**EFC6521**

* De-identification performed off of CSR SDTM datasets.
* The ADS datasets copied over from WISE2 have been zipped up into /ADS\_SDS/ADS(orig).zip.
* Raw data files not used in de-identification.
* Includes only Control Group patients.

**Data origins:  
All xpt files (SDTM datasets copied from Wise2 to Wise3)**

From Wise2: DEVOPS/AVE5026/EFC6521/CSR/ESUB/DATA

To Wise3: DEVOPS\AVE5026\EFC6521\DATASPHERE\ESUB\DATA (xpt files - SDTM)

**WISE3: DEVOPS\AVE5026\EFC6521\DATASPHERE\EXTERNAL\IMPORT (xpt unpacked files - SDTM)**

**All datasets (ADS datsets copied from Wise2 to Wise3)**

From Wise2: DEVOPS/AVE5026/EFC6521/CSR/ADS\_SDS/DATA

To Wise3: DEVOPS/AVE5026/EFC6521/DATASPHERE /ADS\_SDS/DATA (then zipped up into ADS(orig).zip)

**RAW datasets:**  
WISE3: X:\DEVOPS\AVE5026\EFC6521\DATASPHERE\ETRANSF (not used in de-identification)

**General:  
Total of 1604 randomized subjects from control group are included in the datasets (1583 treated, 21 not treated).   
5 SDTM trial domains are included: TV, TS, TA, TE, TI.**

**AE Dataset:**

**DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

AESEQUCM Free text

AETERM Free text (kept AEDECOD)

AEMODIFY Free text

\*Replaced AEDTHDTC with AEDTHWK.

\*For AEs resulting in death, replaced AESTDY with AESTWK .

**CD Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**CE Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

CETERM Free text (kept CEDECOD)

**CM Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

AEMODIFY Free text

CMDSCOTH Free text (Reason For Discontinuation Other)

\*CMTRT was retained only where there was not a corresponding valued CMDECOD (all these cases were transfusions).

**DM Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY); Created RFSTTM for time componet.

SUBJID Pt ID

RACEOTH Free text

INVNAM Investigator name.

ETHNIC

SITEID

\*RACE – Blanked out certain subjects.

\*AGE was replaced with AGEC (character) and any ages greater than 85 were mapped to ‘>85’.

\*Country (COUNTRY) was replaced with REGION to mask small numbers which could potentially identify subjects.

The mapping is as follows (same as in CSR):

REGION: Western Europe:

AUT AUSTRIA 19

BEL BELGIUM 43

CHE SWITZERLAND 8

DEU GERMANY 227

DNK DENMARK 15

ESP SPAIN 66

FIN FINLAND 4

FRA FRANCE 102

GBR UNITED KINGDOM 72

GRC GREECE 11

IRL IRELAND 9

ITA ITALY 184

NLD NETHERLANDS 32

NOR NORWAY 3

PRT PORTUGAL 17

SWE SWEDEN 35

REGION: Eastern Europe:

BGR BULGARIA 32

BLR BELARUS 65

CZE CZECH REPUBLIC 45

EST ESTONIA 1

HRV HRVATSKA (CROATIA) 52

HUN HUNGARY 171

LTU LITHUANIA 19

LVA LATVIA 108

ROU ROMANIA 141

RUS RUSSIAN FEDERATION 323

SRB SERBIA 25

SVK SLOVAKIA 5

SVN SLOVENIA 15

POL POLAND 173

UKR UKRAINE 125

REGION: North America:

CAN CANADA 53

USA UNITED STATES OF AMERICA 182

REGION: South America:

ARG ARGENTINA 22

BRA BRAZIL 159

CHL CHILE 20

COL COLOMBIA 75

MEX MEXICO 40

PER PERU 112

REGION: Asia:

CHN CHINA 98

HKG HONG KONG 1

IDN INDONESIA 15

IND INDIA 333

KOR KOREA, REPUBLIC OF 94

MYS MALAYSIA 17

TWN TAIWAN 1

REGION: Rest of World:

ISR ISRAEL 12

ZAF SOUTH AFRICA 21

AUS AUSTRALIA 22

**DS Dataset:  
DROPPED: REASON**:xxxDTC Dates (replaced with DY) - Created DSSTTM for time

component.

DSTERM (Reported Term for the Disposition Event) Free text

DSDTCM1 (Comments on Death) Free text

DSBKNAME (Code Breaking Requester Name) Free text

DSBKTRTN (Treatment Number during Code Breaking) Free text

\*For all Death dispositions, replaced DSSTSTC with DSSTWK .

**EX Dataset:  
DROPPED: REASON**:xxxDTC Dates (replaced with DY) - Created EXSTTM for time

component.

EXLOT (Lot Number) specific drug lot #

EXLOT2 (Lot Number 2) specific drug lot #

EXLOT3 (Lot Number 3) specific drug lot #

**FA Dataset:   
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**IE Dataset: No changes**

**LB Dataset:   
DROPPED: REASON**:

xxxDTC Dates (replaced with DY) - Created LBTM for time component.

**MH Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

MHTERM Free text (MHDECOD values in all cases)

MHMODIFY Free text (MHDECOD values in all cases)

**PC Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY) - Created PCTM for time component.

**RA Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**SG Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**SV Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**VS Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

BMI records

Set VSSTRESC & VSORRES to ‘>130’ and VSSTRESN to null for subjects where weight > 130.

**VT Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY)

**Trial Domain Datasets (TV, TS, TA, TE, TI):**

No modifications were made to any of the 5 trial domains .