

MTN 025 Participant Tracking Database

User's Manual

Version 1.0
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Disclaimer

The MTN 025 participant tracking database is an optional tool provided to study sites by SCHARP for use in study visit management/visit tracking purposes. This database does not collect or store any data used for study analyses, and this database will not be transferred, shared, or provided to any persons outside of the study site.

This database is not used to record/collect source data or generate source documents. All information entered into the database is based on source documents contained in participants' study records. Information contained within the database, or printed from the database, is not source data or documentation.

As with all study data, every effort should be made to maintain participant privacy and confidentiality.

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1. Introduction

The MTN 025 participant tracking database is a Microsoft Access application used by MTN 025 site staff to assist in a number of study administrative and management functions, including:

- visit scheduling and tracking
- identifying study participants who are due for visits, in order to conduct visit reminders
- identifying study participants who are late for scheduled visits, in order to conduct timely participant outreach and retention efforts

Output from the database consists of Microsoft Access reports. Use of the database is completely optional, and is not associated with collection, management, or storage of data that will be used for analytic purposes per the MTN 025 study objectives.

Note: The database is to be used for participant tracking purposes only. It should not be used to record source data or generate source documents. All information entered into the database is based on other source documents contained in participants' study records. Information contained within the database, or output/reports printed from the database, are not source data/documentation.

1.1 What the database can do

- ✓ Let you know when Enrollment Visits are coming up
- ✓ List of Participants with One Week and Two Weeks left to Enroll
- ✓ List per week calendar month and past week the # screens, # of enrollments
- ✓ Provide list of all Screening and Enrollment Visits at your site
- ✓ Generate a follow-up visit schedule with target visit dates and windows (Excel Tool)
- ✓ Tell you which PTIDs have visits coming up on which day and what type of visit
- ✓ Tell you study visits for which a PTID is late

1.2 What the database cannot do

- ❖ Indicate what procedures are required at a visit
- ❖ Tell you if a participant is enrolled in MTN-015 or is currently pregnant
- ❖ Be used for co-enrollment identification
- ❖ Allow for separate dates for split visits to be entered
 - Cannot trigger reminders for second half of split visits
- ❖ Allow you to generate retention rates
- ❖ Be used as source for any information
- ❖ Tell you which participants attended the clinic on days prior to today
- ❖ Synch data with Outlook calendars
- ❖ Flag if a visit is scheduled outside of its' visit windows

2. Trusted Location for Access Database

The MTN 025 Participant Tracking Database (PTD) will be available for sites to download onto an existing site clinic computer. The PTD was created as a Microsoft Access 2000-2003 file. Please contact IT staff at your site for any software Microsoft Office Suite and Windows versioning issues that arise.

If the site makes any modifications to the database, the site is responsible for any effects these modifications have on the participant tracking database. SCHARP is not responsible for any data loss and/or future technical or software support needs incurred by the site. To best protect participant confidentiality, the database should not be backed-up or stored on another device/location. If all or part of the database is lost or damaged, it should be possible to re-enter/re-create the database if the site chooses, as the database is not the source for any of the information it contains (all data can be entered based on source documents maintained by the study site).

3. Password-Protection Access to the Database

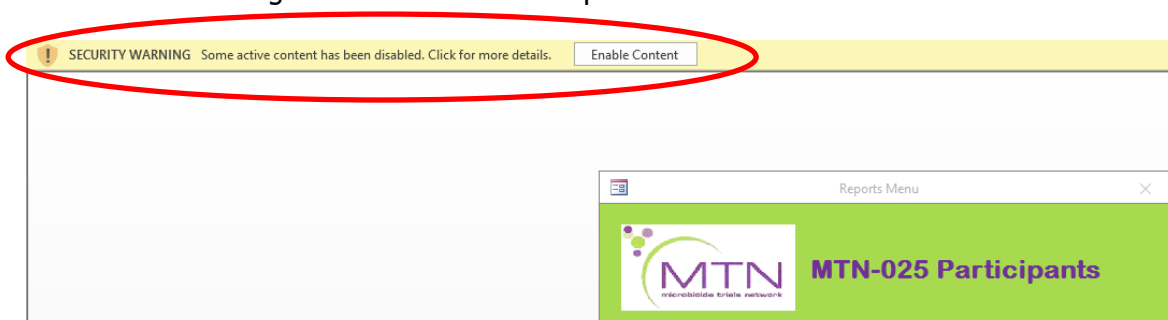
To maintain participant privacy and confidentiality, the database must be maintained in a secure environment. Password protection should be established for each authorized database user by following these steps:

