
Clean Patient Tracking

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Successful and Timely Closeout

- Patient final visits
- Cleaning data, queries
- Coding
- SAE Reconciliation
- Endpoint Adjudication
- Lab reference range verification



Successful and Timely Closeout

Challenges:

- Tasks need to be completed simultaneously
- Progress needs to be tracked
- Time is precious



Our Study

- More than 2500 patients
- More than 60 sites in multiple countries
- Varying times for closeout
- Review of data by distinct teams
- Database lock soon after last patient last visit



Five Teams; One Goal

Completing patient final visits

- Monitoring function
- Tracked via monitoring visit reports

Cleaning data, coding

- Data management function
- Edit checks
- Coding complete
- All queries resolved



Five Teams; One Goal

Reconciling SAEs

- SAE team
- Reconciled data between clinical database and sponsor safety database
- Some manual steps couldn't be tracked in DataFax
- Final Code entered for each SAE in DB



Five Teams; One Goal

Adjudicating endpoints

- Manual processes required in-depth clinical review of endpoint data

Verifying lab reference ranges

- Most work done outside of DataFax
- Ensured ranges were complete
- Edit checks ran on CRF data vs. ranges



Goals and Objectives

- Organized and efficient cleaning of data
- Automated tracking of progress
- Easy identification of clean patients as data cleaning continued
- Timely identification of sites ready for close-out
- Minimal time required to develop and maintain the whole process



Solution

- Clean Patient Tracking
- Add a CRF/plate to study database to record, track and report data on the entire cleaning process

⇒ Inspiration from Vineeta Gulati and Karen Green of VaxGen from DFUG 2004



Clean Patient Tracking CRF

- CRF developed and used to set up a Clean Patient Tracking plate in DataFax
- CRF was not faxed and data were not entered from the CRF
- Clean Patient plate used as placeholder within DataFax



Assessing Clean Status

- Each team was responsible for checking their own 'box' on the CRF
- Each team identified the criteria that would deem a patient clean
- Coordination of schedules despite different processes



DRF Files – Making it Simple

How will all the data be entered and kept up-to-date?

- Criteria for DM Clean, SAE Clean and Adjudication Clean were used to program and create data retrieval files which identified patients that could be marked as clean
- Manual review and identification of patients was also required for Adjudication Clean and Clinical Clean



DRF Files – Making it Simple

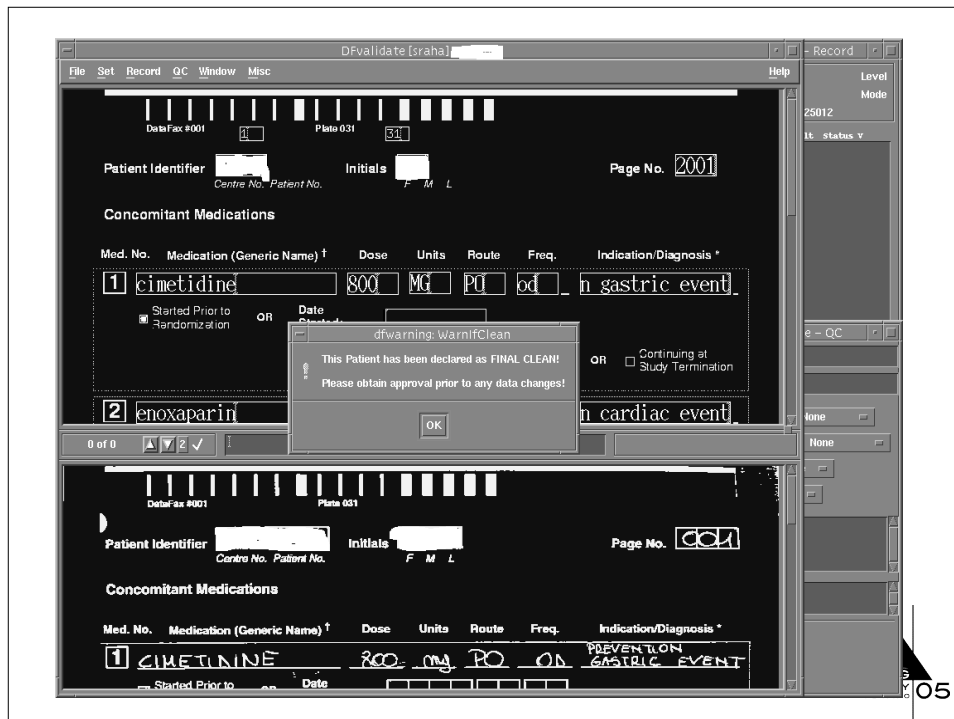
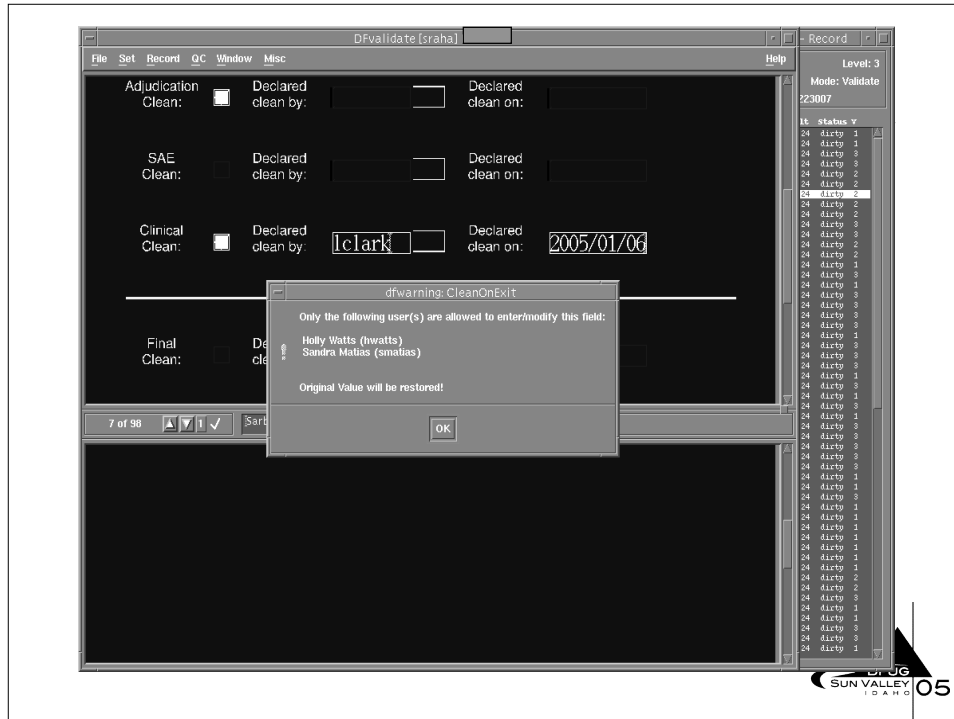
- DRF files were used to bring up patients in the validation tool so that clean status boxes could be easily checked by each team
- DRF files were also used to identify patients that were marked as clean but no longer met the criteria – ensured that clean status codes were correct and accurate



