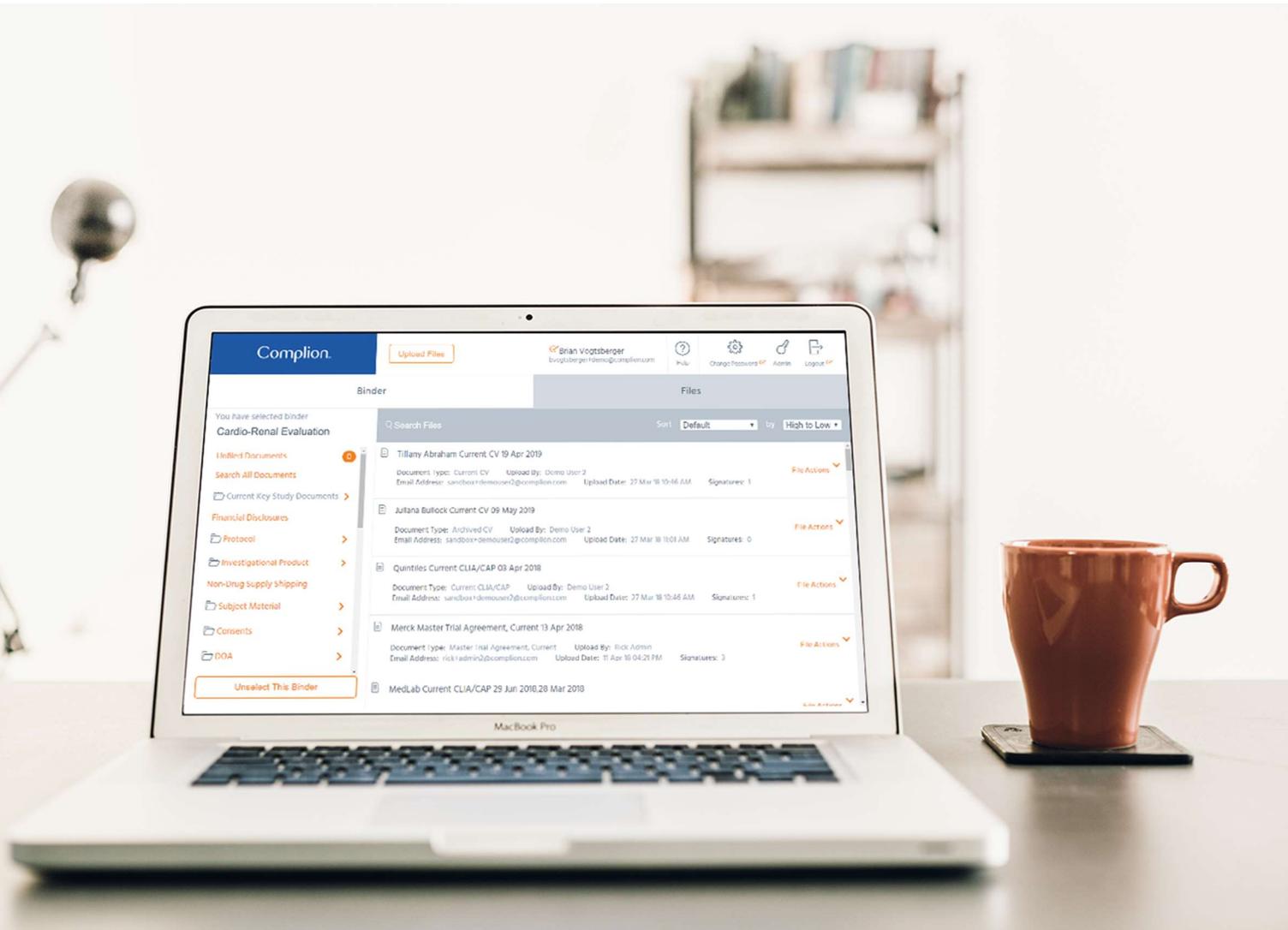


Complion User Guide



Complion Enterprise
February, 2020

Overview

Complion's mission is to revolutionize clinical research site regulatory and document management through the elimination of human error and redundant work to achieve maximum efficiency and compliance. That's why Complion is the first and largest eRegulatory and document management software vendor for sites, health systems, academic medical centers and cancer centers.

About This Guide

The Complion User Guide provides you with an overview of the product and instructions for Complion use. As the specific standards in Complion can be tailored for each client, generic overviews are provided to describe the most common elements of Complion.

This guide is intended for regulatory team members, clinical coordinators and research team members at sites conducting medical research clinical trials and whom are responsible for managing documents, studies and tasks within Complion..

Problems We Can Solve Together

Research sites manage many complex studies, often with limited resources and staff. Maintaining regulatory compliance and human subjects protection for clinical research can be challenging for staff who are managing many diverse aspects of the research study.

Complion helps you to eliminate paper and increase efficiency by standardizing document names and automatically filing documents into their proper location.

Your Feedback Matters

Our software is built on best practices in close collaboration with leading research sites to deliver the most value while exceeding industry best practices for compliance with required FDA Regulations. We listen to your feedback and want to hear from you as your input helps us evolve our solution to meet your new challenges and improve the field of research. Contact us using the Help button, which will be covered later in this guide.

We also want to personally say 'Thank You' for your dedication to research. We know that it is not always easy, but your contributions are critical to providing patients with novel treatment options and to the advancement of the field of medicine. At least now, you have less paper cuts and binders to deal with. We are happy that you have decided to partner with us to improve your regulatory processes. Thank you for this opportunity to serve you.

Welcome to the Complion Community!

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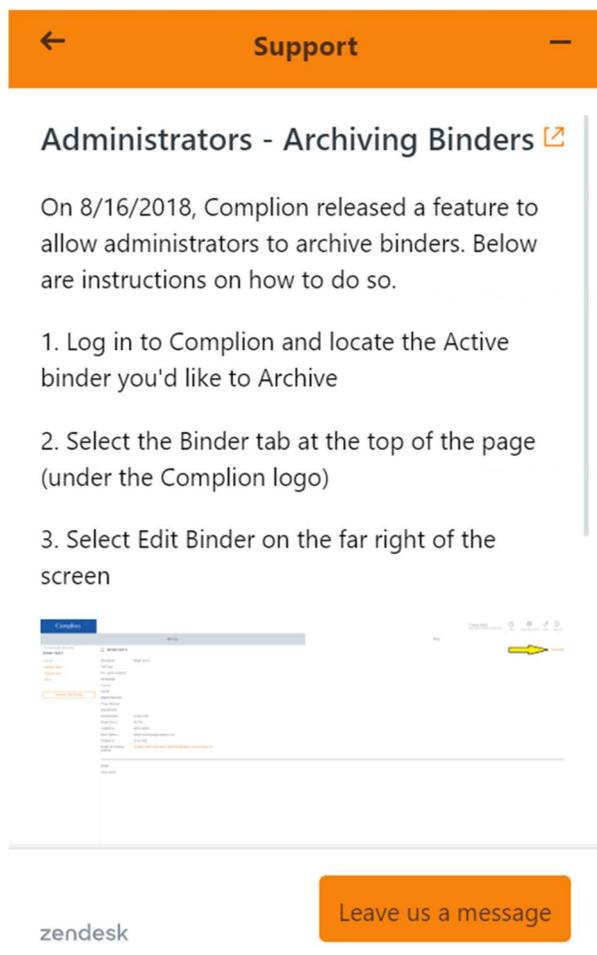
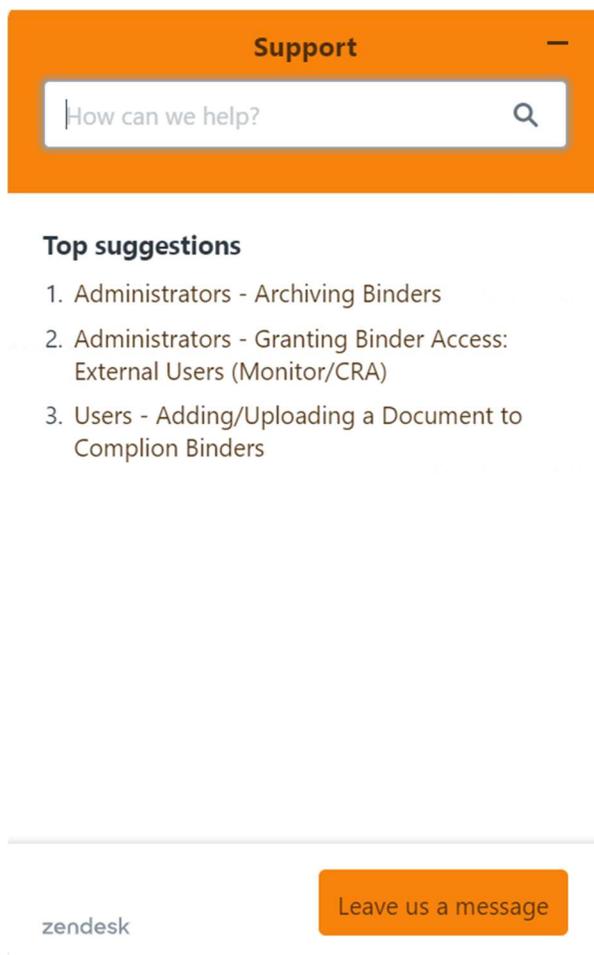
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Accessing the Help Center/Support

Whether you need help resolving technical issues or advice on streamlining operational processes, our highly skilled team is available to ensure your institution is fully supported.

If you are experiencing problems with Complion or want to learn more about how something works, click the round “Help ?” button on the upper right side of the screen. The Help button is available anywhere you are in Complion. An orange support box will appear asking “How can we help?”

You can search by entering keywords. This will yield the greatest number of responses.





In order to pop out the article and access other areas of the Help Center, click on the small arrow next to the article title within the widget. This will open a new tab in your browser.

You can also select Leave Us a Message at the bottom of the widget. If you choose to submit a support request, fill in the details of your question as completely as possible and click “Send.” You will receive an email response from our support team, in which they will provide you additional information, request more information if they still have questions, and work to provide an answer to your question.

Technical support is led by Complion employees located in the US during standard business hours (9:00AM-5:00PM EST)

Registering Your Account

After your Institutional Administrator has created an account for you in Complion, you will receive an email welcoming you to Complion allowing you to complete the account registration process. The registration process includes the following steps:

1. Accessing Complion through the specific link provided in your welcome email
2. Selecting a security question and providing a security answer
3. Creating and confirming an account password
4. Viewing the training video
5. Electronically signing the End User License Agreement (EULA)

At this point you will have completed the registration process and can access Complion.

Accessing Complion

To complete your account creation process, first locate the welcome email you received notifying you that your Institutional Administrator has made you a user of Complion. The following screenshot provides an illustration of this welcome email.



Hello,

Someone made you an account for Complion - the eRegulatory solution empowering clinical research sites.

Follow the instructions below to finish creating your account.

Click [here](#) to set your password, or copy the following url into your address bar:
<https://app.complion.com/newUser?nonce=ab6d4200-f4aa-48be-b828-912962e110d8&email=jaime.ramos%40complion.com>

This link can only be used to set your password once, and expires in 3 months.

Expires on Mon Feb 04 2019 16:49:16 GMT+0000.

Sincerely,
Complion, Inc.

After clicking the link you will be taken to Complion There you will see an option to set up your account.



Welcome to the document management and workflow platform for clinical research sites. Click the button below to start setting up your account.

[Set Up Your Account](#)

Security Question and Answer

Once you've clicked "Set Up Your Account," you will be asked to select a security question and provide your answer.

Note: You will be required to remember the security question and the answer when you need to reset your password.



The screenshot shows a blue background with the Complion logo at the top. Below the logo are three input fields, each with a checkmark icon to its left. The first field is labeled "Email Address" and contains the text "user@complion.com". The second field is labeled "Security Question" and contains a dropdown menu with the text "What street did you live on in third grade?". The third field is labeled "Answer" and contains the text "Compliance Rd". Below these fields is an orange button with the text "Next".

Note: Your email address will be pre-populated based on what your Institutional Administrator used to invite you to Complion. This email will be used throughout the email to uniquely identify actions that you take as you interact with the documents stored in Complion.

Creating Your Password

Once you have answered a security question, you can enter in a password. Passwords accepted by Complion must be at least 8 characters, and meet three of the following four conditions:

- At least one uppercase letter
- At least one lowercase letter
- At least one special character (e.g. !@#\$\$%)
- At least one number

✔ Email Address

Validation error: Password must be a minimum of eight (8) characters., Validation error: The password is required to include three of the following four: 1.) an uppercase letter, 2.) a lowercase letter, 3.) a special character, 4.) a number.

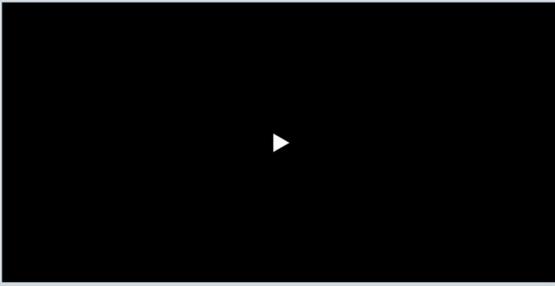
✔ Choose New Password

Confirm Password

Next

Completing Complion Training

The next step in the registration process will be to view training video and to sign off that you have watched the video by entering in your email and password. The training video may be tailored to your role.



I have reviewed, acknowledge, accept, and agree with the information presented herein.

✔ Email Address

✔ Password

Next

End User License Agreement

The final step in the registration process is to review and sign the End User License Agreement (EULA) confirming that you agree to the terms of usage in Complion.

Read EULA

This End User License Agreement and Acknowledgment of E-Signature Policy is subject to the terms and conditions of that Master Service Agreement and any Service Orders between Complion, Inc. ("Complion" or "Licensor") and the organization on behalf of which you are acting ("Employer" or "Customer"), and constitutes an agreement between you ("you" or "User") on both your own behalf and as an authorized representative of Customer concerning your access to and use of certain services made available by Complion ("Services"). You hereby agree that you (and Customer) will access and use the Services only in accordance with the Master Service Agreement, applicable Service Orders and the following terms.

