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**Introduction: About this Guide**

MiLab Central is an innovative e-platform that streamlines clinical trial tasks and communications between the University of California Los Angeles Laboratory Center teams and Clinical Research Site (CRS, also referred to as ‘site’) and Laboratory Staff. This User Guide covers the use and functionality of MiLab Central modules designed for the purpose of assisting staff in completing key tasks during the clinical trial process. Information and instruction on how to use the features and tools are detailed in each chapter and follow sections as outlined in the Table of Contents.

**Note:** The screen shots for this user guide were created from the Windows Edge or Chrome browser; there may be slight variations based on the browser used.

**CHAPTER 1: MiLab Central General Operation**

**Section 1: Overview of MiLab Central**

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiLab Central is a secure online website customized for use by approved users at network (AIDS Clinical Trials Group [ACTG] and/or International Maternal Pediatric Adolescent AIDS Clinical Trials [IMPAACT] sites and affiliated or contracted laboratories to easily manage laboratory requirements for participation in network studies.</td>
</tr>
</tbody>
</table>

All actions in MiLab Central are recorded in the background. While this website is considered secure it is not the official repository for study data.

**Section 2: Accessing MiLab Central**

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The MiLab Central website requires:</td>
</tr>
<tr>
<td>● An internet connection</td>
</tr>
<tr>
<td>● A MiLab Central username/password</td>
</tr>
</tbody>
</table>

**NOTE:** An account, approved by the Network Laboratory Center (LC) must be created for each person at the site and/or lab who needs access to the tools and information on MiLab Central. (Refer to Section 3 for User Accounts Information)

Any of the URL’s (address of the website) listed below can be used to access MiLab Central:

- [www.milabcentral.org](http://www.milabcentral.org)
- [www.milabcentral.com](http://www.milabcentral.com)

**Tip:** Add the MiLab Central URL to the internet browser favorites for easy access to the website.

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(See Next Page)
<table>
<thead>
<tr>
<th>Information / Instructions</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>A sign in page shown opens when accessing the MiLab Central website.</td>
<td><img src="image" alt="Sign in" /></td>
</tr>
</tbody>
</table>

MiLab Central supports the following web browsers:

1. **Google Chrome™**
   - Desktop Browser: Chrome 80 minimum
   - Mobile Browser: Chrome 80 minimum on Android 7.x minimum

2. **Microsoft®Edge®**
   - Desktop Browser: Microsoft Edge 44; New Microsoft Edge 80

3. **Apple®Safari®**
   - Desktop Browser: Safari 13.x minimum
   - Mobile Browser: Mobile Safari on iOS 13 minimum

**Warning:** “Back” and “Forward” and the “Refresh” browser tools are not supported; **using them will sign the user out.**

Example from Google Chrome: Do NOT use back and forward arrows

To navigate to the last page or another page:

1. Use either the “←Back” or “[black] arrow” (⇐) in the navigation bar when available OR,
2. Use a function in the navigation bar when no back arrow is present.
3. Click the HOME icon when available (do not click the ‘box arrow’ icon, this will sign the user out of the system.)
### Illustrations

1. **Use MiLab Back Arrow (when available)**
   
   **Warning:** Back and Forward Browser tools are not supported. Using them will log you out.

   ![Back Arrow Icon](image1.png)

   **A5362: Demo CRS 1**
   
   MiPAL Version: 0

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
</tr>
</thead>
</table>

2. **Use Functions in Navigation Bar**

   ![MiLab Central Logo](image2.png)

   - Study Authorization Certificates for Labs
   - Go to Sites
   - Inventory

3. **Use HOME Icon**

   - Caution: Do Not Click the ‘Box Arrow’ icon unless the user wants to exit MiLab Central

   ![HOME Icon](image3.png)

   - Clicking the ‘Home’ icon returns user to home screen

### Information / Instructions

If assistance is needed with any operational or technical issues related to use of the website questions should be directed to the appropriate network email mailbox:

- IMPAACT: impaact.qaqc@fstrf.org
- ACTG: actg.labcenter@fstrf.org

**NOTE:** All MTA related questions should be sent to the network Laboratory Center (LC) contact or MTA Coordinator (MTAC) assigned to the protocol.
Section 3: MiLab Central User Accounts

Section 3.1: Types of User Accounts

### Information / Instructions

Each MiLab Central user must have an account.

Two types of accounts can be established; the enabled functions are associated with the type of account.

- Site User: A study staff person at the site assigned to perform select module tasks (e.g., requesting new Lab User or assigning Reviewer) related to the assigned study and assumes administrative (account management) responsibilities.
- Lab User: Staff at the lab(s) associated with the study (either an affiliated lab or a contracted lab) whose responsibilities include entering or editing data related to each analyte and uploading all required supporting laboratory documents.

**NOTE:** In select cases a User may have both Site and Lab User privileges; this is handled on a case-by-case basis. If needed this should be discussed with the LC.

Users have access to sites and labs assigned to them.

- If a user is assigned to a lab the user has the ability to modify PALs for sites the lab does work for.
- If a user is assigned to a site the user has the ability to create MTAs for that site. All other users assigned to the MTA have to work outside the module for now (e.g., recipient labs).
- Users with site level access have the ability to assign other Users to perform MiPAL review

All user accounts require approval from the LC.

### Section 3.2: Establishing New Site - Creating Initial User for MiLab Central Account

### Information / Instructions

Prior to accessing MiLab Central at least one account for a user associated with the site must be established by the LC.

**NOTE:** If an account for MiLab Central already exists at the site please skip to Section 3.3

Setting up an initial account for a site new to network studies and the MiLab Central system can be done in one of two ways:

- An account can be initiated by the LC. *(Since this is an internal process, this step is outside the scope of this guide and not described other than to say if an account is set up by the LC the site staff is contacted with the information).*
- Site study staff can initiate setting up the initial account by contacting the LC.

To contact the LC to create an account for a Site User at a new site initiate the initial user process detailed below, must be followed.

The applicant must send an email request to the LC using the appropriate network email address:

- IMPAACT: impaact.qaqc@fstrf.org
- ACTG: actg.labcenter@fstrf.org

The mailboxes are defined by user groups and may at times be referred to as ‘Listserv’.
### Information / Instructions

The email request must include:
- Site Name
- Site Number
- First and last name, study role and email address of requestor and any other Site User (known at this time) who requires access to MiLab Central
- Name of Lab(s) to be affiliated with site and Harmonized Identification Number (HID) if available
- First and last name, study role and email address of all Lab Users (known at this time) who require access to MiLab Central

**NOTE:** If a new site will be affiliated with a lab where a Lab User currently have access to MiLab Central there is no need to request user access for that Lab User.

Once the LC approves the request and creates an account, sign in information is sent to the email address provided in the request.

The LC email will contain:
- Link to the website: [www.milabcentral.org](http://www.milabcentral.org) OR [www.milabcentral.com](http://www.milabcentral.com)
- Account username
- Temporary password **NOTE:** Time limits for activating temporary password is in development

### Section 3.3: Obtaining Additional MiLab Central User Accounts

#### Section 3.3.1: Site User Accounts

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>When a new site is set up all user accounts known at that time should be requested as indicated in Section 3.2.</td>
</tr>
<tr>
<td>When additional accounts are needed if at least one Site User has access to MiLab Central additional requests for Site User accounts can be made following the same steps used to establish the initial Site User account and is detailed below.</td>
</tr>
<tr>
<td>The applicant must send an email request to the LC using the appropriate network email address to:</td>
</tr>
<tr>
<td>IMPAACT:  <a href="mailto:impact.qaqc@fstrf.org">impact.qaqc@fstrf.org</a></td>
</tr>
<tr>
<td>ACTG:  <a href="mailto:actg.labcenter@fstrf.org">actg.labcenter@fstrf.org</a></td>
</tr>
<tr>
<td>The email request must include:</td>
</tr>
<tr>
<td>Site Name</td>
</tr>
<tr>
<td>Site Number</td>
</tr>
<tr>
<td>Requestors first and last name</td>
</tr>
<tr>
<td>Requestors email address</td>
</tr>
<tr>
<td>Lab(s) associated with site</td>
</tr>
</tbody>
</table>

Once the LC approves the request and creates an account, sign in information is sent to the email address provided in the request.
### Information / Instructions

The LC email will contain:
- Link to the website: [www.milabcentral.org](http://www.milabcentral.org) OR [www.milabcentral.com](http://www.milabcentral.com)
- Account username
- Temporary password

#### Section 3.3.2: Lab User Accounts

### Information / Instructions

A Site User can request Lab User accounts by emailing the LC (Refer to Section 3.2)

Lab User accounts can also be requested through MiLab Central by any active user account (Site or Lab User) by following the steps below:

1. Click on the “Request New Lab User” at the top right corner of the screen
3. The fields for first name, last name, email, username of the potential new user and associated lab(s) are all required fields.

**NOTES:**
- The requestor creates the ‘user name’. User names must be unique to each user.
- More than one lab check box may be ticked.

Users can only be assigned to a laboratory associated with the site (affiliated or contract laboratory). If the appropriate lab is not listed in the “Request New Lab User” drop down box under “Labs” contact the LC.

Once submitted, the LC will be notified of the new account request via the network mailbox must approve each request before the account becomes activated. Activation of a new user can take up to 2 business days.

Once the LC approves the request and creates an account, sign in information is sent to the email address provided in the request.

The LC email will contain:
- Link to the website: [www.milabcentral.org](http://www.milabcentral.org) OR [www.milabcentral.com](http://www.milabcentral.com)
- Account username
- Temporary password
## Section 4: User Name and Password

### Information / Instructions
A user name will either be assigned by the LC or can be created by the user.

- The name must be a unique user name. NOTE: User name should not be users initials but may be first initial last name (a minimum of 8 letters up to a maximum of 15 letters)
- If a username is entered and is already assigned the system will flag the name if in use. A prompt will automatically appear indicating the user’s name is in use and another username must be entered.

1. Click “Request New Lab User”

2 & 3. “Request New Lab User” Drop Down Box

NOTE: Tick ANY Lab that Applies (may be more than 1)
**Information / Instructions**

Password configuration requirements are that the password must be a minimum length of 8 characters. For added security purposes users are encouraged to use a mixture of upper case and lower-case letters, numbers 1 special character (e.g., ! @ # ?)

**NOTE:** DO NOT use Angle Brackets (< or >)

Passwords are to be changed every 120 days. If past the 120-day period the sign in will fail, a password expired notification will appear and fields to enter a new password will pop-up.

**Illustration**

![Change Password](image)

**Information / Instructions**

Each user should either memorize or write down the username and personal password and store in a secure place, as this information is needed each time a user signs in to the MiLab Central website.

