Title: Use of conditional power priors to incorporate prior information in sample size calculations.

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Abstract: The assessment of the sample size for a pre-specified level of statistical power is a key component in the design of any clinical trial. When calculating the sample size in the frequentist setting, assumptions need to be made about the outcomes upon which the primary endpoint will be based; for example the assumption of a specific value for the standard deviation of a Normally distributed outcome or the probability of success of a binary one. These assumptions are typically based on existing data available from scientific literature, previous clinical trials (on the same compound), expert opinions or a combination of the above. This existing knowledge though is often not directly transferable to the clinical trial of interest due to the use of slightly different outcomes, differences in the target population, study design, compounds involved. etc. In practice, these differences are used to down-weight to some extent the relevance of the available information when making the assumptions for the sample size calculation. However, this is done implicitly in the decision process because it is not possible to include prior information in the frequentist framework.

The Bayesian paradigm provides a natural framework to incorporate prior information in the inferential process. Furthermore, the use of the so-called conditional power priors allows to *formally* down-weight the impact of the available data on the posterior distribution for the outcome of interest.

In this talk we show how the conditional power priors methodology can be applied to the assessment of the sample size for a clinical trial. We illustrate these techniques in two real case-studies in which a compound, already tested in a adult population, is tested in a paediatric population. The first study is a superiority trial with numeric discrete outcome whereas the second one is a non-inferiority trial with binary outcome. In both cases the use of this methodology leads to smaller sample sizes for a given level of statistical power compared to the frequentist setting.