Edit Checks

- Edit checks used to control access to clean status fields
- Edit checks used to issue warnings to anyone accessing data once patient was declared clean





Reports

- Study specific reports used to track and monitor changes to data after patient declared clean
- DF_PTlist and other DataFax generic reports also used to report on clean data as required
- Changes to clean patient status field are tracked by DF_ATmods



Tracking Changes After Clean

List of Patients, Plates and Visits That Were Modified
After The DM Clean Date on Plate 24

For Patient(s): 2005

Date and Time of Report: Mon Jan 31 12:53:12 EST 2005

Centre	Patient	Plate	Visit	Status	Level	Date/Time Modified	DM Clean Date
2	02005	101	20	clean	3	2005/01/11 15:15:37	2004/09/29
2	02005	102	30	clean	3	2005/01/11 15:15:49	2004/09/29
2	02005	103	50	clean	3	2005/01/11 15:16:11	2004/09/29
2	02005	103	60	clean	3	2005/01/11 15:16:36	2004/09/29
2	02005	103	70	clean	3	2005/01/11 15:19:49	2004/09/29
2	02005	103	80	clean	3	2005/01/11 15:20:15	2004/09/29
2	02005	105	50	clean	3	2005/01/11 15:16:23	2004/09/29
2	02005	105	60	clean	3	2005/01/11 15:19:25	2004/09/29
2	02005	105	70	clean	3	2005/01/11 15:20:02	2004/09/29
2	02005	105	80	clean	3	2005/01/11 15:20:27	2004/09/29
2	02005	105	90	clean	3	2005/01/11 15:20:50	2004/09/29



Exporting Clean Status Data to SAS

- DFsas programs and SAS programs were easily updated to include the new plate data
- Exporting clean patient data to SAS allowed for the creation of the DRF files
- Clean status incorporated into listings and reports to assist with data clean up and end of study preparations



Advantages/Benefits

- Allowed all team members to easily enter, update and review clean patient data as needed
- Ability to run real-time patient summary reports on either site or by-patient basis
- Provided regular reports of data cleaning progress to sponsor
- Easy to implement and maintain



Patient Tracking Site Summary

Centre No.	Investigator	MON	DM	ADJ	SAE	CLI	FIN	Total Enrolled	Total Term.
1	Smith	28	1	26	22	2	1	42	28
2	Nobel	15	5	15	15	5	5	26	20
3	McKenzie	41	17	41	36	52	15	52	42
4	Johns	23	4	23	19	64	4	64	34
5	Purdue	27	10	25	18	5	5	70	30
6	Blake	58	11	49	44	130	11	130	60
7	Pincher	29	5	25	25	9	5	54	31
8	Goulet	29	4	26	21	4	1	52	32
etc.									
Totals		1589	642	1503	1337	1448	510	2553	1738

Note: MON=Monitoring; DM=Data Management; ADJ=Adjudication;
 SAE=SAE Reconciliation; CLI=Clinical Review; FIN=Final Review;



By Patient Tracking Listing

Centre No.	Investigator	Patient Number	MON	DM	ADJ	SAE	CLI	FIN	Total Term.
18	Knox	18001	1	0	1	1	1	0	1
		18002	1	1	1	1	1	1	1
		18003	1	1	1	1	1	1	1
		18004	1	0	1	1	1	0	1
		18005	1	0	1	0	1	0	1
		18006	1	0	1	1	1	0	1
		18007	1	0	0	0	1	0	1
		18008	1	1	1	1	1	1	1
		18009	1	0	1	1	1	0	1
		18010	1	1	1	1	1	1	1
Totals			10	4	9	8	10	4	10

Note: MON=Monitoring; DM=Data Management; ADJ=Adjudication;
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Advantages/Benefits

- Provided more transparency into data cleaning process and identified internal bottlenecks
 - Straightforward validation requirements
 - Progress tracked and compared to study timelines
- ⇒ Resulted in more efficient and productive data cleaning



A Work in Progress...

- Improve the process for tracking changes once clean status is declared
- Smoother process for updating clean status fields
- Incorporate clean status codes into edit checks to exclude clean patients

