

Steve Kopko

From: Steve Kopko
Sent: Thursday, May 27, 2021 3:15 PM
To: COADDataStandards
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: ** QRS Item ** EDSS V1.0 FDA 1st Review
Attachments: CDISC QRS 1st Review Request EDSS V2.0 2021-05-27.docx; EDSS Annotated CRF.pdf; SDTM RS-EDSS V2.0 Public Domain 2021-02-19.docx; EDSS Kurtzke 1983 reference.pdf

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement for review
- The Reference Paper
- There is no user manual Please let me know if you have any questions.

Steve

Steve Kopko | CDISC Subject Matter Expert Consultant



Clear Data. Clear Impact.

401 West 15th Street, Suite 800 | Austin, TX 78701

Office +1.512.363.5826 | Mobile +1.484.868.0251

cdisc.org

STAY INFORMED



Three promotional banners for CDISC events. The top banner is for "2021 EUROPE INTERCHANGE" (Live Stream | 28-30 April) with a "VIRTUAL EVENT!" icon. The middle banner is for "TechniCon 2021" (30 APRIL) with the tagline "NEXT GENERATION TECHNOLOGY SOLUTIONS" and "A VIRTUAL CDISC EVENT". The bottom banner is for "2021 JAPAN INTERCHANGE" (Live Stream | 10-11 June) with the tagline "With Standards - Science Will Prevail!" and a "VIRTUAL EVENT!" icon. Each banner includes a "FIND OUT MORE" button and a "Conference | [Event Name]" label.