MiLab Central

User Guide

For

Clinical Research Sites

Version 1.0

24 November 2021

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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.
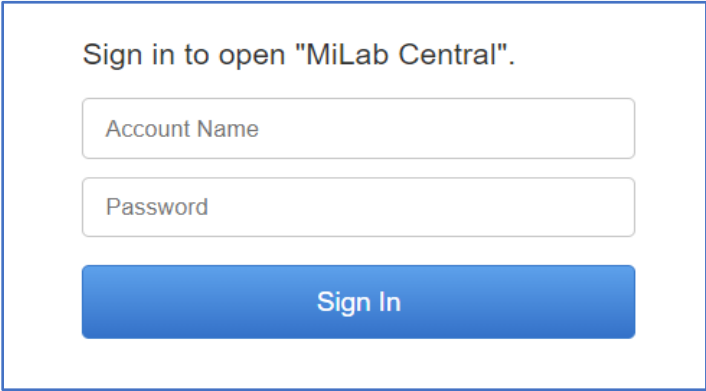
CHAPTER 1: MiLab Central General Operation

Section 1: Overview of MiLab Central

Information / Instructions
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.
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

Information / Instructions
The MiLab Central website requires: • An internet connection • A MiLab Central username/password **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 • www.milabcentral.com **Tip:** Add the MiLab Central URL to the internet browser favorites for easy access to the website.
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Information / Instructions	Illustration
A sign in page shown opens when accessing the MiLab Central website.	Sign in to open "MiLab Central". Account Name Password Sign In
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	1. Chrome 2. Edge 3. Safari
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 google.com/
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

Use MiLab Back Arrow (when available)

1

Warning: Back and Forward Browser tools are not supported. Using them will log you out.

← Back

A5362: Demo CRS 1

MiPAL Version: 0

Lab   **Instrument**   **Manufacturer**   **Model Number**   **Serial Number**   FDA   CE

Warning: Back and Forward Browser tools are not supported. Using them will log you out.

<   Demo CRS 1: A5375 Protocol Version: 1.0

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2   **Use Functions in Navigation Bar**

MiLab Central

🖺 Study Authorization Certificates for Labs   Go to Sites   ⚗ Inventory

---

Use HOME Icon

Clicking the 'Home' icon returns user to home screen

🏠 ☒ 🡒

3

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

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Information / Instructions

If assistance is needed with any <u>operational</u> or <u>technical</u> 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 <u>at least one account</u> 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 **OR** 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

Information / Instructions
When a new site is set up all user accounts known at that time should be requested as indicated in Section 3.2.
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.

The applicant must send an email request to the LC using the appropriate network email address to:
    IMPAACT: impaact.qaqc@fstrf.org
    ACTG: actg.labcenter@fstrf.org

The email request must include: ● Site Name ● Site Number ● Requestors first and last name ● Requestors email address ● Lab(s) associated with site
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 **OR** 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 2. A "Request New Lab User" drop down box will appear. 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 **OR** www.milabcentral.com • Account username • Temporary password
  ## This Space Intentionally Left Blank ### (See Next Page)

Illustration

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.

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

You must change the password for your FileMaker account before opening this file. Please enter your old password once and your new password twice.

Account Name: TAccount1

Old Password: ••••••

New Password: [   ]

Confirm New Password: [   ]
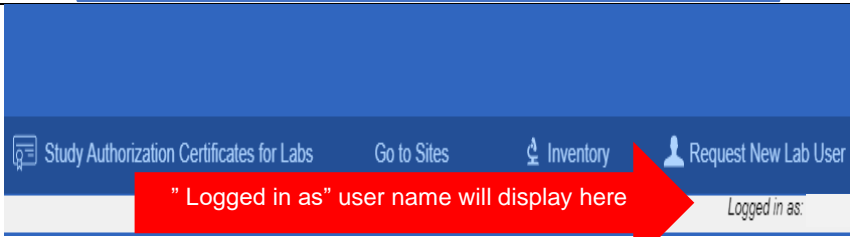
Password Quality: Weak

Cancel   OK

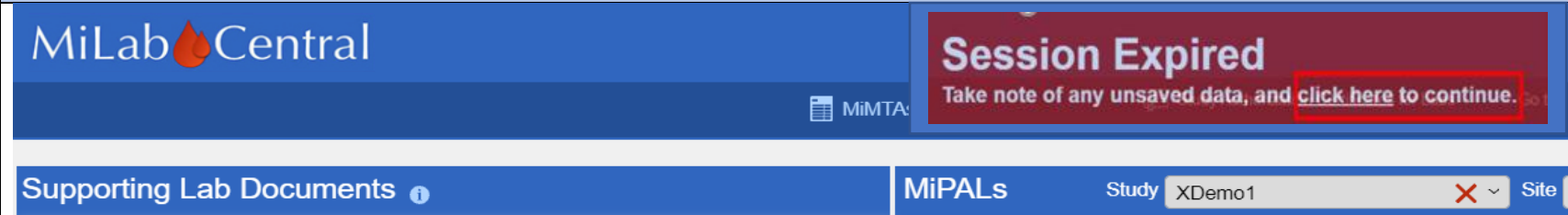| Information / Instructions |
|---|
| Each user should either memorize or write down the username and personal password and store in a secure place, as this information is needed each time a user signs in to the MiLab Central website. |
| **Reminder:** Keep MiLab Central data secure and confidential; users must NOT share usernames or passwords. |
| If a password is forgotten email the appropriate LC (impaact.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

Information / Instructions	Illustration
When accessing the MiLab Central website for the first time enter respectively: 1. Account username 2. Temporary password provided in the email from the network LC Once information is entered click "Sign In".	Sign in to open "MiLab Central". Account Name **1** Password **2** Sign In ← Click
Once signed in the user's name will appear in the upper right-hand corner of the navigation bar.	Study Authorization Certificates for Labs · Go to Sites · Inventory · Request New Lab User " Logged in as" user name will display here → Logged in as:

Section 6: Exiting MiLab Central

Information / Instructions
Once signed in to the website please DO NOT leave the computer unattended.
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.
If the website is left idle for > 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
Illustration

MiLab Central

MiMTA

Session Expired
Take note of any unsaved data, and click here to continue.

Supporting Lab Documents ⓘ

MiPALs   Study XDemo1 ✕ ∨   Site

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

REMINDER: 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.

Section 2: Accessing MiMTA

Information / Instructions
Sign in to MiLab Central using the approved username and password (Refer to Chapter 1) **Note:** The image below may vary slightly; functions in the navigation bar will change dependent upon the user's role/access.
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Illustration

Information / Instructions	Illustration
Click on "MiMTAs" located in the top navigation bar under the MiLab Central logo. This will direct the suer to the MiMTA module.	

Information / Instructions
Once MTA is clicked the user is directed to the MiMTA home page. There is a section for 'Stuides and Sites'; for listing status of 'MTAs for <a specfici study/site>' and a 'Submission in Progress' section which lists MTAs in progress (prior to full execution).

Illustration

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 customzation and edits may be made in preparing the site specific MTA.
Illustration

Information / Instructions
A listing of available templates is displayed.

- Click the "Dowload" 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".
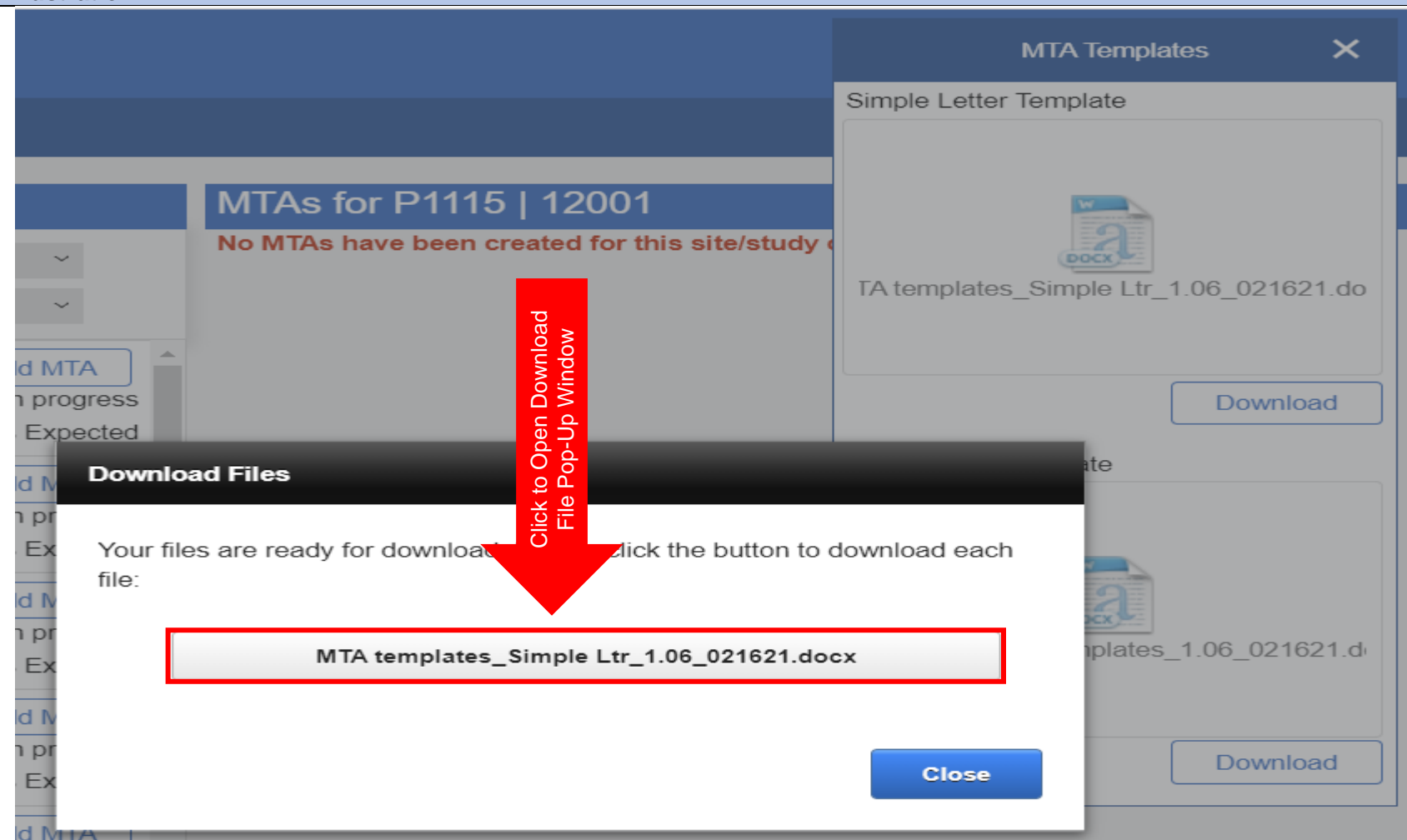- If incorrect click "Cancel".

