Complion eRegulatory Quick User Guide

Website: <https://app.complion.com>

Section 1: Adding New Users to Complion

Section 2: Updating Data Sources in Drop Down Menus

Section 3: Creating a New Study Binder

Section 4: Filing/Naming Documents in the Study Binder

Section 5: Giving Users Permission to View a Study Binder

Section 6: Sending a Document for Signature

Section 7: Changing a Document Name or Attribute

Section 8: How to Remove a Document from the Binder

SECTION 1: Adding New Users to Complion

All study team members should have access to Complion so that they can complete the necessary documentation needed for a clinical trial.

Admin access is needed in order to add a user to the Complion platform.

You will need the following information to add a user:

Full Name

eMail address

UC 6+2 & UC M# (if the user is to log in with single sign on)

1. Click on the Admin key in the upper right toolbar.
2. Click the “Create User” button in the upper left toolbar
3. Enter information: Pay special attention to being perfect in spelling and entry as this will be the permanent record in Complion.
   1. EMAIL ADDRESS: This should be the email the new user uses the most & wishes to receive Complion email correspondence.
   2. DISPLAY NAME: First & Last Name of new user
   3. FIRST NAME: First Name of new user
   4. LAST NAME: Last Name of new user
   5. GROUPS: You will need to select two groups in order to add a user to Complion: All Users and The role assigned to the individual in the system. To select more than one role hold the “CTRL” key when selecting the roles
   6. LOGIN METHOD: There are 2 ways by which a new user can log into Complion. Users can use their UC 6+2 single sign in information or, if they are a person external to UC & do not have a 6+2 login, they can login using a Complion username & password
      1. Single Sign On UC 6+2 Users: Select “University of Cincinnati (saml)”. The UCID (M Number) field will appear. Enter the new user’s M- Number, being sure to include the M. (i.e. M98765432)
      2. Complion Username & Password: Select Password.
4. Click the Create User button at the end of the entry.
5. The new user will be sent a welcome email, which will prompt them to log in for the first time. First time login must only occur from the link in the email.
   1. If you need to RESEND THE WELCOME EMAIL to the new user, the following is required:
      1. Click on the Admin key in the upper right toolbar
      2. Select the Users tab (will appear blue when selected)
      3. Find the new users name, this can be done using the search feature or by scrolling down thru the list.
      4. In the right of the user’s box is the Quick User Actions Menu, choose Account Reset. This will send the new user another welcome email.

SECTION 2: Updating Data Sources in Drop Down Menus

Prior to creating a new study binder, or to adding a new user to your study, you must first update the system drop down menus.

Admin access is needed in order to update drop down menus in the Complion platform.

1. Click the Admin key in the upper right toolbar
2. Select the Data Sources tab (will appear blue when selected)
3. Select the Data Source Drop Down menu you would like to update.
4. Review all previously entered data sources to be sure your entry does not already exist.
5. Click the Add New Item button
6. Enter the new data source/name/item needed.
   * 1. It is imperative that you spell the data source correctly and that you are not duplicating entries. Once a data source is entered into the system & a document is filed using that data source it cannot be corrected.
7. Click Save Changes.

If you are in the process of filing a document and realize that the data source you need is not in the drop down menu required for filing. Please click the Admin key, update the drop down menu and then return to filing your document.

The following are naming conventions for the Drop Down Menu Data Sources:

* DEVICE NAME: Brand Name of Device
* DRUG NAME: Generic Name (if known)/Brand Name – if drug has not yet been named please put the current name.
* NAME OF EDC SYSTEM: name of EDC system with version date (e.g. Rave V2.0)
* NAME OF IRB: UC IRB, WIRB, Advarra. If outside IRB, list out the name such as University of Maryland IRB.
* NAME OF LAB: List out name of lab to match name on CLIA
* PERSON NAME: First Name Last Name. Formal Name, no short names.
* PI NAME: First Name Last Name. Formal Name, no short names. No MD, PHD, etc.
* REPORT TYPE: External SAE, SUSAR, Internal SAE
* SIGNED STATUS: Signed or Not Signed
* SPONSOR: Full Name of Sponsor
* TYPE OF ASSESSMENT: Abbreviation for assessment (example: MRS, MMSE, 6MWT)
* TYPE OF CV: CV, BioSketch, TransCelerate, Sanofi, etc.
* TYPE OF NTF/POLICY/PROCEDURE: full name of the SOP or title of the note to file.
* UC IRB NUMBER: XXXX-XXXX.
* PATIENT ID: name of the patient id the same as would appear on the CRF.
* PHARMACY NAME: name of pharmacy that is on the certification.
* TYPE OF CITI TRAINING: GCARHC CITI, TransCelerate, AirForce, etc.
* TYPE OF DISCLOSURE: UC COI, Sponsor FD
* TYPE OF DOD DOCUMENT: Air Force, Army, etc.

