## Main Steps for Validating Submitted Trial - Include v4.4

Before you begin your review and validation of submitted trial data, open or print the protocol, IRB, consent, and/or other trial-related documents so that you can compare trial details in the document(s) to those displayed in Protocol Abstraction. For instructions, see Editing and Replacing Documents. To facilitate the comparison, you can view and print the Trial Summary Report (TSR), which contains all data as submitted via CTRP Registration. For instructions, see Accessing Trial Summary Reports.

## How to Validate Submitted Trials

- 1. Select a trial to validate by following the instructions in Selecting Trials that Require Validation. The Trial Identification page displays the trial details.
- 2. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
- 3. Optionally, on the Trial Overview menu, click View TSR to view and print the Trial Summary Report.
- 4. On the **Validation** menu, click through each of the trial validation menu options. Review and compare the trial details in the protocol document or other trial-related documents with those displayed on each page.
- 5. Modify the trial details as necessary.
- 6. Click Save.

## A Save your drafts

The system does not automatically save the changes to trial details that you make while validating trials. If you are not able to complete the trial validation process in your current session and want to save the changes you have made so that you can continue with the validation at another time, be sure to save the information before logging out or navigating to another page. You can also put a trial on hold if validation requires additional information. For instructions, see Putting Trial Processing On Hold.

- 7. On the Validation menu, click Trial Validation.
- 8. Accept or reject the trial by following the instructions in Accepting and Rejecting Trials.