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Leveraging Manifest Files for Impact Analysis: Preparing Studies for Critical Deliverables (Interim/Final Run/Submissions)

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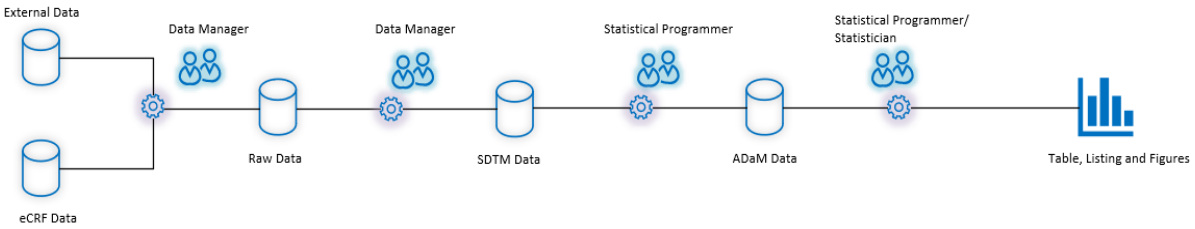
Abstract

Having inconsistent outputs, chronology of the execution timestamps not matching with the quality checklists are common issues encountered by programming teams during the preparation of the outputs needed for a critical milestone. The challenges with clinical trials is multiple sources of inputs, macros, multiple teams involved in changes, lack of traceability between inputs and outputs and impact analysis of the changes. In these dynamic situation teams face issues like- Communicating changes in outputs of one team that impact inputs to another team, Align and communicate modifications in macros or programs used by multiple programmers/teams, Lack of alerts for changes in input data sources. The presented approach uses manifest files in SAS Life Sciences Analytics Framework to automate the impact analysis across all teams/programs and share alerts to the impacted teams. The approach also provides a mechanism to visualize the dependencies for better clarity and communication.