- 👉 Open Microsoft Access. A Password text box will prompt you to enter a password before you can access the database.
- 👉 Type the password given to you during the site-specific training. Click OK.
- 👉 Be sure to record all passwords in a secure location away from the machine on which the database is installed.

4. MS Access Basics: Tips for Navigating the Database






To open the database:

- 👉 Double-click the *MTN 025 Participant Tracking Database* shortcut or icon present on the desktop.
- 👉 A security warning will pop up at the top of the form. Click "Enable Content" prior to selecting from the main menu options.



The database is a menu-driven MS Access application. As such, navigation within the database is based on user selections from options on a series of hierarchical menus. The top level menu, which greets users upon entry, is called the *Main Menu*. From the *Main Menu*, users can select from multiple submenus. Some of these submenus have their own submenus, while others have options for data entry forms or reports.

Like in other MS Access applications, navigation among records in the database is accomplished by use of the Navigation Bar at the bottom of each form. The Navigation Bar indicates the number of existing records and offers 5 navigation buttons:

-  takes users to the first record
-  to the previous record
-  to the next record
-  to the last record
-  to a new record

When closing a form within the database, use the 'Close' button rather than the "x" at the top right of the form. It is fairly easy to confuse the "x" on the intended form with the "x" on the Access window, leading to the unintentional closing the entire database.

5. Dummy PTIDs for Initial Testing of Database

Nine dummy PTIDs are available to be entered so that the database may be tested prior to study start. The following dummy PTIDs can be entered along with dummy screening and enrollment dates to experiment with different components of the database.

- 111111111
- 222222222
- 333333333
- 444444444
- 555555555
- 666666666
- 777777777
- 888888888
- 999999999

If sites choose to enter these PTIDs for testing and training purposes, please ensure that these PTIDs and any associated information are deleted prior to study start. Contact the SCHARP Clinical Data Manager for additional guidance.

6. Entering Health Workers

Before any participant-specific information can be entered in the database, some other information must be pre-populated in the database. This pre-populated information – Health Workers – is used by the system to create drop-down lists on the *Participant Information Form* (see Section 7 below).

6.1 Health Workers

If Health Workers are assigned to specific participants at your site, and you wish to keep track or be able to know which workers are assigned to which participants, you may enter the names (or initials) of the Health Worker assigned to each participant in the database. As a first step, you must enter the Health Workers names in the database to create a drop-down list in the *Participant Information Form*.

To enter or update Health Worker information, from the *Data Entry Menu*,

- ☞ Click the Update Health Worker button.
- ☞ Enter the worker's name (full or partial) or initials in the box on the *Health Worker Form*. You can also search for a Health Worker record by clicking on the arrows at the bottom of the form, and edit that information as needed.

Close the *Health Worker Form* by clicking the Close button.

Note: Once a Health Worker has been entered in the database, that person's name should not ever be deleted from the database, even if that worker stops working on MTN 025.

7. Adding and Updating Participant Information

Participant Information should be entered into the database upon initial screening. You will need the participant's study ID number (PTID) provided by the Medidata Rave clinical database to begin entering data. Each participant with a PTID will have a single record in the database. If a participant screen fails or fails to enroll during the allowable window, yet is deemed suitable for further consideration and re-screening, update the appropriate fields (for example, Screening Visit date, Enrollment Visit date for 2nd screening attempt) in the participant's existing records and proceed accordingly.

7.1 Initial Entry of a Participant

To add a new participant, from the *Data Entry Menu*:

- ☞ Click the *Add New Participant* menu button. This opens the *Participant Information Form* in a new record, where you can begin entering a participant's information.

