

USING VISUAL ANALYTICS TO TRACK CLEAN PATIENTS

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Enter Data Classification Here



Challenges in Tracking Subject Data

- One of the many challenges facing Clinical Data Management and Medical Reviewers is tracking data that have been reviewed and cleaned
- Tracking subjects has been performed by copying data from multiple sources and pasting to excel trackers where Clinical Data Management and Medical Reviewers update columns when review has been completed



Excel Trackers

- Excel spreadsheets with statuses where Clinical Data Management and Medical Reviewers update as they perform review
- Manual Entered Flags (SAE Reconciliation, Coding, etc)
- No audit trail in Excel
- Multiple Study Trackers

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	





Visual Analytics

- Industry has adapted to using Visual Analytics for the exploration of data with automated data delivery from multiple data sources
- These visualizations provide for quick, high level data views with detailed drill downs and the ability to quickly see the status of subjects in your trial in-motion



Visualization Tools

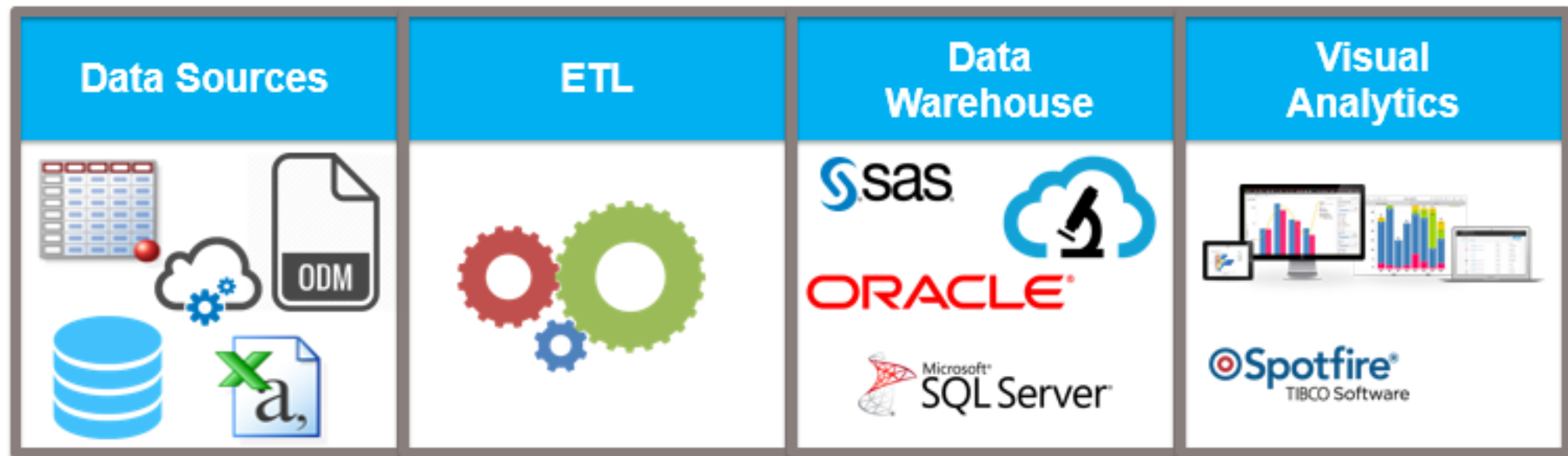


infogr.am



Data Transformation and Normalization

- Data is transformed and stored in data warehouse
- Reduce data handling within Visual Analytics
- Visual Analytics require static structure



