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IT in Clinical Trials

An Academic Sponsor's Perspcetive

Author

Lucy H.H. Parker and Gary C. Roper
are with Imperial College, London.

The use of IT systems for clinical trial management in a non-commercial setting is a complex and contentious issue. The current drive for commercial sponsors to utilise electronic platforms for trial management is leading UK universities to explore how electronic trial management systems can be integrated into their practice.

In the UK law, the sponsor is the individual or organisation, which takes on responsibility for the initiation, management and/or financing of a clinical trial and any IT system designed for clinical trials would require a broad scope to maintain this oversight.

The Role of IT in Clinical Trials Management

It is important to implement an IT system for clinical trial management that reduces the administrative burden placed on investigators, enables them to collect their data in a meaningful manner and ensures that the Chief Investigator and Sponsor are able to meet their legal requirements as defined under the Medicines for Human Use (Clinical Trials) Regulations 2004.

Lack of Rules or Specific Laws in EU

At present, there is no UK or EU guidance on computerised systems in clinical investigations.

In the US, however, there is FDA guidance for Computerised Systems Used in Clinical Trials (1999 and the new draft issued in 2004), which provides a compliance infrastructure that is lacking in the UK. In the European Union Annex 11 of the GMP guidance on Computerised Systems is available but relates only to Good Manufacturing Practice rather than specifically to Good Clinical Practice (GCP) or trial management.

As there are no clearly defined standards for computerised systems for trial management, it is increasingly important for the Sponsoring Organisation to identify and adopt a formal IT structure for clinical trial management in order to meet the legal requirements implicit to the Sponsor role, specifically, project initiation, administration and management as well as authorisation, GCP conduct and training and pharmacovigilance.

Key Requirements

Any IT system used in clinical trial management should meet certain requirements in order to ensure that the system is well designed and implemented. These requirements include:

Ó On-line access to key study information and study documents for all stakeholders

Ó On-line access to document templates, SOPs, training guides

Ó Pre-population of basic project information in documents where possible

Ó Approvals tracking across at project and site level, from internal approvals to UK and international approvals

Ó Version control of study documentation

Ó Email notifications and reminders (e.g. time-based or specific milestones)

Ó Generating reports on key study information and status

Ó Discussion forum

Ó Ability to generate a portfolio of on-going sponsored studies

Ó Integration with internal systems such as finance systems.

Challenges for the Buy-in

There will of course be resistance to new IT systems from Investigators and understandably so. There has been a rapid growth in the number of regulatory systems and procedures since the implementation of the UK Medicines for Human Use (Clinical Trials) Regulations, which were transposed from the EU Clinical Trials Directive. Both Investigator and Sponsor have to familiarise themselves with a diverse number of systems in order to meet their regulatory obligations.

Any IT system that is introduced into a clinical management environment will have to ensure that it does not duplicate other practice, indeed any new IT system should reduce duplication while at the same time ensuring that data collected is relevant to the approved trial protocol.

Specific Challenges for Universities

Implementing and maintaining a computerised system for clinical trial management can be expensive. This can be difficult in an academic environment, in which many studies are funded internally, or by charitable or research council grants. Funds that could be used in research,may instead have to be diverted to an IT system and if the system is poorly developed and designed, this detracts fromthe research and ultimately harms the study's potential. Therefore, any system implemented in an academic environment has to bewell executed and cost effective.

Heterogeneity and Diversity of Current Systems

There is a plethora of IT systems for various aspects of clinical trial management, not only from new complex Electronic Data Capture (EDC) systems but more traditional IT tools used to capture data such as Excel spreadsheets and Access databases. While many studies have developed their own databases and spreadsheets, some ofwhich are highly sophisticated, the diversity of these systems makes regulatory auditing more difficult. By implementing a broader, more integrated solution across a portfolio of studies, there will be a more robust oversight of studies includingmulti-centre and international projects.

Requirements for Real Time Functionality

One of the key areas for the Sponsor is monitoring, "the act of overseeing the progress of a clinical trial, and ensuring that is conducted, recorded and reported in accordance with the protocol, SOPs,GCP and other regulatory requirements" (ICHGCP 1996).

A well defined EDC system would allow the Sponsor and Chief Investigator real time remote access to the repository of data contained within the system and would allow for closer monitoring than afforded by traditional paper based systems. This would give rise to greater pharmacovigilance control, ensuring the risk to the patient is minimised, which is of paramount importance in any trial.

The ability of an EDC system to report in real-time, any serious events, aids both the Investigator in ensuring the safety and well-being of the research participants, but also helps to ensure that the Sponsor is able to report to the relevant Competent Authority within the defined legal timeframes.

Summing Up the Benefits

A well managed IT system implemented across a non-commercial trial portfolio will unify the manner in which data is collated, allowing for a structured approach as opposed to hundreds of individual data management systems that may not have been validated. If an EDC system is used correctly, it will aid in the collection of cleaner data, and reduce the risk of a trial being poorly managed.

A centralised system would also reduce resource requirements for trial management and promote cost effective research practice. Some benefits for the Academic Sponsor and its investigators in deploying a computerised clinical trial management system over a traditional paper based system include:

Ó Patient recruitment monitoring reports

Ó Outcome reports

Ó Patient management system

Ó Questionnaire tracking system

Ó Sample tracking system

Ó Double entry data collection of study data

Ó Effective data validation

Ó Statistical analysis of data

Ó Easy reporting of data to help complete

Ó Payment management system for multi-centre payments

Ó Clinical trials costing tool for per-patient costing

Ó Reduced manpower for trial management.

The Experience of Imperial College

Imperial College London, as an Academic Sponsor, will be implementing a system in 2008 that aims to fulfil three key criteria: a robust and transparent system for the authorisation and management of its healthcare research portfolio to ensure all regulatory requirements and standards are met, a central repository/single data source that will capture the College healthcare research portfolio, including both funded and “own account” (internally funded) research, and a reduction in the administrative burden facing Investigators in complying with research governance requirements.

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