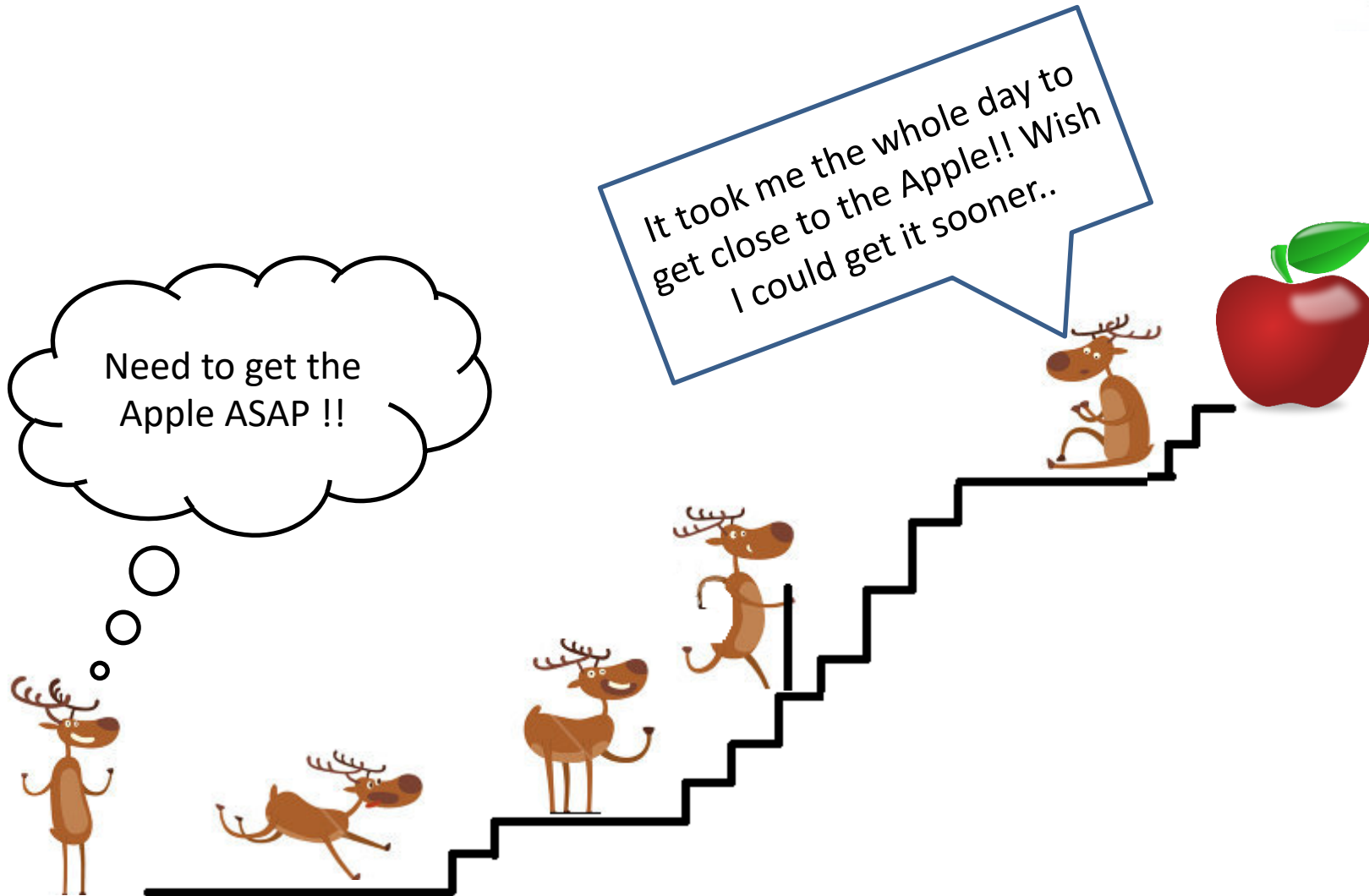


# STAG – Utility Tool for Creating ADaM datasets from SDTM



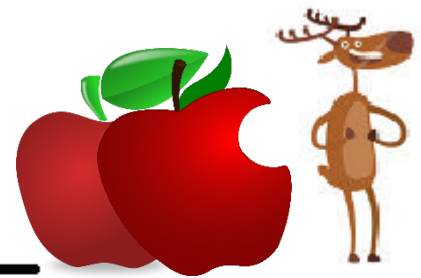
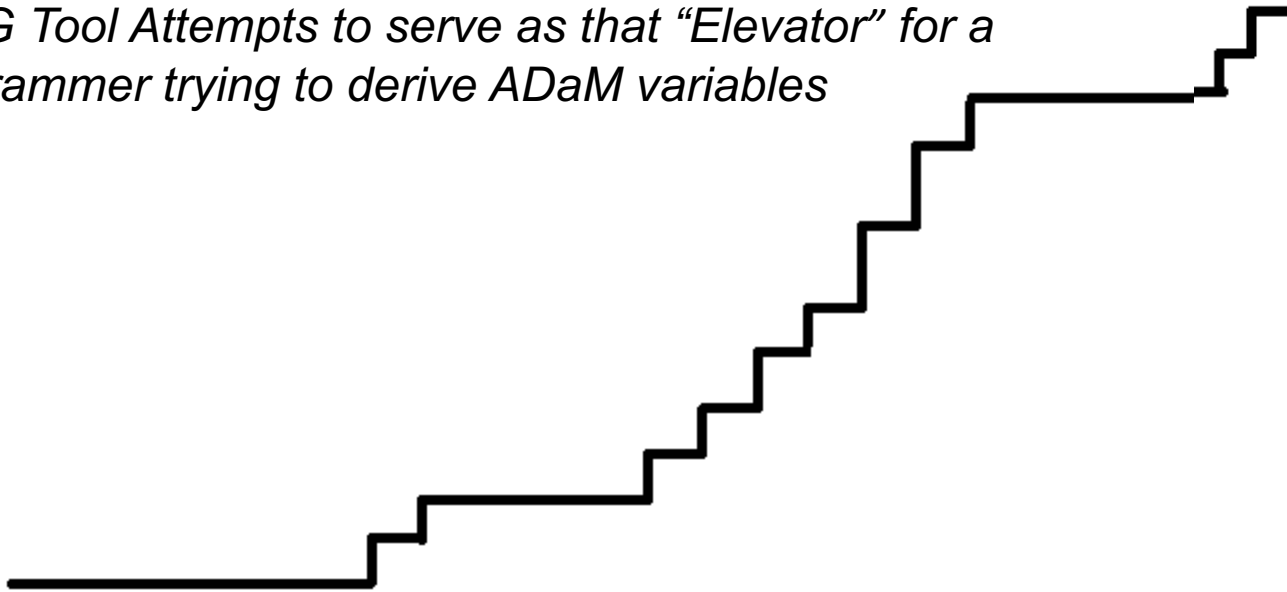
**Diganta Bose,**  
Senior Team Lead – Statistical Programming





