

CT05

# Beyond Sign-Off: Practical Tips for Meaningful Reviews by Leads

**Jisna Joseph**  
Catalyst Flex

[jisna.joseph@catalystcr.com](mailto:jisna.joseph@catalystcr.com)

**Bimal Thomas**  
Catalyst Flex

[bimal.thomas@catalystcr.com](mailto:bimal.thomas@catalystcr.com)

**PHUSE APAC CONNECT**

**February 2026**



# AGENDA

Introduction

---

Checklist

---

Automation Using Macros

---

Future improvement

---

AI to Support Validation Activities

---

PowerShell: A Reliable Companion



# Introduction

## Why a Structured Review Matters

- Quality assurance
- Tight timelines and regulatory complexity
- Ensures consistency, accuracy, and compliance

# ● ● ● ● ● A Checklist for the Final Review

## What is a checklist?

A structured tool with multiple checkpoints for verification

## Why is it important?

- Systematic review
- Consistency & quality
- Training tool
- Flexibility
- Risk mitigation
- Efficiency & accountability



# How to Make a Checklist

- Use an Excel sheet for simplicity
- Include three main columns:
  - Category – Type of checks (General, SDTM, ADaM, TLFs)
  - Checks – Specific tasks or validations
  - Status – Track progress

Example:  
General checks

| Category | Checks                                                                                                                                                                           | Status   |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| GENERAL  | The programming tracker is up to date.                                                                                                                                           | DONE     |
| GENERAL  | Ensure all clarifications and resolutions are properly documented in the tracker, closed, and that responses are fully addressed or implemented in the programming deliverables. | DONE     |
| GENERAL  | Batch programs are updated to include all programs in the directory before sequential batch run.                                                                                 | DONE     |
| GENERAL  | Check the timestamp to ensure everything properly updated                                                                                                                        | DONE     |
| GENERAL  | Check for hard-coded values in programs.                                                                                                                                         | DONE     |
| GENERAL  | All comparison reports are clean.                                                                                                                                                | DONE     |
| GENERAL  | There are no characters outside the ASCII character set (0 to 127)                                                                                                               | NOT DONE |
| GENERAL  | Production and validation logs are clean.                                                                                                                                        | NOT DONE |
| GENERAL  | Sign-off document is completed.                                                                                                                                                  | NOT DONE |

- Add a Notes section for extra details (e.g., macros, tools)
- Tailor the checklist to organization-specific processes
- Keep it organized and easy to filter

Another example:  
Checks for SDTM, ADAM & TFLs

| Category ▼ | Checks ▼                                                                                                    | Status ▼ | Notes ▼ |
|------------|-------------------------------------------------------------------------------------------------------------|----------|---------|
| SDTM       | Data issues are tracked and shared.                                                                         |          |         |
| SDTM       | All partial dates are correctly populated.                                                                  |          |         |
| SDTM       | Raw variables with length >200 are properly handled.                                                        |          |         |
| SDTM       | In TS domain Data Cutoff Date and description are updated.                                                  |          |         |
| SDTM       | All required SDTM production datasets were created in the recent batch run.                                 |          |         |
| SDTM       | All required SDTM validation datasets were created in the recent batch run.                                 |          |         |
| SDTM       | All comparison reports are clean.                                                                           |          |         |
| SDTM       | P21 validation is completed, and all SDTM-related P21 issues have been justified.                           |          |         |
| SDTM       | Annotated CRF has been finalized, bookmarked and flattened.                                                 |          |         |
| SDTM       | Dataset names, Define, CRF, and supplemental documentation are all in lowercase.                            |          |         |
| SDTM       | Define.xml file has been generated.                                                                         |          |         |
| SDTM       | SDRG document has been created.                                                                             |          |         |
| SDTM       | Created supplemental data documentation as required.                                                        |          |         |
| SDTM       | Ensure "Inherit Zoom" is applied to all PDF files such as Annotated CRF and supplemental data documentation |          |         |
| SDTM       | P21 validation done with XPT files and Define.xml.                                                          |          |         |
| SDTM       | Ensure all required SDTM datasets are in the submission folder.                                             |          |         |
| SDTM       | No datasets with zero observations.                                                                         |          |         |



# Automation Using Macros

Why use macros?



**Reduce Manual  
Effort**



**Improve  
Efficiency**



**Enhance  
Consistency**



**Error  
Prevention**



**Proper  
Documentation**



# Practical Macro Tools

## Hardcoding check

- Detect hardcoded subject IDs in SAS programs
- Scans all SAS files in a directory
- Outputs file name, line number, and code snippet

## Log issue check

- Consolidates ERRORS, WARNINGS, INVALID notes from logs
- Runs after batch execution
- Improves efficiency and audit readiness

## Dataset generation check

- Confirms all expected datasets are generated in latest batch
- Compares actual outputs vs inventory
- Flags missing or outdated outputs



## Programming tracker validation

- Ensures tracker reflects latest program modifications
- Compares tracker info with actual program metadata
- Logs mismatches for corrective action

