

Amendment Process Life Cycle - Include 20170606

The CTRP processes submissions in much the same way as it processes original trial data. (For information, refer to [Typical Life Cycle of a Trial](#).) You may need to submit an amendment more than once during the course of your study, and the process is repeated each time you submit an amendment.

The progression of your trial throughout the phases of the life cycle relies on a series of communications. These communications take the form of email messages between you and the system at certain milestone events, as follows:

1. The system sends you a submission confirmation letter.
2. The CTRO validates the new data and documents you provided, and the system sends you an acceptance (or rejection) message.
 - a. If the amendment is rejected, the system provides the reason for rejection and reinstates your latest verified trial submission.
 - b. If your amendment is accepted, the CTRO abstracts all the trial details.
3. When abstraction is complete, the CTRO sends you a Trial Summary Report (TSR) that includes all the newly-modified data in the CTRP.
4. You review and validate the new TSR and email your approval to the CTRO.
5. If you request a change, the CTRO makes corresponding modifications and re-sends the TSR.

The amended trial appears in your Search My Trials results list upon acceptance.



The TSR contains all the information that you submitted and all the trial data abstracted by the CTRO.