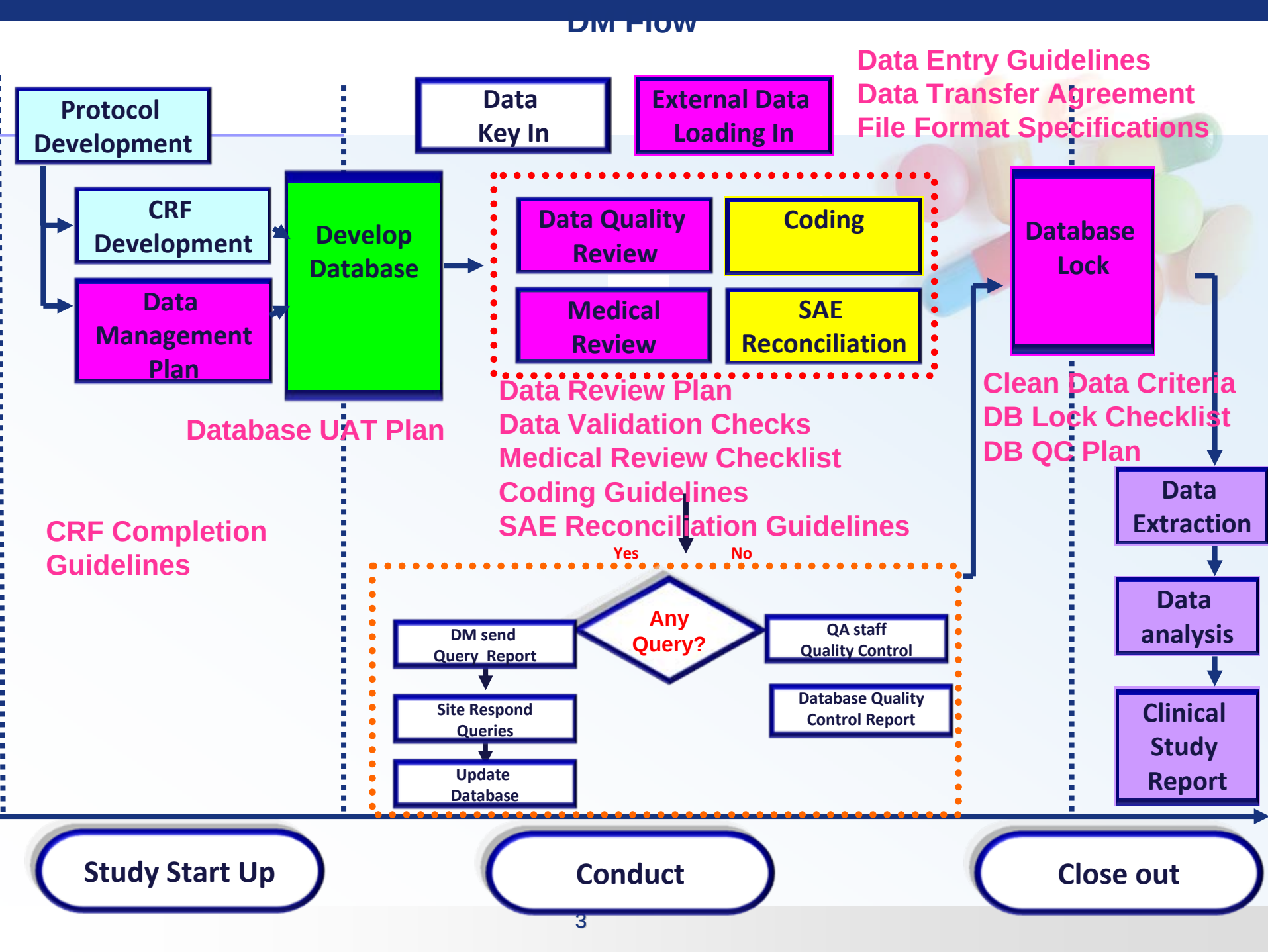
Data Management Documents

September, 2010 at SMMU, Shanghai

Agenda

1. Data Flow and DM Documents
2. Purpose of Data Management Plan
3. Contents of Data Management Plan
4. Creation and Maintenance
5. Key Messages

