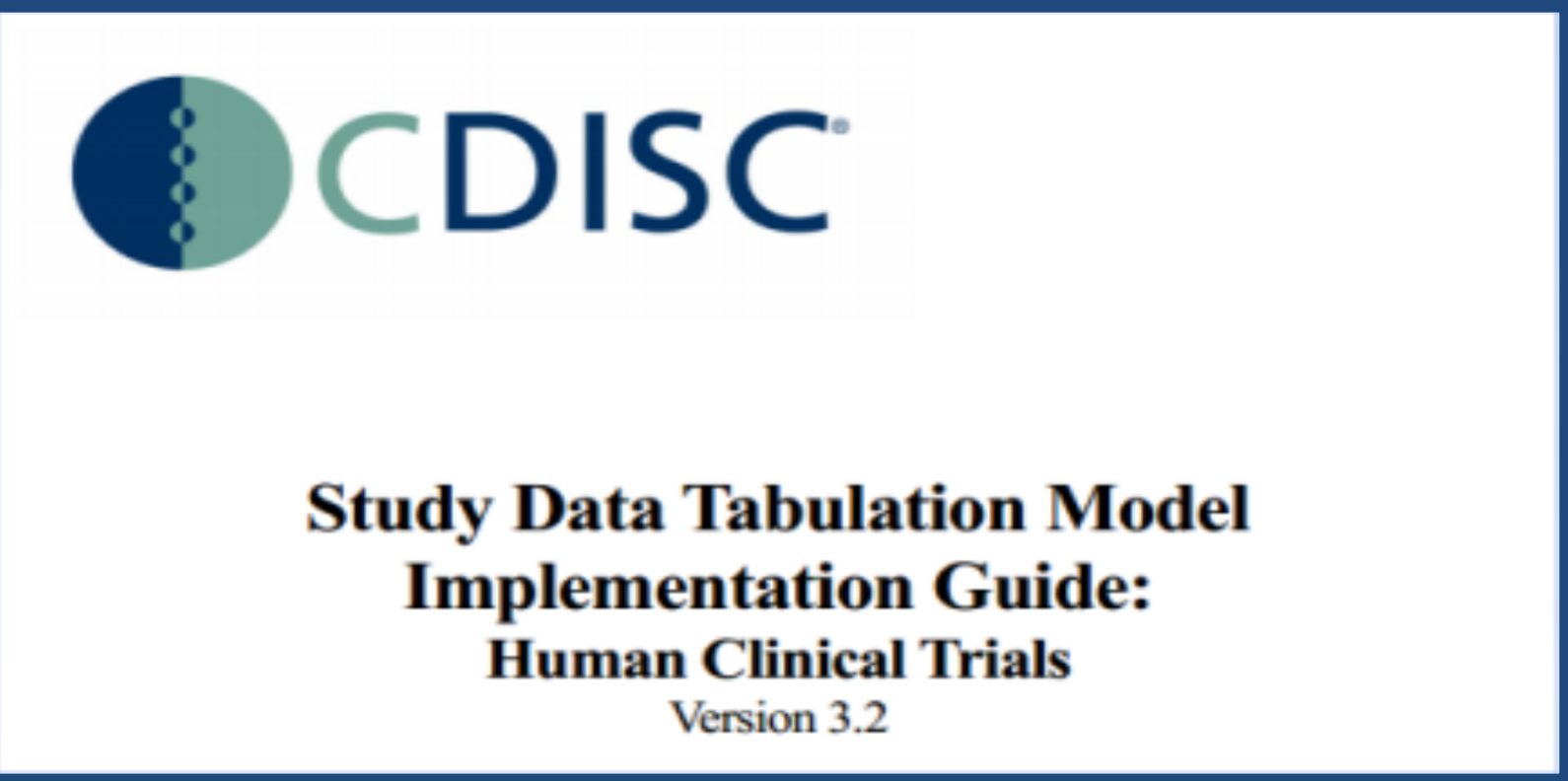


CDISC

IMPLEMENTATION



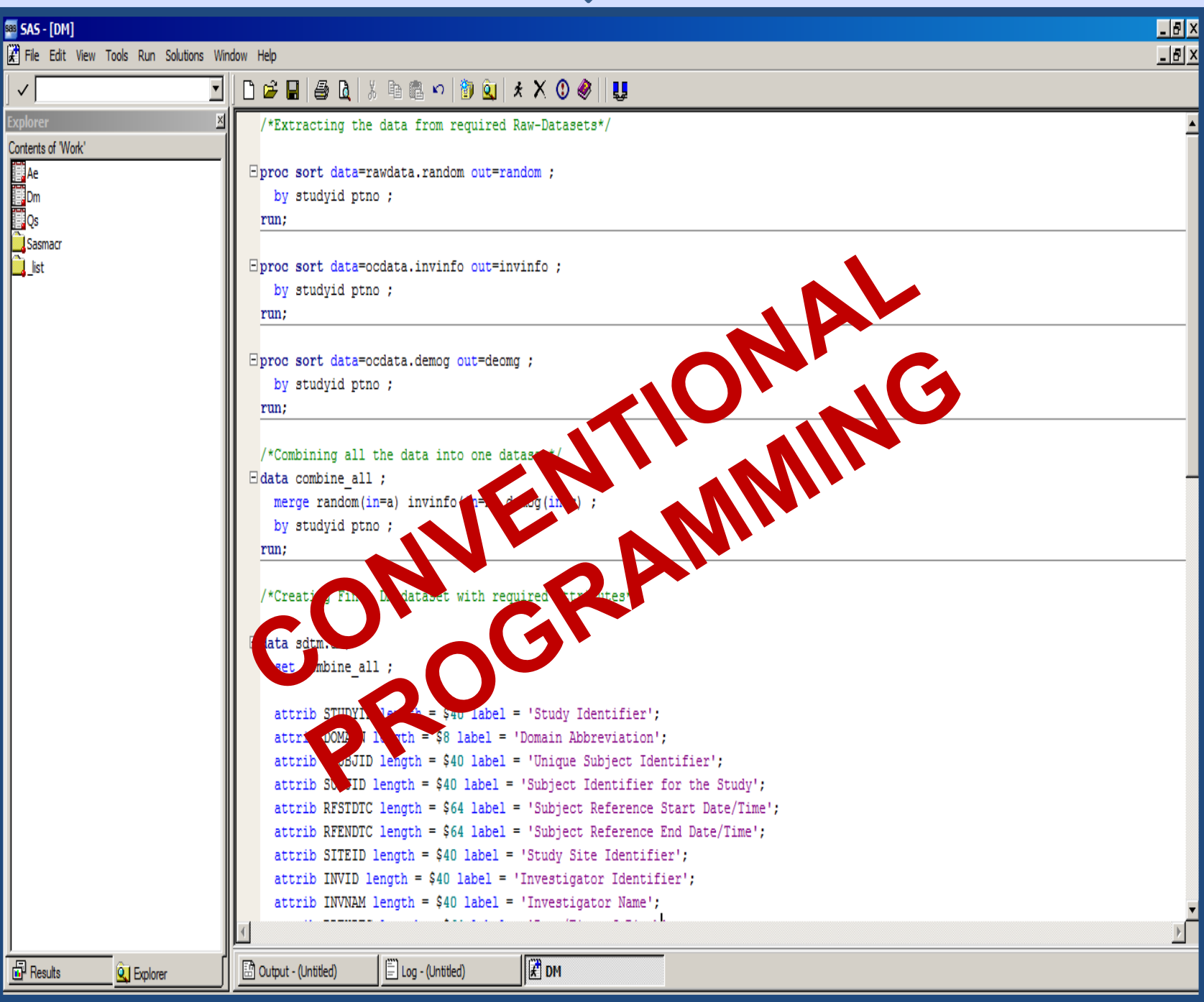
- >350 Pages of Guideline(v3.2)
- Recommended by Regulatory Authorities (US FDA)
- Accelerate Drug Review Process

Ohhh...NO
Again I have to
Program 10 SDTM
Datasets !!!

