

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Monday, September 19, 2022 12:50 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Dana Booth; Diane Corey; barbara.lentz@abbvie.com; Sviglin, Helena; Wilson, Stephen E; Ginsberg, Jennifer; Dlugash, Rachel; Sun, Liping
Subject: ** QRS Item ** Supplement V2.0 C-SSRS SINCE LAST VISIT FDA 1st FDA Review
Attachments: 2022-09-19 CDISC QRS 1st Review Request Supp V1.0 C-SSRS SINCE LAST VISIT.docx; 2022-09-15 C-SSRS_Since_Last_Visit_Annotated CRF.pdf; 2022-09-15 Supp_V2.0_SDTM QS-C-SSRS_SINCE_LAST_VISIT Approved.docx; 2022-09-15 C-SSRS-Brochure-for-Education-1.pdf; 2022-09-15 ScoringandDataAnalysisGuide-for-Clinical-Trials-1.pdf

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement
- There is no Reference Paper but no manual or for this review
 - There is a brochure for education for the review
 - There is a Scoring Data Analysis Guide for the review

Please let me know if you have any questions.

Steve



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