

## Steve Kopko (Contractor)

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**From:** Steve Kopko (Contractor)  
**Sent:** Monday, September 19, 2022 12:54 PM  
**To:** 'COADDataStandards'; CDISC FDA QRS Review  
**Cc:** Dana Booth; Diane Corey; 'barbara.lentz@abbvie.com'; 'Sviglin, Helena'; 'Wilson, Stephen E'; 'Ginsberg, Jennifer'; 'Dlugash, Rachel'; 'Sun, Liping'  
**Subject:** RE: \*\* QRS Item \*\* Supplement V2.0 C-SSRS SINCE LAST VISIT FDA 1st FDA Review

All,  
This is the 1<sup>st</sup> FDA review, not the 2<sup>nd</sup> as mentioned below in the text of the message  
Steve

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**From:** Steve Kopko (Contractor)  
**Sent:** Monday, September 19, 2022 12:50 PM  
**To:** COADDataStandards <COADDataStandards@fda.hhs.gov>; CDISC FDA QRS Review <cdiscfdaqrs@cdisc.org>  
**Cc:** Steve Kopko (Contractor) <skopko@cdisc.org>; Dana Booth <dbooth@cdisc.org>; Diane Corey <dcorey@c-path.org>; barbara.lentz@abbvie.com; Sviglin, Helena <Helena.Sviglin@fda.hhs.gov>; Wilson, Stephen E <Stephen.Wilson@fda.hhs.gov>; Ginsberg, Jennifer <jennifer.ginsberg@fda.hhs.gov>; Dlugash, Rachel <Rachel.Dlugash@fda.hhs.gov>; Sun, Liping <Liping.Sun@fda.hhs.gov>  
**Subject:** \*\* QRS Item \*\* Supplement V2.0 C-SSRS SINCE LAST VISIT FDA 1st FDA Review

Helena,  
Attached are the following files for use with this 2<sup>nd</sup> 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

 **Stephen Kopko**

CDISC Subject Matter Expert Consultant  
Office 1.512.363.5826 | Mobile +1.484.868.0251