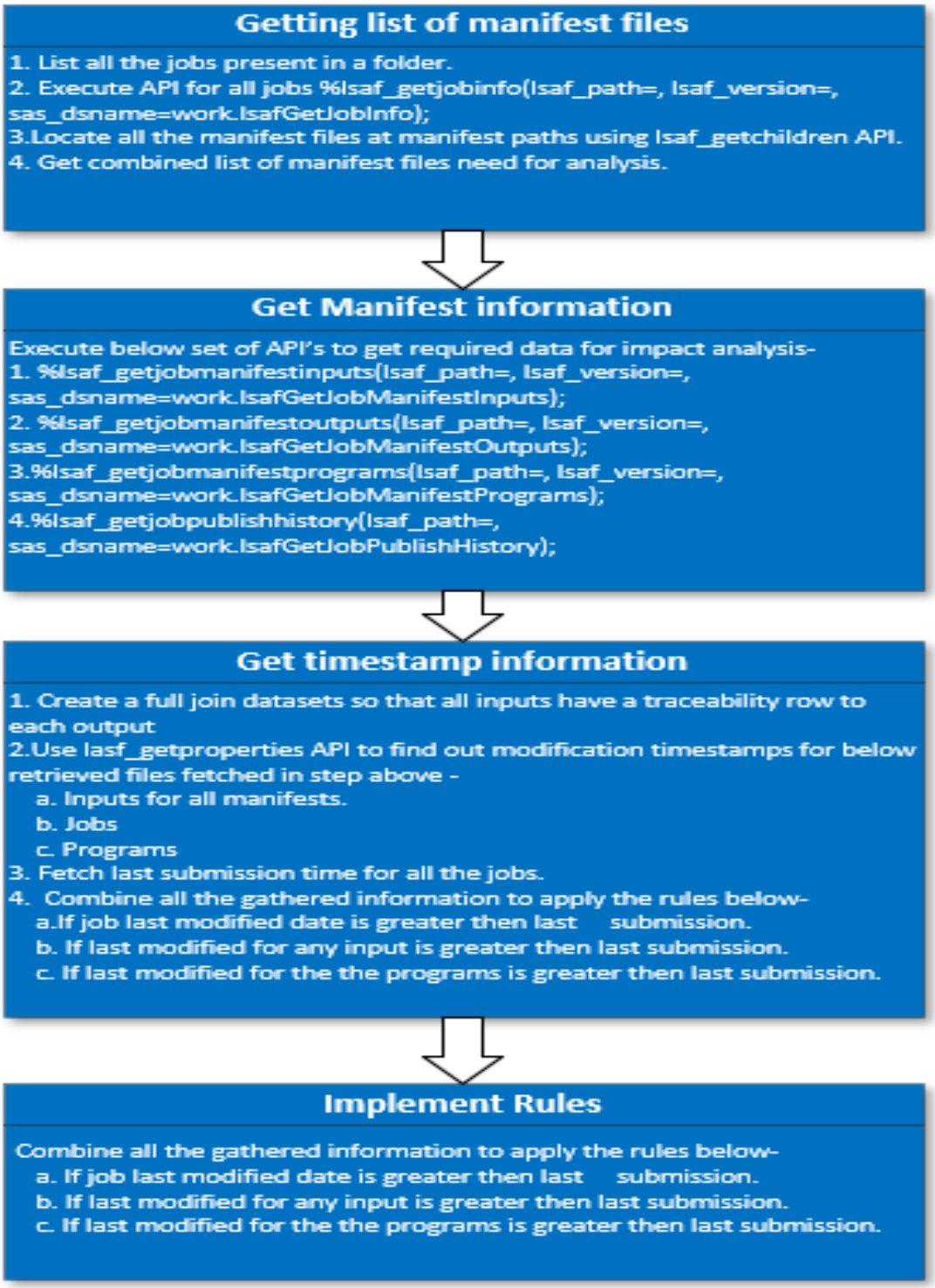
Impact Assessment Types

1. **Single Level (Backward)** : This method is effective in checking the impact of direct inputs to our program. For example, if we are checking impact for ADaM program then we may be interested in any change in the SDTM's used in ADaM program.
2. **Full Impact (Forward)** : This method is effective in checking that any changed file (data, job etc.) having impact on any of the successive outputs in the hierarchy. For

example, if we are checking the impact of raw data file change to SDTM, ADaM and TLF's.

Implementing Single Level Impact Analysis

The proposed solution is based on Life Sciences Analytics Framework (LSAF). This type of impact analysis can be implemented at any level using below mentioned API's-



Final Output : The final outcome is highlighted and give below insights-

1. The output can be filtered by impact due to change in jobs, change in programs and change in inputs.
2. The output showcase impact of one input change to all the outputs of the job.
3. Current screenshot showcase impact for one job (e.g. adae.job). The combined output contain impact for all ADaM level jobs that be used further in gaining full impact analysis at all levels.

