



Introduction of EXACT - a Tool for AdaM Generation

Outline

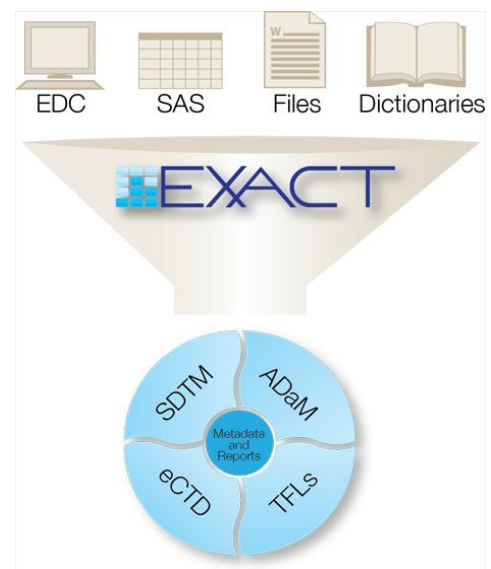
- Introduction
- Generating the ADaM Datasets within EXACT
- QC Process within EXACT
- Summary

Outline

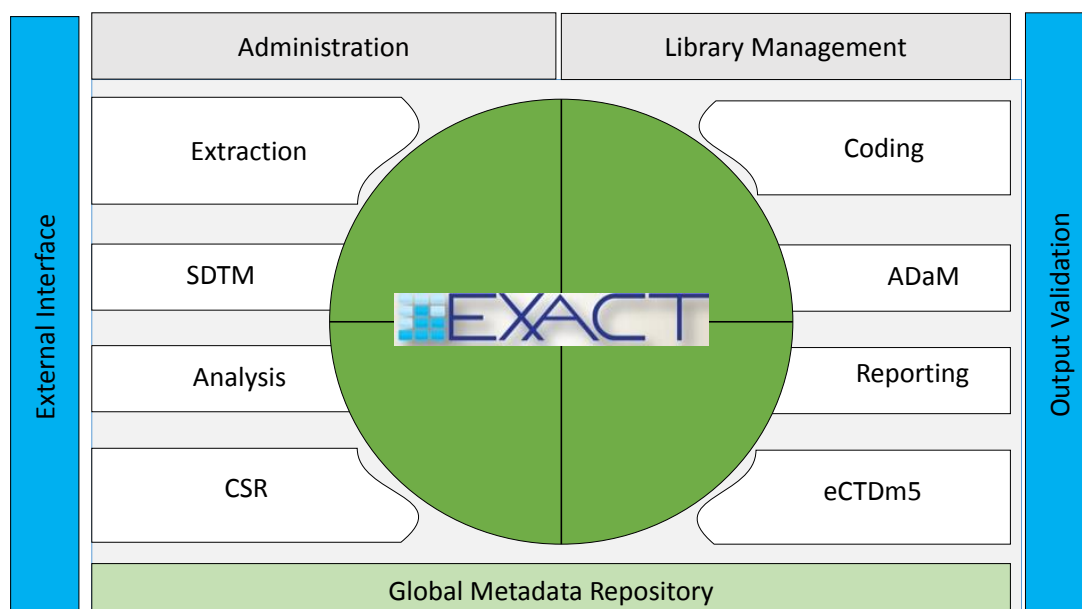
- Introduction
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Introduction

- PRA acquired EXACT system in 2011
 - System designed and implemented over the last 8 years
 - 2 years of focused enhancements
- Faster access to decision information
 - CDISC Standard outputs
 - TFL designs & deliverables
 - eCTD submission capability
- Standards Library Management
 - Industry & customer specific
- Reduced Programming effort
 - Visual environment for development
 - Validation checks



EXACT Functional Architecture



What can be done within EXACT?



SDTM mapping interface

ADaM mapping interface

The screenshot displays the EXACT software interface, which is used for mapping clinical trial data from SDTM (Standard Data Tabular Model) to ADaM (Analysis Data Model). The interface is divided into several panes:

- Left Pane (SDTM Mapping):** Shows a list of SDTM domains and variables. The 'AE' (Adverse Event) domain is selected, and a list of AE-related variables is displayed.
- Center Pane (ADaM Mapping):** Shows a list of ADaM datasets. The 'GS_AE_T_F_038' dataset is selected, and a 'Mockup Preview' window is open, showing a table of adverse events.
- Right Pane (ADaM Mapping):** Shows a list of ADaM datasets. The 'GS_AE_T_F_038' dataset is selected, and a 'Mockup Preview' window is open, showing a table of adverse events.

The 'Mockup Preview' window displays a table titled 'Table AE #0' with the following columns:

Preferred Term	Incidence of Treatment Emergent Adverse Events by Action Taken and Outcome				Incidence of Treatment Emergent Adverse Events by Action Taken and Outcome			
	Not on Study	On Study	Not on Study	On Study	Not on Study	On Study	Not on Study	On Study
Any adverse event	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Preferred Term 1	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Preferred Term 2	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Preferred Term 3	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Preferred Term 4	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Preferred Term 5	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

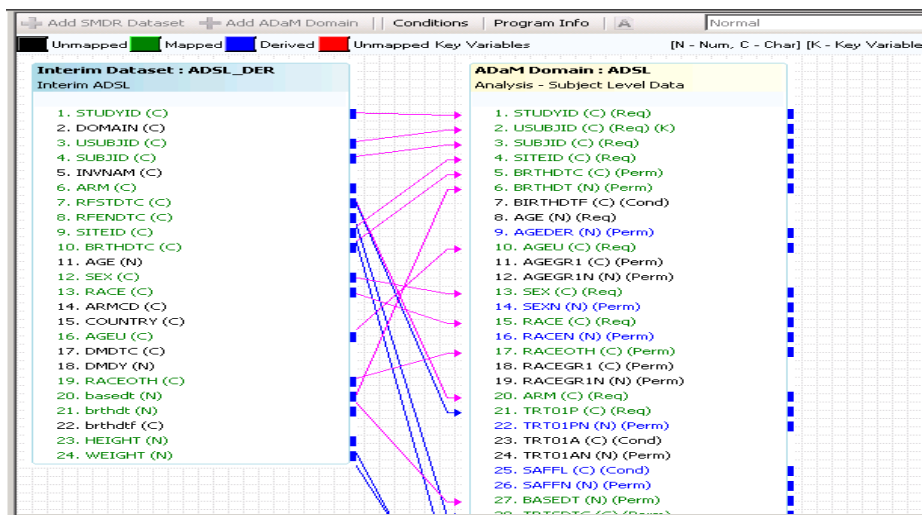
Revolutionary TFL production

Global Excellence China Expertise

What can be done within EXACT?



