In the last 5-10 years I have been exposed to several studies requiring the use of the CDISC standards, either as programmer study lead or as CDISC SME reviewing both internal (Cytel) or external packages (delivered by Pharma or other CROs), where I also regularly provide answers to questions/doubts.

With this presentation I would like to go through the main CDISC “Nonsense” from my experience. This can range from “nonsense” question to a complete misunderstanding of the CDISC Ig(s); some of this “nonsense” has also emerged from the CDISC packages I have reviewed including CDISC documentation such as the reviewer guide. The main focus of the presentation will be the SDTM and ADaM standards.

Abstract

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My concern: “In ADEG you did derive a record with the average of the triplicates; I recommend keeping also original SDTM records from which you created the mean”

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