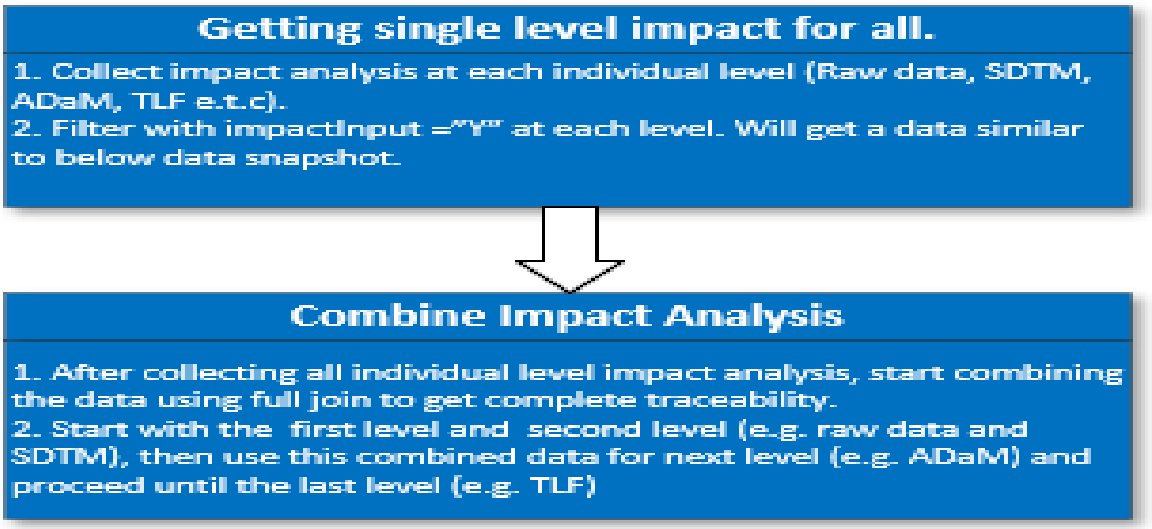
Job Name	Input Path	Output Path	Reference Program	Input Last Modified	Program Last Modified	Job Last Modified	Job Last Execution	impactjob	impactinput	impactprogram
adae.job	<path>/data/sdtm/ae.sas7bdat	<path>/data/adam/adae.sas7bdat	<path>/prg/adam/adae.sas	23Sep22:12:52:29	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34		Y	
adae.job	<path>/data/sdtm/ae.sas7bdat	<path>/data/adam/adqs.sas7bdat	<path>/prg/adam/adae.sas	23Sep22:12:52:29	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34		Y	
adae.job	<path>/data/sdtm/dm.sas7bdat	<path>/data/adam/adae.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:02	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/data/sdtm/dm.sas7bdat	<path>/data/adam/adqs.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:02	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/data/sdtm/ex.sas7bdat	<path>/data/adam/adae.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:03	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/data/sdtm/ex.sas7bdat	<path>/data/adam/adqs.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:03	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/data/sdtm/suppae.sas7bdat	<path>/data/adam/adae.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:04	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/data/sdtm/suppae.sas7bdat	<path>/data/adam/adqs.sas7bdat	<path>/prg/adam/adae.sas	22Sep22:13:02:04	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/macros/request_setup.sas	<path>/data/adam/adae.sas7bdat	<path>/prg/adam/adae.sas	15Sep22:10:19:07	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			
adae.job	<path>/macros/request_setup.sas	<path>/data/adam/adqs.sas7bdat	<path>/prg/adam/adae.sas	15Sep22:10:19:07	23Sep22:09:14:11	14Sep22:14:29:53	23Sep22:09:14:34			

Implementing Single Level Impact Analysis

In order to perform full impact analysis the process need to be started by finding impact at individual levels. Levels here refers to raw data, SDTM, ADaM and TLF's. The outputs received from single level impact will be combined to achieve full impact analysis.

Filtered response from each level :

job_ADaM	input_ADaM	output_ADaM	program_ADaM
adae.job	<path>/data/sdtm/ae.sas7bdat	<path>/data/adam/adae.sa…	<path>/prg/adam/adae.sas
adae.job	<path>/data/sdtm/ae.sas7bdat	<path>/data/adam/adqs.sas…	<path>/prg/adam/adae.sas



Roadmap

Further automation to this approach can be achieved using LSAF Business Process Model and Notation (BPMN) standards. It enables you to develop a workflow process allowing teams to define automated processes, triggered by events. This removes the communication gap within the teams automatically. For more details kindly refer SM08 - PHUSE EU 2021 (lexjansen.com).

Visualisations for traceability can also be generated using the output datasets and the visualisations will be helpful in clearly identifying the dependencies.

Limitation : The only limitation to the approach is the inputs that are not part of the manifest in some cases e.g. Jar files.

Conclusion

The proposed approach use a standard LSAF provided API's to extract the desired information but the same can be achieved by PROC SCAPROC.

Armed with full capabilities of impact analysis users can make sure that the correct data, macro and programs are used to produce the desired outputs. Users can prepare the critical deliverables with greater confidence.

References

1. Paper SM08 :Automation of Process Flow Instances in LSAF. SM08 - PHUSE EU 2021 (lexjansen.com)

Contact Information

Your comments and questions are valued and encouraged. Contact the author at:

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