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STATISTICAL SOFTWARE & SERVICES

CDISC Migration

PhUSE 2010 - Berlin

47 of the top 50 biopharmaceutical firms
use Cytel software to design, simulate and analyze their clinical studies.

Source: The Pharm Exec 50—the world's top 50 pharmaceutical companies according to PHARMACEUTICAL EXECUTIVE

Presentation Objectives

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- Introductions
- CDISC Migration Strategies
- Benefits of Deploying a Migration Utility
- Questions & Answers

Introductions

Cytel Presenters	Title
Irving Dark	Vice President, Clinical Research Services
Jim Nigrelli	Principal Statistical Programmer
Ajay Sathe	CEO, Cytel India

CDISC Experience

- Converted data from more than 50 trials to SDTM compliant data sets
- Practice leaders with extensive CDISC experience
- Recent FDA Approval using data migrated to CDISC by Cytel
- Licensed WebSDM™ for checking SDTM compliance

Irving Dark, Vice President Clinical Research Services
Jim Nigrelli, Principal Statistical Programmer

CDISC MIGRATION STRATEGIES

Migration practices – Key components

Gap Analysis

Trial Design

Annotated CRFs

Data Migration

Define.xml

QC

WebSDM™

GAP Analysis

- Itemization and evaluation of files to support migration activities
- Initiated prior to commencing migration activities
- Document inventory
- Reconcile sample CRFs versus source data
- Comparison of protocol amendments/versions against CRF versions
- Advantages:
  - Proactive approach rather than reactive
  - Clarifies the scope and challenges of migration activities
  - Identifies differences in data collection formats

Trial Design

- Domain that contains a clear representation of the design of a clinical trial
  - Created prior to CRF annotation and data migration
  - Experience needed to create the trial design data set:
    - SDTM Trial Design Concepts
    - Experience with key clinical documents (e.g. Protocol, SAP, Data Sets, CSR)
  - Examples:
    - Standardization across studies
    - Identifying trial ARMS and trial VISITS
    - Planned per protocol versus actual

CRF Annotation

- The annotated CRF provides the migration team with a clear presentation of SDTM variables
- Completed following the GAP analysis and prior to migration
- Experience needed to create the annotated CRF:
  - Knowledge of the SDTM Implementation Guide and Metadata Submission Guidelines (chapter 4 – Guidelines for Annotating CRFs)
  - Standard data management principles

Data Migration

- Currently using SAS programs to migrate data:
  - Use SAS and Excel
  - Mapping specifications generated (Excel)
  - SAS Macros to assist in standardizing the migration process (e.g. ISO date conversion, SDTM templates, Control Terminology Look-ups)

DEFINE.XML

- Metadata describing the format and content of the data sets
- In-House Utility:
  - SAS Generated
  - Metadata / Code-list driven
  - CRF page links
  - Comments insertion

Migration QC

- QC of Migration of Clinical Data
- Derivation of SDTM variables
- Generation of Define.xml
- Compliance to SDTM standards
- Key Components:
  - Data Accountability
  - Source data checks
  - Define.xml
  - Additional QC checks
  - SDTM Compliance

WebSDM™

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- Data review tool used to validate the compliance of data sets and define.xml to SDTM standards
- Identifies:
  - True errors
  - Data related errors (e.g. start / end dates)
  - False errors (e.g. until-less test results)

Ajay Sathe, CEO Cytel India

BENEFITS OF DEPLOYING A MIGRATION UTILITY

Automate – What and how

- Metadata approach
- Tasks most amenable to automation:
  - Mapping of variables (mapping specs document)
  - Mapping Code Generation
  - Validating the mapped datasets

Automate – What and how

- Account for all of Source Data
- Load Target Data definition (SDTM or other)
- Create Custom Domains
- Define global terminology
- Define pre-processing logic, e.g., *TRANSPOSE*
- Supply mapping logic
  - Talk about the seven types of mapping logic?
- Push the button!
  - (no, it's not that simple, of course. Verbal explanation)