Why should I write
program everytime?
Can I use GUI tool??

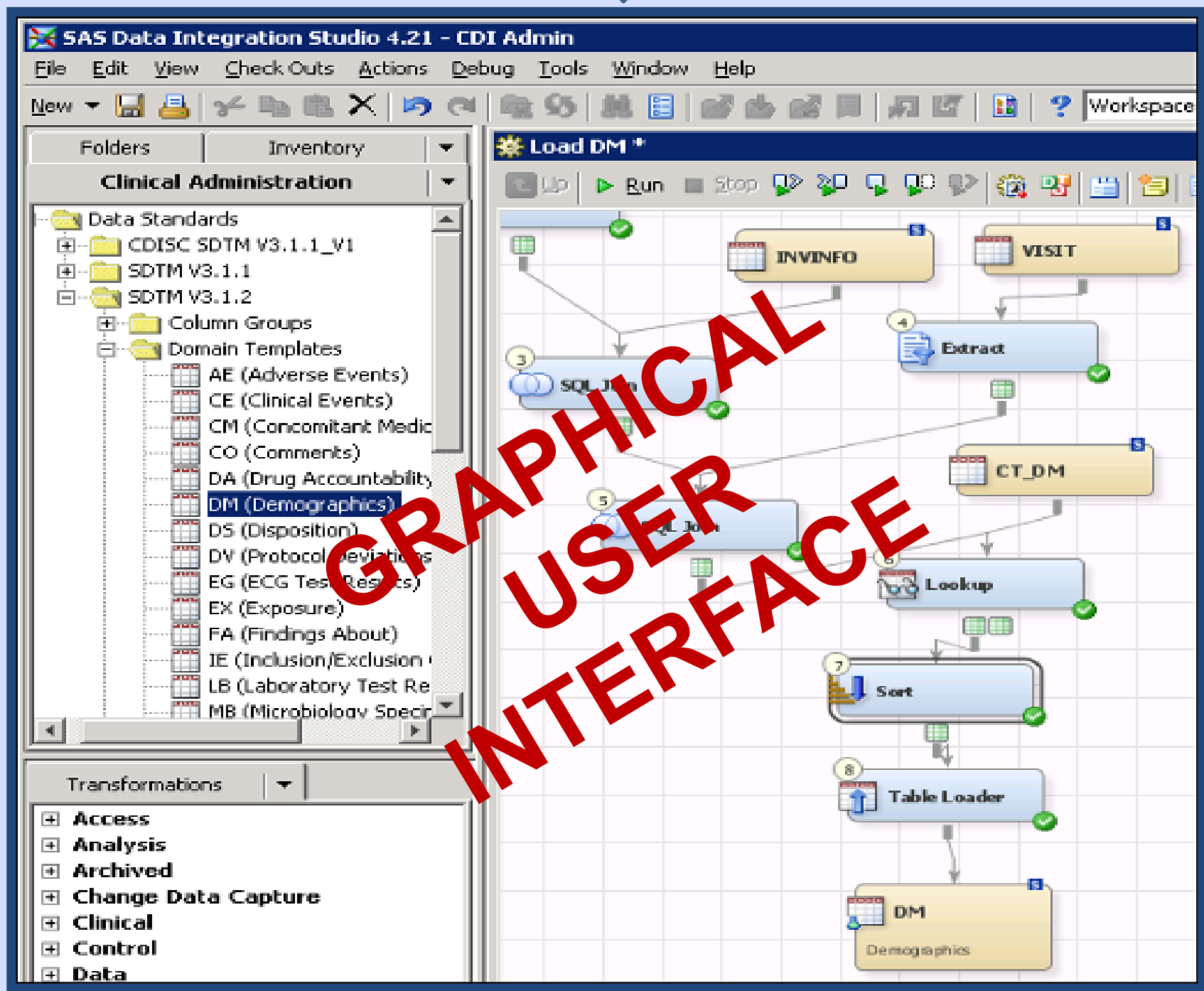
Why should I use GUI??
I am more comfortable
with Programming.

