

## Steve Kopko (Contractor)

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**From:** Steve Kopko (Contractor)  
**Sent:** Tuesday, December 6, 2022 1:55 PM  
**To:** COADataStandards; CDISC FDA QRS Review  
**Cc:** Steve Kopko (Contractor); Diane Corey; Lentz, Barbara; dana.booth@merck.com; Sviglin, Helena; Wilson, Stephen E; Dlugash, Rachel; Sun, Liping; Tinghua.Chen@fda.hhs.gov; Ginsberg, Jennifer; Montes, Carlos \*; Mitchell, Sandra (NIH/NCI) [E]  
**Subject:** \*\* QRS Item \*\* Supplement V1.0 PRO-CTCAE V1.0 1st FDA Review  
**Attachments:** 2022-12-06 CDISC QRS 1st Review Request Supp V1.0 PRO-CTCAE V1.0.docx; 2022-11-21 NCI - PRO-CTCAE™ Items - English; Item Library Version 1.0\_5.3.2021 Annotated CRF.pdf; 2022-11-21 Supp\_V1.0\_SDTM QS- PRO-CTCAE V1.0 Approved NCI Review.docx; 2022-11-21 PRO-CTCAE V1.0 Reference Paper.pdf; 2022-12-06 PRO-CTCAE V1.0 Comparison 2022-09-15 and 2022-11-21.docx

Helena,

This request replaces the initial request submitted on 2022-09-19 based on updates made to the supplement with Sandy Mitchell. Attached are the following files for use with this 1st review.

- 1-page request description
- Annotated CRF
- WORD supplement
- Reference Paper
- WORD comparison document comparing the 2022-09-15 version with the 2022-11-21 version. This was provided based on discussion with the QSuRT team.

Please let me know if you have any questions.

Steve



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