ADaM mapping interface

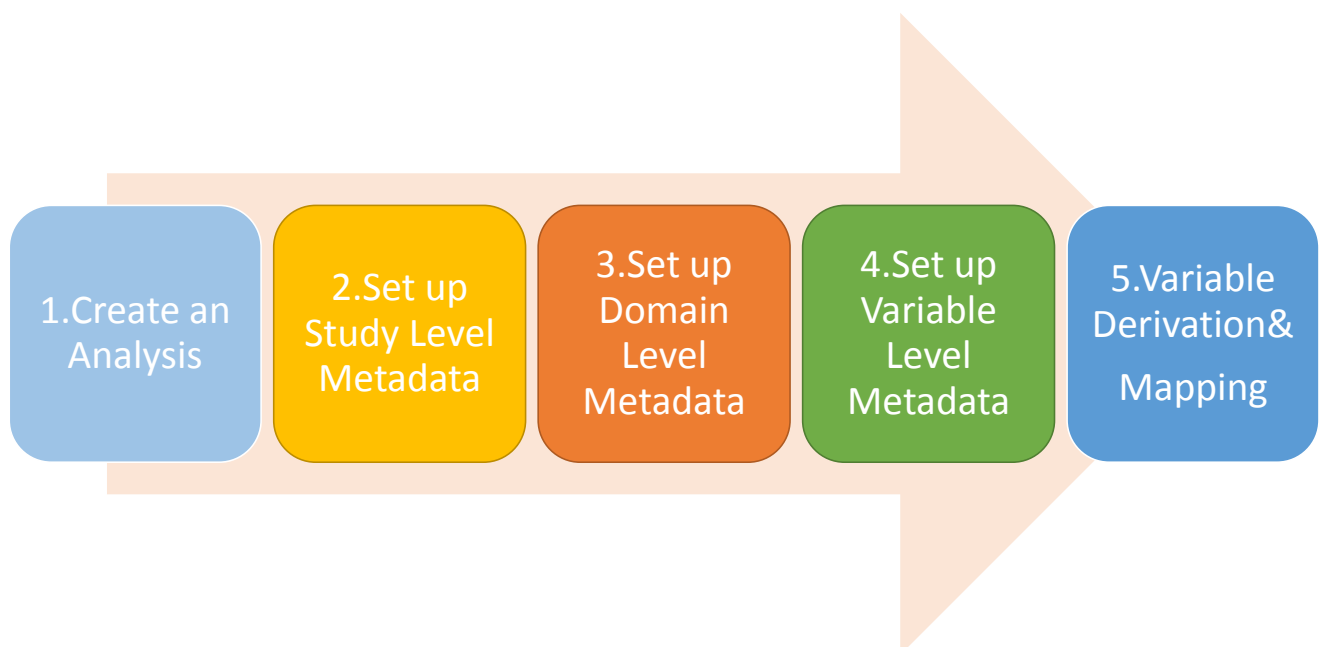


- PRA CDISC standards apply to the following:
 - CRF modules
 - Data entry screens
 - CRF completion guidelines
 - Data edit specifications
 - Data review programs (consistency checks, listings, etc.)
 - SAS Programming (i.e., data extraction, database conversion, analysis programs)
 - Converted datasets are provided to CDISC's SDTM specifications and derived datasets are based on CDISC's ADaM specifications.

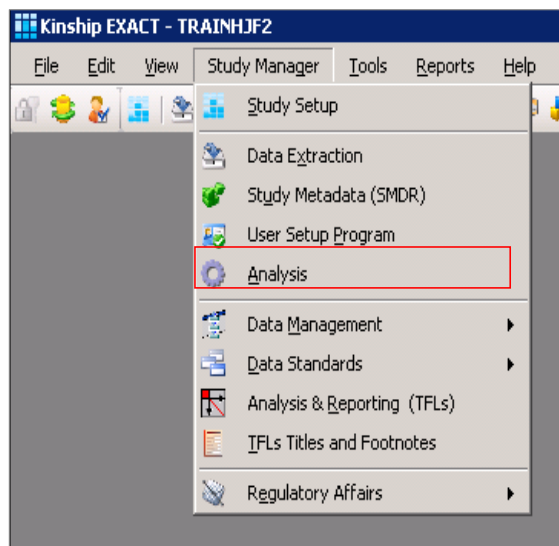
Outline

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Process Flow



1. Create an Analysis



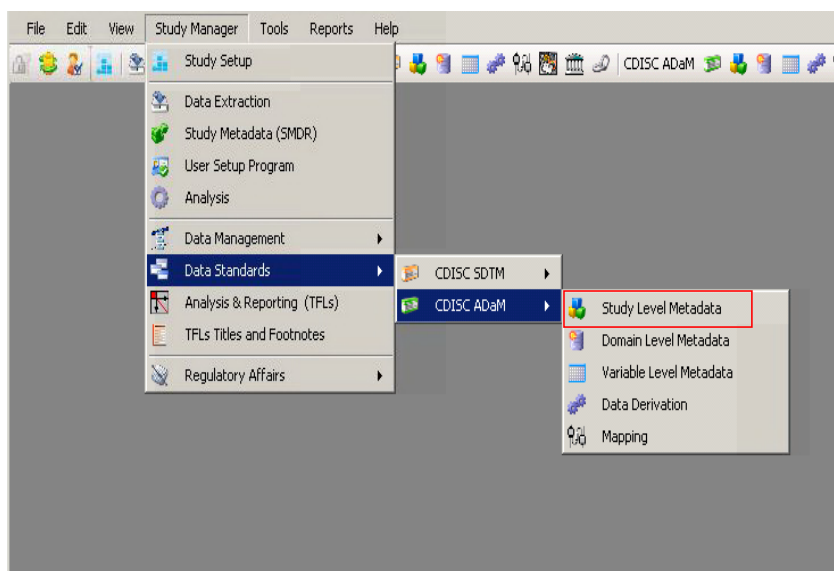
1、From the **Study Manager** menu, select **Analysis**.