Figure 1: Participant Information Form

The first section of this form records information about the participant. Fields on the form are:


- **PTID** – Enter the participant’s assigned MTN-025 PTID (###-#####).
- **Screening Consent Date** – Entering the “Screening Consent Date” is very important because this date is used by the database to determine the last possible enrollment date allowed for this screening attempt. Always double-check the accuracy of this entry.
- **Enroll by** – This field is automatically generated by the database based on the “Screening Consent Date.”
- **Enrollment Date** – Entering the “Enrollment Date” is very important because this date is used by the database to determine the target date and allowable visit window for each of the protocol-defined follow-up visits. Always double-check the accuracy of this entry.
- **Health Worker 1** – If Health Workers are assigned at your site, select from the drop-down list. Otherwise leave this field blank. If the relevant Health Worker is not on the drop-down list, enter the Health Worker’s name in the database by following the procedure in section 5.2.
- **Health Worker 2** – If two Health Workers are assigned at your site, select from the drop-down list. Otherwise leave this field blank. If the relevant Health Worker is not on the drop-down list, enter the Health Worker’s name in the database by following the procedure described in section 5.2.
- **Participant Status** – Select participant’s current status from drop-down list. The default value is “Screening.” Be sure to update if a participant withdraws consent, is lost to follow-up, or becomes ineligible during the screening process. Mark “Invalid PTID Entry” if a PTID was entered incorrectly or if two entries were created in the database for the same participant. If this occurs, please mark in the

comments box that the entry was created in error. If a participant terminates early at any point during the study, update her status to "Early Termination".

The next section of this form contains (optional) fields to enter a participant's home and/or mobile phone number and checkboxes to indicate whether the participant has given permission for the clinic staff to contact her.

The last section of this form is a Comment field. This field can be used to record relevant administrative or study management information for the participant such as preferred/primary language and Date of Birth. No medical information should be entered in this field.

To add another participant:

 Click the **Add New Participant** button at the top of the *Participant Information Form*.


After entering all participant information, close the *Participant Information Form* to return to the *Data Entry Menu*. All data entered will be automatically saved.

7.2 Updating Participant Information


To update participant information:


 From the *Data Entry Menu*, click the **Update Participant Information** button. This will open the *Participant Information Form*.


To search for the participant whose record you would like to update:

 Click the **Find Participant** button at the top of the form. This opens a *Search Dialog Box*.

By using the "Find What" box, you can search for any entry in any field (e.g., all or part of the PTID, participant name or nick name, street address, etc.). To search *all* fields at once, select "Participant Check-in Form" from the "Look In" drop down box, select "Any Part of Field" from the "Match" drop down box and selecting "All" from the "Search" drop down box.

 Click the "Find Next" button to execute search.

 Once you have located the correct participant's record, edit the Schedule Visit Data, Actual Visit Date or Missed Visit fields as needed.

 Close the *Participant Information Form* to return to the *Data Entry Menu*. All edits will automatically be saved.

8. Generating Participant Follow-up Schedules

The database will generate enrolled participant-specific follow-up visit schedules based on the enrollment date entered on the *Participant Information Form*. The generated follow-up


schedule includes the participant's PTID, her enrollment date, and all of the following for each required follow-up visit:

- target visit date
- visit window start (open) date
- visit window end (close) date
- scheduled visit date
- actual visit date

It is recommended that the schedule for each participant is generated upon enrollment, for use as a tracking tool in each participant's study notebook. Subsequent generations of the schedule, generated after follow-up visits have taken place, will contain data on scheduled and actual visits based on information entered on the *Follow-up Visit Master Log* form (as described in section 9).

 Access the participant's *Participant Information Form* as described in section 6.

 Click on the **Schedule Follow-up Visits** button on the *Participant Information Form*. The *Participant Follow-up Visit Schedule* opens.

 Note that the participant information (including Screening Date and Enrollment Date) cannot be edited in this form. This can only be edited in the Update Participant Information form as described above in section 7.1.

9. Managing Participant Follow-Up Visits

Follow-up visits can be scheduled and managed for only those participants with a completed *Participant Information Form*. In particular, the form's **Enrollment Date** field must be complete.

