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Cost-effective clinical trials development

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Summary

Research into the design and analysis of clinical trials conducted within the Mathematics and Statistics Department of the University of Reading has the potential to cut development and regulatory costs, reduce time-to-market for new treatments, and improve patient outcomes.

Background

Traditionally the introduction of a new treatment onto the market involves the implementation of a series of clinical trials, progressing through various pre-defined phases. Each phase normally increases in size and duration, and thus costs and complexity, in order to prove treatment (or treatment combination) safety and efficacy. Such trials can take many years to complete. The later phases of the development process are usually designed such that the number of patients to be recruited to the particular trial is calculated in advance of the study, and data are collected on all of the patients prior to any analyses being undertaken. Clinical trials are costly to the pharmaceutical industry and public funding bodies, require major commitment from volunteer patients and take significant time to lead to patient benefit. In some clinical settings – for example where patient recruitment is slow and over a long duration, combined with rapidly observable measurements – a different approach can be taken, whereby data from patients are analysed as the trial progresses. This is known as an 'adaptive design' trial. The advantage of such methods is that sufficient evidence to draw valid conclusions about the efficacy (or futility) of the treatment(s) under study may become apparent as the trial proceeds.

How is University of Reading research contributing?

This new general approach opens up the possibility of designing clinical trials with many adaptive features, such as combining the phases of research, changing the patient population under study, changing the primary endpoint, or even modifying the treatments being tested. Work undertaken at the University of Reading has led to novel methodology for the design and analysis of clinical trials within this 'adaptive design' framework.

What impact has our research had?

These methods have been implemented by pharmaceutical companies, where they have the potential to reduce the time taken for effective drugs to reach the market (thus benefiting patients) while also reducing the significant cost of such trials to the companies themselves. The methodology developed at Reading has been cited in regulatory authority guidelines, and subsequent discussion of these methods has increased awareness by clinicians and other medical professionals of the potential benefit of adaptive design approaches to their patient groups.

"Due to the Phase II/III trial design, Horizon III is able to move directly into Phase III utilizing all the Phase II data and this saves valuable time in assessing the potential benefit of Recentin in the first line metastatic colorectal cancer setting".

John Patterson
Executive Director for Development, AstraZeneca (now retired)

This research was partially funded by a methodological research grant from the pharmaceutical company, Novartis

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