

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Wednesday, April 26, 2023 3:02 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Alana St. Clair; Kelli Smith; Dana Booth; Diane Corey; Lentz, Barbara; Sviglin, Helena; Wilson, Stephen E; Dlugash, Rachel; Sun, Liping; Copeland, Johanna
Subject: ** QRS Item ** Supplement V2.0 C-SSRS BASELINE 1st FDA Review
Attachments: 2023-04-26 CDISC QRS 1st Review Request Supp V2.0 C-SSRS BASELINE.docx; 2023-02-27 C-CSSR-S Baseline_Annotated CRF.pdf; 2023-02-27 Supp_V2.0_SDTM_QS_C-SSRS_BASELINE Approved.docx; 2023-02-27 C-SSRS Baseline Supp V2.0 PR Comment Resolutions Archive 2023-02-16.xlsx

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement
- CDISC public review comments resolutions

Please let me know if you have any questions.

Steve



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STAY INFORMED

