INA RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

Clinical trial databases are a crucial investment in clinical research

Part 5 - Hitting the Target –
How to successfully close the Database-

PIT PETRI 2018

B-IDeaS

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Speakers: M.Duvenhage
K. Laras
S. Erari
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What is a ‘’database lock’’?

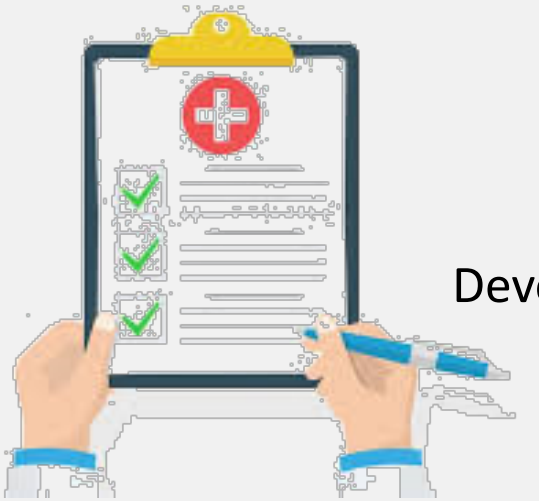
- **Database Lock** is a state of clinical database where no further change to the trial data is permissible and it denotes completion of all clinical trial data collection with **all subjects information being complete, accurate, consistent and free from discrepancy**.
- Database Lock is achieved **after thorough review** performed by Data Management, Site Monitors, Statistician and Clinical Scientist.
- Study data may be locked **by subject and visit, by site, or by study**.

Why it is needed?

- Database lock is required :
  - ✓ to prevent any further changes to the trial database.
  - ✓ to ensure their integrity for the generation of results, analysis and submissions
  - ✓ to make trial database ready for analysis.

Minimum Standards

- Ensure that a procedure defines database closure methodology.
- Prior to database closure, document completion of all defined tasks or criteria.
- At final database closure, ensure that all team members are notified and edit access is removed and documented.
- After closure, have written procedures with clear criteria for unlocking the database.