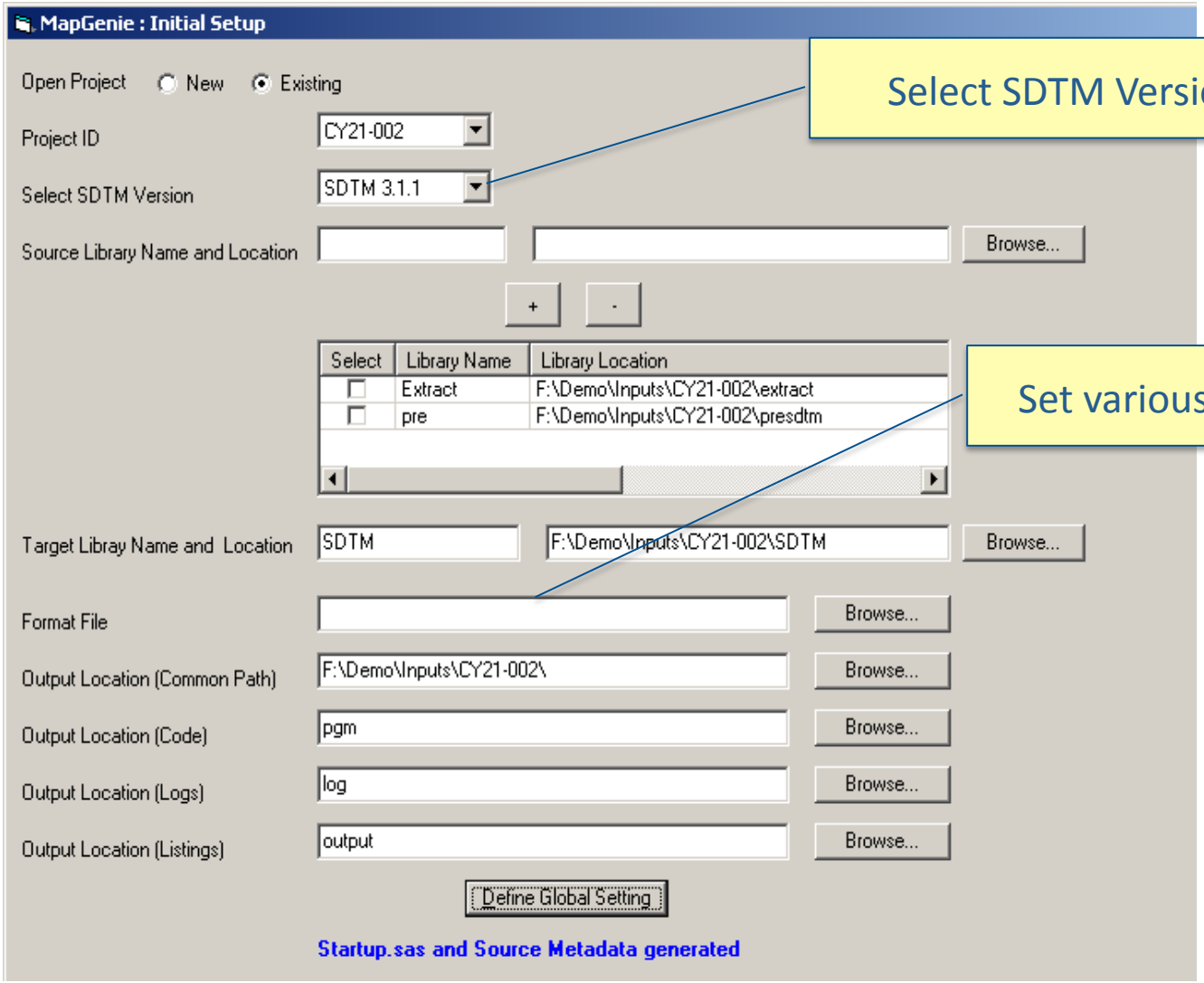
So, what's new in this approach?

- Target Structure flexible, not restricted to SDTM
- Data Driven approach – the logic resides in data
  - Logic stored in mapping description datasets.
- Self-documenting. Generate mapping specification in parallel
- Meta-programming. Generate SAS® code that does the job
- Transformation types – versatile & comprehensive
  - *Automatic – match name and type*
  - *Data Type conversion*
  - *Rename Variables*
  - *Value Conversions, using Controlled Terminology*
  - *Date Conversions (e.g. ISODATE)*
  - *Concatenation or Parsing/splitting*
  - *Compute – user defined SAS® statements*

The Outputs

- Account for all of Source Data
- Mapping Specifications Document
- SAS® code for Mapping
- Migrated Datasets