**Reminder:** Keep MiLab Central data secure and confidential; users must NOT share usernames or passwords.

If a password is forgotten email the appropriate LC (impact.qaqc@fstrf.org or actg.labcenter@fstrf.org) to have the password reset. A delay in accessing the MiLab Central website will occur until the password reset request is completed.
Section 5: Signing in to MiLab Central

<table>
<thead>
<tr>
<th>Information / Instructions</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>When accessing the MiLab Central website for the first time enter respectively:</td>
<td></td>
</tr>
<tr>
<td>1. Account username</td>
<td><img src="image1" alt="Illustration" /></td>
</tr>
<tr>
<td>2. Temporary password provided in the email from the network LC</td>
<td></td>
</tr>
<tr>
<td>Once information is entered click “Sign In”.</td>
<td></td>
</tr>
<tr>
<td>Once signed in the user’s name will appear in the upper right-hand corner of the navigation bar.</td>
<td><img src="image2" alt="Illustration" /></td>
</tr>
</tbody>
</table>

Section 6:Exiting MiLab Central

<table>
<thead>
<tr>
<th>Information / Instructions</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once signed in to the website please DO NOT leave the computer unattended.</td>
<td><img src="image3" alt="Illustration" /></td>
</tr>
<tr>
<td>To keep trial information secure it is important to exit the MiLab Central website when not in use. Simply closing the browser will close the website and exit the user from the session.</td>
<td></td>
</tr>
<tr>
<td>If the website is left idle for &gt; 1 hour the session will expire. A session expired alert may appear; in this case to sign back in “Click here” to continue and return to the sign-in page. It also may be that the user’s connection to MiLab gets lost during the idle period and disconnects; if this occurs the user should simply sign back in to the system in the usual manner</td>
<td><img src="image4" alt="Illustration" /></td>
</tr>
</tbody>
</table>
Section 7: Deactivating Accounts

Information / Instructions
If any site or lab users leave the facility or no longer working on any applicable protocols an email should be sent to appropriate network mailbox requesting the users account be deactivated:

- IMPAACT: impaact.qaqc@fstrf.org
- ACTG: actg.labcenter@fstrf.org

The deactivation is a LC function and cannot be performed by a site or lab user

NOTE: Parameters for account inactivity (e.g., time limit on temporary password, inactive account reminders/auto-expiration) are in development.

Section 8: Website Address and Assistance

Information / Instructions
MiLab Central website addresses:
- www.milabcentral.org
- www.milabcentral.com

Information / Instructions
For any assistance needed with username or password or the MiLab Central system beyond what is contained in this reference guide please contact the appropriate network email mailbox:

- IMPAACT: impaact.qaqc@fstrf.org
- ACTG: actg.labcenter@fstrf.org

REMININDER: All protocol and PAL related questions should be sent to the network LC contact assigned to the protocol.

CHAPTER 2: MiMTA Module
Section 1: Overview of MiMTA

Information / Instructions
This chapter covers the operation and functionality of the Material Transfer Agreement (MTA) module within the MiLab Central (referred to as MiMTA) electronic system for Clinical Research Site (CRS) staff with a Site User account.

NOTE: Illustrations are taken form a test file

The MTA may be needed when AIDS Clinical Trials Group (ACTG) and International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) sites need to ship specimens to a study designated laboratory (lab) for testing.
### Information / Instructions

The MTA is an agreement between the provider institution/scientist (referred to herein as the “Provider”) at the CRS and recipient destination testing lab institution/scientist within or outside the US (referred to herein as the “Recipient”) at a biorepository or testing laboratory for purposes of clinical trial specimen transfer; also known as Specimen Transfer Agreement (STA).

The main features of MiMTA addressed in this chapter pertain to completion of tasks related to the submission, review, execution and archiving of MTAs.

- Accessing the MiMTA module
- Creating the draft MTA
- Submission of the draft MTA
- Laboratory Specialist review of the MTA
- Recipient Review of the MTA
- CRS final MTA signatures
- Return of MTA
- Archiving

The MTA process should commence with preparation of study submission to the Independent Ethics Committee (IEC) or Institutional Review Board (IRB).

MTA completion dates may vary; however, specimens cannot ship without the MTA fully executed (FE). It is preferred that the MTA is completed prior to site study activation. For sites with ‘real time’ testing/shipping requirements, it is required to have the MTA fully executed before site activation. Shipping timeframes are specified in the protocol (LPC). If the LPC indicates “When instructed”, the due date will be set by the study team members.

In select cases where there is a time limit on specimen storage, study team members will determine a target date for MTA completion.

All MTA related questions should be sent to the Laboratory Specialist (LS) or MTA Coordinator (MTAC) assigned to the study.

<table>
<thead>
<tr>
<th><strong>Section 2: Accessing MiMTA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information / Instructions</strong></td>
</tr>
<tr>
<td>Sign in to MiLab Central using the approved username and password (Refer to Chapter 1)</td>
</tr>
<tr>
<td><strong>Note:</strong> The image below may vary slightly; functions in the navigation bar will change dependent upon the user’s role/access.</td>
</tr>
<tr>
<td><strong>This Space Intentionally Left Blank</strong></td>
</tr>
<tr>
<td>(See Next Page)</td>
</tr>
</tbody>
</table>
Click on "MiMTAs" located in the top navigation bar under the MiLab Central logo. This will direct the user to the MiMTA module.

Once MTA is clicked the user is directed to the MiMTA home page. There is a section for 'Studies and Sites'; for listing status of 'MTAs for <a specific study/site>' and a 'Submission in Progress' section which lists MTAs in progress (prior to full execution).
Section 3: Creating the Draft MTA

**Information / Instructions**

Appropriate clinical research site (CRS) staff or legal representative at each “Provider” generates a draft MTA. Blanket MTAs are not acceptable; the MTA must specify a study and the associated CRS.

The draft is created using a template specific to the site and should reflect the associated institutions legal requirements and local/country’s regulations.

If a site template is not available generic templates may be requested from the Laboratory Center (LC) or downloaded from the module. The CRS staff is responsible for customizing the template to conform with local regulations. There are 2 files; the correct template should be downloaded and extracted from the sample file:

1. South Africa File – 2 template examples
2. Simple Letter – 2 template examples

To access MTA templates, click on “Download MTA Template” in the second status bar. This will result in a pop-up with sample templates. The templates are ‘Word’ documents so customization and edits may be made in preparing the site specific MTA.

**Illustration**

![Illustration of MTA process](image)
**Information / Instructions**

A listing of available templates is displayed.

- Click the “Download” button for the desired template.
- An “Export Field to File” dialog box will appear and the file name of the document to be downloaded will be displayed as “Save as:”
- If the File name displays the correct name document click “OK”.
- If incorrect click “Cancel”.

**Illustration**

File Name of Document Generated Once the Download Button is Clicked
**Information / Instructions**

Once ‘Okay’ is clicked a “Download Files” dialog box will appear. To open the download file pop-up window click the file name button.

**Illustration**

Click to Open Download File Pop-Up Window

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(See Next Page)
Information / Instructions
Once clicked the download button will be grayed out. A download function pop-up box will appear; click 'Open file' to save the template to the users files.
To clear the dialog box click “Close”.

Illustration

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(See Next Page)
**Information / Instructions**

If an ACTG site has not previously used an MTA for the ACTG Network, or makes significant revisions the MTA should be discussed with the LC contact prior to submission.

The agreement must detail all specimens being sent per the protocol’s Laboratory Processing Chart (LPC). The LPC provides guidance for the specimen types, collection, processing, shipping frequency and recipient (destination) lab including address and contact information.

**Information / Instructions**

The CRS staff uses the LPC to describe the specimen type(s) and quantities either within the MTA itself OR in an Annexure (separate document that accompanies the MTA and becomes part of the MTA once the MTA is FE).

The MTA template specifies the required signatures for responsible parties for the Provider and Recipient. Signatories may be a Principal Scientist, Principal Investigator (PI), Legal Representative or another Authorized Official.

There may be a pass-through lab (e.g., the Biomedical Research Institute [BRI] or the Bioanalytical Research Corporation South Africa [BARC SA]) associated with specimens on their way to a testing laboratory. If that is the case the MTA is reviewed and signed by the pass-through lab.

**Section 4: Accessing MiMTA Module**

**Information / Instructions**

After clicking on "MiMTAs" located in the top navigation bar the next screen displayed will be a listing of every study/site combination to which the user account has access.

1. Within the listing the status of MTAs in progress (pending) and the number of MTAs fully executed out of those expected is displayed.
2. Once MTAs are created, they appear to the right of the listing. If none are completed to date the information will be displayed in **Red** font.

**Illustration**

![MTAs for 0000 | 10](image)

<table>
<thead>
<tr>
<th>Studies and Sites</th>
<th>MTAs for 0000</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No MTAs have been created for this site/study combination yet</strong></td>
<td><img src="image" alt="Image" /></td>
<td>1</td>
</tr>
</tbody>
</table>

0 FE MTAs of unknown MTAs Expected

**1** Add MTA

**2**
Section 5: Selecting Study and Site

Information / Instructions
The next screen displayed will be a listing of every study and site combination to which the user account has access. Each MTA must be associated with a specific study and a site. Multiple MTAs for the same study/site combination are required if there are multiple recipient (destination) labs as signing requirements for each recipient lab are unique.

Refer to study lab processing chart when determining the number of MTAs needed.

The “Add MTA” function will always remain visible even if the number of expected MTAs are fully executed as the “Add MTA” function is used if an MTA amendment to an existing MTA is needed.

Search for the desired Study and/or Site can be performed in several ways:
1. Scroll through the study/site list; OR
2. Use the ‘Study’ search field; OR
3. Use ‘Site’ search field

**NOTE:** The drop-down lists contain only information assigned to the user’s account. If the study site is missing, the Site User should contact the LC.

1. Scroll List:
Using the scroll bar highlight the desired study/site. The MTA information for the selected study/site will display in the right-hand column on the screen.

Illustration

![Illustration](image-url)
### Information / Instructions

2. **Search Study:**
   a). Click on the Study drop-down arrow to open the list of studies associated with the user account. Click on the desired study, OR
   b). In the free text gray field begin to type study number and click the search button \[ \text{ } \] to narrow the list, then click the appropriate study from the list.

### Illustration

#### Click the Desired Study Number from the Drop-Down Menu

#### Free Text Field Opens for Type & Search

### Information / Instructions

3. **Search Site:**
The correct site can be located in the ‘Site’ drop-down arrow to display the drop-down menu; the site must be associated with a study. One or multiple sites may be listed. Click on the appropriate site selection. The selected site will highlight in blue; when clicked the selected site will populate in the gray search field.

Once fields are populated, the associated MTA status will be displayed in light blue highlight.

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(See Next Page)
Section 6: Reviewing the Selected MTA Listing

Information / Instructions

Once selections are complete, the MTA status associated with the Study/Site will appear below and in the column to the right of the Study and Sites listing.

1. Within the listing the status of MTAs in progress (pending) and the number of MTAs fully executed out of those expected is displayed. Requirements for the MTA are most often established by CRS based upon local requirements. If a MTA is not required this will be displayed as “0 MTAs of 0 MTAs expected”.

Note: The test file (below) lists expected as ‘unknown’; actual sites will have expected number entered by the LC.
2. Once MTAs are created, they appear to the right of the listing. If none are completed to date the information will be displayed in **Red** font and a statement under the MTAs for <Study No./ Site No.> bar indicating “No MTAs have been created for this site/study combination yet”.

