

Steve Kopko

From: Steve Kopko
Sent: Monday, November 30, 2020 1:29 PM
To: COADDataStandards
Cc: Steve Kopko; Dana Booth; Diane Corey
Subject: ** For FDA Review ** Updated QRS Skipped Items Proposal
Attachments: Representation of QRS items in SDTM 2020-11-03.pptx

Helena,

This is an action from the 11/30 CDISC/FDA QRS Specific Meeting. Attached is the updated QRS Skipped Items proposal that covers the use case in which QRS instrument skipped item responses would be assigned according to the instrument's instructions. Dana is planning on scheduling a separate meeting based on the FDA review/comment on this updated proposal. Please let me know if you have any questions.

Regards,
Steve

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