



(Saturday 6:37am) 3 February 2001

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Generic good practice policies and procedures (GPPP)

The GPPP on treatment effects monitoring committees, just distributed, was to mark the end of the GPPP series but such an ending would be like a train without a caboose. And being an avid train watcher I abhor trains without cabooses – Oh for the days of feather bedding and cabooses again! So I conclude with a few GPPPs to live by.

P&P 1: Collect only 10 times the amount of data needed!

Comment

A cynical reminder of the tendency of investigators to collect everything, including the kitchen sink.

P&P 2: When estimating the actual time it will take to do a trial, multiply the time specified in the funding application by 2.

P&P 3: When estimating the finished sample size of a trial, take the sample size, as calculated in the funding proposal, and divide by 2.

Comment

An expression of the maxim: *The way to cure a disease is to start a trial.*

P&P 4: When estimating the amount of time it will take to enroll multiply the time indicated in the funding proposal by 2.

Comment

An expression of the maxim: *The way to make a disease disappear is to start a trial.*

P&P 5: When estimating the observed event rate for the control-treated group, take the event rate used for sample calculation and divide by 2.

Comment

Mortality and morbidity rates in trials are always less than expected because the people enrolled are healthier (due to all the exclusions imposed on selection) than expected. If a person is healthy enough to walk into a clinic that person still has a lot of life left.

P&P 6: Be patient and persevering, but don't be a hard ass.

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P&P 7: Do pick at nits.

Comment

Research is 90% nit picking.

P&P 8: Check, check, check, and check some more.

Comment

The way to be sure is to not check.

P&P 9: When planning, think like a rat.

Comment

Rats do not go down blind alleys.

P&P 10: Don't internalize SEPs, doing so is bad for your viscera.

P&P 11: Put too many pigs under a blanket and they all get away, therefore one pig per blanket.

Comment

A reminder that the objective in a trial is to answer just one question.

P&P 12: Strive for equality of slop.

Comment

A perverse reminder that comparisons in trials are valid even if observations and measurements are not perfect so long as the variation and imprecision is not differential by treatment group.

P&P 13: Do not burn bridges; they may be needed in retreat.

P&P 14: Demand precision of language and terminology.

Comment

Remember the Tower of Babel.

P&P 15: Smile, it could be worse.