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detail will be forgotten by the time you get to the questions anyway. Therefore, you should fly over the passage. You should read it very quickly for a high-level overview (hence the flyover) understanding of

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Technical Rejection Criteria for Study Data

Section 2.2 (Study Data Reviewer's Guide) - Updated link for SDRG in Footnote 10 Section 3.3.2 (Dataset Size) - Increased Data Set Size Section 4.1.1.2 (SDTM General Considerations) - Updated to ...

STUDY DATA TECHNICAL CONFORMANCE GUIDE

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SDTM is one of the required standards that sponsors must use as specified in the FDA's Data Standards Catalog (see section II.C) for NDA, ANDA, and certain BLA submissions effective December 2016. For more information, please visit the Guidance on Standardized Data.

SDTMIG | CDISC

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