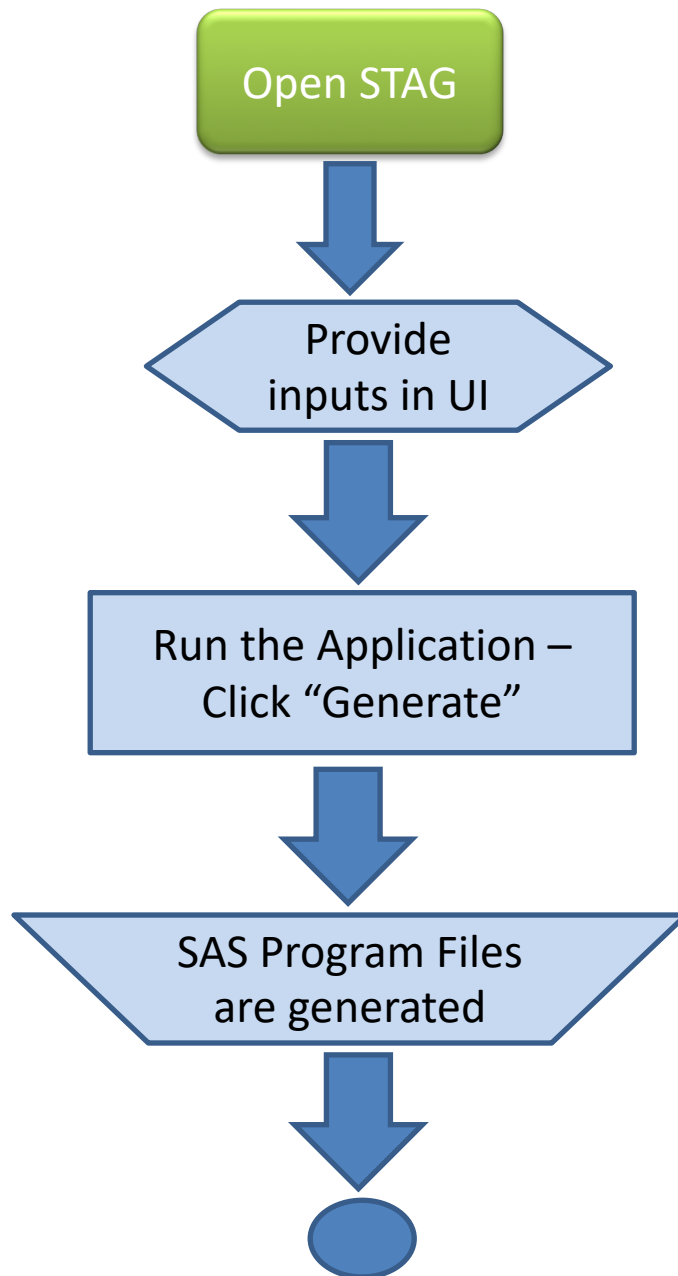
# CAN WE DO IT?

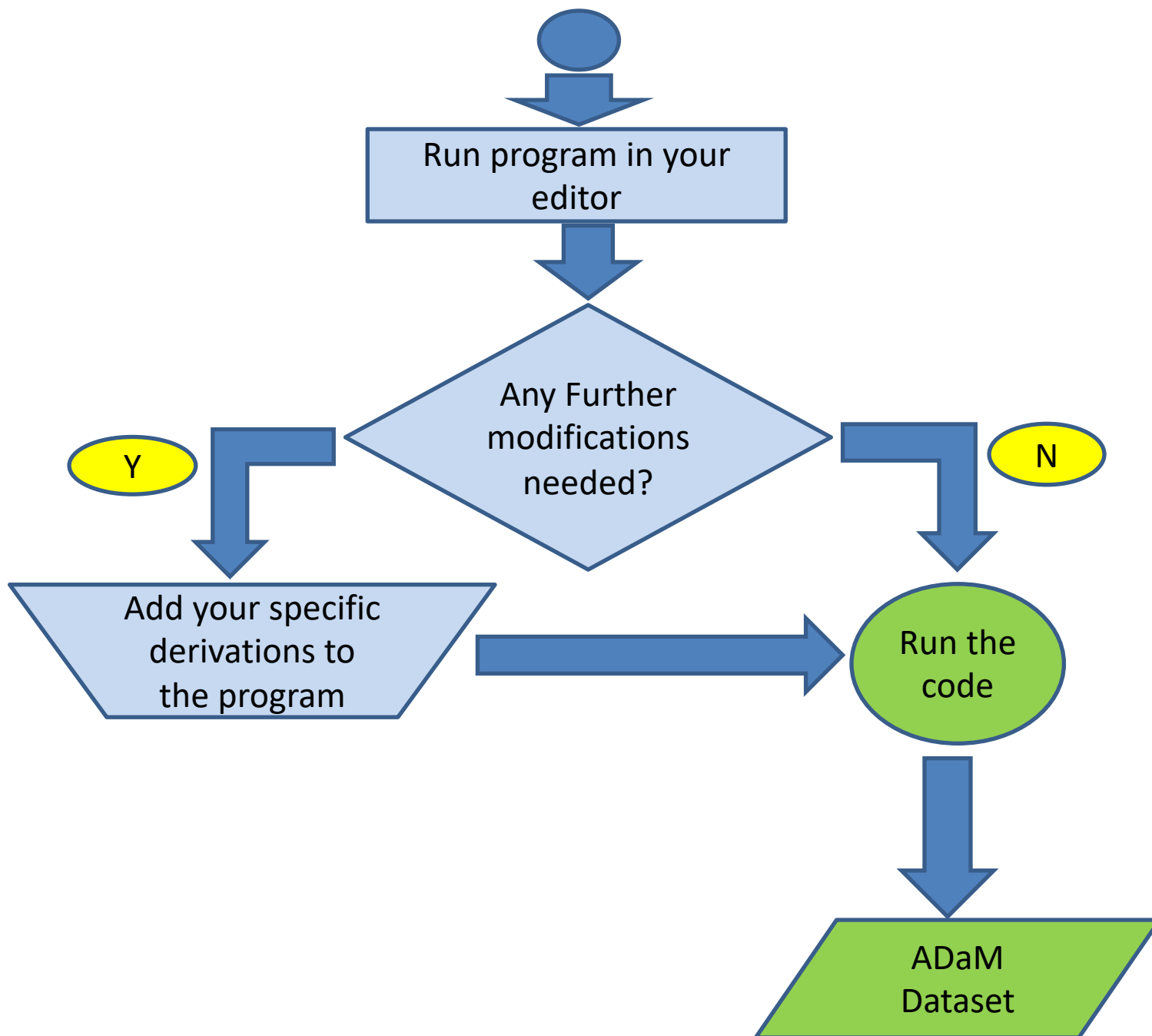
*STAG Tool Attempts to serve as that “Elevator” for a programmer trying to derive ADaM variables*