**Illustration**

**Information / Instructions**

Where a MTA has already been submitted and is currently on file all relevant information will be displayed:

1. Name of the Start Lab, Pass Through (if applicable), Destination Lab(s), Review or Approval Status including date.
2. Under “Status” Fully Executed MTA will be indicated and receipt by LC Network and the MTA team documented.

**Illustration**
Section 7: Adding the MTA
Section 7.1: Add MTA Screen - Items 1-7

Information / Instructions – Item #1
If a new MTA is needed, identify the ‘Study’ and ‘Site’ and populate in the Study and Site fields (as described in Section 5)
Click "Add MTA" function.

<table>
<thead>
<tr>
<th>Studies and Sites</th>
<th>MTAs for A5345</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study A5345</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 12001 Example Site 5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add MTA

0 MTAs in progress
0 FE MTAs of unknown MTAs Expected

Information / Instructions – Item #1
The user will be navigated to the “Add MTA screen”. This is a list of 7 items to be reviewed and responses entered.
At the top of the “Add MTA screen” the study site number and name and the study [protocol] number will be displayed.
A prompt indicates if the site or study listed is incorrect the MTA creation should be cancelled (click cancel function at the bottom of the screen; this will return the user to the previous screen.
Once the study and site are verified the remaining fields should be reviewed. Items 2, 4, 5 & 6 are required fields and marked with an asterik (*).

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(See Next Page)
Click Cancel if Site or Study is Incorrect to Return to Previous Screen
**Information / Instructions – Item #2**

Proceed to item #2 “Choose a starting point”. Using the drop down menu locate the Start Lab (lab associated with the study site) and click to populate the field.

**Illustrations**

1. **Choose a Start Lab**
   - From where will the materials originate? (Click to select)

2. **Correct Lab**
   - From the Drop-Down Menu

**Information / Instructions – Item #2 (continued)**

If the Start Lab is not listed click “Where is my lab” (in blue italicized font).

Write a query in the ‘Request’ field and click send so the lab can be added. An email will be sent to all MTACs and LC leadership. The email will have a reply feature so the sender can be notified when the lab is added or if further information is needed; the email will indicate it’s from MiLab.

**Illustration**

Click Red X to Cancel Selection if Lab Selected in Error

Click the Correct Lab From the Drop-Down Menu

If you cannot find the lab you are looking for please send us a query below so we can fix the issue

Request

Send
The sender will see a dialog box indicating either email sent or failed to send. Click “OK” to close the dialog box.

The email will have a reply feature so the sender can be notified when the lab is added or if further information is needed; the email will indicate it’s from MiLab.
Information / Instructions – Item #3

Proceed to Item #3, “Choose a Pass Through (only if required!)”. Protocol requirements and/or local practices determine if a pass through lab is required.

If a Pass Through Lab is not to be used, skip to Item #4

If a Pass Through Lab is to be used, click the “Yes” function.

Illustration

[Image of a screenshot from MiLab Central showing the selection of a pass through lab]

Information / Instructions

A second verification is required. A dialog box asking for confirmation that a pass-through lab is for this MTA appears.

If ‘yes’ is selected in error click “No”; the screen will return to items 1-7 and the user should proceed to Item #4.
Information / Instructions – Item #3 (continued)

If the “Yes” function is clicked the user is returned the ‘Add MTA’ items 1-7 and the statement “Is a Pass-Through Lab required for this MTA?” replaced by a data entry field with a drop-down menu arrow.

The arrow is clicked and the correct pass-through lab selected from the drop-down menu. If the pass-through lab is incorrect or not needed; click the cancel function.

Illustrations

Information / Instructions – Item #4

Proceed to Item #4, “Choose a Destination” (Recipient Lab). Click on the down arrow at the end of the text filed for the question “Where will the specimens be shipped?”
Information / Instructions – Item #4 (continued)

When clicked a drop-down menu with fields for “Search Name” and “Search Reason” opens.

The Destination Lab (Recipient Lab) can be selected using either the “Search Name” or Search Region” option.

To use the “Search Name” option:

1. Review all labs listed by scrolling through the list and clicking on the correct lab name or number (where indicated), OR,

2. Type the lab name or partial name and click the search icon (magnifying glass). Any lab resembling the typed entry will appear in a list. Click on the correct lab; the lab will populate in the “Choose a Destination” box.

**NOTE:** Labs are listed alphabetically and include the LDMS # (Laboratory Data Management System) and HID # (Harmonized ID, the ID all networks agree upon for the lab), where applicable, associated with the lab. Numbers can be used to search and will be displayed in the text filed when selected. Some labs may not have a number.

Illustrations
Information / Instructions – Item #4 (continued)
If the destination is selected in error, to cancel click the **Red “X”**; the text field will revert to a blank gray field.

Illustrations

4. Choose a Destination Lab*
Where will specimens be shipped? (Click to select, Number = LDMS #)

![Dropdown menu example]

NOTE: To cancel the “Search Region” list click the **Red X**.

Illustrations

4. Choose a Destination Lab*
Where will specimens be shipped? (Click to select, Number = LDMS #)

![Search region example]
Information / Instructions

If the destination lab is not listed in the drop down menu click on “Where is my lab” and write a query in the Destination Lab Request Query dialog box for assistance. **(a)**

If ‘Send’ is clicked before a query is entered an alert dialog box will appear. Click ‘OK’ to close the alert. **(b)**

Click ‘Send’ once the message is complete in the Destination Lab Request Query box. **(c)**

A dialog box indicating the email was sent will appear; click “OK” to acknowledge and return to ‘Add MTA’ screen items list. **(d)**

The email will have a reply feature so the query sender can be notified when the lab is added or if further information is needed. The email will indicate its from MiLab.

Illustrations
Next is the question “Who else in your organization would you like to receive notification emails”.

The gray text field is where email addresses are listed for any persons at the site who should receive emails about the MTA (e.g., legal department reviewer). All addresses listed will be copied on all communications back and forth between the clinical research site (CRS) staff, LC and MTAC.

Instructions noted under the question are to be followed when typing the email addresses (separate email addresses by a comma [ , ] or the start of a new section/line [ create by hitting ‘enter’ to create a paragraph return ]).
1. Site: 12001: Example Site 5

Study: A5345
(If the listed site or study is incorrect, please cancel this MTA creation)

2. Choose a Start Lab*
From where will the materials originate? (Click to select) *Where is my lab?

HID0257/HID0009 - Example Lab 2 - 410

3. Choose a Pass Through (only if required!)

BRI - 996 and 999 *Where is my lab?

4. Choose a Destination Lab*
Where will specimens be shipped? (Click to select, Number = LDMS #) *Where is my lab?

Quest - 33

5. Who else in your organization would you like to receive notification emails?*
(separate email addresses with a comma or a paragraph return)

jsmith@univ.edu, scarr@aol.com
kbell@gmail.com

5. Who else in your organization would you like to receive notification emails?*
(separate email addresses with a comma or a paragraph return)
Section 7.2: Uploading the MTA

Information / Instructions – Item #6

The CRS prepared MTA must be uploaded to the MiMTA module. The draft MTA should be considered the final draft ready for review by the LC.

The user will click on the “Upload MTA” function with the upload icon

An “Insert” dialog box with a “Choose File” function will appear.

Illustration

To complete the upload:

1. Click the “Choose File” function
2. The user will be directed to local files (laptop/computer) where the user can browse for the MTA.
3. Once the MTA is located, click on the correct MTA file name (document highlights in blue)
4. Click “Open”.
5. The file name will appear in the Insert dialog box in place of ‘No file chosen’
6. Click Upload
7. The Insert’ dialog box will disappear and the user will be returned to the ‘Add MTA’ screen items list 1-7. The file name of the MTA uploaded from the computer/laptop files will appear in Item #6 under the “Upload MTA” function.
8. If the incorrect MTA is uploaded, clicking the Red X will cancel the upload. Once cancelled, the user should repeat the upload process to locate the correct document and upload.

This Space Intentionally Left Blank
(See Next Page)
Illustrations

1. Choose File

2. & 3.

4. Open

5. Choose File: Test MTA.docx

6. Cancel

7. Test MTA.docx

8. Cancel

This Space Intentionally Left Blank
(See Next Page)
**Information / Instructions**

The MTA is required. If the document is removed or is not uploaded the MTA submission will not succeed. There are dialog boxes that will appear to ensure the MTA is uploaded.

**Illustrations**

- **Reminder if MTA removed to upload prior to submission**
  - Illustration of a message box asking if the user is sure they want to remove the MTA document. The message states that they will not be able to submit the MTA without a document attached.

- **Error occurs if ‘Submit’ button is clicked without an MTA**
  - Illustration of an error message box appearing if the ‘Submit’ button is clicked without an MTA document uploaded.
Information / Instructions

Once the MTA is uploaded any additional documents can be uploaded, for example, an annexure (a supplement or appendix to the MTA). The same steps used for “Upload MTA” are used to “Add Document” (Click “Add Document”, Locate File, Click Open, Click Upload).

Illustrations

Information / Instructions

Once the additional document is uploaded the “Document Type” must be selected. Click the drop down arrow to open the menu. Highlight the correct selection; the document type will populate in the gray text field. When uploading an additional document if the document type is not listed in the drop down menu, select “Other” and enter the type document in the gray free text field.
Illustrations

7. Upload Additional Documents

- Add Document

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Appendix 1.docx</th>
</tr>
</thead>
</table>

6. Upload the MTA

- Upload MTA

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Test MTA.docx</th>
</tr>
</thead>
</table>

7. Upload Additional Documents

- Add Document

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Appendix 1.docx</th>
</tr>
</thead>
</table>

- Add Document

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Certificate.docx</th>
</tr>
</thead>
</table>

- Add Document

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Certificate for Use</th>
</tr>
</thead>
</table>
**Information / Instructions**

Additional documents may be uploaded if needed. Initially, only one additional row is visible, however, if “Add Document” is clicked and a file is uploaded then additional rows will be added as needed and can be viewed by dragging the scroll bar.

**Illustrations**

### 7. Upload Additional Documents

<table>
<thead>
<tr>
<th>Add Document</th>
<th>Document Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix 1.docx</td>
<td>Annexure</td>
</tr>
<tr>
<td>Appendix 2.docx</td>
<td>Annexure</td>
</tr>
</tbody>
</table>

If a document is uploaded in error, click the **Red X**. A “Remove Document?” query dialog box will appear as a prompt to ensure the user intends to remove the document. There is also a reminder that if the document is deleted in error the document will need to be added again to be included with the submission. Click “Yes” to confirm removal or “No” to disregard the removal.
Section 7.3: MTA Submission

**Information / Instructions**
When “Add MTA” screen items 1-7 are completed review all entries. If all information is correct click the blue “Submit” button. If errors are noted return to the item in question and correct (edit applicable fields).

**NOTE:** DO NOT click cancel (red button) to correct a single entry or the entire MTA submission for all entry items will be deleted and the user returned to the main screen. **Click cancel only if the entire submission should be discarded.**

**Illustration**

Click “Submit” Once All Entries Are Verified as Correct

Cancel voids entire submission and all data entered
NEW FEATURES (JUST ADDED)

Information / Instructions

Ideally items #1-7 are completed in 1 session.

