



# Follow-up Visit Procedures

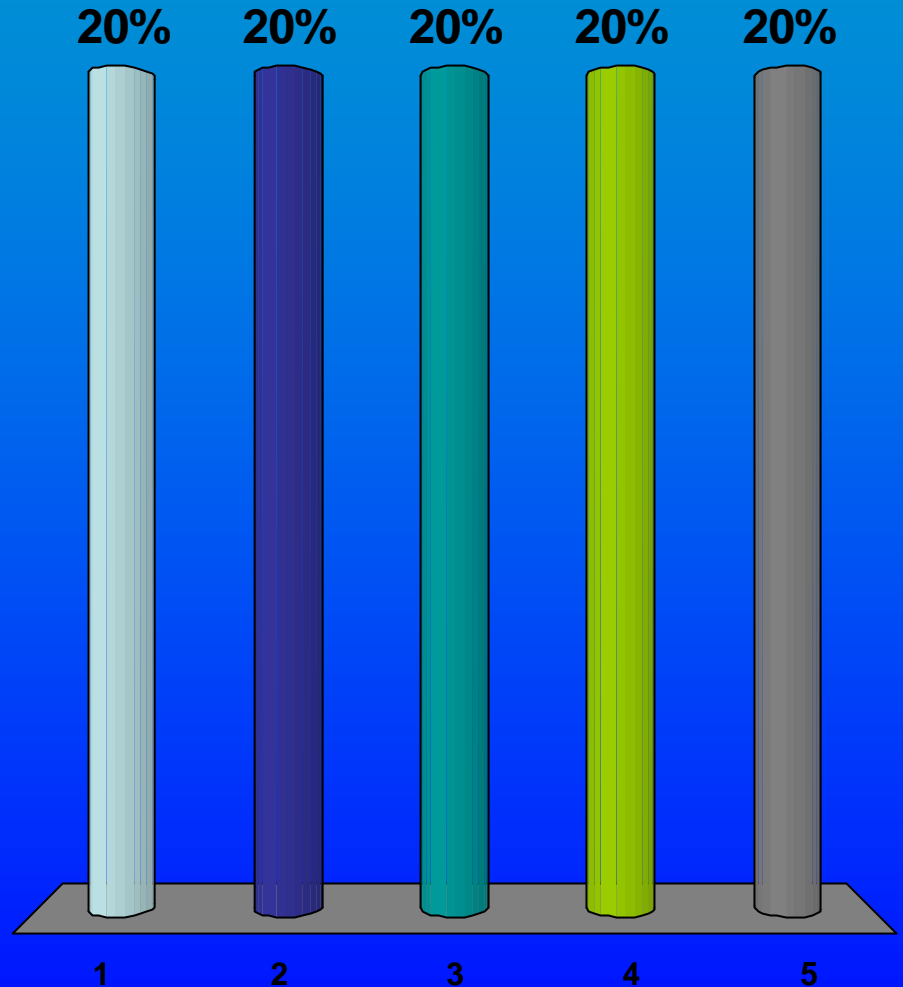
MTN-009

# General Overview

- MTN-009 follow-up visits are only required for participants who are found to be HIV infected
- These participants will have a minimum of two follow-up visits

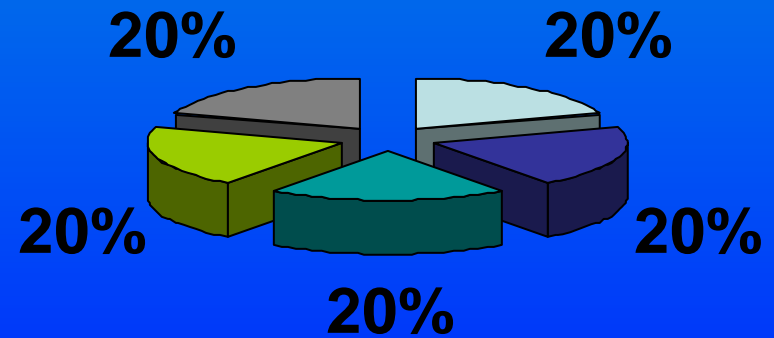
# What is the purpose of these follow-up visits?

