

Clinical Output Review with R

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Clinical Outputs

- **Clinical Trial Outputs** = Tables Figures Listings (TFL)
- **Clinical Output Review** - a quality-control (QC) step before TFL finalization performed by the Trial Statistician
- **The Trial Statistician** ensures that the TFLs are:
 - accurate
 - consistent
 - compliant with the Statistical Analysis Plan (SAP)
 - follow regulatory guidelines

Challenges in clinical output review

- **High volume of outputs**
- **Dynamic nature of clinical trial data**
 - data updates
 - programming changes
- **Manuel review**
 - ● time-consuming
 - ● error-prone
 - ● inefficient

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draft outputs → review → corrections → re-review

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Types of output review

- **PDF – compare**
- **Company SAS macro**
 - Compares all LST files contained in 2 folders
 - output – Excel file with names of output files and changes
 - issues:
 - Uses SAS LST files as input and therefore only Tables and Listings can be checked, but not Figures
 - reviewed LST files must be moved (usually manually) in a separate folder

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R based approach

- Save the results data (.sas7bdat) in an R - specific format (.Rdata)

```
save_test_data(datadir = dir_rds,      ### results data location
               testdir = test_dir_data, ### location where to save the data
               dname   = paste0("data_sXX_1_",gsub("-", "_", Sys.Date())), ### name of data
               subset  = "sXX_1_"      ### subset files)
```

- Load the data
- Run compare

```
chg <- compare_fun(list1 = data_sXX_1_2026_07_01, list2 = data_sxx_1_2026_07_07)
```

```
The date of modification changed for sXX_1_1_1_t.sas7bdat (num=1)
2026-07-01 11:39:48 != 2026-07-06 14:27:12
```

```
The output changed for sXX_1_1_1_t.sas7bdat (num=1)
```

```
chg[[1]]
```

```
V1                V2
1 -0.0870580260762 -0.087058026076175
attr(,"label")
[1] "sXX_1_1_1_t.sas7bdat"
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Challenges and future work



Disadvantages

Does not check for possible updates in titles and footnotes



Future work

Improving the output of the compare function

Thank you for your attention

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