

# Effortless SDTM Up-versioning Leveraging Open-Source R for Efficient Data Standardization

**Author:** Ramya Gangadi,  
**Co-Author:** Madhavi Gundu  
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# Agenda



Introduction to SDTM Version Changes



Leveraging R for Automated Up-Versioning



Transformation Rules for SDTM3.3 Conversion



Read the differences file & Apply transformations



Detailed process flow

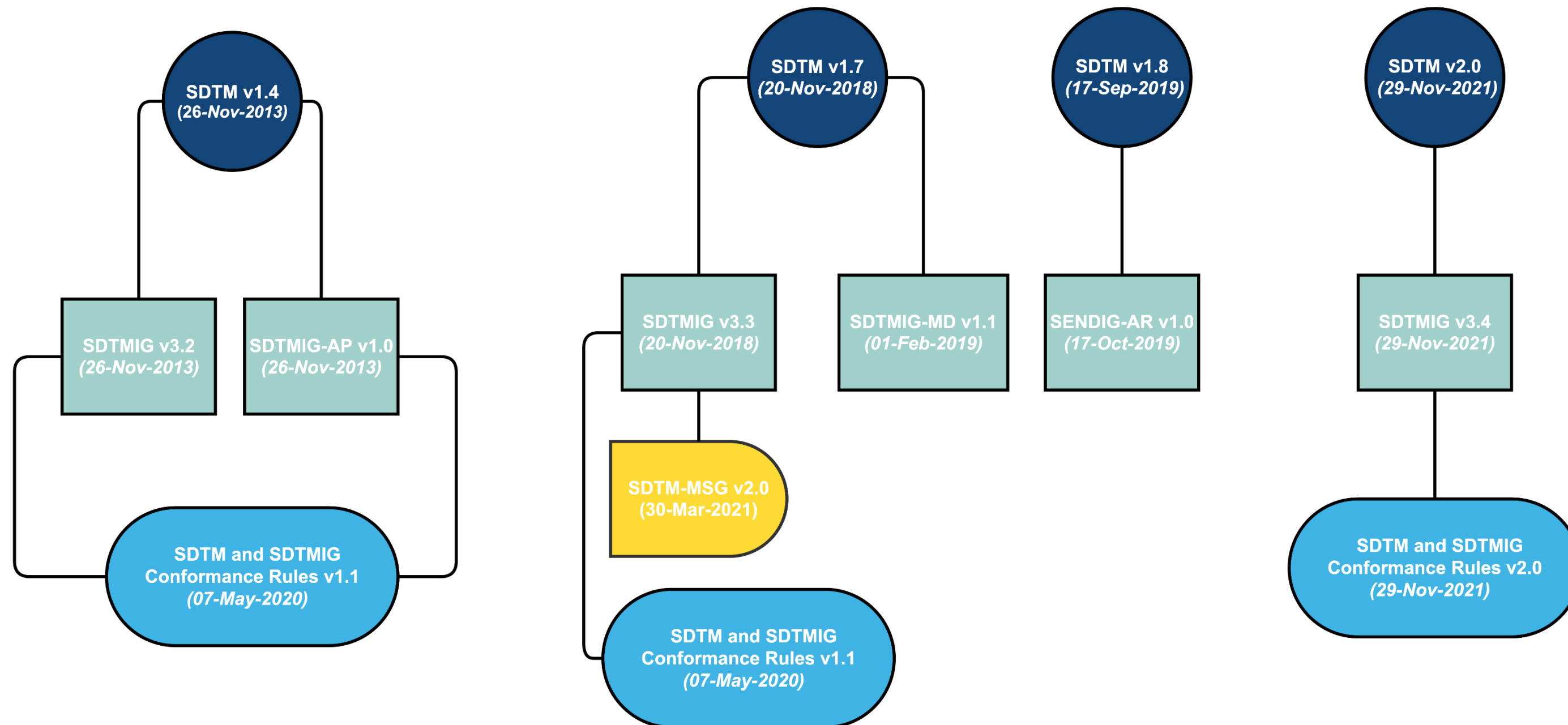


Conclusion



# Introduction to SDTM Version Changes

The CDISC-SDS team regularly updates the SDTM Implementation Guide to introduce new domains, variables, and validation rules, ensuring compatibility with evolving regulatory requirements.