Step 1: Project-level settings



Select SDTM Version here

Set various folder paths here

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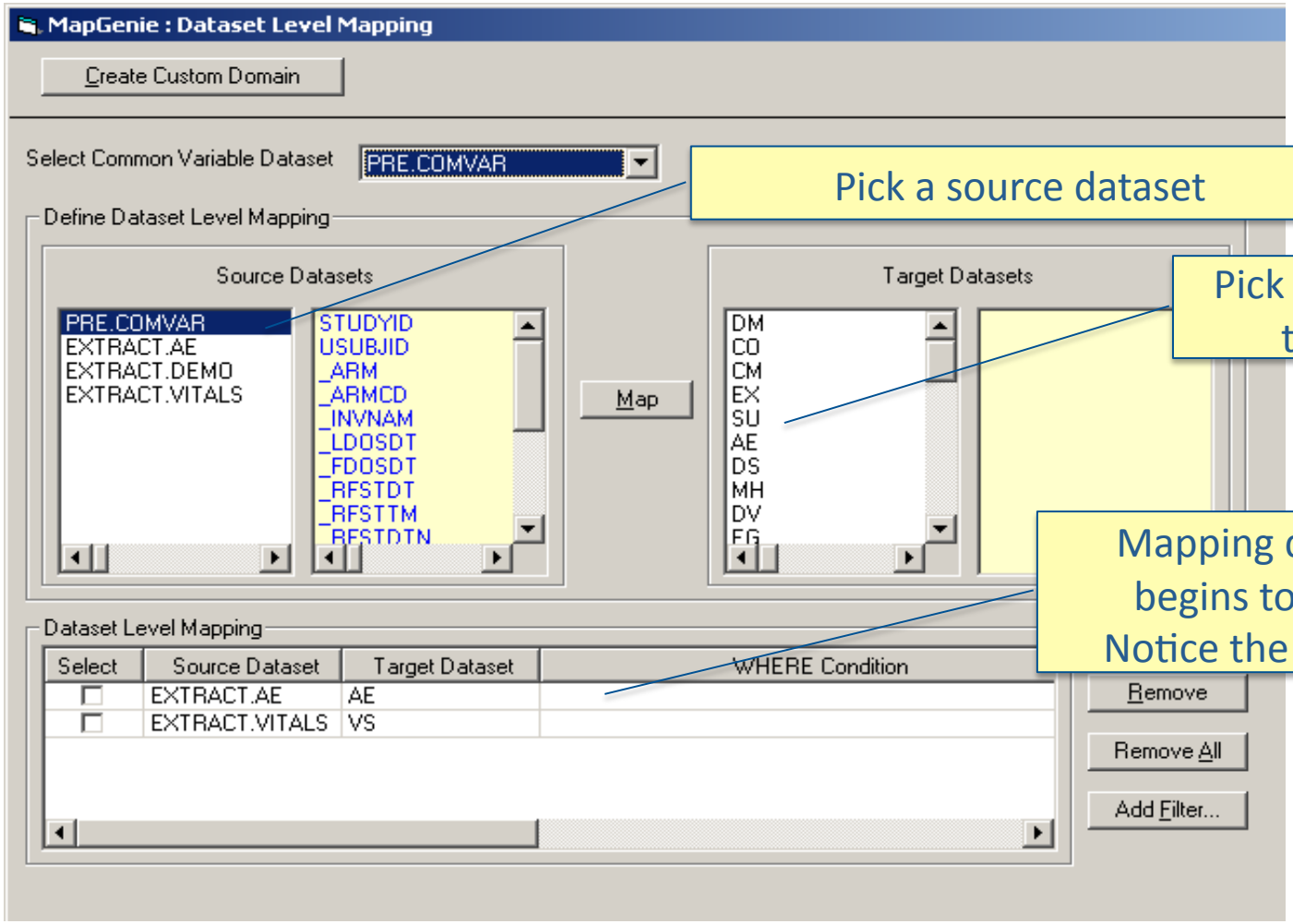
Step 2: Dataset level settings



Pick a source dataset

Pick a target dataset (in this case SDTM)

Mapping definition begins to appear. Notice the "WHERE"

