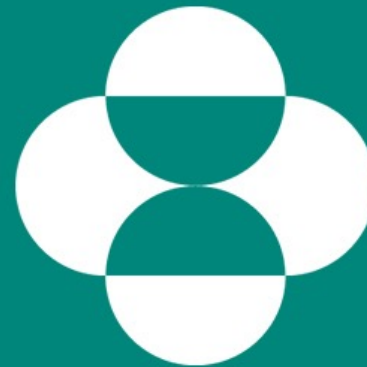


Paper #SM01

SAS ODS Package for Efficient Creation of ZIP file for P21 Validation



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FOR LIFE

PhUSE2024
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About me

- Associate Principal Scientist, Stat programming at Merck & Co., Inc., Rahway, NJ, USA
- 10+ Years of experience in SAS programming
- TA: Oncology, Vaccines, Immunology
- Experience using R as a programmer

Agenda

- Introduction
- SAS ODS PACKAGE
- Macro (XPT0DEF0ZIP.SAS)
- Conclusion
- Q and A

Introduction

Pinnacle 21 is a software suite designed for clinical data management and regulatory submission process in the pharmaceutical and life sciences industries. It plays a crucial role in ensuring the quality, compliance, and submission readiness of clinical data.

P21 is widely utilized for the validation of SDTM and ADaM datasets, with a specific focus on datasets formatted according to CDISC standards.

Some of the key features and reasons for using P21 include:

- CDISC compliance
- Data Quality Assurance
- Submission Readiness

Cont..



- P21 validation is a critical step to prepare FDA eSubmission package.
- ZIP file is a mandatory input to perform P21 validation.
- Although ZIP compression tools like gzip, 7-zip, and WinZip are widely used, they may not always be convenient to use within a .SAS program.
- Manually creating ZIP file leads to inefficiencies and potential errors.

SAS ODS PACKAGE



- This paper presents a novel approach utilizing the SAS Output Delivery System (ODS) to streamline the process of creating ZIP files for P21 validation.
- Beginning with SAS 9.2, it is possible to generate the custom zip file using ODS package statements.
- The approach offers a seamless macro **(XPT0DEF0ZIP.SAS)** with ODS capabilities, enable users to create transport files from libraries.

How it works (xpt0def0zip.sas)?

- Program: xpt0def0zip.sas
- The program calls the macro (setxpt.sas) to create the xpt files
- Creates the XPT files from the specific library
- Checks if required files – ADRG, ARM, Define are present in the directory
- Creates ZIP file with system run date and time and keeps backup for multiple runs with the run date

 round003APR2023T12_49_37.zip

- Issues WARNING message if required files are not present in the directory



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/**** Sample Call Program: 1 (All default values)***/*

%xpt0def0zip(

sdm_in = %str() /*To select SDTMs to include in ZIP (default: DM, EX and AE) */

,adamin = %str() /*TO select ADaMs to include in the ZIP (default:all) */

,sdm_libname = %str() /*To select the library for SDTMs */

,adam_libname = %str() /* To select the library for ADaMs */

,create_xpt = %str() /* To create XPT files */

,xpt_libref = lptsda /*Location of the XPT files (required parameter)*/

,include_sfiles = %str(y) /* To include ADRG, ARM and DEFINE in the ZIP file */

,exclude_file = %str() /* To exclude any files from the ZIP file */

,zip_file = %str() /* Name of the Zip file */

,zip_file_loc = %str() /* Location for the Zip file */

,delete_xpt = %str() /* To delete XPTs after creating ZIP file */

, delete_old_zip = %str() /* To delete the old zip files in the zip_file_loc */

);

Cont..

Xpt_libref is a required parameter and the macro fails with error message when missing value is passed

```
=====Usage for Macro XPT0DEF0ZIP=====
ERROR: (XPT0DEF0ZIP) xpt_libref is a required parameter. Please assign libname
ERROR: (XPT0DEF0ZIP) reference in xpt_libref variable and resubmit.
=====Usage for Macro XPT0DEF0ZIP=====
---End of XPT0DEF0ZIP macro
```

WARNING message when submission files (adrg.pdf, define.xml, analysis-results-metadata.pdf) are missing in xpt_libref location.

```
WARNING: (XPT0DEF0ZIP) The adrg.pdf file is missing in the zip file.
WARNING: (XPT0DEF0ZIP) The analysis-results-metadata.pdf file is missing in the zip file.
WARNING: (XPT0DEF0ZIP) The define.pdf file is missing in the zip file.
WARNING: (XPT0DEF0ZIP) The define.xml file is missing in the zip file.
WARNING: (XPT0DEF0ZIP) The define2-0-0.xsl file is missing in the zip file.
```

Cont..

Datasets in LPTDA:

 adae.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	4,480 KB
 adcm.sas7bdat	3/31/2023 12:43 PM	SAS Data Set	6,656 KB
 adex.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	1,216 KB
 adexsum.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	576 KB
 adsl.sas7bdat	11/9/2023 8:15 PM	SAS Data Set	512 KB
 axpb.sas7bdat	3/31/2023 12:40 PM	SAS Data Set	192 KB
 axsb.sas7bdat	3/31/2023 12:40 PM	SAS Data Set	192 KB

Submission files:

 define2-0-0.xsl	2/24/2023 4:57 PM	XSL Stylesheet	184 KB
 adrg.pdf	9/19/2023 2:47 PM	Adobe Acrobat Docum...	535 KB
 analysis-results-metadata.pdf	9/19/2023 2:17 PM	Adobe Acrobat Docum...	354 KB
 define.xml	2/24/2023 4:57 PM	XML Document	1,117 KB

Cont..