# Key Changes in SDTMIG 3.3

## SDTM 3.3 High-level Updates

 Study References  
(Section 9)  
New domains: DI, OI, PB

 New SDTM Domains  
(ML, AG, SM, FT, TM)

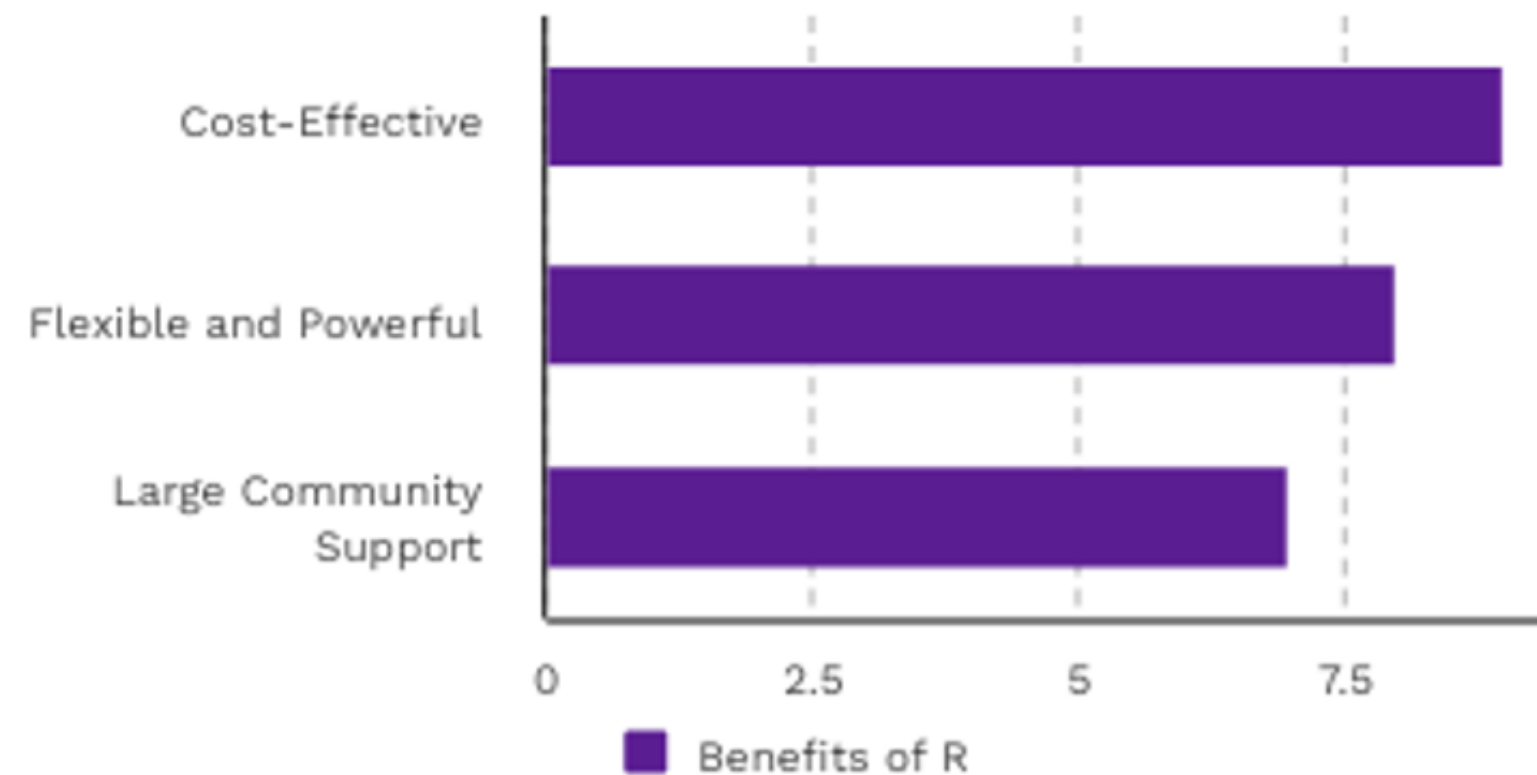
 New Variables &  
Metadata Updates

 Refined Derivations  
(EPOCH, Long Strings)

- ❖ A new Section 9: Study References has been added to define study-specific terminology.
- ❖ New SDTM domains have been introduced across Interventions, Special Purpose, Findings, and Trial Design categories.
- ❖ Some existing domains now include new variables.
- ❖ Additional details clarify variable derivation, including EPOCH rules and handling long character strings.

