![GW | Office of Clinical Research | School of Medicine & Health Sciences | THE GEORGE WASHINGTON UNIVERSITY]
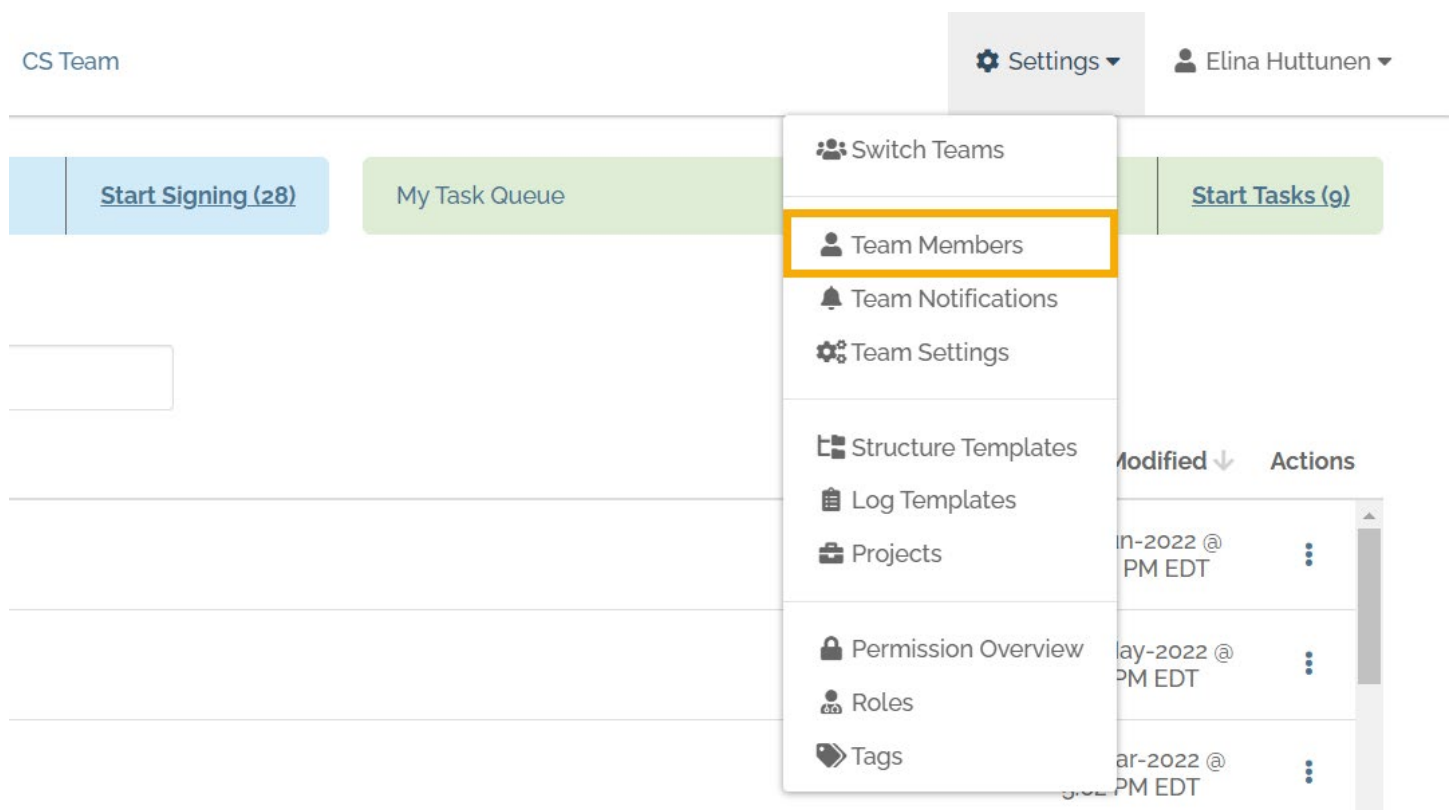
Florence Monitor Access Guidance

Updated February 22, 2024

To Assign Roles to a User:

1. Navigate to the 'Settings' menu in the top left corner and select 'Team Members'

2. On the Manage Team Members page, select the user, click on the 'Actions' button and select 'Manage Access'

Manage Team Members: CS Team

	ADD MEMBERS	REPORT ▾	ACTIONS ▾	🔽	florence	
	Associated Log in(s) ▲		👤 Manage Access	ss	Roles	Actions
			🔒 Permission Overview			
☐	Catalina Villarreal catalina.villarreal@florencehc.com			florencehc.com	Log Signer	⋮
☑	Elina Huttunen elina.huttunen@florencehc.com		elina.huttunen@florencehc.com		Admin, Binder Owner: o. Vaccine Trial, and 13 other(s)	⋮
☐	Florence Support support@florencehc.com		support@florencehc.com		Florence Support	⋮

3. In the Manage Access popup you can type in the role name in the search bar at the top or you can scroll through the list of roles and select the role you want to assign to the user:

Manage Access for **Elina Huttunen**

Search below to add a role and manage their access

🔍 Search Role by name ▾

Pharmacist - Test
Regulatory
Site Staff
Study Coordinator
Study Investigator
Study Pharmacist
Study Staff
Team Admin

CANCEL   SAVE

4. Verify you selected the correct role. Note: the role is not active/turned ON yet

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5. To make the role active, click on the 'Off/On' toggle so it turns green. This will populate the Start and End date and time to 'Now' and 'Never', respectively, by default.
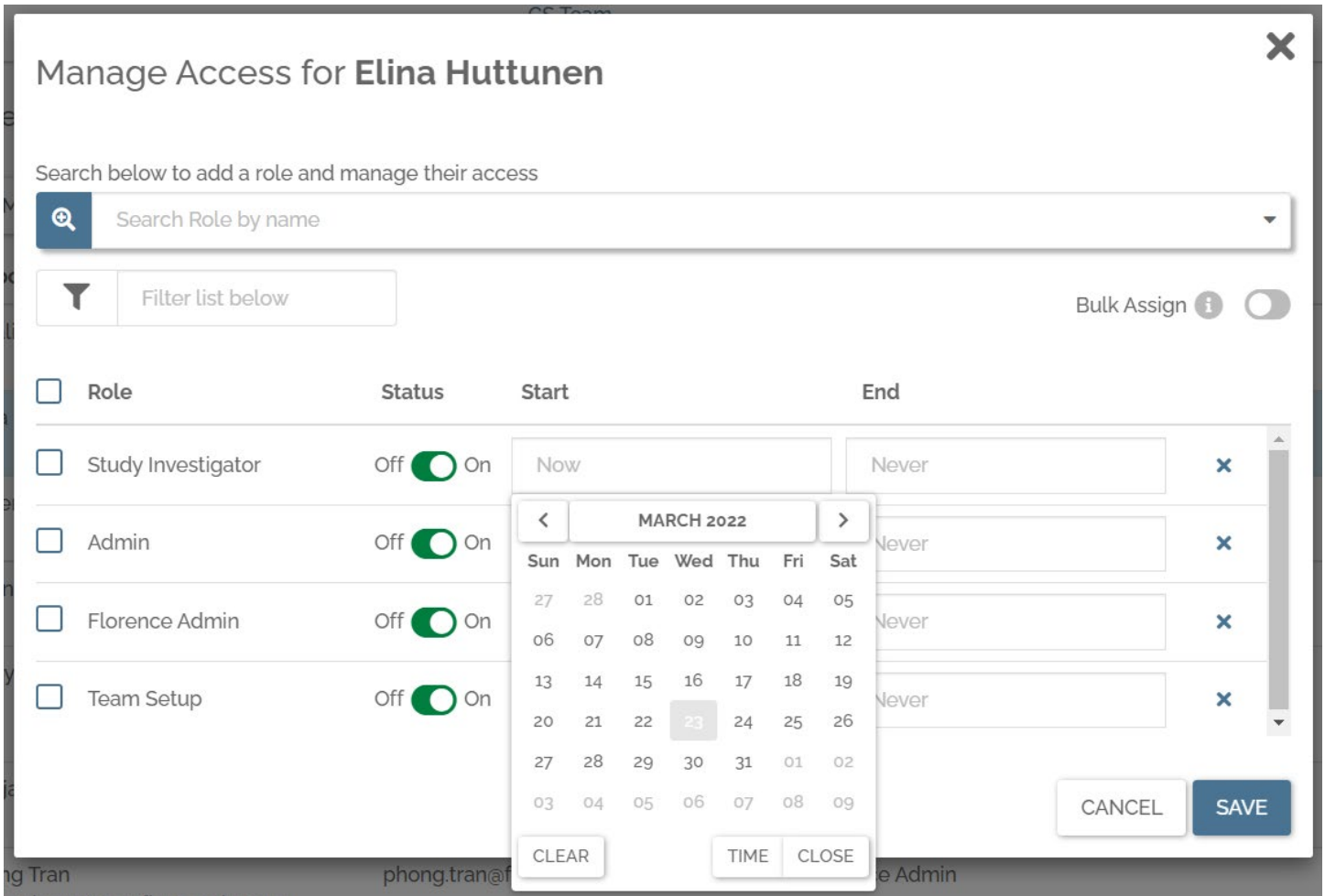
Role	Status	Start	End	
Study Investigator	Off ◉ On	Now	Never	✕
Admin	Off ◉ On	26-Jan-2022 @ 04:45 PM EST	Never	✕
Florence Admin	Off ◉ On	11-Feb-2021 @ 04:34 PM EST	Never	✕
Team Setup	Off ◉ On	11-Feb-2021 @ 04:32 PM EST	Never	✕

