Leveraging Web-Based Clinical Trials to Support the Marketing Platform

In an increasingly competitive environment, pharmaceutical drug and device manufacturers cannot easily tolerate delays in achieving peak sales following launch of their products. Additionally, there are more and more requirements being placed upon manufacturers to examine the safety of their products in the marketplace, the results of which can sometimes pose problems or even post-marketing product withdrawal. In the past, there was often time within a traditional product development programme to generate useful data to enhance market penetration. But now, the emphasis is on speeding products through the development process to market in order to realise a revenue stream as early as possible. Consequently, more is being asked of individual clinical trials, both pre- and post-approval to fulfil both development and marketing needs.

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This article explores how new web-based clinical trial technologies can be used to meet the marketing needs at the time of product launch and beyond.

Fifteen years ago, a typical conversation between the product manager and the clinical research manager was along the lines of, 'We will probably get approval for product X in the next few months and marketing want to do some trials with our opinion leaders so they get experience with the product and act as our advocates. What can the clinical department do for us?' The usual response was to scratch around for a reasonable scientific question to be asked, whilst exposing as many patients and doctors to the product as possible. This was the era of the 'seeding trial'. Examples such as that of the lipid lowering agents in the early 1990s, when multi-millions were spent in post-marketing trials in order to gain marketing advantage encouraged a decade of expanded clinical testing by companies striving to reinforce the positioning of their product and to create data to support key marketing messages, expand the size of the patient group eligible to receive the product and differentiate the product from the competition.

However, times are changing and maximising and protecting one's product in the market is becoming more important. Regulatory agencies, particularly the US Food and Drug Administration (FDA), have become increasingly concerned about the safety of newly marketed products – a concern that has been magnified with highly publicised criticism levied by consumer groups after the withdrawal of products, such as troglitazone. A typical pre-approval clinical development programme generally results in a database of 2,000 to 4,000 patients. However, this can only accurately detect adverse reactions more frequent than one in 1,000. As a result, companies are being encouraged or indeed required to sponsor post-marketing surveillance studies of their product using scientifically rigorous methodology. In constructing expensive trials that purely examine safety, companies may be unable to indulge in those other post-marketing trials that help develop the product's market platform. We propose that the integration of web-based clinical trial systems into pre- and post-approval trials can help deliver on both these objectives.

THE PROMISE OF TECHNOLOGY

Technology has long been hailed as the panacea that will revolutionise the pharmaceutical product development process. Many aspects of the process are ideally amenable to technological optimisation with the need to process millions of data points through repetitive procedures with high quality. Actual experience has often been short of expectations with many people expressing scepticism about the promise of 'technology solutions' and it is therefore perhaps not surprising that 95 per cent of trials are still conducted using traditional paper-based technologies. In addition, there has been an obsessive focus on providing a technological optimisation of only one aspect of the clinical trial process, namely data capture. Electronic data capture (EDC) solutions often fail to add value to the product development process, because even if they do speed up data acquisition they fail to

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reduce total time for study execution due to bottlenecks further down the line. Furthermore, the needs of the investigator (that is – the customer for the product) are seldom considered in the design of EDC technologies and the one-size-fits-all approach is seldom a practical reality. One of the authors' personal experiences in a large post-marketing study indicated that some investigators regarded a specific EDC solution as a marked improvement over paper-based data collection, while others were strongly opposed to the use of the EDC system.

GENERATING MARKETING INFORMATION FROM WEB-BASED TRIALS

Whilst clinical trials rightly concentrate on acquiring data that is fundamental to the safety and efficacy of a product, there is a vast amount of 'soft' data collected that traditionally never gets formally collated and entered into a central repository. From the recruitment process, information can include identification of patient advocate organisations, conference schedules, patient demographics, opinion leaders and rising stars amongst the clinicians. During monitoring visits information is often given to study personnel about perceptions of the product, how easy patients find the product to use and any problems with the pharmaceutical properties of the product such as time to dissolve a freeze-dried product. Many of these get recorded in an informal way, but since they are non-critical data, their implications may be missed or not communicated to the marketing department.

