

Steve Kopko

From: Steve Kopko
Sent: Friday, January 7, 2022 4:31 PM
To: COADataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara
Subject: ** QRS Item ** SMDDS V1.0 FDA 3rd Review
Attachments: CDISC QRS 3rd Review Request SMDDS V1.0 2022-07-07.docx; SDTM QS-SMDDS V1.0 Approved 2022-01-06.docx; SMDDS V1.0 Annotated CRF.pdf; FDA SMDDS V1.0 JIRA Issues Export View - Issue Tracker JIRA 2021-02-12.xlsx; 2016_McCarrier_etal_SMDDS-InitialQualitativeResearch.pdf; SMDDS_UserManualReleasedV1_2017Oct31.pdf

Helena,

Attached are the following files for use with this 3rd review.

- 1-page request description
- WORD supplement for review
- Annotated CRF
- CDISC JIRA export file containing the 1st review FDA comments and the CDISC responses
- The reference article and user guide

Please let me know if you have any questions. Have a great weekend!

Steve



Steve Kopko
CDISC Subject Matter Expert Consultant
Office 1.512.363.5826 | Mobile +1.484.868.0251

