

# What is Final Data Lock in Clinical Data Management?

*Final Data Lock is the point at which the clinical trial database is declared complete, accurate, and ready for analysis or regulatory submission. After this stage, no changes can be made to the data.*









## Why is Data Lock Important?

- Ensures the **integrity of trial results**
- Prevents post-hoc tampering or manipulation
- Establishes a fixed dataset for **statistical analysis** and **regulatory review**

## Key Steps Before Data Lock

1. **All Queries Resolved**
  - No open questions or clarifications pending from study sites.
2. **Database Cleaning Complete**
  - Data is reviewed, consistent, and validated.
3. **Audit Trails Reviewed**
  - All changes are tracked and verified.
4. **Coding Finalized**
  - Medical terms and drugs are correctly coded.
5. **SAE Reconciliation Done**
  - Safety and CDM systems are cross-verified.
6. **Sign-Off from Stakeholders**
  - Data managers, medical reviewers, biostatisticians, and sponsors approve lock readiness.

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-  Coding Finalized
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## Types of Data Lock

- **Soft Lock (or Interim Lock):** Temporary lock used for interim analysis.
- **Hard Lock (Final Lock):** Permanent lock used for final analysis and reporting.

## Post-Lock Rules

- No changes are allowed unless formally **unlocked** (rare and must be documented).
- Any late data or corrections must be handled via **protocol-defined procedures**.