Data Review

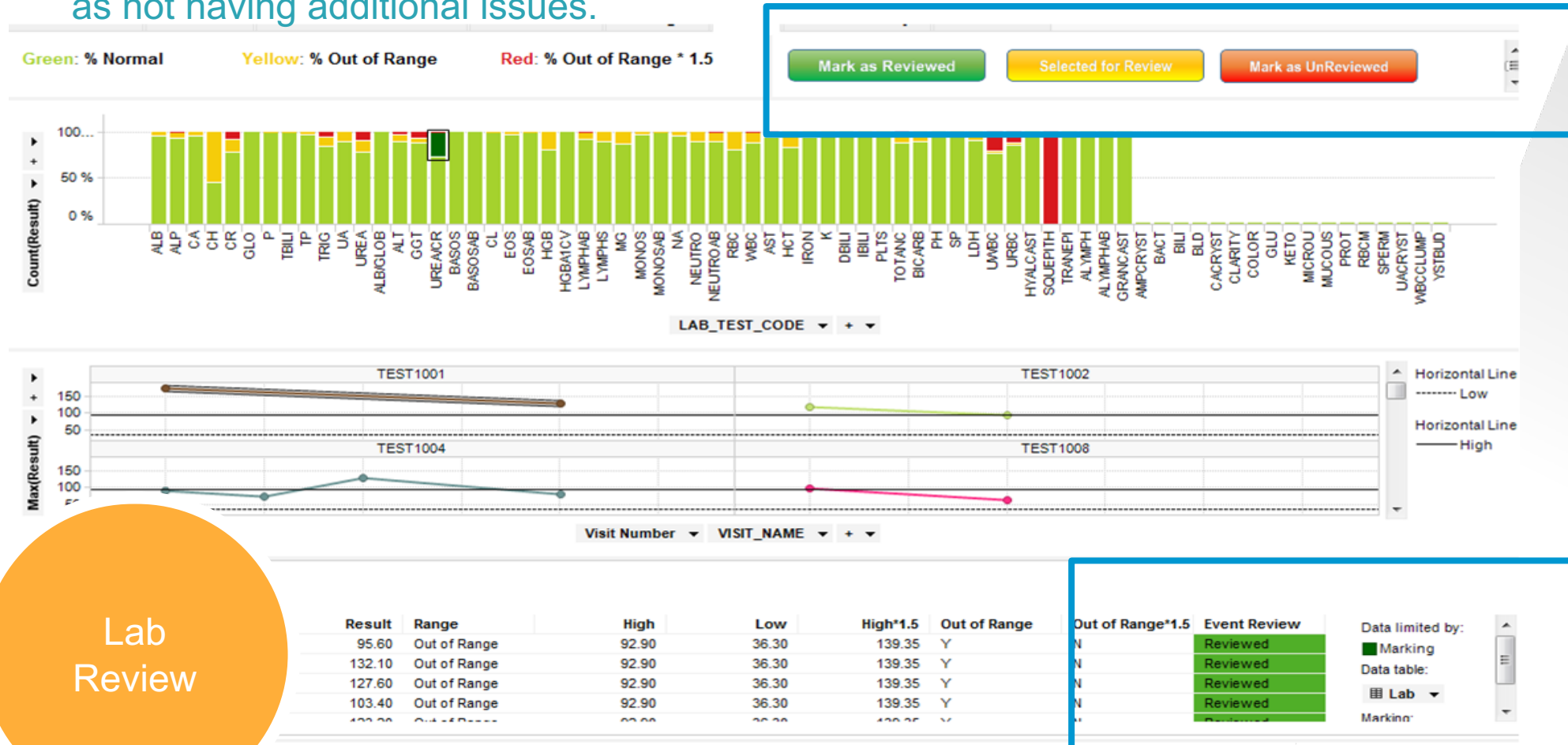
- Outliers are easily identified
- Dynamic Data Investigation
- Review and Tracking in one location



Labs – All
Subjects
over Time

Data Review Status

- By connecting visualizations to metadata repository (SQL database), it provides the functionality to add and update comments at the subject or visit level, identifying subjects as not having additional issues.



Lab
Review

- Data is categorized based on requirements
- Unreviewed and Changed data is identified for future review



Unreviewed/
Changed
Data

Data Reconciliation (Non-CRF)

- Visual Analytics tool can also be used for reconciling non-CRF data such as SAEs
- Data from safety database and EDC is merged within the tool
- Data Management and Medical Reviewers can review data and input comments

Home SAE Reconciliation Report Conceptual Match SAE Category Distribution Audit

Mark the Record from the Table below and Reconcile by choosing the option from the dropdown

Review Status: Reconciled Manually

Critical Review Required: Yes

Comments:

Submit

Legends:

- Missing in Safety
- Missing in EDC
- EDC <-> SAFETY Discrepancy
- Reconciled by System/manually
- Conceptual Match