- If the user is unable to complete all fields in one session (e.g., due to an interruption or additional information or documents are needed) the “Save & Exit” button can be used to preserve data entered pending completion of all items 1-7.
- There is also a “Save & Exit” button to be used when confirming submission if the user discovers edits are still needed.
**Information / Instructions**

After clicking “Submit” three scenarios can occur.

1. A required field in “Add MTA” screen (Items 1-7) is missing information (e.g., MTA upload).
   
   An “Error” dialog box indicating the missing information will appear.
   
   Click “OK” to close the dialog box; correct the error as appropriate for items 1-7.

2. If incorrect information is noted in items 1-7 click “Back” and return to the prior screen to make any needed corrections.

3. If entries are verified and documents uploaded are correct click “Confirm”.

**Illustration**

Sample “Error” Dialog Box when Attempting to Submit without Uploading MTA
Click “Confirm” if All Entries are Correct

Click “Back” to Return to Prior Screen to Make Corrections

Illustration
Information / Instructions
Once the confirmation screen is confirmed, a dialog box titled “Confirm MTA Submission” will appear asking for re-confirmation.

- Click “Yes” to finalize the submission. A dialog box thanking the user for the submission will appear.
- If not correct click “No”, click the back function on the screen and make necessary corrections.

Illustration

Click “Yes” For Final Confirmation

If Incorrect Click “No” in the Dialog Box and then “Back” to Return to Previous Screen to Make Corrections
Information / Instructions

Once the MTA submission is confirmed the user will be reverted back to the MiMTA home screen. The newly created MTA submission will now appear on the study/site listing. The current status for any study/site combination can be viewed by clicking on the study/site (will highlight in blue); the MTA status details will be displayed in the column to the right of the list.

The status will change from “No MTAs have been created for this study/site combination” to “New MTA for Review” when the initial submission is made. The details re: lab name; any passthrough lab, the destination lab and the date the status became effective.
Information / Instructions

Once an MTA is submitted the submission status is listed under ‘Submissions In Progress’. There is an ‘Edit/Review’ button for each MTA listed. The button will return the User to Items 1-7 for edits.

Illustration

After clicking ‘Edit/Review’ the User can make the necessary edits to Items #1-7 by clicking the buttons positioned after Item #7

- Submit;
- Save and Exit
- Cancel (e.g., edit button was clicked in error or no changes required after review).
**Information / Instructions**
Where there are multiples MTAs and/or revisions and amendments all the MTAs will be displayed; the most recent (current) listing is listed last.

**Illustration**

---

**Section 8: Post MiMTA Submission**

**NOTE:** All steps in Section 8 occur outside of the MiMTA Module

**Section 8.1: MTA Reviews and Revisions**

**Information / Instructions**
As soon as the new MTA is submitted the Site User, MTA team at the LC (LS and MTAC), and any other users added to the submission ("Add MTA" screen Item #5) will be emailed with a notification the MTA was uploaded.

The MTAC replies to the Site User who submitted the draft MTA by email and indicates the submission has now progressed to the LS for review. All MTA related email communications will use the following subject line: "<study # MTA>_ <site number, name> to <destination name>.

The LS from the LC assigned to the study reviews the MTA to ensure alignment with the protocol; several rounds of revisions may be required. If content corrections are needed the LS will reply to the Site User using the submission email and provides either comments in the body of the email or a tracked change draft, indicating any needed corrections.

**NOTE:** The LC does NOT conduct a legal review of the document.
The MTAC works with the clinical research site (CRS) staff until all issues are resolved to the satisfaction of all parties and the agreement is finalized.

The LS and MTAC work closely together coordinating and facilitating the MTA process.

**NOTE:** MTAs for NICHD CRSs on IMPAACT studies are handled by Westat (a private company providing clinical trials support services including laboratory)

The Recipient involvement begins once the initial draft MTA is reviewed by the LC. The recipient should not be copied on any correspondence until this occurs.

### Section 8.2: MTA Final Signatures

**Information / Instructions**

The required CRS and Recipient signatures are designated on the template and specified either by name and title or title only (e.g., Provider or Recipient Scientist or Authorized Official). The CRS always signs the MTA last.

**NOTE:** The LC does not sign the MTA.

Wet signature versus electronic signature requirements is determined by each country (e.g., Zimbabwe requires wet signature). The MTAC should confirm the type of signature requirements with the CRS.

Once the MTA is signed by the Recipient, the Recipient sends the partially executed MTA, through either the ACTG (actgmta@fstrf.org) or IMPAACT (impaactmta@fstrf.org) listserv. The MTAC reviews the MTA to ensure Recipient signatures are correct, dated and witnessed.

Next, the MTAC emails the partially executed MTA (signed/witnessed by the Recipient) to the CRS.

The CRS obtains all necessary dated signatures (authorization and witness) and sends the MTA back to the MTAC.

The MTAC reviews the MTA to ensure CRS signatures are correct, witnessed and dated.

The MTAC sends a completion email with the fully signed MTA to the CRS (all designated email accounts identified for the organization), Recipient, LC and LS.

The MTAC updates current status to “Fully Executed MTA Received by Network MTA Team” The agreement will commence on the date of the last signature (the “effective date”) and this is the date used for the “Current Status Date”.

**NOTE:** It is the Provider/Recipients responsibility to ensure the MTA is FE prior to shipping/receiving specimens.

The MTA file name is revised according to the standard ACTG/IMPAACT LC naming convention (<Study Number>_<Site Number>_Destination Name_ _ddmmmyyyy) and archived in the MiMTA module along with a copy of the email. The final MTA can be downloaded by the CRS for archiving.
ONLY the current version of the MTA is available through the module. Originators should maintain a working file of all versions. If a prior version is needed (e.g., for historical information or in the case of a regulatory inspection) and not available an archived version can be requested from the LC. There is an information prompt reminding the account user.

**Section 9: MiMTA Status Updates**

### Information / Instructions

With each subsequent step in the review and approval process the status is updated by the MTAC. The following status updates correspond to emails sent to the clinical research site (CRS) at these time points:

- Submitted/Under Review (new MTA)
- Sent to CRS for Corrections
- CRS Returned Corrections
- Sent to Recipient for Review and Signature
- Sent to CRS for signature
- Fully Executed MTA Received by Network MTA Team

**NOTE:** There will be additional email communications related to the MTA that occur in addition to those listed above. All MTA related correspondence will be retained by the LC in the internal component of the MiMTA module. Any MTA related site correspondence that is generated outside of the MiMTA module should be retained in the site files.
Illustration

Information / Instructions

Once all signatures are complete and verified the MTAC updates the status to “Fully Executed MTA Received by Network MTA Team”.

**NOTE:** The agreement will commence on the date of the last signature (the “effective date”) and this is the date used for the “Current Status Date”.

Illustration

Information / Instructions

There may be a circumstance where a MTA is not required; this would be reflected in the status as “0 FE MTAs of 0 MTAs Expected”.

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### Section 10: Downloading MTAs

#### Information / Instructions

All FE MTAs are archived in the MiMTA module.

The MTA file name is revised according to the standard ACTG/IMPAACT LC naming convention (\(<\text{Study Number}>\_<\text{Site Number}>\_<\text{Destination Name}>\_\text{ddmmyyyy}\))

The final MTA can be downloaded if necessary. To download a file, click on the download icon.

**NOTE:** The current version only will display for each MTA and can be downloaded. If a prior version is needed and was not retained on site as recommended, an email should be sent to the MTAC requesting an archived version.

#### Illustration

<table>
<thead>
<tr>
<th>MTAs for A5345</th>
<th>12001</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start: HID0257/HID0009 - Example Lab 2 - 410</td>
<td>New MTA for Review</td>
<td></td>
</tr>
<tr>
<td>Pass Through: BRI - 996 and 999</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Destination(s): Quest - 33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Status: New MTA for Review - 9/23/2021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Information / Instructions

A “Download Files” dialog box will display. The button displaying the file name is clicked. If the document is not the desired document simply click close to return to the prior page.

**This Space Intentionally Left Blank**

(See Next Page)
The selected file will appear (usually in the lower left-hand corner). Click the "Up" arrow; a pop-up box appears, click open to view the document. Once opened the document can be downloaded and saved to user files and/or printed.

Click up Arrow to Open Pop-Up Box
CHAPTER 3: MiPAL Module

Section 1: Overview of MiPAL

Information / Instructions

The MiPAL module includes network study(ies) laboratory related functions for Clinical Research Site (CRS) and associated laboratory (lab) staff.

The main features of MiPAL include:
- Management of study specific electronic Protocol Analyte Lists (MiPALs)
- Management of required lab supporting documents (including printing of Laboratory Approval Certificates)

NOTE: Management of Instrument Inventories, Management of Validation Documentation and Management of Laboratory Supplies are under development

Operations in the MiPAL module are conducted by various user accounts approved by the relevant network Laboratory Center (LC) (Refer to Chapter 1).

Multiple site labs may be utilized to meet all of the testing requirements of a study. A User from each associated laboratory may need to be assigned as a Lab User to work on the MiPAL module.
Section 2: MiLab Central Site User Account

Section 2.1: Site User Account Features

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Site User panel of tools and features includes the following:</td>
</tr>
<tr>
<td>● Request New Lab Users</td>
</tr>
<tr>
<td>● View available and pending MiPALs for the network site’s participating studies</td>
</tr>
<tr>
<td>● Assign a MiPALs reviewer through the MiLab Central website to complete, review and submit each MiPAL to the LC</td>
</tr>
<tr>
<td>● Navigate between affiliated sites.</td>
</tr>
</tbody>
</table>

A Site User can also be assigned as a Lab User pending approval by the LC. Upon approval, the Site User can assign self as a Lab User for a specific lab if it is necessary for the Site User to gain access to that lab’s information and perform MiPAL lab functions.

Section 2.2: Navigating the Site User Page

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The functions that appear on the Site User page include:</td>
</tr>
<tr>
<td>1. Affiliated Sites: Allows the user to see the list of affiliated labs, MiPAL reviewers and available MiPALs for each site. When a site is selected (clicked) the site will highlight in blue and the screen will display all the corresponding information for that site.</td>
</tr>
<tr>
<td>2. Affiliated Labs: The list of labs associated with the site are loaded in the website by the LC and displayed when clicking on each affiliated site.</td>
</tr>
</tbody>
</table>
| 3. Add/Remove User Account: Allows Site User to assign self as a Lab User for each listed lab. The user with dual roles will be able to use a single sign-on once LC approval is granted.  
  3a). The information icon when clicked reminds the user the functions will grant or remove access to the affiliated lab and the documents inventory (once activated) and MiPALs associated with the lab. |
| 4. Choose Default MiPAL Reviewer: The User selected by the Site User to perform the final MiPAL review and submission to the LC when a specific Reviewer is not assigned. (Refer to Section 4.4)  
  4a) The information icon, when clicked, reminds the User the selected default review will be assigned to all New MiPALs |
| 5. Available MiPALs: Web-based list of study specific analytes based upon study protocol (Refer to Section 4.3) |
| 6. Filter by Study: Allows user to select available MiPALs by study using the drop-down list. |

NOTE: To remove the selected lab click the Red X (X)
**Information / Instructions**

7. **Reviewer:** Select reviewer from the drop-down list. The Reviewer performs final MiPAL review and submission to the LC (Refer to Section 4.4)

8. **Load:** Function that takes user to the list of analytes (Refer to Section 4.3)

9. **Go to Labs:** Takes Site User to the Lab User section of the module **ONLY** if Site User also has Lab User access (Refer to Section 5)

10. **Request New Lab User:** On-line method for requesting a new or additional Lab User (Refer to Section 3.3.2)

11. **“Logged in as”:** Location where user name for person signed in is displayed

---

**Illustration (1-11)**

- **1 Affiliated Sites**
- **2 Add/Remove User Account**
- **3 Available MiPALS**
- **4 Choose Default MiPAL Reviewer**
- **5 Filter by Study**
- **6 Load**
- **7 Lab Center Help**
- **8 Request New Lab User**
- **9 Go to Labs**
- **10 Logged in as**
- **11 Go to Labs**

---

**Illustration (3a/4a)**

- **3a Add/Remove User Account**
- **4a Choose Default MiPAL Reviewer**

---
Section 2.3: Assignment of MiPAL Reviewer

Information / Instructions

Once all MiPAL information has been completed, the data must be thoroughly reviewed by one additional Lab/Site User prior to submission to the LC and DAIDS Clinical Laboratory Team (DCLOT) for approval.