Illustration
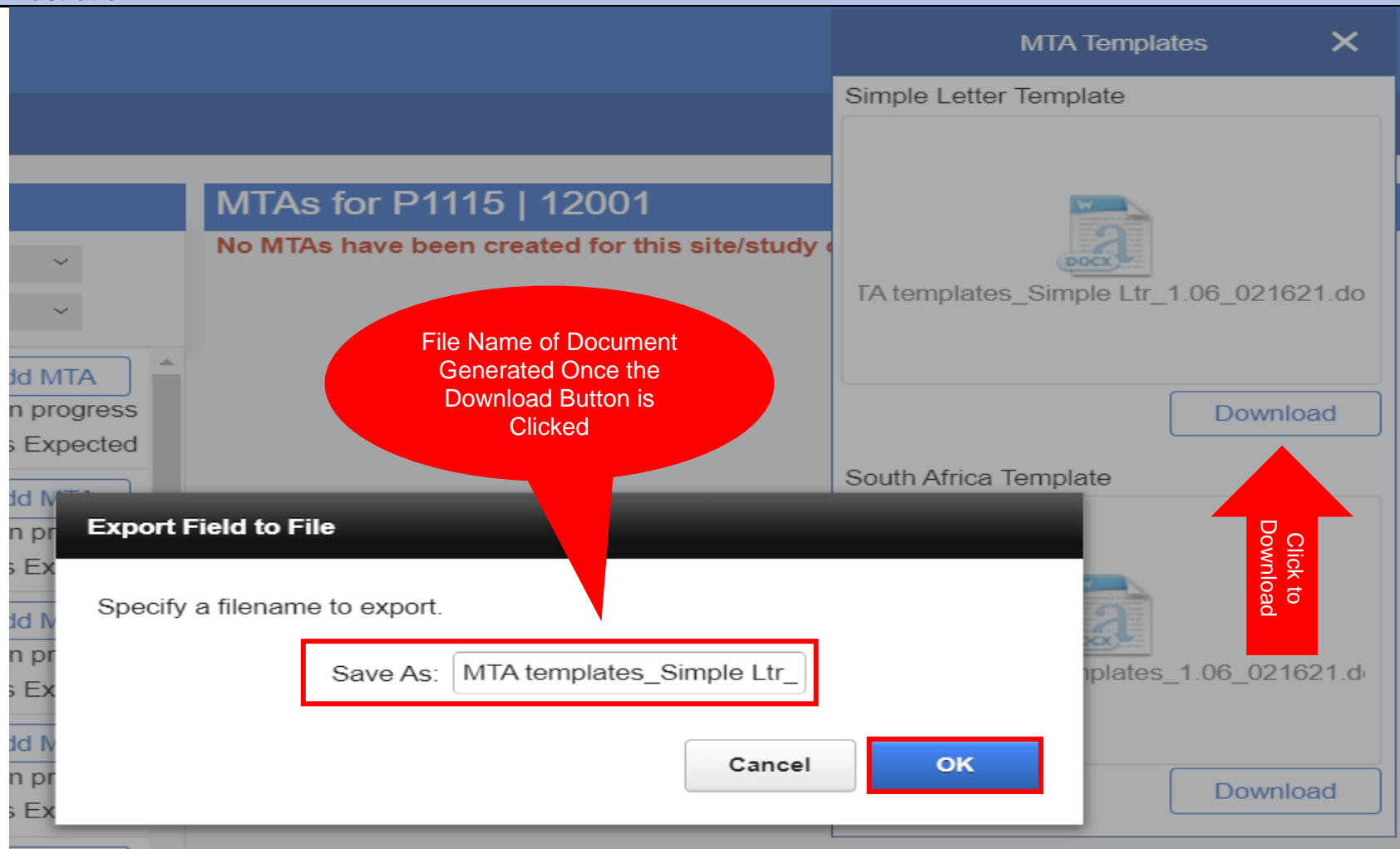
Information / Instructions
Once 'Okay' is clicked a "Download Files" dialog box wil appear. To open the download file pop-up window click the file name button.
Illustration

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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
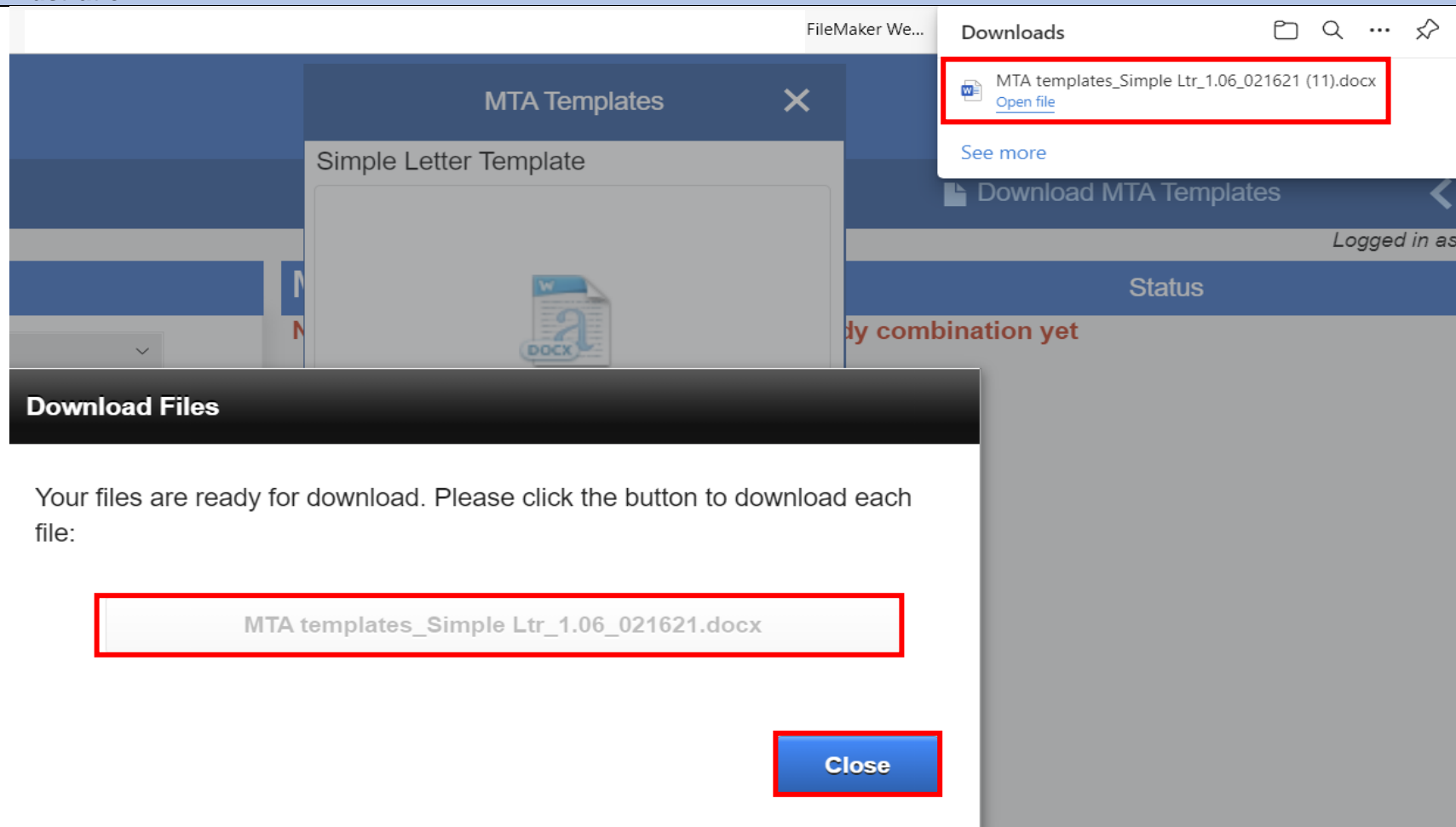
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(See Next Page)

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

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

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 [🔍] to narrow the list, then click the approriate study from the list.

Illustration

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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Illustration

Illustration
One or both study or site selections can be removed by clicking the '**Red X**'s'

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.

Information / Instructions
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

Studies and Sites

Study

Site

0000	10: XXXACTG Example Site#1
	Add MTA
	0 MTA(s) in progress
	0 FE MTAs of unknown MTAs Expected

① ②

MTAs for 0000 | 10

No MTAs have been created for this site/study combination yet

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.
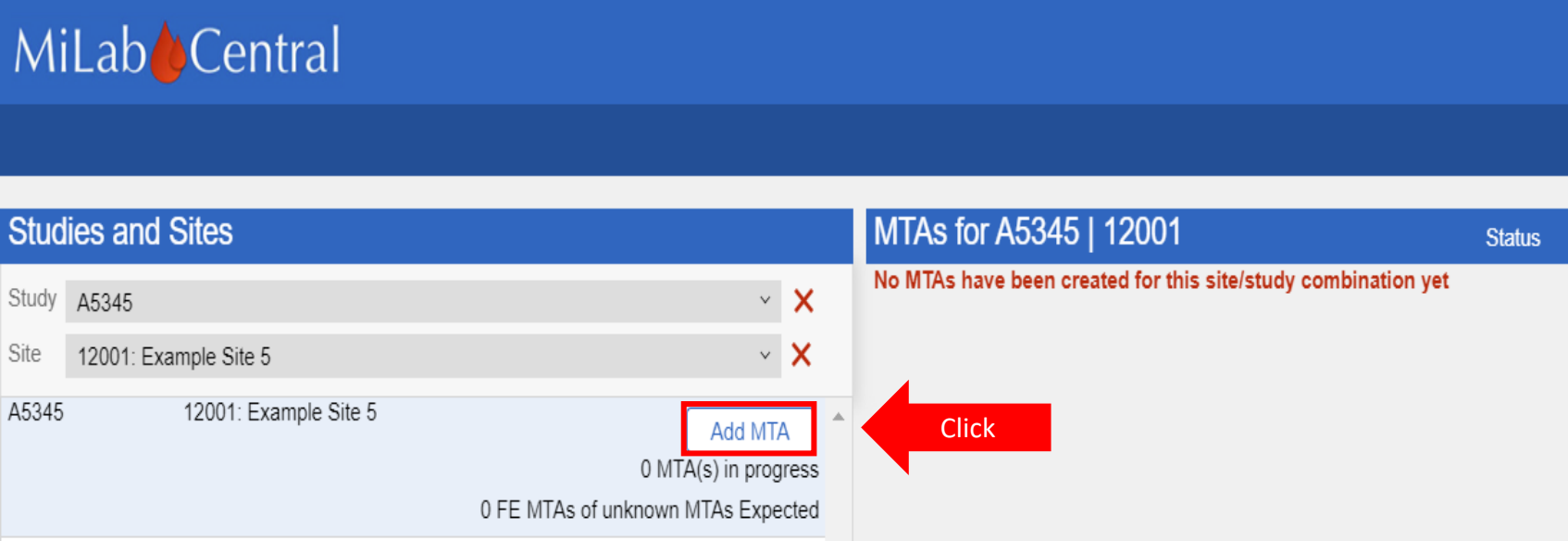
Illustration

MiLab Central

Studies and Sites

Study IMPAACT 2010 ✕

Site

IMPAACT 2010	12001: Example Site 5
	Add MTA
	5 MTA(s) in progress
	5 FE MTAs of unknown MTAs Expected

①

MTAs for IMPAACT 2010 | 12001   Status

Start: HID0154 - Example Lab 10 - 245

Destination(s): HID0308 - U Washington Retrovirus Lab - 15

Status: Fully Executed MTA Received by Network MTA Team - 10/22/2020

Fully Executed MTA Received by Network MTA Team

②

Start: HID0154 - Example Lab 10 - 245

Destination(s): Pharmacology_UCSD_Best - 173

Status: Fully Executed MTA Received by Network MTA Team - 10/22/2020

Fully Executed MTA Received by Network MTA Team

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.