2、Click **New**. The **Add Analysis** screen opens.

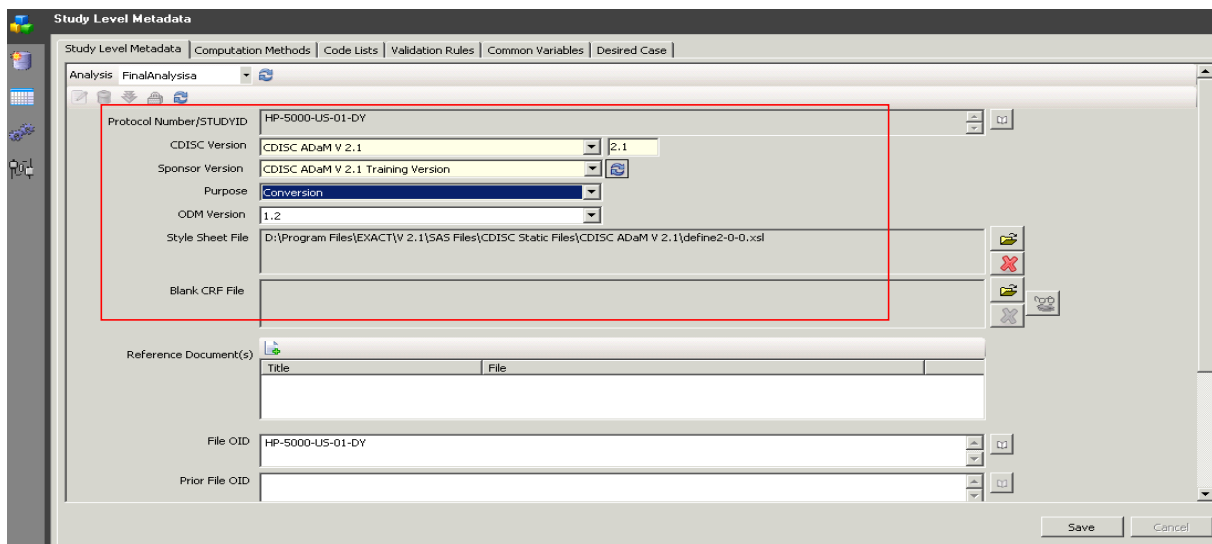
2. Set up Study Level Metadata

- Access Study Level Metadata
- Define CIDISC Versions
- Define Common Variables

➤ Access Study Level Metadata



➤ Define CIDISC Versions



Study Level Metadata

Analysis FinalAnalysis

Protocol Number/STUDYID HP-5000-US-01-DY

CDISC Version CDISC ADaM V 2.1 2.1

Sponsor Version CDISC ADaM V 2.1 Training Version

Purpose Conversion

ODM Version 1.2

Style Sheet File D:\Program Files\EXACT\W 2.1\SAS Files\CDISC Static Files\CDISC ADaM V 2.1\define2-0-0.xml

Blank CRF File

Reference Document(s)

Title	File

File OID HP-5000-US-01-DY

Prior File OID

Save Cancel

➤ Define Common Variables

Common Variables			
Name	Label	Type	Role
STARTDTF	Origin Date Imputation Flag	Character	Trial Dates
STARTDTM	Time to Event Origin Date/Time	Numeric	Trial Dates
STARTTMF	Origin Time Imputation Flag	Character	Trial Dates
STUDYID	Study Identifier	Character	Identifier
SUBJID	Subject Identifier for the Study	Character	Topic
TOXGGPy	Pooled Toxicity Grade Group y	Character	Trial Dates
TOXGGPyN	Pooled Toxicity Grade y (N)	Character	Trial Dates
TRTA	Actual Treatment	Character	Trial Dates
TRTAGy	Actual Pooled Treatment y	Character	Trial Dates
TRTAGyN	Actual Pooled Treatment y (N)	Character	Trial Dates
TRTAN	Actual Treatment (N)	Character	Trial Dates
TRTEDT	Date of Last Exposure to Treatment	Character	Trial Dates
TRTEDTF	Date of Last Exposure Input Flag	Character	Trial Dates
TRTEDTM	Datetime of Last Exposure to Treatment	Character	Trial Dates
TRTEMFL	Treatment Emergent Analysis Flag	Character	Trial Dates

Study Level Metadata

Analysis: FinalAnalysis

Variable Name	Variable Label	Variable Core	Variable Data Type	ODM Data Type
STUDYID	Study Identifier	Req	Character	text

