

NCI CTEP CDISC Controlled Terminology *'Extensible Codelists Approach'*

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Purpose

- To collaborate with CBIIT and find a process to handle extendable codelists.

Use Case

- LPO chooses a codelist from CDISC controlled terminology (CT) that is extendable.
- LPO identifies additional values that need to be added to that the codelist **that are not semantically equivalent to existing codelist values*
- LPO sends the additional values to the CDISC mailbox for review by CDISC SME to ensure the new values:
 - Aren't semantically equivalent to existing values
 - Are appropriate to be added to said codelist
- Request sent to CBIIT to curate those additional values

Reference Information

- **CDISC Extensible Codelist:** as per EVS, “Defines if controlled terms may be added to the codelist.”
 - “New terms may be added to existing codelist values when the codelist has "Yes" in Column C as long as the terms are not duplicates or synonyms of existing terms.”
 - “The expectation is that sponsors will use the published controlled terminology as a standard baseline and codelists defined as “extensible” (or "Yes") may have terms added by the sponsor internally.”
 - “For codelists with "No" in Column C sponsor organizations may not add to the published lists.”
 - “Suggestions for new terms may be requested through the New Term Request Page.”

Discussion Items

- **Currently, per our CTEP CDISC Implementation, we are following CDISC guidelines to advise the LPOs on the use of “extensible” CT.**
- That guidance is, *“LPOs can add values to published CT lists if the CT is marked “extensible” in the CDISC documentation.”*
 - LPOs do need to submit their added values to the NCI mailbox for our CDISC SME to review and ensure that the added values are not semantically equivalent to an existing value in said codelist or aren’t appropriate for said codelist.
 - Once their values are reviewed by the CDISC SME, CTEP CDISC PM sends the values to the CBIIT curation team to be added to the existing caDSR Value Domain (VD) for reuse by other LPOs.
- **Conflicting Process:**
 - NCI CBIIT has advised that they cannot add any values (PVs/PVMs) to a value domain that was curated per published, extensible CDISC CT, unless/until the new values are approved & added by CDSIC to said CT.
 - This is a major risk for our LPOs to miss their OEWG deadlines.
 - CDISC cannot add values without following their own review process.

Recommendation

- Ask the LPOs to follow our guidance of identifying the additional values for extensible codelists, sending them to the CDISC mailbox for review, then adding them directly in Rave versus sending to the CBIIT team for curation and requesting subsequent CDISC approval and CDISC addition prior to updating the corresponding caDSR VD.
- **Potential Risks with this approach:**
 - May creates reuse challenges across the community
 - May create harmonization challenges for our CTEP CDISC Project Team. We will be dependent upon the LPOs to provide their values to us on a regular basis. This is also adds more work for the LPOs.



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