# Automated Up-versioning

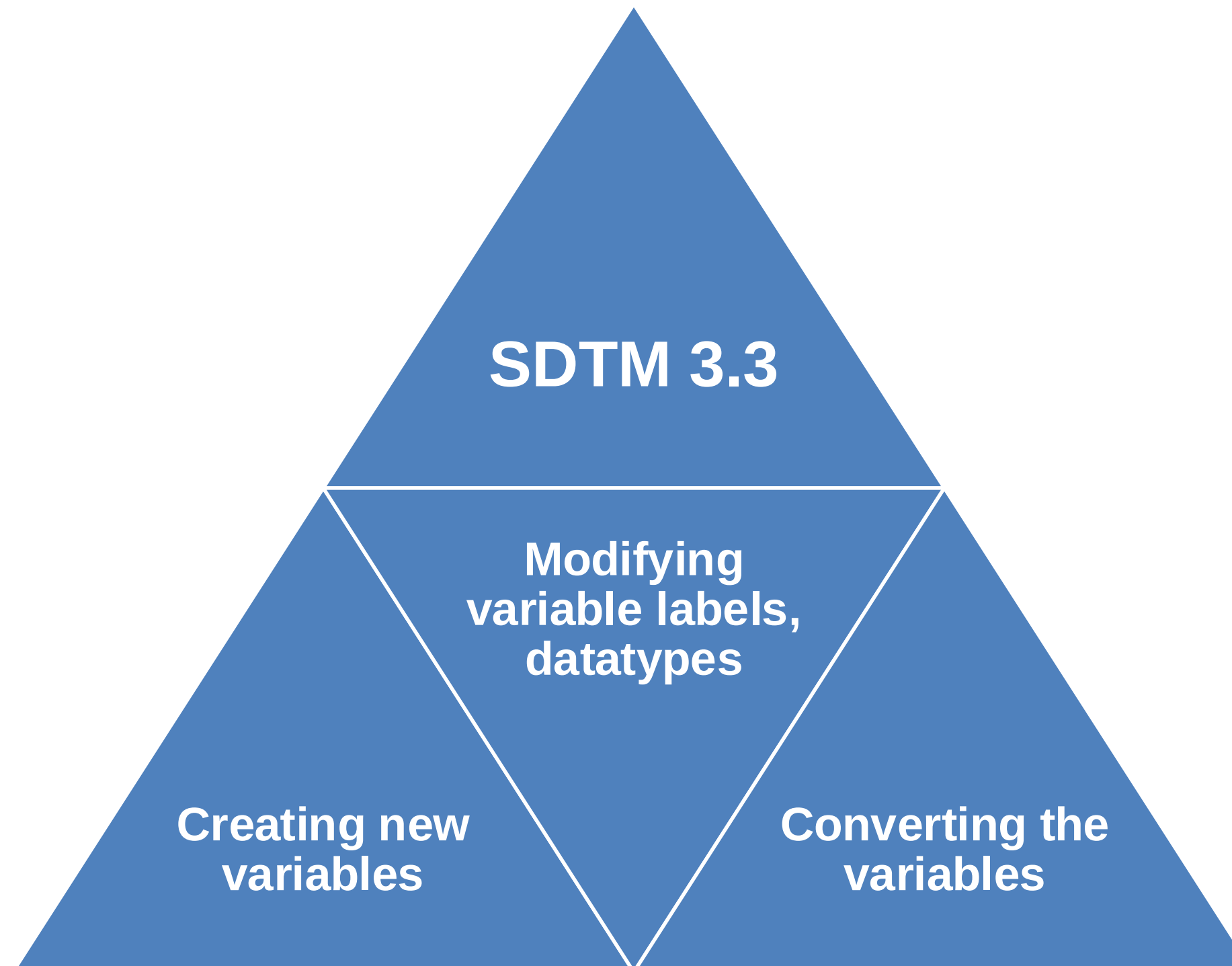
## Benefits of Using Open-Source R



## Leveraging Open Source- R:

This paper introduces an automated post - processing approach using R programming to facilitate SDTM Up-versioning.