Variable Name: STUDYID

Variable Label: Study Identifier

Variable Core: Req

Variable Data Type: Character

Variable Length: 20

ODM Data Type: text

Variable Origin: ☐ Protocol ☐ Predecessor ☒ Other

Computation OID: Select

Origin, Other: DM.STUDYID

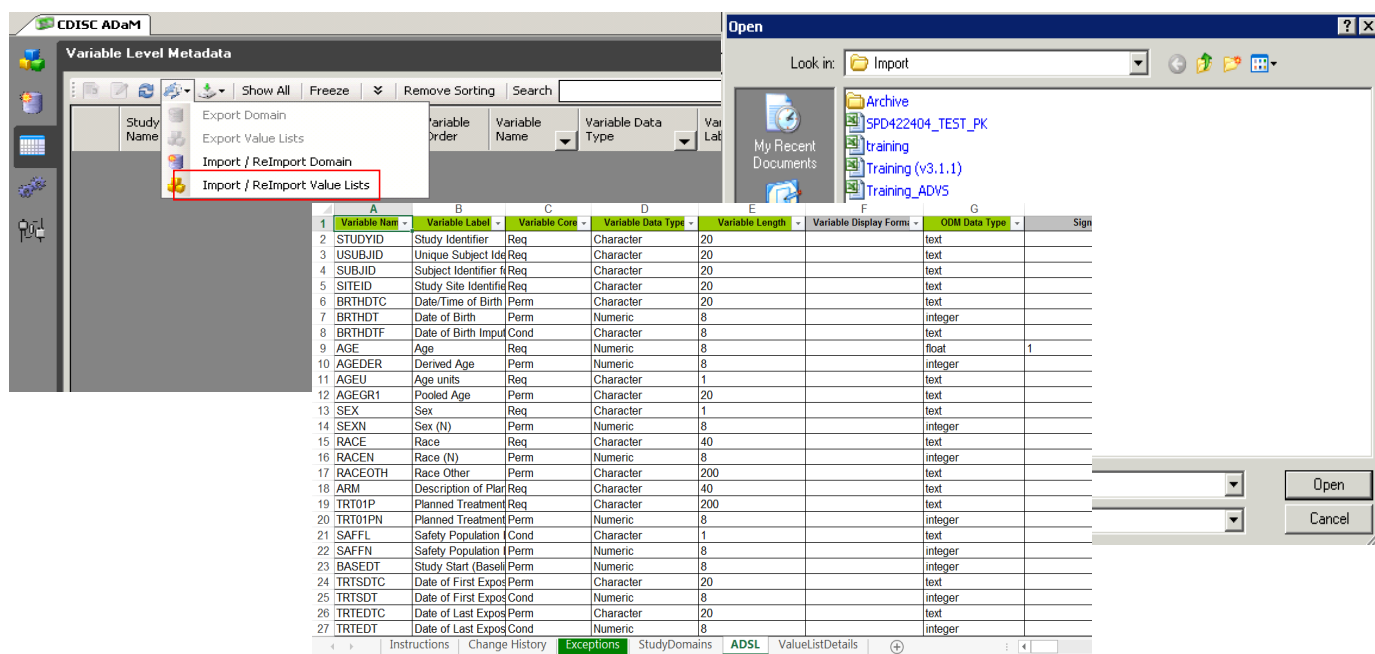
3&4. Set up Domain&Variable Level Metadata

- Upload from an EXCEL Workbook
- Retrieve from Sponsor Library
- Reuse from Other Study

3&4. Set up Domain&Variable Level Metadata

- Upload from an EXCEL Workbook
- Retrieve from Sponsor Library
- Reuse from Other Study

➤ Upload from an EXCEL Workbook



The screenshot shows the CDISC ADaM software interface. The 'Variable Level Metadata' window is open, displaying a table of variables. The 'Import / ReImport Value Lists' menu item is highlighted in the 'File' menu. An 'Open' file dialog is also open, showing the 'Import' folder selected.

Variable Item	Variable Label	Variable Core	Variable Data Type	Variable Length	Variable Display Form	ODM Data Type	Sign
1	STUDYID	Study Identifier	Req	Character	20	text	
2	USUBJID	Unique Subject Identifier	Req	Character	20	text	
3	SUBJID	Subject Identifier	Req	Character	20	text	
4	SITEID	Study Site Identifier	Req	Character	20	text	
5	BRTHDTC	Date/Time of Birth	Perm	Character	20	text	
6	BRTHDT	Date of Birth	Perm	Numeric	8	integer	
7	BRTHDTF	Date of Birth Input	Cond	Character	8	text	
8	AGE	Age	Req	Numeric	8	float	1
9	AGEDER	Derived Age	Perm	Numeric	8	integer	
10	AGEU	Age units	Req	Character	1	text	
11	AGEGR1	Pooled Age	Perm	Character	20	text	
12	SEX	Sex	Req	Character	1	text	
13	SEXN	Sex (N)	Perm	Numeric	8	integer	
14	RACE	Race	Req	Character	40	text	
15	RACEN	Race (N)	Perm	Numeric	8	integer	
16	RACEOTH	Race Other	Perm	Character	200	text	
17	ARM	Description of Plan	Req	Character	40	text	
18	TRT01P	Planned Treatment	Req	Character	200	text	
19	TRT01PN	Planned Treatment	Perm	Numeric	8	integer	
20	SAFFL	Safety Population	Cond	Character	1	text	
21	SAFFN	Safety Population	Perm	Numeric	8	integer	
22	BASEDT	Study Start (Baseline)	Perm	Numeric	8	integer	
23	TRTSDTC	Date of First Exposure	Perm	Character	20	text	
24	TRTSDT	Date of First Exposure	Cond	Numeric	8	integer	
25	TRTEDTC	Date of Last Exposure	Perm	Character	20	text	
26	TRTEDT	Date of Last Exposure	Cond	Numeric	8	integer	

