Session 5: Clinical development

Phase III Clinical Trials for Topical Dermatological Products

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Following successful proof of concept and dose finding phase II trials at least one pivotal study with sufficiently large numbers of patients is required to confirm the safety and efficacy of a new investigational drug.

These phase III trials are usually the most time consuming and expensive studies in the whole drug development process.

While guidance documents exist for some indications, e.g. psoriasis most of the time it is not obvious what regulatory agency will require in order to grant marketing authorization. It is therefore highly advisable to seek scientific advice from regulatory bodies before initiating phase III trials.

According to the size and complexity phase III trials require not only regulatory and dermatological expertise but a competent and experienced interdisciplinary team of data managers, statisticians, field monitors, trial physicians, study nurses, administrative staff all coordinated and directed by an efficient project management.

In this presentation key aspects of phase III studies will be described and illustrated by practical examples.