## **Highlights of the Utility – STAG (SDTM To ADaM Generation Tool)**

- Tool based ADaM Generation
- The commonly used key ADSL and BDS variables
- Front end UI
- SAS Macros/programs at the Backend





## STAG UI Screen ADSL

STAG

Adam Type

☒ ADSL
☐ BDS

Data Input

SDTM Data Library Path

Output

Output Program Path

Output Program Name

Parameter Input

Time Required?

--Select--

Time Format

Age Group List

Reset

Generate

Cancel

Help

Select Output program path

Specify you want to design ADSL or BDS?

Browse to location of all SDTM Datasets

Browse to location where you want to generate program file

Specify preferred program file name e.g. ADSL.sas

Specify "Yes" or "No" based on whether you need timeparts to be captured in Treatment Start and End Dates. If "Yes" specify time format

Specify the ranges for AGEGROUP Variables you need-Based on these variables AGEGRy(N) will be derived

# ADSL Example

## Input Data – DM and EX Data

### DM Data

|   | STUDYID | DOMAIN | USUBJID        | RFSTDTC    | RFENDTC    | AGE | SEX | RACE             | ARMCD    | ARM                |
|---|---------|--------|----------------|------------|------------|-----|-----|------------------|----------|--------------------|
| 1 | CDISC01 | DM     | CDISC01.100008 | 2003-04-29 | 2003-10-12 | 72  | M   | OTHER            | WONDER10 | Miracle Drug 10 mg |
| 2 | CDISC01 | DM     | CDISC01.100014 | 2003-10-15 | 2004-03-29 | 66  | F   | WHITE            | WONDER20 | Miracle Drug 20 mg |
| 3 | CDISC01 | DM     | CDISC01.200001 | 2003-09-30 | 2004-02-02 | 80  | F   | MULTIPLE         | PLACEBO  | Placebo            |
| 4 | CDISC01 | DM     | CDISC01.200002 | 2003-10-10 | 2004-03-28 | 70  | F   | BLACK OR AFRI... | WONDER10 | Miracle Drug 10 mg |
| 5 | CDISC01 | DM     | CDISC01.200005 |            |            | 66  | F   | WHITE            | SCRNFAIL | Screen Failure     |

### EX Data

|    | STUDYID | DOMAIN | USUBJID        | EXSEQ | EXTRT        | EXSTDTC    | EXENDTC    |
|----|---------|--------|----------------|-------|--------------|------------|------------|
| 1  | CDISC01 | EX     | CDISC01.100008 | 1     | Miracle Drug | 2003-04-29 | 2003-05-05 |
| 2  | CDISC01 | EX     | CDISC01.100008 | 2     | Miracle Drug | 2003-05-06 | 2003-05-12 |
| 3  | CDISC01 | EX     | CDISC01.100008 | 3     | Miracle Drug | 2003-05-13 | 2003-05-19 |
| 4  | CDISC01 | EX     | CDISC01.100008 | 4     | Miracle Drug | 2003-05-20 | 2003-05-27 |
| 5  | CDISC01 | EX     | CDISC01.100014 | 1     | Miracle Drug | 2003-10-15 | 2003-10-21 |
| 6  | CDISC01 | EX     | CDISC01.100014 | 2     | Miracle Drug | 2003-10-22 | 2003-10-30 |
| 7  | CDISC01 | EX     | CDISC01.100014 | 3     | Miracle Drug | 2003-10-31 | 2003-11-11 |
| 8  | CDISC01 | EX     | CDISC01.200001 | 1     | Placebo      | 2003-09-30 | 2003-10-06 |
| 9  | CDISC01 | EX     | CDISC01.200001 | 2     | Placebo      | 2003-10-07 | 2003-10-13 |
| 10 | CDISC01 | EX     | CDISC01.200001 | 3     | Placebo      | 2003-10-14 | 2003-10-20 |
| 11 | CDISC01 | EX     | CDISC01.200001 | 4     | Placebo      | 2003-10-21 | 2003-10-27 |
| 12 | CDISC01 | EX     | CDISC01.200002 | 1     | Miracle Drug | 2003-10-10 | 2003-10-16 |
| 13 | CDISC01 | EX     | CDISC01.200002 | 2     | Miracle Drug | 2003-10-17 | 2003-10-18 |
| 14 | CDISC01 | EX     | CDISC01.200002 | 3     | Miracle Drug | 2003-10-19 | 2003-10-23 |
| 15 | CDISC01 | EX     | CDISC01.200002 | 4     | Miracle Drug | 2003-10-24 | 2003-10-30 |
| 16 | CDISC01 | EX     | CDISC01.200002 | 5     | Miracle Drug | 2003-10-31 | 2003-11-05 |
| 17 | CDISC01 | EX     | CDISC01.200002 | 6     | Miracle Drug | 2003-11-06 | 2003-11-06 |

# ADSL Demo

## *Inputs entered in STAG UI*

STAG

Adam Type

☒ ADSL
☐ BDS

Data Input

SDTM Data Library Path

XYZ/.... /foldername.....
generic\_adam\_macros\phase1\_dry\_run
...

Output

Output Program Path

XYZ/.... /foldername.....
generic\_adam\_macros\phase1\_dry\_run
...

Output Program Name

adsl\_test

Parameter Input

Time Required?

