

Steve Kopko

From: Steve Kopko
Sent: Wednesday, October 13, 2021 10:04 AM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Helena Sviglin; Wagschal, Yaffa; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Wilson, Stephen
Subject: ** QRS Item ** EORTC QLQ-C30 V3.0 FDA 1st Review
Attachments: CDISC QRS 1st Review Request EORTC-QLQ-C30L V1.0 2021-10-13.docx; SDTM QS-EORTC QLQ-C30 V3.0 Approved.docx; EORTC QLO-C30_english Annotated CRF.pdf; SCManualQLQ-C30.pdf

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement for review
- There is no reference paper
- There is a user manual
- The EORTC website: <https://qol.eortc.org/> was referenced for all information in developing the supplements.

Please let me know if you have any questions.

Steve



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