DM Flow


Protocol Development
CRF Development
Data Management Plan
Develop Database
Database UAT Plan
Data Key In
External Data Loading In
Data Entry Guidelines
Data Transfer Agreement
File Format Specifications
Data Quality Review
Coding
Medical Review
SAE Reconciliation
Data Review Plan
Data Validation Checks
Medical Review Checklist
Coding Guidelines
SAE Reconciliation Guidelines
CRF Completion Guidelines
Yes
No
Any Query?
DM send Query Report
Site Respond Queries
Update Database
QA staff Quality Control
Database Quality Control Report
Database Lock
Clean Data Criteria
DB Lock Checklist
DB QC Plan
Data Extraction
Data analysis
Clinical Study Report
Study Start Up
Conduct
Close out

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2.1 What is Data Management Plan (DMP)

- Synonym: Data Handling Protocol; Data Quality Plan, etc
- The DMP documents the processes and procedures employed by Data Management (DM) to promote consistent, efficient and effective DM activities for a specific study in order to provide a study database that is accurate, secure, reliable and ready for analysis.
- The contents present here are a guide only and can be customized by adding or removing sections according to company SOP/Guidance and specific study requirements.

2.2 Use and Benefits of DMP

- DM staff use DMP to define or further develop the procedures that describe how they manage data, to what standards and why for a specific study
- Through reference to the DMP, other functions will be able to understand DM requirements, which leads to improved communications between all parties concerned and more efficient and accurate data collection
- The DMP is an auditable document often asked for by regulatory inspectors and should be written in a manner that is professional and of high quality

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3. Contents

General

- Header
- Footer (page number)

Cover Page

- Sponsor name
- Protocol title and number
- Version number of the DMP
- Effective date of DMP
- Signatures and distribution list

3. Contents

Table of Contents

Amendment and Change Procedures

- A statement of how the DMP will be followed
- How to handle deviation or modification to the DMP
  - Who needs to agree them
  - How the changes will be made
- How minor amendments will be made after production

Definitions and Acronyms

3. Contents

Case Report Forms

- CRF Design – Description of the CRF design process or refer to the company SOP
- CRF Completion Guidelines
  - General guidelines
  - Study-specific guidelines
- CRF Change Control – Description of the process for managing post-production changes or refer to the company SOP

3. Contents

Database Design, Creation and Maintenance

- DB Name, Version, and Location
- DB Design – Description of the DB design process or refer to the company SOP
- DB Change Control – Description of the process for managing post-production DB changes or refer to the company SOP
- DB Security
  - User Roles and Access Control
  - DB backup

3. Contents

Data Entry and Processing

- Data Receipt and Tracking
  - Data collection strategy
  - How data receipt will be tracked
- Data Entry
  - Single Entry vs. Double Entry vs. Single Entry + Visual Verification
- Data Entry Guidelines/Conventions
  - General guidelines (e.g. special codes, partial date and time, etc)
  - Study specific guidelines

3. Contents

Data Validation and User Acceptance Testing

- Data Validation Checks and UAT
  - Change control after production
  - Process and procedures of dummy data creation and UAT
- Data Review Plan
  - Electronic Data Review
  - Medical Data Review
  - Reports and tools used for review
- Query Handling
  - Data Clarification Form process (for paper study)
  - Turnaround Time

3. Contents

External Data Transfer

- Data Transfer Agreement
- File Format Specifications
- External Data Review Plan

3. Contents

Coding

- Coding Dictionaries
  - Name and Version
  - How to handle dictionary version upgrade during study
- Define what terms are to be coded (CM, AE, MH?)
- Description of the process for handling terms that are not auto-coded
- Description of the process for approval

3. Contents

SAE Reconciliation

- What fields will be compared and reconciled
- Reconciliation Frequency
- Description of process of how to get the SAE data from safety database and reconcile with CRF data
- Description of discrepancy management

3. Contents

Quality Assurance/Control Processes

- QA plan
  - What checks will be performed for the study
  - The corrective actions to be taken
- QC plan
  - What checks will be performed
  - The criteria of database acceptance
  - The frequency and timing of QC
- QC check documentation processes
  - Define the means by which QC checks are documented
  - How the documentation is maintained

