Delays in clinical trials cost companies millions of pounds in lost revenue. With limited patents, the longer it takes to get a drug to market, the less a company can earn over the life of a brand. At the same time, there's never been more scrutiny over the clinical trial process by external stakeholders which has resulted in an ever greater need for transparency.

Consistent and integrated communication with all stakeholders involved in the design and implementation of a clinical trial can aid progress. It may also improve the likelihood of a brand's success when it comes to market. Clinical trial programmes provide a whole continuum of communications opportunities and yet pharmaceutical companies frequently miss these. From explaining the initial concept right through to announcing results and beyond, communications can help ensure that sponsoring companies achieve both their clinical and commercial goals. Key to this is ensuring that marketing and clinical teams work closely together throughout the course of a trial.

10 ways to improve communications surrounding your clinical trial programme

A practical guide by Ralph Sutton
1. CLINICAL AND MARKETING TEAMS MUST WORK TOGETHER

Although it is increasingly common for clinical and marketing teams to collaborate, historically these parts of the business have remained quite separate. All too often, expensive clinical trials have produced results that are very interesting and satisfy a scientific curiosity but are of minimal commercial value, because they are not designed to answer a meaningful marketing question.

Clinical teams have traditionally been resistant to allowing the marketers too much involvement in clinical trial programmes. But by introducing marketing and communications expertise at an early stage in the planning, the company can help ensure that the trial is designed to support the desired brand profile, implemented efficiently and all opportunities for building the brand are capitalised on.

From the very beginning, it is essential that a multidisciplinary working group, including both external and internal company stakeholders, be established which includes the commercial perspective. This will contribute to the commercial success of a brand, but also helps ensure that all the opportunities presented by the trial are maximized. These may include nurturing relationships with potential opinion leaders, shaping the market, seeding brand messages and identifying potential opportunities and threats.

The close involvement of commercial expertise in the early planning of a study will also help ensure the publications plan can provide the optimal results.

2. PLAN COMMUNICATIONS STRATEGIES EARLY

It is important that the combined clinical and commercial team plan all aspects of communications around the study from an early stage. This includes looking at how communications can help engage and train investigators, recruit and motivate patients and make the most of the results of the study with all relevant audiences.

Central to this process is the publications plan for the study. Throughout the life of a clinical trial, there are numerous opportunities for publications. For example, articles or review papers may raise the questions that the study seeks to answer, help raise the profile of both the compound and the study, and build anticipation of the product in the market. Protocol papers can be published and interim analyses may provide some early opportunities for presentation of data and publication.

Clearly the first presentation of results and subsequent full publication are the key opportunities, and this is discussed in more detail later. But even from an early stage in the planning process, it is important to look at opportunities for ensuring the data reaches your target audiences repeatedly through congresses, publications and media.

Publication of data for patient sub-groups, publication of sub-group data or review papers may raise the questions that are more reflective of the general marketplace and who have experience in participating in large-scale pivotal trials. With Phase IV studies and Clinical Experience Programmes, the focus is likely to be on reaching a range of prescribers.

Irrespective of the type of trial, it is important to make sure that the experience is as positive as possible for the investigator, their role is clear and they are provided with the support they need in order to conduct the trial effectively and efficiently.

Brand messages can be seeded throughout the clinical trial process. Even during Phase II trials it will be important to start communicating messages. A good way to start could be to focus on the company’s commitment to the therapeutic area.

These messages and the brand positioning will evolve as the data emerges. Once again, this is an important area where the clinical and marketing teams need to work closely together. It is essential if they are to shape perceptions of the brand among opinion leaders and the broader medical and, possibly, consumer communities.

4. TWO-WAY COMMUNICATIONS IS CRITICAL FROM THE START

Competition means that it is critical to secure the right investigators for studies. But this is easier said than done. Doctors have to choose which studies to be involved in and which companies to work with. Generally they will want to work with companies that they feel are most professional and credible.

