Insights to Meticulous Clean Patient Tracking via Analytics

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ABSTRACT

The Conventional ways of tracking clean patients by Clinical Data Management is by extracting data from multiple sources or generating reports manually from EDC system into excel spread sheets. Even though this was proven to be successful in the past, still it is a tedious and laborious method along with a high risk of making an error while handling the data.

The modern and most efficient way of tracking clean patients is by using Statistical Analysis Software (SAS®) in combination with Visual Analytics. This approach helps not only the Clinical Data Management, but also the Medical Monitors and Clinical Operations to overcome the challenges in data cleaning, tracking and reviewing the patients. Additional features and functionality can be added through customizations.

INTRODUCTION

Clinical Data Managers and other clinical team members face many challenges in tracking the status of the visits and queries associated with the subjects which define the cleanliness of the subject. The traditional way of tracking the subjects is by reviewing the excel reports, which might be time consuming and error prone because of the manual process. The volume of data involved in tracking the subjects is huge and this makes it difficult to monitor data and identify risks. It is a challenge to collaborate around the data using excel sheets.

Data visualization allows you to view data interactively and helps in data exploration. In analytics tool, the user has the ability to identify trends, filter data, drill down to details and export data for more details. This paper presents a process of tracking subjects using a visual tool TIBCO Spotfire along with a combination of reporting tool SAS.

MANUAL CLEAN PATIENT TRACKER

The typical process of tracking the subjects is by extracting reports or data from EDC and then creating an excel tracker. This process is time consuming and there is a good chance for data alteration.

Site	Subject	Study Completion	Study Completion Date	Verification Required	Queries Open	Queries Responded	Missing Pages	Lab Reconciliation	PK Reconciliation	Clean Status
101	101_001	Yes	1/1/2018	No	0	0	0	0	0	Yes
101	101_002	Yes	2/1/2018	Yes	3	1	0	5	0	No
101	101_003	No		Yes	0	0	7	0	0	No
102	102_001	Yes	1/1/2018	No	1	1	3	0	0	No
102	102_002	No		No	0	0	0	0	0	Yes
102	102_003	No		Yes	0	0	5	0	0	No
102	102_004	Yes	2/1/2018	No	0	1	0	0	0	No
102	102_005	No		Yes	3	2	8	0	0	No
102	102_006	Yes	3/1/2018	Yes	2	1	0	0	3	No
102	102_007	Yes	4/1/2018	No	0	0	0	0	0	Yes
103	103_001	No		Yes	0	0	3	0	0	No
103	103_002	Yes	1/1/2018	No	1	0	0	0	0	No
103	103_003	Yes	2/1/2018	No	1	1	0	0	0	No
103	103_004	No		Yes	0	0	5	0	0	No
103	103_005	Yes	3/1/2018	No	0	0	0	0	0	Yes

Figure 1. Excel Clean Patient Tracker

PATIENT TRACKING USING DATA VISUALIZATIONS

A process or system which is interactive with exploratory analyses feature is ideal for data review or tracking. The process which we developed provides an overall summary of the subject along with the

status of subject and the fields (Number of open and responded queries, source data verification, Missing pages and external data reconciliation) contributed to the status. Figure 2 presents the flow chart of the process that is involved in creating Clean Patient Tracker in TIBCO Spotfire.
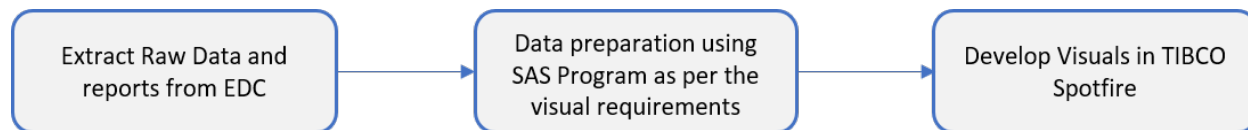

