

Clean Patient Tracker - Using SpotFire Analytics for Patient Data Cleaning

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ABSTRACT

Business Informatics (BI) tools with visual analytics enable a holistic approach to the interaction and exploration of clinical data. There exist many challenges facing Clinical Data Management and Medical Reviewers in tracking subject visits, including those that have been reviewed and cleaned. Customization can be used to add additional functionality to visual analytics to mitigate these challenges.

INTRODUCTION

Tracking clean subjects has been performed by copying data from multiple sources and pasting to excel trackers. Columns are marked completed when reviewed. Manually amalgamating data from multiple systems in excel is laborious and time consuming. The potential for making an error during transcription is high and can thus lead to making incorrect judgements or assessments especially at the time of a milestone deliverable. There are many visual analytical tools available but out of the box functionality is limited and do not solve the challenge of tracking subject visits and workflow.

CLEAN PATIENT TRACKER

Tracking subjects that have been reviewed and cleaned has been performed by copying data from multiple sources, even sometimes by running manual reports from EDC system and pasting to excel trackers where Clinical Data Management update columns when review has been completed.

Manual excel tracker

Country	Site	Subject ID	DM Opened Queries	DM Answered	Missing Pages	SDV Outstandin	CRA Outstanding Pages	SAE Recon Issues (Yes/No)	PD Recon Issues (Yes/No)	External Safety Lab Issue (Yes/No)	Comments
US	10000	1000000001	No	No	No	No	No	Yes	No	Yes	
US	10000	1000000002	No	No	No	No	No	No	No	No	
US	10000	1000000007	No	No	No	No	No	Yes	No	No	SAE Reconciliation outstanding
US	10001	1000100001	Yes	No	No	No	No	No	No	No	
US	10001	1000100002	No	No	No	No	No	No	No	No	
US	10009	1000900001	Yes	No	No	No	No	No	No	No	
US	10009	1000900001	No	No	No	No	No	No	No	No	
US	10028	1002800001	No	No	No	No	No	No	No	No	
US	10029	1002900001	Yes	No	Yes	Yes	No	Yes	No	Yes	SDV Required
US	10029	1002900002	No	No	No	No	No	No	No	No	
US	10029	1002900003	Yes	Yes	Yes	No	No	Yes	No	No	
US	10029	1002900004	Yes	No	No	No	No	Yes	No	Yes	

An ideal tool or system would be one that can quickly provide a summary of status and display flags from EDC and external sources (Central lab, SAE reconciliation, Protocol Deviations, etc), along with an overall status for the subject that would deem a subject “clean”. In addition, the ideal tool would also provide end users the flexibility of determining the criteria for ‘cleanliness’ (e.g., queries closed, SDV status, SAEs reconciled, etc). The ideal tool would also allow the end user the ability to identify clean patients on a milestone basis (e.g., interim database lock, cohort completion, database snapshot, etc) or multiple milestones (e.g., interim1, interim2 and then final database lock).

By adding customization, a Clean Patient Tracker (CPT) can be created that addresses these requirements. CPT gives the end users the ability to quickly view which activities for a subject are pending and require attention in a

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more directed and pointed manner while presenting the data in near real-time. The benefits here are manifold including rolling patient cleaning, lessening the burden to an investigative site in having smaller boluses of data requiring action, more rapid data views for consumers of those data, and assistance expediting interim analyses and/or database locks. For long studies with long enrollment periods, it will help avoid the situation where a site closes and no one is available to answer queries (ie, timely scheduling of monitoring visits, PI accessibility, etc), as such there's a potential for reducing the duration of last patient, last visit to database lock.

Mark the record from the table below and clean a subject by choosing the option from the dropdown

Subject Cleaned? ---

This flag will update the DM Overwrite flag

Insert Comment:

ICPT_Report

Subject	Subject Status	Last Visit Date	DM Opened Queries	DM Answered	Missing Pages	CRA Outstanding Queries	SDV Re
000009-0002	Enrolled						
0001001-0001	Early Termination	30 Apr 2017					
0001001-0002	Completed						
0001001-0003	Completed						
0001001-0004	Treated						
0001001-0005	Screening Failure						
0001001-0006	Screening Failure						
0001001-0007	Screening Failure						
0001001-0008	Screening Failure						
0001001-0009	Early Termination	15 Jan 2017					
0001001-0010	Early Termination	15 Jan 2017					
0001001-0011	Early Termination	15 Feb 2017					
0001001-0012	Early Termination	15 Feb 2017					
0001001-0013	Early Termination	15 Mar 2017					

Details

Subject	DM Answered Queries	DM Opened Queries	Missing Pages	CRA Outstanding Queries	SDV Required	DM Review Required	Frozen Page Status	Hardlocked Page Status
0001001-0001	114	114	150	114	148	148	148	148

Details-on-Demand

Site	Site Name	Subject	Subject Status	Query Status	Query Responded By	Query Opened By	logline	RECORD_ID	Opened_By	Opened_d
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	1449077	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	1449077	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	1449077	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	1449077	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	0	2299988	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	1449077	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001		Open		Clinical Site by System	1	2300000	systemuser	6/1/2016 7:...
0001001	0001001	0001001-0001	On Treatment	Open		Clinical Site by System	0	1256957	systemuser	3/13/2016 6:...
0001001	0001001	0001001-0001	On Treatment	Answered	USER1		1	1256964	USER18	3/13/2016 6:...
0001001	0001001	0001001-0001	On Treatment	Open		Clinical Site by System	1	1257002	systemuser	3/17/2016 6:...
0001001	0001001	0001001-0001	On Treatment	Open		FNAME8 LNAME8	1	1257002	USER8	3/29/2016 1:...
0001001	0001001	0001001-0001	On Treatment	Open		Clinical Site by System	2	1257054	systemuser	3/29/2016 1:...

114 of 776 rows 114 marked 37 columns

When exploring and analyzing data to discern trends or patterns, BI enables insight that is not possible with other tools. Visualizations are added to provide the details of what queries may be outstanding which would prevent a subject(s) from being identified as clean.

CONCLUSION

Tracking status of subjects is challenging. By using Data Visualizations and Analytics software, some of the manual work to pull information together that is prone to errors during transcription can be eliminated and provide quick insight into the data.

By adding customization, a Clean Patient Tracker (CPT) can be created that addresses these requirements. CPT gives the end users the ability to quickly view which activities for a subject are pending and require attention in a more directed and pointed manner while presenting the data in near real-time. The benefits here are manifold including rolling patient cleaning, lessening the burden to an investigative site in having smaller boluses of data requiring action, more rapid data views for consumers of those data, and assistance expediting interim analyses and/or database locks. For long studies with long enrollment periods, it will help avoid the situation where a site closes and no one is available to answer queries (ie, timely scheduling of monitoring visits, PI accessibility, etc), as such there's a potential for reducing the duration of last patient, last visit to database lock.

Some of the advantages of using visual analytics with additional customization to create a clean patient tracker are:

- Quickly provide a summary of statuses.

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- Display flags from EDC and external sources (Central lab, SAE reconciliation, Protocol Deviations, etc).
- Provide overall status for the subject that would deem a subject “clean”.
- Allow end users the flexibility of determining the criteria for ‘cleanliness’ (e.g., queries closed, SDV status, SAEs reconciled, etc).
- Identify clean patients on a milestone basis (e.g., interim database lock, cohort completion, database snapshot, etc) or multiple milestones.

CONTACT INFORMATION (HEADER 1)

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