DIFFERENT APPROACHES FOR SDTM MAPPING

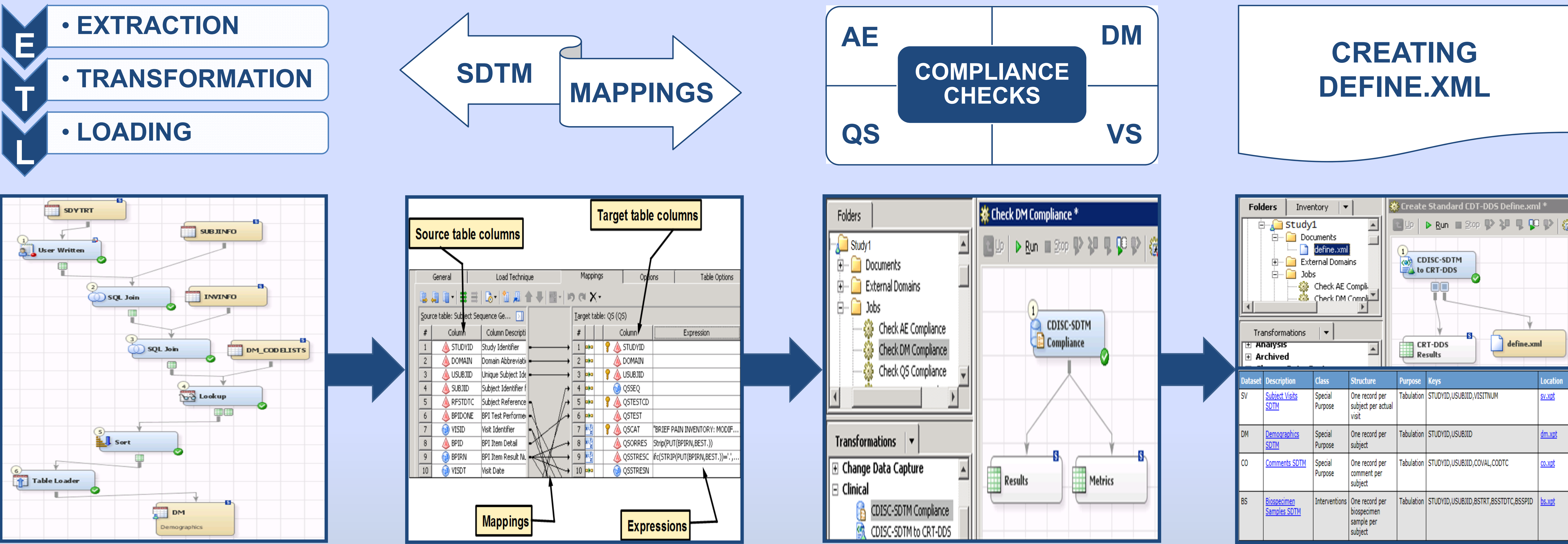


CHALLENGES

- Metadata management
- Compliance with  standards
- Controlled terminology
- Consistency across the Studies
- Automation & Reproducibility



OVERVIEW OF CDISC-SDTM DATASET DEVELOPMENT & VALIDATION PROCESS IN SAS® CDI



CONCLUSION

CONVENTIONAL PROGRAMMING

- Complex logic can be written easily sometimes with programming
- Power of Data step,Procs,Macros,Functions
- SAS Macros for Automation & Consistency
- Relatively Inexpensive compared to GUI

GRAPHICAL USER INTERFACE TOOL

- Minimal manual coding
- Development & Maintenance time
- Drag & Drop wizard for ETL Process
- Centralized Metadata Management
- Pre-Defined ready to use Templates for SDTM domains and Compliance Checks

GUI MAY NOT BE THE BEST, BUT IT'S NOT LIKE THE REST