SAE Reconciliation

Local Review Required?	Review Status	Subject	P Term	Start Date	Reason for Discrepancy	EDC Verbatim	SAFETY Verbatim	EDC Outcome	SAFETY Outcome	EDC Relatedness	SAFETY Relatedness	EDC Action Taken	SAFETY Action Taken	Comments
	Reconciled Manually	811-5501	HEADACHE	10/8/2013 12:00:00 AM	Matching	worsening headaches	WORSENING HEADACHES	Resolved, with sequelae	RECOVERED/... WITH SEQUELAE	Not Related	NOT RELATED	Unchanged	NO ACTION TAKEN	discrep
	Reconciled Manually	811-5501	HYPERTENSI...	10/8/2013 12:00:00 AM	Matching	worsening arterial hypertension	ARTERIAL HYPERTENSION WORSENING	Resolved, with sequelae	RECOVERED/... WITH SEQUELAE	Not Related	NOT RELATED	Unchanged	NO ACTION TAKEN	no discrepancy
	UnReconciled	811-5502	ECG SIGNS OF MYOCARDIAL ISCHAEMIA	8/19/2013 12:00:00 AM		signs of possible cardiac ischemia	POSSIBLE CARDIO ISCHEMIA	Resolved, without sequelae	RECOVERED/...	Not Related	NOT RELATED	Unchanged	NOT APPLICABLE	test
	UnReconciled	821-5544	IDIOPATHIC PULMONARY FIBROSIS	9/8/2014 12:00:00 AM		terminal idiopathic pulmonary	TERMINAL IDIOPATHIC PULMONARY	Death (this AE was cause of death)	FATAL	Not Related	NOT RELATED	Unchanged	NO ACTION TAKEN	
	Reconciled Manually	872-5508	IDIOPATHIC PULMONARY FIBROSIS	2/13/2014 12:00:00 AM	Matching	hospitalisation due to acute exacerbation of	EXACERBATION OF IDIOPATHIC PULMONARY	Resolved, without sequelae	RECOVERED/...	Not Related	NOT RELATED	Unchanged	NO ACTION TAKEN	test4
	UnReconciled	872-5508	IDIOPATHIC PULMONARY FIBROSIS	4/3/2014 12:00:00 AM		hospitalisation due to acute exacerbation of	ACUTE EXACERBATION OF IDIOPATHIC	Death (this AE was cause of death)	FATAL	Not Related	NOT RELATED	Unchanged	NO ACTION TAKEN	

Clean Patient Tracker

- Import Review Statuses from Reconciliation tools, data review, and other external sources
- Automated and Manual Statuses

Definitions **CPT** **Interim Clean Patient Tracker**

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:

CPT Report

Subject	Subject Status	Last Visit Date	DM	Opened Queries	DM Answered	Missing Pag...	CRA Outstanding Queries	SDV R
000 009-0002	Enrolled							
000 001-0001	Early Termination	30 Apr 2017						
000 001-0002	Completed							
000 001-0003	Completed							
000 001-0004	Treated							
000 001-0005	Screening Failure							
000 001-0006	Screening Failure							
000 001-0007	Screening Failure							
000 001-0008	Screening Failure							
000 001-0009	Early Termination	15 Jan 2017						
000 001-0010	Early Termination	15 Jan 2017						
000 001-0011	Early Termination	15 Feb 2017						
0001001-0012	Early Termination	15 Feb 2017						
0001001-0013	Early Termination	15 Mar 2017						
0001001-0014	Completed							

Details

Subject	DM Answered Queries	DM Opened Queries	Missing Pages	CRA Outstanding Queries	SDV Required	DM Review Required	Frozen Page Status	Hardlocked Page Status
0001001-0...	45	45	74	45	54	54	54	54