No

Time Format

Age Group List

>>

<<

0 - 17 # 18 - 45 # 46 - 70 # Abov  
Below 18 # 18 - 65 # Above 65

Reset

Generate

Cancel

Help

Provide hash separated age group List.  
e.g.0-15# 16-30#31-50#above 50

ADSL\_TEST.SAS Generated at specified location

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## ADSL Demo

### *Sample Code Generated By STAG*

```
*=====
libname sdtm_dt 'XYZ/.../foldername.....'
%include 'XYZ/.../foldername.....'
%include 'XYZ/.../foldername.....'
%include 'XYZ/.../foldername.....'

/*Create dummy_ex with formatted EXTRT to match with ARM and ACTARM*/
%dummy_ex(sdtm_lib=sdtm_dt);

/*Create pre_adsl dataset in work library*/
%generic_adsl(sdtm_lib=sdtm_dt, exds=dummy_ex, timereq=No, agegroup=0 - 17 # 18 - 45 # 46

/*If more variables need to be derived in pre_adsl write your code below*/
```



Run the piece of code generated by STAG to  
assess to what extent ADaM ADSL variables  
are derived

# ADSL Demo

**Sample Output Generated by code prepared by STAG**



|   | STUDYID | USUBJID        | RFSTDTC    | RFENDTC    | AGE | SEX | ARMCD    | ARM                |
|---|---------|----------------|------------|------------|-----|-----|----------|--------------------|
| 1 | CDISC01 | CDISC01.100008 | 2003-04-29 | 2003-10-12 | 72  | M   | WONDER10 | Miracle Drug 10... |
| 2 | CDISC01 | CDISC01.100014 | 2003-10-15 | 2004-03-29 | 66  | F   | WONDER20 | Miracle Drug 20    |
| 3 | CDISC01 | CDISC01.200001 | 2003-09-30 | 2004-02-02 | 80  | F   | PLACEBO  | Placebo            |
| 4 | CDISC01 | CDISC01.200002 | 2003-10-10 | 2004-03-28 | 70  | F   | WONDER10 | Miracle Drug 10... |
| 5 | CDISC01 | CDISC01        |            |            |     |     |          | Screen Failure     |

Subject Level Info from DM/SUPPDM gets pulled in

Plus Below Standard ADSL Variables added

| SAFFL | COMPLF | ITFL | TRT01P             | TRT01A             | TRT01SDT  | TRT01EDT  | AGEGR1         | AGEGR1N | AGEGR2         | AGEGR2N |
|-------|--------|------|--------------------|--------------------|-----------|-----------|----------------|---------|----------------|---------|
| Y     | Y      | Y    | Miracle Drug 10... | Miracle Drug 10... | 29APR2003 | 27MAY2003 | Above 70 Years | 4       | Above 65 Years | 3       |
| Y     | Y      | Y    | Miracle Drug 20... | Miracle Drug 20... | 15OCT2003 | 11NOV2003 | 46 - 70 Years  | 3       | Above 65 Years | 3       |
| Y     | N      | Y    | Placebo            | Placebo            | 30SEP2003 | 27OCT2003 | Above 70 Years | 4       | Above 65 Years | 3       |
| Y     | Y      | Y    | Miracle Drug 10... | Miracle Drug 10... | 10OCT2003 | 06NOV2003 | 46 - 70 Years  | 3       | Above 65 Years | 3       |
| N     | N      | N    | Screen Failure     |                    |           |           | 46 - 70 Years  | 3       | Above 65 Years | 3       |

Need More Study specific ADSL Variables ?

Add Custom code of your own below the piece of code generated by STAG

## ADSL Demo

### *Input Data – DM and EX Data*

#### *DM Data*

| STUDYID | USUBJID | BRTHTDC    | SEX | ARM                | ARMCD   | RFSTDTC    | RFENDTC    |
|---------|---------|------------|-----|--------------------|---------|------------|------------|
| CDISC01 | 001     | 1930-08-05 | M   | drugA-drugB-dru... | A-B-C-D | 2010-01-09 | 2010-04-14 |
| CDISC01 | 002     | 1936-11-01 | F   | drugD-drugC-dru... | D-C-A-B | 2010-01-11 | 2010-04-15 |
| CDISC01 | 003     | 1923-09-03 | F   | drugB-drugA-dru... | B-A-C-D | 2010-01-14 | 2010-04-20 |
| CDISC01 | 004     | 1933-07-22 | F   | drugA-drugB-dru... | A-B-D-C | 2010-01-18 | 2010-04-22 |
| CDISC01 | 005     | 1937-02-22 | F   | drugB-drugC-dru... | B-C-A-D |            |            |

#### *EX Data*

| STUDYID | DOMAIN | USUBJID | EXSEQ | EXTRT | EXDOSE | EXDOSU | EXSTDTC    | EXENDTC    |
|---------|--------|---------|-------|-------|--------|--------|------------|------------|
| CDISC01 | EX     | 001     | 1     | drugA | 20     | MG     | 2010-01-09 | 2010-01-09 |
| CDISC01 | EX     | 001     | 2     | drugA | 20     | MG     | 2010-01-10 | 2010-01-13 |
| CDISC01 | EX     | 001     | 3     | drugB | 20     | MG     | 2010-02-09 | 2010-02-09 |
| CDISC01 | EX     | 001     | 4     | drugB | 20     | MG     | 2010-02-10 | 2010-02-13 |
| CDISC01 | EX     | 001     | 5     | drugC | 20     | MG     | 2010-03-09 | 2010-03-09 |
| CDISC01 | EX     | 001     | 6     | drugC | 20     | MG     | 2010-03-10 | 2010-03-13 |
| CDISC01 | EX     | 001     | 7     | drugD | 20     | MG     | 2010-04-10 | 2010-04-10 |
| CDISC01 | EX     | 001     | 8     | drugD | 20     | MG     | 2010-04-11 | 2010-04-14 |
| CDISC01 | EX     | 002     | 1     | drugD | 20     | MG     | 2010-01-11 | 2010-01-11 |
| CDISC01 | EX     | 002     | 2     | drugD | 20     | MG     | 2010-01-12 | 2010-01-15 |
| CDISC01 | EX     | 002     | 3     | drugC | 20     | MG     | 2010-02-11 | 2010-02-11 |
| CDISC01 | EX     | 002     | 4     | drugC | 20     | MG     | 2010-02-12 | 2010-02-15 |

