

Supplemental Data Definitions Document

Bigg Pharma Company

Study BPC123-001

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1. Introduction

1.1 Purpose

This document provides complex derivation descriptions, which require formatting and are too long to be displayed in the comment/derivation cell of the define.xml.

2. ADTTE – Time-to-Event Analysis Dataset

2.1 ADTTE.ADT

Derive in the following order:

1. If subject has a record with non-missing ADHO.ADT where ADHO.PARAMCD = 'HOSPDIS' and subject did not die on the day of discharge (DTHDT ne ADHO.ADT where ADHO.PARAMCD = 'HOSPDIS' or DTHDT is missing) and ((ADHO.ADT is less than or equal to D28DT and D28DT is not missing) or (D28DT is missing and ADHO.ADT is less than or equal to EOSDT and EOSDT is not missing)), then set to ADHO.ADT where ADHO.PARAMCD = 'HOSPDIS'.
 - Set CNSR to 0.
 - Set EVNTDESC = 'Subjects Discharged from Hospital Alive Before Day 28'.
 - Set SRCDOM = 'ADHO'.
 - Set SRCVAR = 'ADT'.
 - Set SRCSEQ = ADHO.ASEQ.
2. Else:
 - a) if subject discontinued study on or before day 28 visit and did not die [EOSSTT = 'DISCONTINUED' and (D28DT is missing or EOSDT <= D28DT) and DTHDT is missing], then set to discontinuation date (EOSDT).
 - Set CNSR to 1.
 - Set EVNTDESC = 'Subjects Lost to Follow-up/Discontinued Study Before or on Day 28'.
 - Set SRCDOM = 'ADSL'.
 - Set SRCVAR = 'EOSDT'.
 - Set SRCSEQ to missing.
 - b) else if subject completed day 28 visit (D28DT is not missing) and did not die or on before day 28 visit (DTHDT is missing or DTHDT > D28DT) then set to D28DT.
 - Set CNSR to 1.
 - Set EVNTDESC = 'Subjects Still in Hospital at Day 28'.
 - Set SRCDOM = 'ADSL'.
 - Set SRCVAR = 'D28DT'.
 - Set SRCSEQ to missing.
 - c) else if subject died on or before day 28 visit [DTHDT is not missing and (D28DT is missing or DTHDT <= D28DT)], then set to RANDDT + 28 days.
 - Set CNSR to 1.
 - Set EVNTDESC = 'Subjects Who Died Before or on Day 28'.
 - Set SRCDOM = 'ADSL'.
 - Set SRCVAR = 'RANDDT'.

Set SRCSEQ to missing.

- d) else set to missing.
 - Set CNSR to missing.
 - Set EVNTDESC to missing.
 - Set SRCDOM to missing.
 - Set SRCVAR to missing.
 - Set SRCSEQ to missing.