Process Innovation and Automation in Clinical Data Sciences

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INTRODUCTION

External Data Specialist managing to clean the colossal lab data within short duration of time. With aid of data cleaning tools life of Data Managers gets tranquil.

External Data Validator is the tool which can help to polish the data from setup until close out making it a perfect example for 100% programmed reconciliation
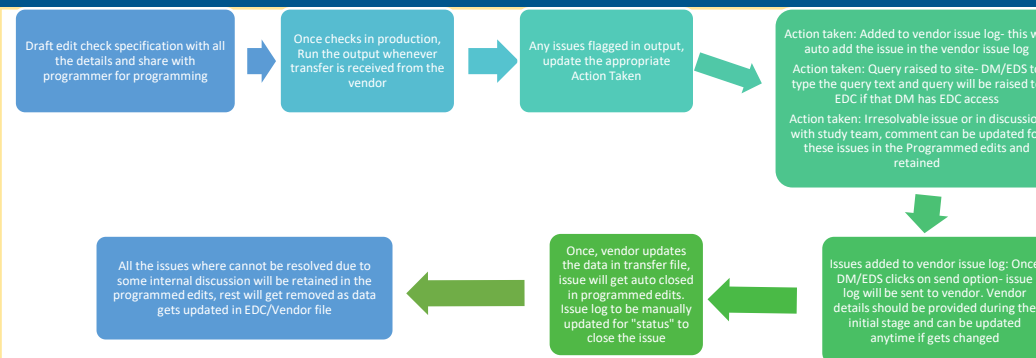
AIM

- To perform quality cleaning of vast clinical data

- To reduce manual efforts during the timelines

- To benefit cross functional team by saving the workaround time on the data

- Avoid minor errors like incorrect spelling, loss of information or incorrect data entry while transferring data from one file to another.

- Setting up standard that will lessen burden of many Data Managers and/or External Data Specialist

RESULTS

Crisp and clear message will be delivered to vendor to take appropriate action which will reduce turnaround time of issue resolution.

CONCLUSION

This tool not only allows to have the 100% programmed reconciliation but also reduces the loss of information while updating different documents involved with issue resolution as well as maintains audit trail. This will help DM and also be beneficial to cross functional teams and vendors.

ACKNOWLEDGEMENT

Edit Checks for Safety Data

Program run date: 15Nov2022
Transfer file date: 15Nov2022

Edit Check Number	Subject number	Visit Name	Accession number	Sample Collection Date in EDC	Sample Collection Date in Vendor file	Issue Descripion	Action Taken	Additional Comment	Date issue created	Reviewer's Name
1	10012	Day 1	1234567890123	1-Nov-22	2-Nov-22	Sample Collection date in EDC 01Nov2022 does not match with the sample collection date in vendor file 02Nov2022 for Day 1 Visit and accession number 1234567890123	Added to vendor issue log	Please confirm if the sample collection date and update if the date provided in transfer file is incorrect.	28-Oct-22	Sayali Kale

Vendor Issue Log for Safety Lab

	Updated by DM										Updated by Vendor	
Subject Number	Visit from EDC	Sample Collection date from EDC	Accession number from EDC	Visit from Vendor file	Sample Collection date from Vendor file	Accession number from Vendor file	Issue Descripion	Issue Status	Issue added date (Date when notified to vendor)	Issue added by	Vendor Comment	Transfer file updated (Yes/No)	Vendor comment date
10012	Day 1	1-Nov-22	1234567890123	Day 1	2-Nov-22	1234567890123	Sample Collection date in EDC 01Nov2022 does not match with the sample collection date in vendor file 02Nov2022 for Day 1 Visit and accession number 1234567890123 Please confirm if the sample collection date and update if the date provided in transfer file is incorrect.	Open	16-Nov-22	Sayali K	Date update	Yes	21-Nov-22

METHODS

Draft edit check specification with all the details and share with programmer for programming

Once checks in production, Run the output whenever transfer is received from the vendor

Any issues flagged in output, update the appropriate Action Taken

Action taken: Added to vendor issue log- this will auto add the issue in the vendor issue log
Action taken: Query raised to site- DM/EDS to type the query text and query will be raised to EDC if that DM has EDC access
Action taken: Irresolvable issue or in discussion with study team, comment can be updated for these issues in the Programmed edits and retained

Issues added to vendor issue log: Once DM/EDS clicks on send option- issue log will be sent to vendor. Vendor details should be provided during the initial stage and can be updated anytime if gets changed

Once, vendor updates the data in transfer file, issue will get auto closed in programmed edits. Issue log to be manually updated for "status" to close the issue

All the issues where cannot be resolved due to some internal discussion will be retained in the programmed edits, rest will get removed as data gets updated in EDC/Vendor file