

1. How to Complete a MiPAL (Title Slide)

2. Topic Overview

This video tutorial covers the following topics:

- Loading a MiPAL,
- Required Information for a MiPAL, and
- Completing a MiPAL.

Note: We will use the terms MiPAL and PAL interchangeably to refer to a protocol analyte list within MiLab.

3. Loading a MiPAL

Once a MiPAL is available, the MiLab Central users from the site and any affiliated laboratories will receive an email notification that the MiPAL is available to be completed within the MiLab Central Portal. If the laboratory is supporting multiple studies or even multiple sites, the MiPAL list can be filtered to easily find and access the PAL you want to work on. And for the heavy-duty users, the list can be further refined by PAL status within the approval process.

So, looking to the MiLab homepage. Under the list of Pending MiPALs, that's where you will see a list of all of the PALs that are able to be worked on. So, selecting the one that you want to work on in your current session, go over to the far right, and click "Load." This will load the PAL and bring you to a new screen.

4. Required Information for a MiPAL

All the study required analytes are listed and organized under test categories, for example Chemistry, Hematology, Virology, et cetera. So, here you see the Chemistry test grouping with all of the chemistry analytes: Albumin, ALT, AST, et cetera. And as you scroll down, you will see the additional test categories. So, for each analyte listed you will be required to provide two sets of information.

The first is specific details of the instrument, including the instrument name, manufacturer, model number, and serial number. Secondly, you will provide the method or reagent kit name, the manufacturer, and product details. This information will be verified by the Lab Center against any validation documents you submit in support of your testing requirements, as well as verification of the FDA approval and/or the CE status. It's critical that you take care to ensure that all the information entered is complete and accurate, as any discrepancies or missing information will be flagged during review and the PAL will require revision. Remember, this is a regulatory document subject to audit and must accurately reflect all the details of your testing plan.

5. Completing a MiPAL

When completing a MiPAL, users are required to provide both primary and backup testing information. We'll use Chemistry: Albumin as an example to demonstrate how to enter primary testing information on a MiPAL. Here you see the Primary, that refers to your primary testing laboratory. So, to enter the lab, here we have it completed for you, but for example if you wanted to change the lab you would select the little pen icon and that will pull up a list of any of the site's affiliated laboratories. The lab user should select the applicable laboratory. Here we've chosen an example IExLab1. Next, you will complete the instrument information. Again, under the instrument column select the little pen icon and that will give you a list of the laboratory's inventory of instruments. Now, you can filter this list by showing only the instruments that are applicable to the test category. In this example, showing the Chemistry instruments only. Or if needed, you can filter to show the entire laboratory's full inventory. You would then review the inventory list and select the instrument that is applicable for the current test. So, as this is an example, we'll just select New Instrument. And you will see that information details populate under the instrument fields.

The same process will be used for the method. Again, select the pen icon under the Method column. Review the inventory list and select the method applicable to the testing. So, again we'll just use an example here. And again, you see the details populate for you. As needed, you can adjust the FDA and CE status. Again, these will be reviewed by the Lab Center and DCLOT, and matched against the product codes and model number of the instrument submitted.

6. How to Complete a MiPAL (End Slide)

This concludes the How to Complete a MiPAL video tutorial. Additional information about using MiLab is available on the ACTG IMPAACT Laboratory Center website, which is available at www.actg-impaaact-lc.org/.