➤ Upload from an EXCEL Workbook

CDISC ADaM

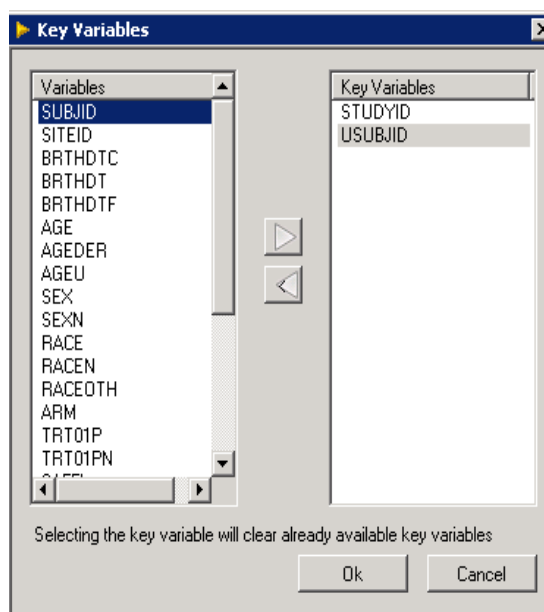
Variable Level Metadata

Show All Freeze Remove Sorting Search

	Study Name	Analysis Name	Domain Name	Variable Order	Variable Name	Variable Data Type	Variable Label	Core Variable	Variable Core	Variable Length	Variable Display Format	OCM Data Type	Signif Digits
1	HP-5000-U...	FinalAnalysis	ADSL	1	STUDYID	Character	Study Identifier	☒	Req	20		text	
2	HP-5000-U...	FinalAnalysis	ADSL	2	USUBJID	Character	Unique Subject I...	☒	Req	20		text	
3	HP-5000-U...	FinalAnalysis	ADSL	3	SUBJID	Character	Subject Identifi...	☒	Req	20		text	
4	HP-5000-U...	FinalAnalysis	ADSL	4	SITEID	Character	Study Site Identi...	☒	Req	20		text	
5	HP-5000-U...	FinalAnalysis	ADSL	5	BRTHDTC	Character	Date/Time of Birth	☐	Perm	20		text	
6	HP-5000-U...	FinalAnalysis	ADSL	6	BRTHDT	Numeric	Date of Birth	☐	Perm	8		integer	
7	HP-5000-U...	FinalAnalysis	ADSL	7	BRTHDTF	Character	Date of Birth Im...	☐	Cond	8		text	
8	HP-5000-U...	FinalAnalysis	ADSL	8	AGE	Numeric	Age	☐	Req	8		float	1
9	HP-5000-U...	FinalAnalysis	ADSL	9	AGEDER	Numeric	Derived Age	☐	Perm	8		integer	
10	HP-5000-U...	FinalAnalysis	ADSL	10	AGEU	Character	Age units	☐	Req	1		text	
11	HP-5000-U...	FinalAnalysis	ADSL	11	AGEGR1	Character	Pooled Age	☐	Perm	20		text	
12	HP-5000-U...	FinalAnalysis	ADSL	12	SEX	Character	Sex	☐	Req	1		text	
13	HP-5000-U...	FinalAnalysis	ADSL	13	SEXN	Numeric	Sex (N)	☐	Perm	8		integer	
14	HP-5000-U...	FinalAnalysis	ADSL	14	RACE	Character	Race	☐	Req	40		text	
15	HP-5000-U...	FinalAnalysis	ADSL	15	RACEN	Numeric	Race (N)	☐	Perm	8		integer	
16	HP-5000-U...	FinalAnalysis	ADSL	16	RACEOTH	Character	Race Other	☐	Perm	200		text	
17	HP-5000-U...	FinalAnalysis	ADSL	17	ARM	Character	Description of Pl...	☒	Req	40		text	
18	HP-5000-U...	FinalAnalysis	ADSL	18	TRT01P	Character	Planned Treatm...	☒	Req	200		text	
19	HP-5000-U...	FinalAnalysis	ADSL	19	TRT01PN	Numeric	Planned Treatm...	☒	Perm	8		integer	
20	HP-5000-U...	FinalAnalysis	ADSL	20	SAFFL	Character	Safety Populatio...	☐	Cond	1		text	
21	HP-5000-U...	FinalAnalysis	ADSL	21	SAFFN	Numeric	Safety Populatio...	☐	Perm	8		integer	
22	HP-5000-U...	FinalAnalysis	ADSL	22	BASEDT	Numeric	Study Start (Bas...	☐	Perm	8		integer	

The Variable Level Metadata screen now shows the variable configurations for ADSL

➤ Define Key Variables

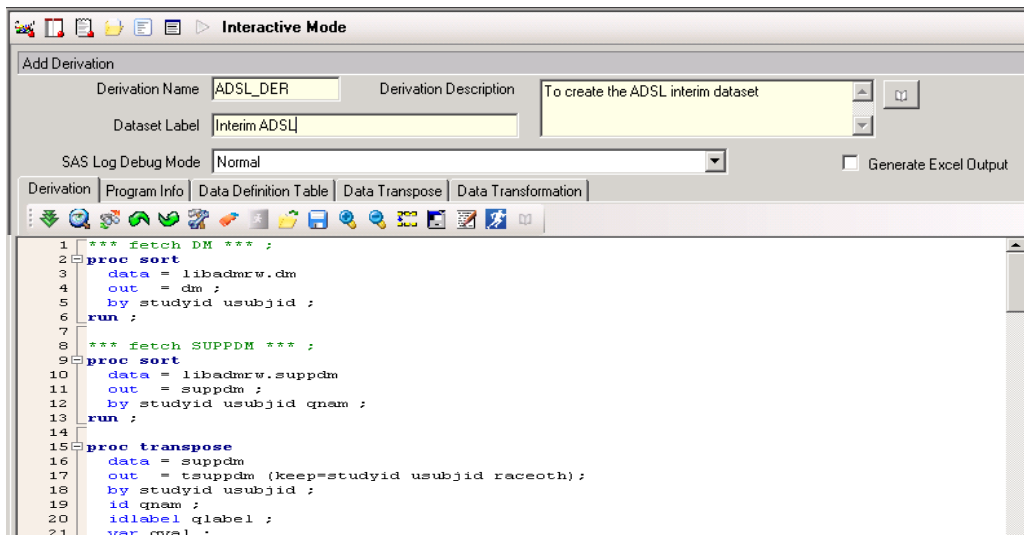


Select **STUDYID** and **USUBJID** as Key Variables for this domain(ADSL).