The MiPAL data review MUST be performed by a Lab/Site User different than the user who entered majority of the MiPAL data.

The Site User will determine which User is most appropriate to function as the MiPAL Reviewer and submit to the LC.

A list of Reviewers is automatically generated from all Lab/Site Users at site affiliated labs.

A Reviewer is assigned from the “Choose Default MiPAL Reviewer” drop down list.

Illustrations

XXXACTG Example Site#1

Choose Desired Lab from Drop-Down Menu
Information / Instructions

Setting a “Default MiPAL Reviewer” is optional. If selected, moving forward the Default Reviewer will automatically be assigned when a new MiPAL is available in MiLab Central.

The Site User has the option to change the Reviewer to another user (e.g., a Reviewer with specific MiPAL expertise or default reviewer is on vacation and another temporary reviewer is needed), by clicking on the dropdown list and selecting the person that will be responsible for final review and submission to the network LC.

A MiPAL Reviewer will be notified via an automatically generated email once they have been assigned to a MiPAL.
Section 2.4: Viewing the Protocol Analyte Lists (MiPALs)

**Information / Instructions**

The MiPALs for all new network studies will be completed and submitted through MiLab Central.

**NOTE:** Microsoft® Excel spreadsheets are no longer used for this purpose.

The Site User can view all available and pending MiPALs for all participating studies at the site but does not have the ability to edit or revise data unless the Site User also has Lab User privileges.

For every new MiPAL, the Site User will always be included in any email notification in order to access the MiPAL, view the progress of pending MiPALs and assign the default reviewer (or if necessary, assign a new reviewer).

To view the MiPALs, on the Site User screen select a protocol under “Available MiPALs” by clicking the down arrow to “Filter by Study”. Once the study is selected the protocol name/number will appear in the row below.

To the far right of the screen click “Load” to bring up the MiPALs for the study.

**Illustration**

[Image showing the MiLab Central interface with highlighted selections and buttons]
## Section 3: MiLab Central Laboratory User Account

### Section 3.1: Laboratory User Account Features

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A MiLab Central laboratory account is provided to approved lab staff for the associated study(ies).</td>
</tr>
</tbody>
</table>

The User will have access to the supporting lab documents and study specific MiPALs.

Account features include the ability to:

1. Access and upload Supporting Lab Documents
3. View and complete MiPALs including uploading any study-specific lab related documents required by the LC (e.g., HIV algorithms, Specimen Flowcharts) by clicking ‘Load’.
4. Download Study Authorization Certificates for Labs
5. Go to Sites [Available ONLY if Lab User is also a Site User]
6. View and complete MiPALs including uploading any study-specific lab related documents required by the LC (e.g., HIV algorithms, Specimen Flowcharts) by clicking ‘Load’.
7. View and edit inventory for assigned labs [NOT an activated function at this time]
8. Request New Lab User

### Illustration

#### Supporting Lab Documents

1. Create New

#### MiPALs

2. Pending MiPALs
3. DCLOT and Lab Center Approved MiPALs
4. Study Authorization Certificates for Labs
5. Go to Sites
6. Inventory
7. Request New Lab User

---

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### Section 3.2: Managing Supporting Lab Documents

#### Section 3.2.1: Purpose of Supporting Lab Documents Module

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>In accordance with ICH E6(R2) 8.2.11 and 8.2.12 and the National Institute of Allergy and Infectious Diseases guidelines, study supporting document files must include documentation that identifies all labs used during the course of a study.</td>
</tr>
<tr>
<td>As part of the lab readiness process for participation in all network studies, current copies of required regulatory documents for each site-associated lab utilized for the study must be uploaded to MiLab Central and be approved by the network LC prior to site activation/permission to enroll subjects.</td>
</tr>
<tr>
<td>The supporting lab documents listed below are an example of documents required for approval of lab readiness for study activation (may vary for US and non-US sites). Other documents may be required as requested by DCLOT or your network LC.</td>
</tr>
<tr>
<td>1. Lab Director Curriculum Vitae (CV) – <em>must show affiliation with labs in question and be current within 2 years unless otherwise specified</em></td>
</tr>
<tr>
<td>2. Lab accreditation certificates</td>
</tr>
<tr>
<td>● College of American Pathologists (CAP)</td>
</tr>
<tr>
<td>● Clinical Laboratory Improvement Amendments (CLIA)</td>
</tr>
<tr>
<td>● South African National Accreditation System (SANAS)</td>
</tr>
<tr>
<td>● International Organization for Standardization (ISO)</td>
</tr>
<tr>
<td>● Other as applicable</td>
</tr>
<tr>
<td>3. Current age-appropriate normal ranges for all assays</td>
</tr>
<tr>
<td>4. International Air Transport Association (IATA) or Dangerous Goods Shipping training certificates</td>
</tr>
<tr>
<td>5. Laboratory Standard Operating Procedure (SOP) (Index/Table of Contents of SOPs). In some cases, specific actual SOPs may be requested by the network LC.</td>
</tr>
<tr>
<td>6. Clinical Pharmacology Quality Assurance (CPQA) training certificates</td>
</tr>
<tr>
<td>7. Centers for Disease Control (CDC) Import Permits</td>
</tr>
</tbody>
</table>

All submitted documents must be current (e.g., not expired or within a timeframe defined by the LC).

Any questions pertaining to supporting documents should be directed to the site network LC via the central email mailbox:

**IMPAACT:** impaact.qaqc@fstrf.org

**ACTG:** actg.labcenter@fstrf.org

---

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(See Next Page)
Section 3.2.2: Locating Supporting Lab Documents

**Information / Instructions**

The supporting lab documents section allows Users to manage (create new, view and download) all the supporting documents for all affiliated labs in one location referred to verbally as the “Documents Library”.

Once uploaded, these documents remain easily accessible to MiLab Central users and the network LC as needed to meet lab requirements for study activation. If desired, users can sort and access documents by type and current version.

The page opens to the complete list of supporting documents associate with the lab(s) the user is affiliated with.

To view supporting documents:
1. For a specific lab, click on the “By Lab” drop-down menu and select the desired lab.
2. To select a specific supporting document click on the “By Type” drop down menu.

**Illustrations**

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(See Next Page)
Information / Instructions

To remove selections click on the appropriate Red Circle with an X.

The supporting document list includes:
- Supporting document type/name (no header for column 1)
- Number (for laboratory certifications)
- Effective Date
- Expiration Date

**NOTE:** The certification ID number for laboratory certification will be displayed in a column following the relevant document name. This is a required field.

"Current Only" can be ticked to display current versions only of the supporting documents.
Section 3.2.3: Uploading and Submitting Supporting Documents

<table>
<thead>
<tr>
<th>Information / Instructions</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>The supporting lab documents module allows only MiLab Central Users to upload documents.</td>
<td><img src="image_url" alt="Image" /></td>
</tr>
<tr>
<td>All required documents must be uploaded prior to study activation. If a delay is hindering study start up the User may receive an email to upload missing documents.</td>
<td></td>
</tr>
<tr>
<td>Within the section, click on the blue “+ Create New” button in the upper right corner of the document list.</td>
<td></td>
</tr>
<tr>
<td>A new page opens where the User can complete the document upload.</td>
<td></td>
</tr>
</tbody>
</table>

**Instructions/Information**

Click on the “Upload” Icon to add the appropriate document from a local drive OR “Drag and Drop files to the white box. The uploaded file can be in Word, Excel, PDF, txt or csv format. There are no rules for site file naming conventions, however, the file name MUST, at minimum, indicate the type document, associated name and date.

Some examples are:

- Director CV_ Smith, A_04Jul2021
- CAP Certificate_ X Hospital Lab_ Exp.04Jul2021

Complete the appropriate fields in the pop-up window.

**NOTE:** Illustration is an example, fields may vary depending upon document type

1. Document Type * (use drop down menu and choose)
   NOTE: For lab certifications the certification or ID Number should be entered in the designated field
2. Document Name*
3. Lab (lab associated with the document) *
4. Effective Date (plus Expiration Date which will appear for specific document types where appropriate)
5. Comment
6. Related Protocol

(*) Denotes Required Fields. When data entry is complete click “Submit”.
The option exists to “update” submitted documents. When a document is expired a prompt to update will appear in the “Expiration Date” column. Click “update” displayed for the document that requires updating. A newer version of the old document can be submitted and the system will “tie them together”. There is an information icon that explains this process.

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(See Next Page)
Illustrations

Clicking "Update" on an expired document will automatically fill in the type/lab of the expired document and give the option to upload a new document directly tied to the expired document. If a document has expired and has a new updated version, please use this option to add the new updated document.

Document Type and Lab are automatically filled in when Update of Expired Document is Clicked.
**Instructions/Information**

All pending submissions will appear in gray font and indicate “pending” until approved by the network LC.

The network LC contact is notified of each new document submission.

---

**Information / Instructions**

The network LC contact will review each document submitted.

If there is an issue with the document the network LC contact will communicate with the User and address the issue.

Once confirmed the document is appropriate and meets required criteria the network LC contact will officially add the document to the Document Library. The document name changes to black font and can be accessed by users in the Document Library.

---

**Section 3.2.4: Downloading Study Authorization Certificate for Labs**

**Information / Instructions**

The ACTG or IMPAACT Laboratory Networks authorize select CRS labs to conduct lab testing for the relevant protocols.

The authorization certificates are posted to MiLab Central by the LC.

If the User chooses to download the certificates and print and file or file electronically the option is available through MiLab Central.

The User clicks the “Study Authorization Certificate for Labs” in the sub-navigation bar.

**NOTE:** “Go to Sites” in navigation bar is only present if Lab User is also a Site User.

---

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(See Next Page)
A “Select Lab” pop-up box will appear. The user then clicks the drop-down arrow and selects the desired lab from the drop-down menu.

Once the lab is selected, the associated protocol for the testing laboratory must be indicated by clicking either the ACTG or IMPAACT function.
Instructions/Information

The next screen will display a “Download Files” dialog box indicating the selected file is ready for download.