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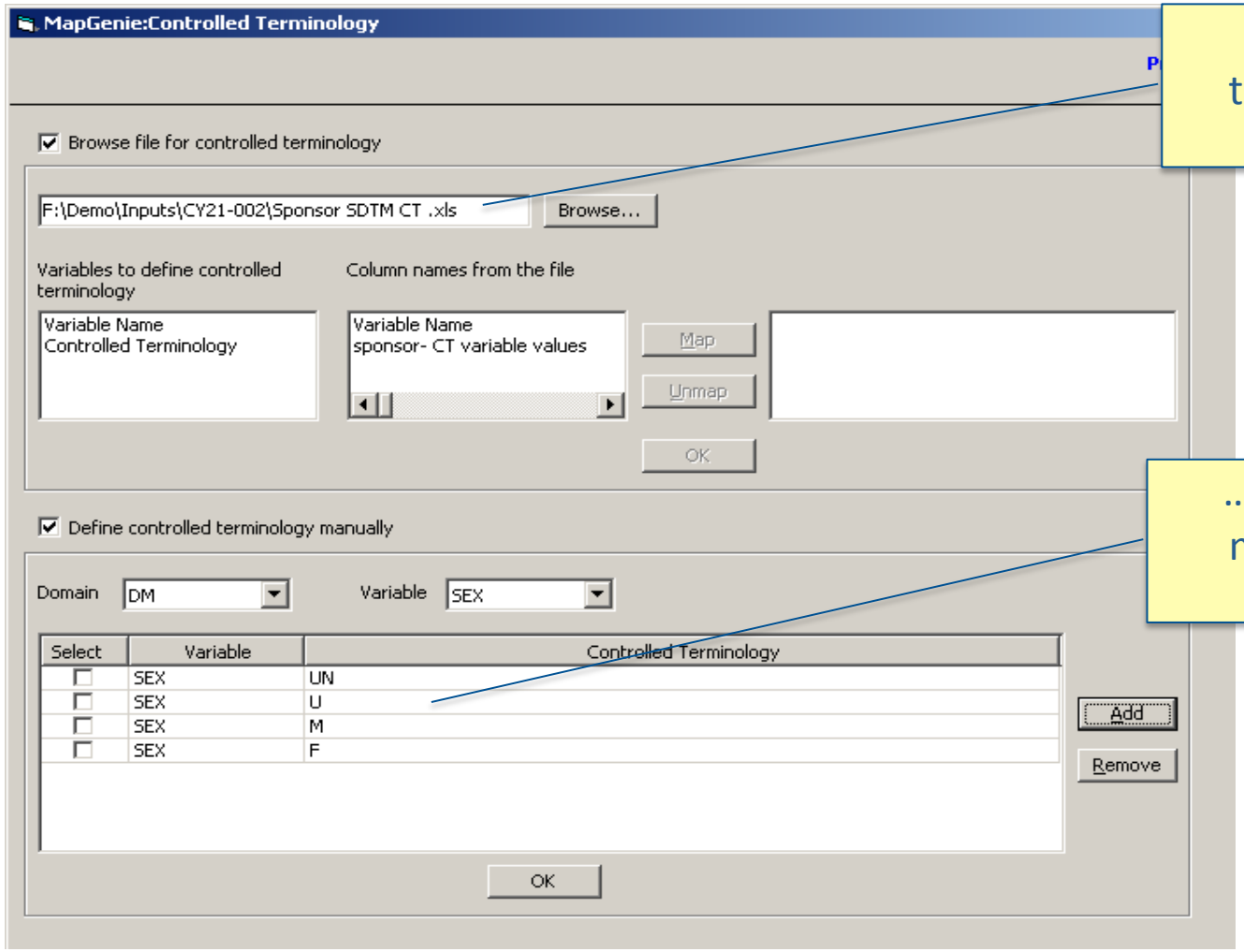
Step 3 – Global controlled terminology