Illustration

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 verfied the remaining fields should be reviewed. **Items 2, 4, 5 & 6 are required fields and marked with an asterik (*)**.

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Illustration

MiLab Central

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?*

3. Choose a Pass Through (only if required!)
Is a Pass-Through Lab required for this MTA?   [Yes]

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

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

6. Upload the MTA*
[⬆ Upload MTA]

7. Upload Additional Documents
[⬆ Add Document]

Click Cancel if Site or Study is Incorrect to Return to Previous Screen

*required for submission

[Submit] [Cancel]

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

Information / Instructions – Item #2 (continued

If the Start Lab is not listed click "Where is my lab" (in *blue italizied 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

Illustration

Information / Instructions – Item #2 (continued
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.

Illustration

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
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 (Recipent 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 ressembling 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

Information / Instructions – Item #4 (continued)
To use the "Search Region" option.

1. Click the drop-down menu.
2. A list of regions (e.g.Asia, North America) will appear.
3. Select the correct region from the list, when the region is clicked the search will narrow to those labs within that region.
4. Click the correct lab and the lab will appear in the "Choose a Destination" box

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

Illustrations

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 emal 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

Illustrations

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   ⌄   [Cancel]   *Where is my lab?*

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

⌄

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

◄   **Destination Lab Request Query**   ✕

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

Destination Lab is XXX-123 and is not listed Please assist.| **(c)**

[Send]

---

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   ⌄   [Cancel]   *Where is my lab?*

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

Email Sent!   ▢

Destination Lab Request Query   ✕

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

Destination Lab is XXX-123 and is not listed. Please assist.   **(d)**

5. **Who else in y**
(separate email

[**OK**]

[Send]

6. **Upload the M**

Information / Instructions – Item #5

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].

Illustrations

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
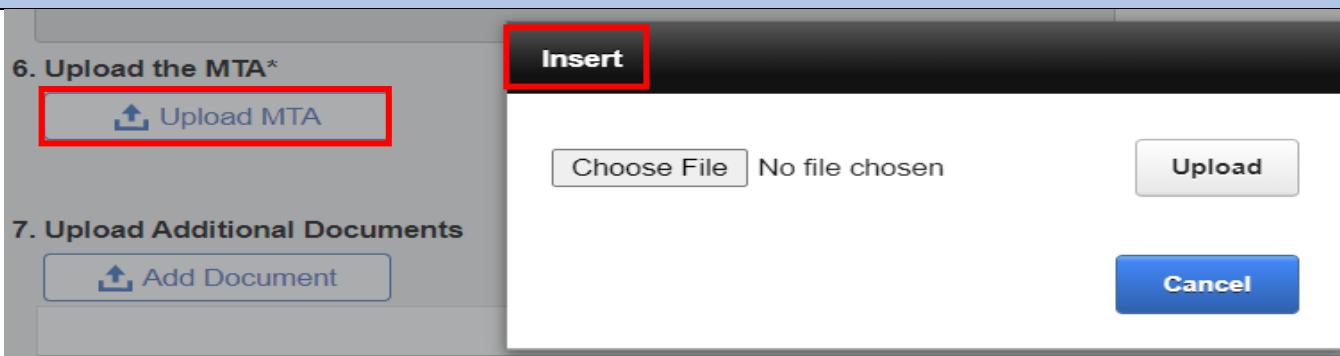
Information / Instructions
To complete the upload:

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.

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Illustrations

This Space Intentionally Left Blank
(See Next Page)
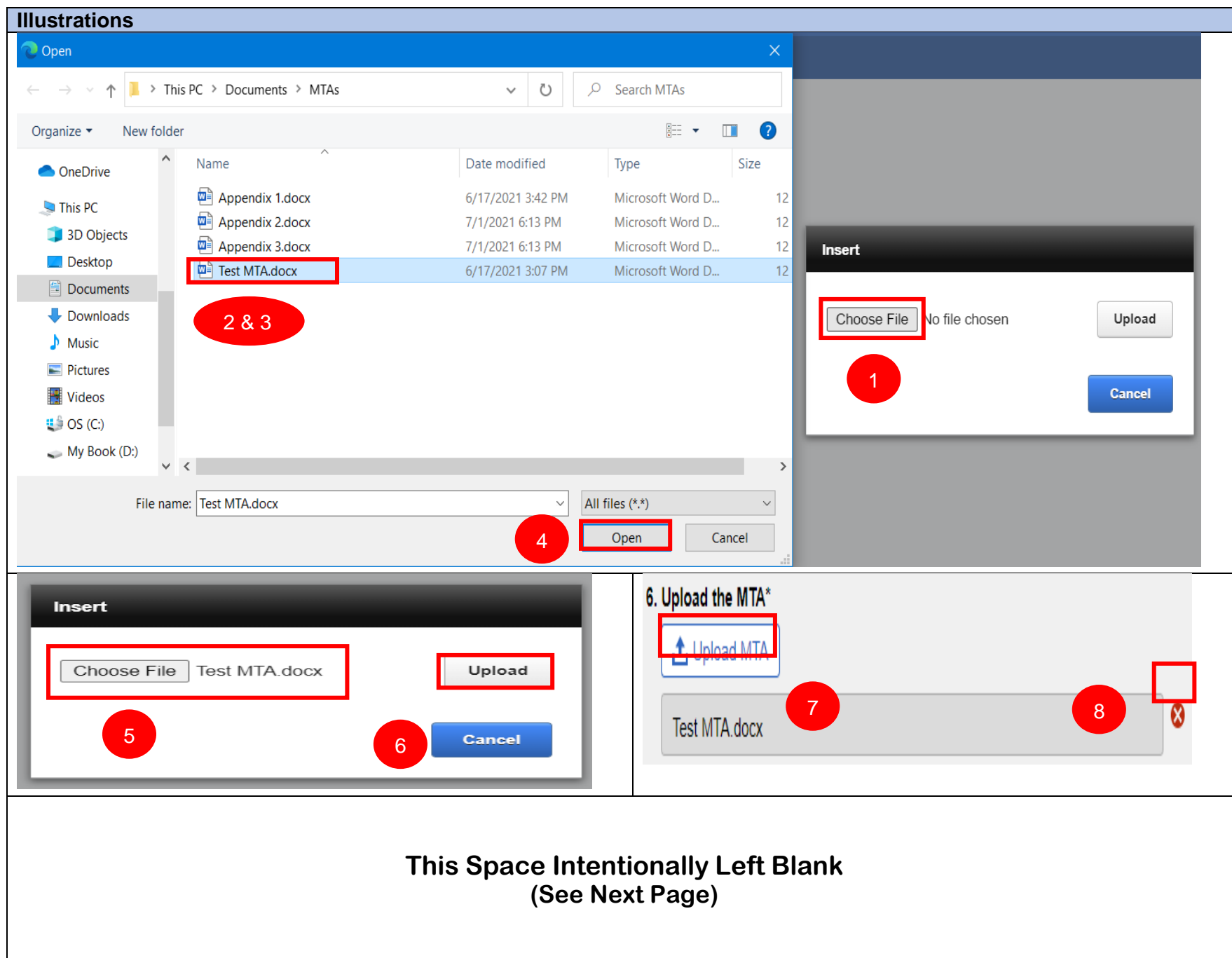
Information / Instructions
The MTA is required. If the document is removed or is not uploaded the MTA submission will not succeed. There are dialog boxes that will appear to ensure the MTA is uploaded.
Illustrations

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 the type document in the gray free text field. |

Illustrations

7. Upload Additional Documents

[↑ Add Document]   Document Type

Appendix 1.docx   [▼]   ⊗

---

6. Upload the MTA*

[↑ Upload MTA]

| Annexure |
| CDC Permit |
| Export Permit |
| Import Permit |
| Other |

Test MTA.docx   ⊗

7. Upload Additional Documents

[↑ Add Document]

Appendix 1.docx   Annexure [▼]   ⊗

---

7. Upload Additional Documents

[↑ Add Document]   Document Type

Appendix 1.docx   Annexure [▼]   ⊗

---

7. Upload Additional Documents

[↑ Add Document]   Document Type

Appendix 1.docx   Annexure [▼]   ⊗

Certificate.docx   Other [▼]   Certificate for Use   ⊗

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 additonal rows will be added as needed and can be viewed by dragging the scroll bar.

Illustrations

Information / Instructions
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.

Illustration

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

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 neeed.

MiLab Central

1. Site: 10: XXXACTG Example Site#1

Study: 0000
(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?*

[⌄]

3. Choose a Pass Through (only if required!)
Is a Pass-Through Lab required for this MTA? [Yes]

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

[⌄]

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

[   ]

6. Upload the MTA*
[⬆ Upload MTA]

7. Upload Additional Documents
[⬆ Add Document]   Document Type

*required for submission

[Submit] [Save & Exit] [Cancel]

MiLab Central

Site: 10: XXXACTG Example Site#1

Start: IExLab1 - 998

Pass-Through: None

Destination: ARUP

Emails: ExampleUser@gmail.com

Document:

Doc_wo_ExpDate.xlsx

Additional Documents:

[Confirm] [Save & Exit] [Back]

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

Illustration

MiLab Central

Please Review Your Selections and Confirm All Information is Correct

Study: A5345

Site: 12001: Example Site 5

Start: HID0257/HID0009 - Example Lab 2 - 410

Pass-Through: BRI - 996 and 999

Destination: Quest - 33

Emails: jsmith@univ.edu, scarr@aol.com
         kbell@gmail.net

2 or 3

Document:

Test MTA.docx

Click "Confirm" if All Entries are Correct

Click "Back" to Return to Prior Screen to Make Corrections

Additional Documents: Appendix 1.docx
                        Certificate.docx

Confirm   Back

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

Illustration

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.

