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# Statistical Significance and Clinical Significance in Clinical Trials

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***Abstract:*** *Any Investigator would like to maximise the probability of concluding that the difference in the two groups exists when in fact the difference truly exists. This corresponds to the concept of power of the study (1-β ) .Usually β is selected to be 0.10 or 0.20 i.e., power of study as 90% or 80% respectively. Power of study depends on value of true difference between the study groups. When study size is larger the study would be the higher power. Probability level at which difference will be regarded as Statistically significant. Most of the People wrongly interpret the P value due to numerous reasons here the article intends to give guidance to rightly represent P - value and rightly interpret the results of investigations and sign and symptoms using the P – value.*

***Keywords:*** *statistical significance , Clinical Significance.*

## 1. INTRODUCTION:

The P value is defined as the probability under the assumption of no effect or no difference (null hypothesis), of obtaining a result equal to or more extreme than what was actually observed.What is P in P value ? . Its nothing but Probability level at which as particular investigation or sign and symptom is statistically significant or not significant. It its significant at what level of P – value its significant and if its not significant at what level its not significant. Statistical significance need not necessarily be clinically significant and a particular parameter, value or score which is clinically significant need not necessarily be statistically significant. For large sample size it is statistically significant but not clinically important. Ally Not statistically significant but clinically important. When evaluating the validity of a study, the reader must consider both the clinical and statistical significance of the findings. A study that claims clinical relevance may lack sufficient statistical significance to make a meaningful statement. Conversely, a study that shows a statistically significant difference in 2 treatment options may lack practicality. After thoroughly studying the values which have been obtained statistically such as Athematic Mean and S.D ie Standard deviation and S.E.M ie Standard Error of Mean we have to do the interpretation. A statistician who has good knowledge in handling the clinical data for over a period of time can do accurate interpretation of the clinical data which plays a very vital role in clinical research. Please note that the author has more than one decade of experience in handling clinical data, has attended many national and international conferences and delivered lectures of biostatistics at national and international seminars and he is author of books, research articles. He has done the statistical analysis for thesis of numerous medical students . He has prepared number of randomization tables for randomization in clinical trials. He has calculated sample size for numerous clinical and preclinical studies and is a expert in the field of biostatistics and research methodology.

The **Co author Mr.Pathan Jamal Khan** has more than three decades of experience in the field of biostatistics he is the author and co-author of many research publications and prepared and published many monographs related to clinical research. He is an expert in planning surveys and collecting data in surveys. He has done the statistical analysis for thesis of numerous medical students. He is Expert in handling clinical data, has attended many national and international conferences and delivered lectures of biostatistics at national and international seminars and is a expert in the field of biostatistics and research methodology.

The **Co author Dr.Anwar Ahmed research officer Unani S-4** is an expert in the field of unani. He has worked on many clinical trials. He is a expert physician in Unani. He is vast knowledge on unani system of medicine. He is expert in diagnosis and treatment of all disease specially skin related and respiratory disease. has attended many national and international conferences and delivered lectures of unani medicines and its out comes at national and international seminars. The concept of power of a clinical trial refers to the probability of detecting a difference between study groups

when a true difference exists. We will discuss statistical power by examining studies too small to identify important differences, studies so large as to identify differences that are not clinically significant, difficult-to-design studies without very large patient populations, and those studies with both adequate power and clinically relevant findings.

## 2. DISCUSSION:

Most of the People using statistical software's to statistically analyse the data and in some software's the P – Value is generated like 0.000001 or 0.0000005 which is not a correct way of representing the P value. Here are few guidelines how to represent the P – Value correctly.

- P Should be italicized and capitalized.
- Do not use 0 before the decimal point for statistical values P, alpha, and beta because they cannot equal 1, in other words, write P<.001 instead of P<0.001
- The actual P value* should be expressed (P=.04) rather than expressing a statement of inequality (P<.05), unless P<.001.
- P values should not be listed as not significant (NS) since, for meta-analysis, the actual values are important and not providing exact P values is a form of incomplete reporting.
- If P>.01 then the P value should always be expressed to 2 digits whether or not it is significant. When rounding, 3 digits is acceptable if rounding would change the significance of a value (eg, you may write P=.049 instead of .05).
- If P<.01, it should be expressed to 3 digits.
- For P values less than .001, report them as P<.001, instead of the actual exact P value. Expressing P to more than 3 significant digits does not add useful information since precise P values with extreme results are sensitive to biases or departures from the statistical model.
- P=.000 (as outputted by some statistical packages) is impossible and should be written as P<.001
- All footnote symbols within a table are superscripted letters (a-z). The use of *, **, *** footnotes to mark significance levels (eg, *P*<.05, *P*<.01, *P*<.001) is discouraged. Authors are asked to provide exact *P* values instead. While we prefer the exact *P* values, there are exceptions to this general rule. The use of *, **, *** footnotes to indicate significance levels is allowed in the following instances

Statistical analysis in clinical research is used to show that the findings are not likely due to chance. However, it is easy to misinterpret the results of statistical tests. Often, the language of statistics obscures the findings of clinical trials. For example, a small study that claims clinical relevance may lack sufficient statistical power to justify its conclusions. Conversely, authors of a study may speak of the statistical significance of a treatment effect that has little, if any, clinical utility. Therefore, when evaluating the validity of a study presented in the dermatologic literature, the reader must consider both the clinical and statistical significance of the findings.When clinical trials are designed, a subject population of the appropriate size should be chosen. Often, this is based on preliminary studies that provide an estimate of the expected effect size. For example, if preliminary studies show a new psoriasis treatment to be successful in 50% of drug-treated patients and placebo to be successful in 10% of placebo-treated patients, then a sample of 18 subjects per group provides 80% power (an 80% chance of showing a statistically significant difference) to detect a difference with *P*<.05 (a difference large enough that it would occur by chance alone <5% of the time).

Notice that this hypothetical study is powered to detect success. It is not necessarily powered to detect statistically significant differences from other outcomes. While this design offers sufficient power for the efficacy outcome (successful treatment), it would not have the power to show statistically significant differences in adverse events that occur uncommonly. It would be a mistake to conclude, just because the study was sufficiently powered for efficacy, that we can draw strong conclusions about safety. Indeed, studies may claim to show a treatment is safe and effective, but such studies often have proven only efficacy. Statistical significance is heavily dependent on the study's sample size; with large sample sizes, even small treatment effects (which are clinically inconsequential) can appear statistically significant; therefore, the reader has to interpret carefully whether this "significance" is clinically meaningful.

## 3. CONCLUSION:

An assessment of study power is essential in determining both the statistical significance and clinical relevance of any study and has serious implications for any conclusions that can be drawn. Consequences of an inappropriate sample size can be dangerous in either extreme. An excessively large sample may show statistical significance even when there is no clinical practicality; an inappropriately small sample will fail to demonstrate important clinically significant differences. When clinicians evaluate studies reporting significant differences, they should ask whether these differences are both statistically and clinically meaningful. randomized trials, emphasizes the need for reporting of the

estimated effect size and its precision (such as 95% confidence interval) for each primary and secondary outcome. Researcher should bear in mind that interpretation of study results should take into account the clinical significance by looking at the actual treatment effect (with confidence intervals) and should not just be based on "P" values and statistical significance.

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