6. If desired, select a different start/end date and time by clicking in the 'Start' and 'End' fields and using the date and time pickers

7. Click Save

To Assign Users to Roles:

1. Navigate to the 'Settings' menu in the top left corner and select 'Roles'
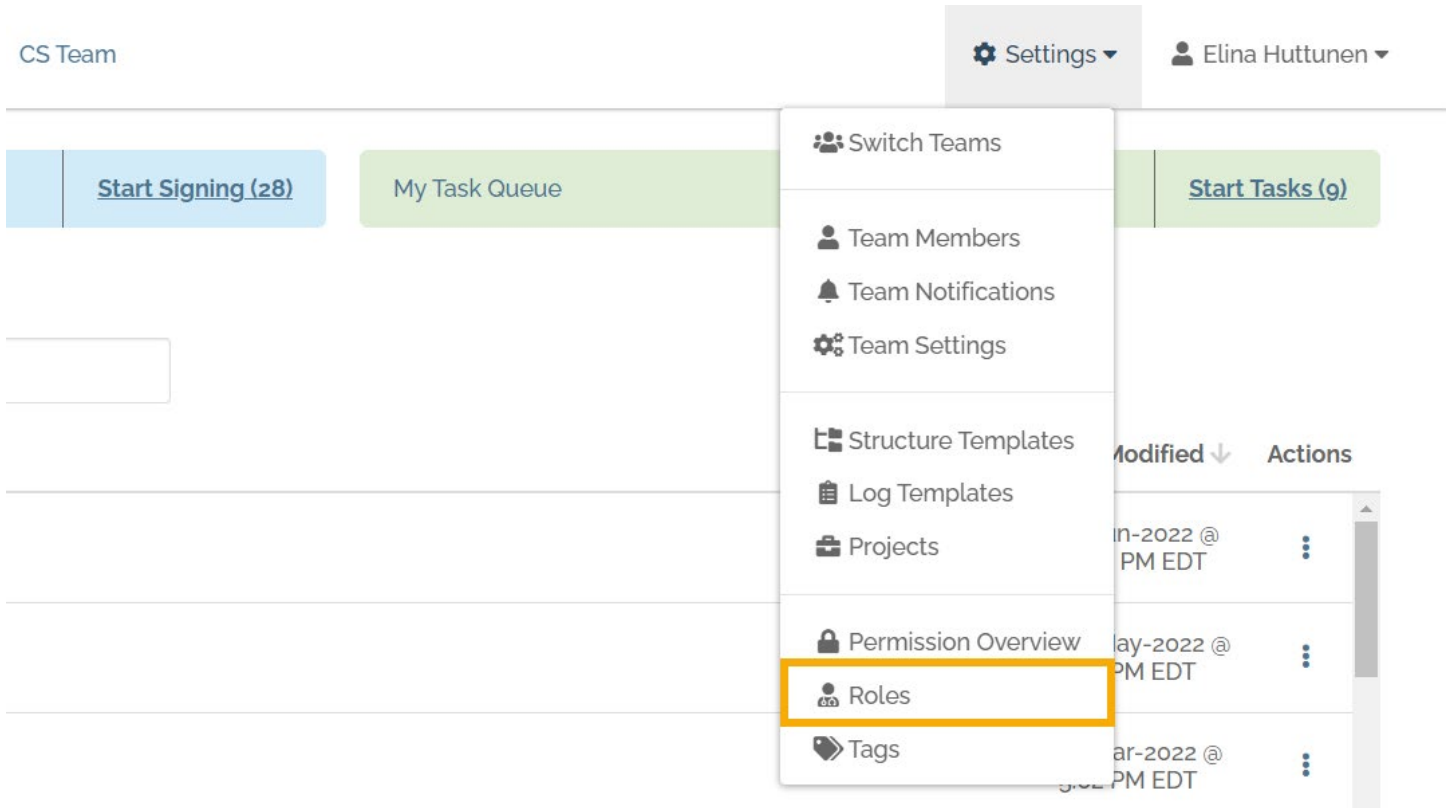
2. Once you're on the Manage Roles page, check the box next to the role you want to assign, click on the 'Actions' button and select 'Manage Access'
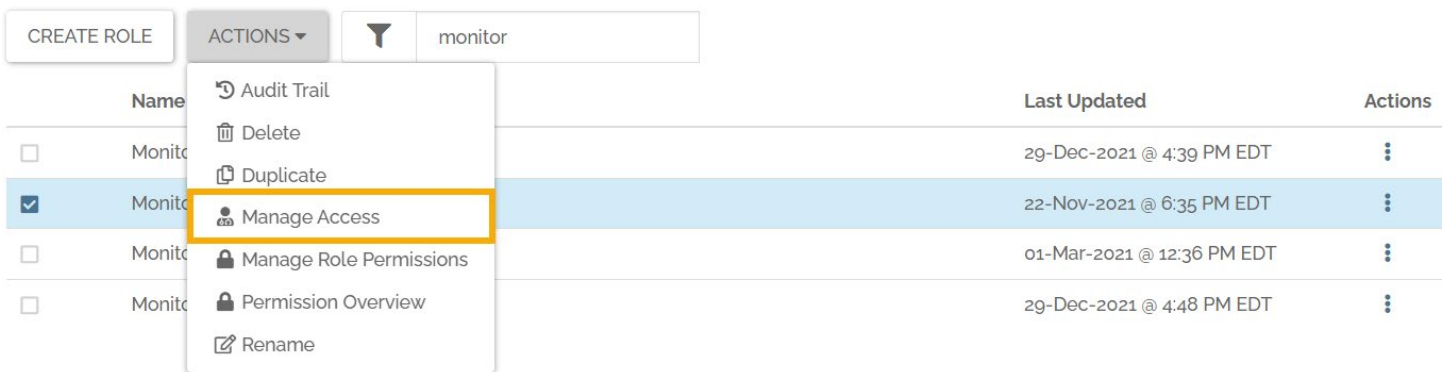
3. In this next window, enter the name or email address of the user or users who should have this role assigned:
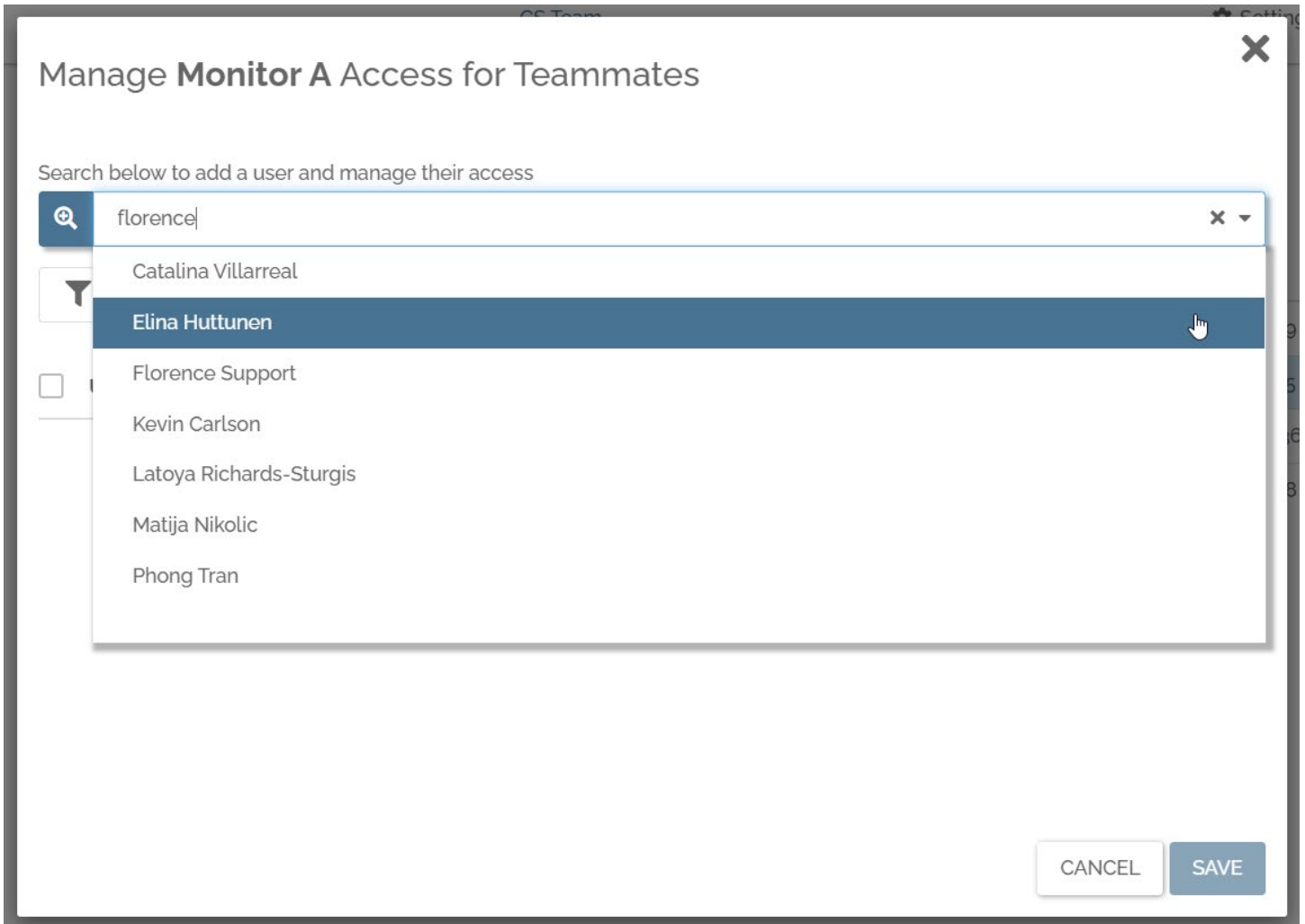
4. Verify you selected the correct user. Note: the user's role is not active/turned ON yet

