Steve Kopko

From: Steve Kopko

Sent: Friday, December 10, 2021 3:26 PM

To: COADataStandards

Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wagschal, Yaffa; Garrard, Lili;

Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Wilson, Stephen E

Subject: QRS Item ** BPRS 1988 VERSION V1.0 FDA 2nd Review

Attachments: CDISC QRS 2nd Review Request BPRS 1988 VERSION V1.0 2021-12-10.docx; BPRS 1988

Version Annotated CRF MSG V2.0.pdf; SDTM RS-BPRS 1988 VERSION V1.0 Public Domain 2021-11-30.docx; BPRS 1962 original reference paper.pdf; BPRS 1988 ref

article.pdf

Helena,

Attached are the following files for use with this 2nd review.

- 1-page request description
- Annotated CRF
- WORD supplement for review
- Reference Papers

Please let me know if you have any questions.

Steve



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