

# Section 12. Data Management

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This section describes data management for HPTN057 and DataFax, the data management system used by SCHARP. DataFax is a tool that allows for the collection and processing of accurate data for statistical analysis. The success of DataFax depends on the people who use it—both at the sites and at SCHARP. The purpose of this section is to provide site staff with the information they need to successfully complete and transmit DataFax forms for HPTN057.

## 12.1 DataFax Overview

DataFax is the data management system used by SCHARP to receive and manage data collected at study sites. The site transmits an electronic image of each case report form (CRF) to SCHARP DataFax, and the original hard copy CRF is retained by the site.

### CRF Transmission

SCHARP's Information Technology (IT) Group works with each site to determine the best solution for data transmission on a site-by-site basis.

### Data Entry/Quality Control

Once a CRF image is received by SCHARP DataFax, the following occurs:

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.
- Next, each CRF is reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control (QC) notes.
- QC notes are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and retransmit the corrected CRFs to SCHARP DataFax.
- When the retransmitted pages are received, SCHARP staff review the corrected pages and resolve the QC notes.

*Note:* If a change is made to a CRF but the updated page is not retransmitted to SCHARP DataFax, the change will not be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC note, the note will continue to appear on subsequent QC reports until the modified CRF is received at SCHARP. Therefore, it is very important that the site retransmit updated CRF pages to SCHARP DataFax **any time** a change is made to data, regardless of whether or not the change was made in response to a QC report.

## 12.2 DataFax Form Completion

### 12.2.1 Guidelines

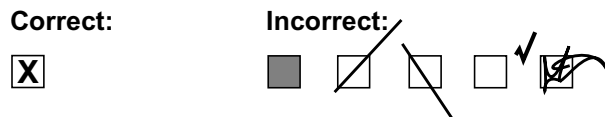
Based on the use of fax technology and Good Clinical Practices (GCPs), the following guidelines should be used for completing DataFax CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.

- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before transmitting CRFs.
- Because some CRFs are source documents, the site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Transmit forms as soon as possible after they have been completed and reviewed (within the time period specified for the study).

### 12.2.2 How to Mark Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.



Mark only one response box for each item unless the “Mark all that apply” instruction is present.

### 12.2.3 How to Record Numbers

Some questions on DataFax CRFs include boxes for recording a numeric response. DataFax can only read the numbers in these boxes if they are recorded clearly. The following instructions should be followed when recording numeric responses:

- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

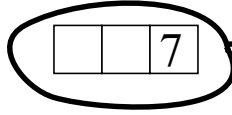
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The following example shows how a value of 7 is recorded when three response boxes are

**Correct:**

0 0 7

**Incorrect:**



This example would result in a QC note.

provided:

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

**Correct:**

4

**Incorrect:**

4

- Write the number(s) simply, with few loops.

The following example shows the format in which numbers will be most easily read by DataFax. Also included are some commonly used formats that may be difficult for DataFax to identify.

**Easily Identified:**

0 1 2 3 4 5 6 7 8 9

**Difficult to Identify:**

ø 1 2 3 4 7

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## 12.2.4 How to Record Dates

Dates are recorded using the “dd MMM yy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yy” represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English* for the date to be read in DataFax. Abbreviations are shown below:

Month	Abbreviation
January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

For example, June 1, 2003 would be recorded as follows:

0	1
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J	U	N
---	---	---

0	3
---	---

  
*dd*                      *MMM*                      *yy*

Sometimes, only a month and a year are required (e.g., dates of mother’s previous doses of nevirapine), in which case the response boxes will look like this:

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*MMM*                      *yy*

A dosing date of October, 2002, would be recorded as follows:

O	C	T
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0	2
---	---

  
*MMM*                      *yy*

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## 12.2.5 How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock, in which hours are designated from 0–24. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

1	4	:	2	5
<i>hr</i>			<i>min</i>	

**Note:** Midnight is recorded as 00:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

## 12.2.6 Data Corrections and Additions

Sometimes, data on a DataFax CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before transmitting.