6. To make the role active, click on the 'Off/On' toggle so it turns green. This will populate the Start and End date and time to 'Now' and 'Never', respectively, by default. Modify if needed.

7. Once you have entered all your desired users and their dates, click on 'Save'

To Bulk Manage Access Dates:

1. Select multiple users

2. Activate the 'Bulk Assign' toggle

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3. Select the users you want to assign the role to (select all by checking the box next to 'User'), click on the Off/On toggle, and select Start and End dates if needed.

4. Click 'Save'. The role has now been activated for all the selected users with the same Start and End dates.

Manage **Monitor A** Access for Teammates

Search below to add a user and manage their access

🔍 Search User by name ▾

▼ Filter list below   Bulk Assign ⓘ ⬤

☐	User	Status	Start	End	
☐	Catalina Villarreal	Off ⬤ On	23-Mar-2022 @ 07:14 PM EDT	Never	✖
☐	Elina Hu	Off ⬤ On	23-Mar-2022 @ 07:14 PM EDT	Never	✖
☐	Elina Huttunen	Off ⬤ On	23-Mar-2022 @ 07:14 PM EDT	Never	✖
☐	Florence Support	Off ⬤ On	23-Mar-2022 @ 07:14 PM EDT	Never	✖

CANCEL   SAVE

Monitor Guidance

Navigation

The Monitor menu is available on individual documents only. Documents can be found inside the available Binders and Folders within your Team.