1. By accepting a user role in Complion, Site eRegulatory Platform, as defined by Complion management, your electronic signature in Complion becomes the legally binding equivalent to full handwritten signatures and shall be viewed as meeting the requirements of 21 CFR Part 11, and shall consider the electronic signatures to be equivalent to handwritten signatures, initials, and other general signings as required by the Federal Drug Administration (FDA), unless specifically excepted by regulations (s) effective on or after August 20, 1997.
2. You agree to provide accurate, current and complete information, to the extent required by FDA regulations for your role as a creator and/or as an approver of Electronic Records. This applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the FDA, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this does not apply to paper records that are, or have been, transmitted or created by electronic means. You agree in your acceptance and your use of your Electronic Signature not to impersonate any other person or entity.
3. You are responsible and liable for any activity on your user account with respect to the use of Electronic Signatures. You are responsible for maintaining the confidentiality of your password and for any liability resulting from disclosure of your password. You agree that, upon becoming aware that your password or account is (or possibly is) being used without authorization, you will immediately change your password and notify Complion within one (1) business day.
4. You acknowledge that information, communications, electronic records (such as a combination of text, graphics, data, audio, pictorial, or other information represented in digital form), and other materials may be accessible to you through your use of the Electronic Signature and may be proprietary to the user and/or the user's institution(s).

Accessing Complion

Complion is accessible via the following compatible web browsers:

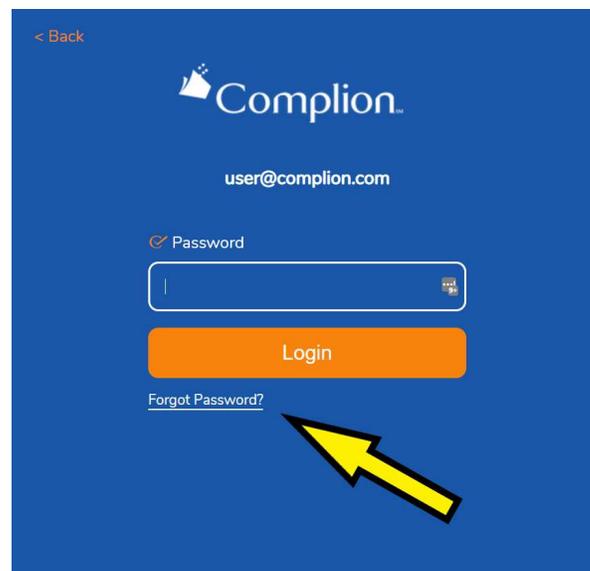
- Chrome (*latest release*)
- Internet Explorer 11
- Microsoft Edge (*latest release*)
- Firefox (*latest release*)
- Safari (*latest release*)

To log into Complion, navigate to app.complion.com from an internet browser and click “Login”. This destination may vary based on your organization as some URLs are customized.

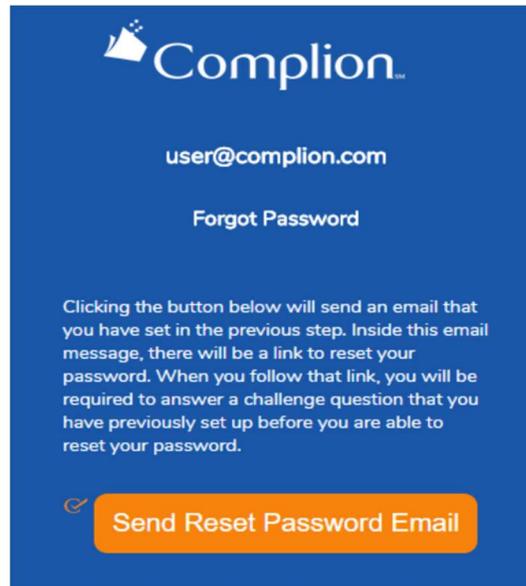
Forgotten Passwords

If you have forgotten your password, you can reset it in a few easy steps.

Step 1: Navigate to the login screen, enter your email address, and select “Forgot Password.”



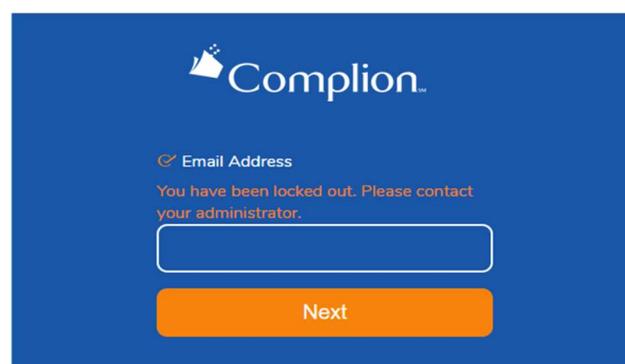
Step 2: Select “Send Reset Password Email.” You will receive an email with a link to reset your password. Copy and paste it into your browser, or simply click it..



Step 3: Answer your Security Question. After following the link, you will be asked to answer your security question and from there you can enter a new password.

Complion Lock Out

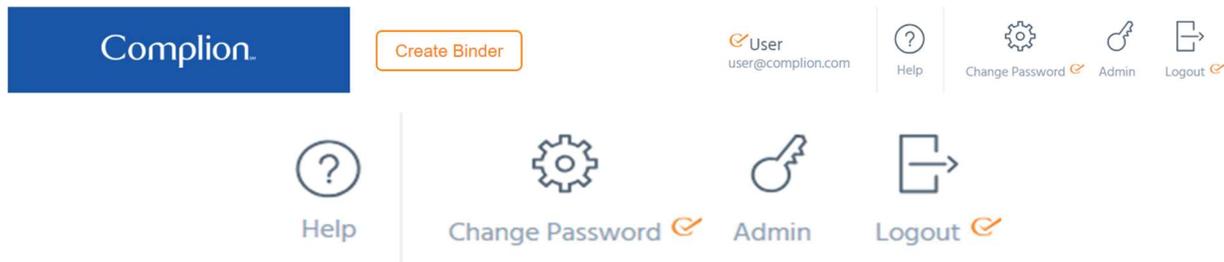
If you fail to enter your password correctly 5 times you will receive this message:



At this point you must have your Institutional Administrator reset your password to login.

General Navigation

Top Navigation Bar



The Navigation bar is designed to make it easy to quickly navigate throughout Complion or perform common Complion functions.

On the left in blue is the Complion logo that will take you back to the main Binder List at any time.

You may see an orange button at the top of the screen, depending on your user permissions and on which page you're located. For that particular page (Binder, Users, Files, etc.), this button will be the primary action button, allowing you to initiate key functions such as creating a new binder, uploading a new file, and more.

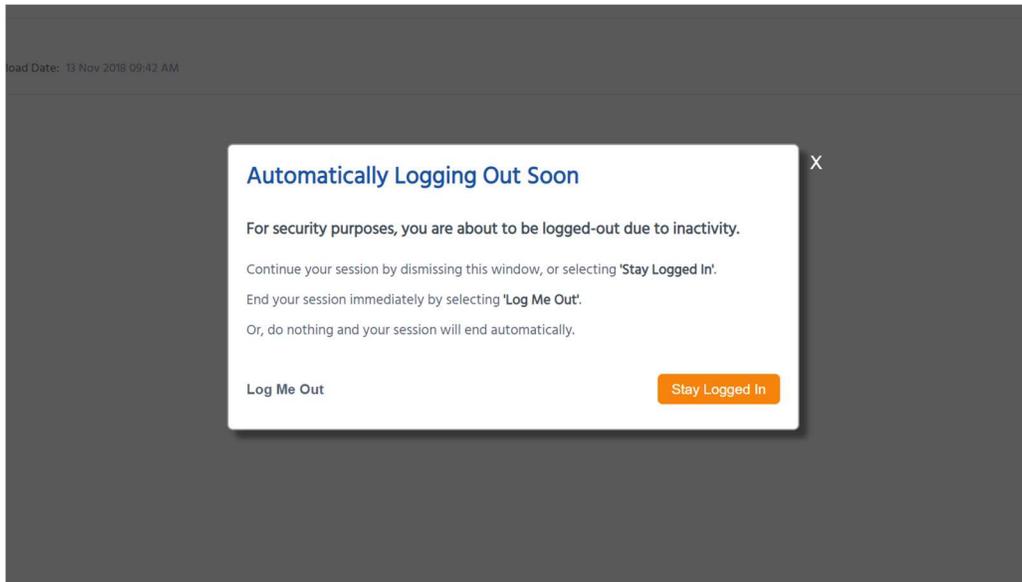
On the right side of the screen you will see your username. Ensuring you are logged in as the correct user is an important security component for maintaining Part 11 compliance.

The Help icon can be used to contact our support team when you have an issue while using Complion. For more information, view the [Support](#) section of this manual.

The gear icon can be used to change your password. This will open a new window that will ask you to confirm your current password, then enter and confirm a new password.

Lastly is the option to log out. This should be done any time you are finished using Complion or walk away from your computer to ensure no one can gain access to your account.

Note: Upon 18 minutes of system inactivity, users will receive an alert that their session is about to expire. Unless an action is taken, users will be logged out of the system after 20 minutes of inactivity.



Binder List

The Binder List is the default view when you sign into Complion or when you select the blue Complion logo in the top left of the screen. Here you can select an individual binder that you would like to view. This will allow you to access that binder and all of its contents. From this list you may also make changes to the binders via the Quick Binder Actions drop down.



Selecting Quick Binder Actions will expand a drop down menu that allows you to manage users, change the binder setup, or upload a file, depending on your permissions. Each of these functions will be explained in later sections.

Quick Binder Actions ^

- Manage Users
- Binder Setup
- Upload file

Sent View

The Sent view enables you to quickly see all tasks or documents you have sent out for an action to be taken in one convenient location. To learn more about how documents are sent, see [Sending Documents for Action](#) (Tasks).

Binders
Inbox
Sent

Show All ▼

Sort Sent Date ▼

By Descending ▼

▶

Subject: Test Task Loading

Sent: 05 Nov 2019 12:26 PM-05:00 **Due:** 08 Nov 2019 **Status:** Incomplete

Test

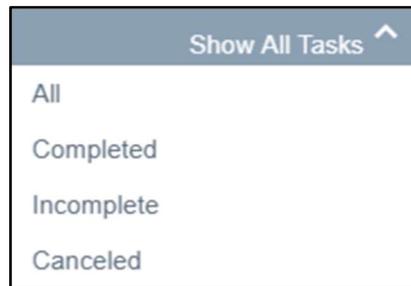
Here you can see when documents are signed and approved, which is the date by when the document needs to be signed, as well as the status of the document.

Sent View Statuses:

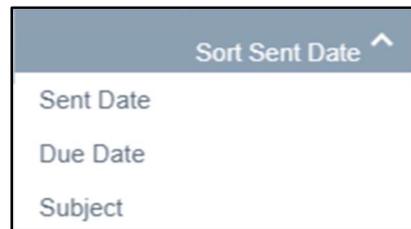
- **Completed:** The action has been completed or the document has been signed by everyone requested.
- **Incomplete:** The action has not been completed or the document has been sent out but not signed by everyone requested.
- **Cancelled:** The requested action has been withdrawn and/or the document no longer requires a signature.

You also have the ability to search, filter and sort these documents. Each option for sorting works in conjunction with the other sorting methods.

The first method is to filter by task status. Your options are All, Completed, Incomplete, and Canceled with the default option displaying All Tasks. This will only display tasks that represent the task status you select.



The next option allows you to sort by Sent Date, Due Date, and Subject.



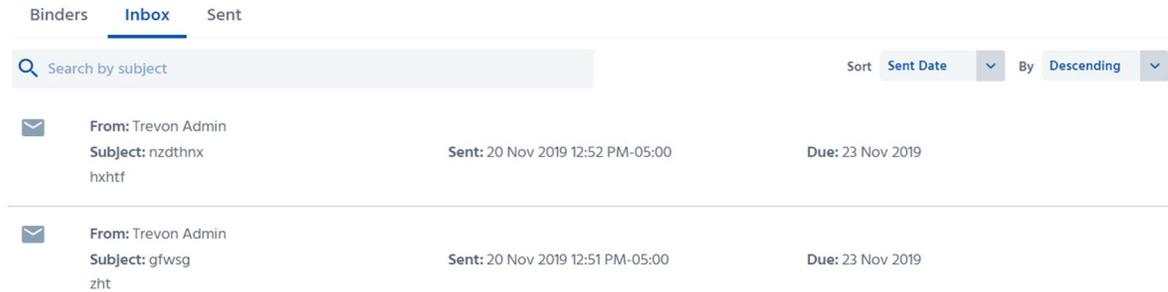
Lastly you have the option to sort by Ascending or Descending. This is referencing the second column sort, not the task column.



Inbox View

When you are sent a document and particular action will be requested. An action is defined as reviewing and signing. For more information, see [Sending Documents for Action](#).

Any documents with a required action are viewable in your Inbox view. You can select, review, and sign the documents.



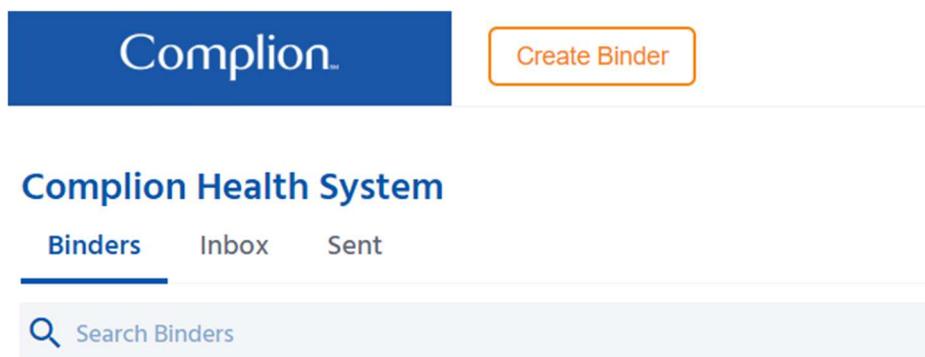
Creating a Binder

Binders can be created in Complion anytime you require a new regulatory binder, most commonly when a new study is approved and the regulatory process is initiated. Only certain individuals at your institution have the ability to create a new binder. Access to this functionality is determined by your Institutional Administrator.

Creating a New Binder

To create a binder, you first need to be on the Binders List tab. Next, select “Create Binder” action button at the top of the screen.

Note: Only users with the appropriate permissions to create a binder will see this option.