## ADSL Demo

***Output Data – as generated by code from STAG (Showing Only Treatment Variables)***

|  USUBJID |  TRT01P |  TRT02P |  TRT03P |  TRT04P |  TRT01A |  TRT02A |  TRT03A |  TRT04A |
|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 001                                                                                     | drugA                                                                                    | drugB                                                                                    | drugC                                                                                    | drugD                                                                                    | drugA                                                                                      | drugB                                                                                      | drugC                                                                                      | drugD                                                                                      |
| 002                                                                                     | drugD                                                                                    | drugC                                                                                    | drugA                                                                                    | drugB                                                                                    | drugD                                                                                      | drugC                                                                                      | drugA                                                                                      | drugB                                                                                      |
| 003                                                                                     | drugB                                                                                    | drugA                                                                                    | drugC                                                                                    | drugD                                                                                    | drugB                                                                                      | drugA                                                                                      | drugC                                                                                      | drugD                                                                                      |
| 004                                                                                     | drugA                                                                                    | drugB                                                                                    | drugD                                                                                    | drugC                                                                                    | drugA                                                                                      | drugB                                                                                      | drugD                                                                                      | drugC                                                                                      |
| 005                                                                                     | drugB                                                                                    | drugC                                                                                    | drugA                                                                                    | drugD                                                                                    |                                                                                            |                                                                                            |                                                                                            |                                                                                            |

|  TRT01SDT |  TRT02SDT |  TRT03SDT |  TRT04SDT |  TRT01EDT |  TRT02EDT |  TRT03EDT |  TRT04EDT |
|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| 09JAN2010                                                                                | 09FEB2010                                                                                  | 09MAR2010                                                                                  | 10APR2010                                                                                  | 13JAN2010                                                                                  | 13FEB2010                                                                                    | 13MAR2010                                                                                    | 14APR2010                                                                                    |
| 11JAN2010                                                                                | 11FEB2010                                                                                  | 11MAR2010                                                                                  | 11APR2010                                                                                  | 15JAN2010                                                                                  | 15FEB2010                                                                                    | 15MAR2010                                                                                    | 15APR2010                                                                                    |
| 14JAN2010                                                                                | 14FEB2010                                                                                  | 14MAR2010                                                                                  | 14APR2010                                                                                  | 19JAN2010                                                                                  | 19FEB2010                                                                                    | 19MAR2010                                                                                    | 20APR2010                                                                                    |
| 18JAN2010                                                                                | 18FEB2010                                                                                  | 18MAR2010                                                                                  | 18APR2010                                                                                  | 22JAN2010                                                                                  | 22FEB2010                                                                                    | 22MAR2010                                                                                    | 22APR2010                                                                                    |
| *                                                                                        | *                                                                                          | *                                                                                          | *                                                                                          | *                                                                                          | *                                                                                            | *                                                                                            | *                                                                                            |

# STAG UI Screen BDS Screen 1

STAG

Adam Type

☐ ADSL
☒ BDS

Input\_1 | Input\_2

Input

Domain

SDTM Library Path

ADSL Data

Output Program Location

Output Program Name

Additional Param Option(s)

☐ unit  
☐ pos  
☐ spec  
☐ loc  
☐ method  
☐ nam

Time Required?

--Select--

Time Format

Baseline

Definition

--Select--

Function

--Select--

Subset Condition

CHG Required?

--Select--

Reset

Generate

Cancel

Help

Enter the name of the SDTM Domain from which ADaM BDS has to be created  
e.g. Enter 'lb' when you need to create ADaM ADLB from SDTM LB.

Specify 2 Letter SDTM Domain Abbreviation – e.g. for ADLB enter “LB”

Browse to location where the study ADSL is placed

What else you need to add to include in the PARAM(CD) ? E.G. For example for ADVS PARAM May include Units

Specify “Yes” or “No” based on your need timeparts to be captured in ADT(M). If “Yes” specify time format

Baseline Flag derivations vary from one study to another, Use these fields to define them.

Enter “Yes” or “No” based on you need “Change from Baseline” Derived

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## STAG UI Screen BDS Screen 2

STAG

Adam Type ☐ ADSL ☒ BDS

Input\_1 Input\_2

Visit

Copy SDTM Visits?  Visit File

☒ Define Missing Value Imputation and EndPoint Rule

Do you want to define Same Imputaion & End Point Rule for entire data? ☒ Yes ☐ No

Impute Missing?  Method

End point ?  Function

EndPoint Subsetting condition

Derive EndPt of Last 'X' Post Baseline Records?  'X' records

Reset Generate Cancel

Help

Select 'Yes' if visit values to be

Browse to the excel file that defines "Visit Windowing" based on ADY Targets, This will be used to derive AVISIT(N). If you just simply want to copy SDTM VISIT(NUM) to AVISIT then Select "No"

Check if you need to add derived records

You want to add similar Derived Records for all the Parameters in the Given BDS ?

Use these fields to define how you want your derived records - Current Options available are LOCF and BLOCF for missing value imputations and Common Functions for Derived Endpoint Records

## BDS Demo

*Derivation of Baseline related variables may need you to focus on Certain Terminologies used in STAG to understand your study's Baseline Definition better*

The screenshot shows a software interface for defining baseline variables. The 'Baseline' section is highlighted with a red box. Within this section, the 'Definition' dropdown menu is open, showing options: '--Select--', 'GENERIC', 'CUSTOM', 'DERIVED', and 'OTHER'. The 'Subset Condition' label is also circled in red. The 'Function' label is circled in red. The 'Time Required?' dropdown is set to '--Select--'. The 'Time Format' field is empty. The 'CHG Required?' checkbox is unchecked. At the bottom, there are three buttons: 'Reset', 'Generate', and 'Cancel'.

Time Required? --Select-- Time Format

**Baseline**

Definition --Select-- Function --Select--

Subset Condition

CHG Required?

