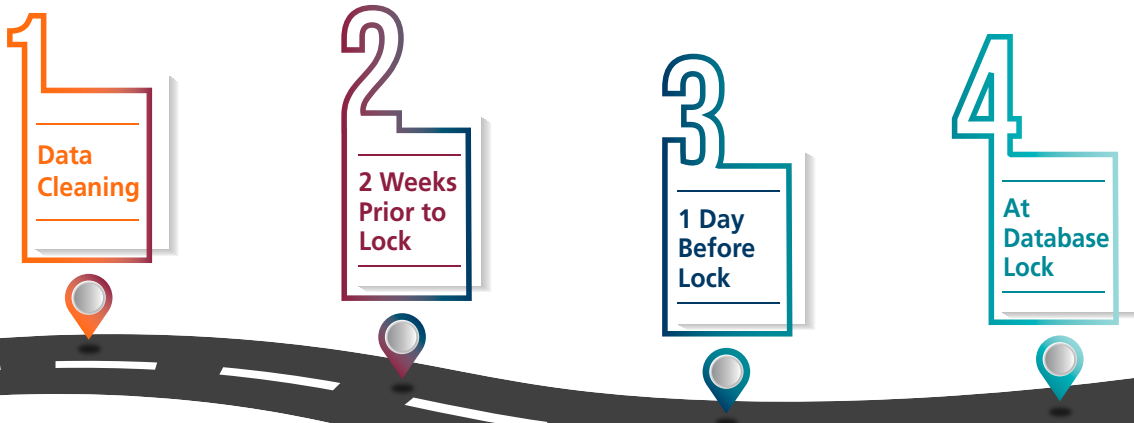


Database Lock

CHECKLIST

Here are some key actions Clinical Trial Managers should take when preparing for Database Lock. It is essential that these items are checked and completed within the timeframes indicated below so you are proactive and can meet database lock timelines.

In general, please meet with your study sponsor and internal team members on an on-going basis as you prepare for database lock activities and adjust this checklist as needed to your specific trial.



DATA CLEANING



Leading up to database lock, the following tasks should be completed throughout Study Conduct/Maintenance:

- Ensure study data is cleaned on an ongoing basis. Work with Data Management to receive weekly or bi-weekly reports on pending queries, missing pages, pending SDV as well as answered queries to be reviewed and closed.
Work with your CRAs and site staff on an ongoing basis to avoid a backlog of data to enter or clean prior to database lock deadlines.
- Review protocol deviation trends and ensure your CRAs are performing re-training and/or implementing Corrective and Preventive Actions (CAPAs) at their sites. Ensure all corrective actions are followed to completion.

AT LAST PATIENT...

- Once the last patient is consented to the trial, estimate the last patient, last visit date and the visit window (the soonest the visit can occur and the latest the visit can occur). Confirm the projected visit date with the site.

Schedule regular meetings with the following colleagues to discuss trial data and issues requiring resolution:

- Vendors:** After meeting with study vendors, follow-up with your CRAs and/or sites to address queries or other open issues.
- Medical Monitor:** After the Medical Monitor review of safety listings, follow-up with your CRAs and/or sites if additional clarifications are needed and/or coding updates are required.

- Communicate the last patient, last visit date to your study team after confirming with the site, including vendors and set a tentative database lock deadline. Vendors should be prepared to send final data transfers prior to the database lock deadline.



Database Lock

CHECKLIST



2 WEEKS PRIOR TO DATABASE LOCK

The following tasks should be completed at least 2 weeks prior to Database Lock:

- Ensure the CRA can conduct a monitoring visit and complete pending SDV within 1 - 2 days of the last patient, last visit.

Confirm the following is true across all patients and sites:

- All missing pages are entered
- All open queries are answered
- All answered queries are closed by the CRA or DM
- All Source Data Verification is completed

- Work with team members on plans of action and associated timelines for resolution (if needed)
- Circulate a calendar invite to all Principal Investigators to block time in their schedule for EDC casebook signing
- Confirm PIs can access the EDC and do not require a password reset



1 DAY PRIOR TO DATABASE LOCK

The following tasks should be completed 1 day before Database Lock:

- Receive confirmation from Data Management that database is deemed "cleaned"



ON THE DAY OF DATABASE LOCK

The following tasks should occur on the day of Database Lock:

- Receive notification from Data Management when all EDC casebooks have been signed and the Database is officially locked or help rectify any open issues.

Send a congratulations email and let the following team members know that the Database is officially locked:

- Sponsor
- Vendors
- Internal Team
- Investigator Sites

- Schedule Close-Out Visits
Some studies may have Close-Out Visits occur prior to Database Lock. Check with your Sponsor and/or company for specific requirements. In general, Close-Out Visits occur after Database Lock.