## Validation sequence check

- Confirms validation datasets created after production
- Compares creation dates using sashelp.vtable
- Flags discrepancies for review

## Variable length check

- Detects raw variables >200 characters
- Compares across data cuts
- Prevents truncation during SDTM conversion



# Future Improvement

## Advancing Lead Reviews with R

- Advance lead review techniques using R for greater efficiency
- Provides a powerful and flexible alternative to SAS
- Integrates interactive dashboards for systematic, user-friendly, and visually insightful reviews
- Delivers enhanced visualizations for better decision-making
- Modular R functions automate tasks like log checks, validation sequencing, and dataset comparisons
- Improves efficiency, reduces manual effort, and ensures consistency across reviews



# R Shiny Based Lead Review Dashboard

- Implemented using R Shiny for interactive and dynamic reviews
- Secure authentication via shinymanager to manage user access and enforce data-level permissions
- Customizable design: Tabs can be added based on organizational requirements
- Comparison reports: Displays production vs validation dataset matching
- Log diagnostics: Summarizes warnings, errors, and unresolved notes



# Key Tabs

## Checklist tab

- Dropdowns for status updates
- Integrates automated checks (log issues, hardcoding detection, comparison reports)
- Captures manual checks for complete traceability

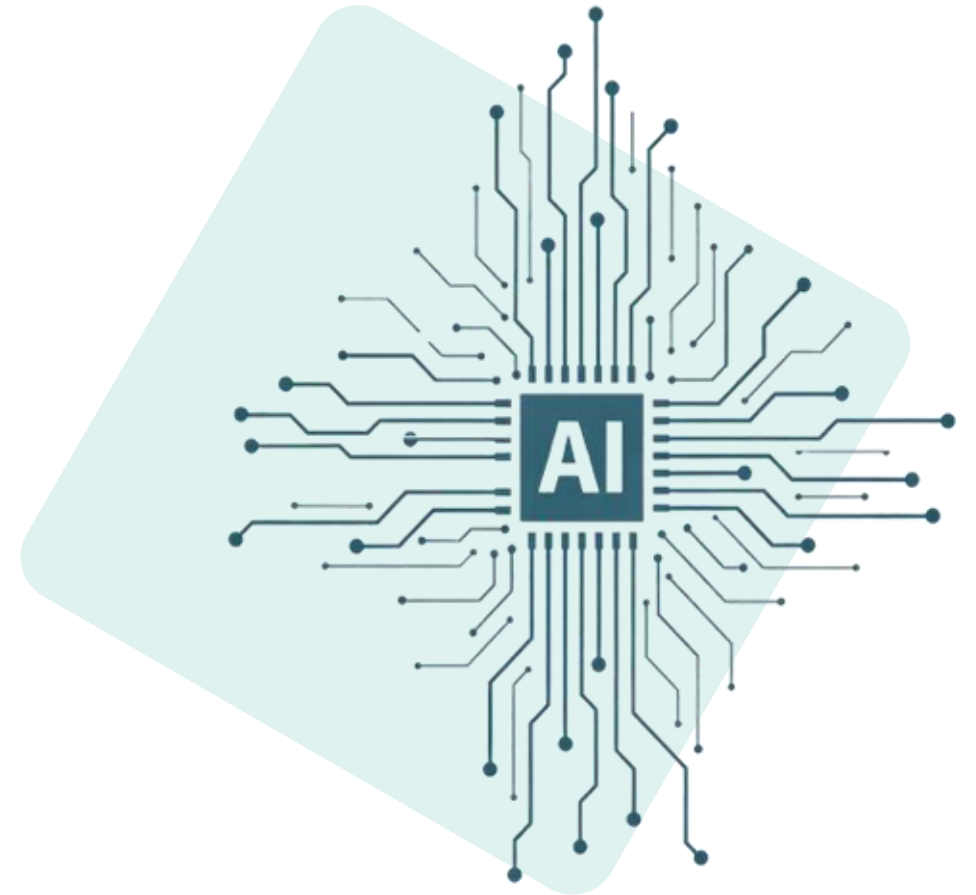
## Specialized tabs

- Comparison reports: Displays production vs validation dataset matching
- Log diagnostics: Summarizes warnings, errors, and unresolved notes
- Like these, more tabs can be added as per organizational requirements



# Using AI to Support Validation Activities

- AI such as ChatGPT or Copilot can be used
  - Only for non-confidential support tasks
  - Useful when quick assistance is needed during validation
- Confidentiality is a major limitation
- Non-confidential validation activities supported by AI
  - Generating quick checklists
  - Reviewing non-confidential metadata
  - Clarifying general domain questions





# PowerShell: A Reliable Companion

- A scripting-based command-line tool for automation
- Reduce time and effort through automation
- Can generate PowerShell codes using AI such as ChatGPT/Copilot
- Checks and validations you can automate with PowerShell
  - Build order & data freshness checks
  - Deliverable completeness & file integrity checks
  - Naming & structure hygiene
  - Tracker synchronization
  - Log review & risk flagging
  - Archival controls



# THANK YOU

---

QUESTIONS?