If the file name is the correct certificate click on the button.

If incorrect or when clicked – the “close button will close the dialog box.

Illustrations (sample screen shots of file download for Microsoft/edge)

Once the file name button is clicked the button will gray out and the downloaded PDF file will appear in the lower left hand corner of the screen. Click the “Up” arrow to reveal the pop-up menu and click “Open” to open the document. Once opened the document can be downloaded and saved to user files and/or printed.
If no certificate is available an “Error” dialog box superimposed over a blank certificate appears.
If there are any questions regarding a presumed missing certificate the network LC contact should be contacted.
Section 4: MiPAL Workflow

Section 4.1: MiPAL Overview

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The list of analytes is based upon the study protocol and finalized internally by the network LC.</td>
</tr>
<tr>
<td>The network LC contact for each study assigns the MiPALs to participating sites in MiLab Central.</td>
</tr>
<tr>
<td>Any updates to the initial analyte list necessitated by protocol amendments are made by the network LC and Site and Lab Users are notified by email.</td>
</tr>
<tr>
<td>New testing information can always be submitted, for example, as new methods and instruments are validated. Once approved by the network LC, this information will be added to the site’s laboratory’s instrument and method lists.</td>
</tr>
<tr>
<td>For every new lab, instrument and method submission is required to be approved by the network LC.</td>
</tr>
<tr>
<td>MiPAL Submission is a two-step process.</td>
</tr>
<tr>
<td>1. Any User(s) assigned to a lab affiliated with the site completes all MiPAL data fields. The User who does the most entries is assigned as the Primary User.</td>
</tr>
<tr>
<td>2. The initial data entries are required to be reviewed by another Lab User or Site User with Lab User access. This person must be a User other than the Primary User and is referred to as the “Reviewer”.</td>
</tr>
</tbody>
</table>

Section 4.2: Accessing MiPAL

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once a MiPAL is assigned to the appropriate site the applicable Lab/Site User(s) will receive an automated email indicating which study specific MiPAL(s) is available for data entry for internal review of a completed MiPAL or submission to the network LC.</td>
</tr>
<tr>
<td>To access MiLab Central the User signs in to the website. MiPALs are accessible from the home screen, under the “Pending MiPALs” module. NOTE: “Go to Sites” in navigation bar is only present if Lab User is also a Site User.</td>
</tr>
</tbody>
</table>

Illustration

MiPALs can be filtered by:

1. Study
2. Site
3. In Progress (includes initial data entry)*
4. Awaiting Review*
5. Submitted to LC/DCLOT*
6. Archived*

*When ticked these filters will display current status of item(s) checked.
Section 4.3: Entering MiPAL Data and Uploading Documents

Section 4.3.1: Loading MiPALs Data

Information / Instructions
Site and Lab Users are notified by an automated email when a new site study specific MiPAL is assigned and available for data entry.

The User will select the “Study” from the drop-down list and “In Progress” should be checked. The protocols will display, and “MiPAL Available for Entry” will be displayed next to the protocol. Click “Load” to the right of “MiPAL Available for Entry” to access the MiPAL.

NOTE: “Go to Sites” in navigation bar is only present if Lab User is also a Site User.

Illustration
Once data entry has been started for an analyte the status will update to “MiPAL Entry in Progress”.
Information / Instructions

There is a copy feature that allows the user to copy the data in one MiPAL onto another MiPAL for the same study. An information button next to ‘Copy’ to the right of “MiPAL Entry in Progress” provides instructions how to operate the copy feature.

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(See Next Page)
Information / Instructions

The copy feature is useful in cases where a user is working on MiPAL entry for two sites that use the exact same labs for testing. The User can fill out a single MiPAL for Site A, copy that MiPAL’s data, and then paste it into the MiPAL for Site B.

Illustration

Once a MiPAL has been "copied to the clipboard" the button that says "Copy" will turn into "Copied" on the MiPAL that was copied. Clicking “Insert” will paste all the values in the copied MiPAL into the other MiPAL. Any MiPAL is qualified if it is for the same protocol for a site that's been flagged as eligible in the system by the LC.

Illustration
Information / Instructions

Once "Insert" is clicked a ‘Copy MiPAL’ dialog box will appear requesting confirmation of data to be copied. The dialog box includes a reminder that any preexisting data will be overwritten.

Illustration

![Copy MiPAL dialog box]

Information / Instructions

When ‘Load’ is clicked on the Pending MiPALs listing the User is redirected to the protocol analyte list for the specified protocol.

For each line of an analyte:

- the lab may be marked as "N/A" if no testing will be done; the system will automatically fill out in instrument name and method name as N/A.
  
  OR,

- the User enters the Lab (Laboratory Name) entered and MUST chose an Instrument and Method/Kit Name (Test).

  **Note:** the instrument can be manual; the instrument name would be entered as "Manual".

All other information needed to complete the analyte, will be automatically filled in to the appropriate columns as appropriate (Model Number, Serial Number, FDA, CE, Method/Kit Name, Manufacturer, Product Code #, US FDA, CE) when selecting the Instrument and Method (See Section 4.3.3).

If any analyte line is missing an entry for a lab instrument or method this will prompt a dialog box indicating missing data.

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*(See Next Page)*
**Information / Instructions**

The Primary and Backup rows under each MiPAL requiring data entry for the first time

- There is a single “Edit” and “Copy” function in the Lab column under each new analyte.
- Data entry for the primary lab is completed first.

The copy button for the lab name and instrument takes the information in the row and adds the same information into all other analyte rows for the same grouping (e.g., Hematology or Chemistry).

The information will be automatically copied to all analytes in the category grouping.

This is different that the duplicate row as the duplicated information applies to a specific analyte row.

---

**Illustration**

<table>
<thead>
<tr>
<th>A5362: Example Site 5</th>
<th>Header &amp; Data Columns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lab</strong></td>
<td><strong>Instrument</strong></td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td><strong>Model Number</strong></td>
</tr>
<tr>
<td><strong>Serial Number</strong></td>
<td><strong>FDA</strong></td>
</tr>
<tr>
<td><strong>CE</strong></td>
<td><strong>Method/Kit Name</strong></td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td><strong>Product Code#</strong></td>
</tr>
<tr>
<td><strong>US FDA</strong></td>
<td><strong>CE</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Address:</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>Copy</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Backup</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>Copy</strong></td>
</tr>
</tbody>
</table>

---

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(See Next Page)
### Section 4.3.2: Selecting Laboratory Name

#### Information / Instructions

“Edit” is clicked to select the site associated lab that will be performing the testing for the selected analyte.

**NOTE:** If the Lab intended to perform the testing is not currently in the list of available options, the network LC contact should be contacted to confirm the lab should be added to the list of site and network approved laboratories.

#### Illustrations

Once the correct Lab is chosen, “Edit” options for instruments and methods linked to the selected laboratory become available.

#### Illustration

<table>
<thead>
<tr>
<th>A5362: Example Site 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>Calcium</td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Backup</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Select Appropriate Associated Lab
**Information / Instructions**

All fields must be filled out, so if a lab is not being used for a given analyte, choose Not Applicable “N/A” for the lab.

For storage analytes the analyte header indicates “Storage”; the data fields will be blank and grayed out prior to the required fields being populated.

The User must select the Lab storing the samples. After the Lab is selected the required fields of Instrument and Method will auto-fill with N/A*; the storage can then be submitted.

*Note: Storage samples are considered a special case; the instrument/method does not apply since samples are just being stored not operated upon.

---

**Illustration**

Select N/A if the Analyte Listed is Not Applicable for the Named Lab
Each Analyte has a text box that can be utilized for notes to either the MiLab Central users or the network LC contact, as appropriate. The field is a free text field intended for information useful to processes. This is a general note section visible to all.

To add text a note, click ‘Notes’ to open dialog box. Then click ‘+Add Note’. Notes are cumulative, all prior notes will be visible. The most recent entry is listed first.
Old notes that are resolved or no longer applicable can be deleted by clicking the trash can icon. Once clicked a confirmation to delete is required.

Section 4.3.3: Selecting Instruments and Methods

Information / Instructions
After selecting the “Lab”, clicking on “Edit” under “Instrument” and Method/Kit Name” will reveal a list of the laboratory’s approved instruments or methods.

To locate the instrument or method, type the name into the search bar or scroll through the list. Once the appropriate choice is found click to add to the MiPAL. The listing can be narrowed by checking “Show Chemistry Instruments Only”

NOTE: There may be analytes in which manual testing is performed. In such cases, DO NOT leave the field blank. Any fields left blank will prevent submission to the network LC. Select the field and click “Mark as Manual” for any manual testing.

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(See Next Page)
### Select Primary Instrument for ALT (SGPT)

**Mark as Manual** | **Show Full Inventory** | **Show Chemistry Instruments Only** | **Can't find what you're looking for?**
---|---|---|---

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>Verified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select COBAS C System</td>
<td>Roche</td>
<td>COBAS c311</td>
<td>1201-08</td>
<td>Yes</td>
</tr>
<tr>
<td>Select Manual Method - Creatinine Clearance (calculated)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Select Manual Method - Globulin, Calculated value</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Search Bar** – Type and Click

**Click Select Next to the Appropriate Instrument**

**Selected Instrument Loads Data in Primary Analyte Row**
### Illustration (Methods)

#### Select Primary Method for ALT (SGPT)

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Product Code/Number</th>
<th>FDA Approved</th>
<th>CE Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select</td>
<td>ALB2</td>
<td>Roche</td>
<td>3183688122</td>
<td>Yes</td>
</tr>
<tr>
<td>Select</td>
<td>ALP2L</td>
<td>Roche</td>
<td>03333701</td>
<td>Yes</td>
</tr>
<tr>
<td>Select</td>
<td>ALTL</td>
<td>Roche</td>
<td>20764957</td>
<td>Yes</td>
</tr>
<tr>
<td>Select</td>
<td>ASTL</td>
<td>Roche</td>
<td>20764949</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Search Bar**
- Type & Click

**Click to Select Appropriate Method**

**Selected Method Automatically Fills in Data in Primary Analyte**

---

**Illustration (Methods)**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
<th>Product Code/#</th>
<th>US FDA</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT (SGPT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add Additional Row</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Primary
  - Example Lab 1
  - Example Lab 2

- Backup
  - Example Lab 1
  - Example Lab 2
Users may complete an analyte but can not create new instruments or methods for any lab the user does not have access to. The error message highlighted below will appear on the screen. The user is directed to the network LC contact to obtain permission. Another option is to have a user from the lab complete the edit function.

**Adding a NEW Instrument or Method**

If a new instrument or method needs to be added and the user account has access to that lab the user can:

1. Complete all of the fields at the bottom of the screen including:
   a. Name (of instrument or method)
   b. Manufacturer
   c. Model # (for instruments only)
   d. Serial Number (for instruments only)
   e. Product Code (for methods/kits only)
   f. FDA approval status.
   g. CE Marked (Conformité Européenne: manufacturer’s declaration that the product meets EU standards for health, safety and environmental protection)

2. Upload Validation Documents: If this is the first time using the instrument or method for network protocols upload documentation of successful validation. **NOTE:** Documentation of successful External Quality Assurance (EQA) performance for a new assay will be needed prior to final lab activation for a study.
**Information / Instructions**

3. Confirm all fields are completed and click “Create New” to submit. Submissions that are missing fields or are otherwise incomplete or are not accompanied by appropriate documentation, when necessary, may be rejected, which will result in the removal of all MiPAL information associated with the instrument and/or method.

