

Steve Kopko

From: Steve Kopko
Sent: Thursday, May 27, 2021 2:56 PM
To: COADDataStandards
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: RE: ** QRS Item ** HAMD 17 V2.1 FDA 1st Review
Attachments: CDISC QRS 1st Review Request HAMD 17 V2.1 2021-05-27.docx; Hamilton Depression Rating Scale (HAMD 17) CDISC Annotated CRF.pdf; SDTM RS-HAMD 17 V2.1 Public Domain 2021-04-27.docx; HAMD 17 1960 reference.pdf; HAMD_1967 Reference Paper.pdf; 2005 Assessment Scales in Depression, Mania and Anxiety -Lam, Michalak, Swinson.pdf; HAMD with ref info from Guy ecdeu assessment manual.pdf; HAMD 17 Gold Standard Reference Paper.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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