To search for a specific document, enter its name in the Search Bar in the top left of the eBinders screen:
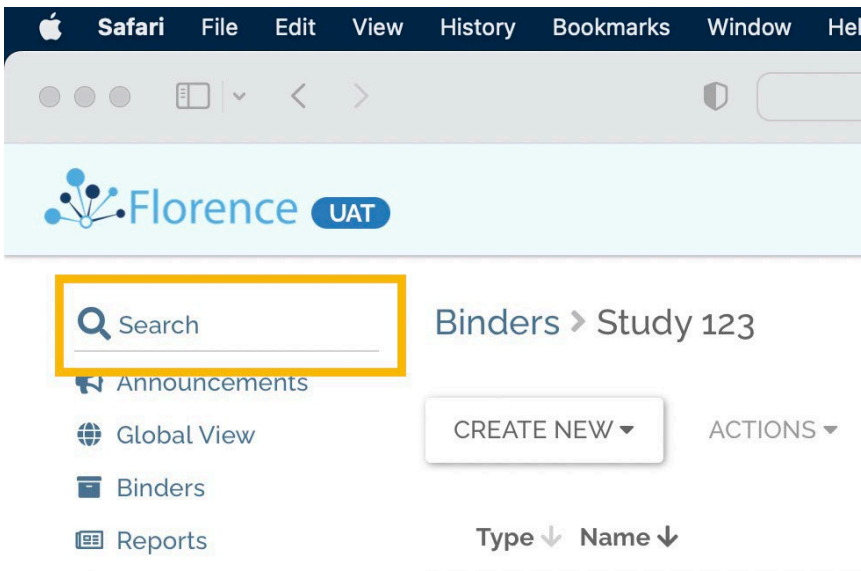
You can also filter your view by typing the name of the folder or binder you're looking for.
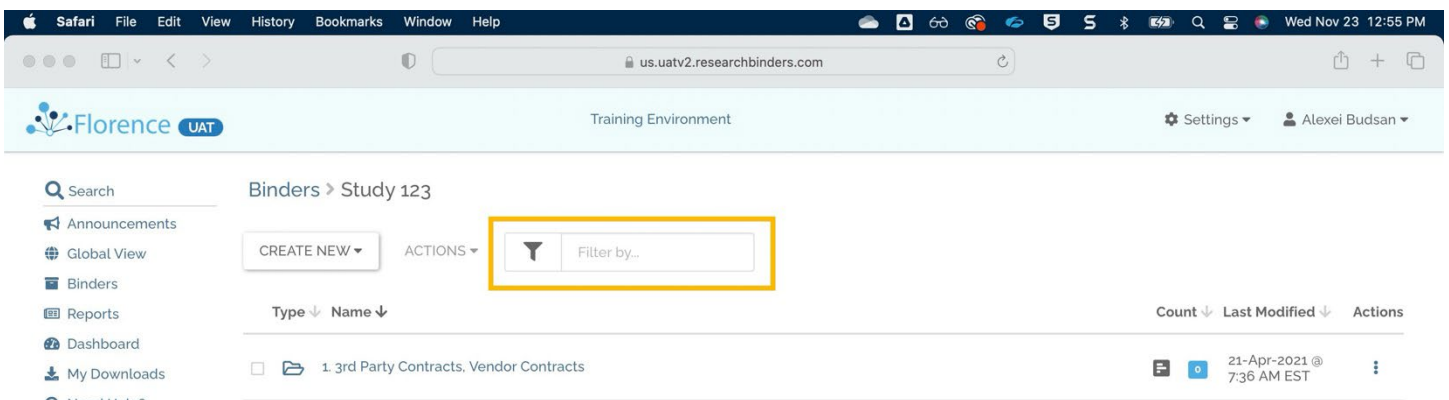
Don't see your Study?

Contact your Team's Administrator so they can grant you access to the study you need.

Document View

Once you've found the document you're looking for, you should see the Monitor menu at the top of the document, next to the Manage menu and Version. Under the Monitor menu, you have two options (*three if Review is enabled*).

Review if document is under review (optional feature)*

Approve if document meets requirements

Create Query if you have any questions/issues for the site to resolve.