**Illustration (example of Adding a New Instrument)**

**Select Primary Instrument for AST**

<table>
<thead>
<tr>
<th>Mark as Manual</th>
<th>Show Full Inventory</th>
<th>Show Chemistry Instruments Only</th>
<th>Can’t find what you’re looking for? Search by name...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA Approved</th>
<th>CE Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Select | Manual | | | | |
|        | Manual Method - Calcium | | | | |

| Still can't find what you're looking for? Add a new instrument. | | | | | | |
| Name | Manufacturer | Model # | Serial # | FDA Approved? | CE Marked? | Validation | |
|------|--------------|---------|----------|--------------|------------|------------|
|      |              |         |          |              |            |            |

Create New

**Illustration (example of Adding a New Method)**

**Select Primary Method for Calcium**

<table>
<thead>
<tr>
<th>Show Full Inventory</th>
<th>Show Chemistry Methods Only</th>
<th>Can’t find what you’re looking for? Search by name...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Product Code/Number</th>
<th>FDA Approved</th>
<th>CE Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Still Can't find what you're looking for? Add a new method. | | | | | | |
| Name | Manufacturer | Product Code | FDA Approved? | CE Marked? | |
|------|--------------|-------------|--------------|------------|
|      |              |             |              |            |      | Create New | 3 |
Information / Instructions

Once all the data is entered for the primary lab, the applicable data is also entered for the backup lab. If the instrument/method added for either the primary or backup lab is not already approved by the LC, a blue notification will appear, indicating the entry is awaiting LC approval. Once the approval is granted, the entry becomes a valid instrument/method in the system and can be used on any MiPAL where appropriate.

Illustration

**Select Primary Instrument for Platelet Count**

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA Approved</th>
<th>CE Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI 3500xI</td>
<td>Applied Biosystems</td>
<td>3500xI</td>
<td>23319080</td>
<td>No</td>
<td>-</td>
</tr>
<tr>
<td>Alinity I</td>
<td>ABBOTT</td>
<td>Alinity I</td>
<td>A01727</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Clinitek status plus</td>
<td>Siemens</td>
<td>Status plus</td>
<td>251335</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Cobas Integra 2</td>
<td>Roche</td>
<td>400 Plus</td>
<td>400164</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>New Instrument</td>
<td>Cobas</td>
<td>12355</td>
<td>54321</td>
<td>Yes</td>
<td>-</td>
</tr>
</tbody>
</table>

**Awaiting Lab Center Approval**

**Awaiting Lab Center Approval**

**Section 4.3.4: Backup Laboratory Data**

Information / Instructions

Once all primary lab data entry is completed for each analyte, all the data fields must be entered as appropriate for the backup lab for each analyte. The same steps used for the primary lab are followed:

- Start with clicking the “Edit” function in the “lab” column.
- The “Edit” functions for instrument and method will display once the Lab is selected.
- Click the Instrument and Method Edit functions once visible to complete data and click the appropriate selection for both the instrument and method.

**Note:** If the desired item is not listed and the user has access to the account, there will be a prompt to add and follow the procedure for adding a new instrument/method described in section 4.3.3 above.
### Illustrations

**A5362: Example Site 5**

**MiLab Version:** 0

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
<th>Product Code#</th>
<th>US FDA</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>HDO0154 - Example Lab 10</td>
<td>COBAS C Systems</td>
<td>COBAS c311</td>
<td>SN 1208-05 and SN 1485-09</td>
<td>Yes</td>
<td>ALB2</td>
<td>Roche</td>
<td>3183688122</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backup</td>
<td>HDO0257/HDO0099 - Example Lab 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Roche</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Creatine Kinase**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
<th>Product Code#</th>
<th>US FDA</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>HDO0154 - Example Lab 10</td>
<td>COBAS C Systems</td>
<td>COBAS c311</td>
<td>SN 1208-05 and SN 1485-09</td>
<td>Yes</td>
<td>ALB2</td>
<td>Roche</td>
<td>3183688122</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backup</td>
<td>HDO0257/HDO0099 - Example Lab 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Roche</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Calcium**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
<th>Product Code#</th>
<th>US FDA</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>HDO0154 - Example Lab 10</td>
<td>COBAS C Systems</td>
<td>COBAS c311</td>
<td>SN 1208-05 and SN 1485-09</td>
<td>Yes</td>
<td>ALB2</td>
<td>Roche</td>
<td>3183688122</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backup</td>
<td>HDO0257/HDO0002 - Example Lab 2</td>
<td>ABBOTT</td>
<td>Allinityi</td>
<td>Al 01825/Al 01857</td>
<td>Yes</td>
<td>Broncired Green</td>
<td>ROCHE</td>
<td>3183688122</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

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Section 4.3.5: Uploading Study-Specific Documents

**Information / Instructions**

In addition to submission of the MiPAL data, the network LC contact may require study specific documents such as a specimen flowchart or adult or infant HIV testing algorithms.

Specific document requests are added to MiLab Central by the network LC contact when the MiPAL is created. The LC will indicate the document(s) type and list in the MiPAL module.

The required document(s) may be uploaded by the primary User or the Reviewer at any time prior to submission to the LC by selecting the “Upload” or “+ Add Document”. There are no restrictions on the document format (e.g., Word, Excel, PDF).

**Illustrations**

- **Click to Add Document From Files**
- **Click to Upload Study Specific Documents**

If required documents are missing when attempting to submit for review an error dialog box will appear indicating required documents must be uploaded to continue.
### Section 4.3.6: Setting Default and Using Autofill

<table>
<thead>
<tr>
<th>Information / Instructions</th>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary and Backup MiPAL information commonly used across studies for a particular analyte can be saved as the default configuration for future MiPALs only if all data entry fields (Primary Lab/Instrument/Method + Secondary Lab/Instrument/Method) are completed.</td>
<td><img src="image" alt="Illustration" /></td>
</tr>
</tbody>
</table>

The “Set Default” function can be set at any time. As long as the combinations of lab/instrument/method differs from the current default the default can be set to the new combination.

To create the default, when entering specific MiPAL data for the first time, select the “Set Default” function, situated under “Backup”. Hitting “Set Default” creates a record of what the user, who was logged in, entered for that particular row of data (Basically, each user has a set of defaults for what they fill in for Analyte). This will save all Primary and Backup information for each analyte.

Once the Set Default is activated the analyte row will display a message “Assigned as default data”.

If a MiPAL is rejected by the LC the “Set Default” will reappear when revised.
**Information / Instructions**

Analyze data fields from previously completed and saved MiPALs can be used at a later date or with another study when “Autofill with Defaults” is selected. Any user who has access to the MiPAL can fill the MiPAL with the Users saved defaults.

- To input the default data when a new MiPAL is loaded, click “Autofill with Defaults”.
- The saved data fields will populate for the applicable analytes.
- The User must verify entries once uploaded to confirm accuracy.
- If a user clicks “Autofill with Defaults” the application will go through the PAL the user is currently looking at line by line and see if the user has saved any defaults for the analytes in the PAL and enter the saved data in for them.

**NOTE:** Any new lab must complete all information for each analyte. The default function is only used where a site/lab already has approved MiPAL(s) in MiLab Central.

**Illustration**

<table>
<thead>
<tr>
<th>Ready for Final Review Before LC Submission</th>
<th>Notes</th>
<th>Autofill with Defaults</th>
<th>Save &amp; Exit</th>
</tr>
</thead>
</table>

**Section 4.3.7: Submitting for Internal Review**

**Information / Instructions**

When the MiPAL fields have been completed by the Lab User and are ready for review by a Site or different Lab User (referred to as the Reviewer) the “Ready for Final Review Before LC Submission is checked.

**Illustration**

![Check this Box when MiPAL is Ready for Final Review Before LC Submission]
Information / Instructions

If the user attempts to tick the “Ready for Final Review before LC Submission” and information is missing an “error” dialog box will appear prompting the user to add the missing data and submit again for final review.

Illustration

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>CE</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT (SGPT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>HID0154 - Example Lab 10</td>
<td>COBAS C Systems</td>
<td>Roche</td>
<td>COBAS c311</td>
<td>SN 1206-06 and SN 1465-08</td>
<td>Yes</td>
<td>ALTL</td>
<td>Roche</td>
</tr>
<tr>
<td>Backup</td>
<td>HID0040 - COBAS C Systems</td>
<td>Roche</td>
<td>COBAS c311</td>
<td>4715MS-10T B30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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(See Next Page)
### Section 4.4: Final Lab Review – Reviewing Data Entered into MiPALs

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “Reviewer” is assigned by a Site User any time after the MiPAL is made available by the network LC contact. The reviewer should be a User most familiar with the analyte specifics required for data entry.</td>
</tr>
<tr>
<td>When the User checks the box “Ready for Final Review Before LC Submission” the Reviewer will be notified via an automated email that the MiPAL is pending review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Illustration</strong></td>
</tr>
<tr>
<td>In the “Pending MiPALs” select the Study and Site from the drop-down list. MiPALs that have been completed and are awaiting final [internal] review prior to submission to the LC will be marked with the phrase “MiPAL Awaiting Review Before LC Submission” alongside the associated protocol under the “Pending MiPALs” module.</td>
</tr>
<tr>
<td>By clicking on “Load” to the right of “MiPAL Awaiting Review Before LC Submission” the MiPALs screen will be displayed. The Reviewer will scroll through the listing for the MiPAL(s) to be reviewed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Illustration</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="MiPAL Ready for Final Review" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MiPALs</th>
<th>Study</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>XDemo1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pending MiPALs</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="MiPAL Awaiting Review Before LC Submission" /></td>
</tr>
</tbody>
</table>

Click to Access Analytes
**Information / Instructions**

The system will verify the completeness and the reviewer will verify accuracy of all data entered. An error dialog box will appear if any required field is left blank.

**NOTE:** The requirement is each line must have a primary lab, instrument, method and a backup lab, instrument, method.

Reviewer’s privileges include the ability to:

- make any changes needed to update and revise information entered into the MiPAL
- view and enter additional notes
- upload additional study specific lab documents, if not done previously

Once all MiPAL(s) verifications are confirmed and determined complete and ready for submission to the LC the Reviewer will click “Submit to LC” (button appears once the box for internal review is checked). Every new MiPAL, instrument and method submission are required to be approved by the network LC.

The Reviewer will be prompted to download a PDF of the submitted draft for their reference and the status will be changed to “MiPAL Available for Lab Center Review” on the Pending MiPALS module on the homepage.

---

**Illustration**

[Image of MiPAL interface with highlighted text: Complete and Ready for Review by Network Laboratory Center]

---

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Section 4.5: MiPAL Data Review by Network Laboratory Center

**Information / Instructions**

The network LC contact will be notified once the reviewer has submitted the MiPAL.

