Courier integration in the CT process

Integration of the courier into the clinical trial process completes the last piece of the “jigsaw” in developing a fully integrated web-based solution to managing clinical trial supplies.

Dr Drew Kilpatrick and Peter Crespin, TNT

Clinical trials are a major financial investment and risk for pharmaceutical and biotechnology companies. The Boston Consulting Group estimated that, when interest and drug failure costs are taken into consideration, the cost of developing a new drug could be as high as $500 million (1). Two market-driven strategic imperatives for major drug companies are both to increase their pipeline of new products to 2–4 per year and reduce the time to bring them to market to below ten years (2) – both of which require that trials be conducted more efficiently to either confirm or eliminate candidate products as quickly as possible. Therefore, as a consequence of the escalating pace and costs of drug development, pharmaceutical and biotechnology companies (and their suppliers) are looking for efficiency savings in the way clinical trials are conducted.

One approach taken by many companies within the pharmaceutical industry has been to apply information technology and internet solutions to various parts of the clinical trial process to improve the flow of information necessary for their successful management. This applies especially to the USA, where in one survey around 90% of respondents confirmed they would use net-linked resources in the conduct of trials and exchange of data, and around 80% would use electronic recruitment of patients. Comparable figures for European respondents were around 50% and 40% respectively – but the situation is likely to change rapidly (3).

Meanwhile, leading logistics players are gearing up for the expected web-based revolution and positioning themselves as key partners in the overall study process. Until now, clinical trial logistics with respect to shipping of samples from investigators to laboratories, unlike other areas of the clinical trial process, has not benefited from web-based technologies (WBT). The recent introduction of web-based systems – such as TNT’s Clinical Trials Network (CTN) – allows the courier for the first time to be fully integrated into the clinical trial process, leading to cost savings through more efficient shipping logistics and fewer repeat sampling/patient recall problems. This article outlines the scope and importance of courier integration before describing an example of an integrated logistics system in a little more detail.

Strategic IT-based efficiency investment
Considerable investment has been made by companies in Clinical Trial Management Systems (CTMS) and Electronic Data Capture (EDC) to integrate clinical trial information from both internal and external sources. A key feature of the newer systems is that they allow the integration of information from paper, intranet and internet sources, giving the individual clinical researcher in each centre a level of information undreamed of only a few years ago.

The introduction of WBT into the clinical trial process has already benefited patient recruitment into clinical trials (4, 5), shortened clinical trial start-up through the improved distribution of protocols (6), improved data management through...
remote electronic data capture via the e-CRF and patient diary cards (7) and provided a more efficient distribution of study status information to the medical community (8). The availability of WBT offers a way to reduce the vast quantity of paper now generated in clinical trials and provides a better platform for communication between all parties involved in the clinical trial process. Thus, WBT has given rise to improvements in trial start-up time, shortened the patient recruitment period, improved data management metrics for processing the data and, lastly, assisted in the communication of information essential for the effective management of the trial.

Before describing the benefits of the CTN system to the clinical trial process, the important role of the courier in sample transportation will be described.

The importance of the courier
In all clinical trials, it is routine for investigators to take samples, either for measurement of safety data or to gauge the efficacy of the drug. Samples being sent by investigators to a central laboratory can range from simple blood samples for routine biochemical and haematological assessment, to hazardous materials such as radiolabelled material and viral-infected tissue. Thus, at the onset of the trial, especially if it is a global study, the clinical researcher spends a great deal of time and effort defining the central laboratory process and the samples to be taken at the investigational site. Selection of the courier and their ability to provide the appropriate global coverage can appear to be an afterthought, but since shipping logistic costs are typically in the range of 20-30% of the total laboratory costs, and problems with logistics can have major cost implications for the trial, careful selection of the courier is important.

In fact, the capabilities of the courier partner should be taken into account at the earliest planning stages to decide what is (and what is not) realistically feasible. Ideally they should be consulted as potential trial management partners before finalising the definitive list of study centres and laboratory locations, since their specialist knowledge can often inform the logistic realism or otherwise of the proposed trial set-up. In addition, working with the right partner can enhance parallel corporate efforts in CROs and pharma companies to reduce their vendor base by selecting a full-service global organisation capable of optimising physical material flow, information flow, condition control and regulatory compliance.

One consequence of the increased emphasis on performing long-term global trials is the greater reliance on logistics for the successful management of these studies. In a recent survey, 84% of respondents believed that improving shipping logistics can reduce the duration of clinical trials, and a convincing 95% also believed that problems with an inefficient courier service can make trials more expensive (9). There is therefore a strong economic argument for integrating the courier into the clinical trial process as one approach to reduce the overall costs for clinical trials and drug development as a whole.

For the majority of clinical trials the relationship between the investigator, courier and laboratory is as shown in Figure 1.

Procedures and pitfalls
Traditionally the investigator, following appropriate preparation of the sample, completes a requisition form and fills in the necessary supporting courier documentation before finally contacting the courier to arrange collection and transportation of the samples. Although the Internet has undoubtedly improved the flow of information between laboratories, investigators and sponsors of clinical trials, the logistics for providing samples to the laboratory can also benefit by making it easier for investigators to comply with the most efficient routines.

Previously, in situations where patient visits might have been scheduled for late afternoons, samples might easily not be available for collection until after the cut-off time, resulting in them needing to be put in storage for collection next day. Calling on special couriers ad hoc to compensate for missed pick-ups, can easily cost up to ten times as much as the services of companies offering specialist clinical trial contracts. In addition to cost considerations, if the site is some distance from the laboratory it could in theory take up to three days from the time the sample was taken to its arrival for analysis. This becomes critical if the agreement is that samples will reach the laboratory within 48 hours, especially if sample stability and temperature control are factors.