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By using electronic records, this information can easily be captured by sponsor or CRO study staff and rapidly relayed into a central database and then made available to interested parties. We routinely construct an electronic study knowledge base (e-KB) which is made available to the study site, the CRO and the sponsor over the Internet. We deliberately design forms used to record the activities of site monitors to include feedback sections to record their discussions with study site personnel. Using optical mark read technology, we can scan the responses on these forms into the e-KB, usually on the same day of receipt and then make that information available via secure access. We do not allow this information to mix with the formal clinical trial data, but instead form a separate structure within our overall electronic trial management process. We have found that the e-KB allows numerous and disparate information to be easily located and accessed through web browsers with little or no additional training for the people involved – this is particularly important if study site staff are given access. The e-KB is a dynamic tool, evolving over the course of the study and its utility grows as the study progresses.

During the course of the study, additional high value information can emerge as fundamental to the marketing success of a product. For example, in a trial involving a powder for injection, it quickly became apparent that pharmacies were spending much longer reconstituting the product than anticipated by the manufacturer. This was inconvenient for the hospital staff and comments were fed back via the e-KB. As a result, new guidelines on reconstituting the product were issued which solved the problem and avoided a potential marketing disadvantage before the drug was launched.

FROM INVESTIGATOR TO PRODUCT ADVOCATE

The e-KB has an additional benefit of relevance to the marketing of pharmaceutical products – that of an open communication channel between the sponsor and the clinician. With real-time, 24-7 access to the e-KB via the Internet, sharing of information is easily achieved at the convenience of the clinician. Using the clinical trial as the basis for interaction, frameworks and processes can be designed for early identification of qualitative data on the advantages and disadvantages of the product, for example, in terms of its ease of use, presentation, formulation and new therapeutic indications. The e-KB can be extended to allow interaction via web casting, interactive frequently asked questions, chat rooms and more formal meetings between personnel in different geographical locations. Although it is no substitute for the more traditional method of interacting with the customer at a marketing level, this approach allows far more interaction between the product manager and the study sites as the trial progresses and using factual data and feedback to facilitate a more balanced peer-peer dialogue than is normally the case.

In addition, the establishment of this communication channel and the ability to monitor the performance of individual sites and investigators on a daily basis can help identify investigators as potential product advocates and the timing for the potential publication of data. Both qualitative and quantitative information can be formulated into a bespoke 'opinion leader database' that can be utilised by a sponsor with the inclusion of additional specified fields to supplement and guide their decision-making in the recruitment and adoption of investigators as product advocates.

This information will also assist the sponsor in creating the brand identity of the product prior to launch. Critical to the success of the launch will be establishing the product positioning, and the creation of opportunities to support this positioning through the publication of data and key communication messages.

The timing and accessibility of data is crucial to a successful publication plan. It is important to know what data will be available and when; which investigators are available to present it; and what aspects of the data can be published. All of these need to be considered to ensure your investigators and data support your product's positioning. In addition, if the sponsor works with a CRO that can provide a framework to assist the investigator in getting his or her results published or to provide timely opportunities to present at international meetings and conferences, this can facilitate and promote a successful relationship between investigator and sponsor. It can also encourage the investigator to become product advocate, potential advisory board member and future spokesperson and author of articles promoting your product.

CONCLUSION

New clinical trial technologies are here to stay and the need to integrate the technology with people and processes to achieve full benefits is being realised. There are many side benefits of using electronic clinical trial systems based on their ability to easily capture and handle data no matter what the input might be. An extension of this ability is to better prepare the marketing platform for new products by allowing a greater level of interaction to occur between the marketing and clinical departments and between the pharmaceutical company and the clinicians and other health care professionals. ◆

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