MiPALS submitted to the LC and pending approval will be marked with the phrase “MiPAL Available for Lab Center Review”

**Illustrations**

For submissions where there are questions or issues raised by the network LC contact on the submitted MiPAL:

- the User(s) who entered MiPAL data or requested to receive notification and the Reviewer will be notified via an automated email indicating the network LC contact has requested revision of the MiPAL(s) and the MiPAL is available for updating.
- the entry in “Pending MiPALS” will be flagged “Awaiting Query Response”.
- the MiPAL will be reactivated for the User and can be accessed via MiLab Central for revision and resubmission.

**Illustration**

If there are no questions or issues that arise during the review, the MiPAL will be sent by the network LC contact to the DAIDS Clinical Laboratory Oversight Team (DCLOT) for review and sign-off.
## Section 4.6: MiPAL Review and Finalization by DCLOT and Lab Center

### Information / Instructions

Following review and approval by DCLOT, a final PDF version of the approved MiPAL that includes the DCLOT name and sign-off date is sent automatically to the Users listed on the MiPAL(s) and the network LC contact(s) on the study. Additional emails are sent to the DCLOT user who reviewed the MiPAL and the Patient Safety Monitoring in International Laboratories (pSMILE) contacts who work with the labs included on the MiPAL (with a copy to the network LC contact).

Once the MiPAL(s) is reviewed by the network LC contact is reviewed, approved and finalized by DCLOT the Users will receive an automated email indicating which study specific MiPAL is available and any documents attachments to the approved MiPAL.

The final approved MiPAL(s) can be accessed 2 ways:

1. The finalized MiPAL may be loaded and a read only version viewed
2. A printed listing may be downloaded and printed

### Illustration

#### DCLOT and Lab Center Approved MiPALs


[Finalized] 1  [Copy]  [Load]  

[Download] 2

#### Information / Instructions

Some of the listed approved MiPALs have a “Copy” function. There is an information icon that can be ticked and provides information on how to copy to and from the listing where allowed by the LC

Copy paste function is for the scenario where 2 different sites are using the exact same set of labs for the same study; the MiPAL can be copied in this scenario. If not allowed the function won’t exist.

#### Illustration

**DCLOT and Lab Center Approved MiPALs**


Read Only; Any Edits Require a Query

To Copy:
1. Select the MiPAL you want to copy FROM by clicking "Copy"
2. Select the MiPAL you want to copy TO by clicking "Insert"
### Demo CRS 1: A5375 Protocol Version: 1.0

MIPAL Version: 1.0 IND Study: No

READ ONLY: This MIPAL cannot be edited as it has already been approved to make edits

<table>
<thead>
<tr>
<th>Lab</th>
<th>Instrument</th>
<th>Manufacturer</th>
<th>Model Number</th>
<th>Serial Number</th>
<th>FDA</th>
<th>Method/Kit Name</th>
<th>Manufacturer</th>
<th>Product Code/#</th>
<th>US FDA</th>
<th>Provider</th>
<th>Panel Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>HIV0040 - OCM-JHU AP</td>
<td>Roche</td>
<td>4715MS-10T B30</td>
<td>Yes</td>
<td>ALE2</td>
<td>Roche</td>
<td>3183688122</td>
<td>Yes</td>
<td>CAP</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Backup</td>
<td>HIV154 - Lilongwe</td>
<td>Roche</td>
<td>1208-05</td>
<td>Yes</td>
<td>ALE2</td>
<td>Roche</td>
<td>3183688122</td>
<td>YES</td>
<td>CAP</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

### Illustration

Your files are ready for download. Please click the button to download each file:

A5375_ Version_ 1.0 MIPAL Version_ 1.0 for 30301_ Demo CRS

Click to Download File

Close
**Section 4.7: Subsequent MiPAL Data Changes**

**Information / Instructions**

If changes are needed to the MiPAL data (e.g., changes in lab instrumentation or methods) a query should be sent to the network LC contact by the User.

Any changes after the MiPAL are finalized follows the same process as new entries.

In brief, the LC will release the MiPAL to the Lab/Site User, changes will be made and verified by the Reviewer. The network LC contact will complete a review and submit back to DCLOT.

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*(See Next Page)*
Illustration

Following completion and finalization of the initial MiPAL, any subsequent changes (e.g., instrument changes, revisions needed because of a protocol version change) are automatically captured in a revision history at the end of the MiPAL.

Section 4.8: Additional Features

Information / Instructions
As a point of reference Users and the Reviewer are listed at the bottom of the MiPALs screen.

Illustration
External Quality Assurance (EQA) information (“provider” and “panel detail” columns) is linked to the MiPAL analytes through the MiLab Central database. The information is automatically generated on the final MiPAL listing once approved and finalized by the LC and DCLOT. Users do not have access to enter any EQA information. The information will be visible on the approved MiPAL document.

**Illustration**

![Illustration](image)

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CHAPTER 4: Acronyms and Glossary

Introduction: The chart below includes the definitions of acronyms and terms used throughout the *MiLab Central User Guide for Clinical Research Sites*. The listing is in alphabetical order. The definitions are derived from relevant standard operation procedures and select federal and international research regulations and guides.

<table>
<thead>
<tr>
<th>Acronym / Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTG</td>
<td>AIDS Clinical Trials Group</td>
</tr>
<tr>
<td>ACTG Laboratory Center (ALC)</td>
<td>Responsible for laboratory activities associated with ACTG sponsored clinical trials. This group is located at the University of California Los Angeles (UCLA).</td>
</tr>
<tr>
<td>ACTG MTA Team</td>
<td>This team is comprised of members from the ACTG Laboratory Center (ALC) as well as the International Scientific Office (ISO) Team. Team members can be reached via the <a href="mailto:ACTGMTA@fstrf.org">ACTGMTA@fstrf.org</a> email address. This email is used to monitor all communications related to MTAs.</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
</tr>
<tr>
<td>Biomedical Research Institute (BRI):</td>
<td>The AIDS Clinical Trials Group (ACTG) specimen repository that is used to collect, process, store, and distribute biological specimens to support scientific investigations. This facility is located in Rockville, Maryland.</td>
</tr>
<tr>
<td>CRS</td>
<td>Clinical Research Site</td>
</tr>
<tr>
<td>DAIDS</td>
<td>Division of AIDS</td>
</tr>
<tr>
<td>DCLOT</td>
<td>DAIDS Clinical Laboratory Oversight Team</td>
</tr>
<tr>
<td>Supporting Documents</td>
<td>Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate the compliance of the investigator with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements.</td>
</tr>
<tr>
<td>IMPAACT</td>
<td>International Maternal Pediatric Adolescent AIDS Clinical Trials</td>
</tr>
<tr>
<td>Lab User</td>
<td>Staff at the lab(s) associated with the study (either an affiliated lab or a contracted lab) whose responsibilities include entering or editing data related to each analyte and uploading all required supporting laboratory documents</td>
</tr>
<tr>
<td>Laboratory Processing Chart (LPC)</td>
<td>A non-regulatory document that supplements the protocol with details for specimen collection, processing, storage, and shipping in both a general and visit-by-visit format</td>
</tr>
<tr>
<td>Laboratory Specialist (LS)</td>
<td>A member of the ACTG Laboratory Center (ALC) team responsible for laboratory specific activities associated with trials sponsored by DAIDS. Also known as a Laboratory Center (LC) Representative</td>
</tr>
<tr>
<td>Acronym / Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>LDMS</td>
<td>Laboratory Data Management System associated with the site. It is an identification number assigned for data management purposes. LDMS is an information management system for managing collections of biological specimens.</td>
</tr>
<tr>
<td>Listserv</td>
<td>ACTG or IMPAACT mailboxes</td>
</tr>
<tr>
<td>Material Transfer Agreement (MTA)</td>
<td>An agreement between a provider institution/scientist at the Clinical Research Site (CRS) and recipient institution/scientist at the Biorepository or testing laboratory for purposes of clinical trial specimen transfer; also known as a Specimen Transfer Agreement (STA)</td>
</tr>
<tr>
<td>MiLab MTA Module</td>
<td>The electronic system used to track and store MTA documents within the ACTG Laboratory Center (ALC) and provide routine data transfer to the ACTG Network Coordinating Center (NCC)</td>
</tr>
<tr>
<td>MTA Coordinator (MTAC)</td>
<td>ACTG Laboratory Center (ALC) staff member responsible for coordinating and facilitating the Material Transfer Agreement (MTA) process</td>
</tr>
<tr>
<td>NIAID</td>
<td>National Institute of Allergy and Infectious Diseases</td>
</tr>
<tr>
<td>Network</td>
<td>IMPAACT or ACTG clinical trials</td>
</tr>
<tr>
<td>Network Laboratory Center (LC)</td>
<td>Responsible for laboratory activities associated with ACTG or IMPAACT sponsored clinical trials.</td>
</tr>
<tr>
<td>Network Laboratory Center (LC) Contact</td>
<td>A Laboratory Center (LC) person who is affiliated with either the ACTG or IMPAACT network and a particular study and/or site and serves as a link for information for the site or lab user.</td>
</tr>
<tr>
<td>MiMTA</td>
<td>The portion of MiLab Central that is used to electronically track the requirements, creation and tracking of material transfer agreements.</td>
</tr>
<tr>
<td>MiPAL Module</td>
<td>The portion of MiLab Central that is used to electronically track the Protocol Analyte List (PAL)</td>
</tr>
<tr>
<td>Patient Safety Monitoring in International Laboratories (pSMILE)</td>
<td>A contractual resource at Johns Hopkins University designed to evaluate and develop the capability of laboratories to participate in the National Institute of Health (NIH) DAIDS supported prevention, vaccine and therapeutic clinical studies conducted in international (non-US) sites; and ensure the integrity and reliability of tests for monitoring safety and efficacy of experimental products investigated in DAIDS supported studies in international (non-US) sites (Adapted from Source: <a href="https://psmile.org/index.cfm">https://psmile.org/index.cfm</a>).</td>
</tr>
<tr>
<td>Primary User</td>
<td>The Lab User who enters analyte information and is different than the Reviewer</td>
</tr>
<tr>
<td>Acronym / Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Protocol Analyte List (PAL)</td>
<td>The PAL lists all the tests that will be performed by a laboratory to support a site for a specific protocol.</td>
</tr>
<tr>
<td>Provider</td>
<td>Institution from which transferred samples originate (sometimes referred to as “Start Lab”)</td>
</tr>
<tr>
<td>Recipient</td>
<td>The destination institution of transferred study samples</td>
</tr>
<tr>
<td>Site User</td>
<td>A user based at the study site with approved access to MiLab Central</td>
</tr>
<tr>
<td>UCLA</td>
<td>University of California Los Angeles</td>
</tr>
</tbody>
</table>

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(See Next Page)
# CHAPTER 5: Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Change</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>dd/Nov/2021</td>
<td>XX Group</td>
<td>N/A – Initial document</td>
<td>This user guide was created to aid MiLab Central Site and Lab Users in completing system processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Screen shots of all user actions included with text to enhance understanding.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Includes guidance for accessing MiLab Central (e.g., website, acquiring accounts, user names and passwords), the MiMTA and MiPAL modules and a glossary of acronyms and terms.</td>
</tr>
</tbody>
</table>