report
Comments: *Initial and date all comments.*	

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Overview Of Visit Procedures

- Confirm eligibility
- Obtain written informed consent for Screening and Enrollment
- Collect Locator Information
- Assign a unique Participant Identification (PTID) Number
- Collect Demographic Data
- Administer Behavioral Questionnaire
- Conduct in-depth interview (IDI) or Focus Group Discussion (FGD)
- Complete Participant Status Form (PSF)
- Provide Reimbursement for study visit

Prior to Enrollment of participants review data collection tools and ensure that staff is aware of which category of participant they will be interviewing (i.e. overall drug level classification and corresponding visual tool, and HIV status).

IDI Process

Before Visit:

- Confirm time with participant
- Appropriate space for interview identified and reserved
- Current versions of ICF, discussion guide, other tools (e.g. drug level results visuals, theme cards, etc.) and checklists
- Audio-recorder charged, has batteries, and tested that day for functionality
- Verify participant status (i.e. adherence results, HIV status)

During Visit:

- Confirm identity
- Informed consent, Locator Information
- Confirm eligibility
- Demographic Information (DEM) form, Behavior Assessment (BA)
- Begin IDI (as per guide)

IDI Process

During Visit:

- Present drug level results
- Fill out/note adherence response for/on Participant Status Form (PSF)
- Complete IDI (Notes to be taken on separate sheets of paper labeled with PTID, date and staff initials)
- Complete Participant Status Form (PSF)
- Reimburse participant

After Visit:

- Interviewers and note-takers: check recording and expand notes, if necessary
- Review CRFs for completeness and clarity
- Complete IDI Debrief Report template

FGD Process

Before Visit:

- Confirm time with participants
- Appropriate space for discussion identified and reserved
- Current versions of ICF, discussion guide, other tools (e.g. drug level results visuals, theme cards, etc.) and checklists
- Audio-recorder charged, has batteries, and tested that day for functionality
- Verify all participants' status (i.e. adherence results, etc)

During Visit:

- Confirm identity
- Informed consent, Locator Information
- Confirm eligibility
- Demographic Information (DEM) form, Behavior Assessment (BA)
- Present individual drug level results

FGD Process

During Visit:

- Review FGD ground rules
- Begin discussion as per FGD guide (Notes to be taken on separate sheets of paper labeled with all participant PTIDs, date, and staff initials)

Interview should flow naturally and flexibly, however ensure that primary research topics/questions are addressed

- Complete FGD
- Reimburse all participants

After Visit:

- Complete Participant Status Form (PSF) for all participants
- Interviewers and note-takers: check recording and expand notes, if necessary
- Review CRFs for completeness and clarity
- Complete FGD Debrief Report template

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Debrief Reports

Purpose:

To provide a summary of the participants' attitudes towards the key themes, the mood of the discussion, whether it was dominated by certain participants (FGD), unique comments, and any other important information in REAL TIME.

- ❑ Report to be completed immediately after IDI or FGD.
- ❑ Will be discussed on study team calls and shared across sites.

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Required Documentation

- Documentation of eligibility
- Documentation of informed consent process
- Complete visit checklists
- Interview notes
- Expanded notes
- Debrief report
- A record of all contacts, and attempted contacts, with the participant.

What are your questions?

Acknowledgements

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