Load controlled terminology from an Excel file…

… and / or, add it to mapping metadata manually

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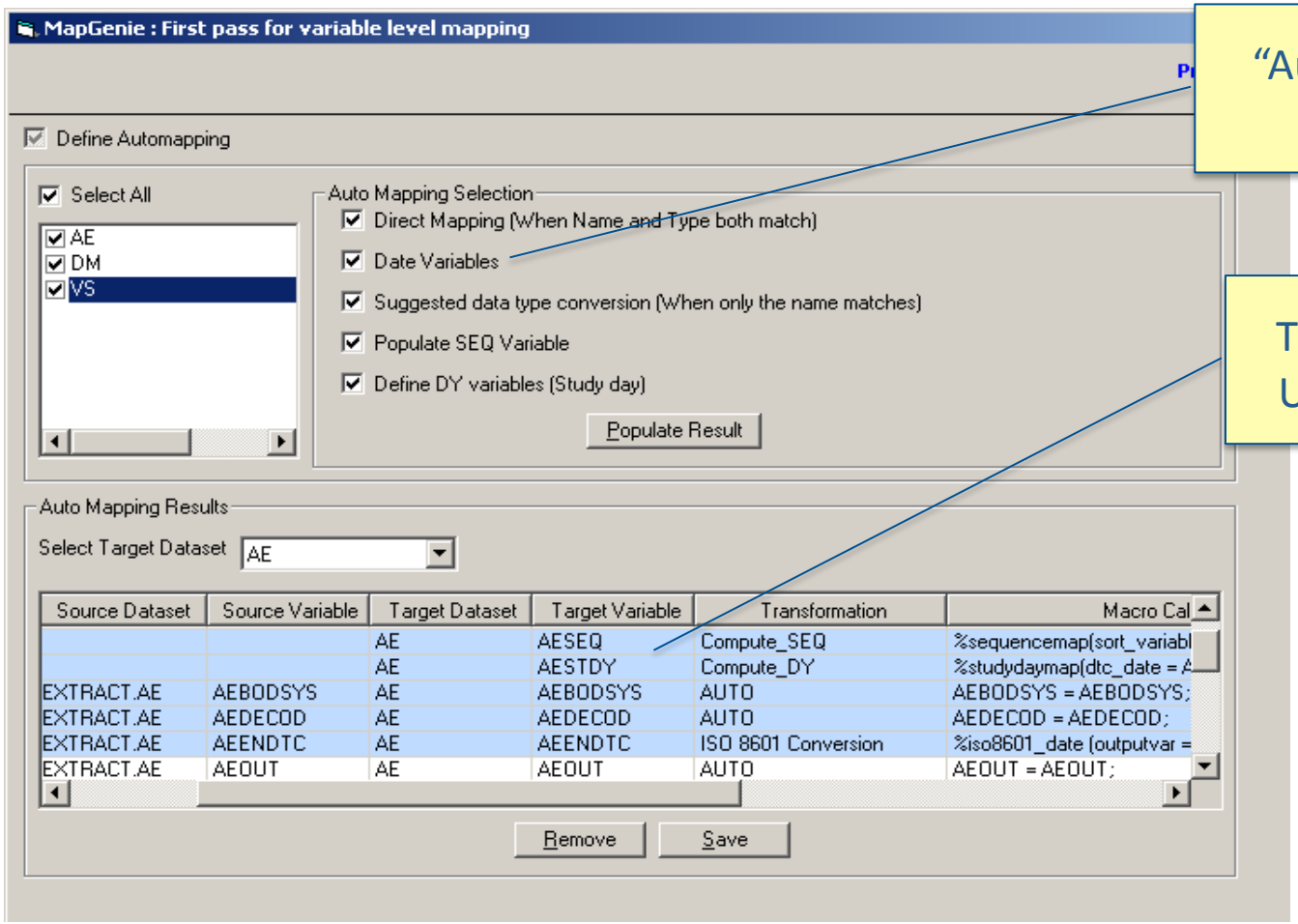
Step 4 – Mapping the variables



