

SIMPLIFYING P21 PROCESS FOR DEFINE CREATION



PhUSE2019

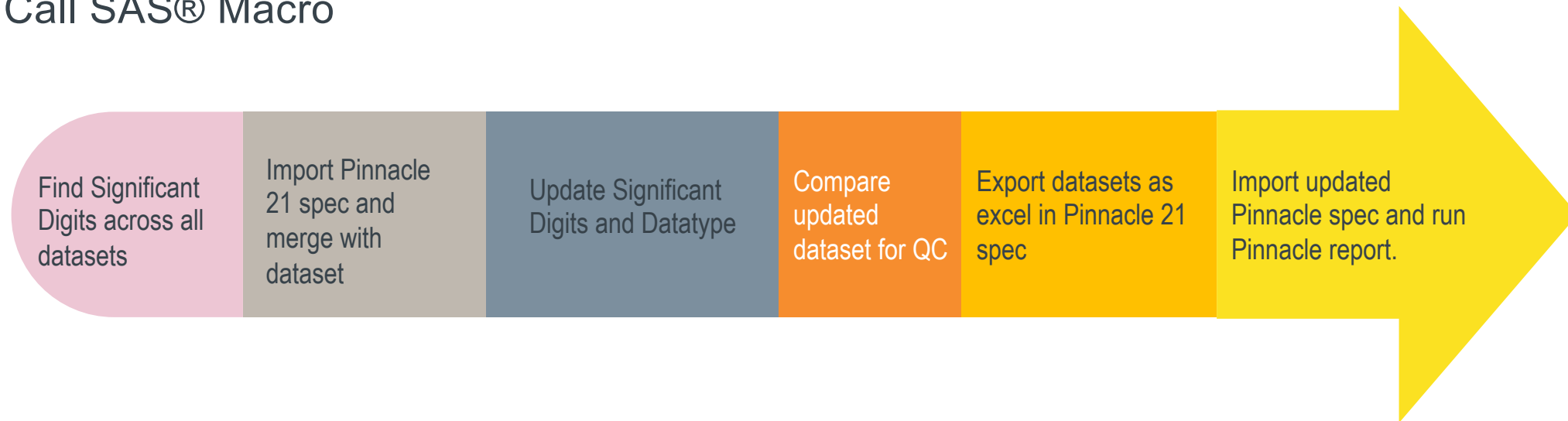
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Objectives

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

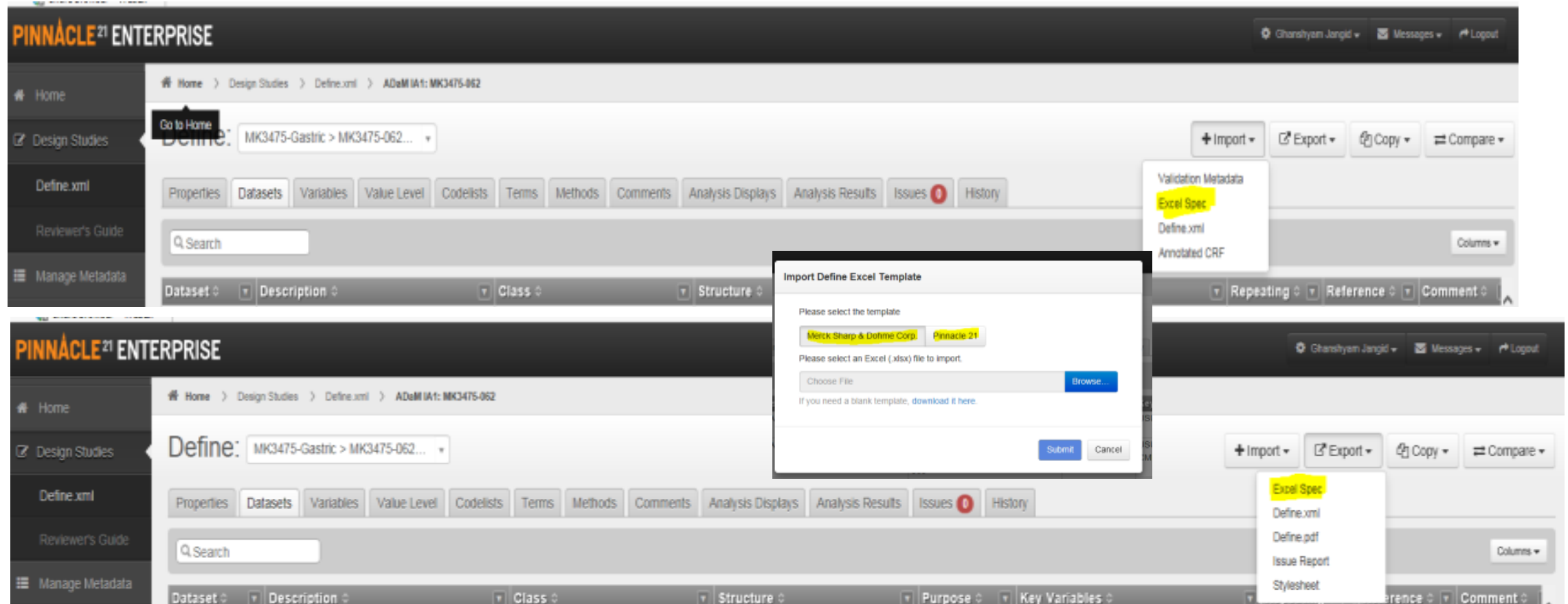


Macro call

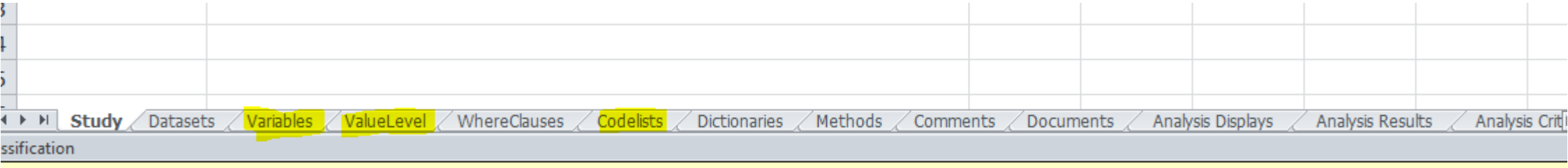
- ❖ SAS® macro(*infile=P21_File_path*);
- ❖ Review compare reports (P21 Specification vs Updated sheets):
 - ✓Variables
 - ✓ValueLevel
 - ✓Colelists

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

E	F	G
Data Type	Length	Significant Digit
float	8	4
float	8	4
float	8	2
float	8	2

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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