It is important to make these changes to the original CRF—*never* copy data onto a new form. After making the change, the CRF *must* be retransmitted to SCHARP DataFax.

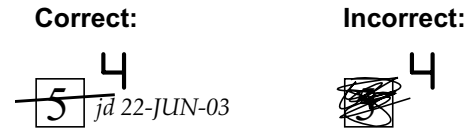
**Note:** If a correction or addition is made to one page of a multiple-page CRF, only retransmit the page that was changed.

**Note:** Never write over an entry once it is recorded. Use the standards outlined below when changing, clarifying, or amending data.

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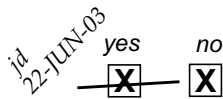
Whenever an entry on a DataFax CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



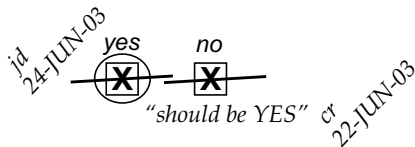
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and
- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item,
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:



**Note:** The standards above must be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed to SCHARP for the first time.

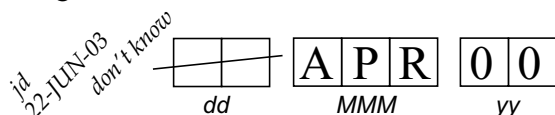
## 12.2.7 How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the blank boxes, in addition to initialling and dating the entry.

**Note:** A skip pattern is the only valid reason to leave a response blank.

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For example, when recording a date, if the exact day is not known, draw a single horizontal line through the “dd” boxes and write “don’t know” next to the response boxes, as shown below:



### 12.2.8 Staff Initials/Date

Every DataFax CRF includes a line in the lower-right corner for a staff member’s initials and the date on which the form was completed. When more than one staff member records data on a CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible.

## 12.3 Site Review of DataFax Forms

Each form must be reviewed for completeness and legibility before being transmitted to SCHARP DataFax. As part of the review, the site should check the following:

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item has been skipped as instructed by a skip pattern.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no:
  - missing dates,
  - missing visit codes,
  - incorrect PTIDs,
  - incorrect visit codes, and/or
  - missing data for items beginning a series of skip patterns.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been transmitted to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF.

**Important:** Use *only* the back of the CRF for a date stamp, *never* the front. Be sure to date stamp the back of the CRF each time it is transmitted, including retransmissions.

## 12.4 Faxing DataFax Forms

To streamline the submission of DataFax forms, the site should identify which staff members will be responsible for transmitting forms to SCHARP DataFax and receiving and responding to QC reports.

It is important that the site transmits completed CRFs to SCHARP within 24-48 hours whenever possible, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

## 12.5 Participant IDs

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The site should assign one PTID to each study participant in sequential order, crossing out each PTID after it has been assigned to ensure that it is used only once.

PTID boxes are located near the upper left corner of each DataFax CRF. On multiple page CRFs, the PTID must be filled in on each page. Below is the PTID structure used for HPTN057 and other perinatal studies:

<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>													-	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>								-	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table>		-	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table>	
Site Number		Participant Number		Chk		Type																					

**Site Number/Unit ID** = assigned by SCHARP

**Participant Number** = unique number assigned to each participant

**Check Digit (Chk)** = ensures accuracy of PTID

**Type** = number assigned to identify participant as mother (0) or infant (1,2,3)

**Protocol** = unique number assigned to each protocol

## 12.6 Visit Codes

DataFax CRFs include boxes in the upper right corner for a visit code. DataFax uses this number to identify the visit at which the CRF was completed.

**Visit Code**

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In the above example, visit 1 would be recorded as 01.0. All study visit codes are listed in the table below:

Study Visit	Visit Code
Mother's Screening	1.0
Enrollment/Delivery; Birth	2.0
24-48 Hours; Day 3	3.0
Day 5-7	4.0
Week 6	5.0
Week 12	6.0
Month 6	7.0
Month 9	8.0

Study Visit	Visit Code
Month 12	9.0

### 12.6.1 Cohort 4 Visit Codes

Because the visit windows for the Day 5-7 Visit are slightly different for Cohort 4, DataFax required that the visit code for the Day 5-7 Visit for cohort 4 be different. Please see the table below for the Visit Codes for Cohort 4 mothers and infants.