Ready

7,099 of 7,099 rows 74 marked 39 columns CPT_Report

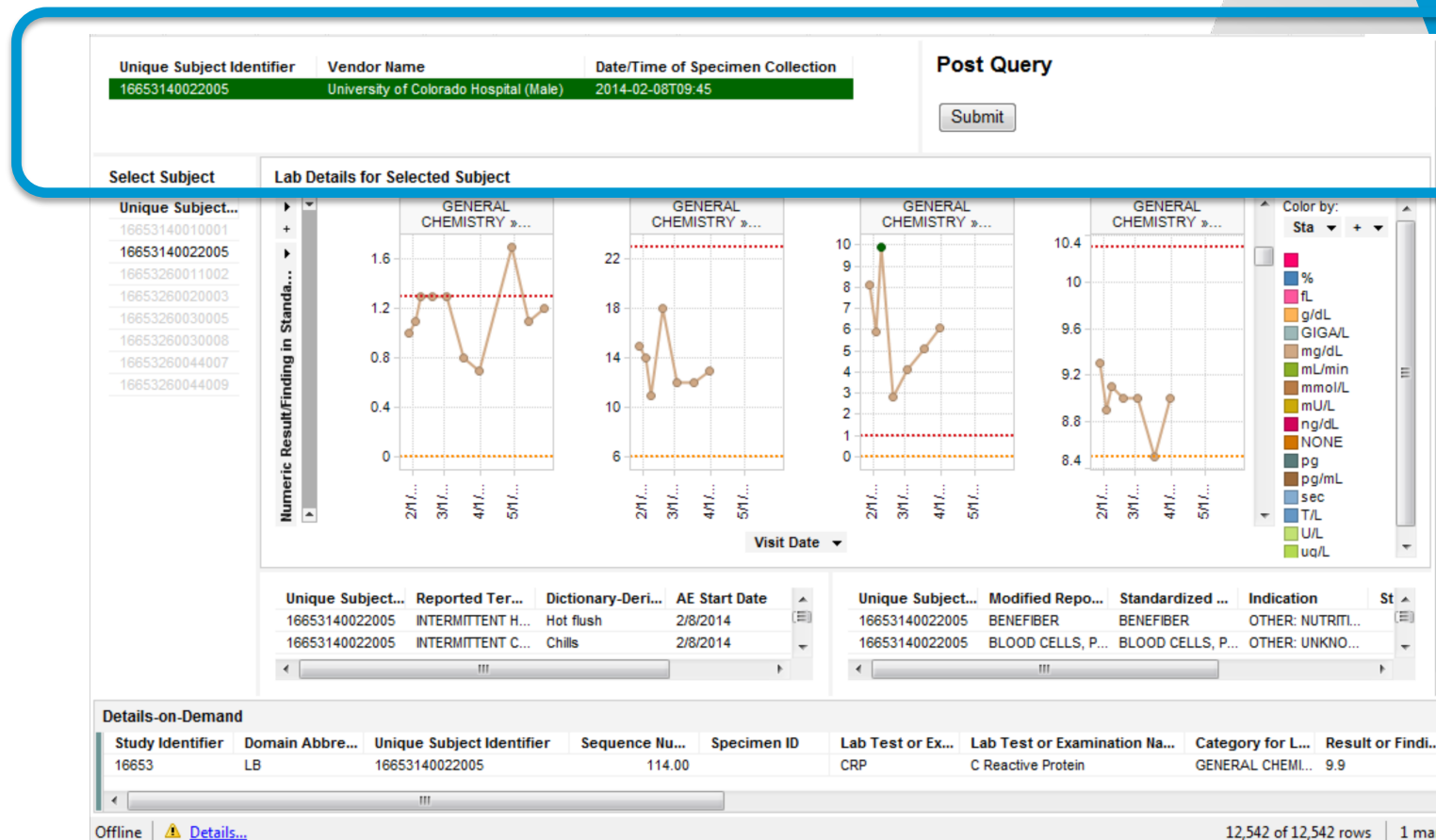
Users Actions Recorded

- Data entered from input fields is stored in metadata repository (SQL database)
- Audit trail is kept for data entered by users
- Data can be exported if necessary

Visit	DM_Comment	Overall_Sta...
End of Screening	Visit folder should actually not output in CPT.	Unclean
Safety Reports	Test 3	Unclean
Subject Identification	Test 2	Unclean
End of Run-In	This comment was entered for subjects 666621001 ...	Unclean
Informed Consent	DM 123	Unclean
Study Medication	DM 2345	Unclean
End of Follow-up	test DM	Unclean
End of Treatment	Test2	Unclean
Post-treatment Visit	Test Comment - Added by Tom Auckinson during U...	Unclean
End of Follow-up	sPOTFIRE TEST	Unclean
End of Screening	TEST_DM_12	Clean
Visit 3 (Month 4)	test 4	Unclean
Screening	DM12	Unclean
End of Run-In	this subject is really clean.	Unclean
Informed Consent	LT reviewed this subject	Unclean
Run-In	this subject is reviewed	Unclean
Screening	TEST	Unclean
End of Follow-up	TEST	Unclean
End of Run-In	spotfire	Unclean
End of Treatment	test Michael	Unclean
Subject Identification	NULL	Unclean
Visit 4 (Month 8)	DM-32	Unclean
Visit Independent ...	Spotfire_12	Unclean
End of Follow-up	spotfire _testing	Unclean
End of Screening	TEST	Unclean

Future Enhancements

- APIs provide the ability to post data from external sources to EDC using Web Services
- Queries can be posted from the same system by users
- Query text can be predefined or manually entered by user



Conclusions

- Visualizations Improve Business Processes
- By making Visual Analytics truly interactive, users not only can consume the information but they also capture their decisions
- Automate manual processes as much as possible

Subject Cleaned?

Uncleaned ▼

This flag will update the DM Overwrite flag

Insert Comment

This subject is now cleaned

Submit

Unmark Selected Rows

ICPT

	Coding	SDV Required	DM Review Required

SUBJECT	DM Overall	DM Overall	Missing Pages	CRA Outstanding	Coding	SDV Require
989893004	N	14	14	14	14	
	(Empty)	0	182	182	182	
Grand total		14	196	196	196	

Thank you!