Illustration
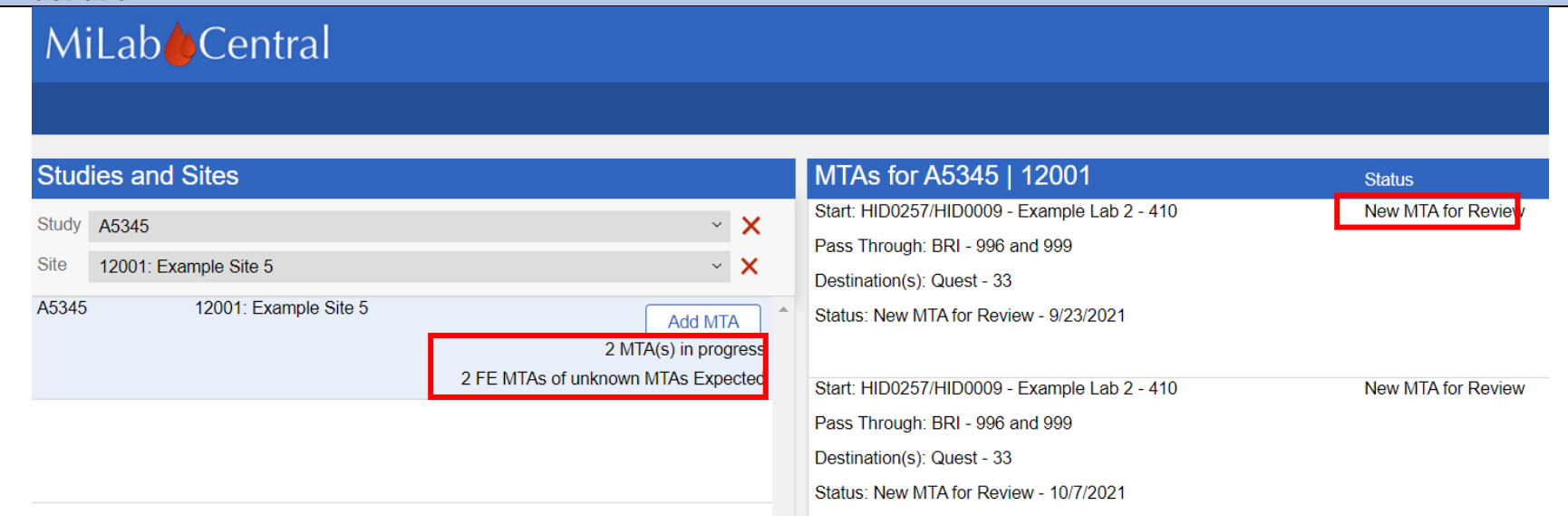
Information / Instructions
Once an MTA is submitted the submission stastus is listed under 'Submissions In Progress' . There is an 'Edit/Review' button for each MTA listed. The button will return the User to Items 1-7 for edits.
Illustration

Information / Instructions	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.
Information / Instructions

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.
Information / Instructions

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.

Illustration

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 verifed 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".

Illustration

Section 10: Downloading MTAs

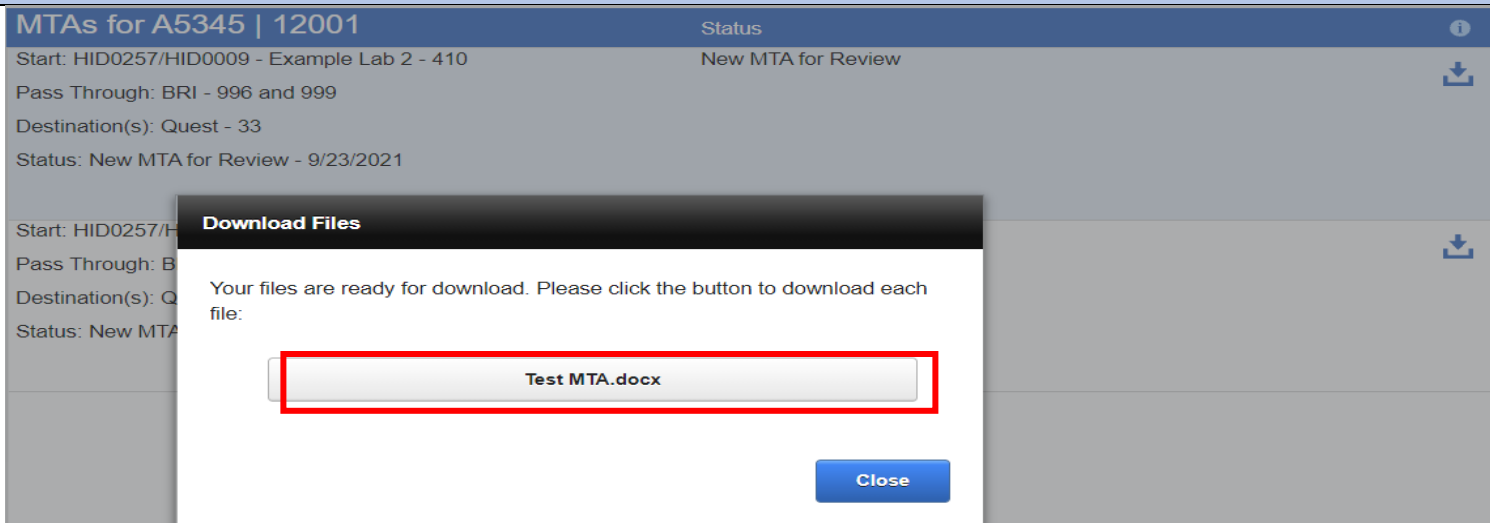| Information / Instructions |
| --- |
| All FE MTAs are archived in the MiMTA module. |
| The MTA file name is revised according to the standard ACTG/IMPAACT LC naming convention (<Study Number>_<Site Number>_Destination Name_ ddmmmyyyy) |
| The final MTA can be downloaded if necessary. To download 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

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.

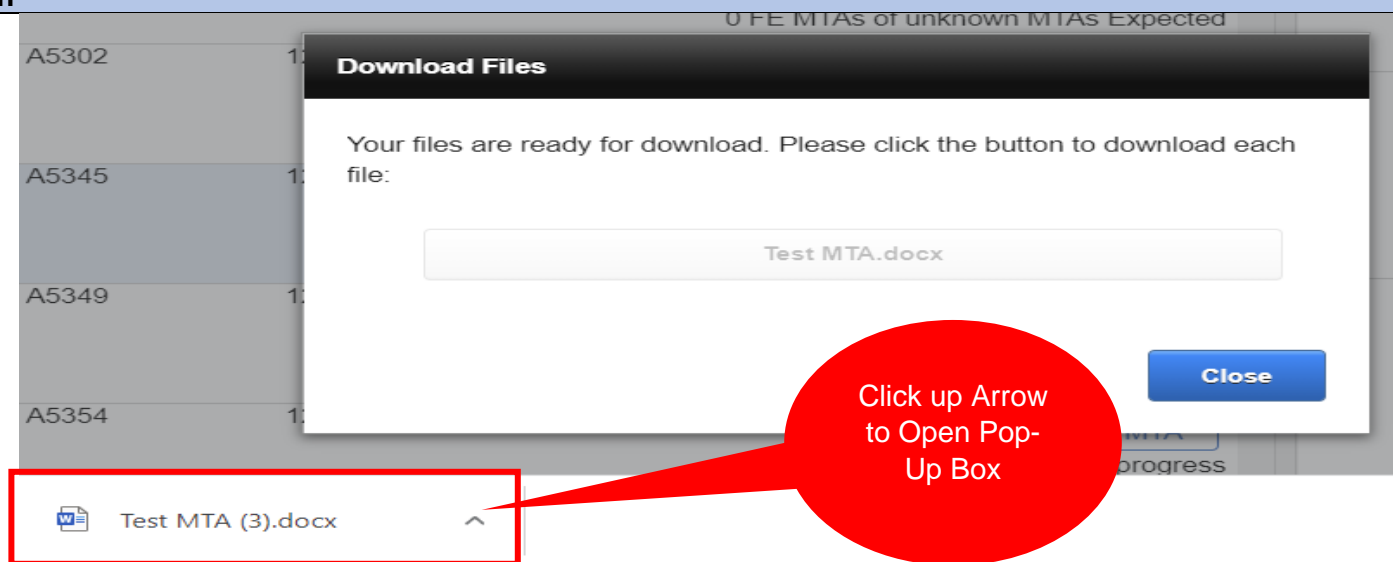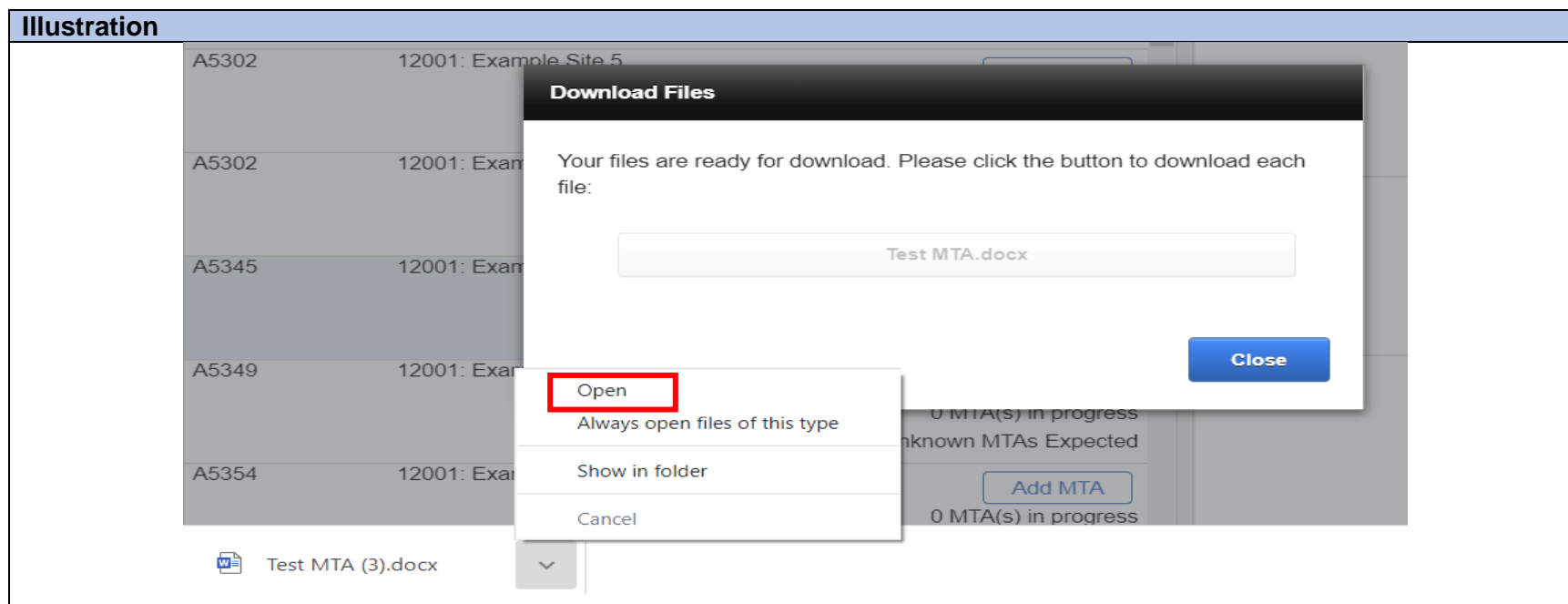## This Space Intentionally Left Blank
(See Next Page)

Illustration

Information / Instructions

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.

