

Country Setup

Setup Overview

Study Owners can create new countries in the eTMF with the Country Wizard.

[CTMS data](#) defines which countries can be created.

Starting the wizard for a Country creates the Country in a Draft state, where no documents can be added until the Country is activated.

The country remains in a Draft state until the wizard is finished successfully.

A Wizard can be saved and resumed multiple times as necessary.

Running the Country Wizard

From the Actions Menu on a Study's home page, select Activate Country in eTMF.

The Country Wizard includes the following steps:

1. Country Template
2. Questions
3. Principal Investigator Placeholders
4. Sub Investigator Placeholders
5. Country Vendors
6. Add Additional Items
7. Final Review

Country Template

The Country Template step allows you to see the list of documents that you get for this country based upon the execution of the Study Wizard. This step allows you to select the Functional Line or specify document-type specific Additional Attributes for each item, if applicable.

1. Review the list of documents to be aware of the list of

- country items you will automatically get in your TMF.
2. For any items that are listed, you can change/select the preset Functional Line and Additional Attributes as necessary.

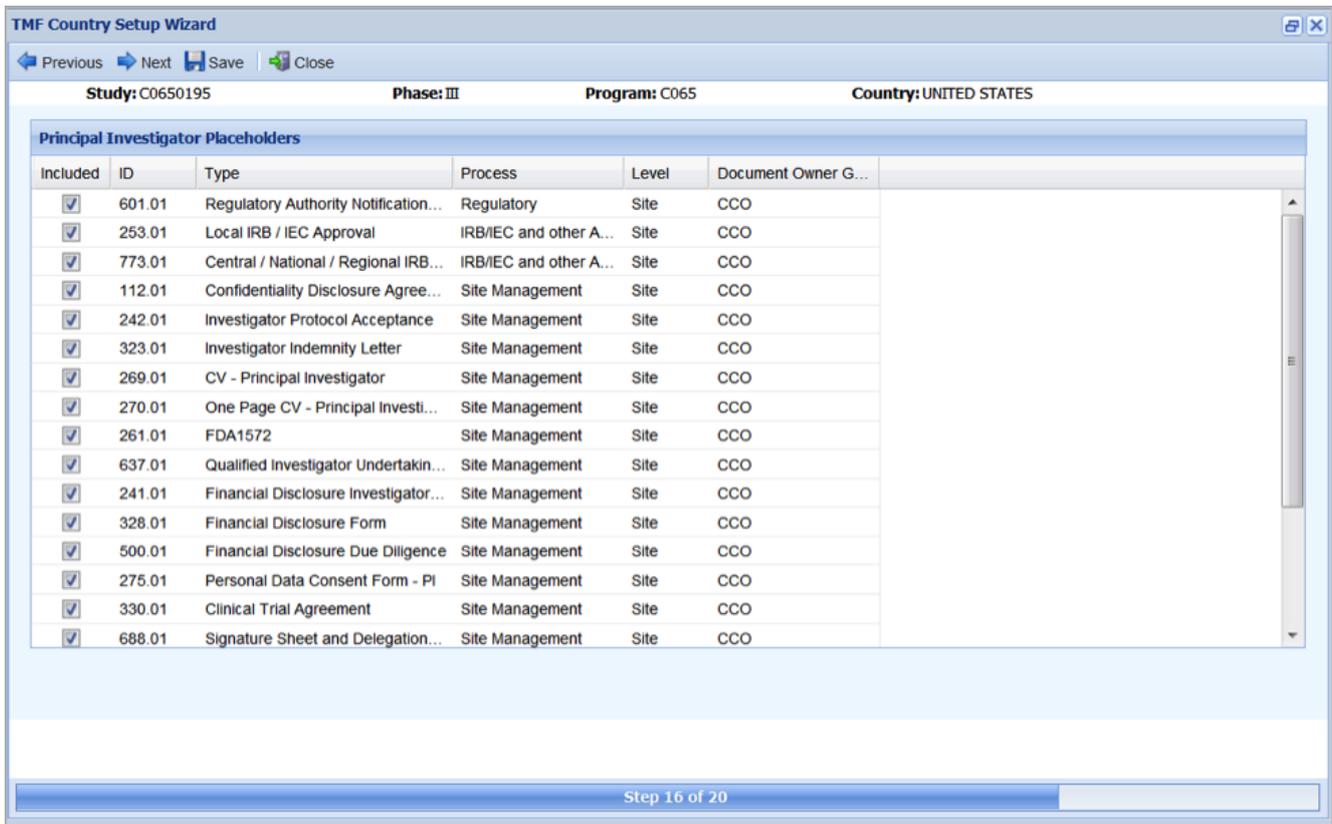
Answering Questions

The Questions steps are like the Questions steps during the [Study Wizard](#), except with country-specific questions.

Setting Up Principal Investigator Placeholders

The Principal Investigator Placeholders step allows you to define the Master Items that are associated with each new principal investigator for which there is information about from the CTMS Data Feed. Any items selected in this step will be created for each new principal investigator for sites associated with this country.

1. Review the list of possible items for a new principal investigator to see if they apply for this country.
2. Deselect any of the items that you do not want to include in this study for new principal investigators.
3. For any items that are still selected, select Functional Line as necessary.



Setting Up Sub Investigator Placeholders

The Sub Investigator Placeholders step allows you to define the Master Items that are associated with each new sub investigator for which there is information about from the CTMS Data Feed. Any items selected in this step will be created for each new sub investigator for sites associated with this country.

1. Review the list of possible items for a new sub investigator to see if they apply for this country.
2. Deselect any of the items that you do not want to include in this study for new sub investigators.
3. For any items that are still selected, select Functional Line as necessary.

Country Vendors

This step allows you to define vendors that will be used at the country level for this study. Defining a vendor (and its associated vendor type) will determine a list of master items

needed for that vendor. If you have no vendors at the Country level, you can simply move to the next step.

How to Add Country Vendors

1. Click on Add Country Vendor.
2. Select a Vendor from the list of vendors within the TMF application.
3. Select a Vendor Type from the list of Vendor Types defined within the TMF application. Selecting a Vendor Type will display the list of master items that are associated to that vendor type.
4. Deselect any of the items that you do not want to include in your TMF for this vendor.
5. For any items that are still selected, select Functional Line as necessary.
6. When the items for this vendor are complete, click Save. The vendor will be added to the Country Vendors screen.

Add Additional Items

This step allows you to select other master items that are associated with a milestone, but are not associated with any questions, vendor types, new subjects, new primary investigators, or new sub investigators. You have the ability to add any of these other items as necessary for the study.

1. Review the list of items presented to see if they apply for this study.
2. Select any of the items that you want to include in this study.
3. For any items that are selected, select Functional Line and complete Additional Attributes as necessary – see Core Items step above for description of these steps.

Final Review

The Final Review step is similar to the Final Review step

during the Study Wizard, except the tabs are appropriate for the sections executed in the Country Wizard.