One of the key ways to build trust among investigators is to seek their opinion early on. How do they think the trial will best benefit patients and can they foresee any challenges when the study is implemented? While it will always be important to have a small steering group of lead investigators who can help develop the protocol and assess the results, it is also important to consider seeking the views of other investigators to ensure that the study design is practical and realistic.
Preliminary research among investigators and their site staff will help identify potential needs and concerns. Based on this, the company can then help address any challenges and provide resources to help investigators and their staff with the study. The findings of this research can help shape the protocol (to maximise the success of the trial) and contribute to the development of investigator trial site staff educational programmes that meet their needs.

By conducting this research early, investigators will feel more involved and motivated, resulting in better participation in investigator meetings and a greater level of understanding of their role in the trial. They will also feel that the company is respecting their views.

5. THE VALUE OF STUDY BRANDING
All studies begin life as a series of letters and numbers and many never get any further. As a result, when faced with a plethora of studies from multiple companies, it is almost impossible for the medical profession to remember one set of data from another. It is also difficult for anyone to be engaged and motivated by a set of numbers.

Branding a study makes it distinct. Giving it a personality immediately adds impact. The branding of a study should be approached as a proper branding exercise. Combined clinical and marketing teams should seek to shape the branding based on the positioning and messages that they wish to communicate. This can be applied to a single trial or to an entire clinical programme. The advantage of developing branding for a series of trials is that the association with the brand is greatly strengthened. It also supports internal communications around the clinical trial.

Many clinical trial brands are derived from an acronym based on the name of the study – or perhaps it is more accurate to say that study names are derived from a convenient acronym. Acronyms are fine, if they do the job that branding sets out to do – ie, provide an impactful, differentiated and memorable identity for the study, but this does not always happen. Before adopting an acronym, evaluate whether it really is doing the job of a brand or not.

Once a brand has been settled on, it needs to be communicated to all target audiences in a consistent manner. A logo is required which will need to have a proper set of branding standards setting out how and when it can be used. All materials associated with the study should carry the branding.

At the same time, it is important for the marketing team to look at how the branding from the study can be closely linked to the product’s brand name so that the credibility and authority of the study branding can be transferred to the product brand as the study progresses. This is something which should be considered and planned before publication of the data for the first time.

6. ENGAGING AND MOTIVATING INVESTIGATORS
The key opportunity for engaging investigators and study co-ordinators is the kick-off meeting (called the Investigator Meeting) where they are briefed on the study and their role in it. These meetings generally involve participants sitting in a meeting room for a day or more, being talked to by presenters about specific details of the study and reviewing paperwork.

Research conducted by Axon Communications has demonstrated that investigators frequently find these meetings tedious and may leave them feeling unenthused and often unclear on specifics. It can often be difficult to persuade investigators to attend these meetings, and only the study co-ordinator may show up. This may impact on the study in terms of data management, speed of recruitment and ultimately completion.

At the same time, these meetings can provide a terrific opportunity for building relationships with and motivating investigators, who one day are likely to be key prescribers for the company. Therefore, running a highly professional meeting can have both immediate and long-term benefits for the company.

We have talked previously about the importance of doing some preliminary research among investigators. This in itself will help begin the process of getting the investigator to think about the study and will also help shape the agenda.

The investigator meeting should be as interactive and exciting as possible. There are plenty of opportunities for using well-proven adult-learning techniques to involve participants actively in a hands-on fashion, particularly using problem-based learning techniques with small group workshops. A highly interactive format provides greater scope for feedback that then provides further follow-up opportunities. Formal evaluation is also recommended.

Providing advice and, potentially, resources which help address challenges identified by the investigators in the preliminary research will help ensure the investigator meeting goes well and the study progresses smoothly while demonstrating the professionalism of the company.

7. ENGAGING AND MOTIVATING PATIENTS
Each study will have its own set of challenges when it comes to the patient. In some cases, it may be difficult to recruit patients due to rarity of the condition, or the taboo nature of the topic. In other studies, patient retention may be the key problem either due to the complexity of the treatment regimen or for some other reason. Whether the need is in the area of recruitment, retention or both, investigators and their staff require support in this area.

Patient recruitment needs to be managed carefully as there are some potential pitfalls. The nature of it may vary from highly targeted, surgery-based communications to more broad-based communications including mass-media such as radio and newspaper advertising. Activities need to be approved by the relevant ethics boards and inquiries need to be channelled in a highly professional manner.

