

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Tuesday, October 25, 2022 11:21 AM
To: COADDataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Dana Booth; Diane Corey; barbara.lentz@abbvie.com; Sviglin, Helena; Wilson, Stephen E; Sun, Liping; Dlugash, Rachel; Ginsberg, Jennifer
Subject: ** QRS Item ** Supplement V2.0 Kurtzke Expanded Disability Status Scale (EDSS) 3rd FDA Review
Attachments: 2022-10-20 CDISC QRS 3rd Review Request Sup V2.0 EDSS 2022-10-20.docx; 2022-10-20 EDSS Annotated CRF.pdf; 2022-10-20 Supp_V2.0_SDTM RS-EDSS Public Domain.docx; 2022-10-20 EDSS Kurtzke 1983 reference.pdf; 2022-10-20 Sup V2.0 EDSS FDA 2nd Review Comments Resolutions 2022-10-20.xlsx

All,
Please ignore the title on the original message for the 3rd review of the KFSS supplement. This review is for the EDSS 3rd Review. You can delete the original message with the incorrect title.
Steve

From: Steve Kopko (Contractor) <skopko@cdisc.org>
Sent: Tuesday, October 25, 2022 11:11 AM
To: COADDataStandards <COADDataStandards@fda.hhs.gov>; CDISC FDA QRS Review <cdiscfdaqrs@cdisc.org>
Cc: Steve Kopko (Contractor) <skopko@cdisc.org>; Dana Booth <dbooth@cdisc.org>; Diane Corey <dcorey@c-path.org>; barbara.lentz@abbvie.com; Sviglin, Helena <Helena.Sviglin@fda.hhs.gov>; Wilson, Stephen E <Stephen.Wilson@fda.hhs.gov>; Ginsberg, Jennifer <jennifer.ginsberg@fda.hhs.gov>; Dlugash, Rachel <Rachel.Dlugash@fda.hhs.gov>; Sun, Liping <Liping.Sun@fda.hhs.gov>
Subject: ** QRS Item ** Supplement V2.0 Kurtzke Functional System Scores (KFSS) 3rd FDA Review

Helena,
Attached are the following files for use with this 1st review.

- 1-page request description
- Annotated CRF
- WORD supplement
- Reference Paper but no manual for this review
- FDA 2nd review comments and CDISC resolutions

Please let me know if you have any questions.
Steve

 | **Stephen Kopko**

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