

Steve Kopko

From: Steve Kopko
Sent: Thursday, May 27, 2021 2:28 PM
To: CODataStandards
Cc: Dana Booth; Diane Corey; Helena Sviglin; Massoud.Motamed@fda.hhs.gov; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Wilson, Stephen E; Steve Kopko
Subject: ** QRS Item ** BPRS 1988 VERSION V1.0 FDA 1st Review
Attachments: CDISC QRS 1st Review Request BPRS 1988 VERSION V1.0 2021-05-27.docx; BPRS 1988 Version Annotated CRF.pdf; SDTM RS-BPRS 1988 VERSION V1.0 Public Domain 2021-02-19.docx; BPRS 1962 original reference paper.pdf; BPRS 1988 ref article.pdf

Helena,

Attached are the following files for use with this 1st 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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