Best Practices

Develop and use a database closure checklist

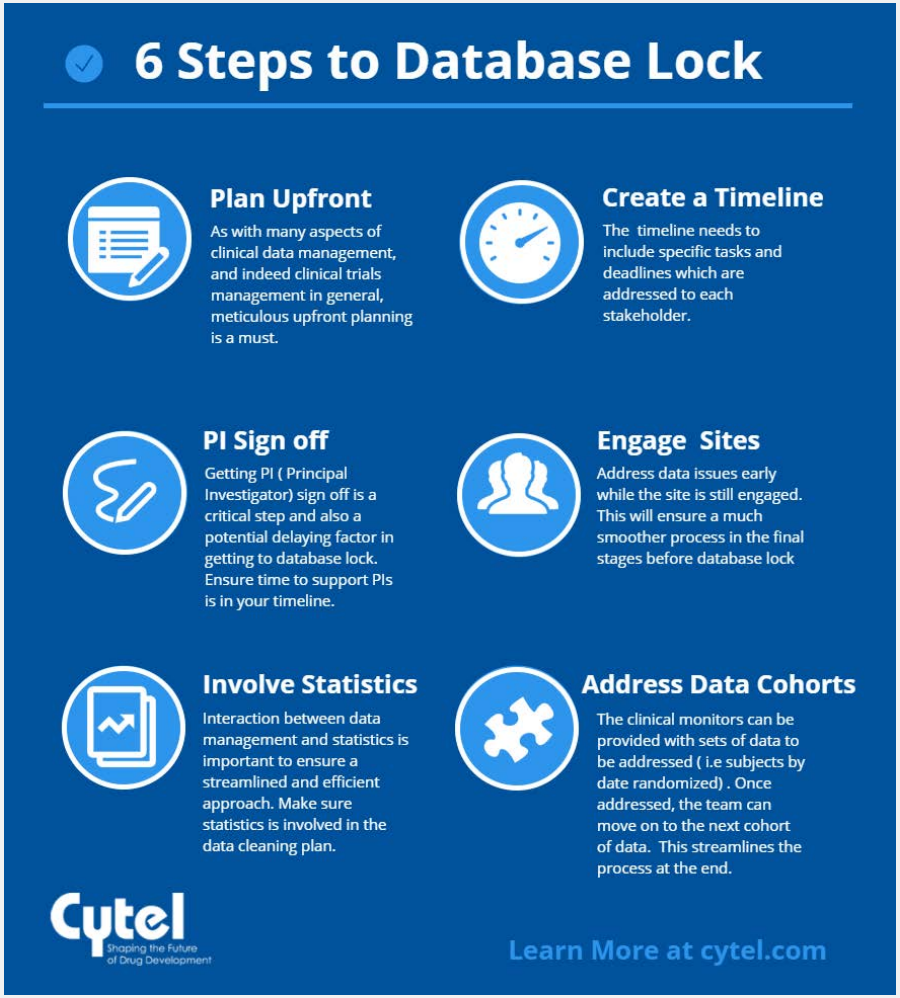
Different types of database Locks

- *Interim lock* refers to processes used to take a “snapshot” of a database at a particular point in time while the study is still in progress. (this could be for an interim analysis or a quarterly data review)

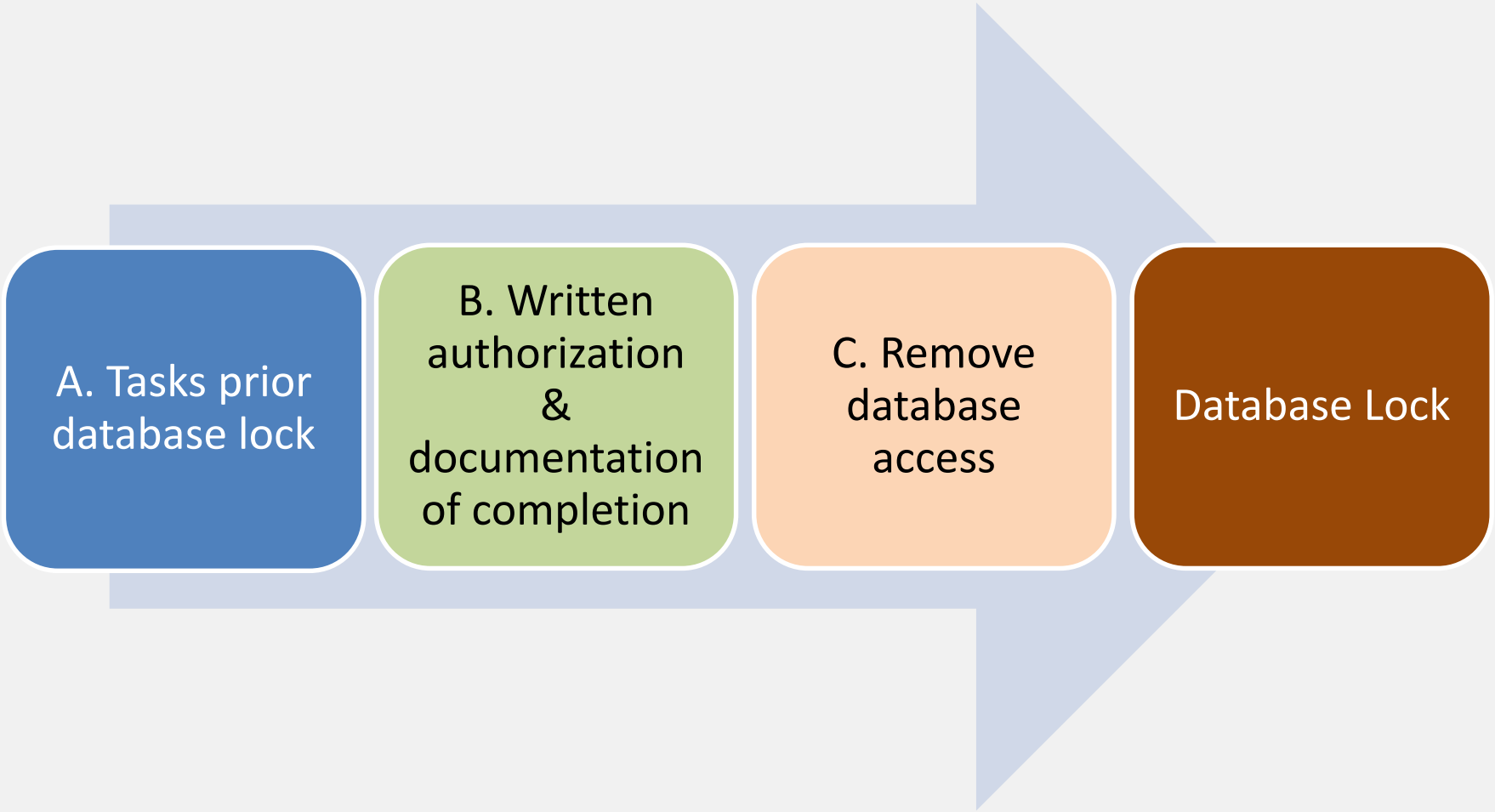
- *Soft lock* refers to processes during which access to the database is limited while CDM personnel confirm the suitability of the data for final analysis