Illustration

Illustration

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

Information / Instructions

The Site User panel of tools and features includes the following:
 	
    ● Request New Lab Users
    ● View available and pending MiPALs for the network site's participating studies
    ● Assign a MiPALs reviewer through the MiLab Central website to complete, review and submit each MiPAL to the LC
    ● Navigate between affiliated sites.

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

Information / Instructions

The functions that appear on the Site User page include:
 	
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.
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.
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** (XDemo1 ✕ ⌄)

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)

Illustration (3a/4a)

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

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.
Illustrations

Illustrations

XXXACTG Example Site#1		

Affiliated Labs	Add/Remove User Account ⓘ	Choose Default MiPAL Reviewer ⓘ
IExLab1	Add	Lab Center Help ⌄
XXXACTGLAB01	Remove	**Available MiPALs**

Filter by Study [⌄]

Selection Populates in Gray Reviewer Field

Reviewer

XDemo1 | Protocol Version: 1   Test Account ⌄

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

MiLab Central

🗐 MiMTAs   ⚗ Go to Labs   👤 Request New Lab User

Warning: Back and Forward Browser tools are not supported. Using them will log you out.

Logged in as: ilc_he...

Affiliated Sites	XXXACTG Example Site#1		
10: XXXACTG Example Site#1			
	Affiliated Labs	Add/Remove User Account ⓘ	Choose Default MiPAL Reviewer ⓘ
20: XXXIMPAACT Example CRS#2	IExLab1	Add	Lab Center Help ⌄
	XXXACTGLAB01	Remove	**Available MiPALs**

Filter by Study [XDemo1   ✕ ⌄]   Reviewer

Click

XDemo1 | Protocol Version: 1   Lab Center Help ⌄   Load

Section 3: MiLab Central Laboratory User Account

Section 3.1: Laboratory User Account Features

Information / Instructions
A MiLab Central laboratory account is provided to approved lab staff for the associated study(ies).
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 2. Filter MiPALs listing by 'In Review', 'Awaiting Review', Submitted to LCDCLOT', 'Archived' 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 edit inventory for assigned labs [**NOT an activated function at this time**] 7. Request New Lab User 8. View and download DCLOT and Laboratory Center Approved (Finalized) MiPALs
Illustration

Section 3.2: Managing Supporting Lab Documents

Section 3.2.1: Purpose of Supporting Lab Documents Module

Information / Instructions
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.
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.
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.   1. Lab Director Curriculum Vitae (CV) – *must show affiliation with labs in question and be current within 2 years unless otherwise specified*   2. Lab accreditation certificates   - College of American Pathologists (CAP)   - Clinical Laboratory Improvement Amendments (CLIA)   - South African National Accreditation System (SANAS)   - International Organization for Standardization (ISO)   - Other as applicable   3. Current age-appropriate normal ranges for all assays   4. International Air Transport Association (IATA) or Dangerous Goods Shipping training certificates   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.   6. Clinical Pharmacology Quality Assurance (CPQA) training certificates   7. Centers for Disease Control (CDC) Import Permits
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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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	Illustrations
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 certifcation** 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

Information / Instructions	Illustration
The supporting lab documents module allows only MiLab Central Users to upload documents.	
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.	
Within the section, click on the blue "+ Create New" button in the upper right corner of the document list. A new page opens where the User can complete the document upload.	

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 filed
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".

Illustrations

Submit New Document ✕

* = Required Field *Warning: Back and Forward Browser tools are not supported. Using them will log you out.*

Upload Document*

Drag and Drop or Click Upload..

⬆ Upload

Document Type* ①

Document Name* ②

Lab * ③

Click the Up Arrow Icon to Upload File

Effective Date ④

Expiration Date

Comment ⑤

Related Protocol (If applicable) ⑥

Click to Submit

Submit   Cancel

Submit New Document ✕

* = Required Field *Warning: Back and Forward Browser tools are not supported. Using them will log you out.*

Upload Document*

Drag and Drop or Click Upload..

⬆ Upload

Document Type*

CAP Certification

Document Name*

Drag and Drop to Upload File

Lab *

Effective Date

Expiration Date* Listed on certificate

Certification or ID Number*

Comment

Related Protocol (If applicable)

Submit   Cancel

Instructions/Information

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

MiLab Central

Supporting Lab Documents ⓘ

Updating Documents ✕

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.

By Lab:

By Type:

Current Only: ☐   Number   Effective Date   Expiration Date

XXXAC

CAP Certification - test   🔍

Pending

MiLab Central   MiMT

Supporting Lab Documents ⓘ

By Lab: [▼]   [➕ Create New]

By Type: [▼]

Current Only: ☐   Number   Effective Date   Expiration Date

Other Certificates - 2019   12/31/2018   **12/31/2019**   🔍 ⬇
IMPAACT Lab Certificate
                                            Update..

Update Expired Document   ✕

* = Required Field   *Warning: Back and Forward Browser tools are not supported. Using them will log you out.*

Upload Document*

Drag and Drop or Click Upload..

⬆ Upload

Document Type*

Other Certificates

Document Name*

[   ]

Lab *

Example Lab 3

Effective Date   **Expiration Date**

[   ]   [   ]

Comment

[   ]

Related Protocol (If applicable)

[▼]

[Submit]   [Cancel]

Document Type and Lab are Automatically filled in when Update of Expired Document is Clicked

---

Instructions/Information	Illustration
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.	**MiLab Central** MiMT **Supporting Lab Documents** By Lab: [ ] By Type: [ ] Current Only: ☐ Number Effective Date Expiration Date CAP Certification - test Gray Font ----------Pending Label *Pending*

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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Illustration

Illustration

MiLab Central

MiMTAs   Supply Orders   Study Authorization Certificates for Labs   Go to Sites

Supporting Lab Documents ⓘ

By Lab: [dropdown]   **+ Create New**

By Type: [dropdown]

Current Only: ☐   Number   Effective Date Expiration Date

MiPALs   Study XDemo1 ✕ ⌄   Site [field]

Pending MiPALs ☐ In Progress ☐ Awaiting Review ☐ Submitted to LC/DCLOT ☐ Archived

Information / Instructions

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.

Illustrations

Instructions/Information

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

Illustration

Instructions/Information	Illustration
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.	**Download Files** Your files are ready for download. Please click the button to download each file: Example_Lab_2_7_14_2021_ACTG_LabCertificate.pdf **Close**

Instructions/Information
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.

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

Illustration

Sample ACTG LC Certificate

Download & Print
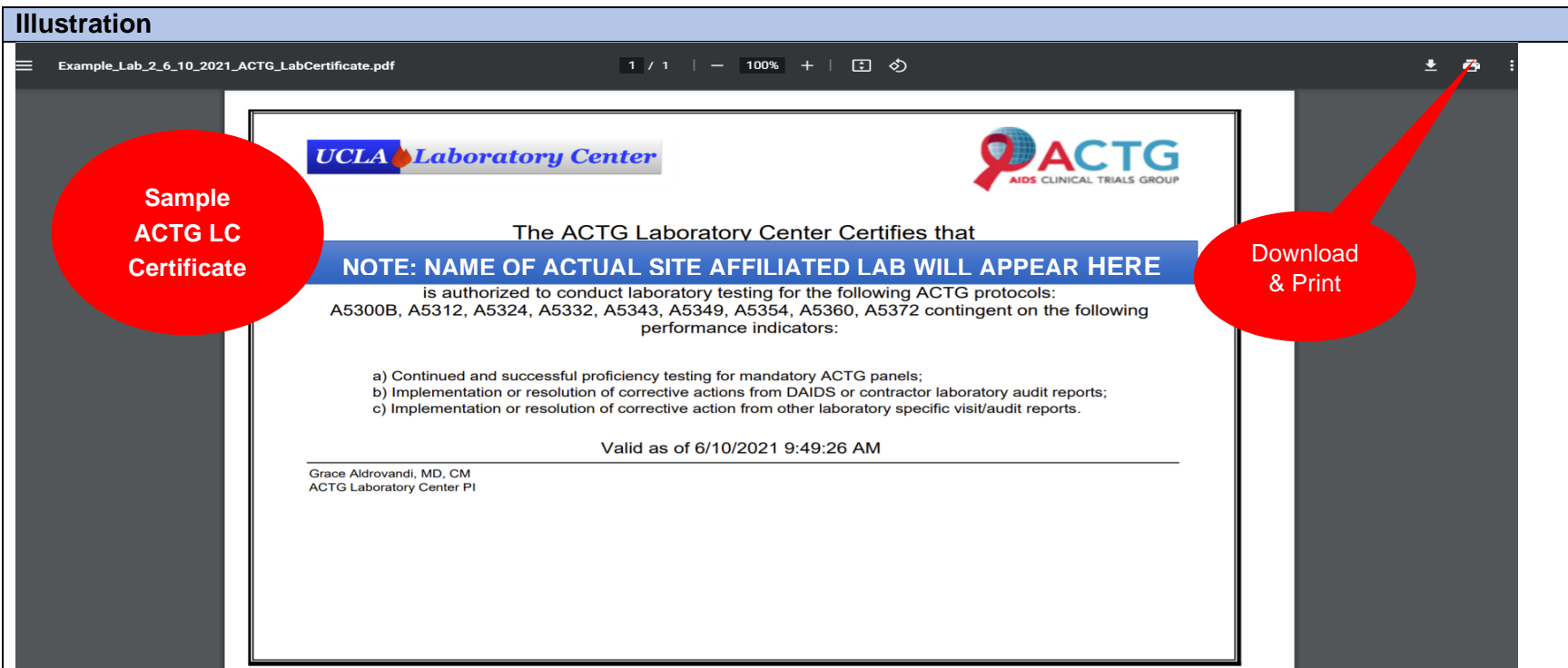
Information / Instructions

If no certifcate is available an "Error" dialog box superimposed over a blank certicate appears.

If there are any questions regarding a presumed missing certificate the network LC contact should be contacted.

The IMPAACT Laboratory Center Certifies that

<<☐☐☐0003D005E00108>>

is authorized to co...
<<☐☐☐0003D005E...

Error

No certificate eligible studies found. If you believe this to be an error please contact the network laboratory center.