5. Variable Derivation&Mapping

- Generate SAS Code for Derivation
- Generate Study Metadata for Derivation
- Graphic Mapping
- List View Mapping

➤ Generate SAS Code for Derivation



The screenshot shows the SAS Interactive Mode interface. The 'Add Derivation' dialog is open, with the following fields:

- Derivation Name: ADSL_DER
- Derivation Description: To create the ADSL interim dataset
- Dataset Label: Interim ADSL
- SAS Log Debug Mode: Normal
- Generate Excel Output: ☐

The 'Derivation' tab is selected, showing the following SAS code:

```

1 *** fetch DM *** ;
2 proc sort
3   data = libadmrv.dm
4   out = dm ;
5   by studyid usubjid ;
6 run ;
7
8 *** fetch SUPPDM *** ;
9 proc sort
10  data = libadmrv.suppdm
11  out = suppdm ;
12  by studyid usubjid qnam ;
13 run ;
14
15 proc transpose
16  data = suppdm
17  out = tsuppdm (keep=studyid usubjid raceoth) ;
18  by studyid usubjid ;
19  id qnam ;
20  idlabel qlabel ;
21  var race1 ;

```

➤ Generate Study Metadata for Derivation(SMDR)

Select Dataset to Generate SMDR

☒ Check All ☐ Uncheck All

Dataset

SDTM Datasets

☐ DM

☐ SUPPDM

Interim Datasets

☒ ADSL_DER

Generate Cancel

Study Metadata (SMDR)

Study Metadata Repository SMDR Mapping

CDISC ☒ SDTM ☐ ADaM

Analysis: FinalAnalysis

Generate SMDR Apply ODM

SMDR Dataset

Interim Datasets

ADSL_DER

Library Member Name: libadmdr Observations in Dataset: 69

Engine Name: JVS Created Date: 2014-11-11T11:11:11

Last Modified Date: 2014-11-11T19:34:56 Maximum Number of Generations:

Generation Number: Next Generation Number:

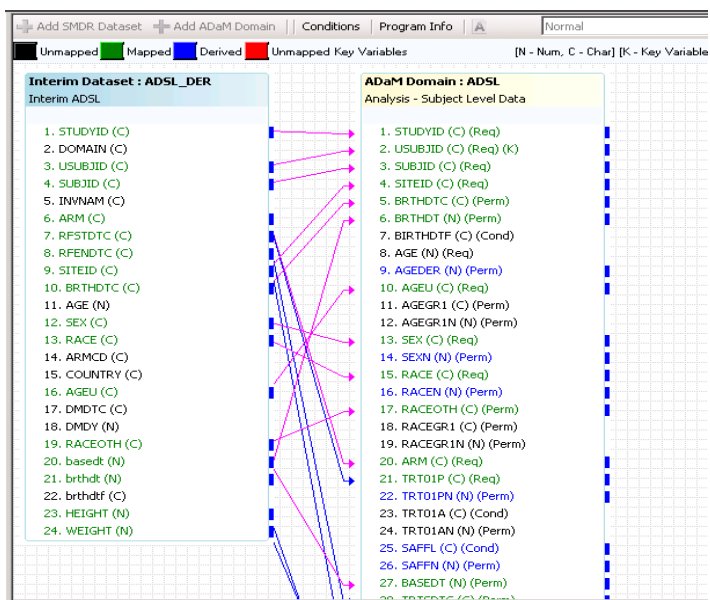
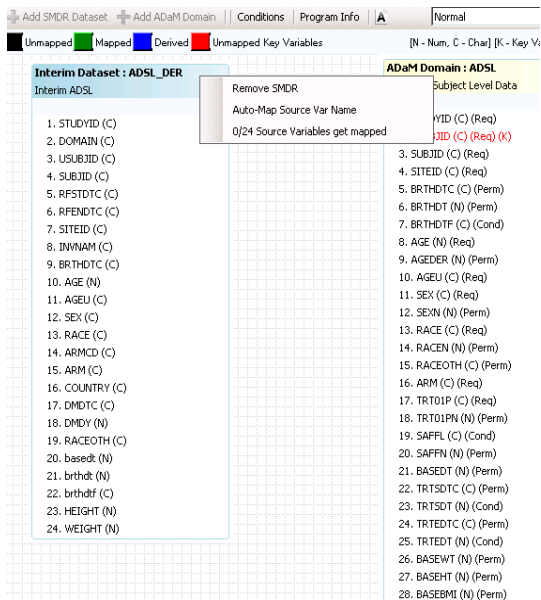
Dataset Label: Interim dataset

Dataset Variable Details

Number	Variable Name	Variable Type	Variable Label
1	STUDYID	Character	Study Identifier
2	DOMAIN	Character	Domain Abbreviation
3	USUBJID	Character	Unique Subject Identifier
4	SUBJID	Character	Subject Identifier for the Study
5	RFSTDTCT	Character	Subject Reference Start Date/Time
6	RFENDTCT	Character	Subject Reference End Date/Time
7	SITEID	Character	Study Site Identifier
8	INVTNAM	Character	Investigator Name
9	BRTHDTC	Character	Date/Time of Birth
10	AGE	Numeric	Age

Variable Details: Interim dataset

➤ Graphic Mapping



➤ List View Mapping

Graphical Mapping | List View Mapping

Search: Search Columns: Remove Sorting: ADSL

(SMDR)	Source	Format Type	User Defined	SAS Format	Date Variable	Time Variable	SAS Format...
20					Select	Select	
20					Select	Select	
9					Select	Select	
6					Select	Select	
19					Select	Select	

Derivation Code  ADSL.AGEDER

ADSL. STUDYID (C) | STUDYID = 'HP-5000-US-01-DY';

ADSL. USUBJID (C) | usubjid=%usubjid(usubjid,&subjidlen);