This will take you to the Binder Creation page. The fields required are the Binder Template, the Title, and a Description. All other information is optional but may be helpful for the purposes of searching or conveying information to others.

- The Binder Template provides the standardized document folder structure and contents used for very specific purposes within Complion. Binder Templates may include study binders, central binders and other folder structures necessary to manage your regulatory documents.

- The Title is used to name the binder and will be visible on the Binder List once you have created the specific binder.
- The Description is displayed on the Binder List to provide more context for the binders you are selecting.

Once complete, select the “Create Binder” button at the bottom of the page to complete the process.

Binder Template	<input type="text"/>
Title	<input type="text"/>
Description	<input type="text"/>
Trial Type	<input type="text"/>
Principal Investigator	<input type="text"/>
IRB Number	<input type="text"/>

Binder Setup and Activation

After the binder is created you will see the Binder Setup page. The Binder Setup page is used to keep some essential binder information, and to determine what documents are pulled into the binder. Here you can input the necessary information to activate the binder. In the example below, the Study ID, Name of Researchers, and Expiration Date are used.

Note: The Binder Setup must be completed prior to activating the binder.

<p>You have selected binder</p> <p>Reg Binder 2</p> <p>Details</p> <p>Setup</p> <p>Unselect This Binder</p>	<p>Binder Setup</p> <p>Study ID Select a value</p> <p>Name of Researcher Select one or multiple values from the list</p> <p>Expiration Date Select a date</p>	<p><input type="text"/></p> <p><input type="text"/></p> <p>15 Aug 2017 </p>
--	--	--

Note: All fields on the Binder Setup page are required to ensure the appropriate documents may be filed and found in this binder.

Once all fields have been completed, you can select the “Activate Binder” option. This action will complete the binder creation process and allow full use of the binder within Complion.

Note: If you choose not to activate the binder, it will be saved as a “New” binder. You cannot work with a binder until it has been made active.

Explanatory Tip

The Binder Setup page is a really important page! The information you enter on this page helps to determine what documents will automatically show up in this study binder, as well as helping to define certain standards to make filing future documents easier.

Example

If you select an option in the “Name of Researcher” dropdown list, you’ll be choosing who will be associated with this study binder. After doing so, the appropriate documents related to that person (which would have previously been set up in the Central Binder), will automatically show up in this study binder. The same applies to any documents you manage centrally, such as Training documents, some lab documents, and more.

What the System is Doing

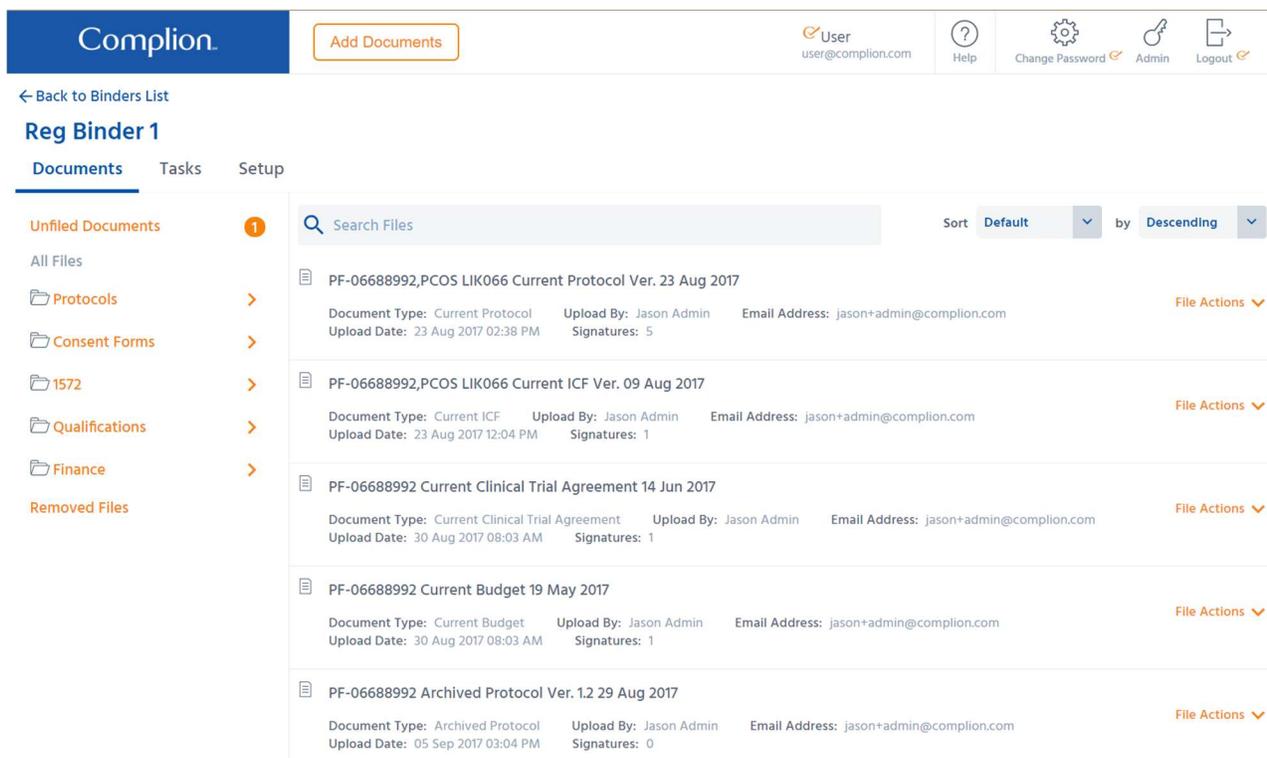
In the example above, the system is taking the Name of Researcher that you have selected, combined with other important information (such as the start date of a study), and automatically grabbing the right documents from other places in the system, like your central binder. This is meant to help avoid mistakes and eliminate manual processes that you have had to do on your own in the past.

Managing a Binder

Binder Navigation

When a binder is selected, you will notice that documents within the binder are organized into subfolders on the left side of your screen. The main view will show all of the documents contained within the currently selected folder.

By default, you will initially be directed to a folder where you can view all of the documents that are currently in the binder. This “master folder” can be named anything you wish, such as “All Files”, “Table of Contents”, etc.



The screenshot shows the Complion interface for a binder named "Reg Binder 1". The top navigation bar includes the Complion logo, an "Add Documents" button, and user information (User: user@complion.com). Below the navigation bar, there are links for "Back to Binders List", "Reg Binder 1", and tabs for "Documents", "Tasks", and "Setup".

On the left side, there is a sidebar with a list of folders: "Unfiled Documents" (with a notification icon), "All Files", "Protocols", "Consent Forms", "1572", "Qualifications", "Finance", and "Removed Files".

The main content area displays a list of documents with a search bar and sorting options. The documents listed are:

Document ID	Document Type	Upload Date	Upload By	Email Address	Signatures	File Actions
PF-06688992,PCOS LIK066 Current Protocol Ver. 23 Aug 2017	Current Protocol	23 Aug 2017 02:38 PM	Jason Admin	jason+admin@complion.com	5	File Actions
PF-06688992,PCOS LIK066 Current ICF Ver. 09 Aug 2017	Current ICF	23 Aug 2017 12:04 PM	Jason Admin	jason+admin@complion.com	1	File Actions
PF-06688992 Current Clinical Trial Agreement 14 Jun 2017	Current Clinical Trial Agreement	30 Aug 2017 08:03 AM	Jason Admin	jason+admin@complion.com	1	File Actions
PF-06688992 Current Budget 19 May 2017	Current Budget	30 Aug 2017 08:03 AM	Jason Admin	jason+admin@complion.com	1	File Actions
PF-06688992 Archived Protocol Ver. 1.2 29 Aug 2017	Archived Protocol	05 Sep 2017 03:04 PM	Jason Admin	jason+admin@complion.com	0	File Actions

Using the “Search Files” bar, you can filter out any files that do not meet your search criteria. This is the easiest way to quickly find a document you are looking for. Partial searches are accepted. For example if you are looking for all Archived documents, you can type “arch” and it will find all files with “arch” in the name

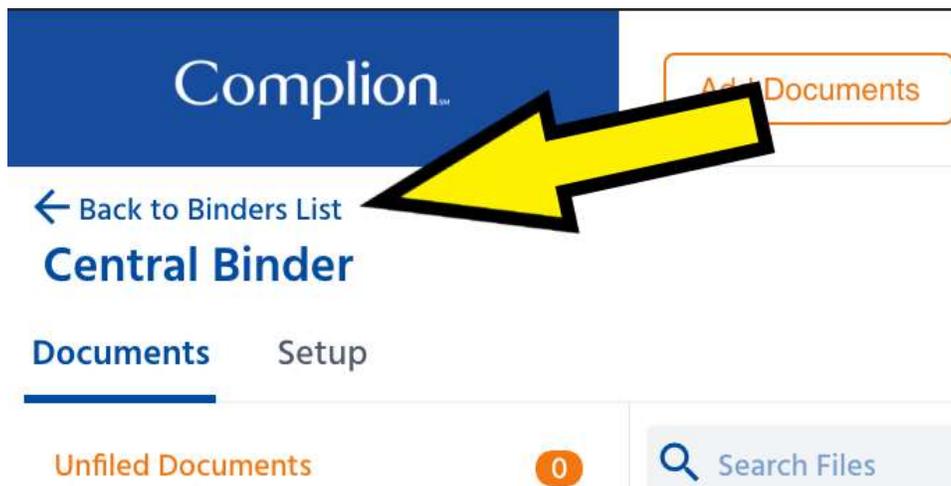
Search bar: arch | Use 'Enter', or Search | Sort: Default | by: Descending

Found 4 results for 'arch' | Clear Your Results

Archived IRB Document	Document Type: Archived IRB Document	Upload By: Jaime Admin	Email Address: jaime+adminuser@complion.com	Upload Date: 25 Jul 2018 01:36 PM	Signatures: 2	File Actions
Archived FDA 1572	Document Type: Archived FDA 1572	Upload By: Jaime Admin	Email Address: jaime+adminuser@complion.com	Upload Date: 15 Nov 2018 04:35 PM	Signatures: 0	File Actions
Archived FDA 1572	Document Type: Archived FDA 1572	Upload By: Jaime Admin	Email Address: jaime+adminuser@complion.com	Upload Date: 24 Jul 2018 10:19 AM	Signatures: 1	File Actions
Archived CV	Document Type: Archived CV	Upload By: Jaime Admin	Email Address: jaime+adminuser@complion.com	Upload Date: 05 Sep 2018 04:01 PM	Signatures: 0	File Actions

Alternatively, you can also search for documents within a specific folder by first selecting the folder and then entering information into the search bar. This works on the All Files folder as well as all of the subfolders.

Just below the blue Complion logo is a link to return you to your All Binders List.



Complion™ | Add Documents

← Back to Binders List

Central Binder

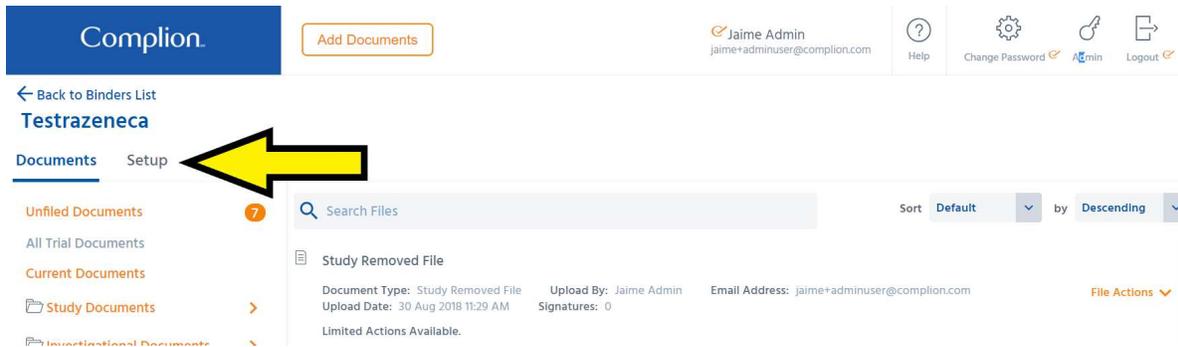
Documents | Setup

Unfiled Documents 0 | Search Files

Managing Binder Details

The Binder Details page allows you to make changes to essential binder information. All of these fields are descriptive in nature to provide additional context about the binder. This is the form you initially filled out as part of the Binder Creation process.

Binder details can be changed at any time after initial creation. These changes will not affect documents being pulled into the binder, as they would be if the Binder Setup page were to be altered. To make changes, navigate to the binder you wish to modify, then select “Binder” as seen below.



Once selected you will be taken to the Binder Details page. In the top right corner there is an option to “Edit Binder”.



Clicking this will allow you to change the Binder Details as necessary. When done, click the Save button at the bottom of the screen.

Edit Binder

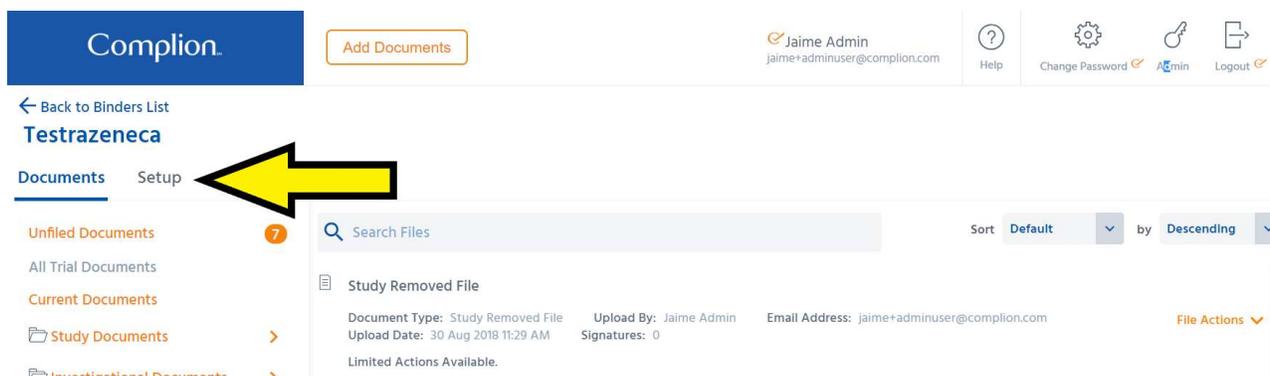
Title	Reg Binder 1
Description	<div style="border: 1px solid gray; padding: 5px; min-height: 40px;">Reg Binder 1</div>
Trial Type	Trial Type
Principal Investigator	Principal Investigator
IRB Number	IRB Number
Contact	Contact
Trial ID	Trial ID
Department / Site / DG	Department / Site / DG
CT.gov Number	CT.gov Number
Sponsor / CRO	Sponsor / CRO
Renewal Date	25 Apr 2018

Managing Binder Setup

Editing the Binder Setup page affects how documents are filed into the binder by altering the filter from the Central Binder to the Study Binder. It defines what the Study Binder will pull in. There are two ways to access the Binder Setup page. This is the second page you filled out before activating the binder as part of the Binder Creation Process.