GENERIC  
CUSTOM  
DERIVED  
OTHER

Reset Generate Cancel

## BDS Demo ADLB

### *Input Data – SDTM LB Data (showing only important SDTM Variables)*

| STUDYID | USUBJID        | LBSEQ | LBTESTCD | LBTEST              | LBCAT      | LBORRES  | LBSTRESC | LBSTRESN | LBSTRESU | LBSPEC | VISIT   |
|---------|----------------|-------|----------|---------------------|------------|----------|----------|----------|----------|--------|---------|
| CDISC01 | CDISC01.100008 | 1     | BILI     | Bilirubin           | CHEMISTRY  | 0.4      | 6.8      | 6.8      | umol/L   | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 2     | BILI     | Bilirubin           | CHEMISTRY  | 0.3      | 5.1      | 5.1      | umol/L   | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 3     | BUN      | Blood Urea Nitro... | CHEMISTRY  | 26       | 9.28     | 9.28     | mmol/L   | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 4     | BUN      | Blood Urea Nitro... | CHEMISTRY  | 18       | 6.43     | 6.43     | mmol/L   | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 5     | GLUC     | Glucose             | CHEMISTRY  | 100      | 5.5      | 5.5      | mmol/L   | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 6     | GLUC     | Glucose             | CHEMISTRY  | 87       | 4.8      | 4.8      | mmol/L   | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 7     | VITB12   | Vitamin B12         | CHEMISTRY  | 366      | 270      | 270      | pmol/L   | SERUM  | SCREEN  |
| CDISC01 | CDISC01.100008 | 8     | VITB9    | Vitamin B9          | CHEMISTRY  | 55.8     | 126.4    | 126.4    | nmol/L   | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 9     | HCT      | Hematocrit          | HEMATOLOGY | 36.2     | 0.36     | 0.36     |          | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 10    | HCT      | Hematocrit          | HEMATOLOGY | 32.9     | 0.33     | 0.33     |          | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 11    | HGB      | Hemoglobin          | HEMATOLOGY | 12.0     | 120      | 120      | g/L      | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 12    | HGB      | Hemoglobin          | HEMATOLOGY | 11.3     | 113      | 113      | g/L      | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 13    | LYM      | Lymphocytes         | HEMATOLOGY | 1.68     | 1.68     | 1.68     | 10**9/L  | BLOOD  | SCREEN  |
| CDISC01 | CDISC01.100008 | 14    | LYM      | Lymphocytes         | HEMATOLOGY | 1.34     | 1.34     | 1.34     | 10**9/L  | BLOOD  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 15    | OCCBLD   | Occult Blood        | URINALYSIS | 1+       | 1+       | .        |          | URINE  | SCREEN  |
| CDISC01 | CDISC01.100008 | 16    | OCCBLD   | Occult Blood        | URINALYSIS | NEGATIVE | NEGATIVE | .        |          | URINE  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 17    | PH       | pH                  | URINALYSIS | 8.0      | 8        | 8        |          | URINE  | SCREEN  |
| CDISC01 | CDISC01.100008 | 18    | PH       | pH                  | URINALYSIS | 8.0      | 8        | 8        |          | URINE  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 19    | GLUC     | Glucose             | URINALYSIS | NEGATIVE | NEGATIVE | .        |          | URINE  | SCREEN  |
| CDISC01 | CDISC01.100008 | 20    | GLUC     | Glucose             | URINALYSIS | TRACE    | TRACE    | .        |          | URINE  | WEEK 24 |
| CDISC01 | CDISC01.100008 | 21    | GLUC     | Glucose             | URINALYSIS | 10       | 0.6      | 0.6      | mmol/L   | URINE  | SCREEN  |
| CDISC01 | CDISC01.100008 | 22    | GLUC     | Glucose             | URINALYSIS | 30       | 1.7      | 1.7      | mmol/L   | URINE  | WEEK 24 |

# BDS Demo ADLB

## *Inputs entered in STAG UI*

STAG

Adam Type

☐ ADSL
 ☒ BDS

Input\_1 | Input\_2

Input

Domain

LB

SDTM Library Path

XYZ/.... /foldername.....

...

ADSL Data

XYZ/.... /foldername.....

...

Output Program Location

XYZ/.... /foldername.....

...

Output Program Name

ADLB\_test

☒ unit
 ☐ pos
 ☒ spec
 ☐ loc
 ☒ method
 ☐ nam

Additional Param Option(s)

Time Required?

Yes

Time Format

time5

Baseline

Definition

GENERIC

Function

--Select--

Subset Condition

CHG Required?

Yes

Reset

Generate

Cancel

Help

Select 'Yes' if want the program to derive change from baseline i.e. ADaM BDS Variable 'CHG'. Else select 'No'

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## BDS Demo ADLB

### *Sample Code Generated By STAG*

```
libname sdtm_dt 'XYZ/... /foldername.....'
libname adam_dt 'XYZ/... /foldername.....'
%include 'XYZ/... /foldername.....'
%include 'XYZ/... /foldername.....'
%include 'XYZ/... /foldername.....'
%include 'XYZ/... /foldername.....'

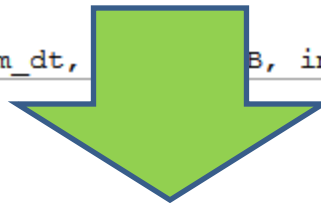
/*%generic_bds0x Macro Call*/
%generic_bds0x(sdtm_lib=sdtm_dt, domain=LB, add= unit spec method, adsl_data=adam_dt.adsl, basedef=GENE

/*Avisit Macro call*/
%avisit(indata=work.bds_LB, copy_sdtmvis=Yes);

data bds_out;
    set bds_vis_out;
run;

/*%generic_bds0y Macro Call*/
%generic_bds0y(inds=bds_out, sdtm_lib=sdtm_dt, LB, impmissyn=no, endtptyn=no);

data pre_bds_LB;
    set bds_out_der_recs;
run;
```



Run the piece of code generated by STAG to  
assess to what extent ADaM ADLB variables  
are derived

