Adaptive and flexible designs

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The term adaptive design refers to a clinical trial where accumulated data are used to modify some aspects of the ongoing trial. Methods for adaptive designs aim at preserving the validity and the integrity of the trial despite the design modifications.

Following the publication of FDA reports stressing the need to develop new tools to enhance the medicinal products development path, many interests and debate on adaptive trials have appeared in the literature. In this talk, we review the principles and methodology of flexible trials, i.e. group sequential trials where design modifications are allowed at an interim analysis, and present some future developments in combined phase 2/3 desings.