**EFC6521**

* De-identification performed off of CSR SDTM datasets.
* Includes only Control Group patients.

**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.

**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 .