OK

a) Continued and successful...
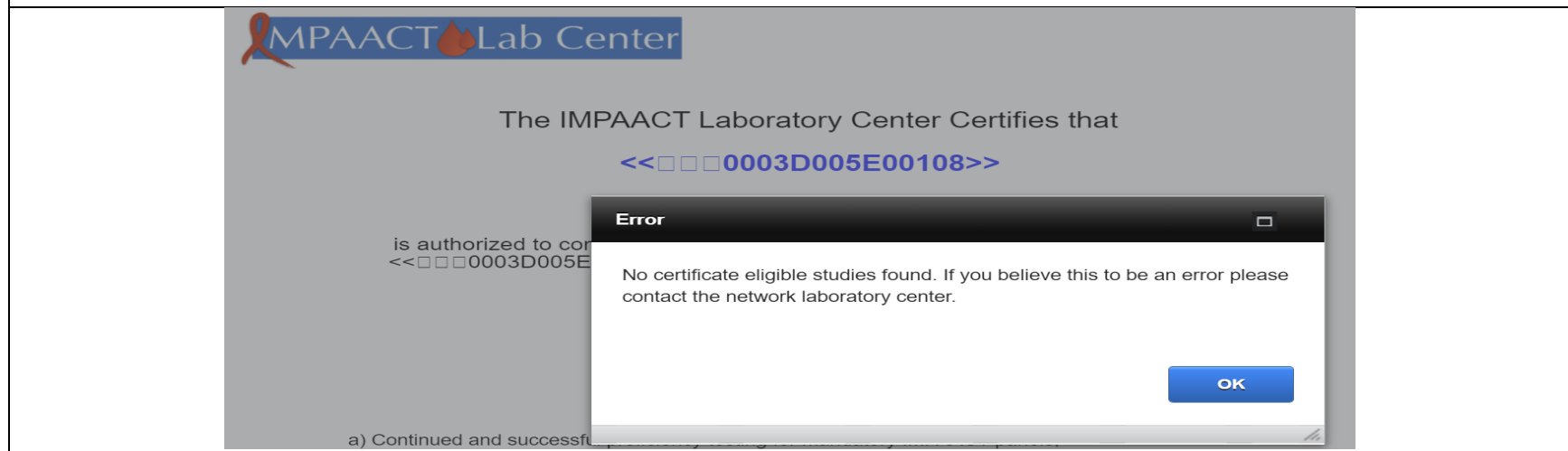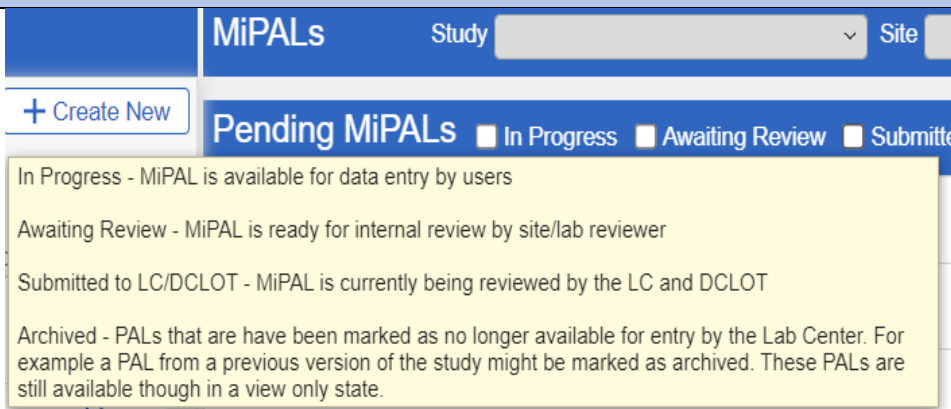
Section 4: MiPAL Workflow

Section 4.1: MiPAL Overview

Information / Instructions
The list of analytes is based upon the study protocol and finalized internally by the network LC.
The network LC contact for each study assigns the MiPALs to participating sites in MiLab Central.
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.
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.
For every new lab, instrument and method submission is required to be approved by the network LC.
MiPAL Submission is a two-step process. 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. 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".

Section 4.2: Accessing MiPAL

Information / Instructions
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.
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.

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.

Information / Instructions	Illustration
Hovering over the filter options opens a description of each function	

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

Illustration

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.

Illustration

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Information / Instructions
The copy feature is useful in cases where a user is working on MiPAL entry for <u>two sites that use the exact same labs for testing.</u> 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

Information / Instructions
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
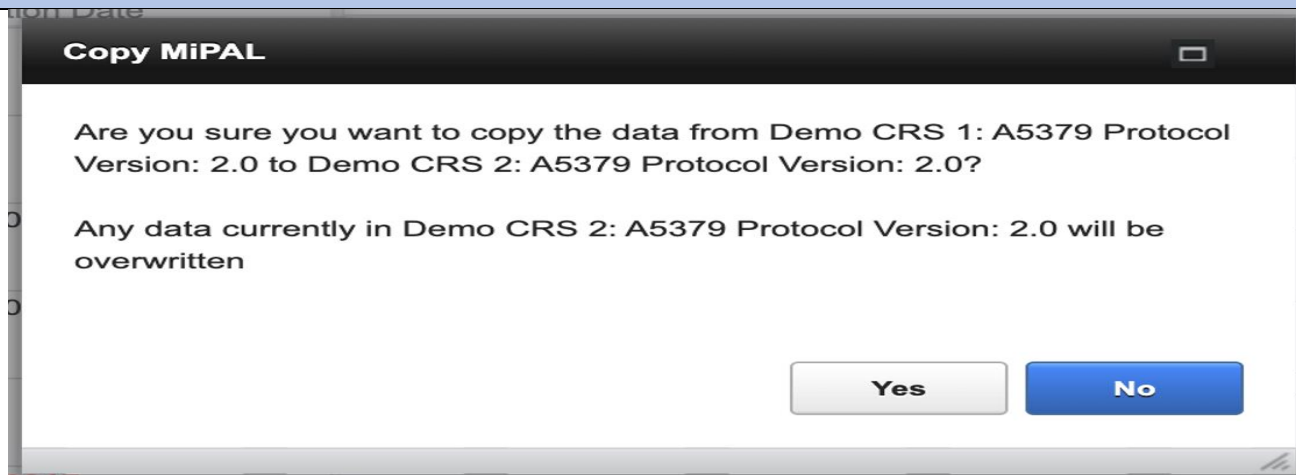
Information / Instructions

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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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

A5362: Example Site 5
MiPAL Version: 0
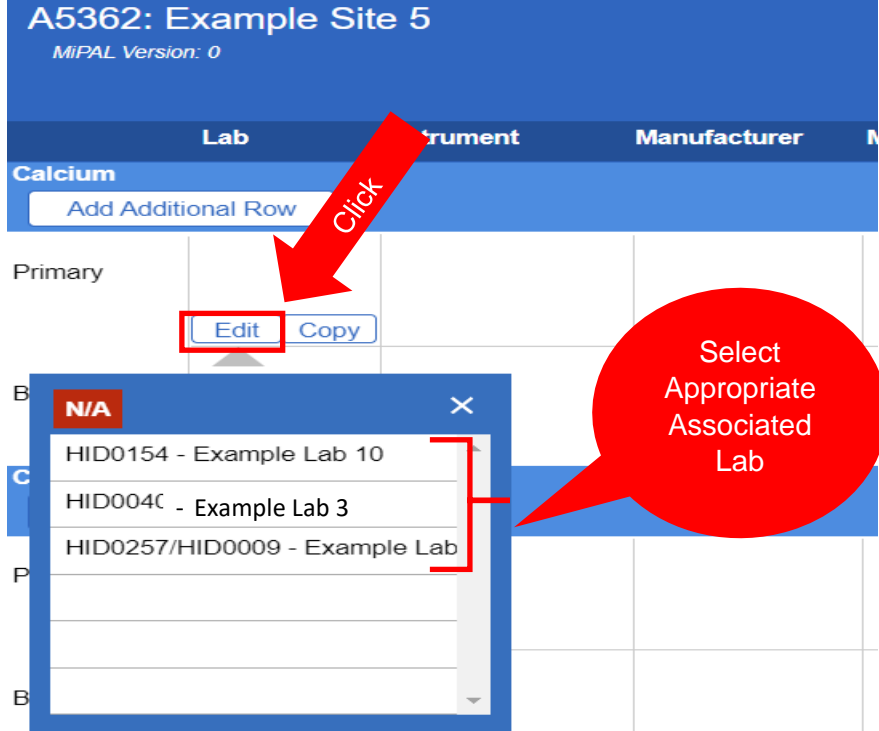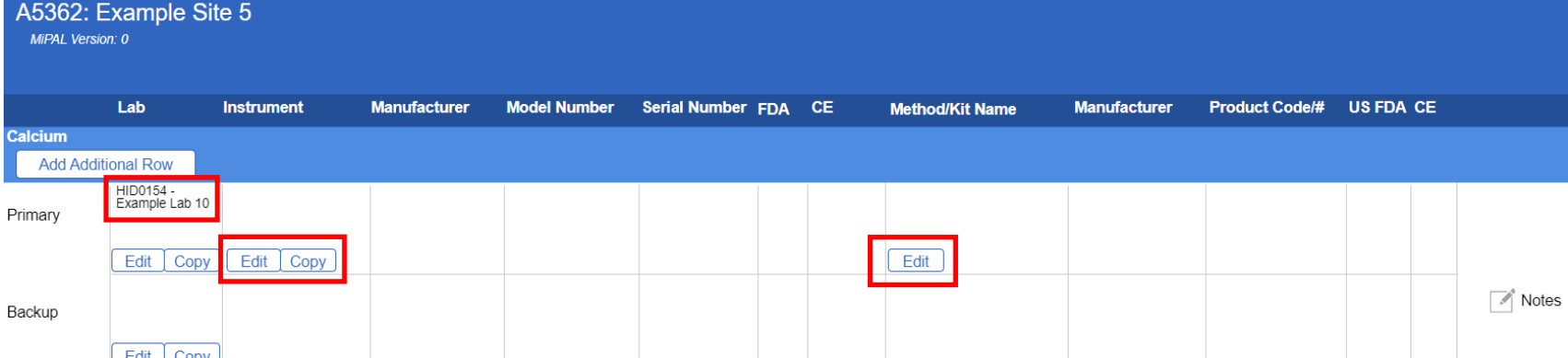
Header & Data Columns
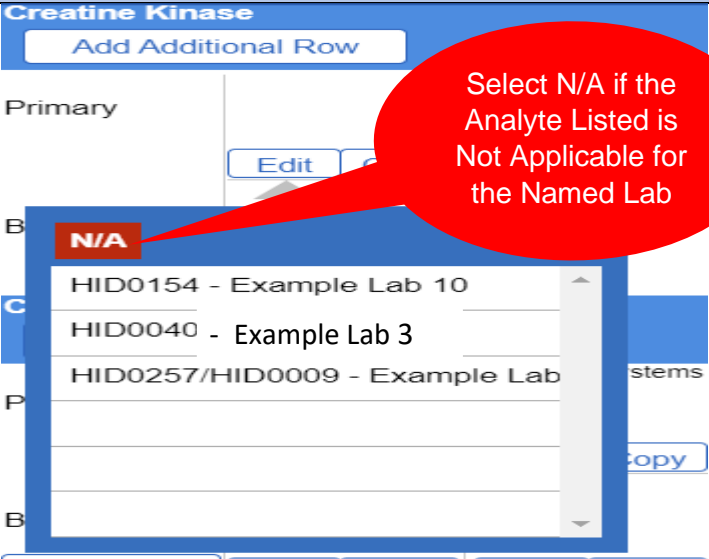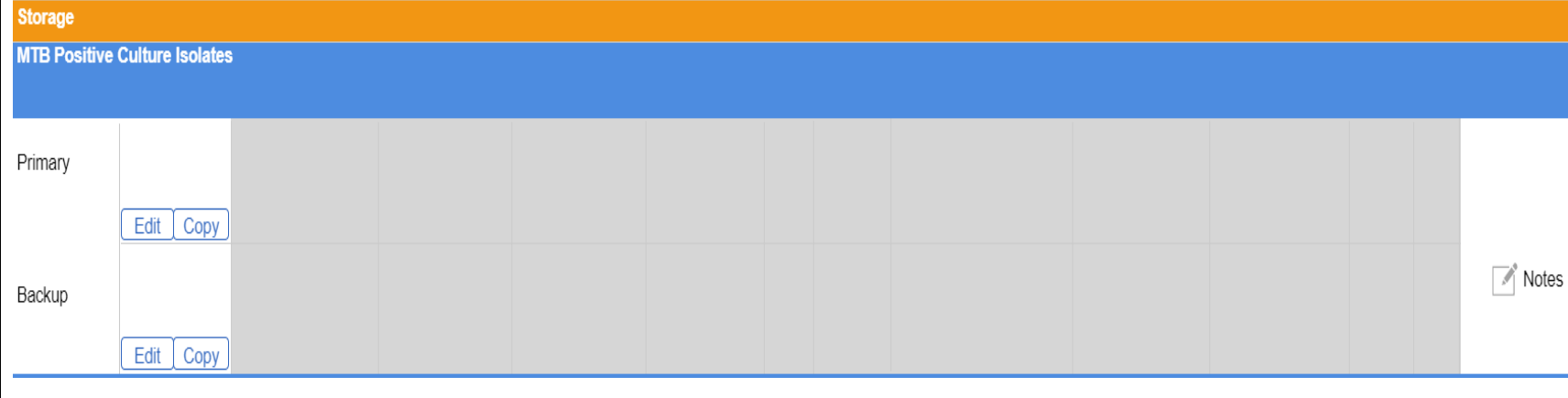
Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE

Calcium

Add Additional Row   1   2   3

Primary

Edit | Copy

Backup

Edit | Copy

✎ Notes

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(See Next Page)

Section 4.3.2: Selecting Laboratory Name

Information / Instructions	Illustrations
"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.	

Information / Instructions
Once the correct Lab is chosen, "Edit" options for instruments and methods linked to the selected laboratory become available.

Illustration

Information / Instructions	Illustration
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.	

Information / Instructions
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

Illustration

Information / Instructions

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' [Notes icon] to open dialog box. Then click '+Add Note'. Notes are cumulative, all prior notes will be visible. The most recent entry is listed first.

Illustration

Illustration	
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.	
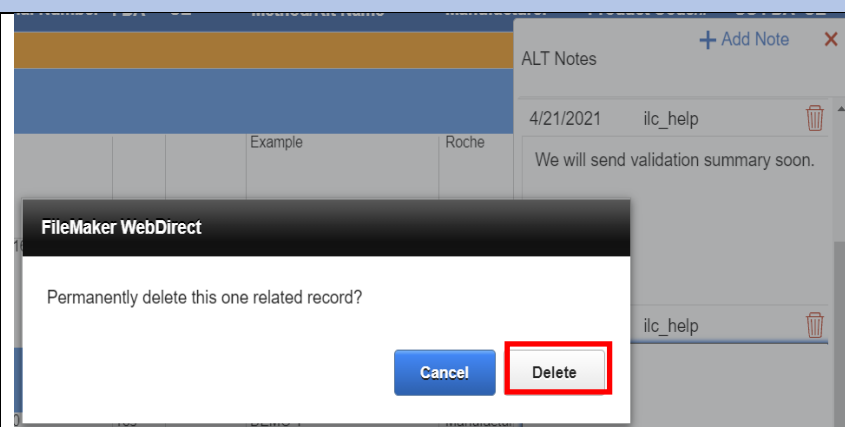
Section 4.3.3: Selecting Instruments and Methods

Information / Instructions
After selecting the "Lab", clicking on "Edit" under "Instrument" and Method/Kit Name" will reveal a list of the <u>laboratory's approved instruments or methods.</u>
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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Illustration (Instruments)

Select Primary Instrument for ALT (SGPT)

| | | Mark as Manual | ☐ Show Full Inventory | ☑ Show Chemistry Instruments Only | | Can't find what | 🔍 |

Search Bar – Type and Click

	Name	Manufacturer	Model Number	Serial Numb...	...d
Select	COBAS C System	Roche	COBAS c311	1201-08	Yes ⌄	⌄
Select	Manual Method - Creatinine Clearance (calculated)			N/A	⌄	⌄
Select	Manual Method - Globulin, Calculated value			N/A	⌄	⌄

Click Select Next to the Appropriate Instrument

Illustration (Instruments)

Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE
Chemistry											
ALT (SGPT)											
Add Additional Row											
Primary	HID0040 - Example Lab 1	COBAS C System	Roche	COBAS c311	1201-08	Yes					
	Edit Copy	Edit Copy					Edit				
Backup	HID0154 - Example Lab 2	cobas c311	Roche	1208-05		Yes	ALTL	Roche	20764957		📝 Notes
	Edit Copy	Edit Copy					Edit				

Selected Instrument Loads Data in Primary Analyte Row

Illustration (Methods)

Select Primary Method for ALT (SGPT)

Search Bar Type & Click

☐ Show Full Inventory   ☑ Show Chemistry Methods Only

Can't find what you're looking for? Search by name...

	Name	Manufacturer	Product Code/Number	FDA Approved	CE Marked
Select	ALB2	Roche	3183688122	Yes	
Select	ALP2L	Roche	03333701	Yes	
Select	ALTL	Roche	20764957	Yes	
Select	ASTL	Roche	20764949	Yes	

Click to Select Appropriate Method

Illustration (Methods)

	Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE
Chemistry												
ALT (SGPT)												
Add Additional Row												
Primary	HID0040 - Example Lab 1	COBAS C System	Roche	COBAS c311	1201-08	Yes		ALTL	Roche	20764957	Yes	
	Edit Copy	Edit Copy						Edit				
Backup	HID0154 - Example Lab 2											
	Edit Copy	Edit Copy						Edit				

Selected Method Automatically Fills in Data in Primary Analyte

✎ Notes

Information / Instructions
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.
Illustration

Information / Instructions

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)

Illustration (example of Adding a New Method)

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

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 slected.   - 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
MiPAL Version: 0

	Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE
	Edit Copy											

Calcium
Add Additional Row

Primary	HID0154 - Example Lab 10	COBAS C Systems	Roche	COBAS c311	SN 1208-05 and SN 1465-09	Yes		ALB2	Roche	3183688122	YES	
	Edit Copy	Edit Copy						Edit				
Backup												Notes
	Edit Copy											

Creatine Kinase

N/A	×
HID0154 - Example Lab 10	
HID0040 - COM-JHU RP	
HID0257/HID0009 - Example Lab	

P												
B												Notes
C												

	Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE
	Edit Copy											

Calcium
Add Additional Row

Primary	HID0154 - Example Lab 10	COBAS C Systems	Roche	COBAS c311	SN 1208-05 and SN 1465-09	Yes		ALB2	Roche	3183688122	YES	
	Edit Copy	Edit Copy						Edit				
Backup	HID0257/HID0009 - Example Lab 2											Notes
	Edit Copy	Edit Copy						Edit				

	Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	CE	Method/Kit Name	Manufacturer	Product Code/#	US FDA	CE
	Edit Copy											

Calcium
Add Additional Row

Primary	HID0154 - Example Lab 10	COBAS C Systems	Roche	COBAS c311	SN 1208-05 and SN 1465-09	Yes		ALB2	Roche	3183688122	YES	
	Edit Copy	Edit Copy						Edit				
Backup	HID0257/HID0009 - Example Lab 2	ALINITYi	ABBOTT	Alinityi	Ai 01825/Ai 01867	Yes		Bromcresol Green	ROCHE	3183688122	YES	Notes
Set Default	Edit Copy	Edit Copy						Edit				

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

Illustrations

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

Information / Instructions	Illustration
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. 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
Analyte 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

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

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

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Section 4.4: Final Lab Review – Reviewing Data Entered into MiPALs

Information / Instructions
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.
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.

Information / Instructions
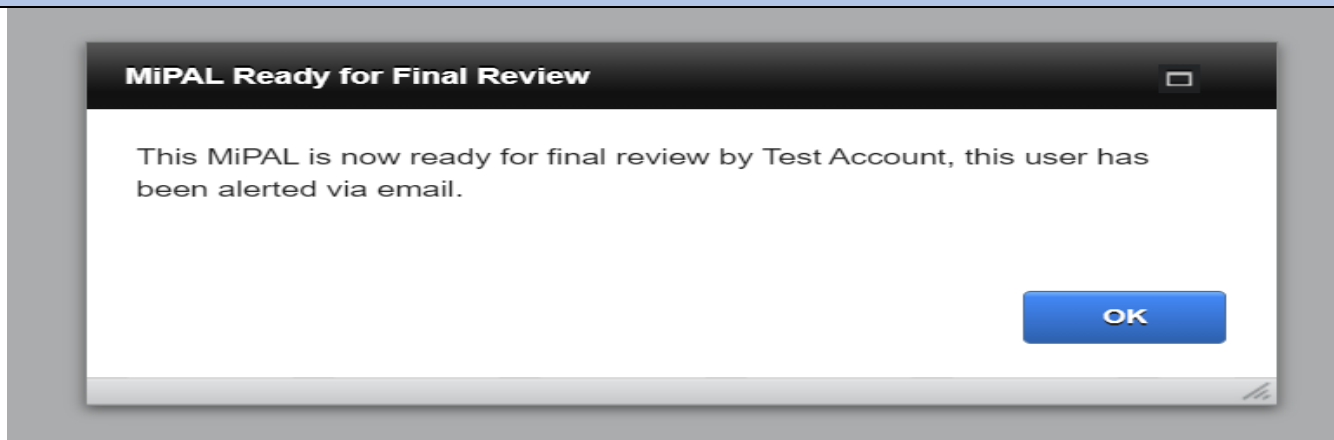
Illustration
In the "Pending MiPALs" select the Study and Site from the drop-down list. MiPALs that have been completed and are awaiting final [internal] review prior to submission to the LC will be marked with the phrase "MiPAL Awaiting Review Before LC Submission" alongside the associated protocol under the "Pending MiPALs" module.
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.