SECTION 3: Creating a New Study Binder

All clinical research studies, must have a Complion eRegulatory binder created. To create a study binder you will need to begin at the Complion main page. The main page can always be reached by clicking on the blue Complion name badge in upper left hand corner.

Click the Create Binder button in the upper left toolbar.

Select the Type of Binder: Study Binder. Based on the type of binder selected, the needed fields will appear.

The first page of the binder building is Binder Details page. This page will give list out general information about the study. This information will be visible in the name of the binder on the main landing page.

* + - TITLE: This will be the short name for the study. This short name should match the short name used in the UC IRB system as well as the short name used on your UC Health Research Approval Submission form.
    - DESCRIPTION: This will be the entre title of the protocol.
    - TRIAL TYPE: This shall be designated as one of the following: Pharmaceutical, Investigator Initiated, Cooperative Group or Grant
    - PRINCIPAL INVESTIGATOR: List the principal investigator’s name (First Name Last Name, MD/PhD/etc.)
    - IRB NUMBER: List out the IRB Name: IRB Number. If more than one IRB is being used list both. (example: UC: 2016-1234 or UC: 2016-3423 WIRB: 20162258).
    - CONTACT: List the regulatory staff person or lead coordinator that is charge of the regulatory binder filing for the study. (First Name Last Name order)
    - TRIAL ID: If the trial has a short name (i.e. BLAST Trial) list here. If not applicable, leave blank.
    - DEPARTMENT/SITE/DG: List your UC College of Medicine designated Department (i.e. Internal Medicine). Site is the location of the study (i.e. UCMC, West Chester, DCI). DG stands for Disease group and should designate the division within your department (i.e. Digestive Disease, HLVI, Epilepsy). These names should be listed out with a / between each field (i.e. Internal Medicine/UCMC/Digestive Disease)
    - CT.GOV NUMBER: List the NCT number for the study drug if applicable.
    - SPONSOR/CRO: List study sponsor and the CRO name if CRO being used. Sponsor Name required. If Investigator Initiated with no sponsor please type Investigator Initiated. These names should be listed out with a / between each field (i.e. Novartis/PPD). If grant funded list funding source/agency.
    - RENEWAL DATE: This will be filled in with the expiration date for the approval once approval is received. At the beginning of building a study binder this will be left blank to be filled in once IRB approval received and updated at times of Continuing Review Renewal.
    - STATUS: This will be listed as Active for new studies. When you wish to Archive the binder at the end of the trial this can be changed to Archived.

The second page is the Binder Details page. This page is connected to the Complion Central Binder for your platform. Selections for this page will be made from drop down menus, not in free text as with the previous page, therefore, it is imperative that you first update the appropriate data sources for the drop down menus prior to building your binder. You can select the needed item from the drop down menu by either clicking on the magnify glass in the field which will make the drop down appear or using the field as a search bar and the parts of the drop down that apply to what you have typed will appear. To select multiple items from the drop down menu, select the first item, press enter & then select the second item & select enter, and continue this process until all needed items have been selected.

