Accrual Data Elements Table with CTRP-Accepted Values for Complete Trials - Include v4.4

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

Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CTRP Accepted Values	Information Model Class / Diagram Mapping	Comments/Conditions
Study Identifier	М	Unique identifier assigned to the study	NCI, CTEP, or DCP Identifier	Study Protocol / assignedIdentfier	
Study Subject Identifier	Μ	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	Study Subject / identifier	-
ZIP Code	С	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	Patient / postalAddress	Mandatory if patient's Country of Residence is U.S.
Country of Residence	С	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. <u>Note</u> : Either Zip code (if U.S resident) or country code (if not U.S resident) is mandatory.	2-letter ISO Country Codes	Patient / postalAddress	Mandatory if not U.S.
Patient's Date of Birth	м	The month and year on which the person was born	YYYYMM	Patient / birthDate	Year and Month are mandatory.
Gender of a Person	М	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	 Male Female Unspecified Unknown 	Patient / sexCode	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc. Genders in batch files do not have to correspond to the gender indicated as a trial eligibility criterion.
Ethnicity	М	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	 Hispani c or Latino Not Hispani c or Latino Not Reported Unknown 		-

Payment Method	0	Term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for	Private	StudySubject / paymentMethod	Payment Method Codes in batch files are not case-sensitive.
Method		sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service	 Private Insuran ce Medicar e and Private Insuran ce Medicai e and Private Insuran ce Medicai d and Medicai d and Medicai d and Medicare Military or Veteran s Sponsor ed (Includi ng CHAMP US & TRICA RE) Veteran s Sponsor ed Self- Pay (No Insuran ce) No Means of Payment t (No Insuran ce) Manage d Care State Supple mental Health Insuran ce Other Unknown 	Code	are not case-sensitive.
Subject Registration Date	М	Date the subject was registered to the study	YYYYMMDD	PerformedSubje ctMilestone / registrationDate	
Registering Group Code	0	Unique CTEP Group code assigned to the group that originally registered the patient for the study		StudySubject / registrationGrou pld	For trials with Group participation, provide CTEP Group Code, if available
Study Site Identifier	М	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTRP Person /Organization ID (PO ID)	Study Site / identifier	
Subject Disease Code	Μ	Code that identifies a disease	 CTEP Simplifi ed Disease Code (SDC) terms ICD-9- CM codes ICD-0- 3 codes ICD-10 	For SDC Disease Code: StudySubject / diease_identifier For ICD-9 Disease Code: StudySubject / icd9diease_iden tifier	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 For trials using ICD-O-3 terminology, use this position for Site and Morphology (which must include Histology and Behavior Codes). When using both Site and Histology codes, separate them by a semicolon (;). Site codes are available at https://codes.iarc.fr/usingicdo.php. For Disease Codes for Disease not specified, healthy volunteers and donors see Disease Codes for Disease not Specified, Healthy Volunteers and Donors - Include v4.4

Race	М	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	 America n Indian or Alaska Native Asian Black or African American Native Hawaiia n or Other Pacific Islander Not Reported Unknown White 		Multiple races in batch files are permissible even if "Not Reported" or "Unknown" is indicated.
Change Code	0	Additions or changes since the last report	• 1 • 2 • NULL	AccrualCollectio ns / changeCode	1 or NULL = changes in the file; the CTRP system processes and saves the submission 2 = If the trial's current accrual is 0, the CTRP system processes the file as a Code 1 change. If the trial's current accrual is greater than 0, the system saves the file but does not process it.