*To enable this feature (permission-driven access), please see your Team's Admin.
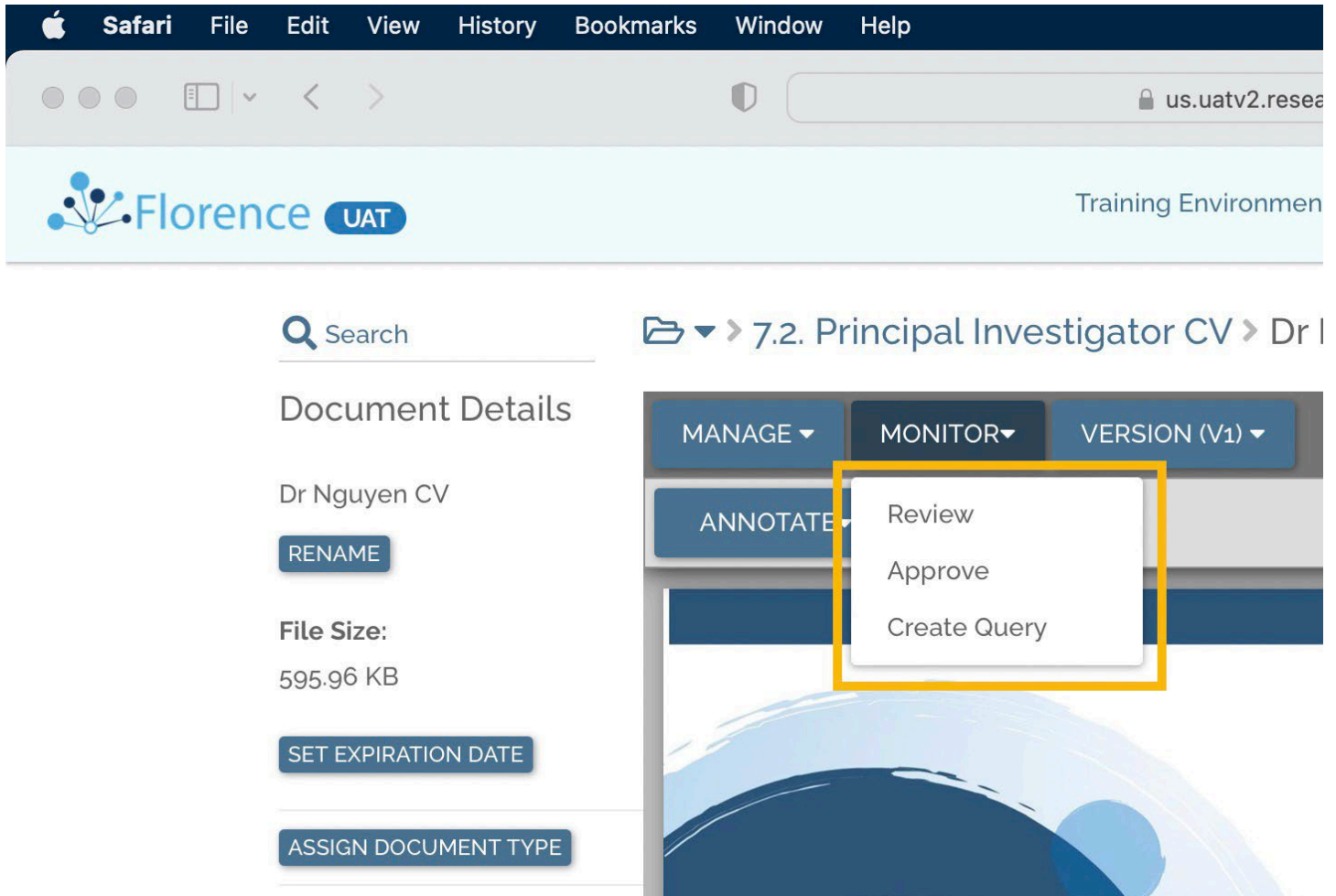
Click to zoom or rotate using the arrow icon on the top right of the document for better visibility.
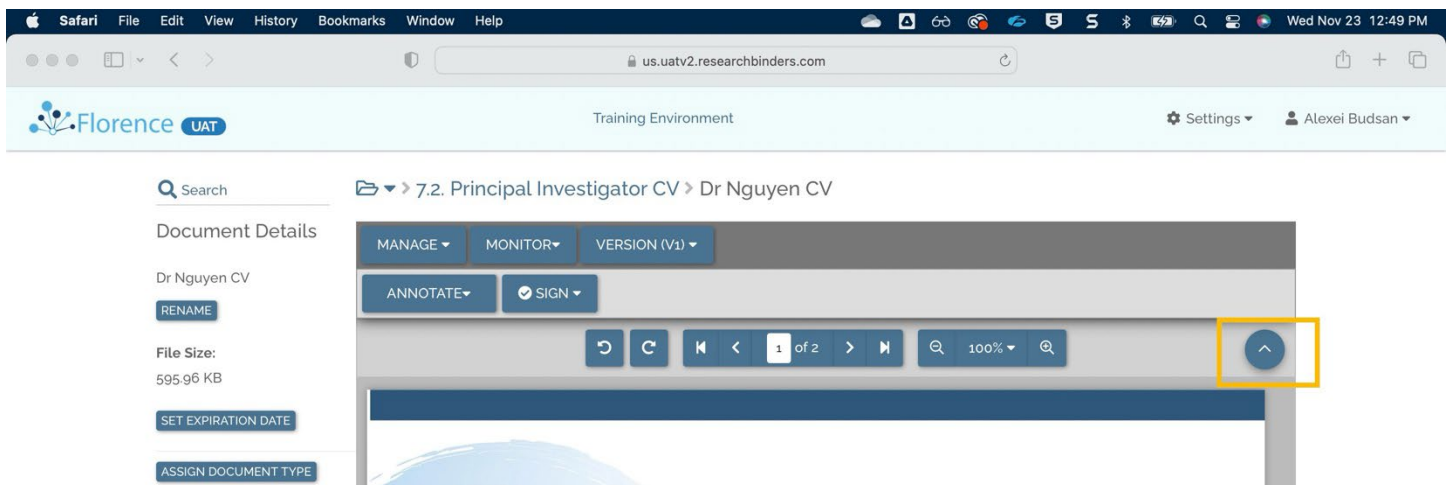
*Next, either Mark as **Approve**, **Create Query**, or Mark as **Review** (if available).*
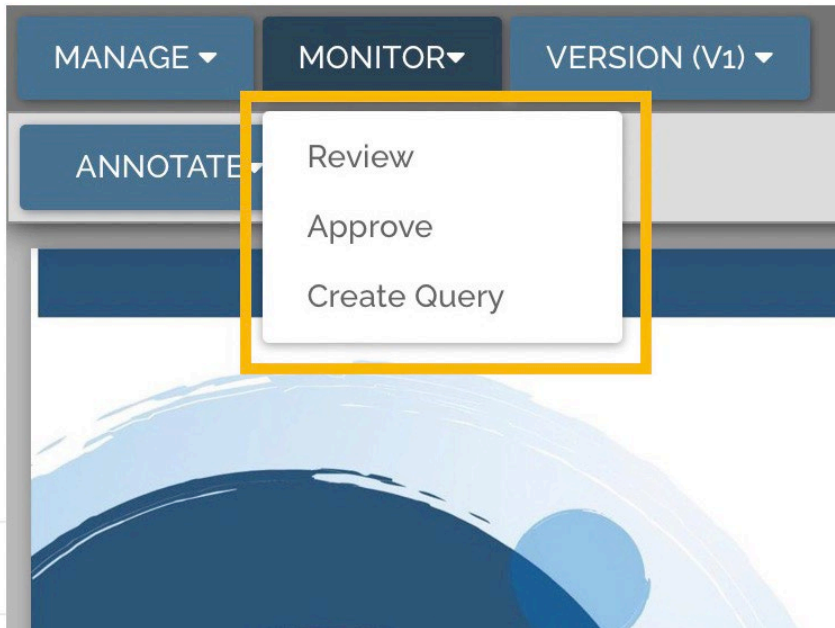
Approve – If you're happy with the document, click Approve from the menu, and then the Approve button within the popup window, you're done!