A second weakness of traditional sample movement practice, which is largely avoided by specialist WBT systems, is that it puts great emphasis on the investigator being aware of any special requirements related to the packaging and transportation of ‘dangerous goods’ (DG) as many biological samples are normally categorised (10). In law, the investigator is responsible for compliance with despatch regulations and poor awareness becomes critical if there are fines and other sanctions for non-compliance. Even though packaging and shipping issues are covered in the sample-handling manual provided by laboratories, human nature means that not every detail is either read or absorbed, so that many investigators are not fully aware of their entire logistic costs are typically in the range of 20-30% of the total laboratory costs, and problems with logistics can have major cost implications for the trial, careful selection of the courier is important
responsibilities. WBT systems prompt investigators and have additional information available in ‘drill-down’ form when the required tabs are clicked.

A final weakness of most traditional methods compared to WBT systems is the fact that, from the time the sample leaves the investigational site until the moment it arrives at the central laboratory, neither the investigator, sponsor nor central laboratory can easily check the sample’s transit status. To all intents and purposes, it can disappear for a time. Transit information can be obtained from some couriers via a telephone tracking system, but what is really required is “real time” tracking through a simple easily-accessed track and trace system that allows this information to be readily available when required by the investigator, laboratory or sponsor of the clinical trial. This lack of “real time” information on the transit status of clinical trial samples is no longer acceptable in a clinical trial environment, where so much time and effort is spent in managing the other parts of the process. Web-based systems overcome this lack of information.

**Courier integration: the TNT example**

The challenge for sponsors of clinical trials is to recognise the importance of the courier to the clinical trial process, and for the courier is to think beyond the shipping of clinical trial samples. TNT, a global courier offering dedicated services for the biomedical and pharmaceutical industry and Europe’s leader in clinical trials shipping, has taken on board the current weaknesses associated with the movement of clinical samples. TNT is a strong advocate for the full integration of the courier service into the clinical trial process, and has recognised that, without the full picture of sample shipping status, optimal management of the clinical trial is impossible. Having recognised the gaps in the process, it has invested to improve its service and is now one of the few couriers able to provide information on the status of all shipped goods from their point of uplift to final delivery.

The new service, called Clinical Trials Network (CTN), is a dedicated web-based system, which allows investigators, laboratories and sponsors to schedule and track collection and shipment of Coupling the CTN system to existing sponsor or laboratory clinical management systems offers the following advantages:

**Schedule of sample collection** Many busy investigators have trouble completing shipping forms fully and accurately, for either drug supplies or blood or tissue samples. An advantage with the CTN system is that on-screen prompts ensure that the investigator provides the appropriate information for each shipment. This is especially important if the samples are designated as dangerous or hazardous materials. The on-screen guide removes any uncertainty by providing information on the correct packaging requirements to comply with the respective shipping regulations.

**Integrated dry ice supplies** The ordering of dry ice can be co-ordinated on a “just-in time” basis.

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**Figure 1.** Schematic diagram of the logistics involved in providing a central laboratory with clinical samples for analysis.
together with sample collection – removing one of the “headaches” experienced by investigators organising sample shipping.

**Track collection and shipment information**

Following access to the CTN system through its secure Internet site, investigators, sponsors and laboratories can track the shipping progress of their samples from point of collection through to final delivery. Access to the tracking information held in the CTN system allows laboratories to optimise their equipment and resources, which in turn should improve sample turnaround times. Real-time tracking allows earlier corrective action to be taken by those monitoring the clinical trial in the event of lost or damaged samples.

**Storage of trial information**

CTN, if required, can be used as platform for sharing information pertinent to the study. This facility is likely to be important, as study durations of several years are now common. Documents maintained within CTN can range from contracts (courier, laboratory), communication plan (points of contact at courier, sponsor, laboratory) to agreed sample schedule dates for the varying samples being analysed. In a world of staff mobility, the courier can be a force for continuity.

Late sample delivery is almost invariably a result of missed collection, poor documentation giving rise to customs problems, or transport delays – especially if the samples are considered dangerous or due to the fact that dry ice was not available. The ability of CTN to provide “just in time” sample collection and dry ice collection and delivery, on-line tracking of sample shipment from the point of uplift to its final destination, and improved access to information such as compliance requirements for the transport of dangerous goods will improve the logistics associated with the clinical trial process. This improvement in sample logistics will be reflected in the dual benefits of reductions in cost and clinical trial duration.

**Conclusion**

The introduction of WBT has benefited many aspects of the clinical trial process ranging from the recruitment of patients to the entry and validation of patient data. Until recently, the courier’s role has simply been to provide the means of shipping samples from one place to another. Information on sample or drug shipping status has not formed part of the clinical trial information flow. The investment of major players such as TNT in the development of services like the CTN system effectively integrates the courier into the process and completes the last piece of the “jigsaw” in developing a fully integrated web-based solution to managing clinical supplies. The obvious benefits derived from systems such as CTN through their more efficient management of logistic information will be a reduction in clinical trial duration, which in turn will be reflected in reduced clinical trial costs.

Dr Drew Kilpatrick is Associate Director of Project Management at Inveresk Research, a global CRO providing pre-clinical and clinical support to the pharmaceutical industry. He has extensive clinical research and project management experience gained in both CROs and pharmaceutical companies.

Peter Crespin established The Writers Bureau in 1995 (www.thewritersbureau.com) to provide medical and marketing communications consultancy services. He has extensive industry and agency experience, specialising in international programmes, and today serves most of the big agencies as well as pharma clients direct.

**References**

9. TNT Customer Survey. Details available on request.