3. Contents

Database Lock Strategy

- Data Clean Criteria
- Database Lock Checklist
- Database Lock Strategy
  - Ongoing, by site, or lock a whole study
  - Locking timelines
  - Locking process, etc

3. Contents

Other sections that may be added

- Study team member list and communication plan
- Study preliminary timelines
- Interim analysis
- Archiving and record retention process

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4. Creation and Maintenance

- For **each new study**, **CDM** personnel should compose a detailed DMP based on the protocol, work scope, contract (for CRO), analysis plan and other supporting documents and DM standards and practice.
- The DMP should be reviewed and approved by all responsible parties **prior to** commencement of the work it describes.
- Strict change control (change history) and version control should be implemented.
- The document is a living doc and periodic review is required.
- Upon conclusion of the study, the DMP should be archived with all other pertinent study documentation.

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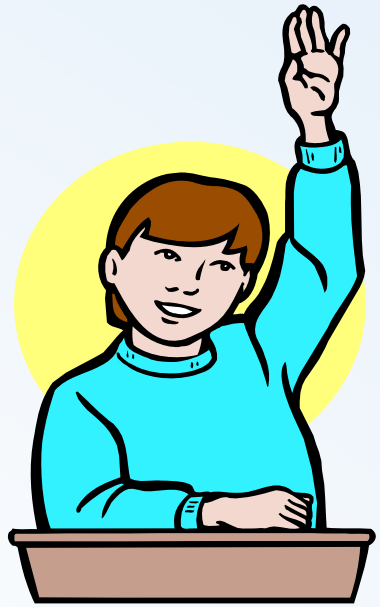
5. Take-home Key Messages

- The DMP documents the processes and procedures of DM activities for a specific study in order to provide a study database that is accurate, secure, reliable and ready for analysis.
- The DMP should be reviewed and approved by all responsible parties **prior to** commencement of the work it describes.
- Strict change control (change history) and version control should be implemented.
- The DMP is an auditable document and should be written in a manner that is professional and of high quality.

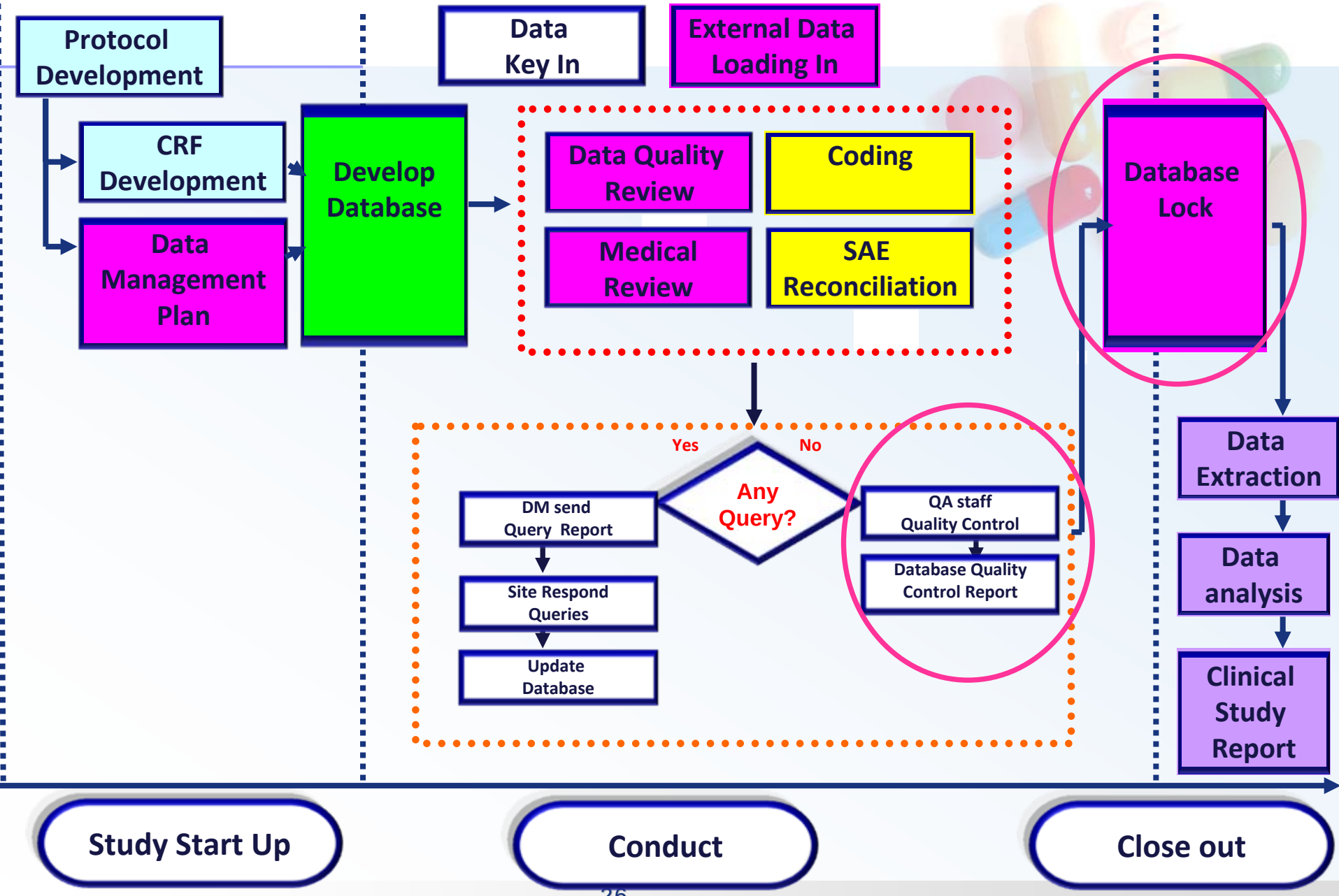
The 2nd Clinical Data Management Training

