

## Steve Kopko

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**From:** Steve Kopko  
**Sent:** Thursday, May 27, 2021 3:09 PM  
**To:** CODataStandards  
**Cc:** Dana Booth; Diane Corey; Helena Sviglin; Massoud.Motamed@fda.hhs.gov; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Wilson, Stephen E; Steve Kopko  
**Subject:** RE: \*\* QRS Item \*\* CDRS-R V1.0 FDA 1st Review  
**Attachments:** CDISC QRS 1st Review Request CDRS-R V1.0 2021-05-27.docx; CDRS-R v1 Annotated CRF from Manual.pdf; SDTM RS-CDRS-R V1.0 Approved 2021-04-27.docx

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement for review
- There are no Reference Papers
- The user manual is copyrighted and not available for distribution

Please let me know if you have any questions.

Steve

Steve Kopko | CDISC Subject Matter Expert Consultant



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Three promotional banners for CDISC virtual events. The top banner is for '2021 EUROPE INTERCHANGE' with a red-to-orange gradient background, featuring the CDISC logo, the text '2021 EUROPE INTERCHANGE', 'VIRTUAL EVENT!', 'Live Stream | 28-30 April', 'FIND OUT MORE', and 'Conference | TechniCon'. The middle banner is for 'TechniCon 2021' with a black background and white text, featuring the CDISC logo, 'NEXT GENERATION TECHNOLOGY SOLUTIONS', 'TechniCon', '30 APRIL', 'A VIRTUAL CDISC EVENT', and '2021'. The bottom banner is for '2021 JAPAN INTERCHANGE' with a blue-to-red gradient background, featuring the CDISC logo, '2021 JAPAN INTERCHANGE', 'VIRTUAL EVENT!', 'Live Stream | 10-11 June', 'FIND OUT MORE', and 'Conference | Education'.