

Steve Kopko

From: Steve Kopko
Sent: Friday, February 12, 2021 2:51 PM
To: COADDataStandards
Cc: Helena Sviglin; Garrard, Lili; Sun, Liping; Jimenez, Sara; Motamed, Massoud; Dlugash, Rachel; Wilson, Stephen; Dana Booth; Diane Corey; Amy Palmer
Subject: RE: ** QRS Item ** SMDDS V1.0 FDA 2nd Review
Attachments: CDISC QRS Review Request SMDDS V1.0 2021-02-12.docx; SDTM QS-SMDDS V1 Approved 2021-02-12.docx; FDA SMDDS V1.0 JIRA Issues Export View - Issue Tracker JIRA 2021-02-12.xlsx

Helena,

Attached are the following files for use with this 2nd review.

- 1-page request description
- WORD supplement for review
- CDISC JIRA export file containing the 1st review FDA comments and the CDISC responses

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

Steve

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