Trial Design Datasets
From Excel to SAS

CDISC DACH User Network

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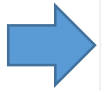
Possible Input Scenarios

- Trial Design Data (TS, TA, TE, TV, TI) available in Excel
  - either in
    - separate files
    - separate worksheets within 1 file
- Data stored in Excel
  - Equivalent to what is needed in the respective final valid trial design domain
  - May include additional information (e.g., completion instructions)
  - May require additional derivations in SAS for creation of the final trial design domains
    - e.g., look-up of CDISC CT C-Codes for TSVALCD
    - e.g., derivation of some Trial Summary Parameter Values like
      - actual number of subjects
      - study start date
    - e.g., splitting of long TSVAL values into TSVAL, TSVAL1, TSVAL2, etc. as needed
    - e.g., assignment of standard values
      - STUDYID
      - DOMAIN

Excel to SAS

Option 1: Prerequisite – SAS/ACCESS Interface to PC Files licensed

	A	B	C	D	E
1	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT
2	STUDYX	TI	IN01	Subjects between 18 and 85 years of age	INCLUSION
3	STUDYX	TI	IN02	Normal blood chemistry (ALT, AST, Bilirubin, Glucose) results, normal Urine Glucose results	INCLUSION
4	STUDYX	TI	IN03	Normal Vital Signs findings	INCLUSION
5	STUDYX	TI	IN04	Normal ECG findings	INCLUSION
6	STUDYX	TI	EX01	Drug addiction	EXCLUSION
7	STUDYX	TI	EX02	Pregnant or breastfeeding woman	EXCLUSION



	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT
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5	STUDYX	TI	EX01	Drug addiction	EXCLUSION
6	STUDYX	TI	EX02	Pregnant or breastfeeding woman	EXCLUSION

```
/* Import TI sheet from Excel Workbook trialdesign.xlsx */
proc import datafile="&path./trialdesign.xlsx" out=ti dbms=xlsx replace;
     sheet="TI";
run;

/* Perform post-processing as required */

/* Create final dataset by utilizing information from the SDTM specifications file   */
/* (e.g., dataset label, variable order, label, type)                                 */

%finalds(ds=ti);
```

Excel to SAS

Option 2: No SAS/ACCESS to PC Files licensed

- Store Excel File content in CSV files per domain
- Import CSV file
  - proc import datafile= " &path/ti.csv" out=ti dbms=csv replace;
- Proceed as shown in Option 1

➢ *For further details, other options refer to SAS Online Documentation*

Caveats

- Consider interactions with Windows Regional Settings
- Avoid special characters in Excel files
  - e.g., carriage return, curly quotes
- Depending on input method chosen, make sure that there is no truncation
- Keep track and follow-up on missing input data
  - e.g., Trial Summary Parameter REGID

- Obviously, when updates are required, update in Excel and rerun the SAS program
- When CSV files are created, make sure Excel and CSV are in sync

Contact Information

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