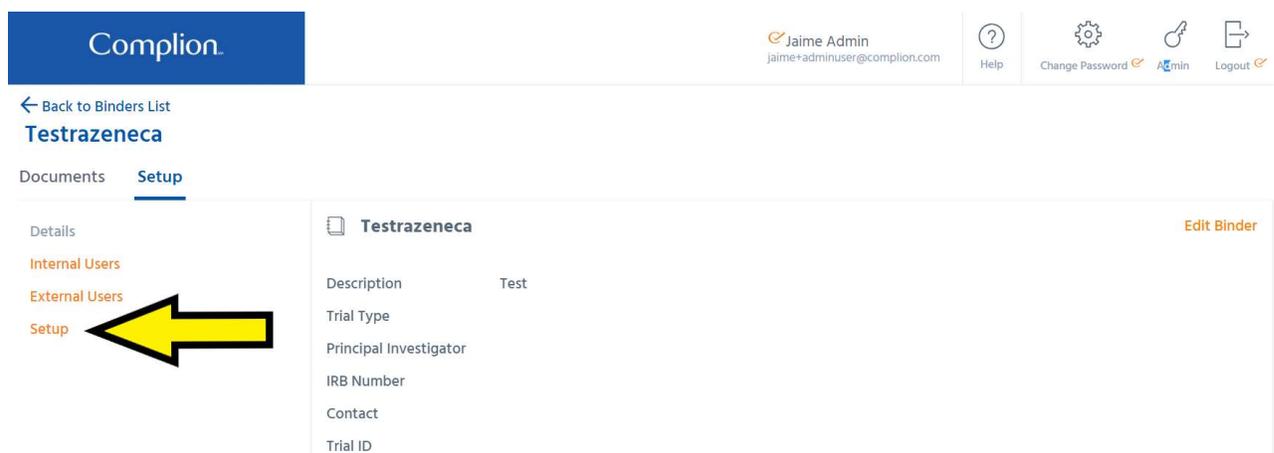
The first option is to go to the Binder List and find the binder you wish to modify. From there you can select the “Quick Binder Actions” and from that drop down select “Binder Set Up” option. At that point you will be taken to the Binder’s Binder Setup page to make changes.

Alternatively, you can access the Binder Setup page from the “Binders” tab.



The screenshot shows the Complion interface. At the top, there is a blue header with the 'Complion' logo and a user profile for 'Jaime Admin'. Below the header, there is a navigation bar with 'Documents' and 'Setup' tabs. A yellow arrow points to the 'Setup' tab. The main content area shows a list of documents, with a search bar and a 'Study Removed File' entry. The 'Setup' tab is highlighted in the sidebar.

On the Binder Setup page you can make any changes you need and then save those changes with the “Save Binder” button at the bottom of the screen.



The screenshot shows the Complion interface. At the top, there is a blue header with the 'Complion' logo and a user profile for 'Jaime Admin'. Below the header, there is a navigation bar with 'Documents' and 'Setup' tabs. A yellow arrow points to the 'Setup' tab. The main content area shows a list of documents, with a search bar and a 'Study Removed File' entry. The 'Setup' tab is highlighted in the sidebar.

Note: Changes to the Binder Setup will affect which documents are pulled into the binder.

Adding Documents to a Binder

Complion is built to ensure that each document is filed correctly, and in accordance with your institutional standards. As such, Complion eliminates much of the time and guesswork typically needed to understand where and how documents should be stored.

Adding documents to a binder is a three step process:

- Step 1:** Upload the document.
- Step 2:** Inform Complion about the document.
- Step 3:** The document is filed for you!

Uploading a Document

To add a document to a binder, you must first upload the document to a binder in Complion. Once documents are uploaded to a binder they can be found in the “Unfiled Documents” folder where they can then be filed or deleted. In the paper world, the “Unfiled Documents” folder is synonymous to the front pouch of your study binder; a temporary storage location for documents waiting to be filed in a binder.

The process of filing a document includes selecting the appropriate type of document and then providing information about the document.

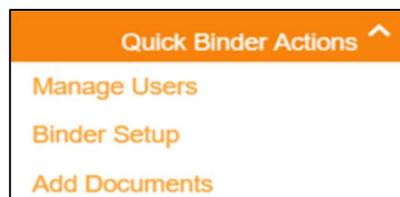
There are two ways you can upload a document into Complion:

- Upload a document from your computer’s files
- Upload a document from email

Uploading Documents from your computer’s files to Complion

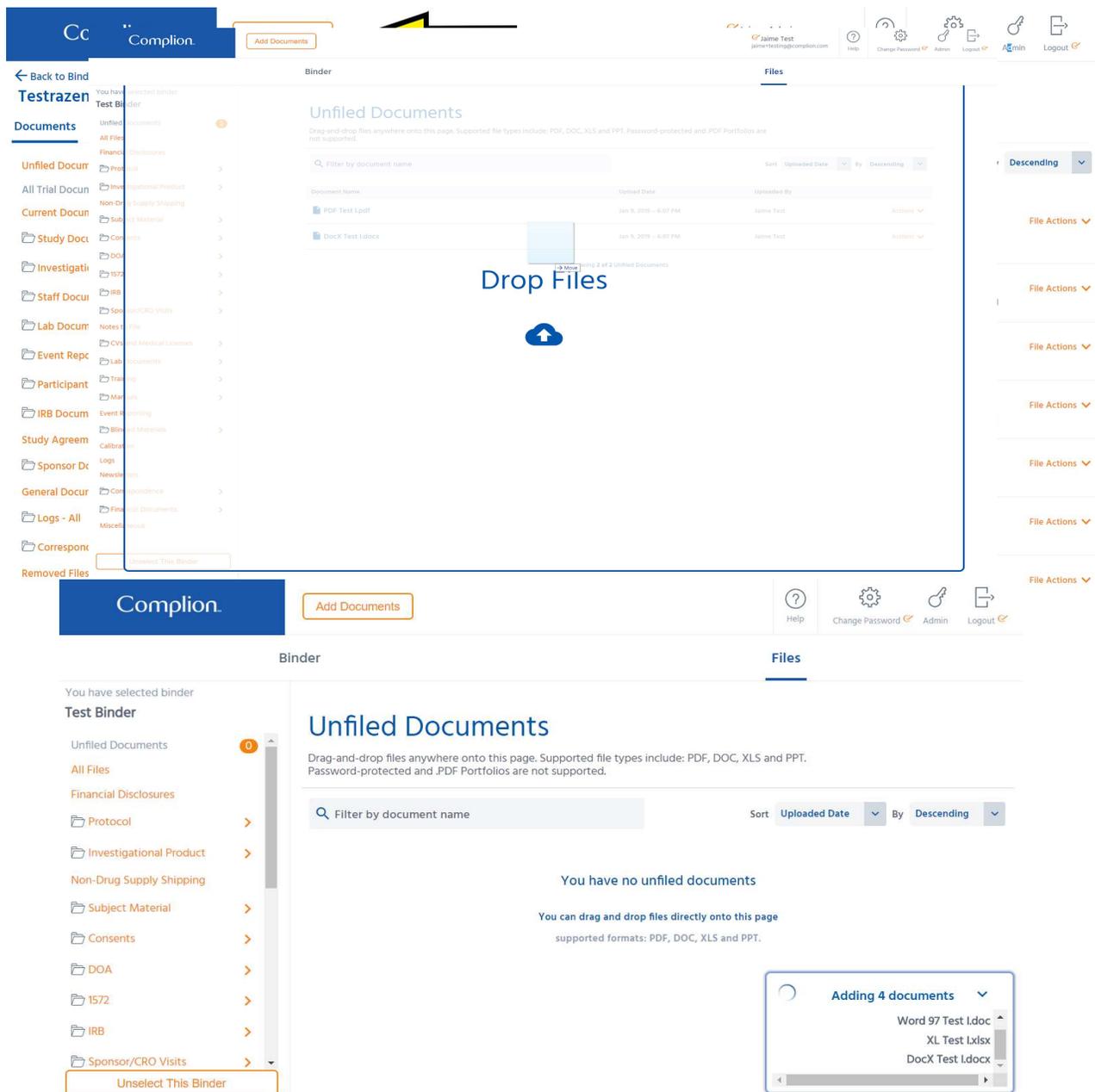
To upload a document directly into Complion, navigate to the binder to which you wish to add documents, and select the “Add Documents” action button at the top of the page.

You can also do so from the Binder list, by selecting “Quick Binder Actions”.



Upon hitting the Add Documents button, you will receive a pop up allowing you to add the files necessary from your computer's file selector. Simply double click on the desired files to do so. Alternatively, if you access the Unfiled Document page, you can simply drag them onto the screen

You will see an upload queue in the bottom right-hand corner of your screen, indicating the upload status(es). When the document is finished uploading you will be able to view it in the Unfiled Documents folder.



Note: Documents uploaded to Complion which exceed 20 MB may take longer to upload. File attachments uploaded via email should not exceed 30 MB.

Uploading Documents from Email

We understand that research teams often deal with a multitude of daily emails and correspondence from Sponsors, CROs, IRBs and other parties that must be maintained in your regulatory binder. Complion makes it easy to quickly send emails and attachments directly to a study binder, without a printer or scanner!

Any email (and corresponding attachments) can be uploaded to Complion by simply forwarding the email to a unique Complion binder email address, or the “Binder Forwarding Address.” Upon forwarding an email to this address, the body of the email message and each attachment will be uploaded into the “Unfiled Documents” folder as a separate document within that particular binder.

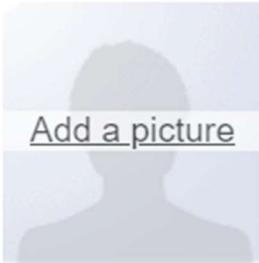
The binder forwarding address can be found on the [Binder Details](#) page of any binder:

Renewal Date	25 Apr 2018
Binder Status	ACTIVE
Created by	User
Email Address	user@complion.com
Created on	25 Apr 2018
Binder Forwarding Address	df2a3631-f38b-40c0-ac07-0db4a74fd4b5@complionbinder.com

Note: This is a unique email address that is generated for each binder in Complion. This address is only visible if you have document upload permissions for the binder.

A recommended practice when uploading several emails to a binder is to save the Binder Forwarding Address as a contact in your email application. As each client may have their own email solution, generally these steps include the following:

1. Open your email application (Outlook, Mail, Gmail, etc...).
2. Add the Binder Forwarding Address to your email contacts list.
3. Assign the contact name as the title of your binder, or another unique identifier that works for you and your organization.
4. With the contact created in your email application you can now forward emails to this binder by typing the binder title in the “To” field to quickly forward emails into your binder.



Binder ABC-123D



Home ▾

8f876bf-ef57-48c1-985d-9c6ae8557f9b@complio 

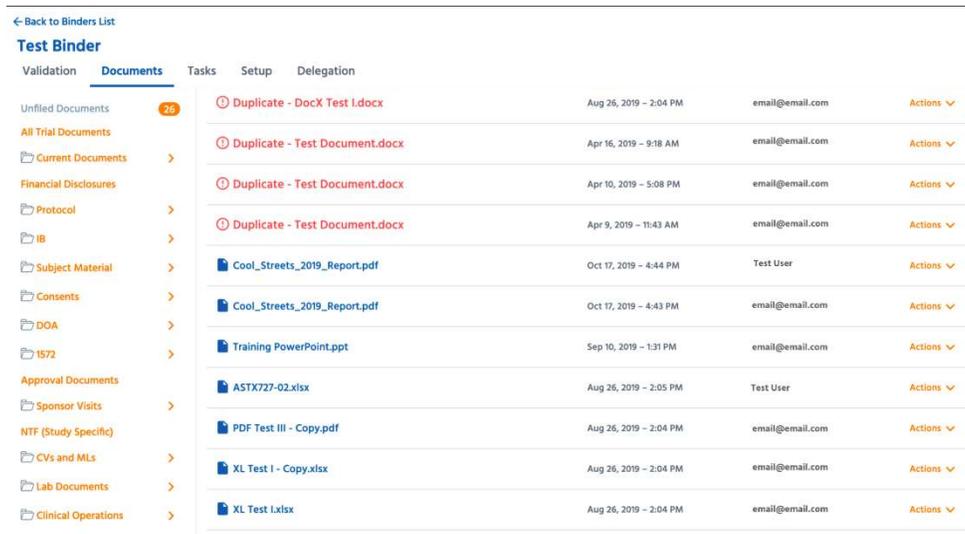
Add email

Emails forwarded to your Complion binder will be uploaded to the “Unfiled Documents” folder for that binder. Each attachment will be uploaded as an individual document with the email message being uploaded as a separate PDF.