"Auto" mapping using smart rules

The rules appear here; User override possible

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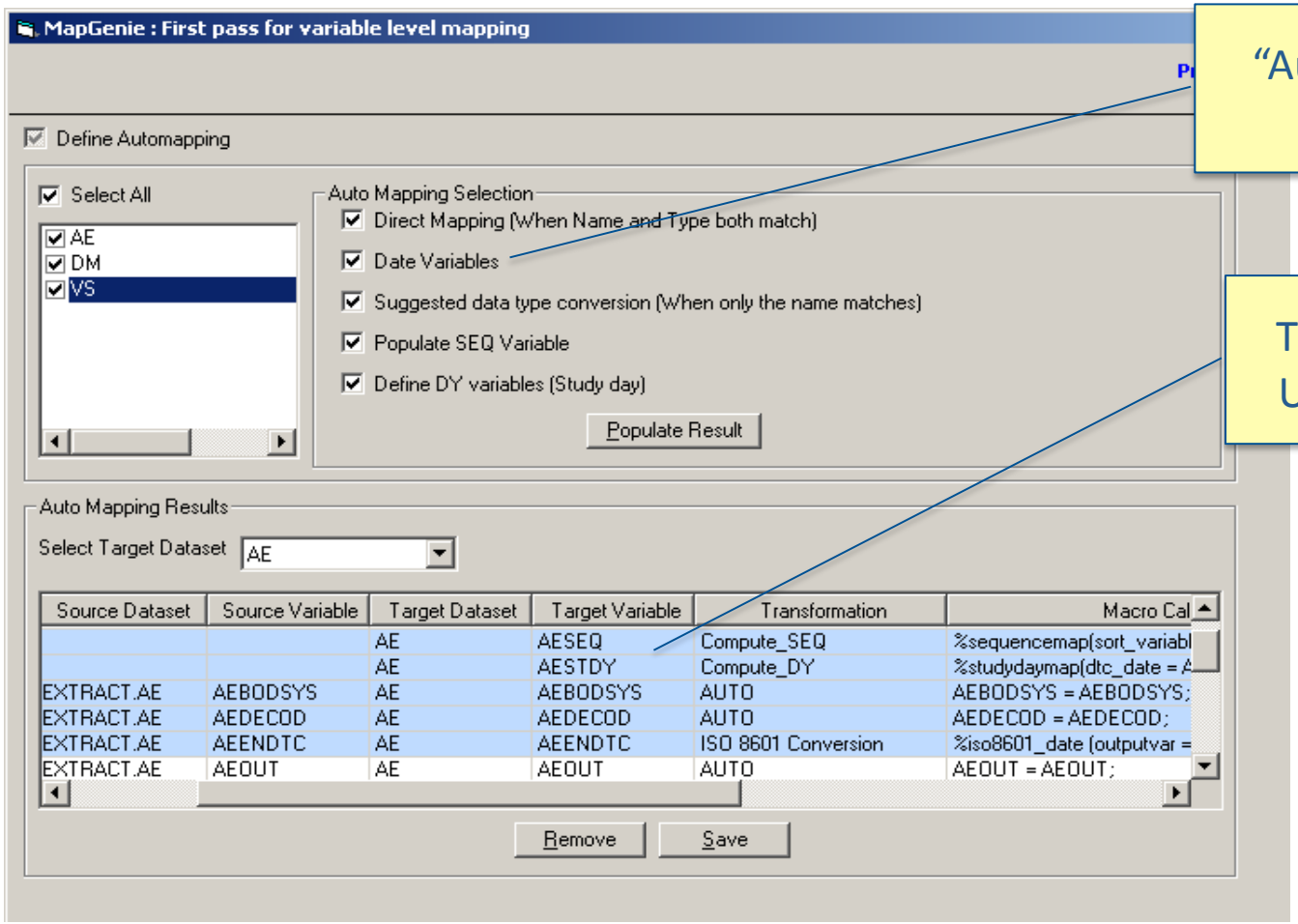
Step 4 – Auto-mapping rules



