R for SDTM and ADaM Data

**BACKGROUND**

A General Data Analysis Project Structure

Program

- Clinical statisticians involved in every step, from importing data to communicating the results to clinicians
- Every step is critical to deliver a high-quality clinical trial report

Adapted from: http://r4ds.had.co.nz/introduction.html

**IMPLEMENTATION**

Access SDTM and ADaM Data in R

**SDTM R Package**

- An R package to access SDTM and ADaM standard data:
  - 50 functions to input each data domain
  - 15 functions for data manipulation
  - 3 functions for data validation
  - 7 functions to set up working environment

**RESULTS**

Data Extraction Time Comparison

- Running time comparison between SDTM::get_data and haven::read_sas
  - SDTM::get_data in our SDTM package is >35X faster in large data set
  - SDTM::get_data only retrieves commonly used variables

<table>
<thead>
<tr>
<th>Domain</th>
<th>Number of Rows</th>
<th>Number of Columns</th>
<th>get_data (seconds)</th>
<th>read_sas (seconds)</th>
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<tbody>
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<td>0.7</td>
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<td>CF</td>
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<td>EX</td>
<td>191,021</td>
<td>66</td>
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<td>52.1</td>
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</tbody>
</table>

*Using the default setting of the function

**Clinical Statisticians With R Experience**

- Document review
  - Review and validate SAS code to create ADaM data and TFLs
  - Review CSR/DMC TFLs
- SAPIsSAP development
  - Sample size calculation
  - Explore data sets
  - Post-hoc analyses
- Statistical methods evaluation

**CONCLUSION**

- R works well with SAS to support clinical data review
- SDTM R package builds a foundation to help users access SDTM and ADaM data efficiently
- Data and code access: Same as SAS programs in the analysis and report folder