Study Visit	Visit Code
Mother's Screening	1.0
Enrollment/Delivery; Birth	2.0
24-48 Hours; Day 3	3.0
<b>Day 5-7</b>	<b>44.0</b>
Week 6	5.0
Week 12	6.0
Month 6	7.0
Month 9	8.0
Month 12	9.0

### 12.6.2 Interim Visit Codes

In addition to the scheduled, protocol-required visits listed above, Interim Visits may occur after enrollment into the trial. Interim visits occur when the participant visits the study clinic outside of the regular study schedule (e.g., for an Adverse Experience or confirmatory HIV testing). Interim visit codes should only be assigned if DataFax CRFs are completed at that interim visit.

**Note:** *If no DataFax CRF pages are required to document the visit, then an Interim Visit code should not be assigned because skipping of Interim Visit codes is not allowed in the DataFax database at SCHARP and would cause a QC note to be added to the QC report.*

Interim visit codes are assigned using the following guidelines:

- In the box(es) to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit (even if this visit was missed).
- Use the guide below to complete the box to the right of the decimal point:
  - 1 = the first interim visit after the most recent scheduled visit,
  - 2 = the second interim visit after the most recent scheduled visit,
  - 3 = the third interim visit after the most recent scheduled visit, and so on.

For example, the first interim visit after the infants's 4 Week scheduled study visit would be recorded as follows:

Visit Code   .

The second interim visit after the participant's third scheduled study visit would be recorded as follows:

Visit Code   .

In addition to AE or sick visits, other examples of interim visits include when infants are brought in for confirmatory HIV testing before the next scheduled visit, repeat safety lab tests, or urinalysis after a grade 2 or greater abnormal creatinine value.

### 12.6.3 Page Numbers

Not all DataFax CRFs include boxes for visit codes. If a form is only completed and faxed in one time during a study (e.g., Mother's Demographics or Screening Laboratory Results), the visit code will be automatically assigned in DataFax.

Other CRFs, such as log forms (e.g., Adverse Experience Log or Concomitant Medications Log), may include boxes in the upper right corner for page numbers, as shown below:

Page

In the example of the Adverse Experience Log, the participant's first adverse experience would be reported as page 01, the second would be 02, and so on, through out the infant's participation in the study, regardless of the visit when the adverse experience was reported.

## 12.7 Study Visit Timing

All visits after enrollment are based on the day of birth, which is considered to be Day 0. The table below lists the visit target dates and window periods for both infants and mothers.

Visit	Visit Code	Visit Target Day (post delivery)	Mother Visit Window	Infant Visit Window
Mother Screening	1.0	≥ 34 weeks gestation		
Delivery/Enrollment	2.0	Day 0	Days 0 - 1	
Birth	2.0	Day 0		Days 0 - 2
Mother 24-48 Hour	3.0	Day 2	Days 1 - 4	
Infant Day 3	3.0	Day 3		Days 3 - 4
Day 5-7	4.0	Day 5	Days 5 - 7	Days 5 - 7

Visit	Visit Code	Visit Target Day (post delivery)	Mother Visit Window	Infant Visit Window
Week 6	5.0	Day 42	Days 28 - 62	Days 28 - 62
Week 12	6.0	Day 84	Days 63 - 137	Days 63 - 137
Month 6	7.0	Day 182	Days 138 - 228	Days 138 - 228
Month 9 <sup>a</sup>	8.0	Day 274		Days 229 - 320
Month 12	9.0	Day 365	Days 321 - 441	Days 321 - 441

a. Mothers have no study procedures at the 9 month visit

### 12.7.1 Cohort 4 Visit Scheduling

Because Cohort 4 requires extended dosing of the infant, the visit window for the 5-7 Day Visit was extended to allow for all infant dosing to be completed within the visit window. The Mother visit Day 5-7 Visit is extended to match the infant visit window. All other visit windows remain the same. Below is are the Cohort 4 5-7 Day Visit windows for both mothers and infants:

Visit	Visit Code	Visit Target Day (post delivery)	Mother Visit Window	Infant Visit Window
<b>Day 5-7</b>	<b>44.0</b>	<b>Day 6</b>	<b>Days 5 - 8</b>	<b>Days 5 - 8</b>

### 12.7.2 Missed Visits

A scheduled visit is considered to be missed if not completed within the visit windows in the table above.

For example, if a mother does not bring the infant in for the 6 Week Visit until after the infant is 63 days old, the mother's and infant's 6 Week Visit is considered to be "Missed" and the Missed Visit form must be completed and faxed for both. A Missed Visit form should only be completed after the Visit Window period has passed, or if the study site staff know that the visit will be missed. For example, the mother tells site staff that the 6 Week Visit will be missed because her family is going to visit her parents.

If it happens that a participant returns to complete a visit after a Missed Visit form has been submitted but still within the visit window, draw a line through the previously submitted Missed Visit form, add a note that it should be deleted and why, initial and date, and re-submit it to SCHARP DataFax. Complete all of the scheduled visit procedures, code all visit forms with the scheduled visit code, and transmit the CRF pages.

## 12.8 Termination and Reactivation

Participants are terminated from study participation when they have completed the final study visit; died; refused further participation in the study; cannot adhere to the study visit schedule; relocate; investigator decided they can or should no longer participate (however, see Section 12.1.6 of the HPTN Manual of Operations); or the study site staff can no longer contact the participant (lost-to-follow-up). Participants who

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have been terminated from the study due to lost-to-follow-up, refusal, or relocation, who return to the study site before the end of the 24 Month Visit window period (441 days after delivery) may be allowed to rejoin the trial, and should be encouraged to do so. Participants are reactivated by writing “unterminate” or “delete” on the previously submitted Termination form and refaxing to SCHARP. Please note that a Missed Visit form must be completed for each missed visit during the period the participant was not in contact with the site.

## **12.9 Required CRFs for enrolled participants not exposed to study drug**

Eligible mothers enroll in the trial when they present at the study site for delivery. There may be cases where mother enroll but neither the mother nor infant take the study drug. Those participants are terminated after the Enrollment/Delivery visit. The Termination CRF must be completed with item 2k “Other, specify” marked and the reason given as “not dosed.” All other required CRFs are listed below.

### **Cohort 1, 3, or 4 and mother did not take study drug:**

- Mother Demographics
- Mother Screening/Enrollment Laboratory Results for screening visit
- Mother Delivery and Enrollment
- Mother Screening/Enrollment Laboratory Results for enrollment visit (if done)
- Mother Termination
- No infant CRFs are completed

### **Cohort 2 Mother with stillborn infant:**

- Mother Demographics
- Mother Screening/Enrollment Laboratory Results for screening visit
- Mother Delivery and Enrollment
- Mother Screening/Enrollment Laboratory Results for enrollment visit (if done)
- Mother Termination
- No infant CRFs are completed

### **Cohort 2 Infant did not receive study drug:**

- Mother Demographics
- Mother Screening/Enrollment Laboratory Results for screening visit
- Mother Delivery and Enrollment
- Mother Screening/Enrollment Laboratory Results for enrollment visit (if done)
- Mother Termination
- Infant Birth
- Infant Laboratory Results for birth visit (if done)
- Infant Termination



## 12.10HPTN 057 Schedule of Forms–MOTHER (All cohorts)

The data collection forms required for each study visit are listed on the Visit Checklists and are summarized in the table below.

