

## Steve Kopko

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**From:** Steve Kopko  
**Sent:** Friday, April 8, 2022 11:22 AM  
**To:** COADDataStandards  
**Cc:** Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara; Ginsberg, Jennifer  
**Subject:** \*\* QRS Item \*\* PASI V2 V1.0 FDA 1st Review  
**Attachments:** 2022-04-08 CDISC QRS 1st Review Request PASI V2 V1.0.docx; 2022-04-08 PASI V2 Annotated CRF.pdf; 2022-04-06 SDTM RS-PASI V2 V1.0 Public Domain.docx; 2022-04-08 PASI V2 reference.pdf; 2022-04-08 PASI article\_highlighted\_with notes.pdf; 2022-04-08 guideline-clinical-investigation-medicinal-products-indicated-treatment-psoriasis\_en.pdf

Helena,

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

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

Please let me know if you have any questions.

Steve



Stephen Kopko

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