

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Monday, September 19, 2022 12:55 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Dana Booth; Diane Corey; barbara.lentz@abbvie.com; Sviglin, Helena; Wilson, Stephen E; Ginsberg, Jennifer; Dlugash, Rachel; Sun, Liping
Subject: ** QRS Item ** Supplement V1.0 PRO-CTCAE V1.0 1st FDA Review
Attachments: 2022-09-19 CDISC QRS 1st Review Request Supp V1.0 PRO-CTCAE V1.0.docx; 2022-09-15 NCI - PRO-CTCAE™ Items - English; Item Library Version 1.0_5.3.2021 Annotated CRF.pdf; 2022-09-15 Supp_V1.0_SD TM QS- PRO-CTCAE V1.0 Approved.docx

Helena,

Attached are the following files for use with this 1st review.

- 1-page request description
- Annotated CRF
- WORD supplement
- There is no Reference Paper or manual or for this review

Please let me know if you have any questions.

Steve



Stephen Kopko

CDISC Subject Matter Expert Consultant
Office 1.512.363.5826 | Mobile +1.484.868.0251



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