

Steve Kopko

From: Steve Kopko
Sent: Friday, January 7, 2022 4:26 PM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara
Subject: ** QRS Item ** NSCLC-SAQ V1.0 FDA 3rd Review
Attachments: CDISC QRS 3rd Review Request NSCLC-SAQ V1.0 2022-07-07.docx; SDTM QS-NSCLC-SAQ V1.0 Approved 2022-01-06.docx; NSCLC-SAQ V1.0 Annotated CRF.pdf; FDA NSCLC-SAQ V1.0 JIRA Issues Export View - Issue Tracker JIRA 2021-02-12.xlsx; NSCLC-SAQ V1.0 ref article.pdf; NSCLC_UserManual.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



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