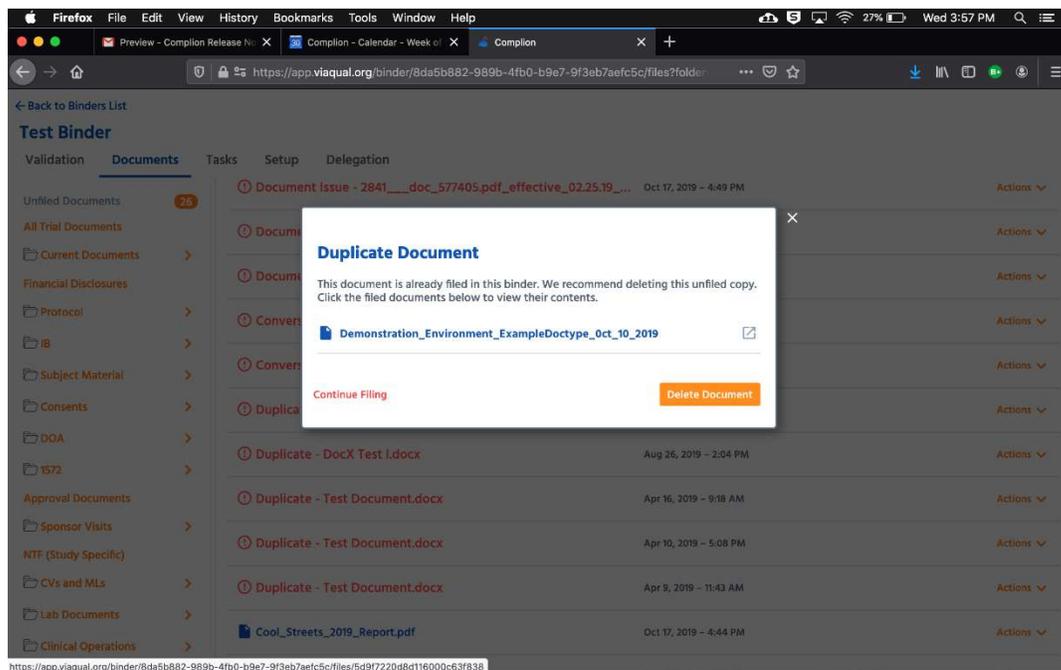
Note: If you don't want specific attachments to show-up in the Unfiled Documents folder, delete the unwanted attachment from the message before forwarding the message into the binder.

Duplicate Document Detection

Any document that is uploaded into a binder, as well as any document that is currently unfiled in the binder, will be automatically checked for duplication and flagged accordingly. Duplicates will be highlighted in each binder’s Unfiled Documents section.



Clicking a duplicate will trigger an alert advising the removal of this newly-added duplicate. Or, you can choose to continue filing a duplicate if your purposes require so. When an unfiled document duplicates an already-filed document, the alert will provide a direct link to view the filed document for reference.



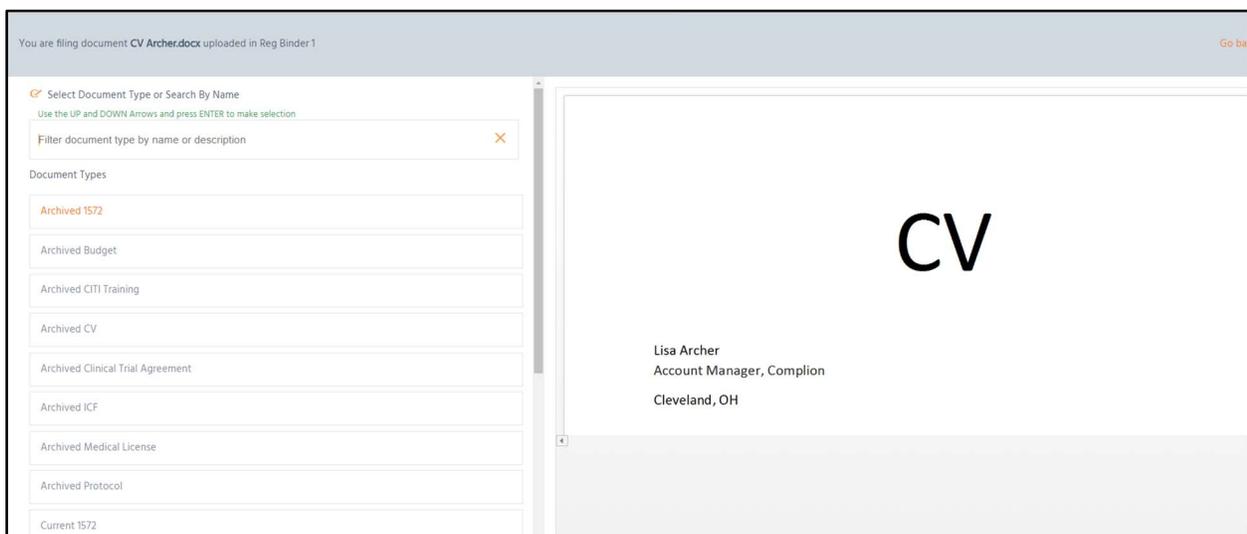
Filing a Document

Complion needs to collect key pieces of information about each document from you. By providing this information, Complion ensures each document is named and filed correctly (and consistently). This ensures that the right people have access to the document.

Filing a document in Complion is a three step process:

Step 1: Select the document from the “Unfiled Documents” folder.

Upon selection, you will be directed to a screen that shows a list of possible document types to select from on the left, and a document preview to aid in filing on the right.



Step 2: Select the Document Type.

In this step, Complion needs to know what kind of document you are filing, or the “Document Type”. Your answer here will determine additional questions that may be asked in Step 3. Selecting the right document type here is critical to ensuring it is filed correctly.

On the left side of the screen, you are provided with pre-determined Document Types from which to choose. You can scroll through the list and click on the document type you want, or, you can simply start typing keywords into the Search Box (which by default says “Filter document type by name or description”) and the list will be quickly filtered for you.

Complion.

Binder

You are filing document **Protocol V2.docx** uploaded in Drug Cure Study

 Select Document Type or Search By Name

Use the UP and DOWN Arrows and press ENTER to make selection

protocol ✕

Document Types

Archived Protocol

Archived Protocol Signature Page

Current Protocol

Current Protocol Signature Page

Step 3: Enter vital information about the document.

The final step in the filing process is important to ensuring Complion has the information it needs to file and name the document correctly. Depending on which Document Type you've selected in the previous step, different supplemental informational fields will appear.

As an example, if you are filing a CV, Complion needs to know the name of the researcher to whom the CV belongs (see the example below). If you are filing an External Safety Report, Complion needs to know the name of the drug to which the safety report is related. The information you enter into these fields will determine the title of the document you're filing. As you complete each field, you will notice the document title automatically updates at the top of the page to match your organization's preconfigured naming conventions. This ensures that all documents adhere to standard naming conventions. To learn more about automatic naming, see [Standard Naming Conventions](#).

You are filing document CV Archer.docx uploaded in Reg Binder 1

✕
Current CV

Expiration Date Required

✕
25 Apr 18

✕
At least one value is required.

✕
At least one value is required.

Reset
Save

CV

Lisa Archer
Account Manager, Complion
Cleveland, OH

W PAGE 1 OF 1

Certain fields may be required and therefore must be completed before you can save the document. By default, the Save button is inactive. Once all required fields have been completed, the Save button will become active. Once saved, you will be returned to the “Unfiled Documents” section where you may process the next document.

Explanatory Tip

A key Complion component is the assigning of document types and attributes. Document types and attributes determine which binder the document will show up in and in which folder/s the document is viewable.

Example

When filing a document as a protocol in your study binder, the system will automatically add the Protocol Number/Study ID to the document based on the binder you uploaded it to. This will ensure that the document is tagged to the binder. Additionally, by choosing the “Protocol” document type the system will make it viewable in all the folders where the protocol should be, as determined by you and your solution architect.

What the System is Doing

When you file a document, it first looks at the attributes you have filled on the different fields (i.e. Protocol Number, Name of Researcher, etc.), to see if they match they match the attributes listed on the binder setup page for those fields to make sure you are saving the document in the correct binder. It then looks at the document type used to file the document to determine which folder/s the document is viewable in. This was determined during the onboarding process by your site and your solution architect.

Standard Naming Conventions

A critical part of running studies efficiently and maintaining compliance is ensuring that regulatory documentation is standardized and managed consistently throughout your institution. Complion helps uphold your institution's standards by automatically naming each document you file into a study binder. Not only does this help guarantee consistency, but it also makes it easy to quickly search and retrieve documentation when needed.

Managing Documents

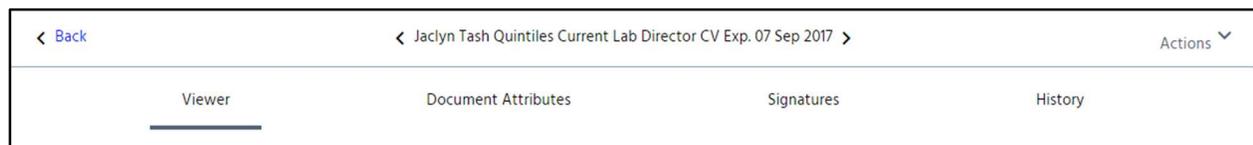
Complion's approach to managing and modifying documents is designed with two primary goals in mind:

- Quickly tell the story of a document and what actions have been taken
- Uphold rigorous institutional and regulatory compliance standards

Therefore, please keep in mind that access to certain information or functionality may be different than your previous experiences.

Viewing Documents

Complion enables you to quickly view all important details surrounding a document, including any important actions that have been taken since the document was uploaded to Complion. Upon opening a filed document, you will notice four main sections. Clicking on any of these sections will take you directly to the specified area of the page.

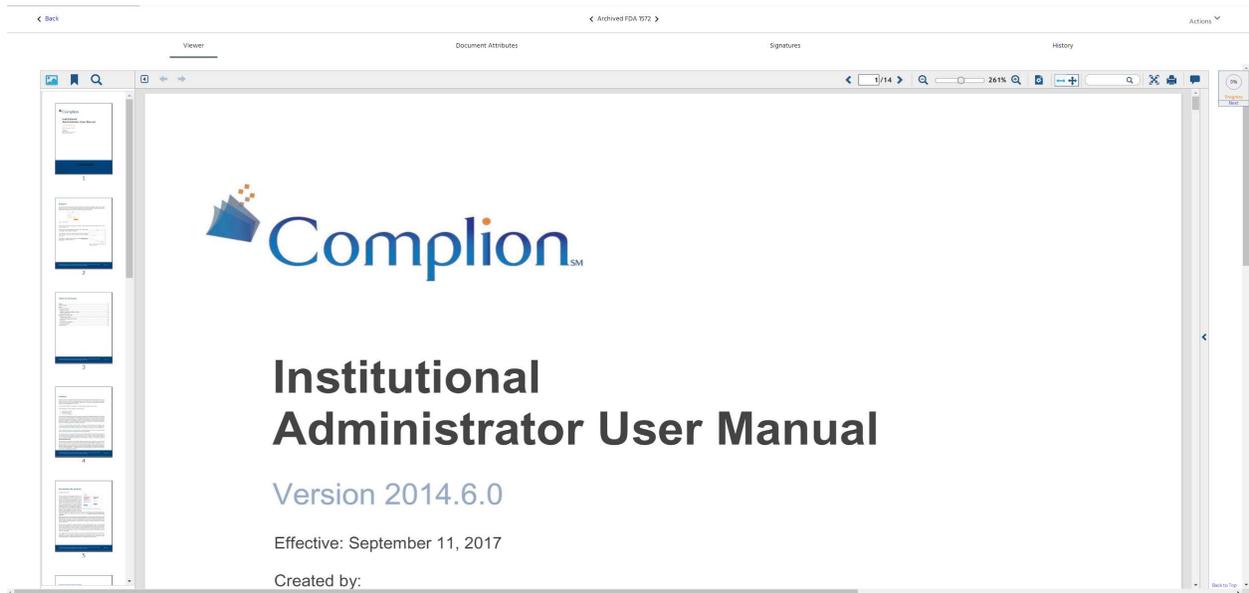


- Viewer: Quickly preview the text and contents of a document.
- Document Attributes: Key information entered when the document was initially filed, when, and by whom.
- Signatures: Displays the name of everyone that electronically signed the document, including the date and time they signed, and the Statement of Testament.
- History: Includes a full audit trail of any actions taken on the document.

04 Feb 2018	08:25 pm	Andrew	Uploaded this Document
10 Jul 2018	01:58 pm	Jaclyn	Downloaded the PDF
10 Mar 2018	09:44 pm	Andrew	Assigned Document Type and Added Document Attributes 
			Type: Added Document Type: Lab Director Medical License, Expired
			Type: Added Archived Date: 31 Jan 2018
			Type: Added Expiration Date: 31 Jan 2018
			Type: Added Lab Director: Taylor Paul (ptaylor @med.miami.edu)
			Type: Added Laboratory: University of Miami Hospital & Clinics,UHealth at Coral Gables,University of Miami Hospital Clinical
	10:31 pm	Andrew	Viewed the Document

Document Viewer

The Document Viewer enables you to view and navigate through the entire document while still inside the binder. A toolbar is included for ease of use. If the document is text searchable, you can search for specific keywords.



Document Attributes

Describes key information entered when the document was initially filed to include when it was filed and by whom.

Viewer	Document Attributes	Signatures	History
System Properties		Document Attributes	
Uploaded By	Rick User	Expiration Date	05 Sep 2017
Uploaded Date/Time	30 Aug 2017 12:31 PM	Lab	Quintiles
Initial Index By	Rick User	Name of Researcher	Jaclyn Tash
Initial Index Date/Time	01 Sep 2017 06:35 PM		
Document Status	Active		

Signatures

The Signatures section displays the electronic signature everyone that has electronically signed the document, including their name, the date and time they signed, and the Statement of Testament.