Keeping patients on their treatment regimen is critical for the success of any study. Companies have a great opportunity for motivating
patients through regular communications. Provide them with cutting-edge information about their condition and its treatment at the start of a study, or send newsletters with helpful tips and updates during the course of its progress.

Patient organisations or patient advisory groups can play a valuable role in shaping communications to patients. Not only will this help with the progress of the study, it will also build important relationships for the future of the brand.

8. MAINTAIN COMMUNICATIONS

Having kick-started the study with an exciting investigator meeting, it is important to maintain regular contact. This should not only be through the company’s study monitors and supplier networks, but from the head-office.

One immediate opportunity to ensure the study progresses quickly from the start is to provide a newsletter to investigators and study co-ordinators, within weeks of the initial investigator meeting, to reiterate key points; address any unanswered questions; and prompt them to ensure speedy recruitment and randomisation of patients.

Regular correspondence is welcome. Provide study updates or share best practice from other participants. Another form of sharing best practice is to set up regular conference calls in which sites that are performing well can share ideas with their colleagues.

If a study is likely to take a long time, either as a result of the duration of treatment, or likely challenges in recruitment, then it is worth considering an interim investigator meeting to maintain dialogue and, again, share best practice. It will also have the impact of further deepening the relationships with those who ultimately are your key influencers over the brand.

9. CLOSELY CO-ORDINATE THE RELEASE OF RESULTS

The communication of clinical trial results has become a real minefield in recent years. The interests of investigators, patients and shareholders have to be balanced. At the same time, the requirements of congresses and publications are strict.

A typical challenge is as follows. The company wants to release its results for the first time at a major congress. The congress organisers are keen for this to happen, as it adds prestige and raises the profile of the congress. They do, however, request that the data is unique — i.e., that it has not been presented previously — and that an abstract be published in advance of the meeting. At the same time, the company wants to share the data with the investigators before communicating it to the wider world. The company’s aim is to look for ways to present the data to as many people as possible. As a backdrop to all of this, the company has requirements to disclose the information to the stockmarket.

There is no easy answer to this challenge. Generally, because of regulatory requirements, companies do need to share top-line data with the stockmarket first, but keep more detailed analyses under wraps until they can be presented to investigators and the broader medical community.

What is key here, is that the clinical, marketing and corporate teams all need to work together to plan the release of data carefully in a co-ordinated manner so that all stakeholders — investors, physicians, patients and, of course, the company’s own staff, feel that they have been informed of the results at the right time.

Of course, all opportunities for release of data through a variety of channels should be explored working closely in conjunction with the publications planning and public relations teams.

10. BE TRANSPARENT

The clinical trial process, and, in particular, the sharing of results, whether positive, neutral or negative, is under considerable scrutiny from politicians, media and investors. The pharmaceutical industry must now plan its clinical trial process with the assumption of transparency. Of course, there will still be allowances for confidentiality of commercially-sensitive information, but failure to communicate negative results is likely to result in criticism of the company and damage to a brand.

The on-going communications process outlined above helps manage the brand and corporate reputation throughout the life of the trial. By developing good working relationships through on-going communications with all relevant stakeholders, a company is able to manage unexpected issues should they arise — e.g., if the study needs to be stopped early, or produces negative results.

Publication of all study data, whether on a company or centrally co-ordinated database is becoming a reality of life. These databases may be accessible publicly and therefore it is essential that the company is in a position to handle enquiries from a very wide variety of stakeholders including financial analysts, prescribers, patients, family members or media. Such enquiries may be very detailed, or potentially quite emotional. In the evolving era of transparency it is critical that all parts of the company be aligned for handling enquiries about studies and that these are channelled and addressed appropriately.

The medical profession appreciates this transparency and professionalism. It encourages them to work with one company over another and ultimately these relationships are key, not only to the success of a study, but of the brand as a whole.

In conclusion, every step in the clinical trial’s life presents opportunities for forging relationships, educating stakeholders and seedling brand messages. If marketing and clinical teams work effectively together to seize these opportunities, they can make a huge difference when bringing a brand to market.