1. To collect information about participants' behavior
2. To provide test results
3. To provide counseling and test results
4. To provide counseling
5. To collect additional samples



# What test results will be provided at these visits?

1. HIV rapid test results
2. STI results
3. Viral load, Resistance and CD-4
4. Options 1, and 3
5. Option 1, 2, and 3



# General Overview

- The purpose of follow-up visits in MTN 009 is to provide participants with test results and counseling.
- No data is collected on CRFs at follow-up visits
  - No visit codes are provided by SCHARP
    - Study staff may choose to develop and use local visit codes, for follow-up visits, to label and identify documentation completed for follow-up visits.

# Follow-up Visits

- Two types of follow-up visits:
- **Scheduled visits:** required per protocol as described in Protocol Section 7.2.
- **Interim visits:** take place between scheduled visits.
  - There are a number of reasons why interim visits may take place, including a participant who has a question for study staff, needs additional counseling, or a participant who is informing study staff of a social harm event.

# What is the timeframe for conducting the first follow-up visit?

20% 1. Two Weeks after enrollment

20% 2. Four Weeks after enrollment

20% 3. Any time during the study

20% 4. Whenever possible

20% 5. There are no follow-up visits

# Scheduled Follow-up Visits

## ➤ First Follow-up (Visit 2):

- Approximately two weeks after the date when blood was collected at the screening and enrollment visit.
- The purpose is to provide participants with CD4-T cell count result (CD4+) and associated post-test counseling.



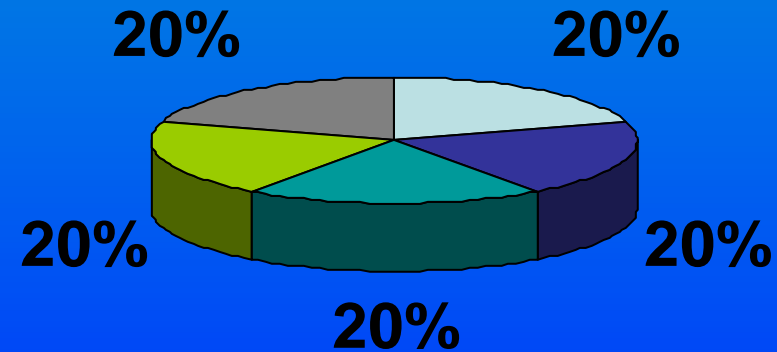
# Scheduled Follow-up Visits

## ➤ First Follow-up (Visit 2):

- The visit may be scheduled depending on when the site expects to receive the CD4+ result.
  - Every effort should be made to conduct this visit within two weeks of blood collection, as the participant's CD4+ result indicates whether or not participant should be started on ART.
- The HIV-1 RNA viral load test results, if available, should also be provided to participants at this visit.

# The second follow-up visit will be scheduled:

1. Two weeks after the first follow-up visit
2. After all test results have been received, ideally within 6 months after enrollment
3. After all test results are received, ideally within 3 months after enrollment
4. After all test results are received, ideally within 3 months after the first follow-up visit
5. Is there a second follow-up visit?

