PharmaSchool GCP Challenge 26th February 2014

You will need to access the following web page to complete the challenge:

http://www.pharmaschool.co/size5.asp

Question 1:

The trial is designed to detect an absolute difference of 15% in response rates between treatment A and B, with the assumption that the response rate in group A is 55% and the response rate in group B to be 40%. With a significance level of 5% and power of 80% the trial would need N patients in total.

What is the N?

Question 2:

The number of patients calculated would be the number evaluable/completed. If a drop out/non-evaluable rate of around 20% was expected how many patients in total would you recruit?

Question 3:

With the 20% drop out/non-evaluable included. How many patients in total would be required if the power level was increased to 90%?

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Question 4:

If the assumed response rates were changed and the trial sample sized again with the following information, how many patients in total would now be needed: The trial is designed to detect an absolute difference of 10% in response rates between treatment A and B, with the assumption that the response rate in group A is 50% and the response rate in group B to be 40%. With a significance level of 5% and power of 90% and a 20% drop-out/non-evaluable rate the trial would need a total of N patients.

What is the N?

Question 5:

If the assumed response rates were changed but the absolute difference remained at 10% and the trial sample sized again with the following information, how many patients in total would now be needed: The trial is designed to detect an absolute difference of 10% in response rates between treatment A and B, with the assumption that the response rate in group A is 30% and the response rate in group B to be 20%. With a significance level of 5% and power of 90% and a 20% drop-out/non-evaluable rate the trial would need a total of N patients.

What is the N?

To check your answers go to the link below:

http://www.pharmaschool.co/ukgcp03.asp?testtitle=pst468

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