Now here is a paradox. If you go to any of the major clinical development departments and ask them what would be the effect of removing one of their major information systems (I/S), it is a good bet they would say that they would be unable to work at their current level, and maybe couldn’t work at all. If you offered to let them go back to using the information system they used before the current system was installed, they would probably say that performance would suffer. But, if you were an I/S project manager and you were evaluating the benefits accrued from implementing a new system, and you asked a clinical development department how much of their recent increase in performance in conducting clinical trials had been because of the introduction of a particular I/S, you would be very likely to get a different answer. They may say that there had been a marginal benefit from use of the system, or they may say that the benefits had not been realised.

This is not a new problem for I/S departments. Proving that a new system has resulted in specific benefits has caused many problems across every industry. A good example of this problem was the introduction of office systems to all professional staffs. Everyone could see that they would provide benefits to the employees, but proving it in the early days was very difficult. Most of the first companies to introduce office systems across their entire operations had to take a huge leap of faith. Their pilot projects gave no measurable returns on investment. Today, removing the e-mail, calendar, word processor and presentation graphics facilities would be unthinkable.

So why doesn’t a clinical development department see the impact from the introduction of a new technology? The problem is that clinical development is very complex, with many factors affecting the effectiveness and efficiency of a clinical trial. Some of the factors preventing the measurement of benefits are listed below:

**Multiple initiatives** In a clinical development group of critical mass, there are always initiatives underway to improve performance. Isolating the effects of any single action is very difficult. Often, it is the improvement project leader with the loudest voice that gets the credit.

**System implementation** When a system or new technology is implemented, there are three types of change that have to occur together; these are technology, process and people changes. This range of activity masks the improvement due to the technology component.

**The drug and indication** The success of a trial is most affected by the drug being studied and its indication. A new technology being used on a very difficult trial may not appear to have made a positive impact. Similarly, a new technology being used on a very straightforward trial may appear to have been more effective than it really was. Only use on a selection of trials will really identify the usefulness of the technology.

**Longterm projects** Clinical studies can take several years to complete, and some technologies are only appreciated over a long time span. This makes it much more difficult for the benefits of the change to be appreciated.
The human factor

No one pretends that a new technology can replace hard work. When a difficult milestone has been achieved, it is always due to the efforts of the team. Not surprisingly, team leaders are reluctant to inform their management that a new technology played a large part in the success of a trial. This would take the credit away from the team.

Technology used in clinical trials

Underpinning improvements in specific technologies used in clinical trials are the huge advances in information technology (I/T) generally made over the last five years. Figure 1 shows a graph of the clock speed of PC computer chips from 1990 to 1998; this increase in clock speed is only one small indicator of the advances that have been made in technology. There have been many more developments occurring in parallel - such as a decrease in the cost of hardware and an increase in the amounts of data that can be held in memory, and on disks and other media. However, Figure 1 does indicate the exponential nature of the increase in computing power. This computing power has led to incredible advances in software functionality and, in particular, user interfaces.

There are many I/T advances that have been applied to the clinical research area. To select those that should be the subject of this article, many papers and presentations on clinical research were reviewed and a list compiled of those technologies that were mentioned the most. The internet was excluded from the list; although it is clearly a very new application of technology, it had the highest number of citations. The internet is discussed specifically later in this paper.

The technologies/system areas mentioned most in the papers and presentations reviewed were:

- Clinical trial management systems (CTMS),
- Electronic data capture (EDC, sub-divided into four areas):
  - Fax EDC,
  - Remote data entry (RDE),
  - Voice recognition,
  - CRF image and optical character reading (OCR),
- Data management (subdivided into four areas):
  - Data base management systems (DBMS),
  - CRF design,
  - Data entry interface,
  - Reporting/analysis,
- Pharmacovigilance,
- Statistical analysis, and
- Document management.
The survey
A survey conducted for this article asked around 50 people involved in clinical R&D or R&D I/T which technologies had made the most impact on clinical research over the last five years. Also, the survey asked about the level of implementation in the industry of the different technologies, both over the last five years and today. The results were normalised so that the highest possible impact or implementation was scored as ‘10’ and the lowest as ‘0’.

The results from the survey are shown in the bubble chart in Figure 2. In the figure, the size of the bubble represents the level of implementation of the technology today. Not surprisingly, the impact and implementation of the technologies over the last five years are closely related without any major exceptions.

The survey found that the area of technology that had made the most impact was data base management systems (DBMS). Here, there is a combination of the development of relational database technology with the specific functionality for clinical data management. The impact is underlined by the fact that most respondents felt that DBMS is implemented universally today.

Surprisingly (at least to the author) the next greatest impact was in the area of statistical analysis. Clearly, increases in computing power have allowed improvements to the user interface of statistical packages. However in addition, there have been improvements in the methodologies used - leading to a more standardised straightforward approach. Closely allied to the developments in statistics are the improvements in reporting analyses from the database. Modern tools now
allow much more insight into the progress of a trial.

Document management is high on the “impact list” and is trailed by CANDA (computer-assisted new drug application), which makes sense in view of the time it has taken to settle on CANDA standards for the regulatory authorities.

Methods for collecting data from investigator sites are the lowest on both the impact and implementation scales. These are clearly technologies that are beginning to have an impact, but the responders did not think that they had made their mark on the industry yet. It has certainly taken a long time for this technology to become widely used. Reasons for this include:

- Regulatory authorities’ position not being clarified,
- The cost of supplying hardware to investigators,
- The difficulty of providing I/S support to investigators,
- The effect of the set-up time delaying the start of a trial,
- The user interface not being good enough, and
- A low level of computer literacy among investigators.

As these six issues have now been largely overcome, and the technologies have not yet been widely implemented, there is a high level of commercial activity in this sector. Electronic data collection, in all its forms, is probably the area of technology that will have the biggest impact over the next two to three years.

A big surprise was the low position of clinical trials management systems (CTMS). These systems collect data about the progress of a trial and make it accessible. Using key performance indicators derived from this data, some companies have used CTMS to spearhead their improvement projects but, in this survey, the impact and the implementation of these systems was seen as low. There must be a great opportunity to either implement CTMS that will have a greater impact, or improve the way these systems are currently used.

Responders to the survey also had the opportunity to mention other areas of technological advance that have had a great impact. The most mentioned were:

- Integration of systems,
- Infrastructure improvements, and
- Project management.

Some responders felt that the integration of all their clinical applications had been a major driver of their company’s improvements.
The future impact of the internet

It is hard to discuss the future of I/T in clinical development without discussing the internet. This technology is clearly a commercial reality - there has been too much invested to consider it disappearing in the near future. Slowly but surely we are seeing most of the pharmaceutical-specific systems becoming internet-enabled or internet-based. The widespread use of the internet protocol means that there will be a very large community of people who can use any system accessed by a browser. The move to the internet dominates technology solutions for clinical development today.

Summary

Although the results of this survey seemed surprising at first, on reflection they become more understandable. The results pinpoint the areas of I/T that have been largely responsible for improving clinical data management and those areas that will make significant contributions in the near future.

Technology will continue to advance. Computers and telecommunications will become more powerful, while at the same time their costs will decrease. This expanding power base will provide the platform for the next breakthrough technologies as yet undeveloped. We can only begin to imagine how this survey might look in five years’ time.

Note: Parexel International is one of the leading full service contract research organisations, conducting clinical development from Phase I through to product launch. In addition, Parexel offers a range of consultancy services including regulatory affairs, training, process improvement and re-invention, knowledge management and benchmarking.