

Steve Kopko (Contractor)

From: Steve Kopko (Contractor)
Sent: Monday, August 8, 2022 3:35 PM
To: COADataStandards; CDISC FDA QRS Review
Cc: Steve Kopko (Contractor); Dana Booth; Diane Corey; barbara.lentz@abbvie.com; Sviglin, Helena; Wilson, Stephen E; Ginsberg, Jennifer; Dlugash, Rachel; Sun, Liping
Subject: ** QRS Item ** Supplement V1.0 PASI FELDMAN 1st FDA Review
Attachments: 2022-08-08 CDISC QRS 1st Review Request Supp V1.0 PASI FELDMAN.docx; 2022-08-08-08 PASI FELDMAN reference article.pdf; 2022-08-08-08 PASI FELDMAN Annotated CRF.pdf; 2022-08-08-08 Supp_V1.0_SDTM RS-PASI_FELDMAN Public Domain.docx

Helena,

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

- 1-page request description
- Annotated CRF
- WORD supplement
- There is a Reference Paper but no manual or for this review

Please let me know if you have any questions.

Steve



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