"Auto" mapping using smart rules

The rules appear here; User override possible

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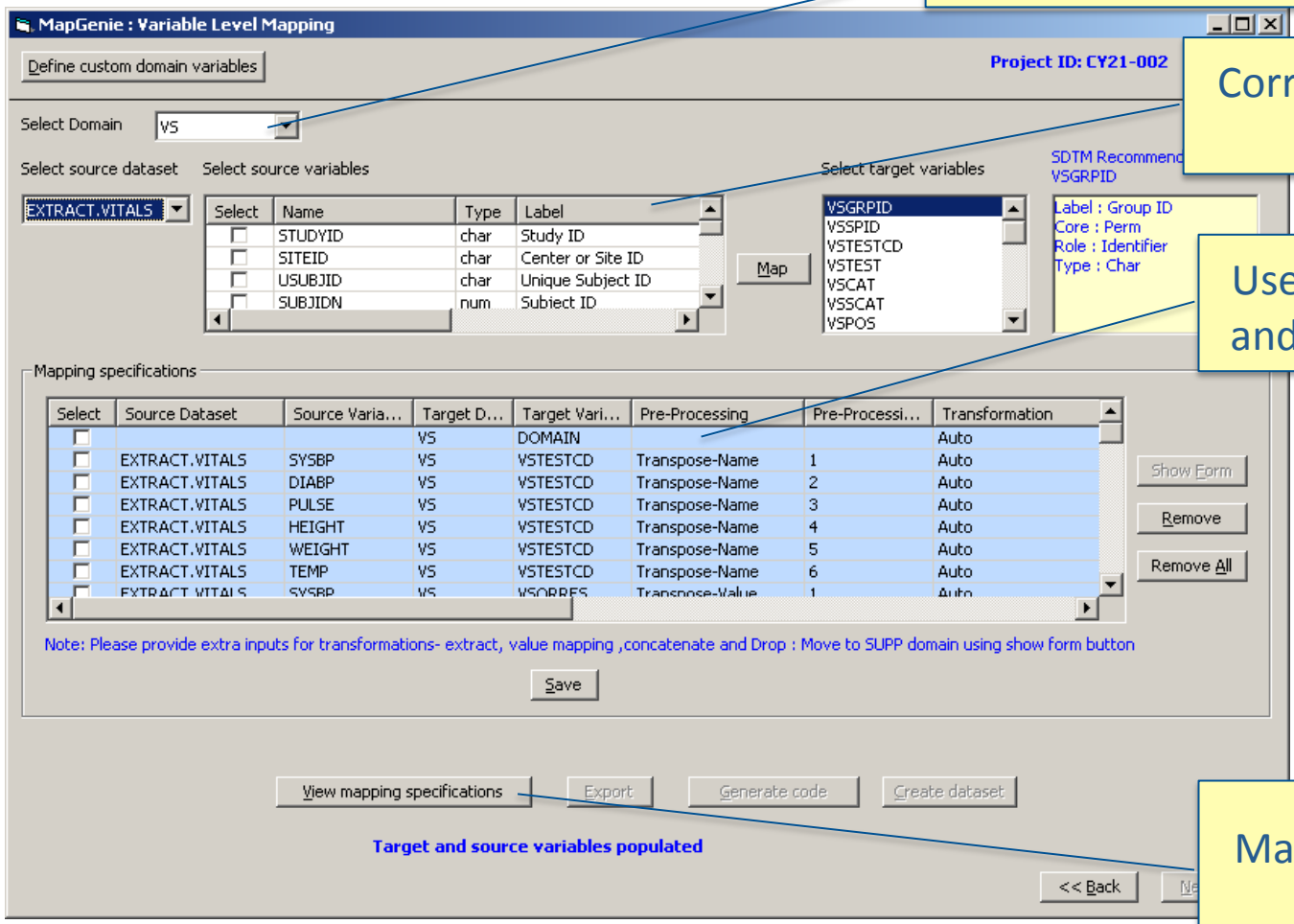
Step 5 – Mapping the variables



Select the domain

Corresponding Source & Targets appear

User sets pre-processing and transformation logic

Mappings specs are saved. Self-documenting!

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Transformation types

- Auto
- Convert Data Types
- Rename
- Drop
- Convert Values
- Convert ISODate
- Concatenate
- Extract
- Compute (any user-defined SAS® code logic)