* UC IRB NUMBER: Select the UC IRB protocol number for the study you are entering.
* PI NAME: Select the site PI name for the study you are entering. PI’s documents such as CV, ML, and training certificates will be pulled into your study binder based on this designation.
* PERSON NAME: Select the names of all study staff listed on the Delegation of Authority Log. Documents, such as CV, ML, and training certificates, for staff selected here, will be pulled into your study binder.
* TYPE OF CV: Select the type of CV needed for the study (CV, Biosketch, Transcelerate, etc.). This selection will tell the system which type of CV to pull into the binder for the staff & PI already selected.
* TRIAL START DATE: Please use the widget to build the start date for the trial. This is the date your site began working on regulatory documents for this study or were awarded the study/chosen as a site. This is not to be confused with the start of enrollment or SIV date. Date will be in the following format: DD MON YYYY.
* Based on the date selected, the binder will pull in only central binder documents that are current as of the date selected, therefore, outdated CVs or training documentation will not be pulled into the system.
* NAME OF EDC SYSTEM: If the study is using an electronic data capture system, select the name of system. If the study is not using an EDC system, select N/A. Often there are several versions of an EDC system, please make sure when entering the name of you EDC system that you put a version number. (i.e. Medidata 2.1). This selection will tell the system to pull in training certificates for the selected EDC system for those staff people previously selected.
* TYPE OF ASSESSMENT: If the study is using an has any assessments as part of the study protocol that training is required to administer the assessment, the name will need to be selected here. If the study does not require administering of trained assessments, select N/A. This selection will tell the system to pull in training certificates for the selected assessments for those staff people previously selected.
* SPONSOR: Select the study sponsor (not the CRO). This selection will allow the system to pull in a Master CTA if applicable.
* NAME OF IRB: Select all the IRBs being used for the study. You will always be selecting UC IRB as they are a required clearing house when using an outside IRB. This selection will trigger the system to pull the FWA statement and IRB roster for the selected IRB(s) into your study binder.
* NAME OF LAB: Select all the labs (local or central) being used for the study. This selection will trigger the system to pull the CLIA and CAP certifications for the selected lab as well as the CV & ML for the Lab Director.
* TYPE OF NTF/POLICY/PROCEDURE: This field is used for any general Note to File or policy that you would like pulled from the central binder to the study binder. Study specific notes to file will be filed in the study binder separately. Examples of this type of Note to File may be a site affiliation memo for study staff or a policy such as the DoA policy for handling DoAs in Complion.
* DRUG NAME: Select the study drugs used for your study. If no study drug being used, select N/A. If you have an Investigator’s Brochure or Package Insert filed in the central binder for the selected drug, this selection will allow the system to pull that document into your study binder.
* DEVICE NAME: Select the study devices used for your study. If no study device being used, select N/A. If you have an FDA approval information or device safety information filed in the central binder for the selected device, this selection will allow the system to pull that document into your study binder.

Selections made during this process can be updated or added to at any time by the following process:

1. On the main landing page locate the study binder you would like to edit.
2. On the right hand side, under the Quick Binder Actions menu, select Binder Setup. This will take you to the Binder Set Up Page.
3. If you need to update the Binder Details page, click Details in the menu on the left.

Be sure to save any updates you make.

SECITON 4: Filing/Naming Documents in the Study Binder

There are two ways to add study documents to the binder: emailing documents into the binder and uploading documents thru the upload files button within the designated study binder.

UPLOADING DOCUMENTS VIA EMAIL:

Each study binder as a designated email address. When you send an email to the system using this email address, both the email and any attachments that were in the email will show up in the unfiled document section of the binder. Below are directions for how to locate the email address for the study binder.

1. Find your study binder on the main landing page.
2. On the right hand side, under the Quick Binder Actions menu, select Binder Setup.
3. Access the Binder Details page by clicking Details in the left menu. This will display the binder details based on how you previously entered them.
4. The Binder Forwarding Address is the email address for the binder. This name is meant to be long for security purposes. Best practice is to copy this email address to your email contacts and save the name of the contact as a short study name that will be easy for you to find when you want to email an email to the binder.

UPLOADING DOCUMENTS VIA THE FILE UPLOAD BUTTON:

1. Select you study binder from the main landing page.
2. Open the binder by clicking the study name
3. Click the Upload Files button in the upper left toolbar.
4. Select file from the file finder popup.

NAMING/FILING DOCUMENTS:

Documents uploaded documents will automatically be place in the “unfiled documents” folder and will need to be named and filed.

