
Approaching Database Lock

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Goal

- Lock the database of a three year, 5,400 subject, 61-site, multi-country trial 6 weeks after the last subject visit.



Issues

- Rolling enrollment at sites.
- Heavy late enrollment, as a result there were many visits towards the end of the trial.
- Need to ensure all issues (Clinical and DM) are resolved.



Solution

- Don't wait until the last subject visit to start clean up.
- Subject by subject clean up as subjects complete the study.
- Track subjects who have been reviewed and maintain a "Clean Subject Database".



What is a Clean Subject?

- CRFs are fully monitored at the clinical site.
- No unresolved data management issues.
- No outstanding issues from the clinical data review.



Monitoring

- Field monitors used excel spreadsheets to track which subject visits had been monitored.
- Excel files were emailed to biostats/programming group, who created a SAS database of monitored visits.
- Future studies are using a Monitoring Visit Log in DataFax.



DM Clean

- Clinical Data Associates reviewed edit check listings for completed subjects and spot checked CRFs.
- Ensured subjects did not have any outstanding queries, missing pages, outstanding visits.
- Subject ID was flagged as DM clean in Clean Subject Database.

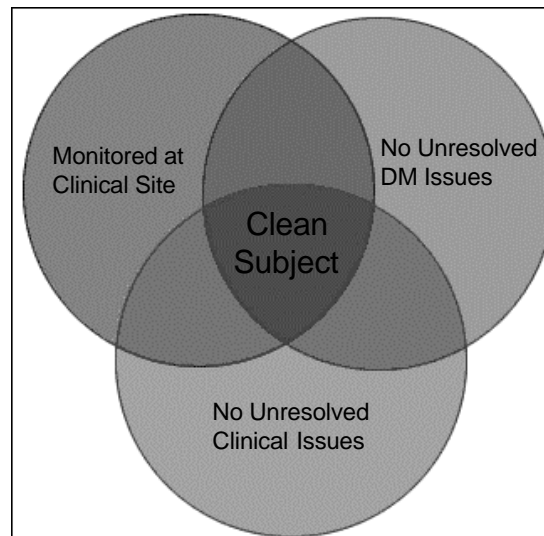


Clinical Clean

- Data for subjects who were fully monitored and flagged as DM clean were output to clinical data listings.
- CRAs added clinical queries in DataFax if they found any issues.
- Subjects who did not have queries added during clinical data review were flagged as Clinical Clean in Clean Subject Database.



Components of a Clean Subject



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VG_subclean: Report Usage

- Used to flag subjects as DM and Clinical Clean.
- In the Reports Tool as a Study Specific Report.
- Options:
 - l # Update the clean flag of the specified Subject ID number.
 - a Add the specified clean flags to the subject.
 - r Remove the specified clean flags from the subject.
 - dm Update the Data Management flag for the subject.
 - cl Update the Clinical flag for the subject.

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VG_subclean: Processing

- Checks that subject has a valid CRF indicating study completion or early termination.
- Checks that subject does not have any unresolved QCs.
- If all conditions are met, a record is added to, or updated in, the Clean Subject Database.
- Record includes name of person adding subject and date subject was added for both DM flag and Clinical flag.
- An audit trail is maintained in separate file.



Edit Check: subclean_check

- Runs at field exit of subject ID number.
- Checks the subject number against the Clean Subject Database.
- A warning is given if the subject is already in the Clean Subject Database.

```

*****
Subject listed in clean database
Added by kgreen on 11/01/02
Do not modify unless required
^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^^
If changes are made, an email will be sent to kgreen
*****

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Edit Check: change_clean

- Runs at plate exit.
- For subjects listed in Clean Subject Database—
 - Checks for any unresolved QCs added to page.
 - Checks for any changes to data.
- Removes subject from Clean Database if there are changes to data or QCs added to page.



Edit Check: change_clean (cont.)

- An email is sent to the CDA if any changes are made.

***** ALERT! *****

There has been a change or QC added to:

Study #1

Subject #12345

Visit #0

Plate #1

Subject Initials was PSO, now changed to POS

Subject has been removed from clean database.



Tracking Closeout: Clean Status

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Study VAX0**

Clean Database Summary Report by Site

Site	Completed or Discont. Study	In Clean Database DM	In Clean Database Clinical	Pending Clean DM/Clin
A	14	12	8	2 / 6
B	10	10	10	0 / 0
C	25	18	16	7 / 9
D	9	3	2	6 / 7
	58	43	36	15 / 22

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Results

- Minimized redundancy in data review.
- Closeout work load was spread out over 6 months.
- By the last subject visit, data for most subjects had completed DM and Clinical review.

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Results (cont.)

Last subject visit	December 9, 2002
Data lock	December 30, 2002
Time from last visit to data lock	3 weeks

- Met goal within normal workload of existing resources!