

## Steve Kopko (Contractor)

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**From:** Steve Kopko (Contractor)  
**Sent:** Monday, August 8, 2022 4:03 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 BOZEK 1st FDA Review  
**Attachments:** 2022-08-08 CDISC QRS 1st Review Request Supp V1.0 PASI BOZEK.docx; 2022-08-08 PASI Bozek 2017 Reference Article.pdf; 2022-08-08 PASI BOZEK Annotated CRF.pdf; 2022-08-08 Supp\_V1.0\_SDTM RS-PASI\_BOZEK 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



Stephen Kopko

CDISC Subject Matter Expert Consultant  
Office 1.512.363.5826 | Mobile +1.484.868.0251



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