1. Click on the unfiled documents folder within the study binder. Here you will see a list of all document that have been uploaded into the study binder but not yet filed/named.
2. Next to each document there is an Actions menu. Select Assign Document Type. This will open the document and the naming window.
3. In the left hand naming window, begin typing the name of the type of document you would like to file. This will narrow the document type selections available to you.
4. Click on the needed document type. Based on the document type selected the appropriate naming fields will appear. Required fields will be marked. The description field can be used to free text any additional information for the document that may not be part of the already assigned naming fields.
5. Once all fields have been completed Click the Save button. This document will then be filed into the appropriate folder of the binder based on the document type you selected.

SECTION 5: Giving Users Permission to View a Study Binder

There are two types of users in Complion. Internal Users are site study staff. External users are monitors or auditors. Even if a person is listed as staff on a study, they will not be able to see the study binder until you give them permission to view the binder.

MANAGING PERMISSIONS FOR INTERNAL USERS:

1. From the main landing page, find the study binder for your study.
2. On the right hand side, under the Quick Binder Actions menu, select Manage Users.
3. The next page will show all users in the Complion system under your platform. Select a user you need to update permissions on by either scrolling down thru the list or searching by their name in the search bar. Click their name.
4. A menu will appear on the right hand side. Click the Change Access button. This will give the user the ability to see the binder and interact with the binder according to their permission group.
5. To remove permission, follow the same pathway, but instead click Revoke Access.

MANAGING PERMISSIONS FOR EXTERNAL USERS (MONITORS):

1. From the main landing page, find the study binder for your study.
2. On the right hand side, under the Quick Binder Actions menu, select Manage Users.
3. The next page will show all users in the Complion system under your platform. On the left hand side there will be a menu. Select External Users.

Adding New External Users:

1. Click the Add External User button in the upper left toolbar.
2. Enter the email address of the user
3. Enter a Start Date. This is the day you would like to them to begin having access to the binder.
4. Enter an End Date. This is the day that permission will no longer be active for the user.
5. Enter the first name and last name of the user.
6. Click the Save button. This will send a welcome email to the External User.

Updating and ReAssigning External User Access:

1. Locate the External User in list of external users on the external users page.
2. Select Edit from the Action menu to the right of the person’s name
3. Update the user’s permissions as needed.

SECTION 6: Sending a Document For Signature

1. Navigate to the document within the binder you wish to send for signature.
2. Select Send Document for Action from the File Actions menu to the right of the filed document.
3. Fill in the Title, Due Date, Description, and add the users you want to send the document to.
4. Click the Send button at the bottom of the page.
5. The user will receive an email that will prompt them to do the selected action and will contain a direct link to the document.
6. Send documents can be from the main landing page under the Sent tab. Documents will show as complete once all selected parties have signed the document as requested.
7. Status of document signature requests can be viewed by clicking on the document.

SECTION 7: Changing a Document Name or Attribute

1. Navigate to the document within the binder you wish to change something in the naming convention (either the document type or an attribute).
2. Select Change Document Type from the File Actions menu to the right of the filed document. This will navigate you to the document naming/filing screen.
3. Click the X next to the document name or the attribute you wish to update.
4. Type in the new name or attribute.
5. Click the Send button at the bottom of the page. This will re-file the document with the new name or attribute.

SECTION 8: How to Remove a Document From the Binder

Due to document tracking you can only fully remove a document from the system when it is in the unfiled state. However, once you name & file the document it cannot be fully deleted from the system. However, you can place it in a Removed file, which will not be visible to you or to external users.

If you have uploaded/pulled a document into the binder, but upon opening it to assign a naming convention & file it you realize it is not the correct document you can delete this type of document out of the system.

1. Navigate to the document in the unfiled documents section of the binder you wish to delete.
2. Select Delete from the Actions menu to the right of the document field. This will delete the document out of the system.

If you have named and filed a document into a binder in error and wish to remove the document, you will need to do so by placing the document in the Study Specific Remove File. Placing a document in this file will make it not visible to the user (internal or external).

1. Navigate to the filed document you wish to remove.
2. Select Change Document Type from the File Actions menu to the right of the filed document. This will navigate you to the document naming/filing screen.
3. Click the X next to the document name.
4. Rename the document with a document type name of Study Specific Removed File.
5. Click the Send button at the bottom of the page. This will re-file the document into the hidden removed file.