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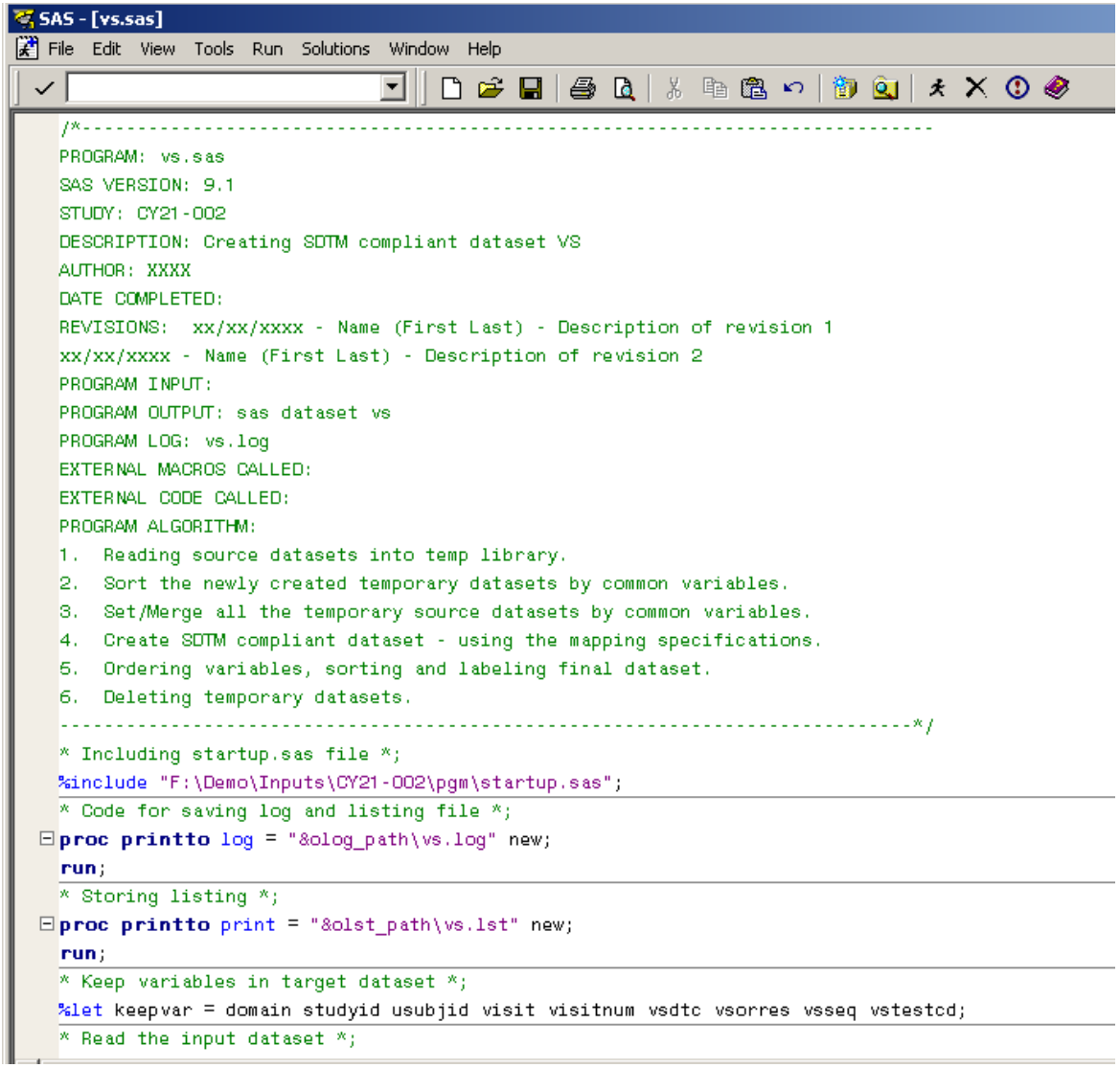
The generated code



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The generated code

SAS - [vs.sas]

File Edit View Tools Run Solutions Window Help

```
6.  Deleting temporary datasets.
-------------------------------------------------------------------------------*/

* Code for saving log and listing file *;

* Including startup.sas file *;
%include "F:\Demo\Inputs\CY21-002\pgm\startup.sas";

* Storing log *;
proc printto log = "&olog_path\vs.log" new;
run;

* Storing listing *;
proc printto print = "&olst_path\vs.lst" new;
run;

* Keep variables in target dataset *;
%let keepvar = domain studyid usubjid visit visitnum vsdtc vsorres vsseq vstestcd;

* Read the input dataset *;
data e_vitals (drop = siteid subjidn subjid age sex race country fdosedt fdosedtc ldosedt ldosedtc trtcd trtgr
  set extract.vitals ;
run;

* Sorting the dataset *;
proc sort data = extract.vitals  out = sort_vsorres ;
  by age country fdosedt fdosedtc ldosedt ldosedtc race sex siteid strata studyid subjid subjidn trtcd trtgrp
run;

* Transpose the dataset *;
proc transpose data = sort_vsorres  out = t_vsorres (rename = (_name_ = name_vsorres _label_ = label_vsorres
  by age country fdosedt fdosedtc ldosedt ldosedtc race sex siteid strata studyid subjid subjidn trtcd trtgrp
  var sysbp diabp pulse height weight temp ;
```


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Thank you.

Questions?

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