XPT files created:

 adae.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	19,395 KB
 adcm.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	29,542 KB
 adex.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	2,487 KB
 adexsum.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	798 KB
 adsl.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	618 KB
 ae.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	1,641 KB
 axpb.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	21 KB
 axsb.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	144 KB
 dm.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	56 KB
 ex.xpt	12/5/2023 8:22 PM	SAS Xport Transpo...	540 KB

Cont..

ZIP file created with default name

> prot013-csr02 > dataanalysis > round005DEC2023T20_22_45.zip

Name	Type	Compressed size	Password prot...	Size	Ratio	Date modified
 adae.xpt	SAS Xport Transport File	540 KB	No	19,395 KB	98%	12/5/2023 8:22 PM
 adcm.xpt	SAS Xport Transport File	933 KB	No	29,542 KB	97%	12/5/2023 8:22 PM
 adex.xpt	SAS Xport Transport File	105 KB	No	2,487 KB	96%	12/5/2023 8:22 PM
 adexsum.xpt	SAS Xport Transport File	19 KB	No	798 KB	98%	12/5/2023 8:22 PM
 adrg.pdf	Adobe Acrobat Document	509 KB	No	535 KB	5%	12/5/2023 8:22 PM
 adsl.xpt	SAS Xport Transport File	31 KB	No	618 KB	96%	12/5/2023 8:22 PM
 ae.xpt	SAS Xport Transport File	131 KB	No	1,641 KB	93%	12/5/2023 8:22 PM
 analysis-results-metadata.pdf	Adobe Acrobat Document	342 KB	No	354 KB	4%	12/5/2023 8:22 PM
 axpb.xpt	SAS Xport Transport File	2 KB	No	21 KB	94%	12/5/2023 8:22 PM
 axsb.xpt	SAS Xport Transport File	6 KB	No	144 KB	97%	12/5/2023 8:22 PM
 define.xml	XML Document	78 KB	No	1,117 KB	94%	12/5/2023 8:22 PM
 define2-0-0.xsl	XSL Stylesheet	26 KB	No	184 KB	87%	12/5/2023 8:22 PM
 dm.xpt	SAS Xport Transport File	8 KB	No	56 KB	87%	12/5/2023 8:22 PM
 ex.xpt	SAS Xport Transport File	59 KB	No	540 KB	90%	12/5/2023 8:22 PM

Cont..

```
%on0xpt0def0zip(  
  sdtm_in = %str()  
  ,adam_in = %str()  
  ,sdtm_libname = lptss  
  ,adam_libname = lptda  
  ,create_xpt = %str(Y)  
  ,xpt_libref = lptsda  
  ,include_sfiles = %str(Y)  
  ,exclude_file = %str(axpb|axsb)  
  ,zip_file = %str(adam_zip)  
  ,zip_file_loc = %str(lptesda)  
  ,delete_xpt = %str(Y)  
  ,delete_old_zip = %str(Y));
```

Datasets from LPTDA:

adae.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	4,480 KB
adcm.sas7bdat	3/31/2023 12:43 PM	SAS Data Set	6,656 KB
adex.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	1,216 KB
adexsum.sas7bdat	3/31/2023 12:41 PM	SAS Data Set	576 KB
adsl.sas7bdat	11/9/2023 8:15 PM	SAS Data Set	512 KB
axpb.sas7bdat	3/31/2023 12:40 PM	SAS Data Set	192 KB
axsb.sas7bdat	3/31/2023 12:40 PM	SAS Data Set	192 KB

prot013-csr02 > dataanalysis > round022JAN2024T14_24_22.zip	
Name	Type
adrg.pdf	Adobe Acrobat Document
analysis-results-metadata.pdf	Adobe Acrobat Document
adae.xpt	SAS Xport Transport File
adcm.xpt	SAS Xport Transport File
adex.xpt	SAS Xport Transport File
adexsum.xpt	SAS Xport Transport File
adsl.xpt	SAS Xport Transport File
ae.xpt	SAS Xport Transport File
dm.xpt	SAS Xport Transport File
ex.xpt	SAS Xport Transport File
define.xml	XML Document
define2-0-0.xsl	XSL Stylesheet

Conclusion



- In general, we run P21 for ADaM multiple times for a study. Manual selection of files is a tedious process, error prone and time consuming
- By using this program, zip file is created in 1-2 min comparing to 13-15 mins manually
- Size of the zip file decreased by 5 MB with SAS ODS package comparing to manually created file

NOTE: Detailed macro is provided in the paper under Appendix 1 and 2

Acknowledgements

PI and ADaM CoE team at Merck

Amy Gillespie, Sai Govind Chenna, Dileep Penmetsa

Your comments and questions are valued and encouraged. You may contact authors at:

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Questions?

Thank you!