

NCI CBIIT CDEs for EC Forms

04/24/2019

CDEs to Support Eligibility Checklists (EC)

- EC Form Questions
 1. Inclusion/Exclusion Criteria
 2. Supplemental Question (not already curated CDASH elements)

EC CDEs – *Inclusion/Exclusion Criteria*

- CDASH does not provide a variable for individual inclusion/exclusion questions
- Continue to curate these CDEs using your current process

TI – Examples for Trial Inclusion/Exclusion Criteria Dataset

This example shows records for a trial that had two versions of inclusion/exclusion criteria.

Rows 1-3 show the two inclusion criteria and one exclusion criterion for version 1 of the protocol.

Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age entry from 21 to 18.

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Has disease under study	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Has disease under study	INCLUSION	2.2
5	XYZ	TI	INCL02A	Age 18 or greater	INCLUSION	2.2
6	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	2.2

EC CDEs – Supplemental Qualifiers Domain Questions

- NCI CBIT team will curate CDEs for the LPOs requesting assistance please submit request(s) to the NCI CDISC Mailbox
- Will curate only EC Forms where questions are not already curated CDASH or Inclusion/Exclusion
- For curation we will need CDISC details – LPOs provide map to SDTM
 - Variable label
 - Variable name
 - Data format
 - List of values (if enumerated)



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