**EFC10547**

* De-identification performed off of CSR SDTM datasets.
* Datasets Include only Control Group patients (273 subjects\*).   
  \*Note that 275 subjects were randomized to a planned treatment arm with **Placebo**, however 2 of these subjects were given Study Drug. These two patients were therefore excluded from all the de-identified datasets, bringing the total patient count down to 273.

**General:**  
A total of **273** randomized control group subjects are included in the datasets (**271** treated, **2** not treated).   
Total of **24** SDTM datasets (including the 5 SDTM trial domains: TV, TS, TA, TE, TI).

Most date fields, if not all, were replaced by a ‘days from’ reference study date variable which is based off of the randomization date for this study. The general formula to compute the ‘days from’ variable is: ((date – reference date) + 1) if the date is on or after the reference date, and (date – reference date) if the date is before the reference date.

When information on a record indicates the patient died, instead of using days since a reference time point the number of weeks until that time point was computed and the days to variable was set to missing. If the ‘days to’ variable is only associated with the date of death, then the ‘days to’ variable is dropped and only the ‘weeks to‘ variable is kept. The week value is rounded up to the next highest integer, if not an exact integer.

**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 and

- replaced AESERDY with AESERWK.

**CD Dataset:  
DROPPED: REASON**:

xxxDTC Dates (retained the DY var)

\*The Date of Progression was captured in variables CDORRES and CDSTRESC, when CDTESTCD = ‘PROGDATE’. For these cases, CDORRES and CDSTRESC were made null and a new variable (**CDPGDY**) was valued with the “Study Day of Progression”.

**CE Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY var)

CECLSICM Free Text (Clinically Significant Comment)

\*When CEDCOD has a value, CETERM and CEMODIFY are cleared out; otherwise they are left as is.

**CM Dataset:  
DROPPED: REASON**:

xxxDTC Dates (retained/replaced with DY)

CMTRT Free text (kept CMDECOD)

CMMODIFY Free text

**DM Dataset:  
DROPPED: REASON**:

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

SUBJID Pt ID (created alternate RSUBJID/RUSUBJID)

BRTHDTC Pt birth date

RACEOTH Free text

INVNAM Investigator name (default drop)

SITEID Site ID (default drop)

\*AGE was replaced with AGEC (character) and any ages greater than or equal to 84 were mapped to ‘>=84’.

\*RACE values of ‘BLACK OR AFRICAN AMERICAN’ and ‘ASIAN’ were collapsed into RACE ‘OTHER’, in order to mask small numbers. Simailarly, RACEC values (race as collected) of ‘BLACK’ and ‘ASIAN/ORIENTAL’ were collapsed into RACEC ‘OTHER’.

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

**DS Dataset:  
DROPPED: REASON**:xxxDTC Dates (retained the DY var.) - Created DSSTTM for time

component.

DSTERM (Reported Term for the Disposition Event) Free text

DSMOTH (Other Method of Contact) Free text

DSBKROTH (Code Break Other Reason) Free text

DSBKTRTN (Treatment Number during Code Breaking) Free text

DSBKNAME (Code Breaking Requester Name) Free text

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

**EG Dataset:  
DROPPED: REASON**:xxxDTC Dates (replaced with DY)

**EX Dataset:  
DROPPED: REASON**:xxxDTC Dates (replaced with DY vars).

Created EXSTTM and EXENTM hold time components.

EXTRTNBA Treatment Number as Received

EXTRTNA2 Second Treatment Number as Received

EXLOT (Lot Number) specific drug lot #

EXLOT2 (Lot Number 2) specific drug lot #

EXLOT3 (Lot Number 3) specific drug lot #

**IE Dataset:**

Required no modifications.

**LB Dataset:   
DROPPED: REASON**:

xxxDTC Dates (retained/replaced with DY)

Created LBTM and LBENTM to hold time components.

LBNAM (Vendor Name) Contains name of laboratory which reveals location information.

**LS Dataset:   
DROPPED: REASON**:

xxxDTC Dates (retained with DY)

**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)

\*Note: When MH Start Date contained only year and month, day was imputed to ‘01’ in order to derived the MHSTDY variable (Medical History Start Day).

**PC Dataset:  
DROPPED: REASON**:

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

**PE Dataset:  
DROPPED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ REASON**:

xxxDTC Dates (replaced with DY)

\*Note: Some PE records had PEORRES/PESTRESC containing ‘OTHER’ free text for Abnormal, Non-Tumor related evaluations. In these cases, the free text occurring after ‘**ABNORMAL – OTHER**’ was stripped off.

**QS Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY var)

**RA Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY vars)

**SG Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY var)

SGTRT Free text (kept SGDECOD)

**SV Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY vars)

**VS Dataset:  
DROPPED: REASON**:

xxxDTC Dates (replaced with DY var)

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

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