

## Kelli Smith

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**From:** Kelli Smith  
**Sent:** Thursday, June 29, 2023 9:40 AM  
**To:** COADDataStandards; CDISC FDA QRS Review  
**Cc:** Steve Kopko (Contractor); Alana St. Clair; Bailey Vickers; Dana Booth; Diane Corey; Lentz, Barbara; Svinglin, Helena; Wilson, Stephen; Dlugash, Rachel; Sun, Liping; Copeland, Johanna; Carlos.Montes@fda.hhs.gov  
**Subject:** \*\* QRS Item \*\* Supplement V2.0 C-SSRS ALREADY ENROLLED SUBJECTS 1st FDA Review  
**Attachments:** 2023-06-29 CDISC QRS 1st Review Request Supp V2.0 C-SSRS ALREADY ENROLLED SUBJECTS.docx; 2023-06-19 C-SSRS Already Enrolled Subjects v2 Annotated CRF.pdf; 2023-06-19 Supp\_V2.0\_SDTM\_QS-C-SSRS\_ALREADY\_ENROLLED\_SUBJECTS\_Approved\_FDA\_Review.docx; 2023-06-19 C-SSRS-Brochure-for-Education-1.pdf; 2023-06-19 ScoringandDataAnalysisGuide-for-Clinical-Trials-1.pdf; 2023-06-19 C-SSRS AES Supp V2.0 PR Comment Resolutions Archive 2023-05-16.xlsx

Dear Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement
- C-SSRS Overview and User Manual
- CDISC public review comments resolutions

Please let me know if you have any questions.

Warm Regards,  
Kelli



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Upcoming OOO: 03 - 05 July 2023



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