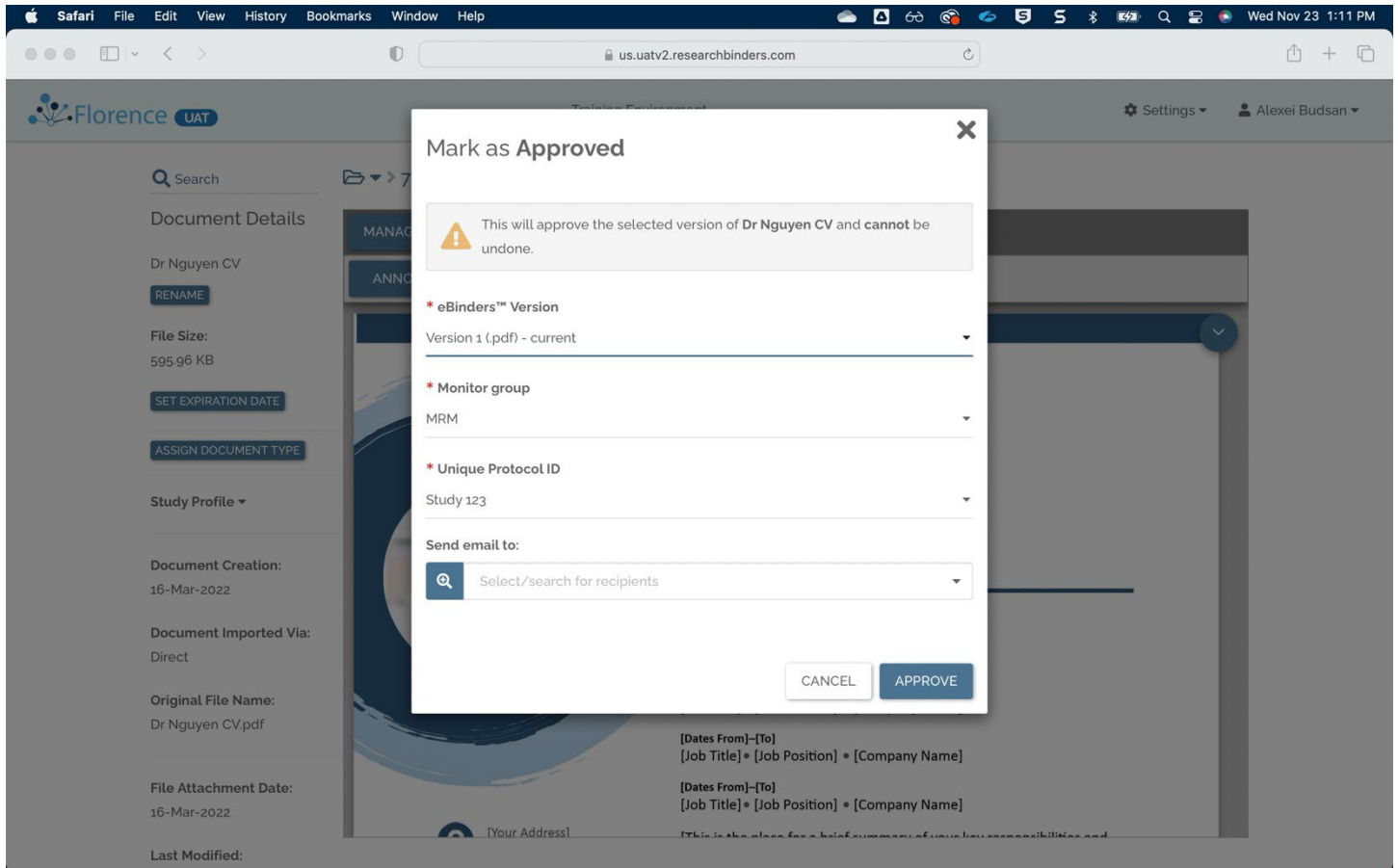
Create Query – If you have questions, click Create Query from the menu. In the popup window, confirm the Organization and Protocol, add comments and click the Save button – wait for Site's response.
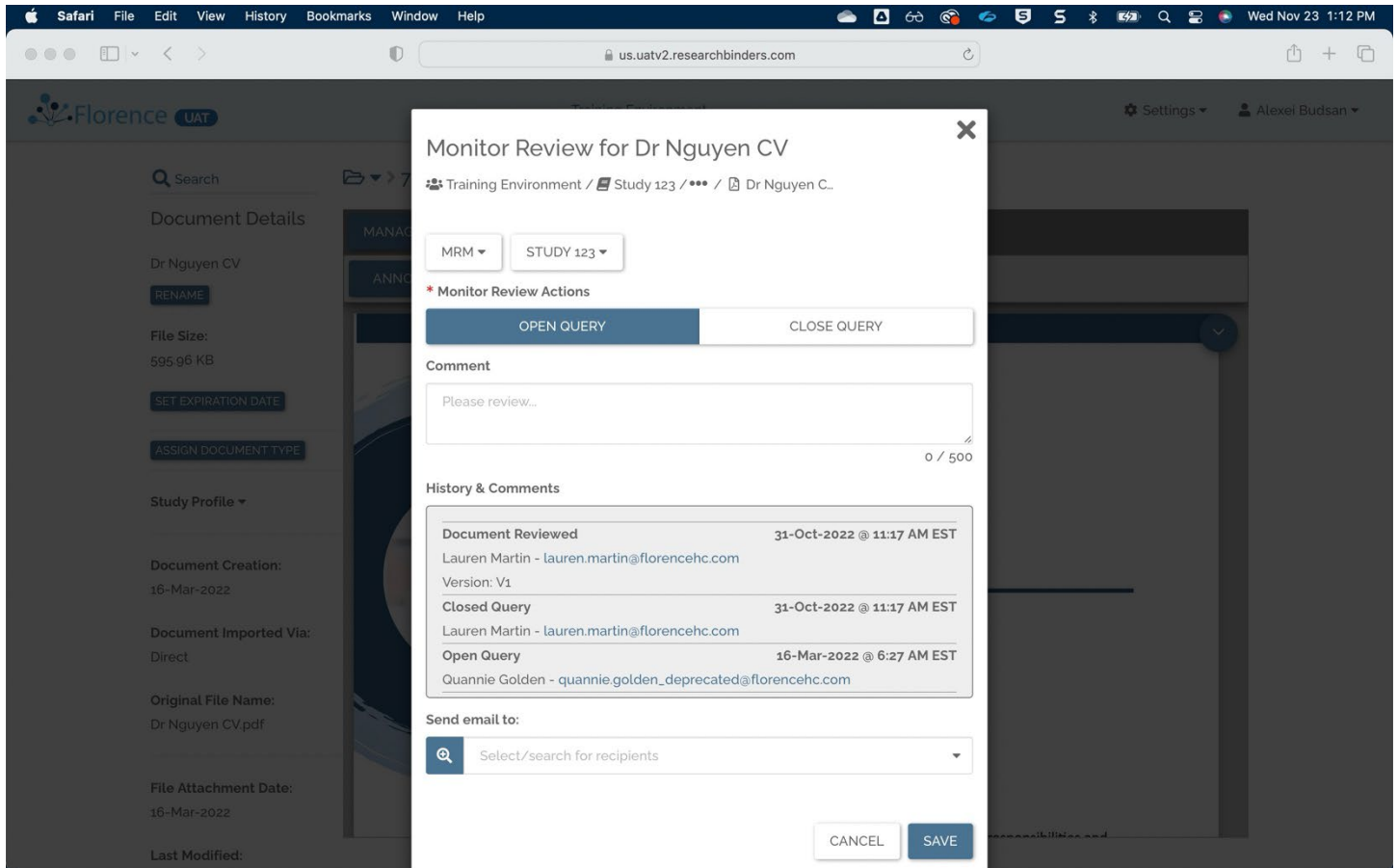
Review – Let others know it has been reviewed (if enabled). Click Review from the menu and within the popup window, click the Review button.
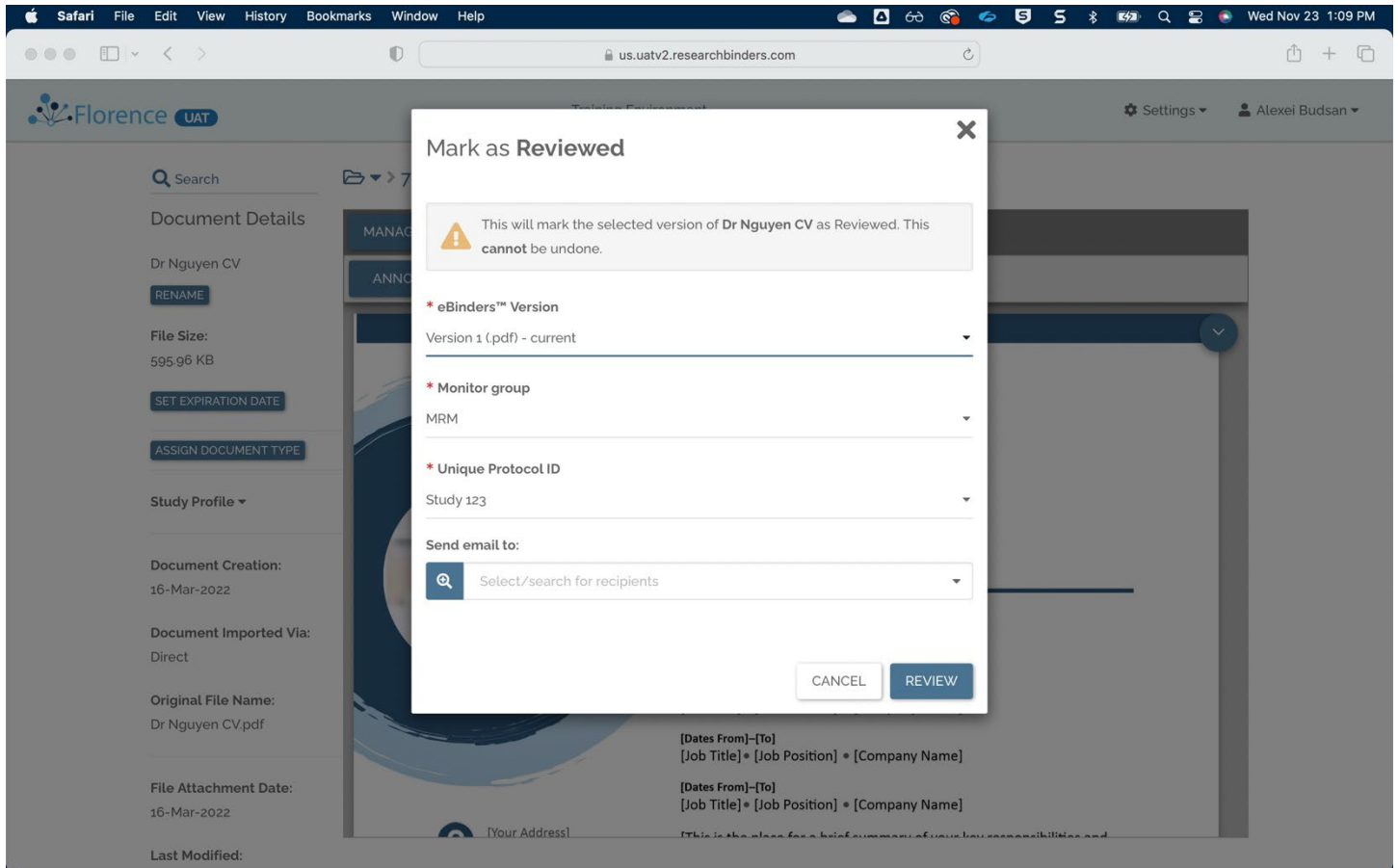
Query Follow up

