

Steve Kopko

From: Steve Kopko
Sent: Monday, June 13, 2022 6:54 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko; Dana Booth; Diane Corey; barbara.lentz@abbvie.com; Sviglin, Helena; Wilson, Stephen E; Sun, Liping; Dlugash, Rachel; Ginsberg, Jennifer
Subject: ** QRS Item ** Supplement V1.0 RISING FROM FLOOR 2nd FDA Review
Attachments: CDISC QRS 2nd FDA Review Request Rising From Floor 2022-06-13.docx; 2022-06-03 RISING_FROM_FLOOR_Annotated_CRF.pdf; 2022-06-03 McDonald_et_al-2013-Muscle_&_Nerve.pdf; 2022-06-03 Supp_V1.0_SDTM_FT-RISING_FROM_FLOOR_Public_Domain.docx

Helena,

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

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

Please let me know if you have any questions.

Steve



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