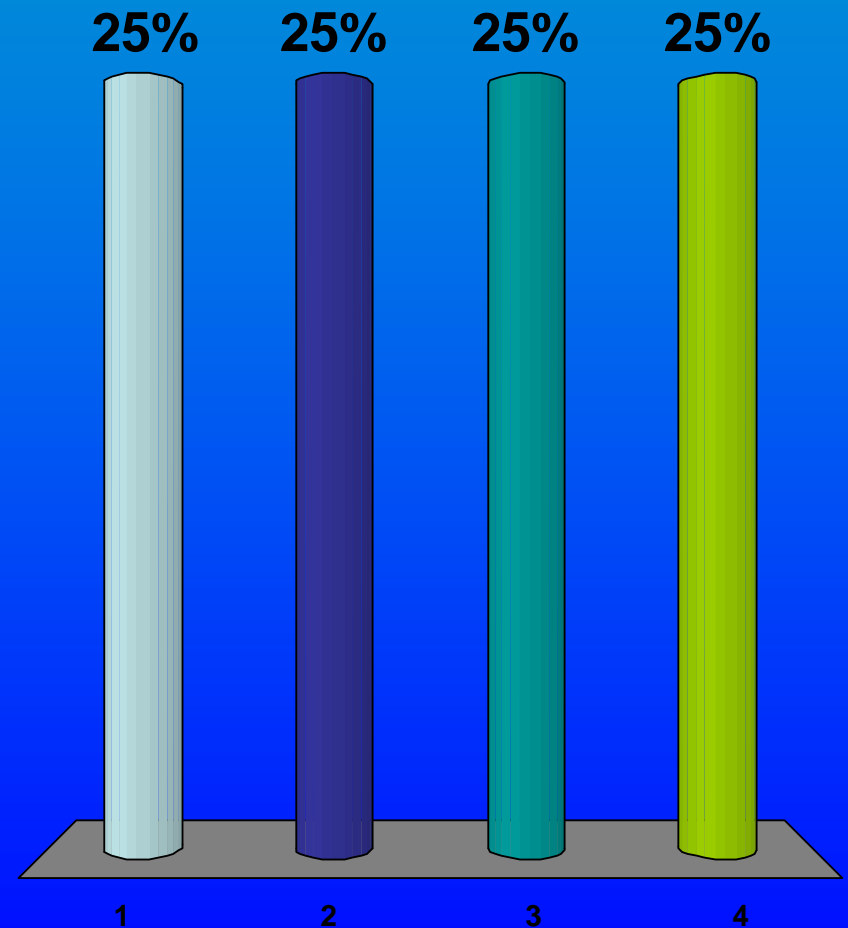


# Scheduled Follow-up Visits

- Second Follow-up (Visit 3):
- The second follow-up visit will be scheduled once the site receives both the HIV-1 RNA (viral load) and HIV resistance test results
- Ideally, it will be scheduled no later than three months after blood was collected at the enrollment visit.

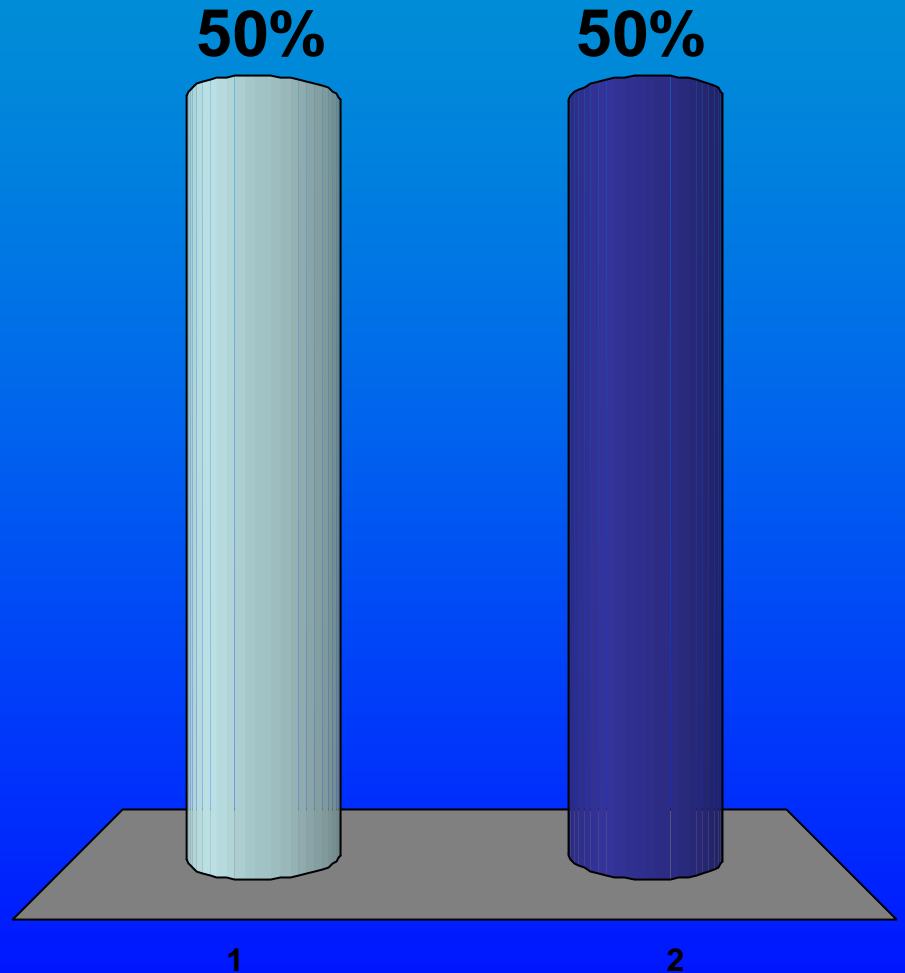
# Who will provide to the site the resistance and viral load test results?