# Transformation Rules for SDTM3.3 Conversion

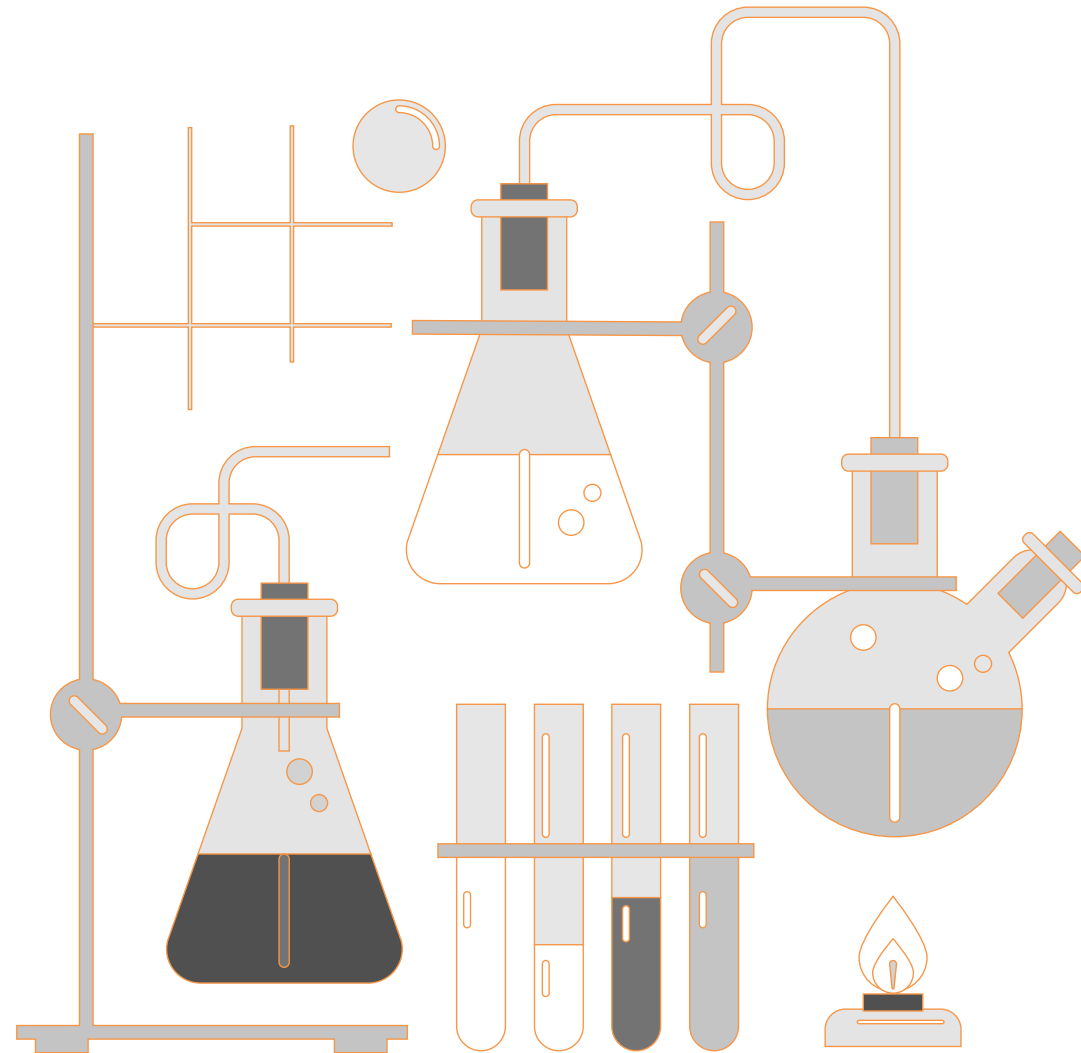


# Read the Differences file



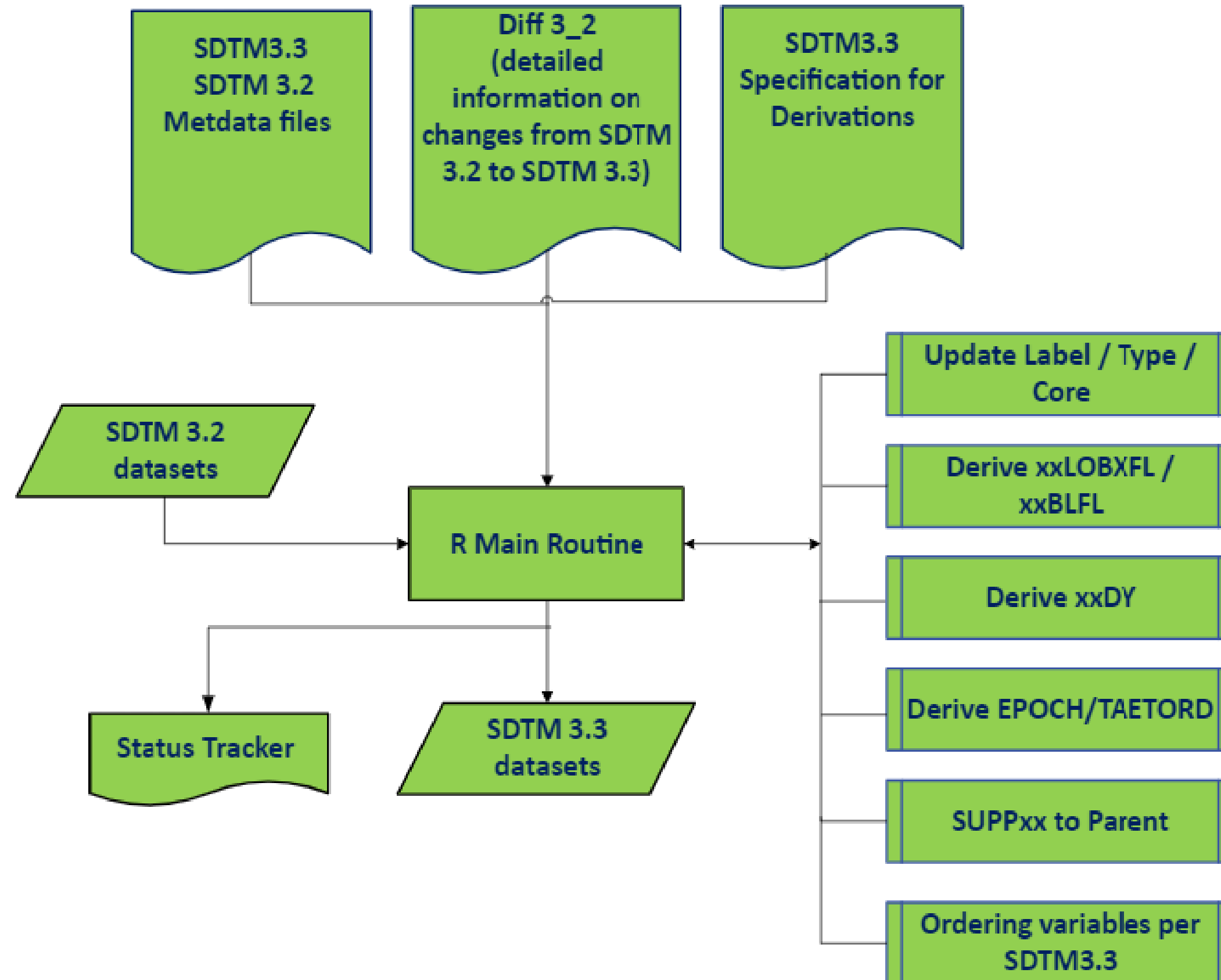
|     | A               | B             | C            | D              | E            | F        | G         | H             | I                       | J                                                                                                                                                                                                                                                                                                                                                                                                               | K                                      | L        |
|-----|-----------------|---------------|--------------|----------------|--------------|----------|-----------|---------------|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|----------|
| 1   | Updated Version | Previous Vers | Action       | Impact         | Change Level | Class    | Dataset N | Variable Name | Automation Needed {Y/N} | Attribute (updated)                                                                                                                                                                                                                                                                                                                                                                                             | Attribute (previous)                   | SUPP_PAR |
| 405 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Core           | Major        | Findings | MS        | MSMETHOD      |                         | Perm                                                                                                                                                                                                                                                                                                                                                                                                            | Exp                                    |          |
| 408 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Variable Label | Major        | Findings | MS        | MSNAM         |                         | Laboratory/Vendor Name                                                                                                                                                                                                                                                                                                                                                                                          | Vendor Name                            |          |
| 410 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Core           | Major        | Findings | MS        | MSORRESU      |                         | Perm                                                                                                                                                                                                                                                                                                                                                                                                            | Exp                                    |          |
| 413 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Variable Label | Major        | Findings | MS        | MSREASND      |                         | Reason Not Done                                                                                                                                                                                                                                                                                                                                                                                                 | Reason Test Not Done                   |          |