Figure 2. Process flow of Clean Patient Tracking via Analytics

The following 3 steps illustrates the process involved in creating data visualizations for tracking subjects:

1. Extract raw datasets and reports from EDC.

2. Transforming data from reports into the required data structure using SAS.

3. Import the datasets created using SAS into TIBCO Spotfire and create visualizations.
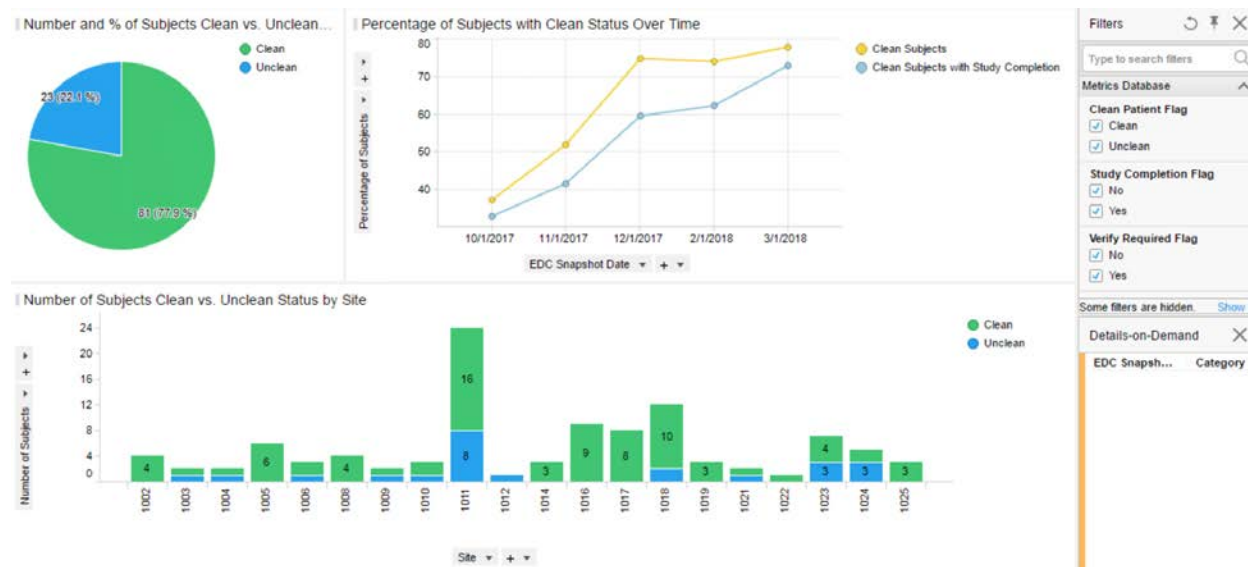

Figure 3. Clean Status Visualizations

Figure 3 shows the visualizations created for tracking subjects. It consists of two visuals with distribution of subjects by clean status and a visual with percentage of subjects clean over time. It provides overall summary of all the subjects and it can be viewed at patient or site level. Columns in the filter section can be used for sub-setting data and review the data at granular level. When you filter, certain data values in the data table are filtered out, and only the filtered values, that is the remaining values, are included in what is being visualized. All visualizations that are based on this data table will immediately update to reflect only the filtered values. However, you can anytime change what is filtered, or return to the full set of data [1].

Site	Subject	Clean Patient Flag	Study Completion Flag	Number of Answered Queries	Number of Open Queries	Lab Reconciliation Flag	PK Reconciliation Flag
1006	1006_001	Unclean	Yes	0	0	1	0
1006	1006_002	Clean	Yes	0	0	0	0
1006	1006_003	Unclean	No	0	1	0	1