1. MRC Laboratory
2. BARC
3. MTN Network Lab
4. Kaila and Stephanie



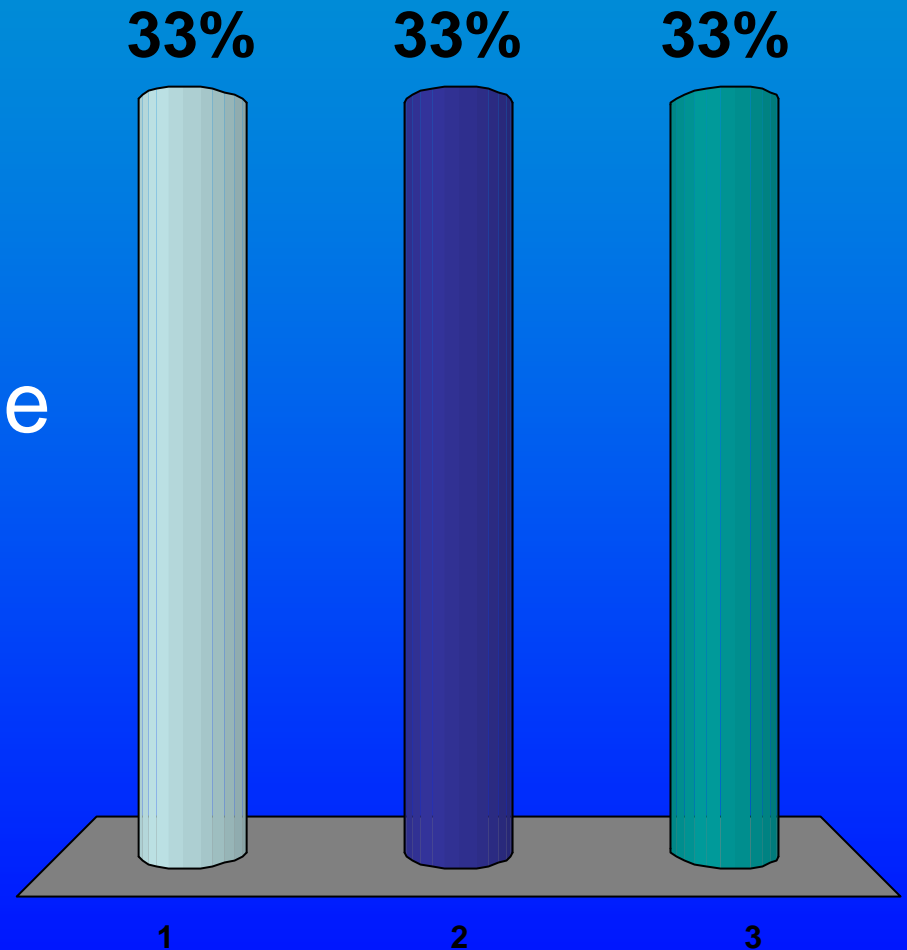
All follow-up visits will take place  
at the study clinic

1. True
2. False



At follow-up visits, the only required procedure is counseling?

1. True
2. False
3. Depends on the participant



# Follow-up Visit Procedures

- Ensure all laboratory test results have been received
- Review previous visit documentation
- Confirm participant identity and PTID per site SOPs
- Review/update locator information
- Explain today's study procedures

# Follow-up Visit Procedures

- Verify participant is ready to receive study results
- Provide laboratory results in the context of pre/post-test counseling (Western Blot, resistance, CD4, viral load)
- Provide referral to available resources per site SOP
- Provide reimbursement
- Schedule next visit (if applicable)



# Missed Visits

- For participants who do not complete scheduled follow-up visits within the specified timeframe, the visit will be considered missed and relevant documentation will be completed (e.g. chart notes, site-specific forms).
- Sites should make a reasonable effort, as defined in site SOP, to make up the visit in order to provide the participant with her test results and appropriate post-test counseling.



# Missed Visits

Where are you  
documenting missed  
visits?

# Missed Visits

- If a participant misses a visit and does not return to the site after adequate follow-up per site SOP, the site must inform the MTN-009 management team.
  - All efforts to contact the participant should be included in the communication with the management team.
- If the visit is missed because of a site's oversight, it will be considered a protocol deviation and reported as such.



