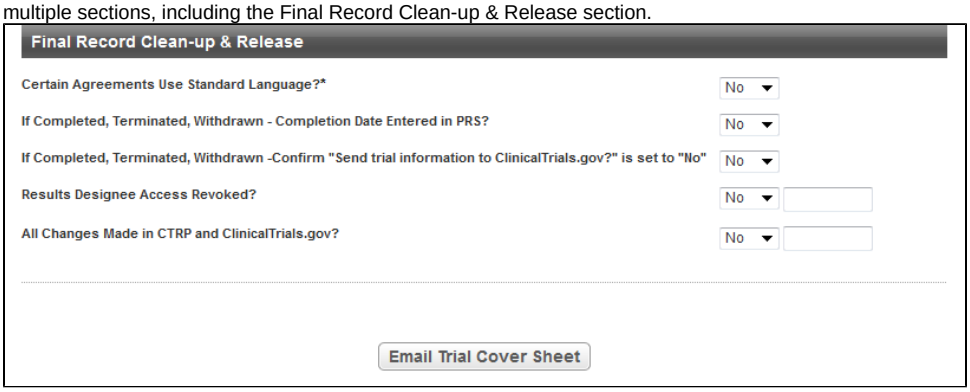
Managing Final Record Clean-up and Release - Include v4.4

After reviewing the results of a trial, some final clean-up is necessary. The questions in this section serve as a confirmation that certain sections of the trial have been examined. However, it is not necessary for a trial to have a Yes in every field before the CTA releases it to the PRS Team.

How to Perform the Final Clean-up

1. In the main menu, under **Dashboards**, click **Results Reporting**. This link is visible only to users with the Results Abstractor role. The Results Reporting Dashboard displays a list of trials.
2. Navigate using one of the following ways:
   a. In the list of trials, click the NCI trial identifier link for the trial you want to edit. A page appears with several sections, including the Final Record Clean-up & Release section.
   b. In the panel next to the pie chart, under **Results Cover Sheet**, type the trial ID and click **Search**. The Cover Sheet page appears with multiple sections, including the Final Record Clean-up & Release section.



3. In the **Final Record Clean-up & Release** section, enter the appropriate information in the fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field	Instructions
Certain Agreements Use Standard Language?*	Select **Yes** in this field after you have provided the following answers in PRS: **PRS Question** — **CTRO Standard Answer** Are all PIs Employees of the Sponsor? — No Results Disclosure Restriction on PI(s)? — Yes PI Disclosure Restriction Type — The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
If Completed, Terminated, Withdrawn – Completion Date Entered in PRS?	This field becomes relevant when the trial has a Current Trial Status of Complete, Administratively Complete, or Withdrawn in the PA application. In that case, select **Yes** in this field if the following is true: In the PA application, under Trial Status, the Completion Date for the trial has a date, and PRS has the same date.
If Completed, Terminated, Withdrawn – Confirm "Send trial information to ClinicalTrials.gov?" is set to "No"	This field becomes relevant when the trial has a Current Trial Status of Complete, Administratively Complete, or Withdrawn in the PA application. In that case, select **Yes** in this field if the following is true: In the PA application, in the NCI Specific Information section, the trial has No in the Send trial information to ClinicalTrials.gov? field.
Results Designee Access Revoked?	This field becomes relevant when the PRS Team publishes the trial with results in ClinicalTrials.gov. In that case, select **Yes** in this field if the CTA removed the Results Designee user account from the trial record access list in PRS. If you select Yes, type or select the date on which the CTA revoked the Results Designee's access. If you type the date, use the following format: MM/DD/YYYY

All Changes Made in CTRP and ClinicalTrials.gov?	This field becomes relevant when the CTRO makes changes to the trial since the Reporting in Process date, in any system (CTRP or PRS). In that case, select **Yes** in this field if both of the following conditions are true: • In the PA Results Reporting Dashboard, in the Record Changes section, the CTRO has completed all action items for the trial. • The CTA has uploaded those changes to ClinicalTrials.gov. If you select Yes, type or select the date on which the CTA uploaded the changes. If you type the date, use the following format: MM/DD/YYYY

How to Send the Trial Cover Sheet

1. Make sure that the trial has a trial comparison document. The system does not send a cover sheet without it.
2. Consider also including a Results Designee contact for the trial.
3. When you are ready for the system to send an email message with an extract from the Cover Sheet page to specific members of the CTRO and CCCT, click **Email Trial Cover Sheet**.