

Study Closeout Policy



Crucial Data Solutions (CDS) allows its clients (“Clients”) to lock and close down a study database in TrialKit upon completion of their study. The two primary steps in doing so are:

- Electing to archive or delete all study data
- Canceling, extending or adjusting the previously executed Software License Agreement (SLA)

When a Client requires either archival or deletion of study in TrialKit, Client is responsible for notifying CDS in writing to request the desired change¹. When doing so, Clients must indicate and confirm the desired option by completing a [Study Closeout Form](#).

In order to modify or terminate monthly invoicing, Client must submit a signed Study Closeout Form with a minimum of 30 days’ notice prior to the requested close/change date. The Client’s request will be indicated by selecting one of the following options¹:

Archive Study

- Study status will be changed to “Archived” by CDS and all study data will remain on the CDS server.
- Study will remain visible to users, however, study data will no longer be accessible.
- CDS will invoice Client annually.
- Annual archiving fees will automatically renew on the anniversary date indicated on the Study Closeout Form, unless otherwise notified in writing¹.

Delete Study

- CDS will remove and permanently delete the requested study and all relevant study data from the CDS server at no charge.
- Study will no longer be visible or accessible to Client.
- ***Important:** Emergency recovery of the study may be possible for up to 180 days from Database Change Date, however, a \$7500 recovery fee will apply. After 180 days, study data will no longer be recoverable.*

Temporarily Hold Study

- In exceptional cases, CDS will temporarily archive an existing TrialKit study upon request if the request is due to unexpected hardship that no longer requires access to the TrialKit study database for a minimum of 3 months and no longer than 6 months.
- Temporary holds will be approved as a result of some sort of FDA issue or other business challenge that results in the study database no longer being required for an expected period of time.
- Study will not be visible or accessible to Client during the hold period.
- The monthly TrialKit fee will be reduced to 25% of the regular monthly fee for the defined period.
- Once the study database is reopened, the previously agreed upon monthly fee will be due.
- Temporary Holds can only occur one time and, once reopened, can not be put on hold again.

Study Closeout Policy



Notes:

1. A minimum of 30 days' written notice is required to process any request to either modify or terminate an existing SLA.
2. Once fully-executed by CDS and Client, the terms indicated in the Study Closeout Form will serve as the updated agreement, thereby replacing the fees invoiced from the previously executed SLA.
3. Invoicing for archival or study extension with limited access will commence on the first of the month following the Database Change Date, as documented in the Study Close Out Form.
4. If Client fails to fully execute a Study Closeout Form within 30 calendar days of changing the study's status to "Completed", regular monthly invoicing will continue at the previously contracted rate, with payment due within 30 days of invoice date.