

Steve Kopko

From: Steve Kopko
Sent: Tuesday, December 7, 2021 3:43 PM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Sviglin, Helena; Wagschal, Yaffa; Garrard, Lili; Dlugash, Rachel; Sun, Liping; Jimenez, Sara; Wilson, Stephen E; Diane Corey
Subject: ** QRS Item ** EDSS V2.0 FDA 2nd Review
Attachments: CDISC QRS 2nd Review Request EDSS V2.0 2021-12-07.docx; SDTM RS-EDSS V2.0 Public Domain 2021-11-30.docx; EDSS Annotated CRF.pdf; EDSS Kurtzke 1983 reference.pdf

Helena,

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

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

Please let me know if you have any questions.

Steve



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