SIMPLIFYING P21 PROCESS FOR DEFINE CREATION
Objectives

Creating a SAS® macro to dynamically update Significant Digits and Data type in P21 Specification for process improvement and increase efficiency
Process Flow

- Import ADaM specification into P21 and run Pinnacle report
- Export Pinnacle 21 specification
- Call SAS® Macro

Find Significant Digits across all datasets
Import Pinnacle 21 spec and merge with dataset
Update Significant Digits and Datatype
Compare updated dataset for QC
Export datasets as excel in Pinnacle 21 spec
Import updated Pinnacle spec and run Pinnacle report.

Display 1. Process flow for SAS® macro
Macro call

- SAS® macro(infile=P21_File_path);
- Review compare reports (P21 Specification vs Updated sheets):
  - Variables
  - ValueLevel
  - Colelists
Demo

- Import ADaM specification
- Export Pinnacle 21 Specification
- Run SAS macro call and reimport Pinnacle 21 Specification
Demo(Cont..)

Display 3. Pinnacle 21 Specification
Highlighted tabs ('Variable' 'ValueLevel' 'Codelists') will be dynamically updated by the SAS® macro for Significant Digits and Data type in Pinnacle Specification

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Length</th>
<th>Significant Digits</th>
</tr>
</thead>
<tbody>
<tr>
<td>float</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>float</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>float</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>float</td>
<td>8</td>
<td>5</td>
</tr>
</tbody>
</table>

Display 4. Example of the updated Significant Digits for highlighted tab ('Variable' 'ValueLevel' 'Codelists')
Time comparison

- Approximate time to update is 3-5 hours (depends on study)
- SAS® macro run time will take around 5 mins
- Significant process improvement
Summary

This SAS® macro can dynamically update the Significant Digits and Data Type in a Pinnacle 21 Specification using a data driven approach and helps to avoid manual updates in the specification which saves significant time in creating a high quality Define.xml for Regulatory submission.
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