- *Final lock* (also known as a “freeze” or “hard lock”) refers to processes used to remove access to the database to ensure no further changes to data can be made. The final lock is a key process of database closure, but not the only process needed to close a database properly.

Which are the most important steps to take before database lock?



Database Lock Process



A. Tasks prior database lock

- All CRF have been received and processed
- All queries have been resolved
- External data (eg. lab data) are complete & reconciled with the study database
- If a separate database exists for AE database, it is reconciled with the main study database.
- Coding has been reviewed & approved as appropriate
- All investigator has reviewed & authorized a list of all self-evident correction (SEC)
- The Final QA must be completed succesfully

Final QA Review

- **Aim**: to detect any remaining anomalies and to ensure that the entire data management process, including data entry and database updates, has produced a high quality database.
- Performed after all routine data management and QC/QA activities and all known data discrepancies have been resolved.
- There are 2 types of Final QA:
  - **Audit of Critical Fields**
    - 100% review of **ALL CRITICAL FIELDS FOR ALL SUBJECTS**
    - To ensure that the data that are considered to be critical in determining the outcome of the study are completely error-free.
  - **Audit of a Random Sample of Subjects**
    - **Review of all data points** – excluding external and derived data – **for a square root of number subjects per site**, selected randomly.

B. Written authorization & documentation of completion

- A documented form and approval process with sign-off by relevant study personnel (e.g., data management, biostatistics, monitoring representative, clinical/scientific representative) should take place.

- Example of document:
  - **Database lock form** (with attachments of QA Forms)
  - **Project Database Change Request** to request the database lock
  - **CDMS Access Authorization Form** to request the removal of all remaining write-access to the study database

C. Remove database access

And FINALLY:

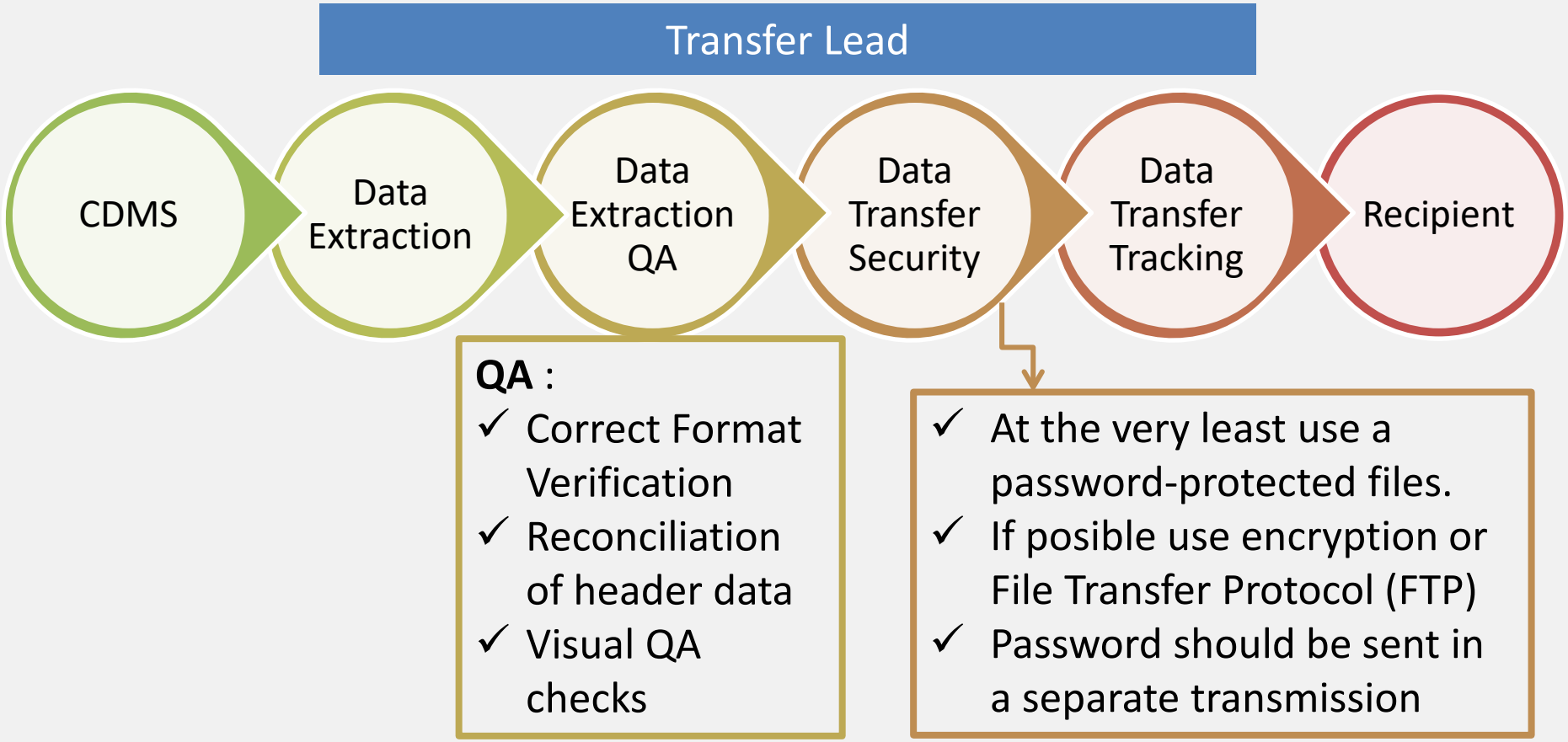
After the final check from the authorized person:

- ✓ The access of the study database will be removed and this removal date will be documented.
- ✓ Database is locked

Final Database Release

- Following database lock, Data Manager or designee will extract the data entered in the study database to produce datasets.
- The datasets will be in the appropriate format as required by analysis.
- The specification of the datasets will be documented in the Data Transfer Specification and Approval (DTSA) document.
- At the minimum, the DTSA contains the following information:
  - Data provider or recipient name
  - Study Protocol ID
  - Type of data being transferred
  - Data file naming convention
  - Method of transfer for the data files
  - Timelines
  - Expected data format (eg. Comma delimited tab, .sav file, rda file etc)
  - Contact information for transfer lead and data provider or recipient points of contact
  - Clear specification for each data variable (eg. Variable name, variable description, variable type, code list etc)

Final Database Release (cont).



What is Database Unlocking

- Database Unlock is a state where locked database is altered and is made available for further changes.

- If a discrepancy or query is identified after the study data or database has been locked, partial or full access to the study database is needed so changes can be made.

- The decision to unlock a previously locked study database is made in consultation with other key collaborators, after consideration of regulatory and procedural requirements for reporting, as well as known logistical concerns with making post-lock data revisions.

- Unlocking a study database requires written authorization and documentation of completion.

- Not all changes requires unlock, for non-critical issues a Memo or Note to File will suffice the need.

Critical and Non-Critical Errors

Critical Error	Non Critical Error
Needs to be corrected and updated in the database	No need to be updated in the database
Unlocking is done	Unlocking is not done
Documented in : - Critical Error Form - Locked Database Change Request	Documented in : - Non-Critical Error Form - DB lock Checklist Note to File Form

Recommended SOPs & other Supporting Documents for Database lock

- SOPs
  - ✓ Study Database Lock and Unlock
  - ✓ Study Database Quality Management
  - ✓ Study Database Access and Control
  - ✓ Study Database Change Control

- A task checklist, sign-off forms for approval, and the details of the lock are recommended for this purpose.