

Steve Kopko

From: Steve Kopko
Sent: Wednesday, December 8, 2021 12:37 PM
To: COADataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wagschal, Yaffa; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara
Subject: ** QRS Item ** CDRS-R V1.0 FDA 2nd Review
Attachments: CDISC QRS 2nd Review Request CDRS-R V1.0 2021-12-08.docx; CDRS-R v1 Annotated CRF from Manual.pdf; SDTM RS-CDRS-R V1.0 Approved 2021-12-08.docx

Helena,

Attached are the following files for use with this 2nd review.

- 1-page request description
- Annotated CRF
- WORD supplement for review
- There are no Reference Papers
- The user manual is copyrighted and not available for distribution

Please let me know if you have any questions.

Steve



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