| 415 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Core           | Major        | Findings | MS        | MSRESCAT      |                         | Perm                                                                                                                                                                                                                                                                                                                                                                                                            | Exp                                    |          |
| 418 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Variable Label | Major        | Findings | MS        | MSSCAT        |                         | Subcategory                                                                                                                                                                                                                                                                                                                                                                                                     | Subcategory for Organism Findings      |          |
| 423 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Variable Label | Major        | Findings | MS        | MSSTRESC      |                         | Result or Finding in Standard Format                                                                                                                                                                                                                                                                                                                                                                            | Character Result/Finding in Std Format |          |
| 424 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Core           | Major        | Findings | MS        | MSSTRESN      |                         | Perm                                                                                                                                                                                                                                                                                                                                                                                                            | Exp                                    |          |
| 425 | SDTMIG v3.3     | SDTMIG v3.2   | Value Update | Core           | Major        | Findings | MS        | MSSTRESU      |                         | Perm                                                                                                                                                                                                                                                                                                                                                                                                            | Exp                                    |          |
| 437 | SDTMIG v3.3     | SDTMIG v3.2   | Add          | Variable       |              | Findings | MS        | EPOCH         |                         | {<br>"_links": "{...}",<br>"core": "Perm",<br>"description": "Epoch associated with the date/time at which the specimen was collected.",<br>"label": "Epoch",<br>"name": "EPOCH",<br>"ordinal": "53",<br>"role": "Timing",<br>"simpleDatatype": "Char"<br>}                                                                                                                                                     |                                        |          |
| 439 | SDTMIG v3.3     | SDTMIG v3.2   | Add          | Variable       |              | Findings | MS        | MSAGENT       |                         | {<br>"_links": "{...}",<br>"core": "Exp",<br>"description": "The name of the agent for which resistance is tested. The agent specified may be based on genetic markers or direct phenotypic drug sensitivity testing. Examples: \\\"Penicillin\\\", name of study drug.",<br>"label": "Agent Name",<br>"name": "MSAGENT",<br>"ordinal": "13",<br>"role": "Variable Qualifier",<br>"simpleDatatype": "Char"<br>} |                                        | Y        |