Check for updates. From the Reports section, using the dropdown menu, select the Monitor Reviews – Open Query report.

If Last Modified by lists a Site's user, click on the Document Name so you can read the Site's response.

Click on the text below the Monitor Review section to display the Query window.
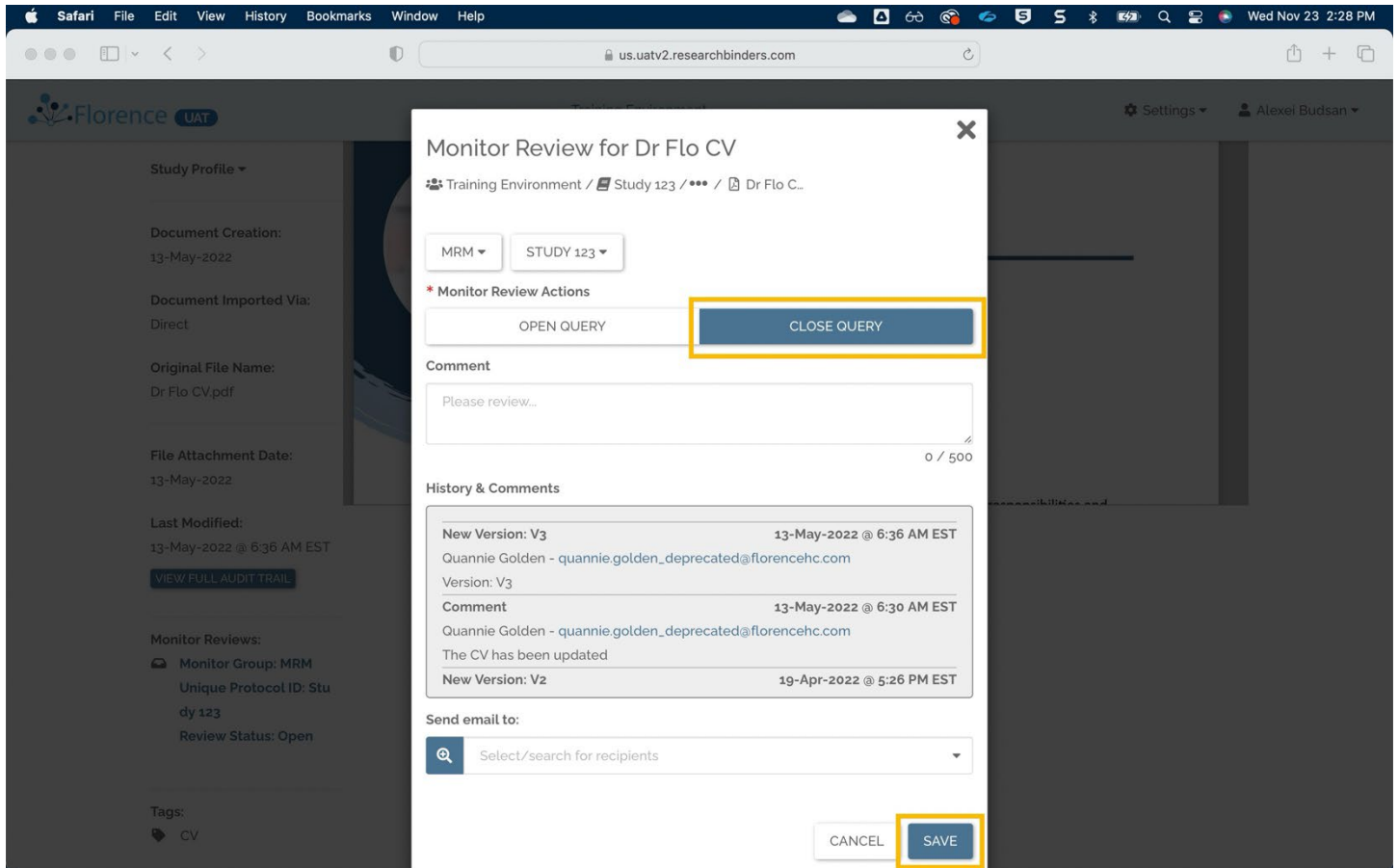
Review the Site's response in the History & Comments section.
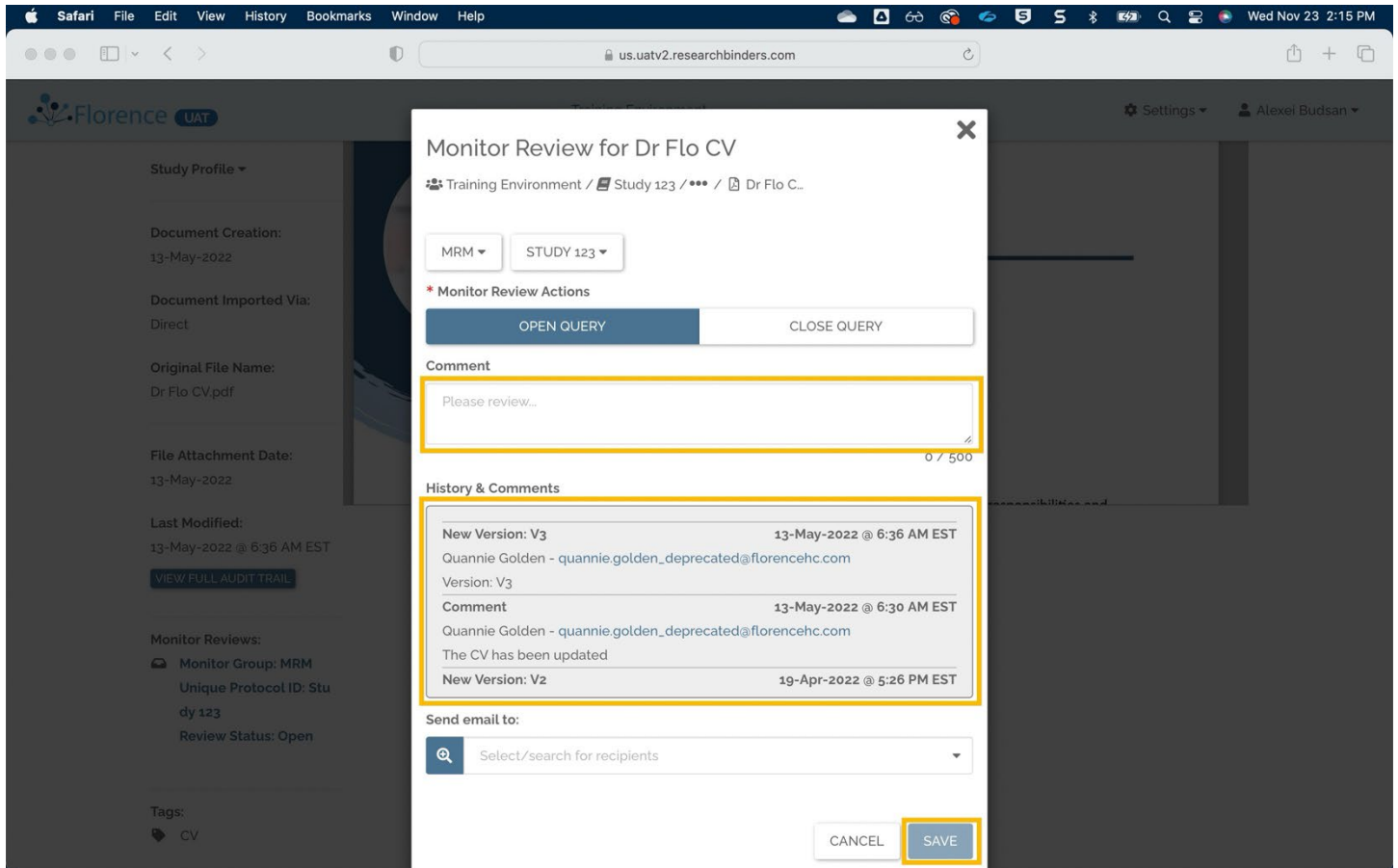
If you need further information, add a Comment and click Save.