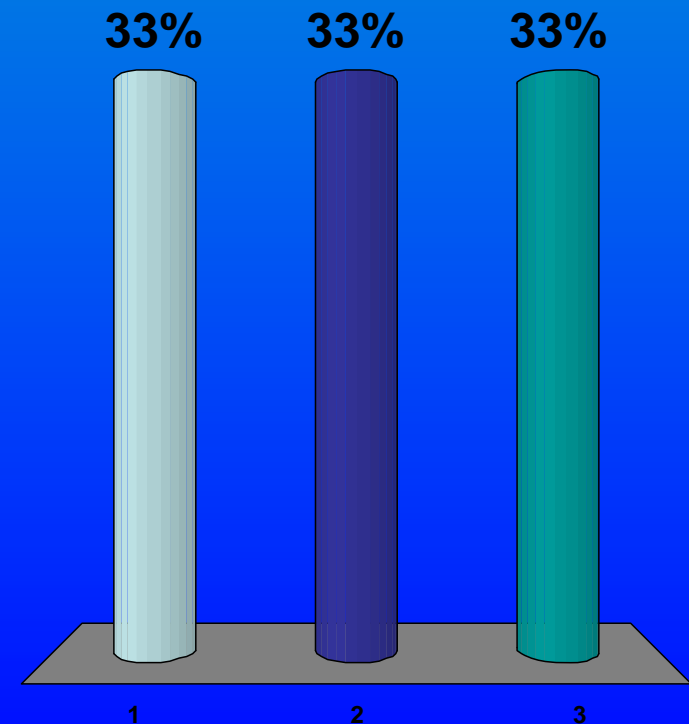
Questions

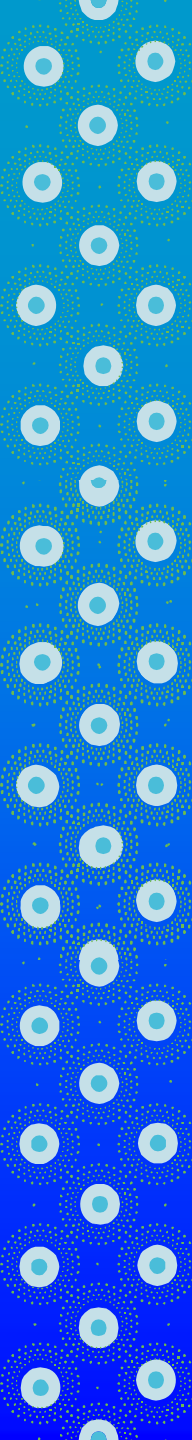


# Follow-up Visit Timeline

If the CD4-positive T cell count result is received one week after enrollment, the first follow-up visit should be scheduled

1. Two weeks after enrollment
2. As soon as possible after receiving the results
3. Anytime during the study





At what point are  
you scheduling the  
follow-up visits?

If the CD4-positive T cell count result is received three weeks after enrollment, the first follow-up visit should be scheduled

33% 1. Two weeks after the enrollment visit

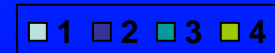
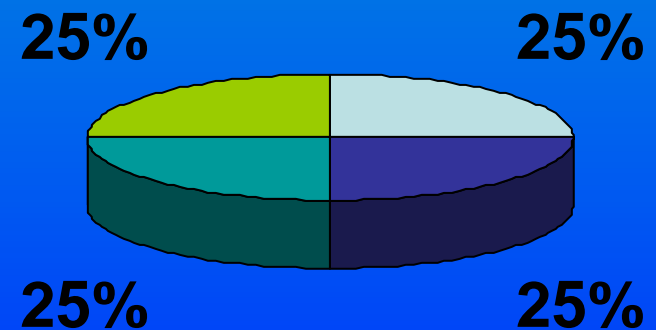
33% 2. As soon as possible after receiving the results

33% 3. Anytime during the study



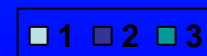
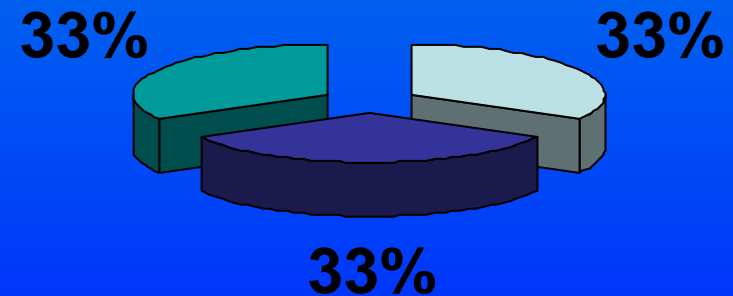
# If the HIV viral load results are received two weeks after the enrollment visit, when should these results be provided to the participant?

