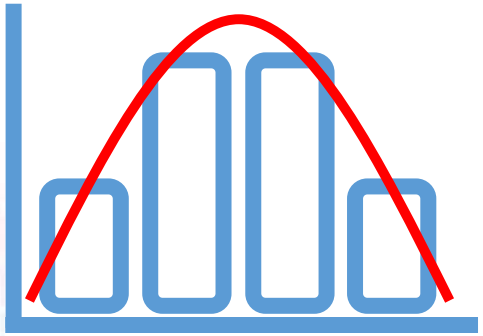
DERMATOLOGY CLINICAL TRIALS

– all you need to know

BIOSTATISTICS



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Planning

Statistical support is an important part of any clinical trial

It may start before a clinical trial sets off and may not end until after the clinical report is submitted to the Sponsor or the Agency. Statistical support usually includes, but is not limited to, sample size estimation, review of study documents, development of statistical analysis plan (SAP), implementation of the SAP, & review of the clinical study report (CSR).

Dermatological indications may be less severe and complicated than some other indications, but thoughtful planning, preparation and execution ***are equally imperative*** for dermatology clinical trials to be executed smoothly.

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Protocol Review

Thorough understanding of the study protocol is the foundation of all. It is achieved through proactive review of the protocol and related literature with insight including, but not limited to –

- *How were past trials of the same indication conducted?*
- *What did the FDA statistical and medical reviews say about the trial design of the same indication, about the selection of the primary and secondary variables, about the analysis populations, about the use of certain statistical methods, etc.?*
- *What are the objectives for the study in planning?*
- *How is the study designed?*
- *What study endpoints are to be collected at which time points?*
- *Which endpoints are considered primary, secondary, exploratory?*
- *How should these study endpoints be analyzed?*
- *What criteria are to be used to determine if the study goals are achieved?*

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Sample Size Estimation

An appropriate sample size is critical to a clinical study.

It safeguards the study to produce a reliable outcome and avoids unnecessary exposure of subjects to possible harmful treatments.

Our key to ensure that the study is properly powered is to team up with the Sponsor with an open and critically thinking mind.

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Sample Size Estimation

Determination of the sample size involves consideration of-

- *What are the null hypothesis and the working hypothesis? They are the "statistical translation" of the primary objectives of the study.*
- *What is required for Type II error rate (probability of erroneously failing to reject the null hypothesis, usually set at 10-20%)? Type I error rate (probability of erroneously rejecting the null hypothesis, conventionally set at 5%)*
- *Is historic data (e.g. FDA medical/statistical review) available with respect to the primary endpoint(s)? Are there other data sources that can be used as reference?*
- *What analysis population(s) should the sample size and power be associated to?*

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SAP

The Statistical Analysis Plan (SAP) is the blueprint for the statistical analysis to be performed for a clinical study. Other than serving as the description of the study objectives and study design, it usually seeks to answer the following questions –

- *What analysis populations are needed and how are they defined?*
- *What are general statistical methods to be used?*
- *How to handle missing data?*
- *Are there derived variables? What algorithm should be used to derive them?*
- *Which efficacy variables are to be analyzed and how?*
- *Which safety variables are to be analyzed and how?*
- *What other endpoints to be analyzed and how?*
- *What do tables, listings and figures look like?*

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SAP

Great attention to detail is always given to the design of the TLF shells from both statistical and programmatical perspectives. This warrants, in Sponsor's preferred format or in our own format, the SAP will be finalized with maximal clarity and executability.

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TLFs

Our statisticians also program and produce TLFs

This shaves off the layer of SAS programmers and benefits in many ways – no statistical methods will be misused, no communication will be missed, no relaying time will be required, etc.

Two different statisticians are assigned to each study. Usually one statistician programs for summary tables and figures and the other statistician independently programs for table validation and listings. Thorough understanding of the SAP promotes the work efficiency and ensures the accuracy of the output results. In the end, every statistic in a summary table is validated before it goes into the final study report. Every data listing will be considered complete only after it has been checked against the raw database for a subset of subjects.

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About Symbio, LLC, Dermatology CRO

- *Ye Wang, PhD has worked as a hands-on Statistician in Dermatology clinical trials for over 20 years. Numerous Sponsors have enjoyed the reward of her hard work and praised Dr. Yang and her team for their quick turn around and thoughtful insight and suggestions resulting in a multitude of approvals. Dr. Yang has been Director, Statistics at Symbio, LLC, Dermatology CRO, since 2007*

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