Figure 4. Details-on-Demand

The source of the data that is being used for the visual can be viewed in the Details-on-Demand area. Figure 4 shows the Details-on-Demand panel presenting the part of the source data of the visual in figure 3. When a particular data is marked in the visual then all the rows of the data of that part will be presented in the Details-on-Demand panel. This functionality can also be used to drill down into specific details and the data rows can be exported to excel sheet.
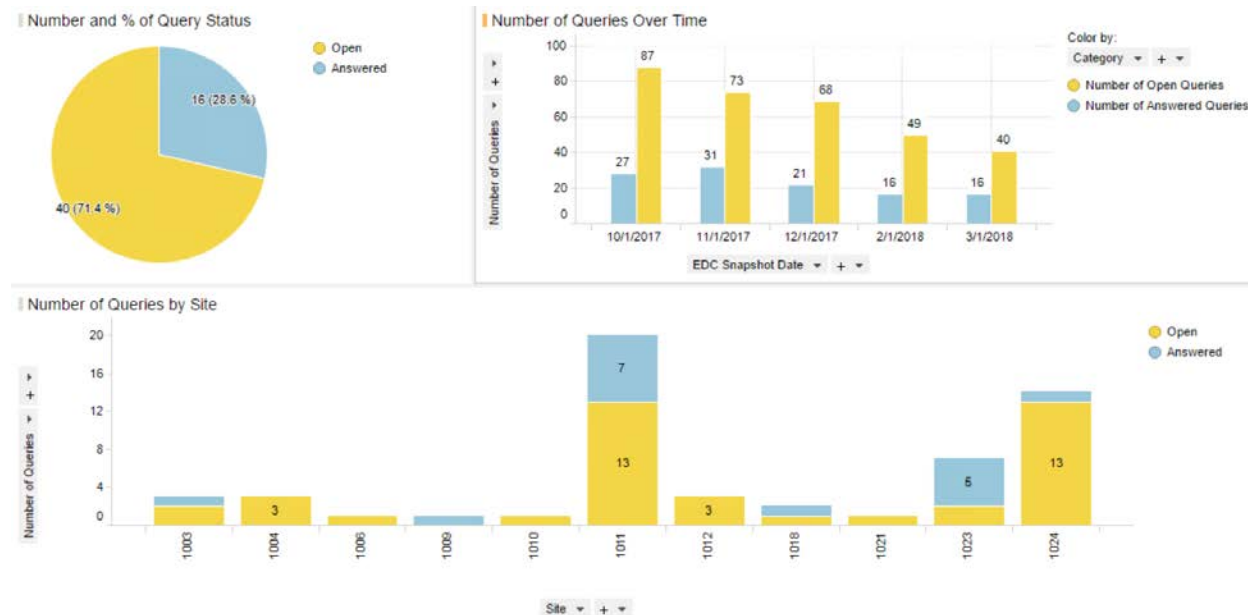

Figure 5. Query Status Visualizations

Additional visuals to track the query details is presented in Figure 5. It consists of the distribution of query status overall and by site. This helps in to keep a track on the number of queries opened and answered at site level and over time. At any given time, the data behind the visual can be viewed in the Details-on-Demand panel and has an option to extract the data. The additional information collected with a query such as duration of query, type, created by, query note, date created on, etc., will be available in Details-on-Demand panel. Additional visuals can be created to track the reconciliation status of the external data at subject and visit level.

SPOTFIRE WEB PLAYER

The Spotfire analysis file (DXP file) can be published onto a Web player, where the user can explore data using interactive visualizations. Spotfire Web Player is a powerful tool for sharing and distributing information within and outside an organization. It is a web browser-based application, which requires no installation, and can be used inside a portal or a web site [2]. Web player lets you to filter data, drill down to details, identify spots or trends and export data.

CONCLUSION

The reports extracted from the EDC for Clean Patient Tracking might be complex and it might not be in required structure. Data visualization gives you a better insight of data and ease of access. The user has the flexibility to define the criteria of the cleanliness of the subject. The visual analytics tool has the ability of filtering data to a granular level which makes the data review process faster and effective. The tool can be shared with all the team members and can be refreshed on a periodical basis. The level of access to the visualizations and data can be controlled using the analytics tool.

REFERENCES

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