

The Value of Prospectively Planned Integrated Analyses Across a Drug Development Programme

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Regulatory authorities have a requirement for integrated summaries of data across a drug development programme. These summaries include analyses looking at the effects of age, gender and race on the efficacy and safety of a drug. Benefit can be gained through the prospective planning of these analyses. Further, the planning of a recent drug development programme illustrates the benefits to be gained through utilising a similar approach being applied to secondary objectives of individual studies. The benefits included enhancement of the design, databasing, analysis and reporting of the programme and demonstrated the value statistician's can have on influencing a development programme.