If the response is satisfactory:

Click Close Query (tab next to Open Query) and click Save.

You can then Approve the document (from Monitor menu > Approve).

The document will appear in the Monitor Reviews – Approved and Reviewed report
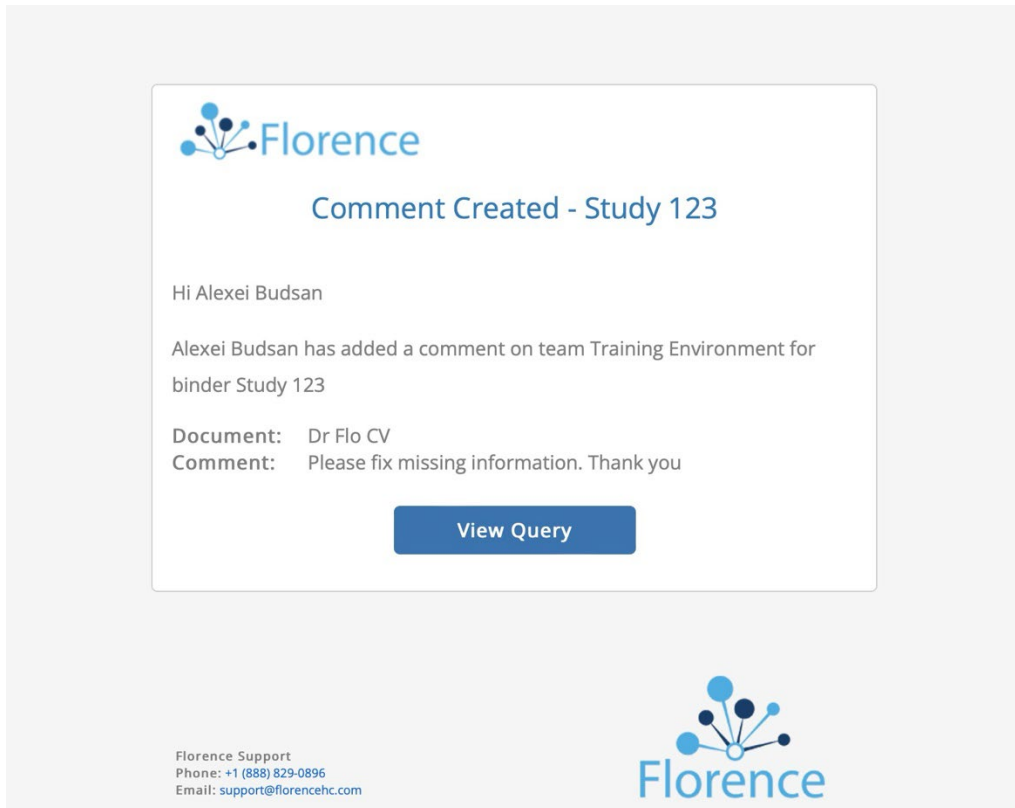
MRM – **Email Notification**

Email notifications are available for:

- Open Query
- Closed Query
- Reviewed (if enabled – marks document as reviewed and closes any open query)
- Approved
- Comment

To send an email, select the team member(s) you would like to notify, enter any comments, and click Save.
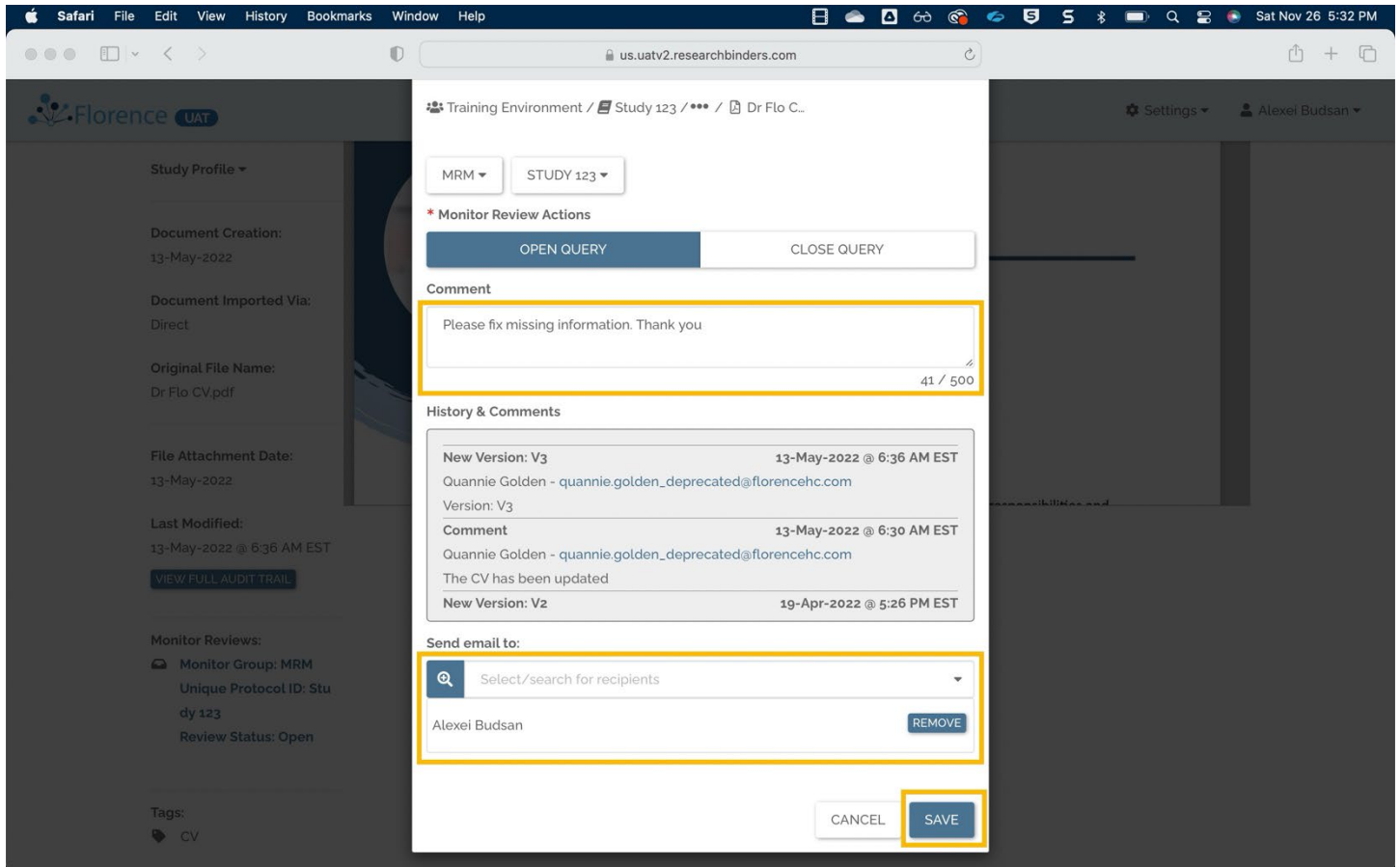
*Note: You can only select members with proper permissions and access to the Monitor Group (Organization). If a user does not appear in the search, it is indicating that they do not have the proper permissions enabled within their role.

Monitor Review also has visual icons in both the global view and document view.

- A green check indicates the document has been approved
- A gold exclamation point indicates there is an open query
- An eye icon indicates the document is being reviewed
- These will only be displayed for users with the appropriate permissions and access.

Global View > Visual Icons for MRM