

Paper SM04

Automated Programming Consistency Checks: Enhancing Clinical Programming Quality, Efficiency, and Scalability

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Agenda

- ❑ Objective
- ❑ Why Manual Review Falls Short?
- ❑ What Automation Aims to Achieve?
- ❑ SAS Macro Architecture & Implementation
- ❑ Results
- ❑ Future Enhancements



❑ Objective

- Develop a SAS macro-based solution that automates comprehensive programming consistency checks.

❑ Why programming consistency checks are essential ?

- Detect programming errors early.
- Align global teams with consistent implementations.
- Preserve data integrity and reproducibility.
- Reduce regulatory risk.

Why Manual Review Falls Short?

- ❑ Ad-hoc checklists 
- ❑ Slow & Time-consuming 
- ❑ Review Inconsistency 
- ❑ Human Error 

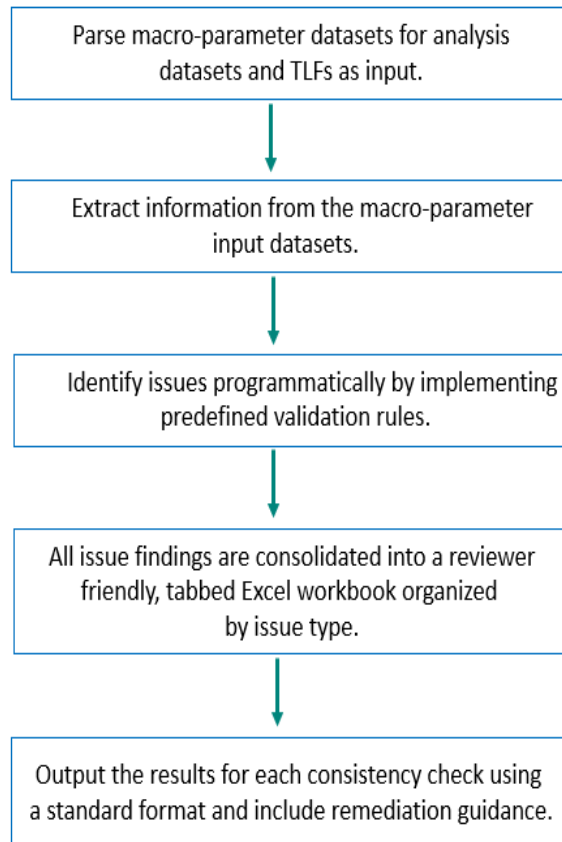
What Automation Aims to Achieve?

- ❑ Identify programming issues early. 
- ❑ Programmatic, standardized checks with clear remediation guidance. 
- ❑ Scale to review hundreds to thousands of programs simultaneously. 
- ❑ Reliable, consistent results and shorter review cycles. 



SAS Macro Architecture and Implementation

Macro Program flow



Sample Macro Call Program

```
%check0prog (  
input_library = LPTIN           /* input macro parameter datasets location */  
,output_library = LPTOUT       /* Path to output results*/  
,output_fileref = FPTOL       /* fileref to output results*/  
,outputs_select = safety      /* select required outputs to review */  
,outputpath = protopath/outlist /* folder path to output an excel file*/  
,rename_output= prog0checks0&sysdate. /* output filename */  
,debug = Y                    /* Y N ANALYSIS */  
);
```

- **Input:** Macro Parameter Datasets
- **Core Logic:** pre-defined validation rules
- **Output:** Excel file with each tab for a specific check

Programming Consistency Checks

	Type of Check	Purpose
1.	Missing program files	❖ Identify and flag expected submission-ready programs that are absent from the repository.
2.	Pre-processing step	❖ Detect and flag call programs that modify input datasets before invoking the macro.
3.	Deviation from standards	❖ Detect and flag any non-standard selection or filtering logic applied during TLF production.
4.	Mismatch between population, therapy variable, and subtitle	❖ Detect and flag inconsistencies among population selection, therapy variable usage, and TLF subtitle text.
5.	Discrepancies between program code and TLF outputs	❖ Detect and flag mismatches between parameter values in programs and the actual values shown in TLF outputs.



❖ Standardized output file structure

TLF Output Name	ADAE subset condition in the call program	Call Program Name	Expected Value/ Remediation Guidance
aeOnset0gr35	SAFFL= 'Y' and TRTEMFL = 'Y' and PDEXCFL ^= 'Y' and atoxgrn in (3,4,5) and AOCC01FL='Y'	call0ae0time0to0onset	ACAT2 variable was not included in the subset condition
rainfall0all		call0ae0toxgr	Safety population subjects were not selected
rainfall0sae		call0ae0toxgr	All AEs were included. Need to keep only serious AEs.
aeOnset0dur	SAFFL= 'Y' and TRTEMFL = 'Y' and PDEXCFL ^= 'Y' and AEOSIGR1 ne " " and AEOSIFL="Y"	call0ae0time0to0onset	ACAT2 variable was not included in the subset condition
ae0outcome	SAFFL= 'Y' and TRTEMFL = 'Y' and PDEXCFL ^= 'Y' and AEOSIGR1 ne " " and AEOSIFL="Y"	call0ae0by0outcome	ACAT2 variable was not included in the subset condition

TLF Output Name	Call Program Name	Macro Parameter	Macro Parameter Value	Percent_Incidence_in_the_title	Expected Value	Explanatory Notes
specific0ae	call0specific0ae	percent_incidence	10		10	Percent incidence value is not matching between the value specified in the macro call program and TLF title
specific0ae0gr35	call0specific0ae	percent_incidence	1		0 1	Percent incidence value is not matching between the value specified in the macro call program and TLF title
toxgr0ae0pct5	call0ae0toxgr	percent_incidence	5		1 5	Percent incidence value is not matching between the value specified in the macro call program and TLF title

Sheet Name	Displays information about
Missing_program_file	Program file for the specified ADaM dataset and TLF outputs was not found.
Missing_macro_param_dataset	Macro parameter dataset for the specified TLF outputs was not found.
TLFs_with_pre-processing_code	Pre-processing code was found in the call program for the specified TLF outputs.
Check_ADAE_subset_cond	ADAE subset condition in the TLF call program for the specified AE tables/listings is missing.
Check_pct_incidence_title	The percent incidence value displayed in the TLF title differs from the value entered in the call program for the specified TLF outputs.
Check_AE_subgrp_table	Checks ADAE variable used in the observation_where subset condition to generate AE sub-group tables for drug-related, gr3-5, action taken, SAE, and deaths.
Check_pop_where_cond	Actual treatment variable or Treated or Safety population flag was used in the call programs for the specified efficacy outputs. Planned treatment variable or Randomized or Allocated or Enrolled flag was used in the call programs for the specified safety outputs.
Check_therapy_variable	Actual treatment variable was used in the call programs for the specified efficacy outputs. Planned treatment variable was used in the call programs for the specified safety outputs.
Check_subtitle	Subtitle does not match the population_where subset condition used in the call program for the specified TLF outputs.
Check_followup_table	Check the variables used to generate follow-up table for DMC/CSR.
Check_disposition_table	Check the disposition variables used from AD5L.
Check_prior_commed_tables	An incorrect variable was used to subset ADCM records for the prior or concomitant medication reports.
All_Param	Macro parameter values used for all TLFs.

Future Enhancements

- ❑ Web-based dashboard (R/Python). 
- ❑ Expand validation rule library. 
- ❑ Integrate with source control (e.g., Git) and CI/CD pipelines. 



Acknowledgements & Contact

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Thank you!