<b>SCREENING</b>		<b>VISIT CODE: 01.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MLS-1, 2	Mother Screening/Enrollment Laboratory Results	016, 017
<b>DELIVERY/ENROLLMENT (DAY 0)</b>		<b>VISIT CODE: 02.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
DEM-1, 2, 3	Demographics	001, 002, 003
MD-1, 2, 3	Mother Delivery and Enrollment	007, 008, 009
MLS-1, 2	Mother Screening/Enrollment Laboratory Results	016, 017
MA-1	Mother Antiretroviral Medication Log	411
CM-1	Mother Concomitant Medications Log	423
PRE-1	Mother Pre-existing Conditions ( <i>Cohorts 1 and 3</i> )	012
<i>AS NEEDED</i>		
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
<b>24-48 HOURS (DAY 2)</b>		<b>VISIT CODE: 03.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	005
MLR-1, 2	Mother Laboratory Results	021, 022
MPK-1	Mother Pharmacokinetics ( <i>Cohort 1, Cohort 3 if dose increased</i> )	061
<i>AS NEEDED</i>		
MA-1	Mother Antiretroviral Medication Log	411
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
CM-1	Mother Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>DAY 5-7</b>		<b>VISIT CODE: 04.0 or 44.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	005
MLR-1, 2	Mother Laboratory Results	021, 022
<i>AS NEEDED</i>		
MA-1	Mother Antiretroviral Medication Log	411
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
CM-1	Mother Concomitant Medications Log	423
MV-1	Missed Visit	463

<b>WEEK 6 (DAY 42)</b>		<b>VISIT CODE: 05.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	005
MLR-1, 2	Mother Laboratory Results	021, 022
<i>AS NEEDED</i>		
MA-1	Mother Antiretroviral Medication Log	411
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
CM-1	Mother Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>WEEK 12 (DAY 84)</b>		<b>VISIT CODE: 06.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	005
MLR-1, 2	Mother Laboratory Results ( <i>Specimen collection only</i> )	021, 022
<i>AS NEEDED</i>		
MA-1	Mother Antiretroviral Medication Log	411
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
CM-1	Mother Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 6 (DAY 182)</b>		<b>VISIT CODE: 07.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	004
MLR-1, 2	Mother Laboratory Results ( <i>Specimen collection only</i> )	021, 022
<i>AS NEEDED</i>		
MA-1	Mother Antiretroviral Medication Log	411
AE-1	Mother Adverse Experience Log ( <i>Never cohort 2</i> )	420
CM-1	Mother Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 9 (DAY 274)</b>		<b>VISIT CODE: 08.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>This visit does not require case report forms for mothers.</i>		

<b>MONTH 12 (DAY 365)</b>		<b>VISIT CODE: 09.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
MFU-1	Mother Follow-up Visit	005
MLR-1, 2	Mother Laboratory Results ( <i>Specimen collection only</i> )	021, 022
MA-1	Mother Antiretroviral Medication Log	411
CM-1	Mother Concomitant Medications Log	423
ESI-1	Mother End of Study Inventory	489
TM-1	Mother Termination	490
<i>AS NEEDED</i>		
MV-1	Missed Visit	463
AE-1	Adverse Experience Log ( <i>Never cohort 2</i> )	420

## 12.11 HPTN 057 Schedule of Forms–Cohorts 1-3 INFANT

The data collection forms required for each study visit are listed on the Visit Checklists and are summarized in the table below.

<b>BIRTH (DAY 0)</b>		<b>VISIT CODE: 02.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IB-1, 2	Infant Birth	001, 002
ILR-1,2	Infant Laboratory Results	024, 025
IA-1	Infant Antiretroviral Medication Log	411
CM-1	Concomitant Medications Log	423
PRE-1	Infant Pre-existing Conditions ( <i>Cohort 2 only</i> )	012
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug ( <i>Never Cohort 1</i> )	300
AE-1	Adverse Experience Log	420
<b>DAY 3</b>		<b>VISIT CODE: 03.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
LR-1	Infant Local Radiology Assessment	018
PK-1	Cohort 1 Infant Pharmacokinetics ( <i>Cohort 1 only</i> )	061
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug ( <i>Never Cohort 1</i> )	300
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>DAY 5-7 (Day 5)</b>		<b>VISIT CODE: 04.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
IP-1,2	Cohort 2 Infant Pharmacokinetics	062, 063
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug ( <i>Never Cohort 1</i> )	300
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463