1. At the first follow-up visit, if it has not occurred yet
2. At the second follow-up visit
3. During an interim visit
4. Is not necessary to provide these results to the participant



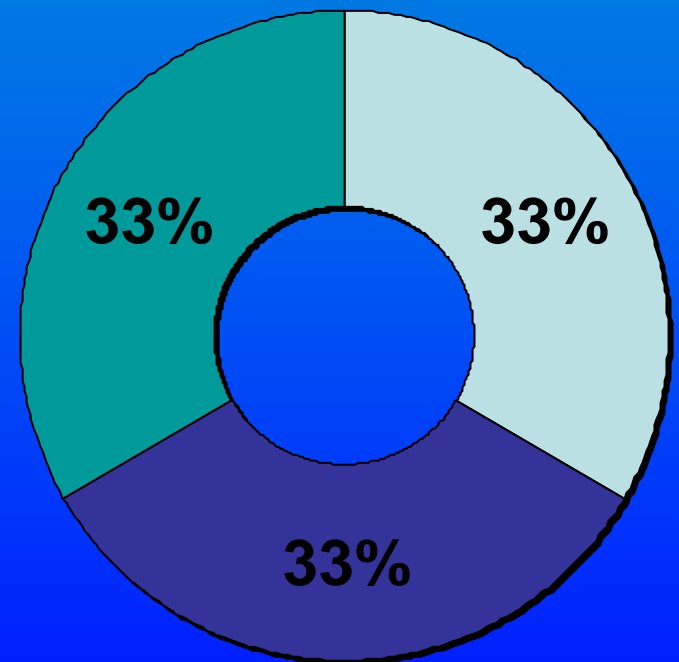
# The resistance test results are received two months after the enrollment visit, when should the second follow-up visit be scheduled?

1. As soon as results are received
2. Within three months from the enrollment visit
3. Within three months of receiving the results



# The HIV viral load test results are received a month after the enrollment visit, how should you provide results to the participant?

1. By scheduling an interim visit to provide these results
2. At the second follow-visit, which will be scheduled immediately
3. At the second follow-up visit, which will be scheduled once resistance test results are received



There was an unexpected delay and the resistance test results are received five months after the enrollment visit, what do you need to do?

33%

1. Schedule the second follow-up visit three months after the enrollment visit, you need to follow the SSP

33%

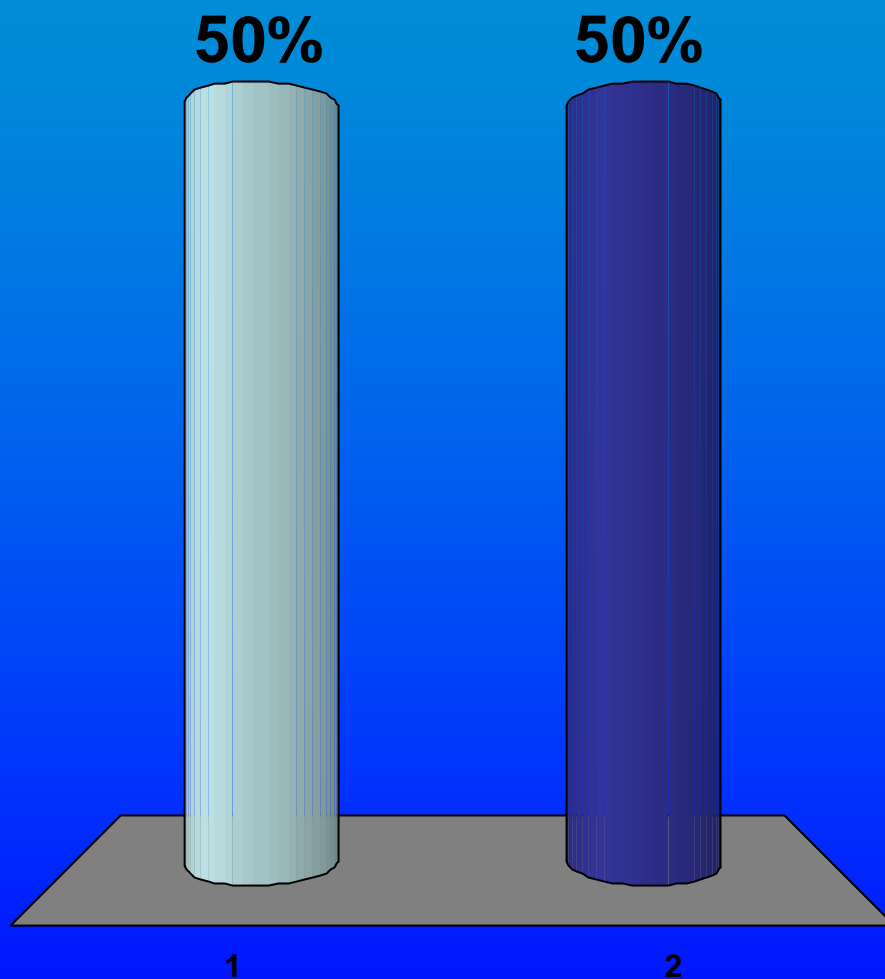
2. Schedule the participant as soon as results are received

