

The logo of Galgotias University is a stylized 'G' composed of several curved, overlapping bands in shades of yellow, orange, and blue, set against a light pink circular background.

Database Lock & Unlock

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TOPICS COVERED

- Introduction to Database Lock
- Why database lock is needed ?
- Importance of database lock
- Steps involved in database lock
- What is Database Unlock ?

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What is Database Lock ?

Database lock is a state of clinical database where no further change to the trial data is permissible and it denotes completion of all clinical trial data collection with all subjects information being complete, accurate, consistent and free from discrepancy. Database lock is achieved after thorough review performed by data management, Site monitors, statistician and Clinical scientist.

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Why Database lock is needed ?

Database Lock is required

- To prevent any further change to trial database
- Make trial database ready for analysis

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Importance of Database lock

- Locking or closing a database is nowadays a crucial practice that is necessary in order to prevent unauthorized or unintentional changes after the final data entry, checkup and analysis.
- While in the past, database locks were done at the end of a study, nowadays, database locks are usually done quarterly. It helps to evaluate and analyze the data, and then decide if the study is worth to continue.

School of biological and biomedical science

course Code : MCRT3003

Course Name: Clinical Data Management



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Even though having a quarterly database lock might put some pressure on people responsible for this, it also pushes them to enter their data promptly and on time. Studies have shown that site staff that's authorized to enter data, actually do this more regularly and more often when they know that they have quarterly database lock. Doing this makes it easier to keep up with data entry so that when the time comes for database closing, everything is cleaner and more organized.

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Steps involved in database lock

DM is provided with a User name and Password

DM log into Data Base

DM works on study and locks it after completion

Access is Revoked after Locking of study

Findings by the Study team

Categorized into Critical or Non critical

If critical , Study DB Is Unlocked

What is Database Unlock ?

- Database unlock is a state where locked database is altered and made available for further changes.
- Permission to update trial data is exercised with extreme care and only selective user/group are granted rights to make further changes.
- A formal request with detailed reasons is required everytime study database is unlocked by database administrator. All unlock request has appropriate quality control, review and approval from higher authorities.

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References

1. Database Management and Design. By Gary W. Hansen, James V. Hansen, Prentice Hall, 2nd edition, 2002.
2. Fundamentals of Database Systems. By Ramez Elmasri, Shamkant B. Navathe, T. Benjamin. 2nd edition, 2002.
3. Database System Concepts By Henry F. Korth, Abraham Silberchatz, Mc Graw Hill. 4th edition, 2002.

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