

Predictive probability of success as a general tool for clinical development

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Predictive probability of success is a (subjective) Bayesian evaluation of the probability of a future successful event in a given state of information. In a clinical development setup, successful events refer mainly to the accrual of positive evidence on the therapy which is being developed, like demonstration of superiority or ascertainment of safety. Positive evidence will usually be obtained via standard frequentist tools, as the rules of the game often impose in this framework.

Within a single trial, predictive probability of success can be identified with expected power, i.e. the evaluation of the success probability of the trial, where success means, for example, a significant result of a standard test of superiority.

Across trials, if we take the higher point of view of clinical development of a drug, predictive probability of success can be the probability of a successful completion of an entire part of clinical development, for example a successful phase III development in the presence of phase II data.