

Steve Kopko

From: Steve Kopko
Sent: Thursday, December 9, 2021 2:57 PM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey; Sviglin, Helena; Wagschal, Yaffa; Wilson, Stephen E; Garrard, Lili; Sun, Liping; Dlugash, Rachel; Jimenez, Sara
Subject: ** QRS Item ** HAMD 17 V2.1 FDA 2nd Review
Attachments: CDISC QRS 2nd Review Request HAMD 17 V2.1 2021-12-09.docx; Hamilton Depression Rating Scale (HAMD 17) CDISC Annotated CRF.pdf; SDTM RS-HAMD 17 V2.1 Public Domain 2021-12-09.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 2nd review.

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

Please let me know if you have any questions.

Steve



Steve Kopko
CDISC Subject Matter Expert Consultant
Office 1.512.363.5826 | Mobile +1.484.868.0251



STAY INFORMED