Viewer	Document Attributes	Signatures	History
Document Signatures			
Joe Admin	18 Dec 2017 03:49 PM	I approved the contents of this document	

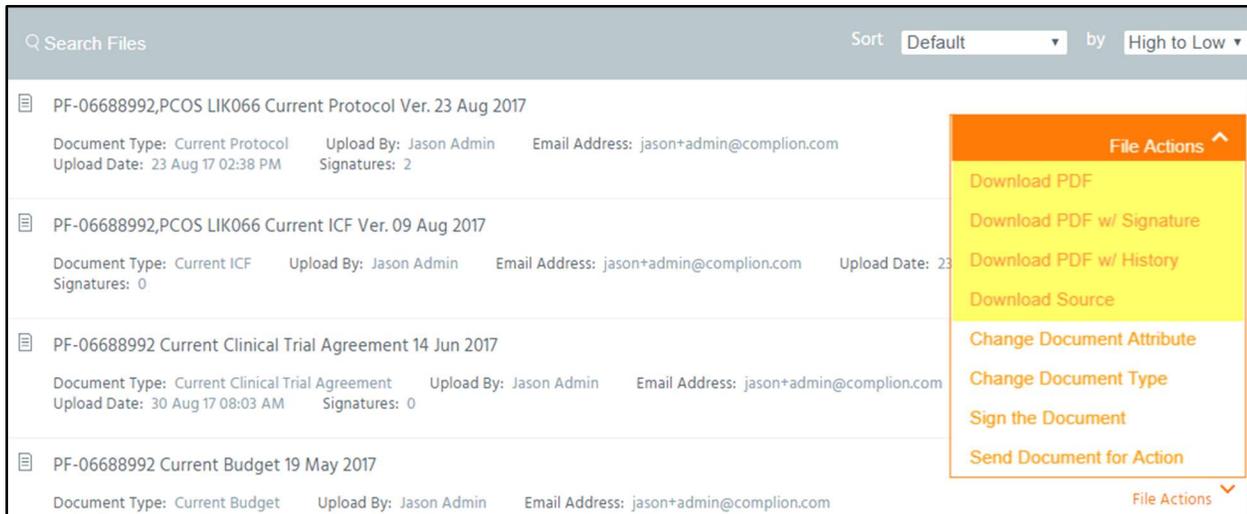
History

The History section displays a full audit trail of any actions taken on the document. If you are looking to see the actions taken during a specific time period, you can filter through the start and end dates on the left.

04 Feb 2018	08:25 pm	Andrew	Uploaded this Document
10 Jul 2018	01:58 pm	Jaclyn	Downloaded the PDF
10 Mar 2018	09:44 pm	Andrew	Assigned Document Type and Added Document Attributes 
			Type: Added Document Type: Lab Director Medical License, Expired
			Type: Added Archived Date: 31 Jan 2018
			Type: Added Expiration Date: 31 Jan 2018
			Type: Added Lab Director: Taylor Paul (ptaylor @med.miami.edu)
			Type: Added Laboratory: University of Miami Hospital & Clinics,UHealth at Coral Gables,University of Miami Hospital Clinical
	10:31 pm	Andrew	Viewed the Document

Downloading Documents

Many times, when a document needs to be shared with someone, the original document or PDF may be difficult to find in your old paper binders or share drives. Luckily, Complion works as not only a document storage solution but as a retrieval application as well. Through the use of the “File Actions” drop down, you can choose from a wide range of methods to retrieve files.



The screenshot shows a web interface for managing documents. At the top, there is a search bar labeled 'Search Files', a 'Sort' dropdown set to 'Default', and a 'by' dropdown set to 'High to Low'. Below this is a list of four documents, each with a document type, upload date, and number of signatures. A 'File Actions' dropdown menu is open over the first document, listing several options: 'Download PDF', 'Download PDF w/ Signature', 'Download PDF w/ History', 'Download Source', 'Change Document Attribute', 'Change Document Type', 'Sign the Document', and 'Send Document for Action'.

- 1) **Download PDF:** This allows you to download the document as a PDF regardless of how the file was originally uploaded.
- 2) **Download PDF w/ Signatures:** This downloads the documents with an additional page showing any signatures that have been finalized on the documents.
- 3) **Download PDF w/ History:** This downloads the document with two additional pages. One showing the document signature page, the other showing any changes that have been made or instances where the document has been viewed or downloaded.

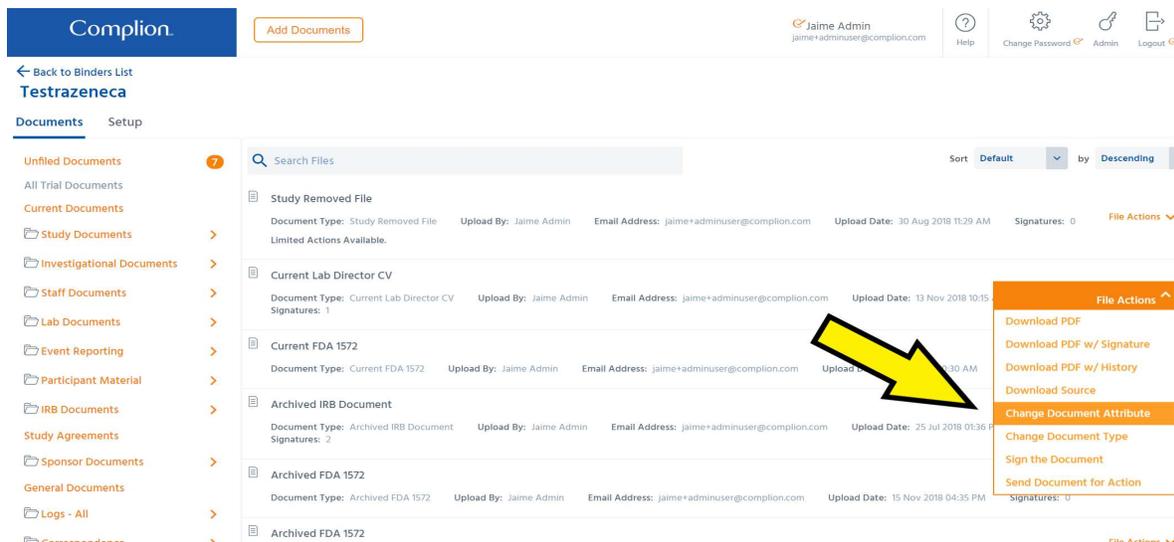
Document History			
Date	Time	Name	Action
27 Apr 2018	15:49 EDT	User	Download PDF with History
27 Apr 2018	15:48 EDT	User	Download PDF with Signatures
27 Apr 2018	15:47 EDT	User	Signed this Document
27 Apr 2018	15:47 EDT	User	Viewed the Document
27 Apr 2018	15:45 EDT	User	Viewed the Document
26 Apr 2018	12:37 EDT	User	Assigned Document Type and Added Document Attributes
26 Apr 2018	12:12 EDT	User	Uploaded this Document

- 4) **Download Source:** This is how you download the original document in the format it was uploaded in. This will not have any of the signature pages or the document history pages attached.

Note: File Actions are dependant on group permissions. If you don't see certain options, this is most likely due to your Complion permissions. File actions are audited and recorded in audit trail section of the document.

Modifying Documents

You can make changes to a document at any point after filing if your Complion permissions allow you to do so. To modify a document, first locate it within the binder folders, and select "File Actions". This will open a drop down menu where you can select "change document attribute" or "change document type".



The screenshot shows the Complion web interface. At the top, there is a navigation bar with the Complion logo, an 'Add Documents' button, and user information for 'Jaime Admin'. Below the navigation bar, there is a breadcrumb trail: 'Back to Binders List' > 'Testrazeneca' > 'Documents' > 'Setup'. A sidebar on the left lists various document categories like 'Unfiled Documents', 'Current Documents', 'Investigational Documents', etc. The main content area displays a table of documents. The 'Current Lab Director CV' document is selected, and its 'File Actions' dropdown menu is open, showing options such as 'Download PDF', 'Download PDF w/ Signature', 'Download Source', 'Change Document Attribute', and 'Change Document Type'. A yellow arrow points to the 'Change Document Attribute' option.

Document Type	Upload By	Email Address	Upload Date	Signatures	File Actions
Study Removed File	Jaime Admin	jaime+adminuser@complion.com	30 Aug 2018 11:29 AM	0	File Actions
Current Lab Director CV	Jaime Admin	jaime+adminuser@complion.com	13 Nov 2018 10:15	1	File Actions
Current FDA 1572	Jaime Admin	jaime+adminuser@complion.com	10:30 AM		
Archived IRB Document	Jaime Admin	jaime+adminuser@complion.com	25 Jul 2018 01:36 P	2	
Archived FDA 1572	Jaime Admin	jaime+adminuser@complion.com	15 Nov 2018 04:35 PM		
Archived FDA 1572					

Changing a Document Attribute

The document attributes vary based on the document type. But here you can change information connected to the document. Once you select Change Document Attribute you will be taken to the filing page. To make a change you can click the X next to the incorrect information and then input the new correct information. When you've finished, click Save.

Viewer	Document Attributes	Signatures	History																
System Properties <table border="1"> <tr> <td>Uploaded By</td> <td>Rick User</td> </tr> <tr> <td>Uploaded Date/Time</td> <td>30 Aug 2017 12:31 PM</td> </tr> <tr> <td>Initial Index By</td> <td>Rick User</td> </tr> <tr> <td>Initial Index Date/Time</td> <td>01 Sep 2017 06:35 PM</td> </tr> <tr> <td>Document Status</td> <td>Active</td> </tr> </table>		Uploaded By	Rick User	Uploaded Date/Time	30 Aug 2017 12:31 PM	Initial Index By	Rick User	Initial Index Date/Time	01 Sep 2017 06:35 PM	Document Status	Active	Document Attributes <table border="1"> <tr> <td>Expiration Date</td> <td>05 Sep 2017</td> </tr> <tr> <td>Lab</td> <td>Quintiles</td> </tr> <tr> <td>Name of Researcher</td> <td>Jaclyn Tash</td> </tr> </table>		Expiration Date	05 Sep 2017	Lab	Quintiles	Name of Researcher	Jaclyn Tash
Uploaded By	Rick User																		
Uploaded Date/Time	30 Aug 2017 12:31 PM																		
Initial Index By	Rick User																		
Initial Index Date/Time	01 Sep 2017 06:35 PM																		
Document Status	Active																		
Expiration Date	05 Sep 2017																		
Lab	Quintiles																		
Name of Researcher	Jaclyn Tash																		

Current Protocol

Date Required

✕

📅

Study ID Required

✕

Version

Once you save the document you will be taken back to the document selection screen.

Note: The file name will be updated based on the changes made.

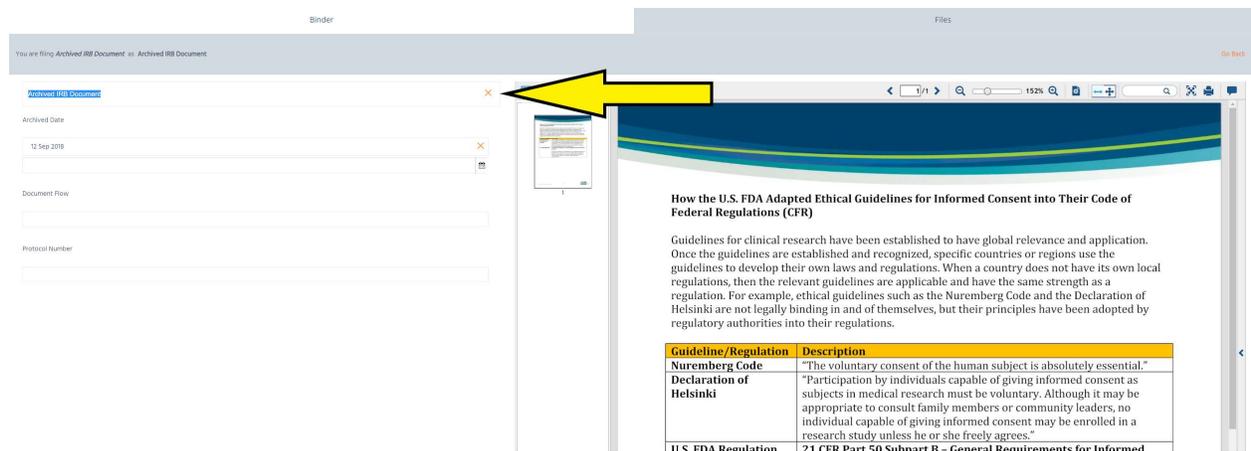
🔍 Search Files

📄 PF-06688992,PCOS LIK066 Current Protocol Ver. 23 Aug 2017

Document Type: Current Protocol Upload By: Jason Admin Email Address: jason+admin@complion.com

Changing a Document Type

This option will give you the ability to change the document attributes as well as the document type. To change the document type you have to first delete the current one by clicking the X. Then search and select your new choice.



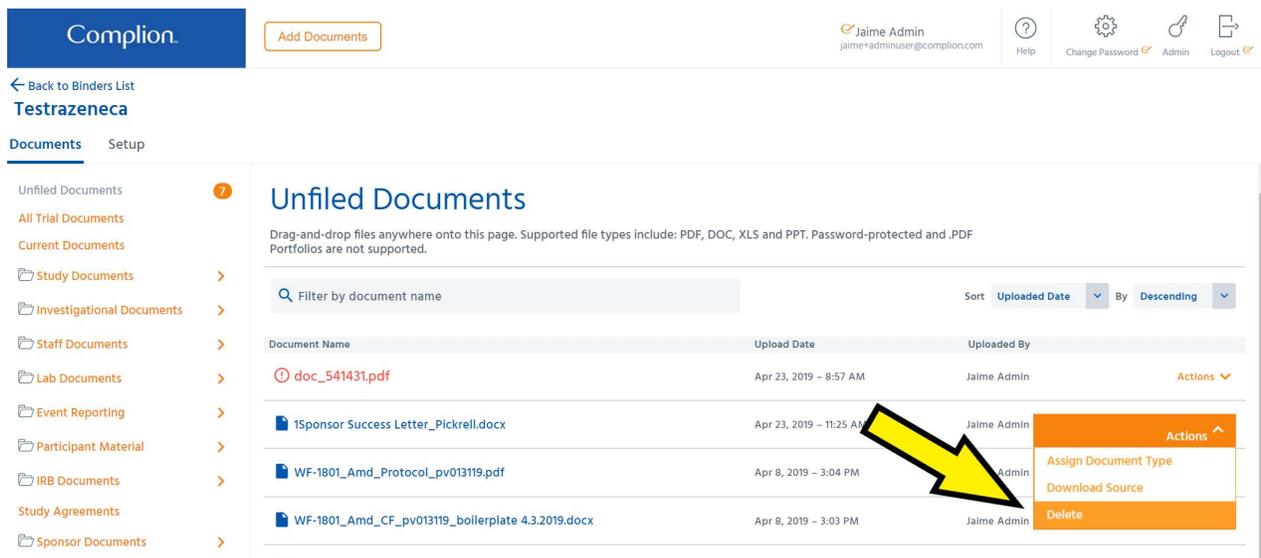
The screenshot shows two windows. The left window, titled 'Binder', is a document editor for an 'Archived IRB Document'. It has fields for 'Archived Date' (12 Sep 2018), 'Document Flow', and 'Protocol Number'. The right window, titled 'Files', shows a document viewer for a document titled 'How the U.S. FDA Adapted Ethical Guidelines for Informed Consent into Their Code of Federal Regulations (CFR)'. A yellow arrow points to the 'X' icon on the document editor tab in the Binder window.