Derivation Code  ADSL.AGEDER

ADSL. AGE (N) |

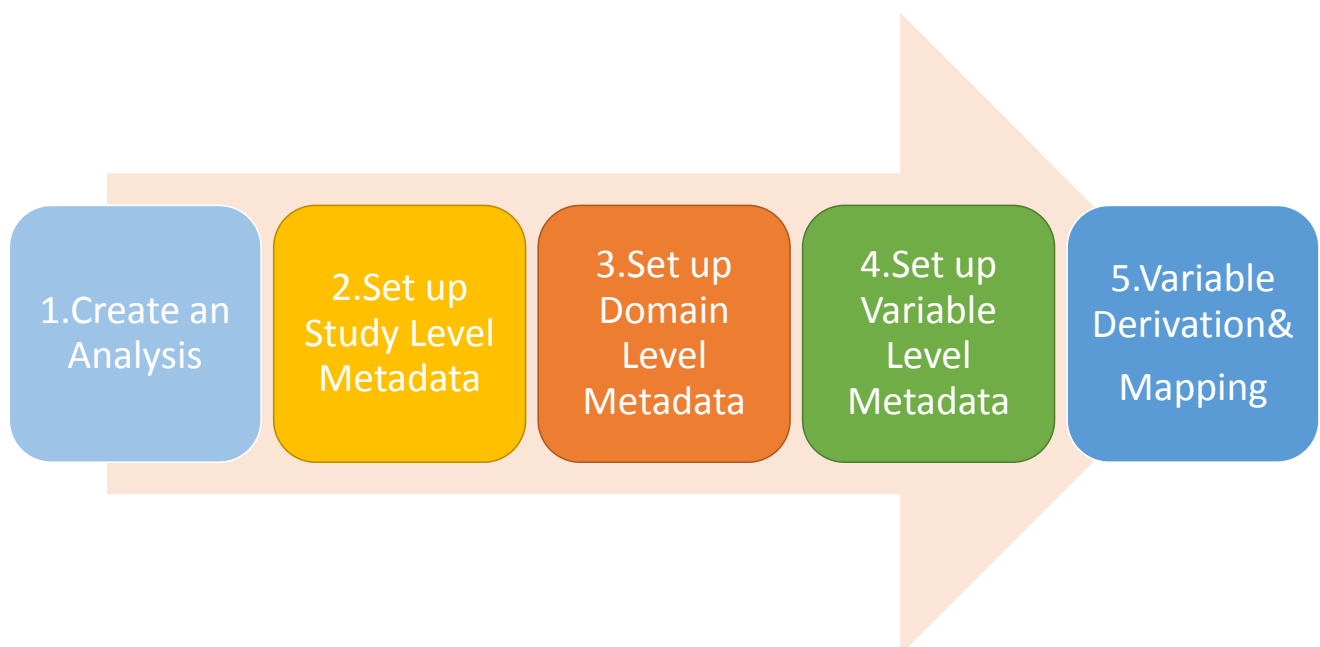
ADSL. AGEDER (N) | agedur=floor(((intck("month",brthdt,basedt)-day(basedt)<day(brthdt))))/12)

ADSL. AGEU (C) |

➤ Removing Variables Not Needed

	Study Name	Analysis Name	Domain Name	Variable Order	Variable Name
1	ADAMTRAI...	FinalAnalysisa	ADSL	1	STUDYID
2	ADAMTRAI...	FinalAnalysisa	ADSL	2	USUBJID
3	ADAMTRAI...	FinalAnalysisa	ADSL	3	SUBJID
4	ADAMTRAI...	FinalAnalysisa	ADSL	4	SITEID
5	ADAMTRAI...	FinalAnalysisa	ADSL	5	BRTHDTC
6	ADAMTRAI...	FinalAnalysisa	ADSL	6	BRTHDT
7	ADAMTRAI...	FinalAnalysisa	ADSL	7	BRTHDTF
8	ADAMTRAI...	FinalAnalysisa	ADSL	8	AGE
9	ADAMTRAI...	FinalAnalysisa	ADSL	9	AGEDER
10	ADAMTRAI...	FinalAnalysisa	ADSL	10	AGEU
11	ADAMTRAI...	FinalAnalysisa	ADSL	11	AGEGR1
12	ADAMTRAI...	FinalAnalysisa	ADSL	12	SEX
13	ADAMTRAI...	FinalAnalysisa	ADSL	13	SEXN
14	ADAMTRAI...	FinalAnalysisa	ADSL	14	RACE
15	ADAMTRAI...	FinalAnalysisa	ADSL	15	RACEN
16	ADAMTRAI...	FinalAnalysisa	ADSL	16	RACEOTH

Process Flow



Outline

- Introduction
- Generating the ADaM Datasets within EXACT
- **QC Process within EXACT**
- Summary

QC Process within EXACT

- Create a New QC Analysis
- QC Reports
- Schedule a Report Group
- View Outputs and Validation Reports

➤ Create a New QC Analysis

New Table		
Study Mockup Name	T_QC_ADSL	Sponsor Mockup
Description	QC of ADSL	
Study Table Mockup	Categories :	
	Data Derivation Program Info	
	Derivation Code   <pre> 1 ods listing close ; 2 ods rtf file="&TLF_Output.\&gbfolder.\&groutfnnm..rtf" ; 3 4 /* 5 * PLEASE place your QC code here 6 */ 7 8 ods rtf close ; 9 ods listing ; </pre>	

➤ QC Reports

Microsoft Word - T_OC_ADGL.rtf (Preview)

File Edit View Insert Format Tools Table Window Help Adobe PDF Acrobat Comments

100%

Close

1 2 3 4 5 6 7 8

The COMPARE Procedure
Comparison of WORK.ADGL with WORK.OC_ADGL
(Method=EXACT)

Data Set Summary

Dataset	Created	Modified	NVar	NObs	Label
WORK.ADGL	09NOV12:06:25:59	09NOV12:06:25:59	28	70	Analysis - Subject Level Data
WORK.OC_ADGL	09NOV12:06:25:59	09NOV12:06:25:59	35	70	