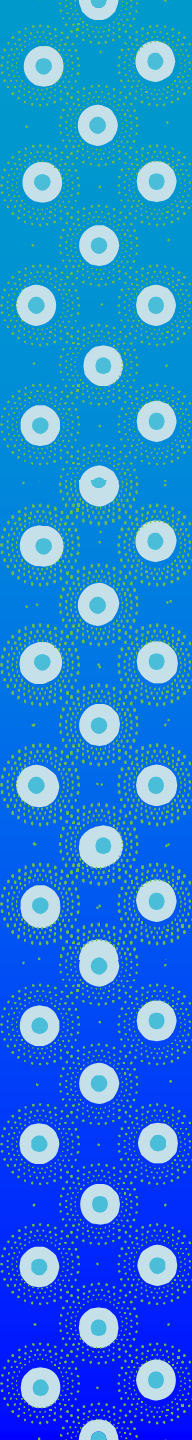
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3. Give the results over the phone or send a letter since the three months timeline are way past

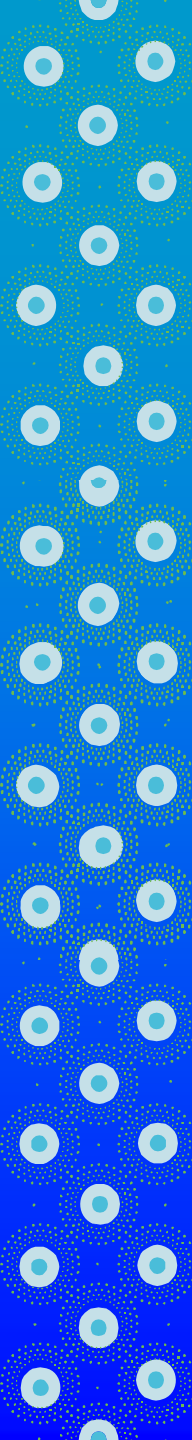
The follow-up visit window will be determined based on the day of enrollment

1. True
2. **False**





What procedures do you have in place to ensure follow-up visits are scheduled in a timely manner?



What tools do you have in place to track timeline for receiving laboratory test results?

Who should you contact if the resistance and viral load results are not received within three months of the enrollment visit?

20% 1. The Network Lab

20% 2. Urvi

20% 3. Urvi and the Network Lab

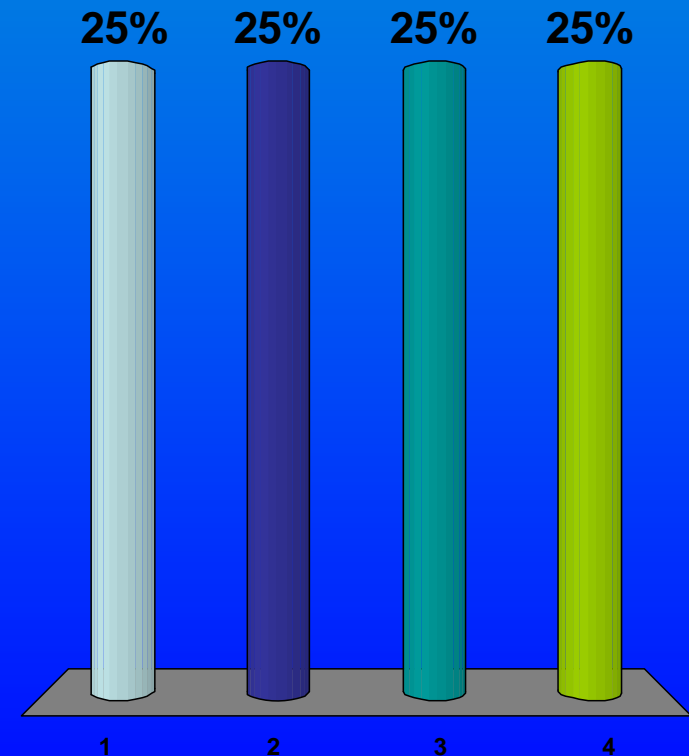
20% 4. Urvi and the MTN-009 Management team