Guideline/Regulation	Description
Nuremberg Code	"The voluntary consent of the human subject is absolutely essential."
Declaration of Helsinki	"Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees."
U.S. FDA Regulation	21 CFR Part 312 Subpart R - General Requirements for Informed

Note: Informational fields that apply to both the original and the new document type will remain filled in. For example, if both document types require a date, that date will stay the same unless changed.

Removing Documents from a Binder

In some cases a document may be uploaded erroneously. Documents can be deleted ONLY if they have not yet been filed. From the Unfiled Documents folder, select the “File Actions” then select “Delete”.



The screenshot shows the Complion web interface. At the top, there is a navigation bar with the Complion logo, an 'Add Documents' button, and user information for 'Jaime Admin'. Below the navigation bar, there is a breadcrumb trail: 'Back to Binders List' > 'Testrazeneca' > 'Documents' > 'Setup'. The main content area is titled 'Unfiled Documents' and contains a table of documents. A yellow arrow points to the 'Delete' option in the 'Actions' menu for the document 'WF-1801_Amd_CF_pv013119_boilerplate 4.3.2019.docx'.

Document Name	Upload Date	Uploaded By	Actions
doc_541431.pdf	Apr 23, 2019 - 9:57 AM	Jaime Admin	Actions
1Sponsor Success Letter_Pickrell.docx	Apr 23, 2019 - 11:25 AM	Jaime Admin	Actions
WF-1801_Amd_Protocol_pv013119.pdf	Apr 8, 2019 - 3:04 PM	Jaime Admin	Actions
WF-1801_Amd_CF_pv013119_boilerplate 4.3.2019.docx	Apr 8, 2019 - 3:03 PM	Jaime Admin	Actions

There is no way to delete a document once it has been filed. Once a document is filed, the only way to prevent a monitor from viewing it is to reclassify it as a “Removed File” (you can name this document type/file anything you wish). This will remove the document in question from all folders except the All Files folder. Search for the Document Type “Removed File,” select it, then save the changes at the bottom of the page.

Sending Documents for Action

Research teams often need to send documents to primary investigators (PI) or other team members for review and/or signature. Complion eliminates the need to manually route paper documents for signature and the need to email, print, and scan documents back and forth for review. Complion also provides a central location to view all completed and outstanding requests, or "Tasks."

There are four common types of Tasks that can be assigned:

- Review
- Approve
- Train
- Read (This is a Read-Only option that will not ask for a signature)

Creating a Task

To send a document for review or signature, you will need to create a Task. Creating a Task in Complion is a three step process.

Step 1: Select a document.

To create a Task, select the document you'd like to send and select "Send Document for Action" under the "File Actions" menu.

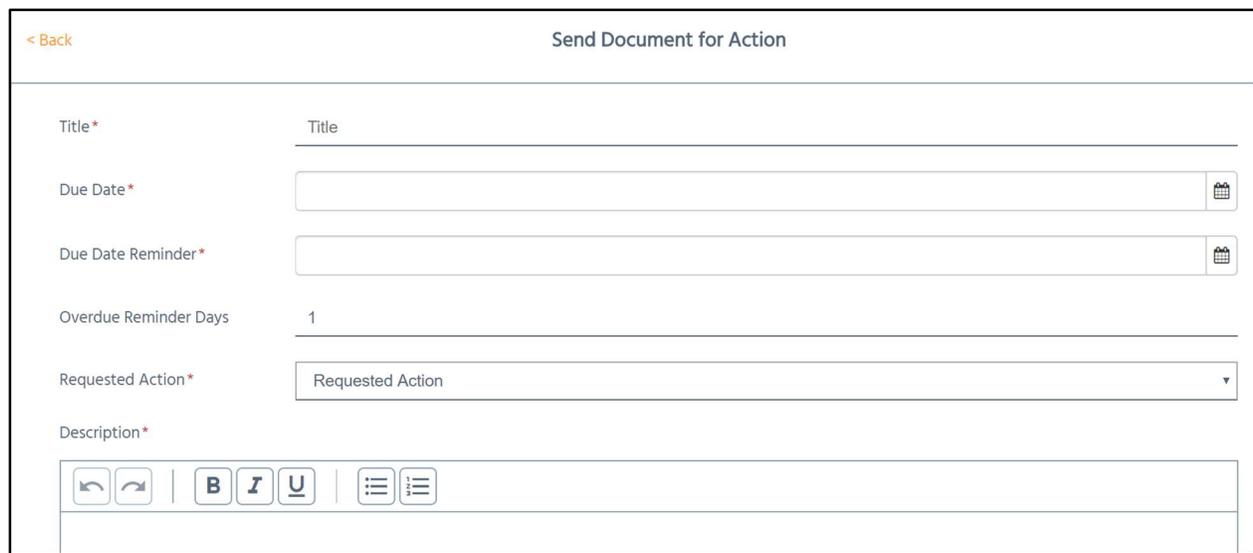


Step 2: Provide related information and assign a Due Date.

You will be directed to the "Send Document for Action" page. Regardless of why you need to send a document, all documents being sent require specific information in order to do so. These items are indicated by a red asterisk.

- **Title:** The header information you would send to the user who needs to sign. Think of this as the Subject line of an email.
- **Due Date:** The date by which the document needs to be signed.
- **Due Date Reminder:** A date that you'd like an email sent to the signer of the document, reminding them that it is due soon (availability dependent on activation of "Reminder Email" feature).
- **Overdue Reminder Days:** If the document goes past its due date, a reminder email will be sent after the number of days input here (availability dependent on activation of "Reminder Email" feature).
- **Requested Action:** One of four actions you'd like the recipient to take: Approve the contents of the document; Review the contents of the document; Train on the contents of the document; and Read the contents of the document. Select the one that is most appropriate.
- **Description:** Any additional information or context you want to provide to the recipient of the task. Think of this as the body of an email.

If you try to send the document for action and the Send button gives you a red warning then one of the items listed above is likely incomplete.



The screenshot shows a web form titled "Send Document for Action". At the top left is a "< Back" link. The form contains the following fields:

- Title*:** A text input field with the placeholder text "Title".
- Due Date*:** A date picker field with a calendar icon on the right.
- Due Date Reminder*:** A date picker field with a calendar icon on the right.
- Overdue Reminder Days:** A text input field containing the number "1".
- Requested Action*:** A dropdown menu with "Requested Action" selected and a downward arrow.
- Description*:** A rich text editor area with a toolbar containing icons for undo, redo, bold (B), italic (I), underline (U), bulleted list, and numbered list.

Step 3: Assign the task.

To assign a task to another user or team member, select the names of the individuals from the User menu. Select the user by finding their name and clicking their row.

Users			Selected Users		
Search Users					
Joe Admin	joe+admin@complion.com	+	Jason Admin	jason+admin1@complion.com	×
Rick Admin	rick+admin@complion.com	+	Paolo Appley	paolo+demo@complion.com	×
Jacob HealthSystems	jacob+healthsystems@complion.com	+	Mack Admin	mack+admin@complion.com	×
Jeremy Complion	jeremy+complion@complion.com	+			
Don Complion Health System	don+complion_health_system@complion.com	+			
Rick Coordinator	rick+coordinator@complion.com	+			
Jason Coordinator	jason+coordinator1@complion.com	+			
			<input type="button" value="Send"/>		

Note: If you need one user to review the document and another to approve the document you will need to go through this process twice.

Cancelling a Task

There are times when it would be useful to cancel a task that you have sent to someone. For example, you may have sent a task to a study team member who is no longer on the study. For any incomplete tasks, you are able to cancel that task in two steps.

Step 1: Select the sent Task.

Navigate to the Sent View and select an incomplete task that you want to cancel.

Binders	Inbox	Sent		
<input type="text" value="Search by subject"/>		<input type="button" value="Show All Tasks"/>	<input type="button" value="Sort Sent Date"/>	<input type="button" value="By Ascending"/>
<div style="display: flex; align-items: flex-start;"> <div style="margin-right: 10px;">▶</div> <div> <p>Subject: Test Task</p> <p>Sent: 04 May 2018 11:34 AM</p> <p>Test Task Information</p> </div> <div style="margin-left: 20px;"> <p>Due: 19 May 2018</p> </div> <div style="margin-left: 20px;"> <p>Status: Incomplete</p> </div> </div>				

Step 2: Cancel the Task.

On the Task detail page, scroll down to the User Assignments header. A list of all the users who have been assigned this task will be displayed. On the far right, select Cancel by the individual user.

< Back Test Task

Title
Test Task

Due Date
19 May 2018 11:32 AM

Reminder Date
10 May 2018 11:32 AM

Status
Incomplete

Requested Action
Approve And Sign

Description

Document Requesting Action
 PF-06688992,PCOS LIK066 Current Protocol Ver. 23 Aug 2017
 File ID: 3123 Uploaded By: Jason Admin Email Address: jason+admin@complion.com Upload Date: 23 Aug 2017 Signatures: (3)

User Assignments

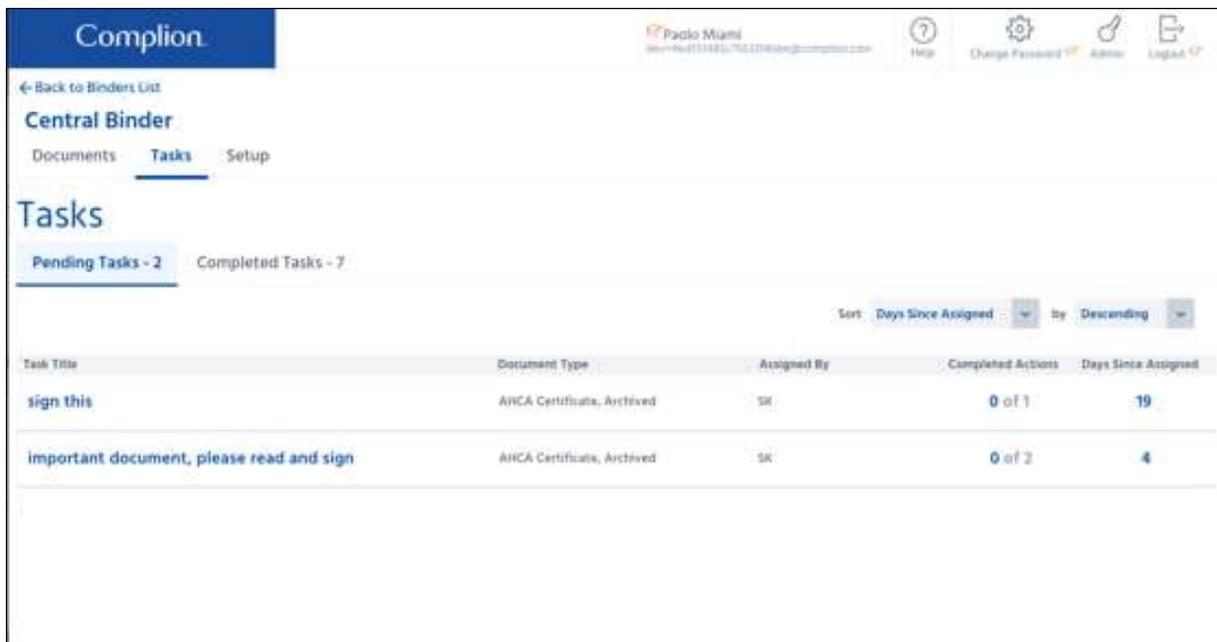
Name	Email	Status	Cancel
User	user@complion.com	Incomplete	<input type="button" value="Cancel"/>

User Assignments

Name	Email	Status	Cancel
Jaime	admin@complion.com	Canceled	

Binder Task Overview

Once logged into a binder you may see the Tasks tab. Within this tab, you can view all pending or incomplete tasks and drill into each task to cancel an assignment if necessary. You may also review all completed tasks in the binder, regardless of who initially sent the task.



Complion Palo Miami
www.hed2148674227@complion.com

Help Change Password Admin Logout

← Back to Binders List

Central Binder

Documents Tasks Setup

Tasks

Pending Tasks - 2 Completed Tasks - 7

Sort: Days Since Assigned by: Descending

Task Title	Document Type	Assigned By	Completed Actions	Days Since Assigned
sign this	AINCA Certificate, Archived	SR	0 of 1	19
important document, please read and sign	AINCA Certificate, Archived	SR	0 of 2	4

Please note: This capability is protected using permissions. This must be granted to you by Complion staff in order to be viewed.

Completing a Task using Electronic Signatures

There are many research documents, forms, and agreements that require signature. Physicians and Coordinators lose precious time when compiling paperwork and chasing down signatures. Complion's Electronic Signature (eSignature) functionality saves you time and eliminates the need to print and manually route forms and documents.

You can review and sign a document in Complion in one of two ways:

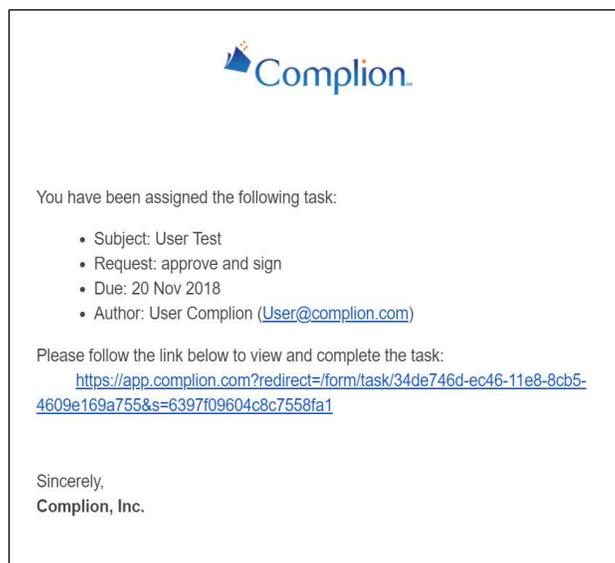
- eSign a document through a Task
- eSign a document directly

eSign a Document Through Tasks

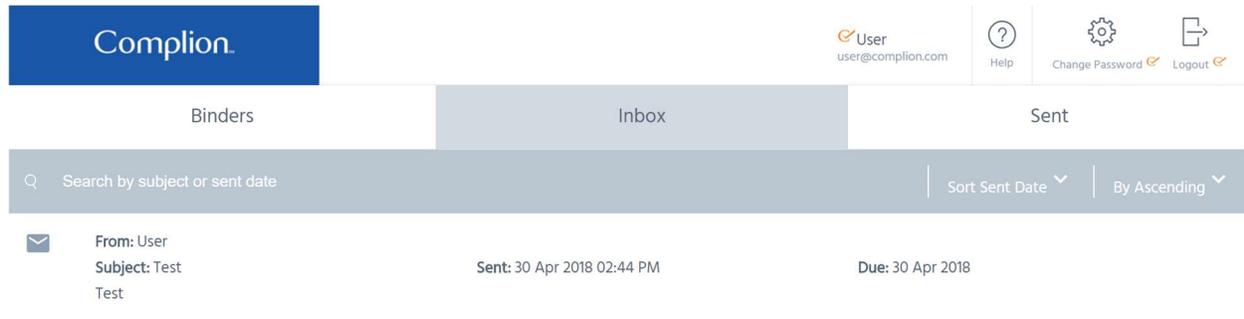
When another user “[Sends a Document for Action](#)” (SDFA) within Complion, Complion will automatically generate an email notification with a direct link for you to review and sign the document. To Electronically Sign (eSign) a document via a task, follow the steps below.