Illustration
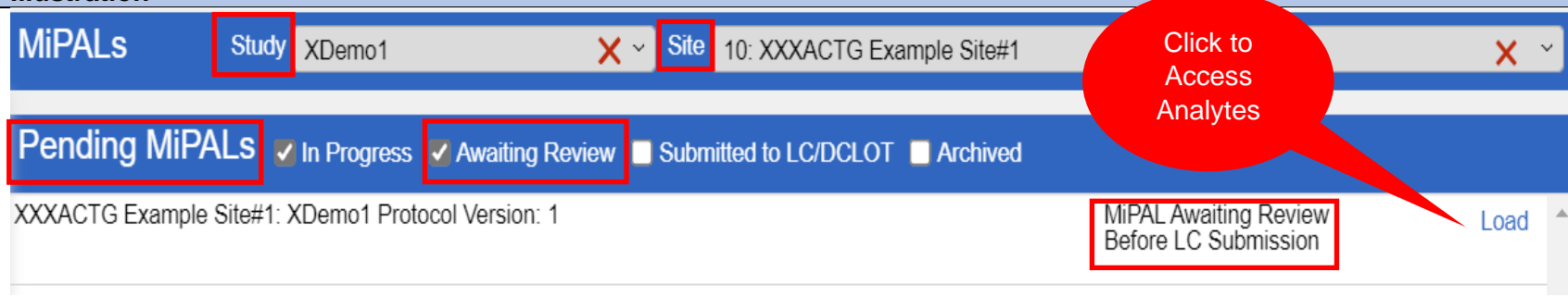
Information / Instructions
The system will verify the completeness and the reviewer will verify accuracy of all data entered. An error dialog box will appear if any required field is left blank. **NOTE:** The requirement is each line must have a primary lab, instrument, method and a backup lab, instrument, 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
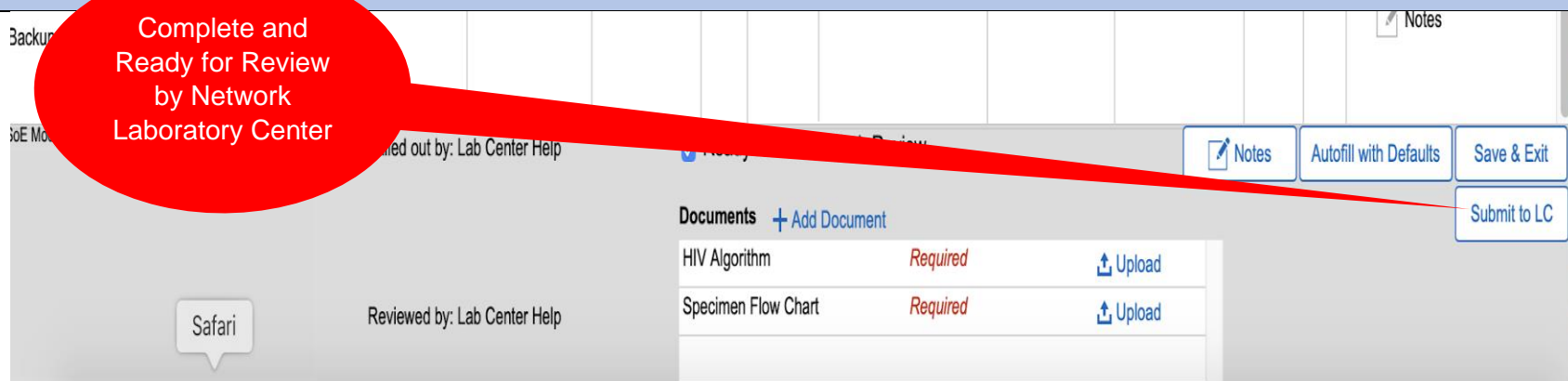
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Section 4.5: MiPAL Data Review by Network Laboratory Center

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

Information / Instructions
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 listings can be located on the lower right-hand corner of the home screen under "DCLOT and Lab Center Approved MiPALs".
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

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
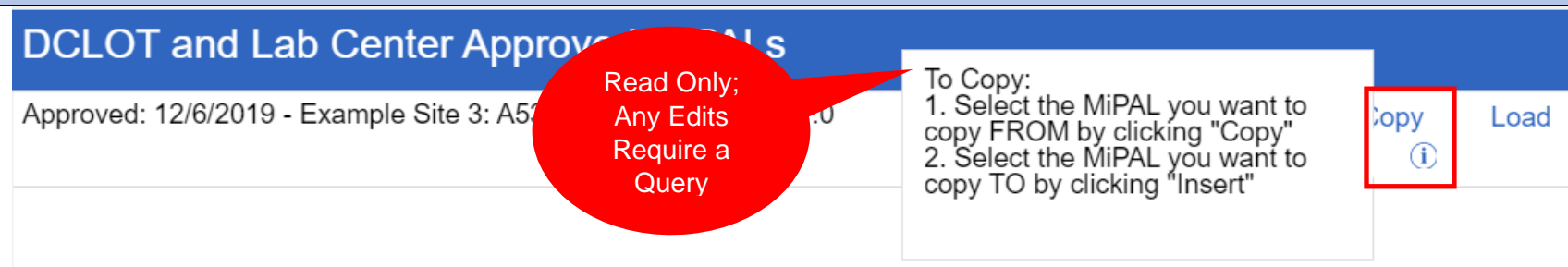
Illustration

Demo CRS 1: A5375 Protocol Version: 1.0

1
(Loaded)

MiPAL Version: 1.0 IND Study: No   READ ONLY: This MiPAL cannot be edited as it has already been ... to make edits

Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	Method/Kit Name	Manufacturer	Product Code/#	US FDA	Provider	Panel Details
Chemistry											
Albumin											
Primary HID0040 - COM-JHU RP	cobas c311	Roche	4715MS-10T B30		Yes	ALB2	Roche	3183688122	Yes	CAP	C
Backup HID0154 - Lilongwe	cobas c311	Roche	1208-05		Yes	ALB2	Roche	3183688122	YES	CAP	C

Illustration

Download Files

2

(Download)

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
1. ...

Click to Download File

Close

Illustration

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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Illustration

Warning: Back and Forward Browser tools are not supported. Using them will log you out.

Demo CRS 1: IMPAACT 2009 Protocol Version: 1.0

PAL Version: 2.0 IND Study: Yes   READ ONLY: This MiPAL cannot be edited as it has already been submitted. Request a Query to make edits

	Lab	Instrument	Manufacturer	Model Number	Serial Number	FDA	Method/Kit Name	Manufacturer	Product Number	US FDA	Provider	Panel Details
Chemistry												
ALT (SGPT)												
Primary	Demo	cobas c311	Roche	4715MS-10T B30		Yes	ALTL	Roche	20764957	Yes	CAP	C
Backup	Demo	cobas c311	Roche	1208-05		Yes	ALTL	Roche	20764957	Yes	CAP	C

Filled out by:Alex Siyasiya   Reviewed by: Dean Soko   Documents   [Request LC Query]

Information / Instructions
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

Filled out by: Lab Center Help

☐ Ready for Final Review Before LC Submission   [Notes]

Documents + Add Document

HIV Algorithm   *Required*   ⬇ Download   ⬆ Upload

Reviewed by: Lab Center Help

imen Flow Chart   *Required*   ⬇ Download   ⬆ Upload

Name of Lab User & Reviewer Completing

Information / Instructions
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

A5375: Version: 1.0 | PAL Version: 1.0 for 30301: Demo CRS 1   **Checked Approved**

IND Study:
PAL Version: 1.0   Completed by:
Letter of Amendment:
Clarification Memo: 1.0
Approved: 10/__/____   Reviewed by:
LC Reviewer: Sara Zabin
Date PAL First Checked ...
DCLOT First Reviewer: Sambasiva Ghanta
Date PAL Approve...
DCLOT Reviewer: Daniella Livnat

Lab	Instrument Name	Instrument Manufacturer	Instrument Model Number	Instrument Serial Number	FDA Approved	Method/Kit Name	Method/Kit Manufacturer	Method/Kit Model Number	US FDA Approved	External EQA Provider	EQA Panel Details
Chemistry											
Albumin											
Primary											
Demo	cobas c311	Roche	4715MS-10T B30		Yes	ALB2	Roche	3183688122	Yes	CAP	C

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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.

Acronym / Term	Definition
ACTG	AIDS Clinical Trials Group
ACTG Laboratory Center (ALC)	Responsible for laboratory activities associated with ACTG sponsored clinical trials. This group is located at the University of California Los Angeles (UCLA).
ACTG MTA Team	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 ACTGMTA@fstrf.org email address. This email is used to monitor all communications related to MTAs.
AIDS	Acquired Immunodeficiency Syndrome
Biomedical Research Institute (BRI):	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.
CRS	Clinical Research Site
DAIDS	Division of AIDS
DCLOT	DAIDS Clinical Laboratory Oversight Team
Supporting Documents	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.
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials
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
Laboratory Processing Chart (LPC)	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
Laboratory Specialist (LS)	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

Acronym / Term	Definition
LDMS	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.
Listserv	ACTG or IMPAACT mailboxes
Material Transfer Agreement (MTA)	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)
MiLab MTA Module	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)
MTA Coordinator (MTAC)	ACTG Laboratory Center (ALC) staff member responsible for coordinating and facilitating the Material Transfer Agreement (MTA) process
NIAID	National Institute of Allergy and Infectious Diseases
Network	IMPAACT or ACTG clinical trials
Network Laboratory Center (LC)	Responsible for laboratory activities associated with ACTG or IMPAACT sponsored clinical trials.
Network Laboratory Center (LC) Contact	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.
MiMTA	The portion of MiLab Central that is used to electronically track the requirements, creation and tracking of material transfer agreements.
MiPAL Module	The portion of MiLab Central that is used to electronically track the Protocol Analyte List (PAL)
Patient Safety Monitoring in International Laboratories (pSMILE)	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: https://psmile.org/index.cfm).
Primary User	The Lab User who enters analyte information and is different than the Reviewer

Acronym / Term	Definition
Protocol Analyte List (PAL)	The PAL lists all the tests that will be performed by a laboratory to support a site for a specific protocol.
Provider	Institution from which transferred samples originate (sometimes referred to as "Start Lab")
Recipient	The destination institution of transferred study samples
Site User	A user based at the study site with approved access to MiLab Central
UCLA	University of California Los Angeles

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CHAPTER 5: Revision History

Version	Date	Author	Change	Rationale
1.0	dd/Nov/2021	XX Group	N/A – Initial document	This user guide was created to aid MiLab Central Site and Lab Users in completing system processes. • Screen shots of all user actions included with text to enhance understanding. • 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.