20% 5. The MTN-009 Management team



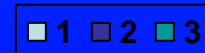
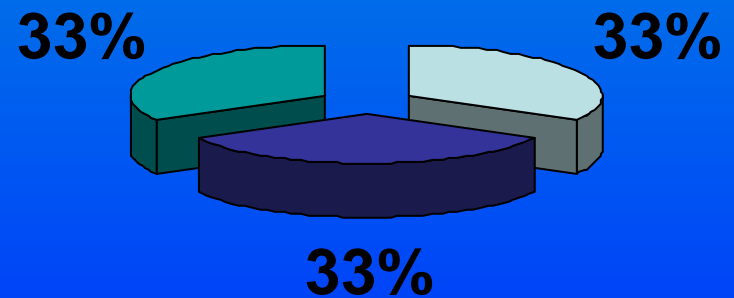
A participant misses her first follow-up visit. After active follow-up, she returns to the site two months after the enrollment visit. At this point, you have received all test results. Which results will you provide to this participant?

1. CD-4, Viral Load, and resistance
2. CD-4 only
3. CD-4 and Viral Load
4. Depends on how many results the participant is ready to receive

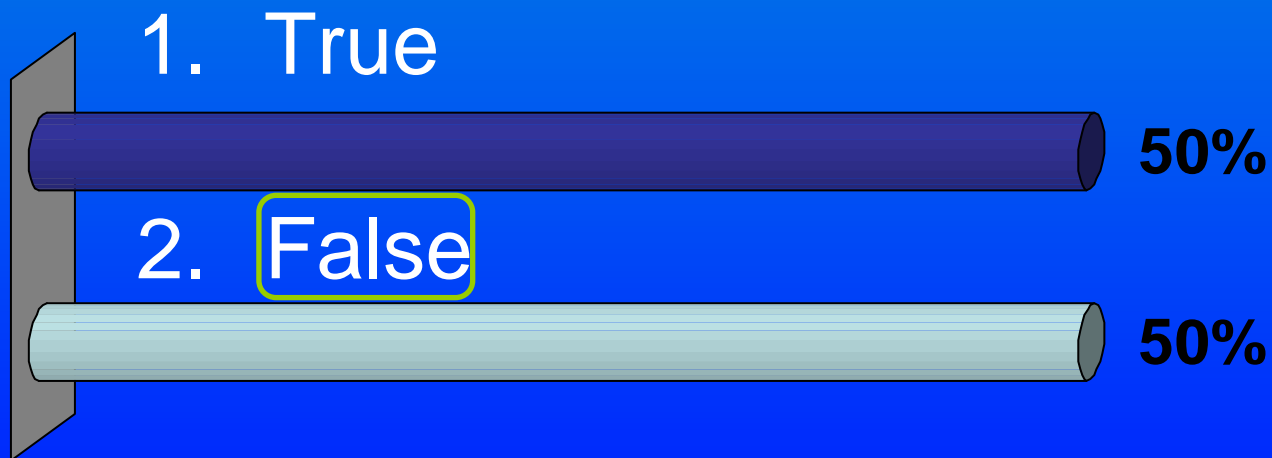


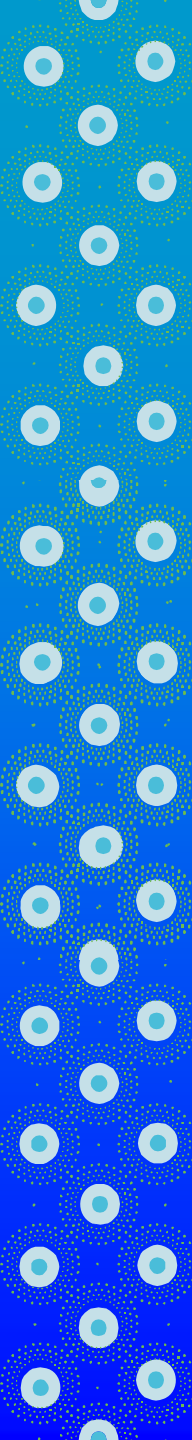
# Continuing from the previous scenario, is a second follow-up visit required?

1. Yes
2. No
3. Depends which results were provided during the previous visit



If all test results are provided at the first follow-up visit, the second follow-up still needs to be scheduled since it's a protocol requirement





Questions?