Step 1: Open the task requiring your signature in Complion.

Click the link within the Complion-generated email notification. You will be asked to login to Complion if you have not yet. Once logged in you will be taken to a document review page. It will be titled according to the action you are asked to take.



You can also navigate to these documents from your Complion Inbox tab. Simply click on the task to be directed to the document.



Step 2: Review the Document.

Once opened, review the contents of the document along with any corresponding notes. Once you have reviewed the document, you can select the “Select Document and Sign” button, which will complete the task.

Step 3: eSign the Document.

You will be taken to a screen to input your email and password. This is where the eSigning actually occurs.

Approve and Sign

PF-06688992,PCOS LIK066 Current Protocol Ver. 23 Aug 2017

Statement of Testament
I approved the contents of this document

✉ Email Address

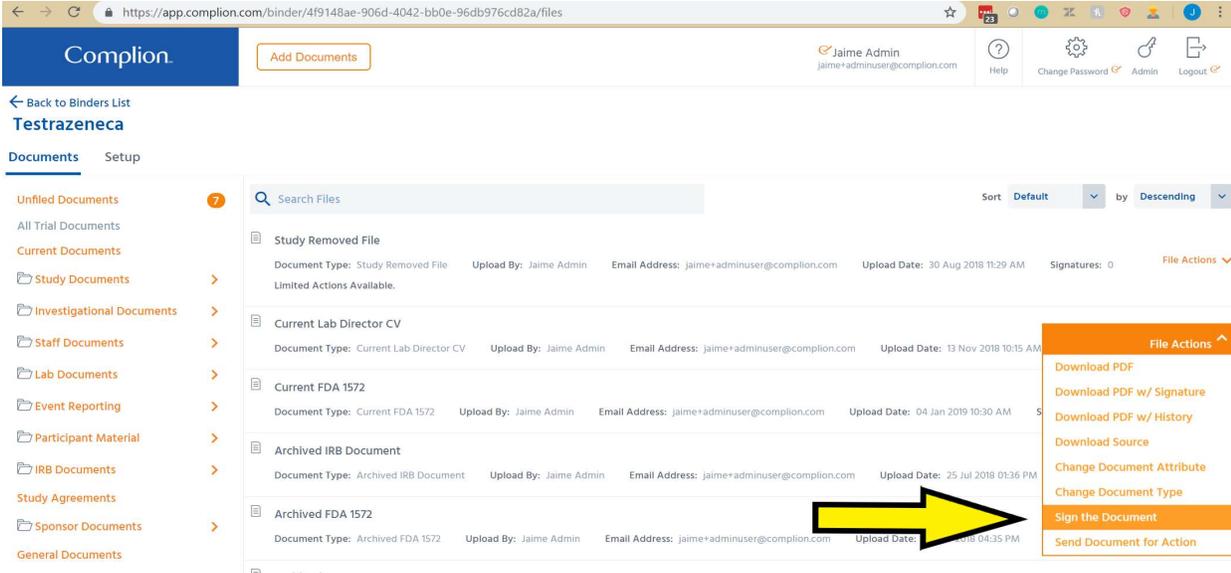
✉ Password

Sign Document and Complete Task

Enter your credentials and click Next. You will then see a blue banner saying that the task was completed successfully. The document is now signed.

eSign a Document Directly

To eSign a document directly, without assigning a task, navigate to the document directly in Complion and choose from the drop down (quick user actions at the right) to sign the document.



The screenshot shows the Complion web application interface. The browser address bar displays the URL: <https://app.complion.com/binder/4f9148ae-906d-4042-bb0e-96db976cd82a/files>. The user is logged in as Jaime Admin (jaimie-adminuser@complion.com). The page title is "Testrazeneca" under the "Documents" section. A sidebar on the left lists document categories: Unfiled Documents (7), All Trial Documents, Current Documents, Study Documents, Investigational Documents, Staff Documents, Lab Documents, Event Reporting, Participant Material, IRB Documents, Study Agreements, Sponsor Documents, and General Documents. The main content area shows a list of documents with columns for Document Type, Upload By, Email Address, and Upload Date. The "Archived IRB Document" row is selected, and the "File Actions" menu is open, showing options: Download PDF, Download PDF w/ Signature, Download PDF w/ History, Download Source, Change Document Attribute, Change Document Type, **Sign the Document**, and Send Document for Action. A yellow arrow points to the "Sign the Document" option.

Document Type	Upload By	Email Address	Upload Date	Signatures	File Actions
Study Removed File	Jaime Admin	jaimie-adminuser@complion.com	30 Aug 2018 11:29 AM	0	File Actions
Current Lab Director CV	Jaime Admin	jaimie-adminuser@complion.com	13 Nov 2018 10:15 AM		File Actions
Current FDA 1572	Jaime Admin	jaimie-adminuser@complion.com	04 Jan 2019 10:30 AM		File Actions
Archived IRB Document	Jaime Admin	jaimie-adminuser@complion.com	25 Jul 2018 01:36 PM		File Actions
Archived FDA 1572	Jaime Admin	jaimie-adminuser@complion.com	13 Aug 2018 04:35 PM		File Actions

eSignature Manifestation

In the research world, signing a document inaccurately is (unfortunately) a common occurrence. Ensuring the accuracy and legibility of names and date formats is critical to ensuring compliance. Complion ensures that every document is signed consistently and that every signature is clearly attributable to the right signer and the right document.

The manifestation of an eSignature within Complion, represented below, is presented in a format consistent with 21 CFR Part 11 requirements and industry best practices.

Document Name: PF-06688992,PCOS LIK066 Current Protocol Ver. 23 Aug 2017

Document ID: 3123

Statement of Testament: I approved the contents of this document

Electronic Signature for: User

Electronically Signed by: user@complion.com

Date and Time of Signature: 30 Apr 2018 14:12 EDT

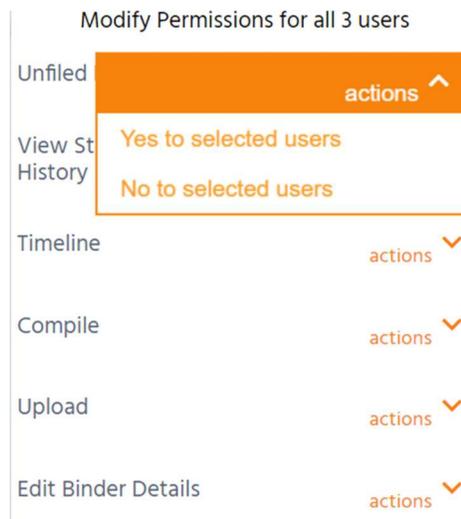
Study Binder User Access

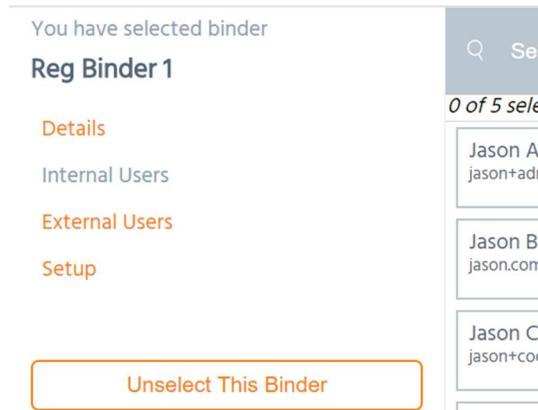
Depending on your organization, access to binders might need to be limited. You may also want to give limited access to monitors for a set amount of time. This can be done by selecting the binder for which you wish to change access, then selecting the Binder Tab through the Document View.



Internal Users

This area is only accessible if you have the proper permissions enabled. When looking at the binder set up you should see a section labeled “Internal Users”. Here you can give users access to a binder as well as modify many other permissions.





To modify Binder access for an internal user, follow the steps below.

Step 1: Select the User(s) you wish to modify.

If different users should have different permissions they should be selected separately. If they all have the same permissions they can all be selected and modified at once.

Search by user or group		Show all users
0 of 5 selected. Click on user to select. Click again to remove.		Select All Unselect All
Jason Admin jason+admin@complion.com	groups	does not have access Showing default permissions for user
Jason Beder jason.complion@gmail.com	groups	does not have access Showing default permissions for user
Jason Coordinator jason+coordinator@complion.com	groups	does not have access Showing default permissions for user
Brian Farrell bfarrell@complion.com	groups	does not have access Showing default permissions for user
Anuj Gupta anuj+ch@complion.com	groups	does not have access Showing default permissions for user

Step 2: Modify the permissions if needed.

Once the users are selected, you can move to modifying permissions for the users if their permissions should be different for this individual binder from what their default permissions are based on their role. You can do this by selecting the “actions” drop down. Each of these is either Yes or No. Yes will mean that

they have access to this area or can make changes to the listed item. For example, allowing Unfiled Documents lets the user view and modify/update any unfiled documents. Changing permissions here will override related default permissions.

Modify Permissions for all 3 users

Unfiled Documents	actions ▼
View Status and Document History	actions ▼
Timeline	actions ▼
Compile	actions ▼
Upload	actions ▼
Edit Binder Details	actions ▼
Manage External User Access	actions ▼
Manage Internal User Access	actions ▼
Edit Binder Level Query	actions ▼

Step 3: Review and Save your changes.

When finished you must select “Save Changes.” There are two ways to view the user list. The Summary view which only shows the user and whether or not they have permissions. The second is the Detailed view, which shows you exactly what the user has access to.



Note: Editing permissions within a particular binder will override the Default Binder permissions previously set for the selected user for that binder only.

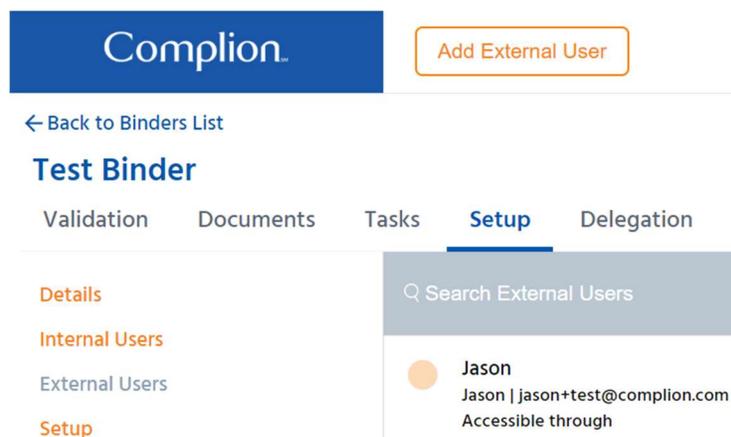
External Users / Monitor Access

Providing external users, or monitors, with access to a study binder in Complion can help streamline the review process and eliminate redundant work for Coordinators and staff.

Complion makes it easy to provide Monitors or CRAs with secure access to a study binder for a specific amount of time. You no longer have to email documents back and forth or upload documents to a portal. Monitors benefit from the ability to get what they need in a faster, more cost-efficient manner. Additionally, when site visits are necessary, they have the ability to prep in advance or catch up after a visit.

To grant an external user with access to a Study Binder, follow the steps below:

Step 1: Navigate to a binder, and select Setup > External Users



Step 2: Add an External User by inputting a valid email address

Add External User

Please provide the email address for the person you wish to add.

Email Address ***Required**

email@example.com

Please fill in a valid email address

Close

Continue

Step 3: If the user already has a Complion account, the system will indicate this. Their email address and first and last name will be unavailable for editing. Simply edit the access date range and save your changes.

Add External User

This person already has an account in Complion. To provide access to this binder, please complete the Access Window and then add this user.

Account Information

Email Address

jason+test@complion.com

First Name

Jason

Last Name

Jason

Access Window

Please select when you would like this monitor to have access to this binder.

Date Range ***Required**

Start Date



End Date

Start Time ***Required**

10:48 AM

End Time ***Required**

10:48 AM

Close

Save Changes

Step 4: If the user has no Complion account, you'll be able to create one here. Enter the user's first and last name, checking if there are any spelling errors in the email address. Edit the access date range and save your changes. That's it!

Add External User

This person does not have an account in Complion yet. Please complete the required information and we will create an account and send out a welcome email to this person.

Account Information

Email Address
add@complion.com

First Name ***Required**

John

Please fill in this field

Last Name ***Required**

Doe

Access Window

Please select when you would like this monitor to have access to this binder.

Date Range ***Required**

Start Date



End Date

Start Time ***Required**

11:55 AM

End Time ***Required**

11:55 AM

Close

Save Changes

Once an External User has been added to your binder the Actions drop-down will allow you to manage the user's account. Edit allows you to update the user's access to your binder; Resend Invitation will reset the user's account to the beginning of the registration process and email them a new registration link; Remove From Binder will entirely remove the user from your binder and revoke their access.

Q Search External Users

<p> User External User user+external@complion.com Accessible 05-01-2018 4:22PM through 05-08-2018 4:22PM</p>	<p>Actions ^</p> <ul style="list-style-type: none">EditResend Invitation Remove from Binder 
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