

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Wednesday, April 26, 2023 3:15 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Alana St. Clair; Kelli Smith; Dana Booth; Diane Corey; Lentz, Barbara; Sviglin, Helena; Wilson, Stephen E; Dlugash, Rachel; Sun, Liping; Copeland, Johanna
Subject: ** QRS Item ** Supplement V1.0 SF36 V2.0 ACUTE and Supplement V1.0 SF36 V2.0 STANDARD 1st FDA Review
Attachments: 2023-04-26 CDISC QRS 1st Review Request Supp V1.0 QRS SF36 V2.0 ACUTE & STANDARD.docx; 2023-04-11 OPTUM United States (English) SF-36v2 Acute Annotated CRF.pdf; 2023-04-11 Supp_V1.0_SDTM_QS-SF36_V2.0 _ACUTE_Approved_QualityMetric_FDA Review.docx; 2023-04-11 User's Manual for the SF-36v2 Health Survey, 3rd Ed (2011).pdf; 2023-04-11 SF-36v2 Advanced Scoring Guidelines MB 2021-04-30.pdf; 2023-04-11 OPTUM United States (English) SF-36v2 Standard Annotated CRF.pdf; 2023-04-11 Supp_V1.0_SDTM_QS-SF36_V2.0 _STANDARD_Approved_QualityMetric_FDA Review.docx

Helena,

Attached are the following files for both supplements for use with this 1st review.

- 1-page request description
- Annotated CRF
- WORD supplement
- User Manual
- Scoring Guidelines

Please let me know if you have any questions.

Steve



Stephen Kopko

CDISC Subject Matter Expert Consultant
Office 1.512.363.5826 | Mobile +1.484.868.0251



STAY INFORMED