# BDS Demo ADLB

**Sample Output Generated by code prepared by STAG**

| USUBJID        | PARAM                                | PARAMN | PARAMCD | AVAL  | AVALC    | ADT       | ATM   | ADTM             | ABLFL | BASE | BASEC    | CHG   |
|----------------|--------------------------------------|--------|---------|-------|----------|-----------|-------|------------------|-------|------|----------|-------|
| CDISC01.100008 | Bilirubin (umol/L) (BLOOD)           | 1      | BILI    | 6.8   | 6.8      | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 6.8  | 6.8      | 0     |
| CDISC01.100008 | Bilirubin (umol/L) (BLOOD)           | 1      | BILI    | 5.1   | 5.1      | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 6.8  | 6.8      | -1.7  |
| CDISC01.100008 | Blood Urea Nitrogen (mmol/L) (BLOOD) | 2      | BUN     | 9.28  | 9.28     | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 9.28 | 9.28     | 0     |
| CDISC01.100008 | Blood Urea Nitrogen (mmol/L) (BLOOD) | 2      | BUN     | 6.43  | 6.43     | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 9.28 | 9.28     | -2.85 |
| CDISC01.100008 | Glucose (URINE) (DIPSTICK)           | 3      | GLUC1   |       | NEGATIVE | 15APR2003 | 11:20 | 15APR03:11:20... | Y     |      | NEGATIVE |       |
| CDISC01.100008 | Glucose (URINE) (DIPSTICK)           | 3      | GLUC1   |       | TRACE    | 13OCT2003 | 11:55 | 13OCT03:11:55... |       |      | NEGATIVE |       |
| CDISC01.100008 | Glucose (mmol/L) (BLOOD)             | 4      | GLUC2   | 5.5   | 5.5      | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 5.5  | 5.5      | 0     |
| CDISC01.100008 | Glucose (mmol/L) (BLOOD)             | 4      | GLUC2   | 4.8   | 4.8      | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 5.5  | 5.5      | -0.7  |
| CDISC01.100008 | Glucose (mmol/L) (URINE) (QUANT)     | 5      | GLUC3   | 0.6   | 0.6      | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 0.6  | 0.6      | 0     |
| CDISC01.100008 | Glucose (mmol/L) (URINE) (QUANT)     | 5      | GLUC3   | 1.7   | 1.7      | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 0.6  | 0.6      | 1.1   |
| CDISC01.100008 | Hematocrit (BLOOD)                   | 6      | HCT     | 0.36  | 0.36     | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 0.36 | 0.36     | 0     |
| CDISC01.100008 | Hematocrit (BLOOD)                   | 6      | HCT     | 0.33  | 0.33     | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 0.36 | 0.36     | -0.03 |
| CDISC01.100008 | Hemoglobin (g/L) (BLOOD)             | 7      | HGB     | 120   | 120      | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 120  | 120      | 0     |
| CDISC01.100008 | Hemoglobin (g/L) (BLOOD)             | 7      | HGB     | 113   | 113      | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 120  | 120      | -7    |
| CDISC01.100008 | Lymphocytes (10**9/L) (BLOOD)        | 8      | LYM     | 1.68  | 1.68     | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 1.68 | 1.68     | 0     |
| CDISC01.100008 | Lymphocytes (10**9/L) (BLOOD)        | 8      | LYM     | 1.34  | 1.34     | 13OCT2003 | 11:55 | 13OCT03:11:55... |       | 1.68 | 1.68     | -0.34 |
| CDISC01.100008 | Occult Blood (URINE)                 | 9      | OCCBLD  |       | 1+       | 15APR2003 | 11:20 | 15APR03:11:20... | Y     |      | 1+       |       |
| CDISC01.100008 | Occult Blood (URINE)                 | 9      | OCCBLD  |       | NEGATIVE | 13OCT2003 | 11:55 | 13OCT03:11:55... |       |      | 1+       |       |
| CDISC01.100008 | Vitamin B12 (pmol/L) (SERUM)         | 10     | VITB12  | 270   | 270      | 15APR2003 | 11:20 | 15APR03:11:20... | Y     | 270  | 270      | 0     |
| CDISC01.100008 | Vitamin B9 (nmol/L) (BLOOD)          |        |         | 126.4 | 126.4    | 15APR2003 |       |                  |       |      |          | 0     |
| CDISC01.100008 | pH (URINE)                           |        |         |       |          | 15APR2003 |       |                  |       |      |          | 0     |
| CDISC01.100008 | pH (URINE)                           |        |         |       |          | 13OCT2003 |       |                  |       |      |          | 0     |

Need More  
Study specific  
ADLB Variables  
?

Add Custom code of your  
own below the piece of  
code generated by STAG

# **BDS Demo ADLB (Derived Records)**

*Input Data Sample Showing only some of the relevant variables*

| USUBJID        | COMPLFL | ITTF | SAFFL | TRT01A             | TRT01SDT  | TRT01EDT  | PARAMCD | AVAL |
|----------------|---------|------|-------|--------------------|-----------|-----------|---------|------|
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HCT     | 0.36 |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HCT     | 0.33 |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HCT     | 0.33 |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HCT     | 0.45 |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HGB     | 120  |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HGB     | 113  |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HGB     | 113  |
| CDISC01.100008 | Y       | Y    | Y     | Miracle Drug 10... | 29APR2003 | 27MAY2003 | HGB     | 113  |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HCT     | 0.46 |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HCT     | 0.48 |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HCT     | 0.43 |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HGB     | 140  |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HGB     | 135  |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HGB     | 135  |
| CDISC01.200001 | N       | Y    | Y     | Placebo            | 30SEP2003 | 27OCT2003 | HGB     | 135  |

| ADTM              | ABLFL | BASE | CHG   | AVISIT  |
|-------------------|-------|------|-------|---------|
| 15APR03:11:20:... | Y     | 0.36 | 0     | SCREEN  |
| 13OCT03:11:55:... |       | 0.36 | -0.03 | WEEK 24 |
| 13NOV03:11:55:... |       | 0.36 | -0.03 | WEEK 28 |
| 13DEC03:11:55:... |       | 0.36 | 0.09  | WEEK 32 |
| 15APR03:11:20:... | Y     | 120  | 0     | SCREEN  |
| 13OCT03:11:55:... |       | 120  | -7    | WEEK 24 |
| 13NOV03:11:55:... |       | 120  | -7    | WEEK 28 |
| 13DEC03:11:55:... |       | 120  | -7    | WEEK 32 |
| 09SEP03:11:02:... | Y     | 0.46 | 0     | SCREEN  |
| 02FEB04:08:58:... |       | 0.46 | 0.02  | WEEK 24 |
| 02MAR04:08:58:... |       | 0.46 | -0.03 | WEEK 28 |
| 09SEP03:11:02:... | Y     | 140  | 0     | SCREEN  |
| 02FEB04:08:58:... |       | 140  | -5    | WEEK 24 |
| 02MAR04:08:58:... |       | 140  | -5    | WEEK 28 |
| 02APR04:08:58:... |       | 140  | -5    | WEEK 32 |

This Subject  
Has no value  
for "HCT" at  
"Week 32"

## BDS Demo ADLB (Derived Records)

Suppose your SAP tells you to impute missing values using BLOCF Method (Baseline Observation Carried Forward).

