

## Steve Kopko

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**From:** Steve Kopko  
**Sent:** Monday, June 13, 2022 6:50 PM  
**To:** COADDataStandards; 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 4-STAIR ASCEND 2nd FDA Review  
**Attachments:** CDISC QRS 2nd FDA Review Request 4-Stair Ascend 2022-06-13.docx; 2022-06-03 McDonald\_et\_al-2013-Muscle\_&\_Nerve.pdf; 2022-06-03 4-Stair\_Ascend\_Annotated\_CRF.pdf; 2202-06-03 Supp\_V1.0\_SDTM\_FT-4-STAIR\_ASCEND\_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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