Steve Kopko

From: Steve Kopko

Sent: Friday, February 12, 2021 2:47 PM

To: COADataStandards

Cc: Helena Sviglin; Garrard, Lili; Sun, Liping; Jimenez, Sara; Motamed, Massoud; Dlugash,

Rachel; Wilson, Stephen; Steve Kopko; Dana Booth; Diane Corey; Amy Palmer

Subject: ** QRS Item ** NSCLC-SAQ V1.0 FDA 2nd Review

Attachments: CDISC QRS Review Request NSCLC-SAQ V1.0 2021-02-12.docx; SDTM QS-NSCLC-SAQ

V1 Approved 2021-01-25.docx; FDA NSCLC-SAQ 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

Steve Kopko | CDISC Subject Matter Expert Consultant



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