

Steve Kopko

From: Dana Booth
Sent: Wednesday, December 8, 2021 6:29 PM
To: COADDataStandards
Cc: Sviglin, Helena; Wagschal, Yaffa; Wilson, Stephen E; Steve Kopko; Diane Corey
Subject: ADSD and ANSD request for FDA 3rd review
Attachments: CDISC QRS 3rd Review Request ANSD V1.0 2021-12-08.docx; CDISC QRS 3rd Review Request ADSD V1.0 2021-12-08.docx; ADSD changes since 2021-05-24 version.docx; ANSD changes since 2021-05-24 version.docx; SDTM QS-ADSD V1.0 Approved.docx; SDTM QS-ANSD V1.0 Approved.docx; ANSD Annotated CRF.pdf; ADSD Annotated CRF.pdf; PROC_ADSD_ANSD_UserManuaReleasedV1_20190330.pdf

Dear Helena et al,

Attached please review requests for the FDA to please perform a 3rd review of the QRS Supplements for ADSD v1.0 and ANSD v1.0. In addition, please find attached:

- PROC_ADSD_ANSD_UserManuaReleasedV1_20190330.PDF.: The Critical Path Institute owns the copyright for the ADSD V1.0 and ANSD v1.0 instruments. They have provided the user manual for this FDA review only.
- SDTM QS-ANSD V1.0 Approved Word Supplement, dated 21-12-08.
- ANSD changes since the 2021-05-24 version: This is a Word comparison of the document we included with the 2nd review and the Word document included in this review and shows all changes since the 2021-05-24 version.
- The annotated CRF for the ANSD V1.0, which did not change.
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- SDTM QS-ADSD V1.0 Approved Word Supplement, dated 21-12-08.
- ADSD changes since the 2021-05-24 version: This is a Word comparison of the document we included with the 2nd review and the Word document included in this review and shows all changes since the 2021-05-24 version.
- The annotated CRF for the ADSD V1.0, which did not change.

Please let us know if you have any questions.

Thank you!

Dana Booth

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