

Steve Kopko

From: Steve Kopko
Sent: Friday, April 8, 2022 11:14 AM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Ginsberg, Jennifer
Subject: ** QRS Item ** EXACT V2.0 FDA 1st Review
Attachments: 2022-04-08 CDISC QRS 1st Review Request EXACT V2.0.docx; 2022-04-08 EXACT Annotated CRF.pdf; 2022-04-06 SDTM QS-EXACT V2.0 Approved.docx; 2022-04-0-8 EXACT_User_Manual_Version 7_17_October_2014 SK notes.pdf

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement for review
- User Manual

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