Thank You !

Question?



DM Flow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Data Clean Criteria - example

- All data (CRF and external data to be in DB) have been received and in the database
- All discrepancies generated (through edit check and medical review) have been resolved or verified
- Coding has been completed and reviewed
- SAE reconciliation has been completed without open discrepancy
- External data reconciliation has been completed without open discrepancy
- Other,….

Quality Control

质量控制

- Definition in ICH E6: the operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the study-related activities have been fulfilled.
- Quality Control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly
- Examples of QC
  - User Acceptance Testing
  - Document review and sign off
  - Compliance with SOP and guidelines
  - Continuous data monitoring and metrics reporting

Quality Control Plan

- What checks will be performed
  - Study binder review (Documentation)
  - Database review through various tools, reports (e.g. Metrics reports)
- Timing of QC
  - The first 10 patients data in house
  - 25%, 50% and 75% of patient data in house
  - Changes in key staff, key process, and system
- Documentation of QC (QC report)
  - Who perform the QC and When
  - What is reviewed and checked
  - Findings
  - Corrective action

Quality Control Plan

- Final database QC (usually for paper study only)
  - Prior to database lock
  - Compare CRF with data in Database
  - Critical data points are checked for all enrolled subjects
  - Non-Critical data points are checked for a set of randomly selected of enrolled subjects
  - Calculate database error rate through dividing the errors found by the total number of data fields reviewed
  - Set the database acceptance criteria (company standards)
    - Critical data points: 0
    - Non-Critical data points: 1% or 0.5%
  - Action taken if error rate is not acceptable

Quality Assurance

质量保证

- Definition in ICH E6 – Planned, systematic actions that ensure trial complies with ICH/GCP, SOPs, and regulatory requirements
- Broader, more systematic, usually performed by independent party
- Examples of QA
  - Compliance with SOPs (documentation)
  - System Validation Report
  - Required certificates (lab, special professionals)
  - Review of staff training records

Database Lock Checklist

- Source document verification completed
- All data (CRF and external data to be in DB) have been received and in the database
- All discrepancies generated (through edit check and medical review) have been resolved or verified
- Coding has been completed and reviewed
- SAE reconciliation has been completed without open discrepancy
- External data reconciliation has been completed without open discrepancy

Database Lock Checklist (cont')

- Final Database QC done and error rate is acceptable
- Randomization list has been released and loaded into the database
- Required signatures have been obtained
- Update privilege removed except for special user
- ….