# Apply Transformations



- ❑ Read the SDTM 3.2 datasets and apply metadata changes based on impact and Action from the Difference file.  
For eg: for the impact 'Variable Label' and Action 'Value Update' which is a Major change based on level categories, read the 'Attribute (previous)' and 'Attribute (updated)'.
- ❑ The process involves analysing the specification file to create new variables like **EPOCH**, **TAETORD**, **XXDY**, **XXSTDY**, and **XXENDY** based on the "Differences" file. The differences file helps identify impacted variables and actions, such as adding new ones. The SDTM3.2 datasets are read and based on "Differences" file, the respective sub-routine is executed to generate the SDTM 3.3 datasets.
- ❑ The specification file is reviewed to identify any existing derivation rules or to define new ones as needed. This process may involve modifying the current **SDTM mapping specification** or incorporating additional rules for derived variables.

# Detailed Process flow



# Conclusions

The journey of SDTM up-versioning is like navigating a winding road, and this revolutionary R-based post processing approach paves a clear path for seamless transitions. By leveraging difference files from the CDISC Library, it streamlines metadata updates, preserves sponsor macros, and minimizes manual effort. The automated workflow ensures smooth dataset transformation, maintaining data integrity while reducing operational burden. Validation reports and status files enhance transparency, making compliance verification more efficient. This innovation redefines regulatory data management, accelerating the industry's journey toward efficiency and compliance.

# THANK YOU

