




# Setting Up A New Study

SCRI

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- Create the new study directories using `%create_new_study(studyid=_training1);`
  - Setup study defaults add a macro named `%study_detail` to the directory  
S:\\_training1\Macro
  - Setup study level formats add a macro named `%study_formats` to  
S:\\_training1\Macro

# Study\_detail Macro

- ▶ This is used to set study default values used by the reporting macros, these may be overridden in the individual macro calls or in the metadata.
- ▶ Sponsor Details

| <b>Value</b>   | <b>Macro variable</b> |
|----------------|-----------------------|
| Sponsor Name   | &sponname             |
| Protocol       | &sponprot             |
| Drug Substance | &drugsubstance        |

# Study\_detail Macro

- ▶ This is used to set study default values used by the reporting macros, these may be overridden in the individual macro calls or in the metadata.
- ▶ Study Report Details

| Value                       | Macro variable | Example                  |
|-----------------------------|----------------|--------------------------|
| Treatment Code Type         | &trtcd         | Cohort or actarm         |
| Format for frequency        | &freqfmt       | 3.                       |
| Format for percent          | &pctfmt        | 5.1                      |
| Preferred output statistics | &outstat       | N mean sd median min max |

# Study\_formats

- ▶ The reporting macros use formats to generate the header labels for the tables. Therefore if the study treatments are based on cohorts two formats need to be created a character format named \$cohort. and a numeric format cohort.
- ▶ In addition a numeric format avar should be created this is used in the disposition table which typically is not split by treatment

# Study\_formats -avar

- ▶ value avar
- ▶ 1='Total';
  
- ▶ The label can be modified as required if the study statistician specifies a different label in the shells

# Study\_formats - Treatment

- ▶ In the example the tables use cohort to define columns therefore we need a cohort format
- ▶ value cohort
- ▶ **1**='Cohort 1@150 mg'
- ▶ **2**='Cohort 2@300 mg'
- ▶ **3**='Cohort 3@600 mg'
- ▶ **4**='Cohort 4(MTD)@900 mg'
- ▶ **5**='Cohort 5@ 1150 mg'
- ▶ **6**='Overall';
- ▶ This format is used as a column label and has a split character @ included to correctly display the heading. The labels are study specific and the reporting macro will add the bigN value as needed

# Study\_formats - Treatment

- ▶ value \$cohort
- ▶ '1'='Cohort 1 150 mg'
- ▶ '2'='Cohort 2 300 mg'
- ▶ '3'='Cohort 3 600 mg'
- ▶ '4'='Cohort 4(MTD) 900 mg'
- ▶ '5'='Cohort 5 1150 mg'
- ▶ '6'='Overall';
- ▶ The character version is used when the cohort is displayed as a row label in which case the split character is not needed.