Variables Summary

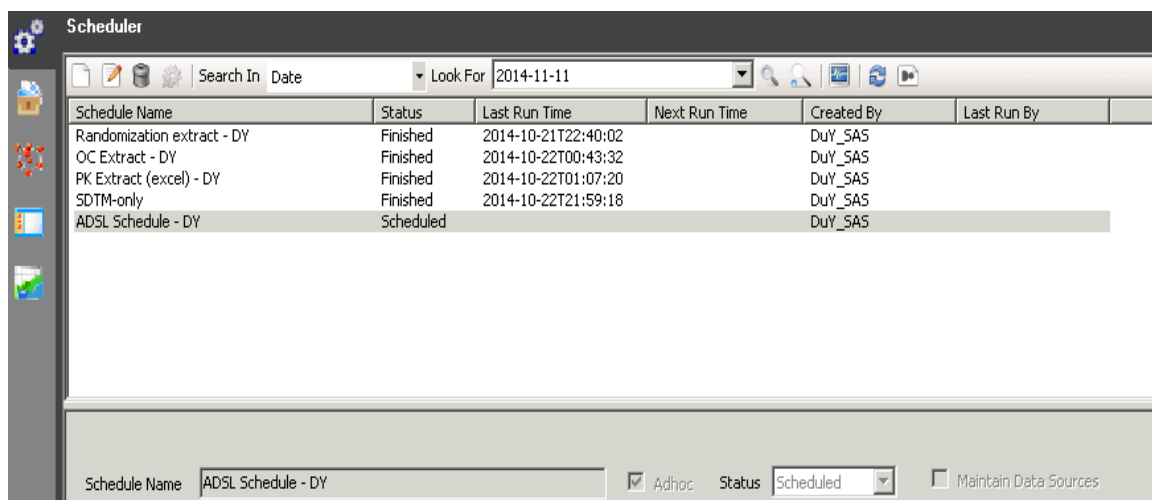
Number of Variables in Common: 28
Number of Variables in WORK.OC_ADGL but not in WORK.ADGL: 10
Number of Variables with Differing Attributes: 20
Number of ID Variables: 2

Listing of Common Variables with Differing Attributes

Variable	Dataset	Type	Length	Format	Label
BIRTHDT	WORK.ADGL	Num	8		Date of Birth
	WORK.OC_ADGL	Num	8	DATED.	Date of Birth (derived)
BIRTHDTF	WORK.ADGL	Char	8		Date of Birth Input Flag
	WORK.OC_ADGL	Char	8		
AGEDER	WORK.ADGL	Num	8		Derived Age
	WORK.OC_ADGL	Num	8		
AGEU	WORK.ADGL	Char	1		Age units
	WORK.OC_ADGL	Char	26		
SEX	WORK.ADGL	Num	8		Sex (N)
	WORK.OC_ADGL	Num	8		
RACE	WORK.ADGL	Char	40		Race
	WORK.OC_ADGL	Char	50		
RACEN	WORK.ADGL	Num	8		Race (N)
	WORK.OC_ADGL	Num	8		
APR	WORK.ADGL	Char	40		Description of Planned APR

Page 1 Sec 1 1/4 At 0.6" Ln 1 Col 1 REC TRK EXT OVR English (U.S.)

➤ Schedule a Report Group



The screenshot shows the 'Scheduler' application window. It features a toolbar with icons for file operations and a search bar. Below the toolbar is a table listing scheduled tasks. The table has columns for Schedule Name, Status, Last Run Time, Next Run Time, Created By, and Last Run By. The tasks listed are: Randomization extract - DY (Finished), OC Extract - DY (Finished), PK Extract (excel) - DY (Finished), SDTM-only (Finished), and ADSL Schedule - DY (Scheduled). The ADSL Schedule - DY task is highlighted. At the bottom of the window, there is a section for editing a task, showing the Schedule Name as 'ADSL Schedule - DY', a checked 'Adhoc' checkbox, a 'Status' dropdown set to 'Scheduled', and an unchecked 'Maintain Data Sources' checkbox.

Schedule Name	Status	Last Run Time	Next Run Time	Created By	Last Run By
Randomization extract - DY	Finished	2014-10-21T22:40:02		DuY_SAS	
OC Extract - DY	Finished	2014-10-22T00:43:32		DuY_SAS	
PK Extract (excel) - DY	Finished	2014-10-22T01:07:20		DuY_SAS	
SDTM-only	Finished	2014-10-22T21:59:18		DuY_SAS	
ADSL Schedule - DY	Scheduled			DuY_SAS	

Schedule Name: ADSL Schedule - DY

☒ Adhoc

 Status: Scheduled

☐ Maintain Data Sources

➤ View Outputs and Validation Reports

Schedules
ADSL Schedule - DY
Filter by Date
From 2014-11-12
To 2014-11-12
Fetch

Schedules
ADSL Schedule - DY
From N/A
To N/A

Schedule - Tree
Schedule - ADSL Schedule - DY (9393)
Batch ID - 57235
SC - ADSL creation group

Domain No.	Conversion	Status	Start Date Time	End Date Time
Analysis - Su...	ADSL creati...	Successfully Completed	2014-11-12T00:05:53	2014-11-12T00:05:55

Program Name	Execution Status	Program Status	Start Date Time	End Date Time
ADSL	Successfully Completed	Successfully Completed	2014-11-12T00:05:55	2014-11-12T00:05:55

Show All
Hide All
log rtf sas7bdat xpt dtd xsd css xml xsl pdf gif xlsx xls sas

File	Type	Date	File Size
Batch57235.log	log	11/12/2014 12:09:13 AM	317 KB
ADSL.log	log	11/12/2014 12:05:55 AM	10 KB
B-57235-12NOV14_ADSL creation group - SAS L...	rtf	11/12/2014 12:09:13 AM	32 KB
delinee.log	log	11/12/2014 12:06:50 AM	64 KB
VariableDerivation_ADSL.log	log	11/12/2014 12:05:53 AM	1 KB
adsl.sas7bdat	sas7bdat	11/12/2014 12:05:55 AM	65 KB
B-57235-12NOV14_ADSL creation group - Variabl...	rtf	11/12/2014 12:05:55 AM	16 KB

Summary

- Efficacy:
 - Programming time and cost
 - Quality: Standard definitions

- Safety:
 - Sufficient QC: double programming
 - Validation Reports

Q & A ?



Thank You