☒ Define Missing Value Imputation and EndPoint Rule

Do you want to define Same Imputaion & End Point Rule for entire data? ☒ Yes ☐ No, I would like to define d rules for diff. subsets

Impute Missing?  Method

End point ?  Function

| USUBJID        | PARAMCD | AVISIT  | DTYPE             |
|----------------|---------|---------|-------------------|
| CDISC01.100008 | HCT     | SCREEN  |                   |
| CDISC01.100008 | HCT     | WEEK 24 |                   |
| CDISC01.100008 | HCT     | WEEK 28 |                   |
| CDISC01.100008 | HCT     | WEEK 32 |                   |
| CDISC01.100008 | HGB     | 120     | 15APR03:11:20: Y  |
| CDISC01.100008 | HGB     | 113     | 13OCT03:11:55:... |
| CDISC01.100008 | HGB     | 113     | 13NOV03:11:55:... |
| CDISC01.100008 | HGB     | 113     | 13DEC03:11:55:... |
| CDISC01.200001 | HCT     | 0.46    | 09SEP03:11:02: Y  |
| CDISC01.200001 | HCT     | 0.48    | 02FEB04:08:58:... |
| CDISC01.200001 | HCT     | 0.43    | 02MAR04:08:58:... |
| CDISC01.200001 | HCT     | 0.46    | 09SEP03:11:02:... |
| CDISC01.200001 | HGB     | 140     | 09SEP03:11:02: Y  |
| CDISC01.200001 | HGB     | 135     | 02FEB04:08:58:... |
| CDISC01.200001 | HGB     | 135     | 02MAR04:08:58:... |
| CDISC01.200001 | HGB     | 135     | 02APR04:08:58:... |

BLOCF

## BDS Demo ADLB (Derived Records)

SAP DOES NOT tell you to impute missing. But it is stated that “endpoint” measurement for Haematocrit is the post baseline measurement

☒ Define Missing Value Imputation and EndPoint Rule

Do you want to define Same Imputation & End Point Rule for entire data? ☒ Yes ☐ No, I would like to define rules for diff. subsets

Impute Missing?

No

Method

--Select--

End point ?

Yes

Function

Avg

EndPoint Subsetting condition

ABLFL ^= Y

Derive EndPt of Last 'X' Post Baseline Records?

Yes

'X' records

2

| USUBJID        | PARAMCD | AVISIT          | DTYPE   |
|----------------|---------|-----------------|---------|
| CDISC01.100008 | HCT     | 0 SCREEN        |         |
| CDISC01.100008 | HCT     | -0.03 WEEK 24   |         |
| CDISC01.100008 | HCT     | -0.03 WEEK 28   |         |
| CDISC01.100008 | HCT     | 0.09 WEEK 32    |         |
| CDISC01.100008 | HCT     | 0.03 ENDPOINT   | AVERAGE |
| CDISC01.100008 | HGB     | 0 SCREEN        |         |
| CDISC01.100008 | HGB     | -7 WEEK 24      |         |
| CDISC01.100008 | HGB     | -7 WEEK 28      |         |
| CDISC01.100008 | HGB     | -7 WEEK 32      |         |
| CDISC01.100008 | HGB     | -7 ENDPOINT     | AVERAGE |
| CDISC01.200001 | HCT     | 0 SCREEN        |         |
| CDISC01.200001 | HCT     | 0.02 WEEK 24    |         |
| CDISC01.200001 | HCT     | -0.03 WEEK 28   |         |
| CDISC01.200001 | HCT     | -0.005 ENDPOINT | AVERAGE |
| CDISC01.200001 | HGB     | 0 SCREEN        |         |
| CDISC01.200001 | HGB     | -5 WEEK 24      |         |
| CDISC01.200001 | HGB     | -5 WEEK 28      |         |
| CDISC01.200001 | HGB     | -5 WEEK 32      |         |
| CDISC01.200001 | HGB     | -5 ENDPOINT     | AVERAGE |

## **BDS Demo ADLB (Derived Records)**

Suppose your SAP tells you derive “endpoint” measurement as the “Average” of “all available post baseline measurements” for HGB and to impute missing values using LOCF Method for HCT and BLOCF for HCT

| USUBJID        | PAR |
|----------------|-----|
| CDISC01.200001 | HCT |
| CDISC01.200001 | HCT |
| CDISC01.200001 | HCT |
| CDISC01.200001 | HCT |
| CDISC01.200001 | HGB |
| CDISC01.200001 | HGB |
| CDISC01.200001 | HGB |
| CDISC01.200001 | HGB |
| CDISC01.200001 | HGB |
| CDISC01.200001 | HGB |

☒ Define Missing Value Imputation and EndPoint Rule

Do you want to define Same Imputaion & End Point Rule for entire data? 
 ☐ Yes 
 ☒ No, I would like to define diff. rules for diff. subsets

Subset Condition

Impute Missing?

Method

End point ?

Function

EndPoint Subsetting condition

Derive EndPt of Last 'X' Post Baseline Records?

'X' records

| # | Subset                | Imp Missing | Method | End Point | Function | Endpt Subset |
|---|-----------------------|-------------|--------|-----------|----------|--------------|
| 2 | PARAMCD = "HGB"       | No          | -      | Yes       | Avg      | ABLFL ^= "Y" |
| 2 | where PARAMCD = "HCT" | Yes         | LOCF   | No        | -        | -            |

| AVISIT   | DTYPE   |
|----------|---------|
| SCREEN   |         |
| WEEK 24  |         |
| WEEK 28  |         |
| WEEK 32  | LOCF    |
| SCREEN   |         |
| WEEK 24  |         |
| WEEK 28  |         |
| WEEK 32  |         |
| ENDPOINT | AVERAGE |

### Scope and Limitations

- ADSL - Suitable ideally for common forms of study designs that has Exposure
- BDS ADaMs that are derived out of “General Observation Class Findings” SDTM Domains are covered so far
- Cannot handle complicated BDS ADaM in a straight forward way. (ADaM BDS sourced from multiple SDTM Datasets e.g. ADTTE or complex efficacy)

### Work in Progress

- ✓ More flexible options evaluated, cater to wider range of Analysis Requirements
- ✓ Cater to More Complex requirements
  - the challenge: Too Many possibilities and variations across Analysis Requirements!!
- ✓ Simpler “Other ADaMs” like the ADAE will be covered shortly, based on Developer’s availability

**Thanks for Your Time**