

Copy of Accrual Data Elements Table with CTRP-Accepted Values for Complete Trials - Include v4.4 - ALT 2/15/2024 v2.0

Accrual Data Elements table with CDUS-Accepted values for Complete trials

Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CDUS Accepted Values	Comments/Conditions
Study Identifier	M	Unique identifier assigned to the study	CTEP Identifier	--
Study Subject Identifier	M	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	--
ZIP Code	C	String of characters used to identify the five-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery.	5 digit numeric ZIP code	Mandatory if patient's Country of Residence is U.S.
Country of Residence	C	For non-U.S. residents only. This should be used when patient participation from foreign countries is involved. For patients from outside the U.S., enter the foreign country code. Leave blank if the patient is a U.S. resident. CTRP is using the International Standards Organization country codes. Note: Either Zip code (if U.S resident) or country code (if not U.S resident) is mandatory.	2-letter ISO Country Codes	Mandatory if not U.S.
Patient's Date of Birth	M	The month and year on which the person was born	YYYYMM	Year and Month are mandatory
Study Subject Sex	M	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	1 = Male 2 = Female 9 = Unknown	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
Ethnicity	M	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	1 = Hispanic or Latino 2 = Not Hispanic or Latino 8 = Not Reported 9 = Unknown	--
Subject Registration Date	M	Date the subject was registered to the study	YYYYMMDD	--
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTEP Site ID	--
Subject Disease Code	M	Code that identifies a disease	- CTEP Simplified Disease Code (SDC) terms - ICD-9-CM codes	Disease code is mandatory for all trials except those managed by DCP PIO. Cancer specific ICD-9-CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com 

Race	M	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	• 01 = White • 03 = Black or African American • 04 = Native Hawaiian or Other Pacific Islander • 05 = Asian • 06 = American Indian or Alaska Native • 98 = Not Reported • 99 = Unknown	--
Change Code	O	Additions or changes since the last report	--	--