9.1 Checking Target and Allowable Dates for Follow-Up Visits

To check the target date and allowable visit window for a specific follow-up visit, consult the Participant Follow-up Visit Schedule previously generated for the participant (see section 7.0). Alternately:

 Click the **Schedule Follow-up Visits** button on the *Participant Information Form*. The *Follow-up Visit Master Log* will open.

 Enter the relevant visit month and hit 'Enter' to display the target and allowable dates for that visit.

9.2 Scheduling and Entering Completion of Follow-Up Visits

To record scheduled dates for follow-up visits:

 Click the **Schedule Follow-up Visits** button on either the *Participant Information Form*. The *Follow-up Visit Master Log* will open.

🔍 Locate the desired participant record by clicking on the **Find Participant** button. This will open a *Search Dialog Box*.

You can search by PTID or by participant name. Remember, to search *all* fields at once, select "Participant Check-in Form" from the "Look In" drop down box, select "Any Part of Field" from the "Match" drop down box and selecting "All" from the "Search" drop down box. If searching by full participant ID, be sure to include the dashes.

🔍 Once you have located the correct participant, close the *Search Dialog Box*.

The top part of the *Follow-up Visit Master Log* contains data populated by the *Participant Information Form*. You cannot change any participant information on the *Log* all changes must be made on the *Participant Information Form* (as described in section 6.2).

Figure 2: Follow-up Visit Master Log

The lower portion of the *Follow-up Visit Master Log* contains the *Follow-up Visits Subform*. This subform contains the fields listed below. This subform is tabulated based upon the participant's enrollment date. The information on this subform is duplicated on the follow-up schedule, which can be printed for each participant's binder. The Scheduled Visit Date, Actual Visit Date and Missed Visit fields can updated during the study at any time.

- **Visit Number** – The follow-up visit number starting with V3 (Month 1) will appear in the "Visit Number" box.
- **Target Visit Date** - The target date will appear in the "Target Visit Date" box. This is pre-filled based on the Enrollment date and cannot be changed.
- **Scheduled Visit Date** – The scheduled visit date will be entered in the "Scheduled Visit Date" box. This date is based upon your clinic schedule and the participant,

provided the scheduled visit date falls within the allowable visit window. Enter the scheduled visit date as agreed upon with the participant.

- **Actual Visit Date** – After a visit takes place, enter the actual date of the visit on the Participant Check-in Form or on the Follow-up Visit Master log
- **Missed Visit** – Mark this box if the visit window for a scheduled visit has passed and the participant has been unable to attend her scheduled visit for that month.

 Close the *Follow-up Visit Master Log*. All data will be saved automatically.

10. Generating Reports

To generate database reports, return to the *Main Menu* and click on the **Reports Menu** button. Reports are grouped in four categories:

- Screening & Enrollment Reports
- Scheduled Visit Reports
- Late & Missed Visit Reports

10.1 Screening and Enrollment Reports

 Click on the **Screening & Enrollment Reports** button on the *Reports Menu* to open the *Screening & Enrollment Reports Menu*.

There are six report options available on this menu:

- Participants with Two Weeks Left to Enroll
- Participants with One Week Left to Enroll
- Screening & Enrollment Report (This report shows the number of screened and enrolled participants for the preceding 7 days and cumulatively by month.)
- Screened & Enrolled Participants (This report is a cumulative list of participants that have been screened and enrolled per month.)

10.2 Scheduled Visit Reports


 Click on the **Scheduled Visit Reports** button on the *Reports Menu* to open the *Scheduled Visit Reports Menu*.

There are six report options available on this menu:

- Scheduled Follow-up Visits for Selected Day: This report allows you select a date in order to see follow-up visits that are scheduled for that particular day.
- Scheduled Follow-up Visits Next 2 Weeks
- Scheduled Follow-up Visits 2 Weeks Out
- Scheduled vs. Actual Visits (Monthly) (This report tabulates the number of visits scheduled, the number of visits completed, and a raw participant follow-up rate on a monthly basis.)

- Scheduled vs. Actual Visits (by Health Worker)
- Participant Visits (Requires PTID)

10.3 Late Visit Report

 Click on the **Late Visit Report** button on the *Reports Menu* to open the *Late Visit Report*

There is one report option available on this menu:

- Participants Late for Follow-up Visits (visit window has not yet expired)