Clinical trials need to better protect participants and research integrity as data accumulate

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An Essay by Susan Ellenberg from the University of Pennsylvania describes alternative approaches to the evaluation of clinical trials, with the objectives both of preventing undue risks to participants and protecting the integrity of data.

Writing in this week's PLoS Medicine, the author outlines the importance of methods for ensuring independence of those involved in analysis of interim data, and for ensuring that early stopping guidelines are clearly laid out before a trial starts.

However, the author emphasises that issues around liability for individuals who provide these functions are currently unclear, and concludes: "DMCs [data monitoring committees] have become expected components of many clinical trials, and provide an important oversight function".

More information: Ellenberg SS (2012) Protecting Clinical Trial Participants and Protecting Data Integrity: Are We Meeting the Challenges? PLoS Med 9(6): e1001234. doi:10.1371/journal.pmed.1001234

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