<b>WEEK 6 (DAY 42)</b>		<b>VISIT CODE: 05.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>WEEK 12 (DAY 84)</b>		<b>VISIT CODE: 06.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
LR-1	Infant Local Radiology Assessment	018
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 6 (DAY 182)</b>		<b>VISIT CODE: 07.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results <i>(Specimen Collection only, HIV testing if infant has been breast-fed since the last visit)</i>	024, 025
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 9 (DAY 274)</b>		<b>VISIT CODE: 08.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463

<b>MONTH 12 (DAY 365)</b>		<b>VISIT CODE: 09.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results <i>(Specimen Collection only, HIV testing if infant has been breast-fed since the last visit)</i>	024, 025
IA-1	Infant Antiretroviral Medication Log	411
CM-1	Concomitant Medications Log	423
ESI-1	Infant End of Study Inventory	489
TM-1	Infant Termination	490
<b>CR-1</b>	<b>Infant Central Radiology Assessment</b>	<b>020</b>
<i>AS NEEDED</i>		
AE-1	Adverse Experience Log	420
MV-1	Missed Visit	463

## 12.12HPTN 057 Schedule of Forms–Cohort 4 INFANT

The data collection forms required for each study visit are listed on the Visit Checklists and are summarized in the table below.

<b>BIRTH (DAY 0)</b>		<b>VISIT CODE: 02.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IB-1, 2	Infant Birth	001, 002
ILR-1,2	Infant Laboratory Results	024, 025
IA-1	Infant Antiretroviral Medication Log	411
CM-1	Concomitant Medications Log	423
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug	300
AE-1	Adverse Experience Log	420
<b>DAY 3</b>		<b>VISIT CODE: 03.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug ( <i>Never Cohort 1</i> )	300
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>DAY 5-7 (Day 6)</b>		<b>VISIT CODE: 44.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
IPF-1,2,3,4	Cohort 4 Infant Pharmacokinetics	065, 066, 067, 068
<i>AS NEEDED</i>		
DOV-1	Infant Early Discontinuation of Study Drug	300
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>WEEK 6 (DAY 42)</b>		<b>VISIT CODE: 05.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411

AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>WEEK 12 (DAY 84)</b>		<b>VISIT CODE: 06.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results	024, 025
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 6 (DAY 182)</b>		<b>VISIT CODE: 07.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results <i>(Specimen Collection only, HIV testing if infant has been breast-fed since the last visit)</i>	024, 025
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 9 (DAY 274)</b>		<b>VISIT CODE: 08.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
<i>AS NEEDED</i>		
IA-1	Infant Antiretroviral Medication Log	411
AE-1	Adverse Experience Log	420
CM-1	Concomitant Medications Log	423
MV-1	Missed Visit	463
<b>MONTH 12 (DAY 365)</b>		<b>VISIT CODE: 09.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
IF-1	Infant Follow-up Visit	004
ILR-1,2	Infant Laboratory Results <i>(Specimen Collection only, HIV testing if infant has been breast-fed since the last visit)</i>	024, 025
IA-1	Infant Antiretroviral Medication Log	411
CM-1	Concomitant Medications Log	423
ESI-1	Infant End of Study Inventory	489
TM-1	Infant Termination	490
<i>AS NEEDED</i>		

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AE-1	Adverse Experience Log	420
MV-1	Missed Visit	463

### **12.13 Form-specific Instructions**

These instructions include the purpose of each DataFax form, how each form should be completed, and when each form is sent to SCHARP DataFax. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all the items in the instructions, but rather, only those items needing detailed explanation. For HPTN 057 the form completion instructions are printed on the back of each CRF.